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To: Community Based Residential Facilities
Adult Family Homes
Resident Care Apartment Complexes

CBRF 05
AFH 05
RCAC 05

From: Kevin Coughlin, Director
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Via: Otis Woods, Administrator
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Medication Return, Donation, and Disposal

This memo provides guidance with medication removal in assisted living facilities, including Community Based Residential Facilities (CBRFs), Adult Family Homes (AFHs), and Residential Care Apartment Complexes (RCACs). In addition, this memo waives a portion of section HFS 83.33(3)(j), Wis. Admin. Code, related to medication destruction.

Background

Circumstances may arise in assisted living facilities that require medications to be removed from the premises, e.g., medication order changes, expired medications, adulterated or contaminated medications, resident discharge, resident death, or other situations. The amount and number of medications, the available options for removing these medications, and concerns for the environment have led assisted living facilities to seek guidance on how medications should be removed. Some assisted living facilities have asked about outside sources picking up medications for removal and how that should be handled. Although not intended to be comprehensive, this memo provides some information and options relating to removal of medications from assisted living facilities.

Rule and Compliance Guideline

Section HFS 83.33(3)(j), Wis. Admin. Code, addresses medication destruction in CBRFs. It states:

HFS 83.33(3)(j) Destruction of medications. 1. A resident's prescription medication shall be destroyed within 72 hours of a practitioner's order discontinuing its use, the resident's discharge (unless the resident needs the medication at a new location), the resident's death,

loss of medication dosage form integrity, removal of the medication from the medication package, or the medication's expiration date.

2. Records shall be kept of all medication returned to the pharmacy for credit or destruction. Any medication not returned for credit or destruction shall be destroyed in the facility and a record of the destruction shall be witnessed, signed and dated by at least 2 of the following: the administrator or designee, a registered nurse or a pharmacist and one other employee.

Community Based Residential Facilities (CBRFs) that contract with pharmacies or other companies to remove medications for the purpose of credit, donation, or destruction may establish compliance with the HFS 83.33(3)(j) 72-hour requirement by either 1) removal of the medications within 72 hours by the pharmacy or other company; OR 2) pending removal, assuring that within 72 hours the medications are: a) physically separated from other medications in current use in the facility; b) locked with access limited the administrator or their designee; and c) readily subject to reconciliation, auditing, or other monitoring to prevent diversion.

Removal

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

1. Medications that can be re-used or returned

Physician Order: Physician orders may be utilized to hold resident medications that are temporarily stopped and will potentially be restarted for the same resident. This process can eliminate some medication destruction or returns. Facilities can hold these medications in facility storage as provided by OQA Memo 05-003.

Return to pharmacy: Wisconsin pharmacy regulations under Wis. Admin. Code, § Phar 7.04, allows medications to be returned from a CBRF to a pharmacy for use by others where:

- The medication was never in the possession and control of the patient;
- The medication was sold, distributed, or dispensed in a tamper-resistant package, including the beyond-use date and manufacturer's lot number;
- The health item is not commingled with a different health item; and
- The health item is in its original container, and the pharmacist determines the contents are not adulterated or misbranded. (See attachment section A for the complete text of Phar 7.04). This return process may eliminate some medication waste.

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 can potentially be used for 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>. An assisted living facility 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 assisted living facility can fill out a donation form and send the medication to that pharmacy.

Note: 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. (Medicaid - other than Part D - continues to have a mechanism to accept returns and credit.)

2. Medications that cannot be re-used or returned

- Generally, controlled substances cannot be returned to a pharmacy to be used for other residents, per Federal Drug Enforcement Administration (DEA) regulations. *See* controlled substance discussion below.
- Other medications that cannot be returned include expired medications, adulterated or contaminated medications, and medications which legally cannot be accepted for return or donated for further use. *See* [Wis. Admin. Code § Phar 7.04](#).

3. Controlled Substances

- Controlled substances can only be in the possession of Drug Enforcement Administration (DEA) Registrants, law enforcement, and consumers (assisted living residents) who have a prescription for the controlled substance or the facility where the residents are residing. Typically, physicians, pharmacies, and hospital are DEA registrants.
- Federal law currently prohibits controlled substances to be returned from a non-DEA registrant, such as a resident in an assisted living facility, to a DEA registrant, such as a pharmacy. Therefore, all controlled substances need to be destroyed. (See Section D Appendix).

Disposal of Medication Waste

Medication waste generally falls into one of three regulatory categories: hazardous waste, infectious waste (commonly called biohazardous waste), and solid waste. All waste generators that are businesses and institutions, including assisted living facilities, are responsible for separating their wastes into the correct regulatory categories and ensuring proper disposal.

- You may return medications to the resident or his/her family for disposal. Residents or family may then take the medications to a pharmaceutical collection under the household hazardous waste exemption. (See Section B Appendix).
- If the assisted living facility assumes responsibility for disposing of medications, solid and hazardous waste regulations DO apply to the waste.
- DO NOT flush medications. 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.

- DO NOT put medications in infectious waste containers. It is not appropriate (nor is it cost-effective) to put medications, empty medication bottles, or empty insulin or vaccine vials in sharps containers or biohazard waste bags. Mixing non-infectious waste with infectious waste is prohibited in Wisconsin. (See Section C Appendix). It is no longer true that most infectious waste is incinerated; typically these wastes are disinfected and put in a landfill instead.

While medications that are hazardous waste are regulated both by state and federal regulations, Wisconsin has authority to run the federal program in Wisconsin. (See Section B Appendix). *Hazardous waste* includes 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 vitamins/minerals. An estimated 5-15 percent of medication waste may be hazardous waste. A reputable hazardous waste hauler can help you separate these wastes. Please refer to Section B in the Attachments to assist you in handling hazardous waste.

Health care products that are *infectious waste* are regulated by the Wisconsin Department of Natural Resources. (See Section C Appendix). 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. Please refer to Section C in the Attachments to assist you in handling infectious waste.

Medications that are neither infectious nor hazardous are classified as *solid waste*. Medications that are considered solid waste can generally be handled like other garbage. A potential problem with disposal via general garbage is that medications can pose safety risks to individuals who inappropriately access the garbage and expose themselves to the medications. In addition, medications that go to a landfill may leach to the groundwater system or be extracted and taken through a wastewater treatment plant. Therefore, DNR recommends that solid waste medications be routed to a licensed municipal solid waste incinerator or hazardous waste incinerator.

The preferred practice is to have a waste hauler take medications to a medical waste or hazardous waste incinerator. The solid waste hauler may have appropriate containers and specific procedures for disposing of medications. If that method of disposal isn't available, place the medications in a container that can be sealed. Add a small amount of water to the medication to make a slurry. Add cat litter, plaster of paris, or some other absorbent material to the slurry. Finally, seal the container and place the container in the garbage. Remove or obliterate any labels identifying the container as containing medications. See Section D for links to federal guidance on this process.

Privacy

It is very likely that medication containers contain personal health information (PHI). It is the responsibility of a CBRF to assess risks of privacy disclosures associated with medication disposal, and the facility should implement security policies and procedures that will provide a reasonable level of safeguards to protect the privacy of their residents.

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

ATTACHMENTS

[Section A - Pharmacy Returns](#)

[Section B – Hazardous Waste](#)

[Section C – Infectious Waste and Trace Chemotherapy Waste](#)

[Section D – Drug Enforcement Administration](#)

ATTACHMENTS

Section A-Pharmacy Returns

Phar 7.04 Return or exchange of health items.

- (1) In this section:
- (a) “Health item” means drugs, devices, hypodermic syringes, needles or other objects for injecting a drug, medicines, or items of personal hygiene.
 - (b) “Inpatient health care facility” means any hospital, nursing home, county home, county mental hospital, tuberculosis sanitarium or similar facility, but does not include community-based residential facilities, jails or prison facilities.
 - (c) “Original container” means the container in which a health item was sold, distributed or dispensed.
 - (d) “Resident health care patient” means a patient residing in a community-based residential facility that controls a resident’s prescribed and over-the-counter medications as specified by s. HFS 83.33 (3) (b) 2.
 - (e) “Secured institutional health care patient” means any of the following:
 - 1. A jail inmate patient whose dispensed health items are maintained under the custody and control of the jail pursuant to an approved policy and procedure manual under s. DOC 350.17, containing policies and procedures for the control and administration of medications complying with s. DOC 350.20.
 - 2. A juvenile patient who resides in a secured correctional facility, as defined in s. 938.02 (15m), Stats.; a secured child caring institution, as defined in s. 938.02 (15g), Stats.; a secured group home, as defined in s. 938.02 (15p), Stats.; a secured detention facility, as defined in s. 938.02 (16), Stats.; or a juvenile portion of a county jail whose dispensed health items are maintained under the custody and control of the health services staff as defined in s. DOC 316.02 (6) and provided to a juvenile patient under the provisions of s. DOC 316.03.
- Note:** Section 938.02 (15m), Stats., was renumbered to s. 938.02 (10p), Stats., by 2005 Wis. Act 344 and the term “secured correctional facility” was changed to “juvenile correctional facility”. Section 938.02 (15p), Stats., was repealed by 2005 Wis. Act 344. Section 938.02 (16), Stats., was renumbered to s. 938.02 (10r), Stats., and “secure detention facility” was changed to “juvenile detention facility” by 2005 Wis. Act 344.
- (f) “Tamper-resistant package” means a container bearing a beyond-use date that is sealed so that the contents cannot be used without obvious destruction of the seal.
- (2) No health items, after being taken from a pharmacy where sold, distributed or dispensed, may be returned to that pharmacy, except for any of the following:
- (a) From an inpatient health care facility, provided they are in their original containers, and the pharmacist determines the contents are not adulterated or misbranded.

- (b) Where the health items were dispensed in error, were defective, adulterated, misbranded, or dispensed beyond their beyond-use date.
 - (c) When in the professional judgment of the pharmacist, substantial harm could result to the public or a patient if they were to remain in the possession of the patient, patient's family or agent, or other person.
 - (d) For a secured institutional health care patient or resident health care patient where all of the following apply:
 - 1. The health item was never in the possession and control of the patient;
 - 2. The health item was sold, distributed or dispensed in a tamper-resistant package and, for a drug, includes the beyond use date and manufacturer's lot number;
 - 3. The health item is not commingled with a different health item unless the health item will be repackaged and redispensed to the same patient; and
 - 4. The health item is in its original container and the pharmacist determines the contents are not adulterated or misbranded.
 - (e) A health item that is prepackaged for consumer use and labeled in compliance with all applicable state and federal laws where all of the following apply:
 - 1. The pharmacist determines that the original package is unopened, sealed and intact and that package labeling is unaltered; and
 - 2. The pharmacist determines the contents are not adulterated.
- (3) Health items returned to a pharmacy, pursuant to sub. (2) (b) and (c), may not be sold, resold, or repackaged and sold or resold, given away, or otherwise distributed or dispensed. Returned health items shall either be destroyed at the pharmacy or delivered for destruction or other disposal by an authorized person or entity.
- (3m) Health items returned from a secured institutional health care patient to a pharmacy, pursuant to sub. (2) (d), must be segregated in the pharmacy and may not be sold, resold, or repackaged and sold or resold, given away, or otherwise sold, distributed or re-dispensed other than to a secured institutional health care patient.
- (4) It is not a "return" for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of repackaging and relabeling of that previously dispensed drug or device, and subsequent return of the drug or device for the same patient's use.
- Note: The DEA does not permit the return of controlled substances to a pharmacy from a non-DEA registrant under any circumstances.
- (5) It is not a "return" for a patient or agent of a patient to deliver a previously dispensed drug or device to a pharmacy for the purpose of destruction at the pharmacy or other disposal by an authorized person or entity.

Note: Cancer and chronic disease drug returns and redispensing pursuant to ch. HFS 148 are allowed provided the pharmacy follows the requirements in ch. HFS 148.

Note: A prescription drug that is returned to a pharmacy that primarily serves patients confined in a state prison is not addressed in this rule. Such a drug may be redispensed to a patient in a state prison provided the requirements of s. 450.09 (7m), Stats., are satisfied.

History: Cr. Register, January, 1983, No. 325, eff. 2-1-83; am. Register, August, 1991, No. 428, eff. 9-1-91; r. and recr., Register, December, 1998, No. 516, eff. 1-1-99; CR 05-029: cr. (1) (c) to (f), (2) (d) and (e), (3m) and (5), am. (2) (intro.) and (b) Register December 2005 No. 600, eff. 1-1-06.

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. There are also publications regarding household pharmaceutical waste. <http://www.dnr.state.wi.us/org/aw/wm/publications/index.html#hazard>

General information about hazardous waste in healthcare, 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>
<http://www.pharmacology.com>

Section C-Infectious Waste and Trace Chemotherapy Waste

Infectious waste information can be accessed at: <http://dnr.wi.gov/org/aw/wm/medinf/>.
One DNR publication that includes basic information is entitled: "For Generators of Small Amounts." Larger facilities should review "Medical Waste Reduction and the Annual Report."

Infectious waste regulations are mostly found in Wis. Admin. Code ch. NR 526.
Trace chemotherapy waste is regulated under Wis. Admin. Code § NR 526.055.

Section D-Drug Enforcement Administration

Office of National Drug Control Policy on destruction of medication:
<http://www.whitehousedrugpolicy.gov/policy/index.html>

Drug Enforcement Administration Frequently Asked Questions:
<http://www.deadiversion.usdoj.gov/faq/general.htm>