



Reverse Distribution of Pharmaceuticals

Guidance for Minnesota healthcare providers

Waste/Hazardous waste #3.36b • June 2011

Contents

What is reverse distribution?	1
When are pharmaceuticals subject to regulation? ...	1
Minimizing waste	2
MPCA requirements	2
Other requirements	3
Sent for use by another party	3
Donating	3
Training use	3
More information	4

What is reverse distribution?

In the course of normal operations, health care providers and pharmacies accumulate pharmaceuticals that, for various reasons, they will not use. The health care industry has developed a management process for returning some of these pharmaceuticals to specialized brokers for management – sometimes with a monetary credit to the provider. This process is known as reverse distribution.

Although the Minnesota Pollution Control Agency (MPCA) and the U.S. Environmental Protection Agency (EPA) considered reverse-distributed pharmaceuticals *products* exempt from hazardous waste requirements, the MPCA has become aware that the majority of these pharmaceuticals are destroyed or disposed of, making them *wastes* subject to the Minnesota Hazardous Waste Rules. Whether a pharmaceutical is eligible for return credit does not affect its *product* or *waste* status. In Minnesota, if a pharmaceutical is not used or reused for its intended purpose, it is a *waste*. The MPCA considers health care practitioners and pharmacies to be *generators* of these pharmaceutical wastes.

Nevertheless, the MPCA believes that the established reverse distribution system provides an environmentally protective method for handling waste pharmaceuticals. Therefore, it will allow Minnesota health care practitioners and pharmacies to manage certain pharmaceuticals through reverse distribution, subject to additional requirements discussed in this fact sheet.

When are pharmaceuticals subject to MPCA regulation?

When pharmaceuticals cannot or will not be used for their intended purpose, they are considered *waste* and are regulated by the MPCA. Assume a waste pharmaceutical is hazardous unless you have evaluated it and have documentation showing it to be non-hazardous. For help evaluating pharmaceuticals, see MPCA hazardous waste fact sheet #4.45a, [Evaluating Pharmaceutical Wastes](http://www.pca.state.mn.us/publications/w-hw4-45a.pdf) at <http://www.pca.state.mn.us/publications/w-hw4-45a.pdf>.

Product pharmaceuticals that will be used for their intended purpose and *waste* pharmaceuticals that have been shown to be non-hazardous are exempt from the Hazardous Waste Rules as well as the MPCA reverse distribution requirements discussed in this fact sheet. However, they may still be regulated by the Minnesota Board of Pharmacy (Board) or the U.S. Drug Enforcement Administration (DEA).

Minimizing pharmaceutical waste

Even though managing pharmaceuticals through the reverse distribution system may cost less than normal hazardous waste management, the cost is likely still considerable – even if you are eligible for return credit. By utilizing waste-minimization practices, you may be able to reduce not only your regulatory burden, but also your costs. The Minnesota Technical Assistance Program (MnTAP) has resources to help you to reduce pharmaceutical waste generation and costs. Contact MnTAP for assistance (see *More information*, page four).

MPCA requirements when using reverse distribution for pharmaceuticals

To be eligible to manage unevaluated or hazardous waste pharmaceuticals through a reverse distributor, you must:

- Get a Hazardous Waste Identification Number (HWID) – also known as an *EPA Identification Number* – free from the MPCA. To get a HWID, complete and submit MPCA hazardous waste form #7.09, [Notification of Regulated Waste Activity](http://www.pca.state.mn.us/publications/w-hw7-09.pdf) at <http://www.pca.state.mn.us/publications/w-hw7-09.pdf>.
- Ensure the reverse distributor you intend to use is licensed by the Board as a pharmaceutical manufacturer or wholesaler. If the pharmaceuticals are controlled substances regulated by the Board or DEA, the reverse distributor must also be a DEA Registrant.
- Document that all pharmaceuticals that (1) have not been evaluated or (2) would be hazardous waste in Minnesota will be disposed of according to hazardous waste disposal requirements. Documentation should include at least:
 - An agreement between you and your reverse distributor stipulating that disposal of those pharmaceuticals will meet hazardous waste disposal requirements; and
 - A management plan from the reverse distributor listing the identity and location of the hazardous waste disposal facility or facilities that will ultimately manage those pharmaceuticals.
- Accumulate and ship for reverse distribution only pharmaceutical wastes that you originally legally possessed as products. For questions on legal possession, contact the Board (see *More information*, page four). You may not accept or ship for reverse distribution any wastes that you have accepted from households or another generator.
- Accumulate and ship for reverse distribution only pharmaceuticals in closed, original manufacturer or appropriate dispensing containers that are labeled with the identity of the pharmaceutical. Containers that formerly held pharmaceuticals may also be shipped if they are closed and labeled with the identity of the pharmaceutical they held, and your reverse distributor will accept them. Wrappers and backing materials are not eligible for this addition.
- Label each pharmaceutical container accumulated for reverse distribution with one of the phrases: *Reverse Distribution*, *Pharmaceuticals for Reverse Distribution*, or *Expired Pharmaceuticals*; or accumulate the closed pharmaceutical containers in an open or closed box, bin or other accumulation container labeled with one of these phrases.
- Maintain the following records at your site for at least three years from the shipping date:
 - Shipping record (obtain or prepare this immediately) that includes at least the date and amount of the shipment by either weight or container count and the name and address of the reverse distributor.
 - Disposal record (obtain from your reverse distributor within 40 days) that includes at least the date of shipment to the reverse distributor and, for each pharmaceutical in the shipment: the identity, weight or unit count, hazardous waste code, and hazardous waste disposal method.
- Comply with all requirements, limitations, and prohibitions of your chosen reverse distributor.
- Comply with all applicable requirements of the Board, DEA, U.S. Department of Transportation (DOT), and any other applicable federal, state, or local law.

Other hazardous waste requirements

Do not count reverse-distributed pharmaceuticals when determining your hazardous waste generator size.

Pharmaceuticals transported within a reverse-distribution system need not be accompanied by a hazardous waste manifest. However, if classified as a hazardous material by the DOT, a pharmaceutical may still be subject to the DOT's Hazardous Materials Regulations (HMR) requirements. Pharmaceuticals originally shipped to you as 'ORM-D' consumer commodities may remain eligible for the 'ORM-D' allowances under the HMR when they become waste shipped for reverse distribution. For questions on the HMR, contact the DOT (see *More information*, page four).

If you are located:

- **Within the seven-county metropolitan area** (Anoka, Carver, Dakota, Hennepin, Ramsey, Scott, or Washington County) – contact your county regulator for county-specific reporting and licensing requirements (see *More information*, page four).
- **Outside the seven-county metropolitan area** – and you generate less than 100 pounds annually of 'countable' hazardous waste, you do not need to obtain a Hazardous Waste Generator License nor pay annual fees to the MPCA. You must still complete and submit a License Application every three years. The MPCA will notify you when you need to complete an Application.

Pharmaceutical manufacturers and wholesalers are not eligible for the reduced requirements for reverse distribution discussed in this fact sheet. Pharmaceutical wastes they generate or receive through a reverse-distribution system are subject to full hazardous waste requirements.

Reverse-distributed pharmaceuticals not managed according to the requirements discussed in this fact sheet remain fully regulated wastes subject to all normal requirements of the Minnesota Hazardous Waste Rules.

Pharmaceuticals sent for use by another party

Pharmaceuticals that can and will be used for their intended purpose remain *products* not subject to MPCA requirements. Health care practitioners and pharmacies who intend to ship pharmaceuticals they cannot use to another party for use, however must be able to document that those pharmaceuticals will be used as intended.

Donating pharmaceuticals

Donating pharmaceuticals for legitimate use by charitable organizations is allowed by the MPCA; however, the practitioner or pharmacy must be able to document a reasonable belief that the donated pharmaceuticals will be used for their intended purpose by the receiving organization. Both the donor and receiver may also need to meet additional state and federal requirements relating to pharmaceutical possession and export. The MPCA cautions that, unless carefully planned in partnership with a responsible relief agency, many such well-intentioned donations end up being abandoned at their destination and remain the legal responsibility of the donor.

Training use

Pharmaceuticals may be supplied in forms (such as some pre-filled dispensing instruments) that require training for proper use. For training purposes, the MPCA previously allowed the use of unevaluated or hazardous expired pharmaceuticals that would not be administered to humans or animals. However, the MPCA has become aware that reasonable non-pharmaceutical training alternatives exist for the majority of training needs. Therefore, it will no longer allow training use of unevaluated or hazardous expired pharmaceuticals for which reasonable alternatives exist.

In the unusual case that a training product is not available, the training program must document that obtaining or constructing a training-only product would be unreasonable before using an unevaluated or hazardous expired pharmaceutical for training.

More information

Your metropolitan county and the MPCA have staff available to answer waste management questions. For more information, contact your metropolitan county hazardous waste office or your nearest MPCA regional hazardous waste staff. For information about waste reduction, contact the Minnesota Technical Assistance Program.

Metro County Hazardous Waste Offices

Anoka.....763-422-7093
Carver 952-361-1800
Dakota 952-891-7557
Hennepin 612-348-3777
Ramsey 651-266-1199
Scott952-496-8475
Washington.....651-430-6655
Websites..... [http://www.co.\[county\].mn.us](http://www.co.[county].mn.us)

Minnesota Pollution Control Agency

Toll free (all offices)..... 1-800-657-3864
Brainerd 218-828-2492
Detroit Lakes218-847-1519
Duluth218-723-4660
Mankato507-389-5977
Marshall507-537-7146
Rochester507-285-7343
St. Paul651-296-6300
Willmar320-214-3786
Website<http://www.pca.state.mn.us>

Minnesota Board of Pharmacy

Statewide 651-201-2825
Website <http://www.phcybrd.state.mn.us/>

Minnesota Technical Assistance Program

Toll free 1-800-247-0015
Metro area 612-624-1300
Website<http://www.mntap.umn.edu>

Minnesota Department of Transportation

Hazardous materials651-215-6330
Website
... <http://www.dot.state.mn.us/cvo/hazmat.html>

U.S. Department of Transportation

Hazardous materials 1-800-467-4922
Website..... <http://www.phmsa.dot.gov/hazmat>

U.S. Drug Enforcement Administration

Office of Diversion Control 1-800-882-9539
Website..... <http://www.deadiversion.usdoj.gov/>