

# Pharmaceutical reverse distribution

## Conditions for Minnesota health care facilities and reverse distributors

### What is pharmaceutical reverse distribution?

In the course of normal operations, health care facilities accumulate pharmaceuticals that they will not use or dispense. The health care industry has developed a process for returning some of these pharmaceuticals to specialized brokers or the manufacturers for management and disposal. The Minnesota Pollution Control Agency (MPCA) refers to this process as *pharmaceutical reverse distribution*.

### When are pharmaceuticals subject to MPCA requirements?

In Minnesota, a material is a *product* only if it can, and reasonably will, be used for its intended purpose. A material must be considered a *waste* if it cannot, or reasonably will not, be used for its intended purpose. Whether a rebate or credit is offered for receipt of a waste does not affect its status in Minnesota. The MPCA has determined that nearly all pharmaceuticals managed through pharmaceutical reverse distribution are ultimately discarded. Unless demonstrably used for their intended purpose as pharmaceuticals, all pharmaceuticals in Minnesota managed through pharmaceutical reverse distribution must be assumed to be waste. Pharmaceutical wastes are subject to the hazardous waste requirements administered by the MPCA and the Metropolitan Counties of Anoka, Carver, Dakota, Hennepin, Ramsey, Scott, and Washington (Metro Counties), regardless of whether the wastes are eligible for a rebate or credit. Health care facilities shipping wastes to a reverse distributor are considered the *generators* of these wastes.

However, the MPCA has determined that the established pharmaceutical reverse distribution system provides an environmentally protective method for handling waste pharmaceuticals. Therefore, the MPCA allows Minnesota health care facilities to manage pharmaceutical wastes through pharmaceutical reverse distribution instead of meeting the full hazardous waste requirements, if they comply with the conditions in this fact sheet.

### Are my pharmaceuticals hazardous wastes?

You must assume all pharmaceuticals managed through reverse distribution are hazardous wastes in Minnesota, unless you have evaluated them to be non-hazardous or can affirmatively show that they are products that will be used for their intended purpose. Note that many more pharmaceutical wastes are regulated as hazardous waste in Minnesota than federally. For assistance, see MPCA fact sheet #w-hw4-45a, Evaluating Pharmaceutical Wastes, at <https://www.pca.state.mn.us/sites/default/files/w-hw4-45a.pdf>.

### Must I report pharmaceuticals managed through reverse distribution?

Do not annually report the volume of pharmaceutical wastes managed through reverse distribution to the MPCA or your Metro County. However, you must still report only whether your site generated any acute pharmaceutical hazardous waste at all during a calendar year or not, regardless of whether shipped off-site under a manifest or for reverse distribution (i.e. just 'Yes or No'). For more information identifying acute pharmaceutical hazardous wastes, see MPCA fact sheet #w-hw2-02, P-list and F-list of acute hazardous wastes, at <https://www.pca.state.mn.us/sites/default/files/w-hw2-02.pdf>.

Do not 'count' any pharmaceutical waste, whether managed through reverse distribution or manifested hazardous waste disposal, towards your site's regulated hazardous waste generator status.

## What are the pharmaceutical reverse distribution conditions in Minnesota?

To manage unevaluated or hazardous waste pharmaceuticals through reverse distribution, you must:

- Obtain a Hazardous Waste Identification Number (HWID, also known as an EPA ID#), from the MPCA if your site does not already have one. See MPCA fact sheet #w-hw1-03, Obtain a Hazardous Waste Identification Number, at <https://www.pca.state.mn.us/sites/default/files/w-hw1-03.pdf>.
- Verify the initial reverse distributor that will receive your pharmaceuticals is licensed by the Minnesota Board of Pharmacy (Board) as a pharmaceutical manufacturer or wholesaler. Pharmaceuticals may be subsequently transferred through an unlimited number of reverse distributors prior to disposal. For questions on Board licensure, contact the Board. See [More information](#) on page 3.
- If the pharmaceuticals are controlled substances regulated by the Board or U.S. Drug Enforcement Administration (DEA), verify the reverse distributor is also a DEA Registrant. For questions on DEA Registration, contact the DEA. See [More information](#) on page 3.
- Accumulate and ship for pharmaceutical reverse distribution only pharmaceuticals in original manufacturer packaging or recalled pharmaceuticals in any condition. Aerosol-dispensed pharmaceuticals are eligible for management by reverse distribution, however not all reverse distributors accept them. Disinfectants and cleaners are not considered eligible pharmaceuticals.
- Comply with all return criteria of your pharmaceutical reverse distributor(s).
- If pharmaceuticals to be shipped for reverse distribution are hazardous materials under the U.S. Department of Transportation (DOT) Hazardous Materials Regulations (HMR), prepare a shipping paper compliant with the HMR. Do not prepare or use a hazardous waste manifest for shipments of pharmaceuticals managed through reverse distribution. Keep copies of shipping papers for three years.  
Note: Pharmaceutical products originally shipped to you as Limited Quantities, previously known as ORM-D Consumer Commodities, may remain eligible for Limited Quantity reduced requirements, including exemption from shipping papers, under the HMR when they become waste. The ORM-D name is being phased out December 31, 2020, however the Limited Quantity category will remain. For questions about HMR requirements, contact the DOT. See [More information](#) on page 3.
- Obtain and keep a copy of the reverse distributor's confirmation of delivery of your shipments.

**If you do not follow these conditions, your pharmaceutical wastes must be managed as fully regulated hazardous wastes.** For a summary of hazardous waste requirements, see MPCA fact sheet #w-hw1-00, Summary of Hazardous Waste Requirements, at <https://www.pca.state.mn.us/sites/default/files/w-hw1-00.pdf>.

## May I manage pharmaceuticals from households under this allowance?

Do not manage pharmaceuticals collected from households under this allowance. Manage collected household pharmaceuticals under the requirements discussed in MPCA fact sheet #w-hhw2-07, Collecting Pharmaceuticals from Households and Long Term Care Facilities, at <https://www.pca.state.mn.us/sites/default/files/w-hhw2-07.pdf>.

## May I donate my unwanted pharmaceuticals instead of discarding them?

You may donate pharmaceutical products for intended use by charitable organizations, however, you must be able to document a reasonable belief that they will ultimately be used for their intended purpose. Both the donor and recipient may also need to meet additional state and federal requirements relating to pharmaceutical possession and export. The MPCA cautions that, unless carefully planned, well-intentioned donations may end up being abandoned or unusable at their destination and remain your legal responsibility.

## May I use my unwanted pharmaceuticals for staff/student training?

Because training aids that do not contain pharmaceuticals are generally available or easily made, the MPCA no longer allows unwanted pharmaceuticals to be used for any training that will result in their release to the environment, unless you document that use of a non-pharmaceutical training aid is unfeasible.

# What are the requirements for reverse distribution facilities in Minnesota?

If you operate a pharmaceutical reverse distribution facility in Minnesota, you must:

- Comply with all [pharmaceutical reverse distribution conditions](#) on page 2 of this fact sheet.
- Maintain a current inventory, updated at least monthly, of all pharmaceuticals at your site.
- Accumulate pharmaceuticals for 180 days or less, regardless of intended destination.
- Meet the emergency planning and preparedness requirements for a Large Quantity Generator of hazardous waste (LQG). For more information, see MPCA fact sheet #w-hw1-08c, Emergency Planning for Large Quantity Generators, at <https://www.pca.state.mn.us/sites/default/files/w-hw1-08c.pdf>.
- Report any shipments of unauthorized waste you receive, including non-pharmaceutical hazardous wastes, infectious wastes, or wastes not complying with the return criteria you have provided your customer health care facilities, to the MPCA or your Metro County within 45 days of receipt of the waste.
- Comply with the regulatory requirements for Very Small Quantity Generators of hazardous waste (VSQG) for all pharmaceuticals that will be shipped from your site under a hazardous waste manifest for disposal, including annual reporting. For more information on VSQG requirements, see MPCA fact sheet #w-hw1-00, Summary of Hazardous Waste Requirements, at <https://www.pca.state.mn.us/sites/default/files/w-hw1-00.pdf>.

## More information

Guidance and requirements in this fact sheet were compiled from Minnesota Rules, Chapter 7045; and Code of Federal Regulations, Title 40, Part 266; and incorporate regulatory interpretation decisions made by the MPCA on May 6, 2011; December 14, 2016; April 12, 2017; and October 14, 2020. Visit the Office of the Revisor of Statutes at <https://www.revisor.mn.gov/pubs> to review Minnesota Rules.

### Metro County Hazardous Waste Offices

Anoka .....	763-422-7093
.....	<a href="https://www.anokacounty.us/">https://www.anokacounty.us/</a>
Carver .....	952-361-1800
.....	<a href="http://www.co.carver.mn.us/">http://www.co.carver.mn.us/</a>
Dakota .....	952-891-7557
.....	<a href="https://www.co.dakota.mn.us/">https://www.co.dakota.mn.us/</a>
Hennepin .....	612-348-3777
.....	<a href="http://www.hennepin.us/">http://www.hennepin.us/</a>
Ramsey .....	651-266-1199
.....	<a href="https://www.ramseycounty.us/">https://www.ramseycounty.us/</a>
Scott .....	952-496-8177
.....	<a href="http://www.scottcountymn.gov/">http://www.scottcountymn.gov/</a>
Washington .....	651-430-6655
.....	<a href="https://www.co.washington.mn.us/">https://www.co.washington.mn.us/</a>

### Minnesota Pollution Control Agency

Toll free (all offices) .....	1-800-657-3864
All offices .....	651-296-6300
.....	<a href="https://www.pca.state.mn.us/">https://www.pca.state.mn.us/</a>

### Minnesota Board of Pharmacy

Statewide.....	651-201-2825
.....	<a href="https://mn.gov/boards/pharmacy/">https://mn.gov/boards/pharmacy/</a>

### U.S. Drug Enforcement Administration

Toll free .....	1-800-882-9539
Minneapolis Field Office .....	612-344-4143
.....	<a href="https://www.deadiversion.usdoj.gov/">https://www.deadiversion.usdoj.gov/</a>

### U.S. Department of Transportation

Customer service .....	202-366-4000
Hazardous materials .....	1-800-467-4922
.....	<a href="https://www.phmsa.dot.gov/">https://www.phmsa.dot.gov/</a>