

Pharmaceutical Reverse Distribution

Conditions for Minnesota healthcare providers and reverse distributors

What is pharmaceutical reverse distribution?

In the course of normal operations, health care providers and pharmacies 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 be, and reasonably will be, used for its intended purpose. A material must be considered a *waste* if it cannot be, 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 providers and pharmacies are considered the *generators* of these wastes.

However, the MPCA believes the established pharmaceutical reverse distribution system provides an environmentally protective method for handling waste pharmaceuticals. Therefore, the MPCA allows Minnesota health care providers and pharmacies to manage unwanted pharmaceuticals through pharmaceutical reverse distribution instead of meeting the full hazardous waste requirements, if the conditions discussed in this fact sheet are followed.

Are my pharmaceuticals hazardous wastes?

You must assume all pharmaceuticals managed through reverse distribution will be discarded and 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. For help evaluating unwanted pharmaceuticals, see MPCA fact sheet #w-hw4-45a, Evaluating Pharmaceutical Wastes, at <https://www.pca.state.mn.us/sites/default/files/w-hw4-45a.pdf>.

May I donate my unwanted pharmaceuticals instead of discarding them?

You may donate pharmaceutical products for legitimate 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, many well-intentioned donations end up being abandoned or unusable at their destination and may 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 a non-pharmaceutical training aid is unfeasible.

What are the pharmaceutical reverse distribution conditions in Minnesota?

To manage unevaluated or hazardous waste pharmaceuticals through pharmaceutical reverse distribution, you must follow all these conditions:

- Obtain a Hazardous Waste Identification Number, also known as an EPA Identification Number, or EPA ID#, from the MPCA if your site does not already have one. For more information on HWIDs, and the weblink to the tool to request 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>.
- Ensure each reverse distributor you intend to use is licensed by the Minnesota Board of Pharmacy (Board) as a pharmaceutical manufacturer or wholesaler. If the pharmaceuticals are controlled substances regulated by the Board or U.S. Drug Enforcement Administration (DEA), the reverse distributor must also be a DEA Registrant. For questions on Board licensure, contact the Board. For questions on DEA Registration, contact the DEA. See [More information](#) on page 4.
- Accumulate and ship to a pharmaceutical reverse distributor only pharmaceuticals that you legally possess. For questions on legal possession, contact the Board. See [More information](#) on page 4.
- Do not manage collected household pharmaceuticals under this allowance; instead 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>.
- Accumulate and ship for pharmaceutical reverse distribution only pharmaceuticals in closed, original manufacturer or appropriate dispensing containers that are labeled with the identity of the pharmaceutical. Containers, wrappers, and packaging that formerly held pharmaceuticals may be shipped for reverse distribution if labeled with the identity of the pharmaceutical they held, and your reverse distributor has agreed to accept them.
- Label each pharmaceutical container accumulated for pharmaceutical reverse distribution with: Reverse Distribution, Pharmaceuticals for Reverse Distribution, Pharmaceuticals for Return, or Expired Pharmaceuticals; or accumulate the closed pharmaceutical containers in a box or bin labeled with one of these phrases. The box or bin may be left open during accumulation.
- Comply with all requirements, limitations, and prohibitions of your pharmaceutical 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.
- Maintain a copy of the following records at your site for at least three years from the shipping date:
 - A written statement from your pharmaceutical reverse distributor that any pharmaceutical wastes that they will ship to a disposal facility from their location will be disposed in compliance with the federal, state, and local requirements applicable at their location. No statement is needed for pharmaceuticals that your reverse distributor will forward to a manufacturer or subsequent reverse distributor.
 - If your reverse distributor is located in Minnesota, see [What are the requirements for reverse distribution sites in Minnesota?](#) on page 3 for allowances and requirements applicable to lethal hazardous waste pharmaceuticals.
 - A record for each shipment of the date, the volume by either weight or container count, and the name and address of the receiving facility.
 - Your reverse distributor's written requirements, limitations, and prohibitions.

If you do not follow these conditions, your pharmaceutical wastes must be managed under the full hazardous waste requirements. 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>.

What are other differences from the full hazardous waste requirements?

When you manage some or all of your pharmaceutical wastes through reverse distribution:

- Pharmaceuticals managed through reverse distribution may be transferred through an unlimited number of reverse distributors or manufacturers prior to their final disposal.
- As long as you keep a copy of the statement from your pharmaceutical reverse distributor required in [What are the pharmaceutical reverse distribution conditions in Minnesota?](#) on page 2, you do not need to identify or obtain documentation from any subsequent handlers, reverse distributors, manufacturers, or disposal facilities.
- Do not use a Uniform Hazardous Waste Manifest to ship your reverse-distributed pharmaceutical waste. However, if your pharmaceuticals are classified as a hazardous material by the DOT, comply with the DOT's Hazardous Materials Regulations (HMR).
 - Pharmaceutical products originally shipped to you as Limited Quantities, also known as ORM-D Consumer Commodities, may remain eligible for Limited Quantity allowances under the HMR when they become waste. For questions about HMR requirements, contact the DOT or Minnesota Department of Transportation (Mn/DOT). See [More information](#) on page 4.
- Do not count reverse-distributed pharmaceuticals towards your site's regulated hazardous waste generator size. For more information on counting hazardous wastes and determining your site's generator size, see MPCA fact sheet #w-hw1-02, Determine Generator Size, at <https://www.pca.state.mn.us/sites/default/files/w-hw1-02.pdf>.
- Aerosol-dispensed drugs, such as asthma inhalers, are considered pharmaceuticals eligible for reverse distribution by the MPCA, however not all reverse distributors will accept them. Always check with your pharmaceutical reverse distributor to ensure you comply with their acceptance criteria.
- Disinfectants and cleaners, such as hand sanitizers and bulk alcohol, are not considered pharmaceuticals eligible for reverse distribution by the MPCA. Manage these wastes as normal hazardous wastes.
- If your site is located within a Metro County, contact your county environmental department to determine your local reporting and licensing requirements for reverse-distributed pharmaceuticals. See [More information](#) on page 4.
- If your site is located outside the Metro Counties, do not report reverse-distributed pharmaceuticals to the MPCA on your annual hazardous waste generator license application. See MPCA fact sheet #w-hw5-13, Hazardous Waste License Application e-Service Instructions, at <https://www.pca.state.mn.us/sites/default/files/w-hw5-13.pdf>.

What are the requirements for reverse distribution sites in Minnesota?

If you operate a pharmaceutical reverse distribution site in Minnesota, comply with all the conditions and other differences discussed above in this fact sheet.

In addition, you may dispose of lethal hazardous waste pharmaceuticals that are not regulated federally as hazardous wastes by solid waste incineration in or outside Minnesota. A Uniform Hazardous Waste Manifest is not required for these shipments. However, the MPCA cautions that if you choose to ship to an incinerator in Minnesota, you must notify the incinerator of the identity of the waste. Incinerators may choose to accept or not accept this waste.

The MPCA will also allow you to ship lethal hazardous waste pharmaceuticals that are not regulated federally as hazardous wastes for disposal in a solid waste landfill outside Minnesota. A Uniform Hazardous Waste Manifest is not required for these shipments. You may not dispose of lethal hazardous waste pharmaceuticals in a landfill in Minnesota.

More information

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

Contact your Metropolitan County or the MPCA with your questions. The MPCA's Small Business Environmental Assistance Program can also provide free, confidential regulatory compliance assistance. The Minnesota Technical Assistance Program offers help to reduce your waste generation, cost, and risk. Report all hazardous waste spills to the environment immediately to the Minnesota Duty Officer.

Metro County Hazardous Waste Offices

Anoka	763-422-7093
.....	https://www.anokacounty.us/
Carver	952-361-1800
.....	http://www.co.carver.mn.us/
Dakota	952-891-7557
.....	https://www.co.dakota.mn.us/
Hennepin	612-348-3777
.....	http://www.hennepin.us/
Ramsey	651-266-1199
.....	https://www.ramseycounty.us/
Scott	952-496-8177
.....	http://www.scottcountymn.gov/
Washington	651-430-6655
.....	https://www.co.washington.mn.us/
U.S. Drug Enforcement Administration	
Toll free	1-800-882-9539
Minneapolis Field Office	612-344-4143
.....	https://www.deadiversion.usdoj.gov/
U.S. Department of Transportation	
Customer service	202-366-4000
Hazardous materials.....	1-800-467-4922
.....	https://www.phmsa.dot.gov/

Minnesota Pollution Control Agency

Toll free (all offices)	1-800-657-3864
All offices	651-296-6300
.....	https://www.pca.state.mn.us/
Minnesota Duty Officer	
Toll free	1-800-422-0798
Metro	651-649-5451
Small Business Environmental Assistance Program	
Toll free	1-800-657-3938
Metro	651-282-6143
.....	https://www.pca.state.mn.us/sbeap/
Minnesota Technical Assistance Program	
Toll free	1-800-247-0015
Metro	612-624-1300
.....	http://www.mntap.umn.edu
Minnesota Department of Transportation	
Toll free	1-800-657-3774
Hazardous materials	612-215-6330
.....	http://www.dot.state.mn.us/cvo/
Minnesota Board of Pharmacy	
Statewide.....	651-201-2825
.....	https://mn.gov/boards/pharmacy/