

# Changes in pharmaceutical waste management

*Pharmaceutical waste* in Minnesota includes any prescription drugs, over-the-counter drugs, homeopathic drugs, dietary supplements, vaping liquids, inhalers, medicated patches, medicated gums and lozenges, and equipment and containers contaminated with these wastes.

Pharmaceutical waste generated by businesses and government agencies in Minnesota is regulated by the Minnesota Pollution Control Agency (MPCA) and the Metropolitan Counties of Anoka, Carver, Dakota, Hennepin, Ramsey, Scott, and Washington (Metro Counties). Pharmaceutical waste may also be regulated by the Minnesota Board of Pharmacy (Board) and the U.S. Drug Enforcement Administration (DEA). This fact sheet will explain changes to existing pharmaceutical waste management requirements in Minnesota. For questions about Board or DEA requirements, contact these agencies directly. See [More information](#) on page 2.

Unless exempted in this fact sheet, or evaluated by the generator as non-hazardous, all pharmaceutical waste must be assumed to be hazardous waste in Minnesota and managed accordingly. Find more information about evaluating pharmaceutical waste in MPCA fact sheet #w-hw4-45a, Evaluating pharmaceutical waste at: <https://www.pca.state.mn.us/sites/default/files/w-hw4-45a.pdf>.

## When are the changes effective?

To give businesses and government agencies time to adjust to changing requirements, the MPCA will be 'phasing-in' these changes over several years. ***However, the most critical change for most generators is the ban on sewerage federally-regulated pharmaceutical hazardous wastes that became effective in 2019.***

### Currently in effect:

- Pharmaceutical wastes that are unevaluated or that have been evaluated as federally-regulated (P-listed, U-listed, Ignitable, Oxidizers, Corrosive, Reactive, or Toxicity Characteristics) may not be sewerage for disposal.
- Pharmaceutical wastes manifested off-site for disposal must list hazardous waste code 'PHRM' on the manifest.
- Controlled substance pharmaceuticals are exempt from hazardous waste requirements if they are:
  - Not sewerage for disposal.
  - Contained and accumulated under Board and DEA requirements.
  - Destroyed by solid waste incineration or hazardous waste incineration or other DEA-approved method.

**Note:** Many controlled substances can also be evaluated and shown to be non-hazardous.

- Fentanyl patches may be assumed non-hazardous in Minnesota. Generators within cities provided sewer service by the Metropolitan Council Environmental Services (MCES) may sewer fentanyl patches for disposal. Generators not served by MCES must contact their sewerage provider before sewerage fentanyl patches.
- Pharmaceutical stock and dispensing containers with a capacity of up to 10,000 tablets or 1 liter of liquid are exempt from hazardous waste requirements if the contents have been removed by normal means.
- Nonprescription (also known as over-the-counter, or OTC) nicotine replacement therapies approved by the U.S. Food & Drug Administration (FDA) are exempt from hazardous waste requirements. Prescription nicotine and vaping products remain regulated pharmaceutical hazardous wastes.
- Pharmaceutical wastes no longer 'count' towards a healthcare facility's regulated generator size, however healthcare facilities must still annually report the volumes of pharmaceutical hazardous waste shipped off-site using a hazardous waste manifest. Pharmaceutical waste managed through reverse distribution does not need to be reported annually to the MPCA or Metro County, except for acute pharmaceutical hazardous waste as below.
- Healthcare facilities no longer must separately report the volume of acute pharmaceutical hazardous waste, and must instead report only whether they generated any acute pharmaceutical hazardous waste at a site at all during a calendar year or not, regardless of whether shipped off-site under a manifest or for reverse distribution.

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**Currently in effect: (continued from page 1)**

- Small Quantity Generators (SQGs) and Large Quantity Generators (LQGs) that generate pharmaceutical hazardous waste may accumulate any pharmaceutical wastes for up to one year from the date of generation. Pharmaceutical wastes accumulated for reverse distribution may be accumulated indefinitely.
- Pharmaceutical waste containers no longer need to be marked with the date of generation, but LQGs and SQGs must still be able to show that the waste has been accumulated for less than a year.
- For shipments of pharmaceutical waste managed through reverse distribution, confirmation of delivery to the intended receiving facility and copies of any applicable U.S. Department of Transportation shipping papers must be maintained on-site at healthcare facilities and available for inspection.

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**Beginning 2021:**

- Annual reports of pharmaceutical wastes generated in 2020 must begin using hazardous waste code 'PHRM'.

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**Expected 2022:**

- Lethal pharmaceutical hazardous wastes will be prohibited from sewerage for disposal.
  - SQGs and LQGs that generate pharmaceutical waste will be required to provide at least one-time hazardous waste training to all employees who handle pharmaceutical hazardous waste.
  - Pharmaceutical hazardous waste containers will be required to be secured or located in secured areas.
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## Who is affected by these changes?

The changes summarized in this fact sheet apply to all businesses and government agencies that provide health care to people or animals, including employees or students, or that sell or offer pharmaceuticals for use. These changes do not apply to pharmaceutical manufacturers. Residential care facilities with a capacity of six residents or less may consider their wastes to be exempt household wastes.

**Note:** This fact sheet only summarizes changes to existing requirements, and is not a complete list of all existing requirements potentially applicable to pharmaceutical waste generators. See the resources at <https://www.pca.state.mn.us/waste/hazardous-waste-documents-and-forms> for complete requirements.

## More information

Discussion of individual changes summarized in this fact sheet may be found in MPCA fact sheet #w-hw3-35, Regulatory consensus on health care issues at: <https://www.pca.state.mn.us/sites/default/files/w-hw3-35.pdf>.

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 17, 2019; October 9, 2019; November 13, 2019; and October 14, 2020.

### Metro County Hazardous Waste Offices

Anoka .....	763-324-4260
.....	<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) .....	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 .....	800-882-9539
Minneapolis Field Office .....	612-344-4143
.....	<a href="https://www.deadiversion.usdoj.gov/">https://www.deadiversion.usdoj.gov/</a>