Changes in pharmaceutical waste management

Pharmaceutical waste in Minnesota includes any prescription drugs, over-the-counter (OTC) 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 many generators will be the ban on sewering federally-regulated pharmaceutical hazardous wastes effective August 21, 2019.

Effective immediately:

- Controlled substance pharmaceuticals will be exempt from hazardous waste requirements if they meet all of these conditions:
  - Not sewered 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 be evaluated and shown to be non-hazardous.

- Pharmaceutical stock and dispensing containers with a capacity of up to 10,000 tablets or 1 liter of liquid will be 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) will be exempt from hazardous waste requirements. Prescription nicotine and vaping products remain fully regulated.

- Large quantity generators (LQGs) and small quantity generators (SQGs) may accumulate any pharmaceutical wastes for up to one year from the date of generation. Pharmaceutical wastes accumulated for reverse distribution and wastes at very small quantity generators (VSQGs) 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.

As of August 21, 2019:

- 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 sewered for disposal.

- Pharmaceutical wastes manifested for disposal must list hazardous waste code 'PHARMS' on the manifest.
As of January 1, 2020:

- Pharmaceutical wastes managed through reverse distribution must begin being reported to the MPCA or Metro Counties. Pharmaceuticals may be reported using hazardous waste code 'PHAR'. All pharmaceutical wastes will be counted towards a site’s status for pharmaceutical waste operational requirements, but will not count towards a site’s status for all other hazardous waste standards.

  **Note:** A site may have two different hazardous waste statuses, or 'sizes'; one for pharmaceuticals that counts all regulated waste at the site, and another one for all other wastes that does not count pharmaceuticals.

Expected 2022:

- Pharmaceutical wastes that are Lethal Characteristic wastes will also be prohibited from sewering for disposal.
- Pharmaceutical LQGs and SQGs will be required to provide initial hazardous waste training to employees who handle only satellite accumulation containers.
- Pharmaceutical hazardous waste containers will be required to be secured.
- Pharmaceutical reverse distributors will be required to meet LQG employee training and emergency preparedness requirements.

Who is affected by these changes?

The changes in pharmaceutical hazardous waste requirements summarized in this fact sheet apply to all businesses and government agencies that provide health care to people or animals or that sell or offer pharmaceuticals for use. Residential care business facilities with a capacity of six residents or less may consider their wastes to be household wastes exempt from these requirements.

**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](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](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. Visit the Office of the Revisor of Statutes at [https://www.revisor.mn.gov/pubs](https://www.revisor.mn.gov/pubs) to review applicable Minnesota Statutes and Rules.

Metro County Hazardous Waste Offices

- **Anoka** .......................................................... 763-324-4260
  ..................................................[https://www.anokacounty.us/](https://www.anokacounty.us/)
- **Carver** .......................................................... 952-361-1800
  ..................................................[http://www.co.carver.mn.us/](http://www.co.carver.mn.us/)
- **Dakota** .......................................................... 952-891-7557
  ..................................................[https://www.co.dakota.mn.us/](https://www.co.dakota.mn.us/)
- **Hennepin** .......................................................... 612-348-3777
  ..................................................[http://www.hennepin.us/](http://www.hennepin.us/)
- **Ramsey** .......................................................... 651-266-1199
  ..................................................[https://www.ramseycounty.us/](https://www.ramseycounty.us/)
- **Scott** .......................................................... 952-496-8177
- **Washington** .......................................................... 651-430-6655
  ..................................................[https://www.co.washington.mn.us/](https://www.co.washington.mn.us/)

Minnesota Pollution Control Agency

- Toll free (all offices) ........................................ 1-800-657-3864
- All offices ..................................................... 651-296-6300
  ..................................................[https://www.pca.state.mn.us/](https://www.pca.state.mn.us/)

Minnesota Board of Pharmacy

- Statewide ..................................................... 651-201-2825
  ..................................................[https://mn.gov/boards/pharmacy/](https://mn.gov/boards/pharmacy/)

U.S. Drug Enforcement Administration

- Toll free ..................................................... 1-800-882-9539
- Minneapolis Field Office ..................................... 612-344-4143