



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.

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 from MPCA factsheet [Evaluating Pharmaceutical Waste](#).

When are the changes effective?

To give businesses 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 August 21, 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 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 sewage 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.

CHANGES IN PHARMACEUTICAL WASTE MANAGEMENT

Currently in effect (cont. from page 1)

- 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 generated from healthcare no longer 'count' towards a site's generator size, however generators must begin keeping records of all pharmaceutical hazardous wastes generated in 2020, including pharmaceutical wastes managed through reverse distribution. All pharmaceutical wastes generated in 2020 will be required to be reported in 2021.
- Generators no longer must separately 'count' or segregate acute pharmaceutical hazardous wastes and may instead solely record whether they generate any acute pharmaceutical hazardous waste at all during a calendar year or not. Acute pharmaceutical hazardous wastes may be comingled with any other pharmaceutical wastes.
- 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. Very Small Quantity Generators (VSQGs) may accumulate pharmaceutical wastes 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.

Beginning 2021:

- Pharmaceutical wastes generated in 2020, including those managed through reverse distribution, must begin being reported to the MPCA or Metro Counties, using hazardous waste code 'PHRM'.

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.

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.

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