

Collecting Pharmaceuticals from Households and Long Term Care Facilities

Discarded pharmaceuticals from households and long term care facilities (LTCFs) present risks to human health and the environment if improperly managed. This fact sheet will discuss the hazardous waste requirements for these wastes administered by the Minnesota Pollution Control Agency (MPCA) and the Metropolitan Counties of Anoka, Carver, Dakota, Hennepin, Ramsey, Scott, and Washington (Metro Counties).

Discarded pharmaceuticals include: *controlled substances* regulated by the U.S. Drug Enforcement Administration (DEA), which include all drugs listed as a Schedule II, III, IV, or V controlled substance; prescription or *legend drugs* regulated by the Minnesota Board of Pharmacy (Board), which include any drugs that require a prescription to dispense; and over-the-counter (OTC) medications. Drugs collected from households and LTCFs must be assumed to include both controlled substances and legend drugs unless sorted.

In addition to the DEA and Board requirements, all collected pharmaceuticals must be assumed to be household hazardous wastes in Minnesota unless evaluated as non-hazardous. See MPCA fact sheet #w-hw4-45a, Evaluating Pharmaceuticals, at: <https://www.pca.state.mn.us/sites/default/files/w-hw4-45a.pdf>.

Note: Sorting and evaluation of collected pharmaceuticals is only allowed at law enforcement-partnered 'take-back' events. Pharmacies collecting discarded pharmaceuticals may not sort the pharmaceuticals they collect.

Who can collect discarded pharmaceuticals?

In Minnesota, only two types of sites may voluntarily collect discarded pharmaceuticals that include controlled substances and legend drugs from households or LTCFs:

- Law enforcement agencies operated by government entities.
- Pharmacies licensed by the Board and authorized by the DEA.

The collection requirements for law enforcement agencies and pharmacies are different. This fact sheet will discuss the collection requirements for pharmacies. Collection requirements for law enforcement agencies are discussed in MPCA fact sheet #w-hhw2-06, Pharmaceutical Collection for Law Enforcement, at: <https://www.pca.state.mn.us/sites/default/files/w-hhw2-06.pdf>.

Collection of discarded pharmaceuticals from households or LTCFs is voluntary for pharmacies in Minnesota and will not change the pharmacy's hazardous waste generator 'size' or increase its annual fees.

How does a pharmacy get authorized to collect pharmaceuticals?

Only pharmacies already properly licensed by the Board may collect discarded pharmaceuticals from households or LTCFs. Contact the Board for questions about pharmacy licensing. See [More information](#) on page 5.

In addition, a pharmacy that would like to collect discarded pharmaceuticals must complete all these steps:

- Modify its DEA registration to become an *authorized collector*. See [More information](#) on page 5.
- Ensure it has obtained a Hazardous Waste Identification Number (HWID) from the MPCA for each separate collection site, including LTCFs. *Household Pharmaceutical Collection Site* must be added as a Hazardous Waste Activity for the HWID. See [Who is responsible for collection receptacles at LTCFs?](#) on page 2 of this factsheet and the instructions for Item 1 on page 2 of MPCA form #w-hhw2-04, at: <https://www.pca.state.mn.us/sites/default/files/w-hhw2-04.doc>.
- Submit a Household Pharmaceutical Consolidation Site License Application, MPCA form #w-hhw2-04, at: <https://www.pca.state.mn.us/sites/default/files/w-hhw2-04.doc>.

Who is responsible for collection receptacles at LTCFs?

The sponsoring pharmacy is responsible for all steps in setting up and operating a collection receptacle at an LTCF, however the LTCF must pay for the installation and operation; pharmacies may violate federal Centers for Medicare and Medicaid Services (CMS) anti-kickback prohibitions if they do not charge the LTCF for collection and disposal services.

The sponsoring pharmacy must obtain a new HWID for sites at LTCFs; they may not use an existing HWID issued to the LTCF itself, nor may the LTCF obtain the HWID for the collection site. See the instructions for Item 1 on page 2 of MPCA form #w-hhw2-04, Household Pharmaceutical Consolidation Site License Application, at: <https://www.pca.state.mn.us/sites/default/files/w-hhw2-04.doc>.

Where can pharmacies collect pharmaceuticals?

Pharmacies may only collect pharmaceuticals inside their own building or inside an LTCF to which they provide pharmacy services. Pharmacies may not conduct off-site 'take-back' events or install drop boxes off-site or that are accessible from outside the pharmacy or when the pharmacy is closed.

What collection receptacles are required?

Pharmaceutical collection receptacles in a pharmacy or LTCF must be:

- Securely fastened to a permanent structure inside the building.
 - At a pharmacy, the receptacle must be visible from the pharmacy counter or otherwise continuously controlled by employees. If the pharmacy is located in a clinic, the receptacle must be in an area controlled by pharmacy employees and not located in or near urgent care treatment or waiting areas.
 - In a hospital with a pharmacy, the receptacle may be located away from the pharmacy space, but must be in placed where it will be regularly monitored by employees (not limited to pharmacy employees) and not located in or near urgent care or emergency care treatment or waiting areas.
 - At an LTCF, the receptacle must be located in a secured area regularly monitored by LTCF employees.
- Substantially constructed with a permanent, lockable outer shell and removable inner liner. The opening in the outer shell for customers to insert pharmaceuticals must be too small for contents to easily be removed through it.
- Labeled with a sign clearly stating that only Schedule II-V controlled substances, prescription drugs, and over-the-counter medications are accepted. No hazardous waste labeling is needed.
- Locked or made inaccessible any time the pharmacy is closed or an employee is not present.
- Inner liners must be:
 - Opaque, waterproof, tear-resistant, tamper-evident, and permanently sealable.
 - Marked with the size (e.g. in gallons) and a permanent, unique tracking number.

Who can put pharmaceuticals into a collection receptacle?

At a pharmacy, only the members of the public bringing in household pharmaceuticals may put discarded pharmaceuticals into collection receptacles. At an LTCF, only residents or LTCF staff may put pharmaceuticals into the receptacles. Pharmacy employees may not take pharmaceuticals directly from the public or place pharmaceuticals into receptacles themselves or handle the pharmaceuticals outside of a sealed inner liner.

Pharmacies are commonly asked who can bring discarded pharmaceuticals to a collection receptacle:

- If the pharmaceuticals include any controlled substances, then only the prescription-holder, a member of their immediate household, or the executor of their property if they are deceased may bring the controlled substances to the pharmacy.
- If the pharmaceuticals include only legend drugs and OTC medications, then the prescription-holder may designate any person to bring the pharmaceuticals to the pharmacy.

Only pharmaceuticals discarded by households may be placed into collection receptacles at a pharmacy. Only pharmaceuticals discarded by residents of an LTCF may be placed into collection receptacles at an LTCF.

Pharmacies may not place their own pharmaceutical wastes into collection receptacles. Other businesses may not bring their business pharmaceutical waste to a pharmacy's collection receptacle. Pharmacies must manage their own pharmaceutical wastes under the normal hazardous waste requirements. However, pharmacies may be eligible to use the existing pharmaceutical reverse distribution system to manage their own hazardous wastes. See MPCA fact sheet #w-hw3-36b, Reverse Distribution of Pharmaceuticals, at: <https://www.pca.state.mn.us/sites/default/files/w-hw3-36b.pdf>.

Law enforcement agencies may not bring discarded pharmaceuticals they have collected to a pharmacy, nor may law enforcement agencies pick up collected pharmaceuticals from a pharmacy for disposal.

Can medication containers be put in collection receptacles?

Medication containers, such as pharmacy vials, pill bottles, and dispensing jars may be placed into collection receptacles or households may empty their containers into a collection receptacle. Emptied household containers may be managed as normal solid waste, however the MPCA recommends that all patient-identifying information be removed from them or obliterated.

How must inner liners be handled when they are full?

When an inner liner is filled, or needs to be removed from the outer shell at a pharmacy, two pharmacy employees together must remove and immediately seal it. At an LTCF, either two pharmacy employees, or one pharmacy employee and one supervisor-level LTCF employee together, may remove a filled inner liner.

Filled inner liners must be stored at a pharmacy in the same manner and security as Schedule II controlled substances. Filled liners at an LTCF may be stored in a secured cabinet or room at the LTCF for up to three days after being removed. Filled liners from an LTCF may not be brought back to a pharmacy.

Inner liners must not be opened, X-rayed, or otherwise internally inventoried, however the liners must be weighed before they are shipped off-site for disposal, to report the amount collected annually to the MPCA.

How must inner liners be disposed?

The contents of filled inner liners must be rendered non-retrievable, or *destroyed*, under the applicable DEA standard. This is a separate standard than *disposal*, which is rendering wastes environmentally safe under the MPCA's requirements. Both standards must be met. The DEA has identified incineration as an acceptable destruction method. The MPCA and Metro Counties will allow collected discarded pharmaceuticals to be disposed by either solid waste incineration or hazardous waste incineration. The incineration does not need to take place in Minnesota.

The contents of filled inner liners may not be sewerred for destruction or burned on-site except in a state-permitted waste incinerator. Filled inner liners may not be disposed directly into the solid waste, even if their contents have been destroyed on-site using a DEA-approved method – they must still be incinerated.

How must inner liners be shipped off-site for disposal?

The MPCA and Metro Counties will allow filled inner liners may be transported for incineration without a hazardous waste manifest as long as all applicable DEA tracking, transport, and security standards are met. For questions on these standards, contact the DEA. See [More information](#) on page 5.

In addition, if you are shipping filled inner liners using a DEA-Registrant reverse distributor as the transporter, you must ensure that the transporter has obtained Special Permit SP-20255 from the U. S. Department of Transportation (DOT). If you are using a common carrier to ship filled inner liners to a DEA-Registrant reverse distributor, then you must obtain the Special Permit from the DOT yourself before shipping the liners.

Filled inner liners being shipped from a pharmacy or LTCF must be:

- Marked by the manufacturer as passing ASTM International Standard D1922.
- Closed and able to be inverted for five minutes with no leakage.
- Placed in a strong outer shipping package of fiberboard, plastic, or metal. Multiple inner liners may be placed into the same shipping package up to a total weight, with all packaging, of 66 pounds.

For questions on the Special Permit or packaging standards, contact the DOT. See [More information](#) on page 5.

What records must I keep and submit?

Keep a record of the date, location, liner tracking number, and liner size each time you install, remove, store, or ship an inner liner off-site, as well as the name and signatures of the two employees performing these actions. Keep a continuous inventory of all inner liners at your site, including both unused and filled liners.

In addition, keep a record of the name, address, and registration number of the reverse distributor each filled inner liner is sent to for destruction and disposal and the date it is sent. For questions about the above DEA records requirements, contact the DEA. See [More information](#) on page 5.

Finally, submit MPCA form #w-hhw2-05, Household Pharmaceutical Collection Program Annual Report, by March 31 each year. This form will be made available to you annually prior to the report period. You will need to report the total weight of pharmaceuticals collected during the previous calendar year at each site and the name of the vendor or disposal facility that accepted the collected pharmaceuticals for disposal.

What about sharps?

Pharmacies may collect household sharps separately from pharmaceuticals. No license or approval is needed from the MPCA or a Metro County to collect household sharps. Keep collected household sharps separate from any waste sharps your pharmacy generates itself, such as through vaccinations. See MPCA fact sheet #w-sw4-30, Infectious Waste: Management Guidance for Generators, at: <https://www.pca.state.mn.us/sites/default/files/w-sw4-30.pdf>.

Do not allow customers to place sharps containing drugs into your pharmaceutical collection receptacles unless you have verified that the reverse distributor you will be shipping the filled inner liners to for disposal agree to accept the sharps. While legal in Minnesota to mix sharps with discarded household pharmaceuticals that will be incinerated, many reverse distributors may be unable to safely accept them.

What about aerosols and liquids?

Similar to sharps, make sure that the reverse distributor you will be shipping the filled inner liners to can safely accept aerosols or liquids before allowing customers to place aerosol-delivered drugs, such as asthma inhalers, or liquids, such as cough syrup, into your pharmaceutical collection receptacles. While legal in Minnesota to mix aerosol and liquid pharmaceuticals with solid discarded household pharmaceuticals that will be incinerated, some reverse distributors or incinerators may be unable to safely accept them.

More information

Guidance in this fact sheet was compiled from the Code of Federal Regulations (CFR), Title 21, Parts 1300 through 1317; CFR Title 49, Parts 105 through 177; Minnesota Statutes, Chapter 151; and Minnesota Rules, Chapters 6800 and 7045; and incorporates regulatory interpretation decisions made by the MPCA on May 19, 2016, and June 8, 2016. To review Minnesota laws, visit the Office of the Revisor of Statutes at: <https://www.revisor.mn.gov/pubs>. To review the CFR, visit the U.S. Government Printing Office at: <https://www.gpo.gov/>.

The MPCA's Small Business Environmental Assistance Program offers free, confidential compliance assistance. Immediately report all hazardous waste spills 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	952-496-8475
.....	http://www.scottcountymn.gov/
Washington	651-430-6655
.....	https://www.co.washington.mn.us/

Minnesota Duty Officer

Toll free	1-800-422-0798
Statewide	651-649-5451

Minnesota Pollution Control Agency

Toll free	1-800-657-3864
Statewide	651-296-6300
.....	https://www.pca.state.mn.us/

Small Business Environmental Assistance Program

Toll free	1-800-657-3938
Statewide	651-282-6143
.....	https://www.pca.state.mn.us/sbeap/

Minnesota Board of Pharmacy

Statewide	651-201-2825
.....	https://mn.gov/boards/pharmacy/

U.S. Drug Enforcement Administration

Toll free	1-800-882-9539
Minneapolis Field Office	612-344-4143
.....	http://www.deadiversion.usdoj.gov/

U.S. Department of Transportation

Hazardous Materials	1-800-467-4922
.....	http://www.phmsa.dot.gov/