Self-Audit
Tips, Action Steps & Resources

Hazardous, infectious and dual waste pharmaceuticals
This section covers pharmaceuticals from your emergency kits, pharmacy, clinic(s) and/or over-the-counter drugs. If you have a clinic, please note that infectious waste (biohazardous, sharps, red bag or regulated medical waste) is not the same as hazardous waste. Each have separate waste disposal requirements. If your clinic generates hazardous waste pharmaceuticals, you will need to keep them in separate containers from your infectious wastes.

However, there are times when a waste can be both. In Minnesota this waste is called Dual Hazardous/Infectious Waste. Dual waste must be placed in a container designed for dual waste and not a red infectious waste container.

Reverse distribution for controlled substances
Any expired or unused pharmaceuticals that are classified as DEA Controlled Substances can go back to reverse distribution for destruction. Your facility will be notified by the county if there are any changes to these guidelines.

For more information
See Reverse Distribution of Non-Controlled Substance Pharmaceuticals at www.pca.state.mn.us/publications/w-hw3-36b.pdf.

Refer to the tips, action steps and resources to help you complete the audit.

1. Does your business return unused and/or expired pharmaceuticals to manufacturers or reverse distributors?
   □ Yes. List the name, phone number and address of the reverse distributor(s):

   ____________________________________________
   ____________________________________________
   ____________________________________________
   ____________________________________________

   Unused and/or expired pharmaceuticals in their original containers can be returned to manufacturers or reverse distributors.
   → Leaking containers, partially used liquids or paste, or pharmaceuticals that are inherently waste-like or exhibit characteristics that preclude their beneficial reuse as products and are determined to be hazardous waste must be managed as hazardous waste by your business and must not be returned to the manufacturer or reverse distributor.
   → Reverse distributors typically send an itemized return invoice that lists pharmaceuticals that were disposed of as hazardous waste. Keep these records on site and available for review for three years.

   □ No, this business does not return pharmaceuticals to a reverse distributor.

2. Pharmaceuticals that may not go to a reverse distributor.
   □ I understand that pharmaceuticals that meet the following descriptions are hazardous waste and must be disposed of through a permitted hazardous waste disposal company and not a reverse distributor.
   Pharmaceuticals that:
   • Are unlabeled, unidentifiable or are in a damaged/leaking container.
   • Are contaminated or mixed inseparably with other pharmaceuticals or other product.
   • Have been dispensed to a customer or released from the control of the pharmacy.
   • Were repackaged by the pharmacy.
   • Do not meet reverse distributor’s return criteria.
   • Are a sample.
   • Are expired.
Section: Pharmaceuticals for Reverse Distribution (continued)

Management Plan Form 2 — Pharmaceuticals for Reverse Distribution
Report how you manage or will manage your wastes. Call 612-348-3777 for assistance. ← Refer to the instructions for more information.

A. Waste name: Expired or Unused Pharmaceuticals

B. Four-digit hazardous waste code: □ D001 □ D009 □ D011 □ D024 □ MN01

C. Year waste was first generated at the site under current ownership: _____

D. Frequency of shipment or treatment: _____ times per _____ year

E. Source or process of generation (check all that apply):

- □ Expired
- □ Partially used
- □ Unusable medications
- □ Other (specify): ____________________________

F. On-site management of waste (select one):

- □ Stored for shipment (You ship or will ship your waste to a disposal or recycling facility)
- □ Other (specify) ____________________________

G. Type of waste storage container(s):

- □ Drum
- □ Pail
- □ Original container
- □ Other (specify) ____________________________

H. On-site storage location of the waste: □ Indoors □ Outdoors □ N/A

I. Amount generated per year: _____ gallons or _____ pounds

J. Check that you understand and follow the requirements for proper labeling and storage:

- □ Labeled with a clear description of the waste (e.g., Pharmaceuticals for Reverse Distribution)

K. Disposal facility management method (contact your disposal company if unknown)

- □ Incinerate
- □ Other (specify) ____________________________
- □ Have not identified a disposal company

L. Transporter name*: ____________________________

- □ Self
  - □ To be determined*

M. Transporter EPA ID number: ______________________

N. Disposer name*: ____________________________

- □ To be determined*

O. Disposer EPA ID number: ______________________