

Quick Start Guide

Management of Hazardous Waste Pharmaceuticals OTC Nicotine Exemption & Subpart P

This Quick Start Guide contains a short overview of the EPA regulations governing the management of hazardous waste pharmaceuticals at healthcare facilities. In 2019, EPA finalized the rule, Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine. It is a tailored set of regulations that apply specifically to the healthcare industry, and it addresses the unique challenges faced by healthcare facilities in complying with RCRA hazardous waste regulations. It is important to note that your state must adopt Subpart P and the OTC nicotine replacement therapy exemption before either can be used by your healthcare facility. For state adoption status of these rules, check with your state environmental agency or use this [EPA State Adoption Map](#). Also, be aware that states may have regulations that are more stringent than the federal regulations discussed in this document.

Exemption for OTC Nicotine Patches, Gums, and Lozenges

- OTC nicotine replacement therapies (i.e., lozenges, gums, and patches) and their wrappers are no longer hazardous waste and can be disposed as non-hazardous pharmaceutical waste or in the trash. This is a separate rule and applies whether or not you are subject to Subpart P. Unlike Subpart P, there is no need to notify your state if you are using the OTC NRT exemption but it can only be used once your authorized state has adopted this rule.

Subpart P

Sewer Ban:

- The sewer ban is in effect in all states, territories, and in Indian country. Regardless of your state's adoption status of Subpart P, as of August 21, 2019, NO hazardous waste pharmaceuticals can be disposed of down the drain at any healthcare facility in any state or territory or in Indian country.

Applicability

- All healthcare facilities must operate under Subpart P, except very small quantity generators (VSGQs).
- If you are a VSQG when counting all your hazardous waste, including hazardous waste pharma-

ceuticals, your healthcare facility is not required to operate under Subpart P. However, EPA encourages VSQG healthcare facilities to opt into Subpart P. That way, you can take advantage of all of the benefits of the rule while managing your pharmaceutical waste in a more environmentally protective manner. For example, if your healthcare facility is operating under Subpart P, then you no longer need to count the amount of hazardous waste pharmaceuticals generated or make individual hazardous waste determinations for each pharmaceutical waste. If you, as a VSQG, opt into subpart P, you must comply with all parts, including notifying your state. For Alaska, Iowa, and most territories, notify your EPA region.

- If a healthcare facility is managing hazardous waste pharmaceuticals under Subpart P, the hazardous waste pharmaceuticals will no longer count towards generator category going forward, but must be accounted for initially when determining whether you must operate under Subpart P. Based on the amounts of non-pharmaceutical hazardous waste generated, a healthcare facility may be able to reduce its generator category. Therefore, you must first determine whether you must operate under Subpart P based on total hazardous waste generated, including hazardous waste pharmaceuticals. Then, once you are operating under Subpart P, subtract the volume of hazardous waste pharmaceuticals to determine your new hazardous waste generator status for managing non-pharmaceutical hazardous waste.
- After Subpart P has been adopted by a state, the regulations are in effect regardless of notification by the healthcare facility. Your state environmental regulatory authority will indicate the exact date of when it goes into effect.

Notifying Under Subpart P

- If your healthcare facility is a small quantity generator (SQG) or a large quantity generator (LQG) of hazardous waste, including hazardous waste pharmaceuticals, you must notify the state by submitting Form 8700-12, the Site Identification Form, or corresponding state form. Some states also allow electronic notification via [myRCRAid](#). SQGs must notify within 60 days of adoption by their state but LQGs may notify with their Annual or Biennial Report, instead. For Alaska, Iowa, and most territories, notify your EPA region.

- The notification requirement applies even if the healthcare facility has already notified previously and has an EPA ID number. If the healthcare facility does not have an ID number, it will be assigned one by EPA upon notification.

Hazardous Waste Determination

- If a healthcare facility is managing hazardous waste pharmaceuticals under Subpart P, the organization does not need to perform a hazardous waste determination on each drug if all pharmaceutical waste, including non-hazardous pharmaceutical waste, is being managed as hazardous waste pharmaceuticals. However, incompatible hazardous waste pharmaceuticals, such as aerosols and oxidizers, must still be accumulated and managed separately, as must a drug that is prohibited from being incinerated, such as discarded arsenic trioxide.

Controlled Substances

- Hazardous waste controlled substances are exempted from hazardous waste regulation IF they are incinerated at one of five types of permitted incinerators listed in 40 CFR §266.506(b)(3). In addition, if in the future, DEA deems in writing that another method of destruction meets the non-retrievable standard, then that method may be used to destroy the hazardous waste controlled substances under this exemption. As of the date of this publication, DEA has not identified any additional methods of destruction that meet their non-retrievable standard.

Empty Container Standards

- Containers that once held pharmaceutical waste are considered RCRA empty, and are therefore, not regulated as hazardous waste if emptied by commonly employed practices. This applies to containers of up to 10,000 pills, and bottles/vials up to 1 liter.
- Empty warfarin containers, including stock bottles up to 10,000 pills and unit dose containers, are no longer P-listed hazardous waste and can be disposed in the trash.
- Empty arsenic trioxide vials and empty IV bags can be discarded as trace chemotherapy waste instead of hazardous waste.
- Arsenic trioxide waste itself must be accumulated and packaged separately and labeled as such by your hazardous waste vendor.
- Triple rinsing of containers that held P-listed hazardous waste pharmaceuticals is no longer allowed.

Outdated/Expired Hazardous Waste Pharmaceuticals

- Expired hazardous waste pharmaceuticals become a waste the day of expiration, or sooner, if a decision has been made to discard them. If they are in the original manufacturer's packaging, have not been dispensed to a patient, are within one year of expiration, and have a reasonable expectation of receiving manufacturer credit, they are considered to be "potentially creditable" and can be accumulated in your returns area and sent to a reverse distributor. If they do not meet these criteria, they must be placed into a hazardous waste pharmaceutical container immediately and managed as non-creditable hazardous waste pharmaceuticals.