Subpart P: Important information you should know

What is Subpart P?

Subpart P covers healthcare-specific regulations for hazardous waste pharmaceuticals generated at healthcare facilities. The EPA recognizes that healthcare is fundamentally different from other industries that generate hazardous waste and the regulations are being revised to reflect the differences.

Who is affected and regulated under Subpart P?

Healthcare facilities as defined by Subpart P include but are not limited to hospitals, pharmacies, clinics, veterinary clinics and hospitals, wholesale distributors and retailers. The definition of healthcare does not include pharmaceutical manufacturers, reverse distributors, and reverse logistics centers.

What pharmaceuticals are regulated under Subpart P?

- Pharmaceuticals that are currently regulated under RCRA as hazardous waste and carry either a P, U, or D code.

The EPA has defined pharmaceuticals as prescription medications, OTC (over the counter) drugs, dietary supplements, compounded drugs, investigational drugs, personal protective equipment (PPE) contaminated with pharmaceutical waste, clean-up material from pharmaceutical spills, or any item for which the FDA requires a "Drug Fact" sheet.

What are the key takeaways from Subpart P?

- Hazardous waste pharmaceuticals do not count towards generator status.
- A Uniform Hazardous Waste Manifest must be used for transportation.
- Waste determination
  - Segregation programs (separation of hazardous and non-hazardous waste) – maintain waste determination process
  - OneContainer® program (co-mingle hazardous and non-hazardous waste into one container) - waste determination is not required.
  - The EPA suggests collecting all pharmaceutical waste and managing it as hazardous waste pharmaceuticals under Subpart P.

"The Agency believes that provisions in the final rule, such as the streamlined standards for healthcare facilities and the elimination of LQG status for the management of hazardous waste pharmaceuticals, address the first two recommendations indirectly by encouraging healthcare facilities to manage their non-hazardous waste pharmaceuticals as hazardous waste pharmaceuticals."

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What happens if my facility is in Michigan or Florida or another state that implemented an UW (Universal Waste) pharma waste rule?

All states are required to adopt the new Subpart P standards. When Florida and Michigan adopt the new rule, pharmaceutical waste will have to be managed according to the Subpart P regulations and can no longer be managed as universal waste.

When does this go into effect in my state?

States will adopt within 2 years of adoption at the federal level, deadline July 1st, 2021. See link below for information about your state.

How does a facility opt-in to be regulated under Subpart P?

As states adopt Subpart P, healthcare facilities will have 60 days to opt-in and be managed under Subpart P. To opt-in, a healthcare facility can either utilize the 8700-12 form and identify itself as a healthcare facility, or if the facility sends in a Biennial Report, identify itself on the report.

How long can I accumulate waste under the new rules?

Waste can be accumulated onsite for one year. This time limit must be tracked in some manner.

Where can I find an actual copy of Subpart P regulations?

https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075#additional-resources

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