Pharmaceutical Waste Solutions

January 7, 2019

Regulatory Summary:

EPA Final Rule on Pharmaceutical Waste Regulations Has Been Released

The Environmental Protection Agency (EPA), under 40 CFR 266 subpart P, released the Final Rule on the **management of hazardous pharmaceutical waste**. Though the rule is final, it is very important to understand that **all current Resource Conservation and Recovery Act (RCRA) regulations will continue to be enforced** until the rule is effective, which will occur **6 months after publication in the Federal Register**. States will be required to adopt the rule but will have the ability to make changes. As a result, the effective dates may vary by state.

Stericycle has been following EPA activity on this rulemaking since its proposal in 2015. The new regulations were detailed in hundreds of pages and have been summarized here to provide highlights of how the Final Rule's regulations may affect health care facilities.

Summary of Changes:

1. Small and Large Quantity Generators (SQG and LQGs) that meet the EPA's new definition of a health care facility or reverse distributor must manage their hazardous pharmaceutical waste under new subpart P.
2. Very Small Quantity Generators (VSQGs) that meet the EPA's new definition of health care facility or reverse distributor have the option of managing hazardous pharmaceutical waste under new subpart P.
3. Facilities have less stringent options to dispose of containers with residual hazardous waste and p-listed wastes.
4. Controlled substances that are hazardous waste are conditionally exempted from being managed as such.

Why Did the EPA Make This Change?

The rule is intended to provide health care specific regulations for the management of hazardous waste pharmaceuticals and help keep pharmaceuticals from entering our waterways. These tailored standards strive to make it easier and safer for health care facilities to follow, rather than the industrial-oriented hazardous waste generator regulations.

When Does the Final Rule Take Effect?

The Final Rule will be effective 6 months **after** the date it is published in the Federal Register. States will be required to adopt the rule, however, will have the ability to make changes. As a result, the effective dates may vary by state. Stericycle will closely monitor state adoption.

The exception to state adoption is the ban on flushing. This requirement is being proposed under the Hazardous and Solid Waste Amendments. Requirements implemented under this authority become effective in all states on the effective date of the federal regulation.

Who Does the Final Rule Cover?

As defined in the final rule, the new regulations will cover most health care entities that manage pharmamceutical products and waste such as hospitals, pharmacies, dentists, nursing facilities or long-term care facilities (LTCF), clinics and reverse distributors. The final rule does not apply to pharmaceutical manufacturers (unless they act as reverse distributors) or production facilities.

What Impact Will the Final Rule Have on Generator Status?

Under the new Final Rule, pharmaceutical waste (including P-listed wastes) **will not** count toward generator status. Hazardous waste from other areas of health care facilities and reverse distributors, such as solvents and other non-pharmaceutical waste, (e.g., products or other retail waste) will still be used to determine generator status.

Continue reading for more information

How Does the Final Rule Apply to Hazardous Waste Flushing?

The Final Rule bans the flushing of all hazardous pharmaceutical waste, **regardless of generator type**. This ban does not affect nonhazardous pharmaceuticals, or controlled substances which fall under DEA regulations.

Are There Any Changes to How Controlled Substances Are Managed?

There are only a few controlled substances that are hazardous waste. These few drugs are conditionally exempted from hazardous waste regulations when managed in compliance with DEA regulations and incinerated at an authorized facility.

What Changes Were Made Regarding the Disposal of Containers with Residual Hazardous Waste and P-Listed Wastes?

The final regulations delineate 4 categories of container types and rules for each:

1. **Stock, dispensing, and unit dose containers** – this includes vials, blister packs, and dispensing bottles (not to exceed 1 liter or 10,000 pills). These items are considered empty when their contents have been removed by normal means and are not regulated as hazardous waste, even if they held P-listed wastes.
2. **Syringes** – syringes are considered empty and not regulated as hazardous pharmaceutical waste when the plunger has been fully depressed. The empty syringe should be managed under applicable federal, state, and local requirements for medical waste and sharps.
3. **Intravenous bags (IVs)** – fully administered IV bags are considered empty and/or those that meet the current definition of RCRA empty.
4. **Other containers, including delivery devices** – this includes items such as inhalers, nebulizers, ointments, gels, and creams. These items are also considered empty when the current definition of RCRA empty is met.

Were There Any Changes Made to Regulations on Nicotine Waste?

Yes. Under this Final Rule, the EPA edited the current listing for acutely hazardous nicotine and salts (P075) designating that FDA-approved, over-the-counter nicotine replacement therapies such as patches, gums and lozenges will no longer be considered acutely hazardous waste.

This new exception applies to all generators of hazardous waste, not just health care facilities as it is outside of subpart P. Other nicotine containing products such as prescription replacement therapies and e-cigarettes are not excluded from the P075 listing and would still be regulated as such.

What Will Happen in the Universal Waste States of Florida and Michigan?

The EPA added language to the Universal Waste section of the current regulations to exclude hazardous pharmaceutical waste from being added as a category of hazardous waste eligible for management as Universal Waste. Therefore, Florida and Michigan will no longer be able to include hazardous waste pharmaceuticals in their Universal Waste program.

What Do You Do Now?

Though these are final regulations, the current rules remain in effect until the effective date in the federal register and states adopt them. It is very important to understand that all current RCRA regulations are being enforced. It is recommended that facilities potentially impacted by the Final Rule review the regulations.

For additional information visit the EPA website at: **https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075.**

For questions, please email us at **EPANewRules@stericycle.com**.

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