Pharmaceutical Waste Rule – Pharmacy Inspections

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Roadmap

- Overview of *Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine*, 84 FR 5816 (Feb. 22, 2019)
- Recap of Final Rule
- California Dept. of Toxic Substances Control Reforms
  - Over the Counter Nicotine Replacement Therapies
  - Container Reform
  - Subpart P Review
- Status of State-Level Implementation
- Benefits of Subpart P Adoption and Empty Warfarin Container Reform

Overview of Final Rule

Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine, 84 FR 5816 (Feb. 22, 2019)

GOALS:

- Reduce the amount of pharmaceuticals that are disposed of down the drain
- Address the various concerns raised by stakeholders regarding the difficulty in implementing the RCRA Subtitle C hazardous waste regulations for the management of hazardous waste pharmaceuticals generated at healthcare facilities.
- Clarify regulatory status of reverse distribution:
  - In enforcement actions against national retail chains with pharmacies, California has directed defendants to "initiate work with appropriate stakeholders" including EPA, USDA and DTSC, and "undertake to promote federal regulatory reform regarding the proper management of non-disposable pharmaceuticals, including OTC medications, through 'reverse distribution.'"

Subpart P

Subpart P to 40 CFR Part 266 for management of hazardous waste pharmaceuticals applies in all states.

- Part 266 includes regulations for specific types of hazardous waste (e.g., spent lead-acid batteries being reclaimed; military munitions; hazardous waste burned in boilers and industrial furnaces)

Who

- "Healthcare facilities" and "Reverse distributors"

What

- Hazardous waste pharmaceuticals (not non-pharmaceutical hazardous waste; not non-hazardous pharmaceutical waste; not "hazardous drugs").
- A healthcare facility may choose to manage its non-hazardous waste prescription pharmaceuticals under Subpart P (to avoid the need to determine which prescription pharmaceuticals are hazardous and which are non-hazardous).

Non-Pharmaceutical Retail Items

- Preamble establishes guidance regarding retail items, including over-the-counter medications and other unsold consumer products, but does not change the definition of "solid waste."

Sewer Ban

Historically

- Prior to the 2019 Rule, EPA stated that RCRA and Clean Water Act requirements allowed disposal of hazardous waste pharmaceuticals down the drain.

Federal Rule

- The new Part 266.505 prohibits all healthcare facilities (including Very Small Quantity Generators) and reverse distributors from disposing of hazardous waste pharmaceuticals down the drain.
- Applies to all healthcare facilities and reverse distributors.
- Does not apply to households or non-hazardous pharmaceutical wastes.

Recalls

- **Pharmaceuticals**
  The final rule establishes in 40 C.F.R. 266.501(g) that pharmaceuticals (prescription and nonprescription) being managed under a recall strategy approved by the Food and Drug Administration or the Consumer Product Safety Commission are not subject to RCRA – including Parts 262 and 266.
  - Whether at the healthcare facility or reverse distributor.
  - Pharmaceuticals become subject to RCRA once the FDA or CPSC approves destruction of the recalled items.
- **Unsold Retail Items**
  The preamble's retail policy (discussed in later slides) also makes clear that EPA does not apply RCRA to recalls of other unsold retail items, provided the recall is overseen by the FDA or CPSC.
  - The unsold retail items would become subject to RCRA once the FDA or CPSC approves destruction of the recalled items.
  - **Final rule** does not address recalls from other processes, such as voluntary or litigation driven recalls.

Empty P-Listed Containers

- **November 11, 2011, EPA guidance confirmed that for containers that previously held p-listed pharmaceuticals, only the residue must count toward the facility's generator status; the weight of the container does not count.**
  - Enabled healthcare facilities to significantly reduce the amount of hazardous waste generated.
    - **Final rule** (40 C.F.R. 266.507) formalizes 2011 guidance, with some additional detail.
  - Stock and dispensing bottles, vials, and ampules (not to exceed 1 liter or 10,000 pills) or a unit-dose container are considered empty, and the residues are not regulated as hazardous waste where the pharmaceuticals have been removed using practices commonly employed to remove materials from the type of container.
  - Syringes, IV bags, and other containers: Section 266.507 also includes provisions to determine whether empty.
  - DTSC has rejected EPA guidance based on unique CA rule regarding the management of containers that previously held p-listed pharmaceuticals.

Prescriptions v. Nonprescriptions: Generally

Prescription Pharmaceuticals

"Potentially creditable hazardous waste pharmaceuticals" that can be sent to a reverse distributor.

Nonprescription Pharmaceuticals

Not considered a solid waste and thus also not a hazardous waste if there is a "reasonable expectation of being legitimately used/reused or reclaimed"; they would, therefore, not yet be subject to RCRA because they're not yet a waste.

Prescriptions: Two Categories of Hazardous Waste Pharmaceuticals

- Two categories of prescription hazardous waste pharmaceuticals – both managed under Subpart P.
  - **"Potentially creditable hazardous waste pharmaceuticals"** (Definition on next slide)
    - Historically, under EPA guidance pharmaceuticals were not a waste until a decision to discard was made at the reverse distributor.
    - Under final rule, prescription pharmaceuticals being sent to a reverse distributor are a waste at the healthcare facility. However, although EPA now considers these pharmaceuticals a waste, EPA is affirming the process currently used for sending prescription pharmaceuticals to reverse distributors.
  - **"Non-creditable hazardous waste pharmaceuticals"** (Definition on next slide)
- Subpart P includes separate management requirements for these categories. "Non-creditable hazardous waste pharmaceuticals" have more stringent management requirements.
- Must notify using Form 8700-12 that a healthcare facility is operating under Subpart P (or as part of next Biennial Report if facility already has an EPA ID and is required to submit a Biennial Report).

Prescriptions: Definitions Related to *Prescription* Hazardous Waste Pharmaceuticals

- **Potentially Creditable Hazardous Waste Pharmaceutical**
  A prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is (1) in original manufacturer packaging (except pharmaceuticals that were subject to a recall); (2) undispensed; and (3) unexpired or less than one year past expiration date. The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs and dietary supplements.
- **Non-creditable Hazardous Waste Pharmaceutical**
  A prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings and clean-up material from the spills of pharmaceuticals.
- **40 C.F.R. 266.500.**
- * Note that definitions are specific to prescription pharmaceuticals, which raises an issue for nonprescription hazardous waste pharmaceuticals managed through reverse distribution.
- ** EPA emphasizes that a healthcare facility is not expected to know for certain whether a prescription pharmaceutical will ultimately receive manufacturer credit.

Non-creditable Hazardous Waste Pharmaceuticals

- **Healthcare facility cannot send non-creditable hazardous waste pharmaceuticals to a reverse distributor; must send to a TSDF.**
- **Subpart P includes specific requirements** in 40 C.F.R. 266.502 (management requirements) and 40 C.F.R. 266.508 (shipping requirements) – similar to Part 262 Small Quantity Generator requirements.
- **Examples include**
  - Training: "[E]nsure that all personnel that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies."
  - Place in structurally sound containers that are not leaking and are compatible with contents.
  - No requirement to segregate types of hazardous waste pharmaceuticals.
  - May be accumulated onsite for up to one year.
  - Must be disposed at a TSDF.
  - Must be shipped using a manifest (using the generic "PHARMS" in Item 13 in lieu of hazardous waste codes).
  - Notify EPA or the State if the facility has not received a copy of a manifest within 60 days of the initial transporter receiving the waste.
  - Not required to include on Biennial Report.
  - Must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals.
  - Allows for accepting non-creditable hazardous waste pharmaceuticals from an offsite healthcare facility that is a VSQG and under the control of the same person. Must comply with certain requirements.

Potentially Creditable Hazardous Waste Pharmaceuticals

- **Healthcare facility can send to a reverse distributor.**
- **Subpart P includes specific requirements** in 40 C.F.R. 266.503 (management requirements) and 40 C.F.R. 266.509 (shipping requirements) – which are more targeted standards compared to Part 262 Large Quantity Generator and Small Quantity Generator requirements. Example management requirements for healthcare facilities (for prescription hazardous waste pharmaceuticals).
- **Examples include**
  - A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment for three years from the date of shipment: (1) confirmation of delivery; and (2) shipping papers prepared in accordance with 49 CFR part 172 Subpart C, if applicable.
  - Must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals.
  - Manifesting requirements are eliminated.
  - Shipments can be made by common carrier (in compliance with DOT requirements).
  - Not required to include on Biennial Report.
  - Allows for accepting potentially creditable hazardous waste pharmaceuticals from an offsite healthcare facility that is a VSQG and under the control of the same person. Must comply with certain requirements.

Prescription Hazardous Waste Pharmaceuticals: At the Reverse Distributor

Subpart P includes specific management requirements in 40 C.F.R. 266.510 – similar to Part 262 LQG requirements, with some similarity to TSDF requirements.

Example management requirements for handling of potentially creditable hazardous waste pharmaceuticals by a reverse distributor:

- **Notification**: Form 8700-12 that it is a reverse distributor operating under Subpart P within 60 days of the rule's effective date (subject to state adoption).
- **Inventory**: Must maintain a current inventory of all "potentially creditable hazardous waste pharmaceuticals" and "evaluated hazardous waste pharmaceuticals" accumulated onsite. Must inventory within 30 days of arrival of each potentially creditable hazardous waste pharmaceutical.
- **Contingency plan**: 40 C.F.R. 266.510(a)(7).
- **Closure requirements**: 40 C.F.R. 262.17(a)(8)(ii) and (iii) apply.
- **Unauthorized waste reports**: If the reverse distributor receives unauthorized waste from offsite, must submit to EPA (or authorized state) within 45 days after receipt of unauthorized waste, with copy to the healthcare facility that sent the waste. Reverse distributor must manage unauthorized waste onsite.
- **Records maintained for three years**: Copies of Notification; delivery confirmation and shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals receives; unauthorized waste reports must be maintained for at least three years.

Prescription Hazardous Waste Pharmaceuticals: At the Reverse Distributor

Evaluated Hazardous Waste Pharmaceuticals

Subpart P includes specific requirements in 40 C.F.R. 266.510(c) for evaluated hazardous waste pharmaceuticals. Examples include:

- Must designate an onsite accumulation area.
- Must inspect the accumulation area at least once every seven days. Check containers for leaks and for deterioration and for signs of diversion.
- Comply with training requirements in 40 C.F.R. 262.17(a)(7) (LQG training requirements).
- Label containers as "hazardous waste pharmaceuticals."
- Containers must be in good condition; compatible with the evaluated hazardous waste pharmaceuticals; kept closed if holding liquid or gel evaluated hazardous waste pharmaceuticals (unless the liquid or gel is in the original, intact, sealed packaging or repackaged).
- Prior to shipping, label containers with hazardous waste codes.
- Ship in compliance with requirements for non-creditable hazardous waste pharmaceuticals (40 C.F.R. 266.508).

Prescription Hazardous Waste Pharmaceuticals: At the Reverse Distributor

- An example of a highly regulated reverse distributor is the Inmar facility located in Grand Prairie, Texas.
- In addition to being subject to Subpart P requirements, the facility is licensed in 34 states and is designed to comply with DEA, BOP, FDA, PDMA, GMP, TCEQ, DOT and EPA regulatory requirements.

State Implementation

States with authorized RCRA programs must adopt portions of the final rule that are more stringent than existing federal regulations.

- The exemption for OTC NRT is less stringent than existing regulations so states may choose whether to adopt.
- Overall, Subpart P is more stringent, so must be adopted. However, states may choose to keep components of state programs that are more stringent than the Subpart P requirements.
- Generally, states were required to adopt Subpart P by August 2021, unless legislative action is required.

Ongoing DTSC Reform

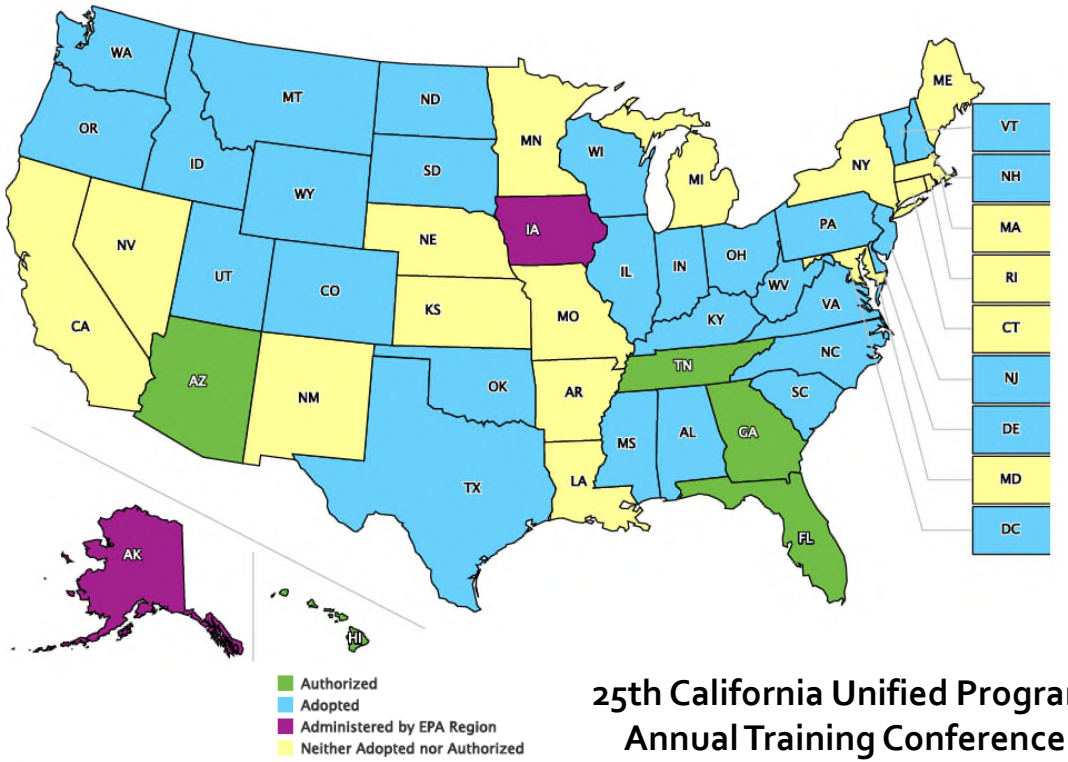
- **DTSC very recently announced its intent to adopt Subpart P under 40 CFR part 266 and expects the regulation to be in effect by the end of 2023.**
- **See https://dtsc.ca.gov/pharmaceutical-waste-rulemaking/**
- The legislative history for amendments to the California Medical Waste Management Act considered the benefits and protections inherent in reverse distribution of pharmaceuticals and granted an exemption from the requirements of that Act and the definition of "pharmaceutical waste" when the pharmaceutical **"is being sent out of the state to a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, that is licensed as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4161 of the Business and Professions Code…." Section 117690(b)(3).**

Management Standards for Hazardous Waste Pharmaceuticals

Adopted and In Effect:

Alabama
Arizona
Colorado
Delaware
District of Columbia
Florida
Georgia
Hawaii
Idaho
Illinois
Indiana
Kentucky
Mississippi
Montana
New Hampshire
New Jersey
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Washington
West Virginia
Wisconsin
Wyoming

EPA Administration:
Iowa / Region 7
Alaska / Region 10



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Benefits of Subpart P Adoption and Empty Warfarin Container Reform

- Subpart P adoption in California will codify current best practices used by retail pharmacies and national drug suppliers.
- Adoption of Subpart P is expected to resolve legal issues associated with necessary drug recalls in California.
- Subpart P adoption will standardize documentation and tracking requirements for reverse distribution and streamline compliance for regulators and pharmacies.
- Adoption of federal empty warfarin analysis and exemption from counting the weight of empty warfarin containers is expected to resolve legal issues associated with whether to include the weight of these containers when determining generator status. This change will allow most retail pharmacies in California to become small quantity generators, a more appropriate regulatory status.
- Subpart P was created after extensive review and study of best practices in California such that its adoption is consistent with current best practices employed by national retail chain pharmacies in California.

Any Questions?

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