News Alert: August 16, 2023 - Hazardous Waste Pharmaceuticals: One More Chance to be Heard!

On August 9, 2023, EPA published two announcements in the Federal Register regarding Technical Corrections to the Hazardous Waste Generator Improvements Rule, the Hazardous Waste Pharmaceuticals Rule, and the Definition of Solid Waste Rule. Only the first two have direct relevance to healthcare facilities. The Federal Register publication can be accessed at https://www.govinfo.gov/content/pkg/FR-2023-08-09/pdf/2023-14731.pdf. Written comments must be received by October 10, 2023. Comments should be identified by Docket ID No. EPA-HQ-OLEM-2023-0081 by either electronic submission at the Federal eRulemaking Portal: https:www.regulations.gov (preferred) or by mail to the U.S. Environmental Protection Agency, EPA Docket Center, Office of Resource Conservation and Recovery Docket Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

We have listed below several clarifications that are beneficial to healthcare facilities managing hazardous waste under the respective regulations. This list should not be considered a replacement for reading the entire Federal Register. We've also included sections that require further clarification by EPA.

Clarifications to the Hazardous Waste Generator Improvements Rule include:

1. Page 54088 *C. Regulations To Be Reworded 2. Hazardous Waste Determination* (§262.11(d) and (g))

   Regulatory change: "…that as long as the listed waste code addresses the constituents or properties that cause the waste to exhibit a characteristic, then it is not necessary to also identify the characteristic."

2. Page 54089 *3. Very Small Quantity Generators that Accumulate Above the Threshold* (1kg acute hazardous waste, 100 kg of residue from a cleanup of a spill of acute hazardous waste, or 1,000 kg of non-acute hazardous waste)(§262.14(a)(3) and (4))

   Regulatory change: "…to restore the independent requirements that were inadvertently left out of the lists, including notification: preparation and use of the Uniform Hazardous Waste Manifest when shipping the waste off site; and complying with pre-transport requirements, recordkeeping and reporting requirements…"

   Regulatory change: "A VSQG that is notifying because it exceeded the accumulation threshold retains its VSQG category and prepares and submits EPA Form 8700-12…as a 'very small quantity generator.'"

3. Page 54089 *4. Accumulation Limit for Small Quantity Generators Generating Acute Hazardous Waste* (§262.26(b)(1))

Regulatory clarification: "…the acute hazardous waste accumulation limit for a small quantity generator is one kilogram."

4. Page 54090 *7. Exception Reporting for an Episodic Event* (§262.232(a)(5))

   Regulatory clarification: "The EPA is revising §262.232 (a)(5) to include a reference to §262.44, which includes maintaining records of manifest and hazardous waste determinations, completing an exception report if the generator does not receive a copy of its manifest from the designated facility indicating that the waste arrived within 60 days from the date upon which the waste was accepted by the initial transporter, and complying with requests from the Administrator for additional reports under sections 2002(a) and 3002 (a)(6) of RCRA.

Clarifications to the Hazardous Waste Pharmaceutical Rule include:

1. Page 54092 *D.EPA Hazardous Waste Numbers* (§§ 266.502, 266.508, and 266.510)

   Clarifying terminology: "…applicable EPA hazardous waste numbers (i.e., hazardous waste codes)"

   Using Hazardous Waste Codes on the Hazardous Waste Manifest: "…clarifying that a healthcare facility may also include the applicable EPA hazardous waste numbers (i.e., hazardous waste codes) in Item 13 of EPA Form 8700-12, in addition to the PHARMS or PHRM code." And "Although healthcare facilities operating under subpart P are not required to include all applicable RCRA hazardous waste codes when manifesting non-creditable hazardous waste pharmaceuticals, the EPA indicated in the preamble to the final rule that we do not object if healthcare facilities or their vendors choose to include RCRA hazardous waste codes…in addition, we recommend for manifested non-creditable hazardous waste pharmaceuticals shipped from a healthcare facility operating under subpart P but passing through a state or going to a TSDF in a state that has not yet adopted subpart P, that the healthcare facility/vendor check with those states regarding whether they require all applicable waste codes to be on the manifest."

2. Page 54094 *K. Residues of Hazardous Waste Pharmaceuticals in Empty Containers* (§266.507)

   Regulatory clarification: Other Containers, Including Delivery Devices: "Healthcare facilities that are VSQGs have the option of operating under subpart P with respect to their hazardous waste pharmaceuticals, including their non-empty containers."

3. Page 54095 *M. PHARMS Code* (§266.508)

   Regulatory clarification: "Both PHRM /PHARMS codes have been and will continue to be available for use in the e-Manifest system, with identical "Hazardous Waste Pharmaceuticals" descriptions."

The following are items under Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine Rule that PharmEcology® is commenting on for further consideration by EPA.

1. Page 54092 *Table 1 Examples of Hazardous Waste Pharmaceuticals Listed in Appendix IV to Part 268 – Wastes Excluded from Lab Packs Under the Alternative Treatment Standards of 268.42(c)*.

   These include the following which should not be listed as they are not relevant to healthcare.

   a. D009 Mercury (Toxicity characteristic): Mercury as a preservative always occurs as part of an organic molecule: thimerosal ($C_9H_9HgNaO_2S$), phenylmercuric acetate ($CH_3COOHgC_6H_5$) (28.53% carbon), and phenyl mercuric borate ($C_6H_7BHgO_3$). Calomel (Hg_2Cl_2) is no longer in active use and always occurs as a powder and would not be used as such in a finished dosage form.

   b. P012 – Arsenic trioxide is a current pharmaceutical entity and is an appropriate example for this table.

   c. P076 Nitric oxide: Is this perhaps a reference to Nitrous Oxide, N_2O, also known as "laughing gas," which is not listed in Appendix IV? Nitric oxide has no known medical use to our knowledge and thus is confusing.

   d. U151 Mercury: Mercury is no longer used as a sole active ingredient in any medication. The salts of mercury, bichloride and iodide, are only available as bulk chemicals and if used at all would be imbedded in some type of organic base.

2. Page 54092 *C. Marking Lab Packs for Shipping*

   Request for clarification: "However, be aware that the shipping standards for non-creditable and evaluated hazardous waste pharmaceuticals require that lab packs containing D004 (arsenic), D005 (barium), D006 (cadmium), D007 (chromium), D009 (lead), D010 (selenium) or D011 (silver) **must be marked with the EPA hazardous waste numbers."** (Bolding added.)

   Is this requirement intended only for reverse distributors since non-creditable and evaluated hazardous waste pharmaceuticals are used in the same sentence or does this also apply to healthcare "lab packs" being shipped through hazardous waste haulers for disposal at a RCRA permitted incinerator? If this does apply to healthcare lab packs, this is a new interpretation of the regulations and needs to be emphasized and added to the FAQs. This should also be included in any revisions of the "10-Step Blueprint for Managing Pharmaceutical Waste in US Healthcare Facilities."

PharmEcology® has an additional request for EPA to clarify the preamble to Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine.

> On page 5896 of Federal Register/Vol. 84, No. 36 Friday, February 22, 2019/Rules and Regulations, Phenobarbital was listed in Table 3 – Pharmaceuticals Still Used in Healthcare That Are DEA Controlled Substances and RCRA Hazardous Wastes. The brand names listed include Bellergal-S, Donnatal, and Luminal. Currently, the only phenobarbital on the market that contains alcohol is the elixir formulation which has less than 24% alcohol, which falls below the exemption and therefore is not a D001 hazardous waste. Phenobarbital continues to be referenced as a hazardous waste-controlled substance and we request that a clarification be made in the EPA FAQs to the effect this is no longer the case to avoid confusion in the marketplace and among state and federal regulatory agencies.

If you also have concerns regarding these topics, please consider submitting your recommendations prior to the deadline.