



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

DEC 19 2019

OFFICE OF
LAND AND EMERGENCY
MANAGEMENT

SUBJECT: Manifesting Non-Creditable Hazardous Waste Pharmaceuticals — New Four Character Code

FROM: Barnes Johnson, Director
Office of Resource Conservation and Recovery (ORCR)

A handwritten signature in black ink, appearing to read "Barnes Johnson", written over the printed name and title.

TO: Land, Chemicals and Redevelopment Division Directors
EPA Regions 1 to 10

The Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine were finalized on February 22, 2019 (84 FR 5816). The final rule established a new subpart P in part 266 for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors. Under part 266 subpart P, healthcare facilities must use a manifest when shipping non-creditable hazardous waste pharmaceuticals to a RCRA designated facility (e.g., a permitted or interim status treatment, storage or disposal facility (TSDF)). However, a healthcare facility is not required to include all applicable hazardous waste numbers (often referred to as hazardous waste codes) in Item 13 of the manifest (see § 266.508(a)(2)(i)). In lieu of the waste codes, a healthcare facility must include the word "PHARMS" in Item 13 of the manifest (see § 266.508(a)(2)(ii)).

As explained in the preamble to the final rule (see page 5909), we used six characters because the e-Manifest system can accommodate six characters, and because PHARMS communicates the nature of the waste. However, since the final rule was published, EPA has become aware of two issues related to using six characters. First, although the e-Manifest system can accommodate six characters and PHARMS can be selected from a prepopulated menu within the e-Manifest system, most generators are currently using paper manifests, not electronic manifests. The paper manifest is designed to accommodate four-character hazardous waste codes which makes it difficult to fit the entire PHARMS code in the box without going over the line. Second, some states and industry stakeholders have told us that their databases are not designed to accommodate six characters, which makes it difficult for them to exchange data with EPA's e-Manifest system.

As a result, to assist implementation, we request that Regions that implement RCRA in Indian Country, territories and non-authorized states, as well as authorized states that have adopted the Hazardous Waste Pharmaceuticals final rule, encourage healthcare facilities to use the four-character code PHRM on both paper manifests and electronic manifests when shipping non-creditable hazardous waste pharmaceuticals under subpart P. This four-digit code achieves the same result as the six-digit code and; therefore, EPA will consider the use of either code to satisfy the requirement at § 266.508(a)(2)(ii). In addition, EPA is

considering developing a technical correction to replace the PHARMS code with the PHRM code in the regulations. In the interim period, both PHRM/PHARMS codes will be available for use in the e-Manifest system, with identical “Hazardous Waste Pharmaceuticals” descriptions.

On a separate but related matter, EPA has received inquiries about whether healthcare facilities can include hazardous waste codes in addition to the PHRM/PHARMS code when manifesting non-creditable hazardous waste pharmaceuticals. 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, 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 on manifests in addition to PHRM/PHARMS (see page 5877). Including all applicable RCRA hazardous waste codes on the manifest when shipping non-creditable hazardous waste pharmaceuticals could help receiving facilities better understand the wastes and determine the best course of management. 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. Further, the regulated community should be aware that as authorized states adopt and become authorized for part 266 subpart P, it is possible that they may choose to be more stringent and require all hazardous waste codes when healthcare facilities manifest non-creditable hazardous waste pharmaceuticals.

We hope that this change eases implementation issues with the final rule. Should you have any questions, please contact Kristin Fitzgerald at (703) 308-8286 or fitzgerald.kristin@epa.gov.