

Revision Checklist 241 Summary

Rule Title:	Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine
Checklist Title:	Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine
Reference:	84 <u>FR</u> 5816-5950
Promulgation Date:	February 22, 2019
Effective Date:	August 21, 2019
Cluster:	RCRA Cluster XXVII
Provision Type:	HSWA/Non-HSWA
Linkage:	None
Optional:	No

Summary: This rule creates a new part 266 subpart P for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors in lieu of the generator regulations in part 262. This new subpart prohibits the disposal of hazardous waste pharmaceuticals down the drain and eliminates the dual regulation of RCRA hazardous waste pharmaceuticals that are also Drug Enforcement Administration controlled substances by finalizing a conditional exemption. The new subpart also maintains the household hazardous waste exemption for pharmaceuticals collected during pharmaceutical take-back programs and events, while ensuring their proper disposal and codifies EPA's prior policy on the regulatory status of nonprescription pharmaceuticals going through reverse logistics. EPA takes two additional actions by finalizing an amendment to the P075 acute hazardous waste listing of nicotine and salts to exclude certain U.S. Food and Drug Administration approved over-the-counter nicotine replacement therapies, and in the preamble establishes a policy on the regulatory status of unsold retail items that are not pharmaceuticals and are managed via reverse logistics.

State Authorization: This rule is placed in RCRA Cluster XXVII. The State modification deadline is July 1, 2020 (or July 1, 2021 if a State statutory change is necessary). This rule is more stringent than the current federal standards except for the amendment to exempt from the P075 listing the nicotine patches, gums and lozenges that are FDA-approved OTC nicotine replacement therapies, which is less stringent and broader in scope. States which do not adopt the changes to the P075 listing for nicotine products (gum, lozenges, etc.) will be considered as broader in scope for that waste. These less stringent provisions are marked in the rule checklist. The prohibition of sewerage hazardous waste pharmaceuticals (§ 266.505, the citation in section XX of the preamble is incorrect) is being finalized under HSWA authority, while the remainder of the rule is promulgated under non-HSWA authority.

Attorney General (AG) Certification Guidance: Specific AG certification of statutory authority may not be required for this checklist as long as the AG has previously demonstrated authority to regulate hazardous wastes.

Program Description (PD) Guidance: A State seeking authorization for this checklist should determine whether the revisions impact the program described in the Program Description.

Incorporation by Reference Guidance: None.