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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 261, 262, 264, 265, 266, 268, 270, and 273

[EPA-HQ-RCRA-2007-0932; FRL-9988-26-OLEM

[RIN 2050-AG39]

Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Some pharmaceuticals are regulated as hazardous waste under the Resource Conservation and Recovery Act (RCRA) when discarded. This final rule adds regulations for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors. Healthcare facilities (for both humans and animals) and reverse distributors will manage their hazardous waste pharmaceuticals under this new set of sector-specific standards in lieu of the existing hazardous waste generator regulations. Among other things, these new regulations prohibit 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 (DEA) controlled substances. The new rules also maintain the household hazardous waste exemption for pharmaceuticals collected during pharmaceutical take-back programs and events, while ensuring their proper disposal. The new rules codify Environmental Protection Agency (EPA)'s prior policy on the regulatory status of nonprescription pharmaceuticals going through reverse logistics. Additionally, EPA is excluding certain U.S. Food and Drug Administration (FDA) approved over-the-counter (OTC) nicotine replacement therapies (NRTs) from regulation as hazardous waste and is establishing a policy on the

regulatory status of unsold retail items that are not pharmaceuticals and are managed via reverse logistics, fulfilling the commitment we made in the Retail Strategy of September 2016.

DATES: This final rule is effective on **[insert date 180 days after date of publication in the Federal Register**].

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-HQ-RCRA-2007-0932. All documents in the docket are listed on the https://www.regulations.gov web site. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through https://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Kristin Fitzgerald, Materials Recovery and Waste Management Division, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania, Ave., NW, Washington, DC 20460; telephone number: (703) 308-8286; email address: Fitzgerald.Kristin@epa.gov, or Brian Knieser, Materials Recovery and Waste Management Division, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania, Ave., NW, Washington, DC 20460; telephone number: (703) 347-8769; email address: Knieser.Brian@epa.gov. Also see the EPA's website at https://www.epa.gov/hwgenerators/management-pharmaceutical-hazardous-waste.

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I. General Information

A. *Does This Action Apply to Me?*

This final rule applies to healthcare facilities that generate, accumulate, or otherwise handle hazardous waste pharmaceuticals and reverse distributors engaged in the management of prescription hazardous waste pharmaceuticals. The list of North American Industry Classification System (NAICS) codes for the potentially affected entities, other than RCRA transfer, storage, and disposal facilities (TSDFs), are presented in Table 1. More detailed information on the potentially affected entities is presented in sections VII and IX of this preamble and the Regulatory Impact Analysis (RIA) which is available in the docket for this final rule.[1]

Table 1: NAICS Codes of Entities Potentially Affected by this Final Rule: Healthcare Facilities and Reverse Distributors

[1] EPA-HQ-RCRA-2007-0932.

NAICS Codes	Description of NAICS Code
4242	Drug Wholesalers
44511	Supermarkets and Other Grocery (except convenience) Stores
44611	Pharmacies and Drug Stores
452311	Warehouse Clubs and Supercenters
54194	Veterinary Services
6211	Physicians' Offices
6212	Dentists' Offices
6213	Other Health Practitioners (e.g., chiropractors)
6214	Outpatient Care Centers
6219	Other Ambulatory Health Care Services
622	Hospitals
6231	Nursing Care Facilities (e.g., assisted living facilities, nursing homes)
623311	Continuing Care Retirement Communities (e.g., assisted living facilities with on-site nursing facilities)
Various NAICS	Reverse Distributors

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities potentially impacted by this action. This table lists examples of the types of entities EPA knows could potentially be affected by this action. Other types of entities not listed could also be affected. To determine whether your entity, company, business, organization, etc., is affected by this action, you should examine the applicability criteria in this rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding "**FOR FURTHER INFORMATION CONTACT**" section of this document.

B. *What Action is the Agency Taking?*

On September 25, 2015, EPA proposed new regulations under part 266 subpart P for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors.[2] This final rule promulgates part 266 subpart P. However, in response to public comments, we have made a number of changes to the proposed rulemaking. The comments and the changes are discussed in detail below. When this final rule becomes effective in their states, a process that is explained in section XX of this preamble, healthcare facilities and reverse distributors must manage their hazardous waste pharmaceuticals under this new set of regulations in part 266 subpart P in lieu of operating under part 262 as they have been. These operating standards include a prohibition on the sewering of hazardous waste pharmaceuticals. Part 266 subpart P also includes a conditional exemption for hazardous waste pharmaceuticals that are also identified as controlled substances by the Drug Enforcement Administration (DEA). Further, subpart P redefines when containers that held hazardous waste pharmaceuticals are considered "RCRA empty." Healthcare facilities that are very small quantity generators (VSQGs) must comply with the sewer prohibition for their hazardous waste pharmaceuticals under part 266 subpart P and have the option of complying with the entire subpart in lieu of operating under the conditional exemption of § 262.14.

EPA is also taking two actions in addition to promulgating part 266 subpart P. First, this final rule amends the P075 acute hazardous waste listing for nicotine and salts to indicate that U.S. Food and Drug Administration (FDA)-approved over-the counter (OTC) nicotine replacement therapies (NRTs) are not included in the listing. Second, the preamble to this final rule also establishes EPA's policy on the regulatory status of unsold retail items, including

[2] September 25, 2015; 80 FR 58014.

nonprescription pharmaceuticals, managed at reverse logistics centers, fulfilling the commitment we made in the Retail Strategy of September 2016.

Although the proposed rulemaking sought comment on ideas for how to expand the universe of pharmaceuticals that are hazardous waste, this final rule does not add pharmaceuticals to the hazardous waste listings or expand the hazardous waste characteristics to include additional pharmaceuticals. At the time of proposal, we indicated that any action to expand the universe of hazardous waste pharmaceuticals would be part of a separate, future action.

Note that throughout the preamble and the RIA for this final rule, the terms "EPA," "Agency" and "we" are used interchangeably.

C. *What is the Agency's Statutory Authority for Taking this Action?*

These regulations are promulgated under the authority of §§ 2002, 3001, 3002, 3004, and 3018 of the Solid Waste Disposal Act (SWDA) of 1970, as amended by the Resource Conservation and Recovery Act (RCRA) of 1976, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6912, 6921, 6922, 6924, and 6939.

D. *What are the Incremental Costs and Benefits of this Action?*

As discussed in section XXI, the Regulatory Impact Analysis (RIA) for this rule estimates the annualized cost to industry to comply with the requirements is between $6.59 and $7.99 million (at a 7 percent discount rate).[3] The streamlined management standards for healthcare facilities and the regulatory relief in regard to FDA-approved OTC NRT products (i.e., patches, gums and lozenges) is estimated to result in an annualized cost-savings of between

[3] See the Regulatory Impact Analysis for the final rule in the rulemaking docket EPA–HQ–RCRA–2007–0932.

$19.58 and $22.95 million (at a 7 percent discount rate). This results in a net annualized cost savings for the rule of $12.99 to $14.96 million at a 7 percent discount rate.

The provisions of the final rule are expected to improve regulatory clarity and reduce regulatory burden. As an example of the increased regulatory clarity and certainty provided in the rule, EPA eliminated the dual regulation of RCRA hazardous waste pharmaceuticals that are also DEA controlled substances by finalizing a conditional exemption. Additionally, to the extent that the rule reduces concentrations of hazardous waste pharmaceuticals in surface and drinking waters, this rule may result in improved ecosystems and human health outcomes. Ideally, the Agency would prefer to quantify and monetize the rule's human health benefits. However, only some categories of cost savings are quantifiable; sufficient data are not available to support a detailed quantitative analysis for many benefit categories. In these cases, the benefits are described qualitatively.

II. List of Acronyms

3PL	Third Party Logistics Provider
AARP	American Association of Retired Persons
AEA	Atomic Energy Act
API	Active Pharmaceutical Ingredient
ASHP	American Society of Hospital Pharmacists
BDAT	Best Demonstrated Available Technology
BR	Biennial Report
CAA	Central Accumulation Area
CCP	Commercial Chemical Product
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
CISWI	Commercial, Industrial Solid Waste Incinerator

CMS	Centers for Medicare and Medicaid Services
CPSC	Consumer Product Safety Commission
CWA	Clean Water Act
DEA	Drug Enforcement Administration
DOE	Department of Energy
DOT	Department of Transportation
DSCSA	Drug Supply Chain Security Act
DQSA	Drug Quality and Security Act
EPA	Environmental Protection Agency
EO	Executive Order
FDA	Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FR	Federal Register
HIPAA	Health Insurance Portability and Accountability Act
HMIWI	Hospital, Medical, Infectious Waste Incinerator
HSWA	Hazardous and Solid Waste Amendments
LQG	Large Quantity Generator
LTCF	Long-term Care Facility
LTCP	Long-term Care Pharmacy
MSWLF	Municipal Solid Waste Landfill
MWC	Municipal Waste Combustor
NAICS	North American Industry Classification System
NIOSH	National Institute for Occupational Safety and Health
NODA	Notice of Data Availability
NPRM	Notice of Proposed Rulemaking
NRC	Nuclear Regulatory Commission
NRT	Nicotine Replacement Therapy
OIG	Office of Inspector General

OLEM	Office of Land and Emergency Management
OMB	Office of Management and Budget
ONDCP	Office of National Drug Control Policy
OSHA	Occupational Safety and Health Administration
OSWER	Office of Solid Waste and Emergency Response
OSWI	Other Solid Waste Incinerators
OTC	Over-the-counter
POTW	Publicly Owned Treatment Works
RCRA	Resource Conservation and Recovery Act
SAA	Satellite Accumulation Area
SQG	Small Quantity Generator
SWDA	Solid Waste Disposal Act
TC	Toxicity Characteristic
TCLP	Toxicity Characteristic Leaching Procedure
TSDF	Treatment, Storage and Disposal Facility
VSQG	Very Small Quantity Generator

III. Rationale for the Final Rule

The impetus behind this final rule is to 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. EPA has met with various stakeholders to learn about compliance challenges and has received input from stakeholders through more formal mechanisms. For instance, when EPA solicited stakeholder input in a notice of data availability (NODA) and request for comment, "Hazardous Waste Management and the Retail Sector: Providing and Seeking Information on Practices to Enhance Effectiveness to the Resource Conservation and Recovery Act Program" ("Retail NODA"), retailers submitted comments detailing compliance challenges with hazardous

waste pharmaceuticals in their stores.[4] Further, EPA's Office of Inspector General (OIG) published a report citing the need to clarify how hazardous waste pharmaceuticals are regulated (for more information on the Retail NODA and the OIG report, see section VI of this preamble).[5] The Retail NODA and the OIG Report, along with input from healthcare facilities and retailers, identified a number of ways in which a healthcare facility differs from a manufacturing facility when it comes to applying the RCRA Subtitle C program to the generation and management of hazardous waste pharmaceuticals.

First, under the current hazardous waste regulatory scheme, healthcare personnel, whose primary focus is to provide care for patients, are typically responsible for making hazardous waste determinations since they are at the point of generation (e.g., a patient's bedside). Yet, healthcare personnel, such as nurses and doctors, do not typically have the expertise to make hazardous waste determinations. In general, healthcare personnel are not prepared to assume hazardous waste management responsibilities, nor is it EPA's expectation that they assume primary hazardous waste management responsibilities. EPA recognizes this challenge and provides a framework through this final rule that allows healthcare personnel to focus on healthcare while still ensuring that hazardous waste is directed to proper management.

Second, in the healthcare setting, a wide variety of hazardous waste pharmaceuticals are generated in relatively small quantities by a number of different employees across the facility. This situation differs from a typical manufacturing facility where fewer employees in a few locations generate comparatively much larger volumes of a smaller range of hazardous wastes.

[4] See 79 FR 8926; February 14, 2014 for the Retail NODA. Also see the associated docket EPA-HQ-RCRA-2012-0426 for public comments.

[5] EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal, Report No. 12-P-0508, dated May 25, 2012). For a copy of the report, please see: https://www.epa.gov/sites/production/files/2015-10/documents/20120525-12-p-0508.pdf or see the docket for this final rule: EPA-HQ-RCRA-2007-0932-0177.

Data from the Biennial Report (BR) show that in 2013, approximately 46 percent of large quantity generators (LQGs) generated between one and five waste streams.[6] Further, a typical manufacturing facility generates a more predictable set of hazardous waste streams. In contrast, a healthcare facility can have thousands of items in its inventory at any one time and these may vary over time, based on the needs of the patients. In addition, pharmaceutical wastes come in many different forms, such as tablets (pills), transdermal patches, lozenges, gums, creams, and liquids, and are delivered by a variety of devices, such as nebulizers, intravenous (IV) tubing, syringes, etc. The combination of having thousands of different pharmaceutical products and little expertise in hazardous waste regulations makes it difficult for healthcare personnel to make appropriate hazardous waste determinations when pharmaceuticals are disposed.

Third, several of the hazardous waste pharmaceuticals that are generated by healthcare facilities are P-listed acute hazardous wastes (see § 261.33(e)), which are regulated with more stringent requirements at much smaller amounts. If a facility generates more than 1 kg of acute hazardous waste per calendar month, it is regulated more rigorously as an LQG. Aside from the pharmaceuticals themselves, residues within pharmaceutical containers that contained P-listed commercial chemical products (CCPs) must be managed as acute hazardous waste even if the pharmaceutical was fully administered, unless the container is RCRA-empty (e.g., by triple-rinsing the container).[7] Triple rinsing can be impractical with certain medical devices, such as syringes and paper cups, so healthcare facilities often manage these containers as hazardous

[6] 81 FR 85735; November 28, 2016, Hazardous Waste Generator Improvements Final Rule.
[7] P-listed hazardous waste residues in containers are themselves considered P-listed hazardous wastes (see § 261.33(c)), unless the container is considered "RCRA empty" either by undergoing triple-rinsing with an appropriate solvent; or cleaning with a method that has been proven in scientific literature or tests conducted by the generator to achieve equivalent removal (see § 261.7(b)(3)).

waste, which can result in being subject to the most stringently regulated generator category (i.e., LQG).[8]

To facilitate compliance among healthcare facilities and to respond to these concerns, EPA is finalizing a new set of sector-specific regulations to improve the management and disposal of hazardous waste pharmaceuticals at healthcare facilities.

In addition to improving compliance and responding to stakeholder concerns, the Agency has three additional goals for this final rule. The first is to reduce the amount of pharmaceuticals that are disposed of down the drain. Studies have found that many healthcare facilities, particularly long term-care facilities, are using drain disposal (e.g., flushing) as a routine disposal method for pharmaceutical wastes, including those that are hazardous waste. Until this final rule, drain disposal has been an allowable disposal method for hazardous waste pharmaceuticals under RCRA (however, since 1990, the Clean Water Act regulations have prohibited the drain disposal of ignitable wastes and those wastes that result in toxic gases, vapors of fumes within the publicly owned treatment works.)[9] Although pharmaceuticals are thought to be primarily entering the environment through excretion, reducing intentional sewer disposal is one mechanism to help reduce the environmental loading of pharmaceuticals into our Nation's waters.[10] See section XIII for more information about how this final rule reduces sewer disposal and pharmaceuticals in water.

[8] On November 4, 2011, ORCR issued a memo to the Regional RCRA Division Directors highlighting three acceptable approaches, beyond triple-rinsing containers, that healthcare facilities can employ when managing P-listed container residues. Please see: Memo from Suzanne Rudzinski to RCRA Division Directors (RCRA Online # 14827). As discussed in section XV of this preamble, this final rule supersedes this memo.
[9] See the Clean Water Act regulations of 40 CFR 403.5(b)(1) and (7)
[10] C.G. Daughton, I.S. Ruhoy, Environmental footprint of pharmaceuticals: the significance of factors beyond direct excretion to sewers, Environ. Toxicol. Chem., 28 (2009), pp. 2495-2521, 10.1897/08-382.1

The second goal is to address the overlap between EPA's RCRA hazardous waste regulations and the DEA regulations for controlled substances. Some stakeholders have indicated that hazardous waste pharmaceuticals that are also controlled substances are stringently regulated and therefore are expensive to manage and dispose of in accordance with both sets of regulations. In addition, stakeholders have indicated that the RCRA hazardous waste pharmaceuticals that are also DEA controlled substances are most likely to be sewer disposed to avoid the costs of compliant incineration. EPA eliminates this regulatory overlap in this final rule, as it has been an unnecessary burden for healthcare facilities. Additionally, we expect that eliminating the overlap will help reduce intentional sewer disposal of pharmaceuticals.

The third goal is to clarify the regulatory status of a major practice used by healthcare facilities, including retailers in particular, for the management of unused and/or expired pharmaceuticals, known as reverse distribution (see section VI for a detailed discussion of reverse distribution). A number of states have taken enforcement actions against retailers that have raised awareness about the reverse distribution of pharmaceuticals. In particular, California has taken numerous enforcement actions against national retail chains with pharmacies for not complying with the RCRA hazardous waste regulations. In recent years, the state took enforcement actions and imposed fines on the following chains: Kmart (2009), Walmart (2010), Target (2011), CVS (2012), Costco (2012), Walgreens (2012), Rite-Aid (2013), and Safeway (2015). In at least two settlement agreements, California directed the defendants (CVS and Costco) to "initiate work with appropriate stakeholders from business and government, including the U.S. Environmental Protection Agency, the U.S. Food and Drug Administration, and the DTSC [Department of Toxic Substances Control], and thereafter either directly or through trade associations or informal coalitions of interested parties, undertake to promote federal regulatory

reform regarding the proper management of non-dispensable pharmaceuticals, including OTC medications, through 'reverse distribution.'"[11] Through these settlement agreements, California is seeking clarity from EPA about its longstanding interpretation about the regulatory status of pharmaceuticals that are routed through pharmaceutical reverse distribution systems.

Additionally, the California legislature directed the DTSC to convene a Retail Waste Working Group with the aim of developing recommendations to the legislature for how to address many retail waste issues, including reverse distribution/logistics.[12] The Retail Waste Working Group, which consisted of large retailers, small retailers, district attorneys, certified unified program agencies, non-government organizations, local governments, other relevant state agencies as determined by DTSC (such as the California Department of Public Health, and the California Department of Resources Recycling and Recovery), manufacturers, reverse distributors, and other interested stakeholders, produced their final report in August 2017.[13] Although the group was convened by and reported to the California legislature, its membership was drawn from across the country. EPA participated in an observer role, but neither contributed to developing recommendations nor to writing the group's report. The group's work has highlighted the need for a national policy in this area.

IV. Background

A. *Summary of the Proposal*

On September 25, 2015, EPA proposed to add subpart P under 40 CFR part 266 (see 80 FR 58014). Part 266 is entitled "Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities." In this new subpart P, we

[11] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932-0169.
[12] California SB-423. http://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201520160SB423
[13] https://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf

proposed a tailored, sector-specific regulatory framework for managing hazardous waste pharmaceuticals at healthcare facilities and reverse distributors. We proposed that healthcare facilities that are small quantity generators (SQGs) or LQGs and all reverse distributors, regardless of their RCRA generator category, would be required to manage their hazardous waste pharmaceuticals under subpart P of 40 CFR part 266, instead of the generator regulations in 40 CFR part 262. The standards were not proposed as a voluntary or optional alternative to managing hazardous waste pharmaceuticals under 40 CFR part 262; they were proposed as mandatory standards.

We discuss the proposed provisions in greater detail in subsequent sections of the preamble, but offer a brief summary of the proposal here. For healthcare facilities, we proposed different management standards for non-creditable and potentially creditable hazardous waste pharmaceuticals. We proposed that non-creditable hazardous waste pharmaceuticals (i.e., those that are not expected to be eligible to receive manufacturer credit) would be managed on site at the healthcare facility similar to how they would have been under a previous proposal for managing these wastes: the 2008 Universal Waste proposal for pharmaceutical waste.[14] We proposed that when shipped off site, the non-creditable hazardous waste pharmaceuticals must be transported as hazardous wastes, including the use of the hazardous waste manifest, and sent to a RCRA-designated facility, such as an interim status or permitted TSDF. Additionally, we proposed to revise our policy regarding pharmaceuticals going through reverse distribution (i.e., those which are "potentially creditable") such that they would be considered hazardous wastes at the healthcare facility. However, given the value associated with these potentially creditable hazardous waste pharmaceuticals, EPA proposed flexibilities for some of the regulatory

[14] 73 FR 73520; December 2, 2008.

requirements. For instance, we proposed that healthcare facilities would continue to be allowed to send potentially creditable hazardous waste pharmaceuticals to reverse distributors for them to be evaluated for manufacturer credit. After considering comments received on the prior Universal Waste proposal regarding the lack of tracking of shipments, EPA's 2015 proposed standards included provisions to ensure the safe, secure and documented delivery of the potentially creditable hazardous waste pharmaceuticals to reverse distributors.

Under the proposal, reverse distributors would no longer be regulated under 40 CFR part 262 as hazardous waste generators, nor would they be regulated under 40 CFR parts 264, 265, and 270 as TSDFs. Rather, the proposal established a new category of hazardous waste entity, called pharmaceutical reverse distributors. EPA also proposed that reverse distributors would have different standards for those hazardous waste pharmaceuticals destined for another reverse distributor (and still considered potentially creditable hazardous waste pharmaceuticals) versus those that are destined for a TSDF (considered to be evaluated hazardous waste pharmaceuticals.)[15] The proposed standards for pharmaceutical reverse distributors were, in many respects, similar to the LQG standards, but with additional standards to respond to concerns expressed by commenters to the proposal to add pharmaceuticals to the Universal Waste program.

EPA proposed several additional standards that apply to both healthcare facilities and reverse distributors. First, EPA proposed to prohibit healthcare facilities and reverse distributors from disposing of hazardous waste pharmaceuticals down a toilet or drain (i.e, flushed or sewered). Second, EPA proposed that hazardous waste pharmaceuticals managed under subpart

[15] The final rule defines an "evaluated hazardous waste pharmaceutical" as a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributed in accordance with §266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

P would not be counted toward calculating the site's generator category. Third, EPA proposed a conditional exemption for hazardous waste pharmaceuticals that are also DEA controlled substances. Fourth, EPA proposed management standards for determining when a container with hazardous waste pharmaceutical residues is considered RCRA empty.

B. *Retail Sector Notice of Data Availability (NODA)*

In 2014, EPA published a NODA for the Retail Sector, in which the Agency requested, among other things, comment on a series of topics related to retail operations in order to better understand the issues retail stores face in complying with RCRA regulations.[16] Many retail commenters to the NODA mentioned that because nicotine is an acute hazardous waste (P075), retailers are considered LQGs when they discard more than 1 kg per month of unused nicotine-containing products (e.g., e-cigarettes and smoking cessation products such as gums, patches and lozenges). Retailers discard these products mainly because they are either expired or they are returned by customers and the retailer does not restock them due to safety concerns. In comments to the NODA, retailers urged the EPA to provide some regulatory relief with regard to nicotine-containing products. See section V of this preamble for a discussion of EPA's amendment of the acute hazardous waste listing for nicotine and salts (P075).

C. *Retail Strategy*

On September 12, 2016, as a follow-up to the comments we received on the Retail NODA, EPA released its Retail Strategy. In the strategy, EPA committed to two sets of activities. First, we committed to completing rulemakings that were already underway, that, although were not specifically developed with retail in mind, contained provisions that might be helpful in resolving some issues that retailers faced in complying with RCRA regulations. This

[16] February 14, 2014; 79 FR 8926.

included completing the 2016 Hazardous Waste Generator Improvements final rule and the Hazardous Waste Pharmaceuticals final rule. Second, we committed to three new activities that specifically address concerns identified by commenters. First, EPA committed to developing guidance on aerosol cans. Second, EPA committed to exploring the potential for adding certain retail items, such as aerosol cans, pesticides, and/or electronics, to the federal universal waste regulations. A proposed rulemaking for adding aerosol cans to the federal universal waste regulations was published in Federal Register on March 16, 2018.[17] Third, EPA committed to developing a policy that addresses the reverse distribution process for the retail sector as a whole. This policy is articulated in detail in section VI of the preamble of this final rule.

D. *EPA Inspector General Report*

On May 25, 2012, the EPA's Office of Inspector General (OIG) issued the report, "EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal."[18] The OIG reviewed EPA's process for identifying and listing pharmaceuticals as hazardous wastes. Because of this review, the OIG provided the following recommendations to the Assistant Administrator for the Office of Solid Waste and Emergency Response (OSWER):[19]

> (1) Identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste.
>
> (2) Establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

[17] See 83 FR 11654; March 16, 2018.

[18] EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal, Report No. 12-P-0508, dated May 25, 2012). For a copy of the report, please see: https://www.epa.gov/sites/production/files/2015-10/documents/20120525-12-p-0508.pdf or see the docket for this final rule: EPA-HQ-RCRA-2007-0932-0177.

[19] OSWER has since been renamed the Office of Land and Emergency Management (OLEM)

(3) Develop a nationally consistent outreach and compliance assistance plan to help states address challenges that healthcare facilities, and others as needed, have in complying with RCRA regulations for managing hazardous waste pharmaceuticals.

As detailed in OSWER's response to OIG, this final rule fulfills our obligation for addressing the third recommendation.[20] In the preamble to the proposed rulemaking we solicited comment as part of our ongoing efforts to identify additional pharmaceuticals as hazardous wastes. EPA does not address the OIG's first two recommendations as part of this final rulemaking directly. That said, the Agency believes that provisions in the final rule, such as the streamlined standards for healthcare facilities and the elimination of LQG status for the management of hazardous waste pharmaceuticals, address the first two recommendations indirectly by encouraging healthcare facilities to manage their non-hazardous waste pharmaceuticals as hazardous waste pharmaceuticals.

V. Amendment to the Acute Hazardous Waste Listing for Nicotine and Salts (Hazardous Waste No. P075)

A. Background

In 1980, EPA promulgated the P- and U- lists of CCPs or manufacturing chemical intermediates that are hazardous wastes if they are discarded or intended to be discarded (40 CFR § 261.33(e) and (f)). Several hundred CCPs were listed on the P- and U- lists, including

[20] For a copy of OSWER's full response to OIG, please see: http://www.epa.gov/oig/reports/2012/12-P-0508_Agency%20Response.pdf

nicotine and salts.[21] The phrase "commercial chemical product or manufacturing chemical intermediate" refers to a "chemical substance which is manufactured or formulated for commercial or manufacturing use which consists of the commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed, and all formulations in which the chemical is the sole active ingredient" (see the *comment* following 40 CFR § 261.33(d)).

The P-listed chemicals are identified as acute hazardous wastes and U-listed chemicals are identified as non-acute hazardous wastes when discarded in unused form. EPA listed nicotine and salts (referred to commonly as just nicotine) as acute hazardous waste P075 in § 261.33(e). A chemical substance is listed in 40 CFR § 261.33(e) as an acute hazardous waste if it meets any of the criteria in 40 CFR § 261.11(a)(2), which, as described below, are based on human toxicity data, or dose of a chemical given orally or dermally that is lethal to 50 percent of the test animals (LD50), or the concentration of a chemical in the air that is lethal to 50 percent of the test animals (LC50). That is, when the solid waste "has been found to be fatal to humans in low doses or, in the absence of data on human toxicity, it has been shown in studies to have an oral LD50 toxicity (rat) of less than 50 milligrams per kilogram, an inhalation LC50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD50 toxicity (rabbit) of less than 200 milligrams per kilogram or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness."

[21] See 45 FR 33124, May 19, 1980.

EPA listed nicotine as an acute hazardous waste based on an estimated oral LD50 toxicity to humans of 1 mg/kg and a dermal LD50 toxicity to rabbits of 50 mg/kg. The acute toxicity criterion for humans, as discussed above, is "fatal to humans in low doses" (see § 261.11(a)(2)).

EPA's Background Document from April 1981 prepared in support of the commercial chemical product hazardous waste listings in § 261.33 provides a basis for what is meant by "fatal to humans in low doses" for chemicals that have been given through the oral route: "fatal to humans upon ingestion of ≤ 100 mg/kg".[22] This Background Document cites an estimated oral LD50 toxicity to humans for nicotine and salts as 1 mg/kg, which corresponds to 50–60 mg of nicotine as a lethal dose for an adult weighing 50–60 kg, and this estimated LD50 value falls within the criterion for "fatal to humans in low doses." However, the Background Document does not provide any information regarding the nicotine product or concentration of nicotine that was used to establish this estimated oral LD50 toxicity in humans for nicotine. According to comments submitted to EPA on the proposal by the retailers, tobacco companies, and trade associations, the only nicotine products being marketed at the time when EPA listed nicotine were pesticides containing up to 40 percent nicotine sulfate. These commenters note that the low-concentration nicotine-containing products (specifically smoking cessation or NRT products) had not yet been developed and, therefore, were not considered when EPA listed nicotine as an acute hazardous waste.

Once the Agency lists chemicals on either the P- or U- lists, these chemicals are P- or U-listed hazardous wastes when discarded or intended to be discarded regardless of chemical concentrations, with two exceptions: warfarin and salts (which are listed as waste number P001

[22] See pp. 21–22 and 33 in Background Document dated April 1981 in the docket for this rulemaking EPA-HQ-RCRA-2007-0932-0171.

when present at concentrations greater than 0.3% and U248 when present at concentrations of 0.3% or less) and zinc phosphide (which is listed as Waste Code P122 when present at concentrations greater than 10% and Waste Code U249 when present at concentrations of 10% or less). Therefore, the P075 hazardous waste listing is applicable to the commercial chemical product nicotine or a commercial chemical product containing nicotine as the sole active ingredient when disposed regardless of the concentration of nicotine. The Agency has previously stated that unused dermal patches containing nicotine, nicotine gum, and nicotine lozenges are listed hazardous waste P075 when discarded.[23] The Agency stated this because nicotine is a listed hazardous waste P075 when discarded, and nicotine is the sole active ingredient in patches containing nicotine, nicotine gum, and nicotine lozenges. However, once the nicotine patches, gums, and lozenges have been used for their intended purpose, regardless of the length of use, they are no longer commercial chemical products and would not be listed hazardous waste P075 when discarded.

B. *Summary of Proposal*

In the preamble to the proposed rulemaking, EPA provided a rationale for why it is considering the possibility of amending the P075 acute hazardous waste listing for nicotine and salts. Primarily, the retail associations, representing a broad range of retailers within the retail industry, asked EPA to undertake a rulemaking to remove low-concentration nicotine products from the P075 hazardous waste listing under RCRA. This is because the retailers did not believe their low-concentration nicotine products meet RCRA's requirements for acute hazardous waste, when discarded. Thus, according to the retailers, the acute hazardous waste classification for

[23] See letter from Robert Dellinger, USEPA to Charlotte Smith, WM Healthcare Solutions, Inc., dated August 23, 2010, RCRA Online # 14817.

their discarded low-concentration nicotine products is inappropriately making them subject to RCRA's LQG requirements. (for more information, see 80 FR 58071; September 25, 2015). Consequently, EPA, in the preamble to the proposed rulemaking, presented and sought comment on two possible approaches for amending the acute hazardous waste listing for nicotine and salts and stated that, depending on the information received during the comment period, EPA could finalize one of them. Under the first approach, EPA would exempt FDA-approved OTC nicotine-containing smoking cessation products (nicotine patches, gums, and lozenges) from the P075 hazardous waste listing if toxicity information received or collected for these products supported a finding that these products, when disposed, do not warrant regulation as acute hazardous wastes under RCRA Subtitle C. We note that this preamble will collectively refer to nicotine patches, gums, and lozenges as FDA-approved OTC NRTs. EPA also stated in the preamble to the proposed rulemaking that e-cigarettes would not be exempted under this approach, because they have not been approved by FDA and the concentration of nicotine in e-cigarettes is not limited by regulation (for more information, see discussion under Comments and Responses included later in this section). Under the second approach, EPA would establish a concentration-based exemption from the P075 listing for low-concentration nicotine-containing products (including e-cigarettes); in other words, a maximum concentration of nicotine in these products below which the P075 listing would not apply. This approach would require submission to EPA of supporting human toxicological data or animal LD50 data for these products at the maximum concentration of nicotine found in these products.

C. *Summary of Comments*

The comments received were mainly from retailers, tobacco companies, individual states, trade and government associations. The retailers, tobacco companies, and trade associations supported an exemption from the P075 hazardous waste listing for FDA-approved OTC NRTs. In addition, these commenters also generally favored an exemption from the P075 listing for all other nicotine-containing products which they considered to have low nicotine concentrations, including e-cigarettes and e-liquids. Alternatively, if the EPA decided not to exempt all low-concentration nicotine-containing products from the P075 listing, the commenters indicated they would support the reclassification of such products as non-acute (i.e., U-listed) hazardous wastes or otherwise require these products to be managed as hazardous waste pharmaceuticals under 40 CFR part 266 subpart P. These commenters stated that classification of low-concentration nicotine-containing products as acute hazardous waste is unjustified. The commenters also expressed a concern that, because of this inappropriate classification, anyone generating more than 1 kg per month of this acute hazardous waste becomes subject to RCRA's LQG regulations, which result in increased economic burdens and reporting requirements. The commenters asserted that the original P075 listing was likely based on a concentration of nicotine that is orders of magnitude greater than today's low-concentration NRTs, and the human toxicity data that EPA relied upon to support the original P075 listing have been recently reassessed and could not be substantiated. They stated further that a U.S. Surgeon General's Report issued in 2014 could not find support for the 1 mg/kg median lethal dose for humans used to support the original listing.

Additionally, the retailers, tobacco companies, and the trade associations commented that EPA listed nicotine and salts as P075 acutely toxic hazardous wastes long before NRT products were in use and thus EPA did not consider if they presented a risk that should be covered by the

P075 listing. According to these commenters, because the OTC NRTs (nicotine patches, gums, and lozenges) contain very low concentrations of nicotine, they clearly do not meet EPA's listing criteria for acute toxicity and in addition have been approved by FDA to be sold to the public over-the-counter (meaning these products can be purchased without a prescription). In summary, these commenters urged EPA to amend the P075 listing to exempt the low-concentration nicotine-containing products based on either 1) type of product and/or 2) a specified concentration of nicotine in these products below which the product would be exempt, because there are no credible toxicity data that would support keeping low-concentration nicotine-containing products listed as acute hazardous wastes.

All of the states and one government association (Northeast Waste Management Officials' Association or NEWMOA) that submitted comments on the proposal generally supported exempting FDA-approved OTC NRTs from the P075 listing, if EPA obtained the necessary toxicity data to show that these products are not acutely toxic. These same commenters, except for one (Oklahoma), did not support exempting e-cigarettes or nicotine-containing e-liquids from the P075 listing. Almost all of the states and NEWMOA wanted continued regulation of e-cigarettes and nicotine-containing e-liquids because the safety of these products is less widely accepted.

In summary, the Agency did not receive any comments that disagreed with the proposed approach to exempt FDA-approved OTC NRTs from the P075 listing, provided this approach is supported by sufficient toxicity information to conclude that concentrations of nicotine contained in these products are not acutely toxic.

D. *Final Rule Provisions*

The Agency is finalizing the first approach for amending the P075 listing discussed in preamble of the proposal. That is, EPA is amending the hazardous waste listing for hazardous waste number (commonly called "hazardous waste code") P075 in § 261.33(e) to exempt FDA-approved OTC NRTs. Specifically, the P075 listing for nicotine is being amended with a parenthetical phrase stating that the listing does not include patches, gums, and lozenges that are FDA-approved over-the-counter nicotine replacement therapies.

The Agency has concluded that FDA-approved OTC NRTs do not meet the acute listing criteria under 40 CFR § 261.11(a)(2), based on review of available toxicity information for nicotine and nicotine-containing FDA-approved OTC NRTs (see discussion under Comments and Responses below).

E. *Comments and Responses*

1. Nicotine Toxicity Data

Some commenters stated that human toxicity data that EPA originally relied upon to list nicotine as P075 acutely toxic hazardous wastes are not credible and do not support classifying low-concentration nicotine-containing products as acutely toxic hazardous wastes. In addition, they also stated that available animal toxicity data do not support classifying low-concentration nicotine-containing products as acutely toxic hazardous wastes. The commenters provided references to several recent reports and an article (see discussion of these references in the following paragraphs) to support their assertions. The commenters stated that these recent reports and article provide evidence that nicotine is not as toxic as originally thought.

Commenters argued that the validity of an estimated oral LD50 toxicity to humans of 1 mg/kg (corresponding to 50–60 mg of nicotine as a lethal dose for an adult weighing 50–60 kg)

for nicotine used by EPA to support the acute hazardous waste listing for nicotine has been questioned by government entities and researchers, most recently by the U.S. Surgeon General's Report, "The Health Consequences of Smoking—50 Years of Progress" (2014)[24] and in an article published in Archives of Toxicology, "How much nicotine kills a human? Tracing back the generally accepted lethal dose to dubious self-experiments in the nineteenth century" (Mayer, 2014).[25] The U.S. Surgeon General's Report cited by commenters states that the toxicity of nicotine is dependent on dose, dose duration and frequency, route of exposure, formulation of the nicotine product, and interpersonal variability. This report also states that numerous poisonings have been documented in the literature since the use of nicotine as a pesticide became widespread in the early part of twentieth century; however, there has not been a systematic assessment of the literature to characterize the dose-response relationship. Furthermore, based on an extensive literature search, the report states that no study was located as a source for the 50–60 mg estimated dose that is commonly reported to be fatal to humans. Finally, according to the report, the literature has also shown that in one case a relatively large dose of 240 mg nicotine administered to a patient accidently did not prove to be fatal.

The Mayer article cited by commenters also points out that fatal nicotine intoxications are relatively rare and that there are countless records of subjects who have survived consumption of nicotine in amounts far higher than 60 mg. One example referenced by Mayer in his article was a person surviving following a suicide attempt with 4 grams (4000 milligrams) of pure nicotine. Mayer asserts that this example and many other literature reports on nonfatal nicotine poisonings show that the oral LD50 toxicity of nicotine to humans of 1 mg/kg does not appear to be reliable.

[24] https://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf
[25] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3880486/

Although Mayer did not conduct any lab testing on nicotine, he uses previously reported nonfatal poisonings to develop an estimate of the oral LD50 toxicity of nicotine to humans in the range of 6.5–13 mg/kg (based on an adult weight of 50–60 kg, this would correspond to an estimated range of 325–780 mg of nicotine as the lethal dose for adults). Mayer concludes that nicotine is less toxic than originally thought. That said, his new estimate of the oral LD50 toxicity of nicotine to humans still falls well within the range of ≤ 100 mg/kg, which was one of the reasons for listing nicotine and salts as P075 acute hazardous waste.

EPA regulations in § 261.11(a)(2) state that, in the absence of adequate human toxicity data, the criteria for identifying acute toxicity should be based on the toxicity of the materials to laboratory animals. Commenters directed us to a recently-issued report summarizing available toxicity information on nicotine by the Committee for Risk Assessment of the European Chemicals Agency (ECHA).[26] The acute toxicity of nicotine to laboratory animals presented in the report issued by the Committee for Risk Assessment in comparison to the regulatory criteria for these animals presented in 40 CFR § 261.11(a)(2) are as follows: the acute oral LD50 for rat is in the range of 52.5–70 mg/kg (ECHA) compared to the acute oral LD50 regulatory criterion for rat of < 50 mg/kg (§ 261.11(a)(2)). The acute oral LD50 values for rats reported by ECHA fall just outside the acute toxicity criterion in EPA's regulations. The acute dermal LD50 for rabbit is 70.4 mg/kg (ECHA) compared to acute dermal LD50 regulatory criterion for rabbit of < 200 mg/kg (§ 261.11(a)(2)). The acute dermal LD50 for rabbit falls well below the acute toxicity

[26] See ECHA's Committee for Risk Assessment Opinion Proposing Harmonized Classification and Labeling at EU Level of Nicotine, adopted 10 September 2015 (https://echa.europa.eu/documents/10162/23665416/clh_opinion_nicotine_5579_en.pdf/0103fadb-e945-4839-c4f4-17d20854adf0)

criterion in our regulations. There were no comparable data available for the acute inhalation LC50 for rat.

Based on the toxicity information discussed above, and the listing criteria in 40 CFR 262.11(a)(2), the evidence is clear that nicotine is still acutely toxic to both humans and animals under the RCRA hazardous waste regulations and must continue to be listed as acute hazardous waste number P075 under § 261.33(e). As already noted, under the hazardous waste regulations the Agency generally lists commercial chemical products, if they are discarded or intended to be discarded, regardless of chemical concentrations. However, EPA is not precluded from amending (through rulemaking) an existing listing, for example, if a particular subset of wastes within that listing can be identified as not posing the risk for which the original listing was established.

2. Food and Drug Administration-Approved Nicotine Replacement Therapies

A number of commenters urged EPA to exempt low-concentration nicotine-containing products (specifically OTC NRTs) from the P075 listing. The commenters stated that millions of people use OTC NRTs daily without showing any signs of acute toxicity, and these products have been approved by FDA to be sold over the counter without a prescription. Therefore, they believe this is the best evidence that these products are not acutely toxic and safe for people to use.

As noted above, the Agency stated in the proposal that if it obtained toxicity data to support the conclusion that FDA-approved OTC NRTs do not meet the criteria for listing as an acutely hazardous waste, then it will exempt these products from the P075 listing. The FDA-approved OTC NRTs are designed to help people quit smoking by delivering controlled amounts of nicotine to ease symptoms of withdrawal and craving. The Consumer Health Products

Association stated in its comments that nicotine gums and lozenges contain 2–4 mg nicotine (approximately 0.2–2 percent by weight depending on lozenge size) and nicotine patches contain 7 mg, 14 mg, or 21 mg of nicotine (approximately 2–7 percent by weight). Comments from Reynolds American Inc. Services Company (RAI Services or RAI) provided similar information on the amount of nicotine in these FDA-approved OTC NRTs.[27] According to information on FDA's website, FDA regulations ensure that OTC drug products are safe and effective for people to use.[28] In most cases, OTC drug products are regulated by FDA through OTC drug monographs. OTC drug monographs state the active ingredients and other conditions of use (including dose, dosage form, and route of administration) that are generally recognized as safe and effective to treat certain diseases or conditions without a prescription. OTC drug products that conform to a final monograph and other relevant requirements are not required to be reviewed by FDA before marketing. Products that do not conform to a final monograph must be reviewed under the new drug application process. The new drug application process is how manufacturers provide evidence to FDA to demonstrate that the new drug product is safe and effective for use as recommended in the product's labeling. Sometimes, an OTC drug product begins as an approved prescription drug and then a drug company will submit an application to FDA to switch the drug product from prescription status to OTC status. FDA reviews the information in the application, along with information about adverse events associated with the use of the drug, and determines whether the prescription drug can be used safely and effectively as an OTC drug. FDA allowed nicotine patches and gums, which were initially available by prescription only, to be switched to OTC status between 1996 and 2002. The nicotine lozenge

[27] See P.9 of RAI's comments dated December 23, 2015 in the docket for this rulemaking EPA-HQ-RCRA-2007-0932-0329.
[28] https://www.fda.gov/Drugs/ResourcesForYou/SpecialFeatures/ucm342560.htm

and mini-lozenge were approved by FDA directly for OTC use in 2002 and 2009 via new drug applications.[29,30]

FDA has determined that OTC NRTs can be used safely and effectively by people without a healthcare professional's supervision when used in accordance with their label instructions. Since FDA first approved NRTs for OTC use, FDA has reviewed a number of studies that examined use of OTC NRTs, including use of OTC NRTs in combination with other nicotine-containing products, use of OTC NRTs at higher than standard-dose, and use of OTC NRTs over periods longer than recommended, and it has not identified any significant safety concerns.[31] It is useful to recognize one characteristic of FDA-approved OTC NRTs when considering the toxicity of nicotine contained in these products, which is that they are designed for controlled release of nicotine to approximate the nicotine amounts obtained from smoking. This characteristic of FDA-approved OTC NRTs means that nicotine enters the body over a period of time and there is a gradual increase in the level of nicotine in the blood when used in accordance with the accompanying label. According to EPA's review of FDA information and RAI's comments, FDA's Center for Drug Evaluation and Research reviewed pharmacology and toxicology data for nicotine polacrilex lozenges and made a number of observations concerning nicotine's toxicology. FDA stated that "oral doses of nicotine that have been reported to be lethal in animals are approximately 8- to 150- fold greater than nicotine exposures that would result from use of Nicotine Polacrilex Lozenges." In addition, the FDA noted that "the toxicological profile of nicotine in animals has been largely superseded by the extensive human experience

[29] See 78 FR 19718; April 2, 2013
[30] See FDA materials for New Drug Application Numbers 21-330 and 22-360 in the docket for this rulemaking EPA-HQ-RCRA-2007-0932.
[31] See 78 FR 19718; April 2, 2013.

with this agent. Based on the established clinical experience with similar nicotine replacement therapy products, acute toxic reactions would not be anticipated from use of Nicotine Polacrilex Lozenges at the recommended dosage."[32]

In summary, the most common dosage of nicotine from OTC nicotine gums and lozenges (2–4 mg) and OTC nicotine patches (7–21 mg) is absorbed slowly and results in significantly lower concentrations of nicotine in blood levels compared to the amount of nicotine that has been determined or estimated to be lethal to animals and humans. The OTC nicotine patch, the strongest of which contains 114 mg of nicotine, delivers 21 mg of nicotine at a relatively steady rate over a 24-hour period when the patch is applied to the skin. The most frequently reported side effects from use of patches are local skin reactions, which can be reduced by moving the site of the patch application daily as instructed.[33] In addition, FDA has reviewed and approved these products as being safe and effective for people to use without a prescription. Furthermore, the FDA-approved OTC NRTs have been in the market for over two decades and although some serious adverse events have been reported, based on the available information, EPA has concluded that the serious adverse events do not meet EPA's criteria for acute toxicity under 40 CFR 261.11(a)(2) (i.e., fatal to humans in low doses or capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness).[34] Finally, the serious adverse events that have been reported have not caused FDA to reverse its decision to

[32] See pages 5 and 6 of the Pharmacology Review for the New Drug Application Number 21-330 in the docket for this rulemaking EPA-HQ-RCRA-2007-0932.
[33] International Journal of Health Sciences (Qassim). "Nicotine Replacement Therapy: An Overview" (July, 2016) 10(3): pp. 425-435.
[34] See the following four FDA documents included in the docket for this rulemaking EPA-HQ-RCRA-2007-0932: (1) Letter from Janet Woodcock responding to a citizen petition, dated June 4, 2015; (2) Memo from Kellie Taylor et al. on citizen petition response, dated May 8, 2015; (3) Memo from Joslyn Swann providing a review of Abuse, Misuse, and Overdose associated with Nicotine Replacement Therapy products, dated October 1, 2010; and (4) Nicoderm OTC Switch Medical Officer Review (NDA 20-165), dated August 7, 1995.

allow the NRTs to be sold as OTCs. Therefore, the Agency finds that FDA-approved OTC NRTs are not acutely toxic and is exempting them from the P075 listing.

The FDA-approved OTC NRTs, prior to the effective date of this rule, were listed hazardous waste P075 when discarded. Therefore, these wastes have been required to be managed under RCRA Subtitle C hazardous waste regulations. Following exemption from the P075 listing, these OTC NRT wastes will be considered non-hazardous wastes and can be managed under applicable non-hazardous solid waste regulations. The Agency does not have any information at this time to suggest that these wastes will be improperly managed as non-hazardous wastes or have the potential to cause human or environmental exposures. The Agency believes, because of the low concentrations of nicotine in these wastes and their design to slowly release the nicotine, any risk from plausible mismanagement scenarios would not be sufficient to cause a substantial present or potential hazard to human health or the environment. Nevertheless, the Agency encourages healthcare facilities to first consider if their unused nicotine-containing products, which are to be discarded, can be legitimately recycled to recover the nicotine. The Agency has recently stated to one recycler that legitimately recycled nicotine-containing products would not be considered solid waste and thus would not be subject to RCRA hazardous waste regulation.[35] In addition, the Agency reminds healthcare facilities, especially retail-sector pharmacies, who may decide to discard expired FDA-approved OTC NRTs in their dumpsters or regular trash, that products' labels direct them to ensure that these products are kept out of the reach of children and pets. Therefore, the Agency recommends that healthcare facilities, including retailers, take the necessary security measures to discard unused, unwanted, or expired OTC NRTs where they are not freely accessible to the public. The recommended

[35] See letter from Barnes Johnson, USEPA to Scott DeMuth, g[2] Revolution, LLC., dated May 8, 2015, RCRAOnline #14851.

security measures could be simple as having locks on the dumpsters and trash cans that are used for discarding OTC NRTs or placing the dumpsters and trash cans in locked areas.

3. E-cigarettes, E-liquids, and Prescription Nicotine Replacement Therapies

There were mixed comments on exempting e-cigarettes, nicotine containing e-liquids, and NRTs requiring a prescription from the P075 hazardous waste listing when discarded (for more information, see Summary of Comments included previously in this section). The comments from retailers, tobacco companies, and trade associations generally favored exempting these categories of products from the P075 listing when discarded, whereas comments from four of five states and NEWMOA did not support exempting these products from the P075 listing when discarded.

The e-cigarettes and nicotine-containing e-liquids (or just e-liquids) are currently not regulated by FDA in the same manner as NRTs. NRTs are regulated as drugs by FDA while e-cigarettes and e-liquids are regulated as tobacco products by FDA. Consequently, the FDA has not been able to evaluate the health risks to the public from e-cigarettes and e-liquids to the same extent as it has been able to for drugs. Moreover, the concentrations of nicotine in e-cigarettes and e-liquids are not limited by any FDA regulation or approval process and are therefore unpredictable. The supplemental comments on the proposal submitted to EPA by the Retail Associations (June 29, 2016)[36] stated that a recent promulgation of a final rule by FDA referred to as the "Deeming Rule" (81 FR 28973; May 10, 2016) will ensure against "unpredictable" nicotine concentrations in e-cigarette products and, therefore, strengthens the case for

[36] See the docket for this rulemaking EPA-HQ-RCRA-2007-0932-0392.

reclassification or exemption of these products from the P075 listing. The Deeming Rule extended FDA's regulatory authority to all tobacco products, including electronic nicotine delivery systems (or e-cigarettes). This rule allows FDA to evaluate factors such as ingredients (e.g., nicotine and its concentration), product design, and health risks to both users and non-users. The Deeming Rule ensures that newly regulated tobacco products, before they are introduced into the market, meet certain requirements, including warning labels, prohibiting sales to minors, registering with FDA, and obtaining marketing authorization from FDA. It is, however, important to note that FDA's review and approval process for introducing new tobacco products to the market is not as rigorous in assessing their safe use as review and approval of drug products. Furthermore, in August 2017, the FDA extended the compliance deadline for the newly regulated noncombustible tobacco products in the Deeming Rule, such as e-cigarettes, from November 8, 2017 to August 8, 2022. Therefore, without controls on the concentration of nicotine in e-cigarettes and e-liquids or FDA's approval of these products as being safe and effective for people to use, the Agency lacks adequate information and certainty to conclude that these nicotine-containing products will not pose the risks similar to those for which the P075 listing was established. For all of the above reasons, at this time the Agency cannot support exempting e-cigarettes and nicotine-containing e-liquids from the P075 listing.

Furthermore, in the short time that e-cigarettes have been in the U. S. marketplace (since about 2007), the calls to poison control centers related to exposures to this product, mostly among young children, have increased substantially. This significant increase can be attributed largely to the rapid rise in the use of e-cigarettes by the public. According to an article published in the Journal Pediatrics, "Pediatric Exposure to E-Cigarettes, Nicotine, and Tobacco Products in the United States" (May 2016), the monthly number of exposures among young children

(younger than six years old) associated with e-cigarettes increased by almost 1500 percent from January 1, 2012 (14 exposures) to April 30, 2015 (223 exposures).[37] During the same period, children under two years old accounted for 44.1 percent of the exposures associated with e-cigarettes. Exposures of children to unregulated nicotine concentrations in e-cigarette cartridges and refill solutions (e-liquids) have the potential to cause much more severe toxic effects compared to exposures of children to FDA-approved OTC NRTs. This is because e-liquid refill containers are available in concentrations up to 100 mg/mL that are then diluted before use. The liquid nicotine, ingested or absorbed through skin, is likely to result in more severe toxic effects because it is available in higher concentrations and absorbed rapidly by the body. In December 2014, a 1-year old child died from liquid nicotine poisoning, the first such death in the U.S.[38]

Prescription NRTs, like OTC NRTs, must be approved for use by FDA as drugs. However, the FDA considers OTC drug products to be safe enough to take without the guidance of a health professional. A prescription for a drug is written by a health professional for an individual at a specific dose after the health professional has diagnosed an illness. Generally, nicotine-containing prescription drugs (e.g., nicotine inhaler and nicotine spray) contain an aqueous solution intended for administration as a metered spray, which means, in comparison to FDA-approved OTC NRTs, nicotine can be delivered rapidly to the body. When a prescription pharmaceutical is transitioned to OTC status, the key question for FDA is whether consumers can achieve the desired medical result without the intervention of a health care professional and

[37] http://pediatrics.aappublications.org/content/early/2016/05/05/peds.2016-0041?utm_source=TrendMD&utm_medium=TrendMD&utm_campaign=Pediatrics_TrendMD_1
[38] https://www.healthychildren.org/English/safety-prevention/at-home/Pages/Liquid-Nicotine-Used-in-E-Cigarettes-Can-Kill-Children.aspx

without endangering their safety.[39] For example, FDA has to review information about adverse events and serious adverse events resulting from use of a prescription drug before it can make a determination on whether a prescription drug is safe to switch over to an OTC drug. FDA has not yet made that determination for the existing prescription NRTs and EPA also did not receive any toxicity or health effects information on prescription NRTs. Prescription NRTs are also expected to be used less frequently than FDA-approved OTC NRTs, and, thus, should not exist in the same quantities at retailers as FDA-approved OTC NRTs. Furthermore, prescription NRTs are not expected to be returned to retailers like FDA-approved OTC NRTs, because they are prescribed by health professionals for specific individuals and can't be resold once dispensed. Therefore, the comments from retailers also expressed less concern about the disposal of prescription NRTs causing a change in their hazardous waste generator category.

Based on the information discussed above and the comments from a majority of the states and NEWMOA, the Agency is not exempting e-cigarettes, e-liquids, or prescription NRTs from the P075 hazardous waste listing. The Agency believes that any plausible mismanagement or diversion of these waste products, if exempted and allowed to be managed as non-hazardous wastes, has the ability to cause substantial present or potential hazard to human health and the environment. This is because prescription NRT products can contain nicotine at much higher concentrations and in a more readily available form (i.e., in liquid and mist), which acts faster on the body, than the nicotine contained in FDA-approved OTC NRTs. Instead, the Agency is allowing e-cigarettes, e-liquids, and prescription NRTs to be managed as hazardous waste pharmaceuticals under 40 CFR part 266 subpart P when they are discarded.

[39] https://www.fda.gov/drugs/resourcesforyou/consumers/ucm143547.htm

4. Concentration-Based Exemption

Some commenters stated that the data and information they provided to EPA should be adequate to support a concentration-based exemption for nicotine-containing products. These commenters requested that EPA exempt from the P075 listing all present and future nicotine-containing products with less than a particular nicotine concentration (e.g., less than 3% or 5%).

The Agency stated in the proposal that it would consider a concentration-based exemption for low-concentration nicotine-containing products if toxicology data (e.g., animal LD50 data) for nicotine-containing products at maximum concentration of nicotine in these products became available. On June 9, 2017, Perrigo submitted additional comments along with oral and dermal LD50 toxicity studies for nicotine gums and lozenges manufactured by Perrigo.[40] The gums and lozenges tested contain 5% nicotine polacrilex. Nicotine polacrilex is a nicotine-containing resin which contains 15% nicotine. With 5% nicotine polacrilex in the gums and lozenges, the total nicotine in these products is less than 1%. The Perrigo LD50 studies reported oral and dermal rat LD50 toxicity values of greater than 5000 mg/kg for both nicotine gum and lozenge products. Based on their data, Perrigo asked the Agency to exempt from the P075 listing nicotine at concentrations below 5%.

EPA's review of the Perrigo LD50 studies revealed several critical flaws in the way these studies were conducted. First, the studies were conducted using nicotine polacrilex instead of nicotine itself. A concentration-based listing for nicotine would require toxicity data for nicotine itself. The amount of nicotine in gums and lozenges with 5% nicotine polacrilex, as stated above, is less than 1% and it is in a form that is not readily available when ingested or applied (nicotine

[40] See the docket for this rulemaking EPA-HQ-RCRA-2007-0932-0398.

is designed to be released slowly when it is in the form of nicotine polacrilex). In fact, the nicotine will not release from the nicotine-containing resin (nicotine polacrilex) until it is exposed to an aqueous solution or proper pH, such as found in saliva. Therefore, nicotine polacrilex would not be expected to be absorbed dermally. In contrast, nicotine is readily absorbed dermally, as indicated by nicotine patches. To support a concentration-based exemption of nicotine, Perrigo should have conducted the toxicity studies for nicotine using the percent of nicotine (not nicotine polacrilex) in the gums and lozenges, since this would have provided data on toxicity of nicotine (the P075 listed chemical). Second, for acute oral testing, a single bolus dose of nicotine should have been administered to the test animals all at once (or over a short period of time) instead of over a period of 24 hours. Third, in EPA's listing regulations under § 261.11(a)(2), the dermal LD50 toxicity value is based on studies with rabbits, but Perrigo's studies used rats. Fourth, Perrigo did not provide LD50 toxicity data for nicotine patches (this could be because Perrigo does not manufacture nicotine patches). Finally, no explanation or justification was included for using their toxicity data which was for nicotine polacrilex with concentrations of nicotine at less than 1%, to extrapolate to exempting all nicotine with a concentration below 5%.

EPA, for the reasons previously stated, has already determined that FDA-approved OTC NRTs are not acutely toxic and is exempting them from the P075 listing. The toxicological data submitted by Perrigo are for nicotine polacrilex, instead of nicotine, and are not considered to be adequate to support a concentration-based exemption for nicotine-containing products. Therefore, the Agency has no other information to conclude that a particular nicotine concentration can be exempt from the P075 listing.

VI. Reverse Distribution and Reverse Logistics

A. Summary

Based on information collected from outreach efforts and comments received on the proposed rulemaking, EPA is finalizing regulations for the reverse distribution of prescription hazardous waste pharmaceuticals, codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals[41], and establishing a policy for the reverse logistics of other unsold retail items.[42] In the case of prescription pharmaceuticals, EPA maintains its position as stated in the proposed rulemaking preamble that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility (e.g., retail store).[43] In contrast, EPA is codifying our existing interpretation that nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the retail store[44] if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose)[45] or reclaimed.[46] Additionally, EPA is establishing a policy that other retail items that are sent through reverse logistics are not solid waste at the retail store if they have a reasonable expectation of being legitimately used/reused (e.g. lawfully redistributed for their intended

[41] Under the final rule, the definition of pharmaceutical includes, but is not limited to, prescription drugs, over-the-counter drugs, dietary supplements, and homeopathic drugs. See the definition of pharmaceutical in § 266.500. For the remainder of this section, EPA refers to over-the-counter drugs, dietary supplements, and homeopathic drugs as nonprescription pharmaceuticals. Prescription pharmaceuticals are defined by 21 CFR 203.3(y).

[42] Under the final rule, other unsold retail items can include any non-pharmaceutical unsold retail item from a retail store that if discarded would otherwise meet the definition of hazardous waste. Examples include but are not limited to aerosol cans, pool chemicals, mercury-containing lightbulbs, some pesticides, certain cleaning products, paint thinner, ammunition, and fireworks.

[43] Under the final rule, the definition of healthcare facility includes, but is not limited to, retail facilities such as pharmacies and retailers of over-the-counter medications. See the definition of healthcare facility in §266.500.

[44] Throughout this section, EPA uses the term "retail store" to describe facilities that send nonprescription pharmaceutical and other unsold retail items through reverse logistics. EPA's understanding is that the retail sector is the only industry that sends nonprescription pharmaceuticals and other unsold items through reverse logistics. However, EPA's final policy that nonprescription pharmaceuticals and other unsold retail items, excluding prescription pharmaceuticals, that are sent through reverse logistics are not solid wastes if they have a reasonable expectation of being legitimately used/reused or reclaimed, is not limited to the retail sector.

[45] Commenters from the retail industry commonly use the terms "liquidation" or "donation" to refer to legitimate methods of redistribution. For example, see comment numbers EPA-HQ-RCRA-2007-0932-0312 and EPA-HQ-RCRA-2007-0932-0340 in the docket. Under RCRA's definition of solid waste regulations in §261.2(e), redistribution would be referred to as use/reuse.

[46] See §261.1(b)(4) for the definition of reclamation and §261.1(b)(5) for the definition of use/reuse.

purpose) or reclaimed. The remainder of this section proceeds as follows. First, EPA provides a brief background on the Agency's work to better understand the retail sector and provide guidance on RCRA's applicability to the retail sector. EPA then describes the proposal to revise the Agency's position regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors under the pharmaceuticals proposed rulemaking. Finally, EPA provides the rationale for finalizing distinct regulations and policies for the reverse distribution of prescription hazardous waste pharmaceuticals and the reverse logistics of other unsold retail items and nonprescription pharmaceuticals and describes new information received in comments on the proposed rulemaking.

B. Background

In 2008, EPA initiated a review of RCRA's applicability to the retail sector in order to understand the challenges the retail sector faces in complying with RCRA. EPA's review consisted of discussions with various members of the retail community and states through meetings, conferences, and site visits. In 2014, EPA published a NODA for the Retail Sector in order to better understand the concerns from all stakeholders regarding RCRA's applicability to that sector.[47]

Subsequent to issuance of the NODA, EPA continued conducting outreach efforts (e.g., meetings, conferences, site visits) with stakeholders to gather information regarding the management of unsold retail items. EPA's outreach efforts, combined with an analysis of comments received on the NODA, improved the Agency's understanding of the challenges that the retail sector faces when managing items that have become unsalable at stores for a variety of reasons. Unsold retail items include excess inventory, such as expired or outdated items, seasonal

47 February 14, 2014 (79 FR 8926)

items, overstock, recalled items, and returned items that cannot be returned to stock/inventory. In the NODA, EPA used the terms "reverse distribution" and "reverse logistics" to describe the process or system employed by the retail sector to manage these unsold retail items.

Based on information gathered through outreach and comments to the Retail NODA, EPA developed a cohesive plan to address the unique challenges faced by the retail sector in complying with RCRA regulations. This plan is called the "Strategy for Addressing the Retail Sector under the Resource Conservation and Recovery Act's Regulatory Framework" (Retail Strategy) and was made publicly available on September 12, 2016.[48]

Throughout the Retail Strategy, EPA used the term "reverse distribution" to describe the system through which unsold retail items flow and the term "reverse logistic center" to describe the facilities managing the reverse flow of these items. In crafting the Retail Strategy, EPA recognized that the reverse distribution process that retail stores employ to send unsold retail items to reverse logistics centers is a well-established business practice in the retail sector and retail stores sometimes rely upon arrangements with manufacturers[49] to determine the ultimate disposition of these goods. EPA also noted that a number of questions have been raised by both retailers and regulators regarding how the reverse distribution process is regulated, or should be regulated, under RCRA. In addition, this issue becomes more complicated for national retailers with store locations in multiple states, as states have taken various positions on how RCRA regulations apply. The Agency's understanding when crafting the Retail Strategy was that "reverse distribution" is the term most commonly used for the return of all pharmaceuticals (both

[48] EPA's Retail Strategy is available at https://www.epa.gov/hwgenerators/strategy-addressing-retail-sector-under-resource-conservation-and-recovery-acts.

[49] EPA has not distinguished among the terms "supplier" and "vendor" (the latter more commonly used in the retail industry) versus "manufacturer" and these terms are used interchangeably in this preamble, although the Agency realizes that the flow of goods/products more commonly occurs between retailers and suppliers/vendors (or agents thereof) and that suppliers themselves may also be manufacturers or product formulators.

prescription and nonprescription) that have the potential to receive manufacturer credit, whereas "reverse logistics" is the term used for the reverse flow of retail items other than pharmaceuticals.[50]

Because of the challenges facing the retail sector in complying with RCRA, EPA stated in the Retail Strategy its intent to develop a policy addressing the reverse distribution process for the retail sector as a whole. In the Retail Strategy, EPA agreed to develop a comprehensive policy that applied to all unsold retail items, not just pharmaceuticals. In order to fulfill EPA's intent to address the reverse distribution process for the retail sector as a whole, EPA is establishing a policy for the reverse logistics of other unsold retail items in addition to finalizing regulations for the reverse distribution of prescription hazardous waste pharmaceuticals and codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals.

C. EPA's Proposed Regulations for Reverse Distribution of Pharmaceuticals

In the proposed Management Standards for Hazardous Waste Pharmaceuticals, EPA proposed to revise the Agency's position regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors to obtain manufacturer credit. EPA's original position was outlined in two RCRA policy memos released in 1981 and 1991.[51] In the first memo, EPA agreed that pharmaceuticals did not become wastes until the decision to discard was made at a manufacturing plant. EPA's interpretation was based on the understanding that the decision to either return goods for reclamation or dispose of them took place only at the manufacturing plant. In the second memo, EPA agreed that pharmaceuticals returned to a manufacturer, wholesaler, or third-party service company would not be considered wastes until a decision to

[50] As discussed subsequently in this preamble, the distinction between "reverse distribution" and "reverse logistics" has become important in light of the Agency's response to comments received on the proposed rule.

51 Refer to the preamble of the proposed rule (pages 58042 and 58043), which includes discussion of the two EPA policy memos, dated May 13, 1981 (RCRA Online #11012) and May 16, 1991 (RCRA Online #11606).

discard has been made. In this 1991 memo, EPA specifically noted that, "to the extent that the materials involved are unused commercial chemical products with a reasonable expectation of being recycled in some way when returned, the materials are not considered waste until a determination to discard them is made." Although EPA made a statement in the preamble to the 2008 Pharmaceutical Universal Waste proposal that linked the value of these pharmaceuticals, in the form of manufacturers credit, to the idea that these pharmaceuticals would not be considered waste, EPA never finalized this universal waste rule or that interpretation. Thus, the 1991 memo describes EPA's interpretation regarding how RCRA applies to pharmaceuticals that are returned to reverse distributors prior to this final rulemaking.

In the preamble to the proposed rulemaking, EPA indicated the Agency's intent to modify its position regarding the point of generation in circumstances where a pharmaceutical is sent to a reverse distributor. EPA proposed that the decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical. That is, EPA proposed that, once the decision is made to send a potentially creditable hazardous waste pharmaceutical[52] from a healthcare facility to a reverse distributor, a decision to discard has been made and the pharmaceutical is considered a solid waste. This proposed change of policy was based on the EPA's understanding that in almost all cases, pharmaceuticals returned to a reverse distributor for manufacturer credit are ultimately discarded.[53] Under the proposed rulemaking, the definition of "pharmaceutical reverse distributor" included any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Additionally, under the proposed rulemaking, the

[52] Potentially creditable hazardous waste pharmaceutical in the proposal was generally defined as a hazardous waste pharmaceutical that has the potential to receive manufacturer credit and is (1) unused or un-administered; and (2) unexpired or less than one year past expiration date. See 80 FR 58014.
[53] See further discussion in the proposed rule preamble at 80 FR 58043.

definition of "pharmaceutical" included not just prescription pharmaceuticals but also nonprescription pharmaceuticals. Therefore, under the proposal, potentially creditable prescription pharmaceuticals and nonprescription pharmaceuticals transported to a facility that facilitates or verifies manufacturer credit, even in cases where a credit determination is yet to be made, would be considered discarded and, therefore, solid wastes at the healthcare facility.

In proposing this shift, EPA specifically stated that, although a pharmaceutical may retain monetary value within the reverse distribution system (i.e., potential exists for a manufacturer to issue credit), the pharmaceutical would still be considered a solid waste. The "decision point" on whether a pharmaceutical is a solid waste is when it has been discarded or when the decision has been made to discard the material. That is, when a pharmaceutical is discarded determines whether it is a solid waste, not whether the pharmaceutical has value. This interpretation is consistent with EPA's approach under RCRA that materials that are discarded are solid wastes, regardless of their monetary value or the economics of the system in which those discarded materials are handled. EPA has long maintained, and continues to maintain, the interpretation that value is not determinative of solid waste status.

In 1986, EPA released a memo on the regulation of hazardous wastes that are recycled, and wrote that "persons transporting and storing hazardous wastes before recycling are similar to persons transporting and storing hazardous waste before disposal: there is nothing about the waste that makes it so valuable that safe handling is assured absent regulation."[54] EPA reaffirmed this interpretation in a 1989 memo on the regulatory status of solder skimmings

[54] See RCRA Online #12762 for the October 8, 1986 letter from EPA to Senator John Glenn titled "Hazardous Wastes that are Recycled, Handling."

(tin/lead alloy) purchased for reclamation, writing that even though the skimmings have value, they are still considered a solid waste.[55]

In a more recent application of this interpretation, EPA outlined its position on chlorofluorocarbons (CFCs) that are processed back into the refrigerant market or sent for destruction, but receive carbon offset credits and thus have value, in two memos signed in 2017.[56] Irrespective of whether facilities pay for hazardous CFCs or receive carbon offsets for the destruction of CFCs, the material is considered a solid waste. As another example of a material that is discarded as solid waste but has monetary value, EPA maintains that spent lead acid batteries being reclaimed are regulated as hazardous waste under part 266 subpart G or under universal waste irrespective of the fact that the batteries may have value and that reclamation facilities sometimes buy batteries due to the monetary value of the lead.[57] This finding was upheld in *United States v. Ilco Inc.*, 996 F. 2d 1126, where the court found that the fact that the batteries were discarded "does not change just because a reclaimer has purchased or finds value in the components." EPA also maintains that recyclable materials that are reclaimed to recover economically significant amounts of gold, silver, and other various previous metals are still regulated as hazardous waste under part 266 subpart F despite the fact that the precious metals have monetary value. Additionally, the holdings of multiple court decisions is that simply because a hazardous waste has, or may have, monetary value does not mean the material loses its status as a solid waste. See *American Petroleum Institute* v. *EPA*, 906 F.2d 741

[55] See RCRA Online #11446 for the July 20, 1989 memo from EPA to Electrum Recovery Works, Inc.
[56] See docket number EPA-HQ-RCRA-2007-0932 for the January 30, 2017 letter from EPA Region 5 to Tradewater, LLC and the July 14, 2017 letter from EPA to A-Gas U.S. Holdings, Inc.
[57] See docket number EPA-HQ-RCRA-2007-0932 for notes from a November 19, 2013 site visit to a lead acid battery recycler.

n.16 (DC Cir. 1990); *United States v. ILCO Inc.*, 996 F.2d 1126 1131-32 (11th Cir. 1993); *Owen Steel v. Browner*, 37 F.3d 146, 150 (4th Cir. 1994).

D. EPA's Final Reverse Distribution Regulation and Reverse Logistics Policy

1. Introduction

In light of comments received on the proposed rulemaking, along with EPA's understanding of current business practices, the Agency is making a clear distinction in the final rule between the reverse distribution of prescription pharmaceuticals and the reverse logistics of other unsold retail items, including nonprescription pharmaceuticals. In addition to receiving information from comments on the proposed rulemaking, EPA gathered information from site visits and by participating as an observer in the Retail Waste Working Group.[58] In the case of prescription pharmaceuticals, EPA is finalizing, as proposed, that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility. However, EPA notes that these tailored RCRA regulations for prescription pharmaceuticals going through reverse distribution are designed with existing business practices in mind. For more explanation, see section 4 below and section XVII of this preamble. EPA is also codifying our existing interpretation for the reverse logistics of nonprescription pharmaceuticals. EPA makes it clear in § 266.501(g)(2) that nonprescription pharmaceuticals are not solid wastes because they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed (also see section IX of this preamble). Also in this preamble, EPA is establishing a policy that other unsold retail items that are sent through reverse logistics

[58] See the report prepared by the Retail Waste Working Group, "Surplus Household Consumer Products and Wastes: Report to the Legislature." Available at: http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.

are not solid wastes at the retail store because they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

2. Comments on EPA's Proposed Reverse Distribution Regulation

EPA received numerous comments on the proposed position that the decision to send potentially creditable pharmaceuticals through reverse distribution is a decision to discard. States were generally supportive of the proposed change in position, while many comments from the retail industry objected to the Agency's proposed change in position.

EPA received many broad comments on EPAs proposed position regarding the waste status of pharmaceuticals going through reverse distribution and reverse logistics, which are discussed in further detail in section XVII. EPA also received many comments describing the potential burden that the revised interpretation would place on the retail industry, which are also discussed in further detail in section XVII. The remainder of this section focuses on comments received on the distinction between the reverse distribution of prescription pharmaceuticals and the reverse logistics of nonprescription pharmaceuticals and other unsold retail items.

EPA received numerous comments that described the key distinctions between reverse distribution and reverse logistics as they pertain to the waste status of pharmaceuticals and other unsold retail items going through these two processes. Multiple commenters argued that EPA mistakenly concluded that pharmaceuticals, including nonprescription pharmaceuticals, transported to facilities that facilitate or verify manufacturer credit are in most, if not all cases, discarded.[59] Commenters argued that the Agency failed to take into account the ability to donate,

[59] See the preamble to the proposed rule for a discussion of the comments received on the 2008 Pharmaceutical Universal Waste proposal and the 2014 Retail Notice of Data Availability that argued that pharmaceuticals transported to reverse distributors to receive credit are rarely, if ever, repurposed, recycled, or reused (80 FR 58043).

liquidate, or reclaim nonprescription pharmaceuticals that are sent through reverse logistics. However, commenters did confirm that prescription pharmaceuticals are in most, if not all cases, discarded. Commenters argued that this fact contradicts EPA's rationale in proposing that all pharmaceuticals, including nonprescription pharmaceuticals, going through reverse distribution and reverse logistics are wastes at the healthcare facility.

Overall, commenters encouraged EPA to adopt the terminology used by industry where "reverse distribution" only refers to the process by which prescription pharmaceuticals are sent to a reverse distributor for the evaluation of manufacturers credit and "reverse logistics" refers to the process by which nonprescription pharmaceuticals and other unsold retail items are sent to a reverse logistics center and evaluated for legitimate use/reuse or reclamation. Commenters requested that if EPA intends to finalize that a decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical, that EPA also adopt separate and distinct policies regarding how RCRA applies to prescription pharmaceuticals going through "reverse distribution" and to nonprescription pharmaceuticals and other unsold retail items going through "reverse logistics."[60] One commenter noted that reverse logistics is an integral component of inventory management, product recall confirmation, sale through liquidation, donation for use, and reclamation of commercial products—contributing billions of dollars to the retail industry annually.[61] Moreover, this commenter noted that the reverse logistics operations help maximize the amount of OTC pharmaceuticals and dietary supplements that can be reused or reclaimed. Another commenter made a similar argument, writing that the purpose of reverse distribution of prescription pharmaceuticals is to determinate

[60] For example, see comment number EPA-HQ-RCRA-2007-0932-0377.
[61] See comment number EPA-HQ-RCRA-2007-0932-0295 in the docket.

creditworthiness while the primary purpose of reverse logistics of nonprescription pharmaceuticals is to aggregate and redirect viable products into another supply chain.[62]

One commenter honed in on the argument that EPA failed to take into account the ability to legitimately use/reuse or reclaim nonprescription pharmaceuticals that are sent through reverse logistics.[63] This commenter pointed out that stringent chain-of-custody documentation and disposal requirements under DEA regulations and state Board of Pharmacy Requirements only apply to prescription pharmaceuticals. In contrast, most nonprescription pharmaceuticals are not susceptible to the same diversion risks as prescription pharmaceuticals and do not face the same documentation and disposal requirements. This makes it possible to use/reuse or reclaim nonprescription pharmaceuticals.

Walmart Stores Inc. commented that pharmaceuticals going through reverse distribution that are ultimately discarded are likely prescription pharmaceuticals.[64] Walmart wrote that only a small percentage of the consumer goods[65] managed at Walmart's six Return Centers, which will be considered reverse logistics centers under EPA's final policy, are discarded. According to Walmart's data, only 2% of the consumer goods managed at Walmart's Return Centers are discarded by Walmart, while 28% are donated, recycled, or liquidated and 70% are returned to the vendor.[66] Further, for the consumer products that are considered RCRA hazardous waste when discarded, only 1% are discarded, 33% are liquidated or donated, and 66% are returned to

[62] See comment number EPA-HQ-RCRA-2007-0932-0312 in the docket.
[63] Ibid.
[64] See comment number EPA-HQ-RCRA-2007-0932-0340 in the docket.
[65] EPA uses the term "unsold retail items" to refer to excess inventory, such as expired or outdated items, seasonal items, overstock, recalled products, and returned items that cannot be return to stock/inventory. Walmart and other commenters from the retail industry use the term "consumer goods" to refer to similar items.
[66] EPA has not distinguished among the terms "supplier" and "vendor" verses "manufacturer" and the terms are used interchangeably throughout the preamble. The Agency more frequently used the term "manufacturer" while retail industry commenters more frequently used the term "vendor."

the vendor.[67] Inmar, Inc. also argued that only a small percentage of the OTC pharmaceuticals returned to a reverse logistics center are disposed rather than liquidated, donated, or returned to the vendor.[68] Inmar does not maintain specific data on this issue, but wrote that it would not be unusual for one of their subsidiary reverse logistics centers handling nonprescription pharmaceuticals and other consumer goods to send as little as 5% of the products for destruction.

Retail Industry Leaders Association (RILA) et al. pointed out that nonprescription pharmaceuticals do not face the same restrictions that preclude the redistribution or donation of prescription pharmaceuticals.[69] RILA et al. added that nonprescription pharmaceuticals are regularly donated and liquidated and cited data from two retailers.

Inmar Inc. also noted that when an item is returned because an expiration date has been exceeded, disposal is more often the required disposition, but the products may be returned to the manufacturer for further evaluation for potential liquidation.[70] Inmar also wrote that nonprescription pharmaceuticals with "best by" dates (as opposed to expiration dates) can still be donated or liquidated after the date has passed.

Overall, these comments help to underscore the differences between how prescription pharmaceuticals and other unsold retail items, including nonprescription pharmaceuticals, are managed within the reverse supply chain. These comments led EPA to make a clear distinction in the final rule between the reverse distribution of prescription pharmaceuticals and the reverse logistics of all other unsold retail items, including nonprescription pharmaceuticals.

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[67] EPA did not receive data on the ultimate disposition of consumer products returned to the vendor. EPA further discusses our policy on unsold retail items that are returned to the vendor in section "e.) Nonprescription Pharmaceuticals and Other Retail Items Going through Reverse Logistics Are Not Wastes."
[68] See comment number EPA-HQ-RCRA-2007-0932-0377 in the docket.
[69] See comment number EPA-HQ-RCRA-2007-0932-0295 in the docket.
[70] See comment number EPA-HQ-RCRA-2007-0932-0377 in the docket.

3. Distinction Between Reverse Distribution and Reverse Logistics

EPA acknowledges that reverse distribution and reverse logistics processes share common elements in terms of the role each plays in the management of pharmaceuticals. However, based on the comments received on the proposal, especially those summarized above, the Agency recognizes that there is a key distinction between how prescription pharmaceuticals and nonprescription pharmaceuticals (see definition of pharmaceutical in § 266.500) are managed in the reverse supply chain. The key distinction is that there is not a reasonable expectation of legitimate use/reuse (e.g., lawful redistribution for its intended purpose) or reclamation for prescription pharmaceuticals, except in very limited circumstances, but there is for other retail items, including nonprescription pharmaceuticals.

Prescription pharmaceuticals shipped from healthcare facilities to reverse distributors for the evaluation of manufacturer credit are almost always discarded. EPA is aware that prescription pharmaceuticals are sometimes lawfully donated, in which case the pharmaceuticals would not be a solid waste.[71] In the case of nonprescription pharmaceuticals and other unsold retail items that are sent to a reverse logistics center, there is often a reasonable expectation that they will be legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed.

EPA recognizes that the awarding of credit for unsold pharmaceuticals is a critical element of both the reverse distribution and reverse logistics processes as it provides a healthcare facility financial incentive to not only stock a particular pharmaceutical but also to defray costs

[71] EPA is aware of one non-profit organization that facilitates donations of prescription pharmaceuticals. See comment from SIRUM in the docket (EPA-HQ-RCRA-2007-0932-0353). EPA is also aware of multiple states, including Iowa, Wyoming, and Oklahoma, that run prescription pharmaceutical return and reuse programs. For more information, see "State Prescription Drug Return, Reuse and Recycling Laws" at http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx.

associated with transporting a pharmaceutical to a reverse distributor or reverse logistics center. However, it is EPA's position that the inherent monetary "value" conferred on any pharmaceutical due to the potential to receive manufacturer credit is not a proper indicator of waste status. Rather, the decision to discard is determinative of when an unsold product becomes a solid waste. Under EPA's final rule and preamble, if a nonprescription pharmaceutical or other retail item becomes unsalable at a retail store it can continue to be considered a product until a reverse logistics center or other subsequent entity makes the decision to discard it, as long as there is a reasonable expectation of it being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

4. Prescription Pharmaceuticals going through Reverse Distribution Are Wastes at the Healthcare Facility

In the case of prescription pharmaceuticals, EPA maintains its position, as stated in the proposed rulemaking preamble and reflected in the regulatory text, that prescription pharmaceuticals moving through reverse distribution are solid wastes starting at the healthcare facility. This includes prescription pharmaceuticals that, as potentially creditable hazardous waste pharmaceuticals, are sent from a retail facility or healthcare facility to a reverse distributor for manufacturer credit evaluation (see definition of potentially creditable hazardous waste pharmaceutical in § 266.500). Although the potential exists for a manufacturer to issue credit for a prescription pharmaceutical, the "decision point" on when a pharmaceutical is a solid waste is when the decision has been made to discard the item. That is, a pharmaceutical is a solid waste when the decision has been made to discard regardless of whether the pharmaceutical has value. Although prescription pharmaceuticals are evaluated for, and in many cases ultimately receive, manufacturer credit, it remains apparent to EPA that these pharmaceuticals will seldom, if ever,

be legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed after they are sent to a reverse distributor. Thus, a decision to send prescription pharmaceuticals to a reverse distributor is a decision to discard the material. None of the comments on the proposed rule alter EPA's position regarding the likelihood of redistribution or reclamation of prescription pharmaceuticals being managed through reverse distribution. Rather, EPA received many comments that agreed with EPA's proposed interpretation that the decision to send a pharmaceutical to a reverse distributor is a decision to discard as it pertains to prescription pharmaceuticals because there are limited opportunities to legitimately use/reuse or reclaim prescription pharmaceuticals. In circumstances when prescription pharmaceuticals are lawfully donated for their intended purpose, they would not be considered a solid waste and we have specifically noted this in the regulations (see § 266.501(g)(1) and the definition of hazardous waste pharmaceutical in § 266.500).

Many of the broad comments in support of the proposed reinterpretation provided examples but did not distinguish between prescription pharmaceuticals and nonprescription pharmaceuticals. For example, multiple commenters argued that pharmaceuticals transported to a reverse distributor are rarely redistributed or reclaimed, and are usually destroyed, but did not explain if this applied only to prescription pharmaceuticals. One commenter observed that many manufacturers contract with reverse distributors to dispose of unsold pharmaceuticals after review for credit eligibility is complete, suggesting that use/reuse or reclamation does not generally occur. This commenter was only aware of one instance of potential reuse of a pharmaceutical after being sent through reverse distribution.[72] That being said, based on what

[72] The example cited was an unconfirmed claim that a rodent poison manufacturer could use discarded pharmaceutical warfarin tablets as feedstock in its process. See comment number EPA-HQ-RCRA-2007-0932-0358 in the docket.

EPA has learned from retail industry commenters, site visits, and discussions with retailers about prescription pharmaceuticals verses nonprescription pharmaceuticals, EPA can infer that these comments likely refer to the reverse distribution of prescription pharmaceuticals .[73] EPA's inference is supported by other comments received on the proposal. For example, Walmart argued that the comments EPA received on the 2008 Pharmaceutical Universal Waste proposal (where pharmaceuticals were defined only as prescription pharmaceuticals) and the 2014 Retail Notice of Data Availability that pharmaceuticals going through reverse distribution are ultimately discarded were likely talking about prescription pharmaceuticals.[74]

In conclusion, a material is considered a solid waste if it is accumulated or stored before or in lieu of being disposed of, burned, or incinerated (§261.2(b)(3)). Even if the healthcare facility intends to receive credit for the prescription pharmaceutical and the reverse distributor intends to evaluate the prescription pharmaceutical for credit, the pharmaceutical is still considered a discarded material (§261.2(a)(2)(i)) because it is being accumulated and stored prior to being sent for treatment (rather than being accumulated or stored prior to being used/reused or reclaimed). Although the healthcare facility or reverse distributor intends to elicit credit from the prescription pharmaceutical in the interim period before it is sent for treatment, the pharmaceutical is still considered a discarded material. An intent to receive credit does not preclude the pharmaceuticals from being discarded; they are not mutually exclusive.

Although EPA maintains its position that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility, this final rule establishes streamlined, practical standards for managing potentially creditable hazardous waste

[73] See docket number EPA-HQ-RCRA-2007-0932 for reverse distributor responses to EPA's questions about reverse distribution of pharmaceuticals, notes from Agency meetings with retail industry representatives, and notes from site visits to reverse distribution facilities.
[74] See comment number EPA-HQ-RCRA-2007-0932-0340 in the docket.

pharmaceuticals that will reduce regulatory burden on retailers and align with the existing practices of the retail sector. Thus, EPA's position that prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility only subjects these hazardous waste pharmaceuticals to the streamlined part 266 subpart P standards versus the full RCRA Subtitle C regulations. For example, EPA does not require healthcare facilities to use a hazardous waste manifest or a hazardous waste transporter when shipping potentially creditable hazardous waste pharmaceutical to a reverse distributor. See section XVI.D for a discussion of the shipping standards for potentially creditable hazardous waste pharmaceuticals.

Because the point of generation of potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, EPA can impose the RCRA Subtitle C cradle-to-grave management of hazardous wastes. Specifically, it allows us to impose consistent and enforceable tracking of hazardous waste pharmaceuticals from healthcare facilities en route to reverse distributors. Lack of tracking was identified as a regulatory gap by many commenters on our 2008 proposal to add pharmaceuticals to the Universal Waste program. The tracking provides the benefit of reducing the risk of diversion of these unused hazardous waste pharmaceuticals onto the black market, thus fulfilling our statutory mandate of protecting human health.

5. Nonprescription Pharmaceuticals and Other Retail Items Going through Reverse Logistics Are Not Wastes If They Have a Reasonable Expectation of Being Legitimately Used/Reused or Reclaimed

Although EPA includes nonprescription pharmaceuticals in the definition of "pharmaceutical" under the final rule, the Agency makes it clear in the definition of "hazardous waste pharmaceutical" that nonprescription pharmaceuticals are not solid wastes, and therefore

not hazardous waste pharmaceuticals, if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed. The applicability of the final rule also has a new provision in § 266.501(g)(2) making it clear that a nonprescription pharmaceutical that is not a solid waste because it has a reasonable expectation of being legitimately used/reused or reclaimed is not subject to parts 260–273. Additionally, the final definition of reverse distributor has been revised so that it applies only to the reverse distribution of prescription pharmaceuticals.

In the final rule, EPA is reaffirming the Agency's previous policies on redistribution expressed in memos in 1981 and 1991 with respect to nonprescription pharmaceuticals and other retail items that have become unsalable at the retail store and are being managed by a reverse logistics center through the reverse logistics process. That is, EPA is maintaining a policy that nonprescription pharmaceuticals and other retail items that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed. EPA recognizes that reverse logistics centers are designed to evaluate unsold retail items, analyze secondary markets, and assess the suitability of the unsold retail items for reuse in those secondary markets. These services promote the donation, liquidation, and reuse of unsold retail items and reduce overall waste. Importantly, these activities are distinct from the activities of reverse distributors of prescription pharmaceuticals. Reverse distributors of prescription pharmaceuticals are not designed to evaluate unsold prescription pharmaceuticals and assess the suitability of the prescription pharmaceuticals for reuse in secondary markets. As mentioned previously, commenters pointed out that the purpose of reverse distribution of prescription pharmaceuticals is to determinate creditworthiness while the primary purpose of reverse logistics of

nonprescription pharmaceuticals is to aggregate and redirect viable products into another supply chain.

Although EPA is reaffirming this policy, EPA remains concerned about the potential for overuse of reverse logistics centers, a concern we originally raised in a 1991 memo related to reverse distribution: "a reverse distribution system cannot be used as a waste management service to customers/generators without the applicable regulatory controls on waste management being in place…to the extent that the materials involved are unused commercial chemical products with a reasonable expectation of being recycled in some way when returned, the materials are not considered as wastes until a determination has been made to discard them."[75] To reiterate, in order to avoid being considered solid waste, items, including nonprescription pharmaceuticals, sent through reverse logistics, must have some reasonable expectation of being legitimately used/reused or reclaimed. The 199l guidance allowing pharmaceuticals to go through reverse distribution without being considered solid waste was based on the notion that they had the potential for recycling by use/reuse. Over the years, however, many have come to disregard the intent behind this guidance and erroneously believed that it was a blanket statement that pharmaceuticals going through reverse distribution were not solid wastes, even if they did not have a reasonable expectation of being redistributed or recycled. We strongly encourage the use of reverse logistics centers to facilitate redistribution and legitimate recycling to the fullest extent possible, and thus, reduce the amount of waste being generated. But we also caution reverse logistic centers not to become *de facto* waste management facilities for their customers. If this were to occur, it could be the case that the decision to discard for nonprescription

[75] See memo dated May 16, 1991, From Lowrance to Schulz, RCRA Online #11606.

pharmaceuticals and other retail items would have occurred at the retail store or healthcare facility.

Of course, once a reverse logistics center makes a decision to discard an item, it becomes a solid waste and, if it is listed or exhibits a characteristic, a hazardous waste. The reverse logistics center is subject to the applicable RCRA regulations, such as part 262, for the generation and accumulation of hazardous waste, including hazardous waste pharmaceuticals, but not part 266 subpart P.

EPA notes that although nonprescription pharmaceuticals and other retail items that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused or reclaimed, the items must be shipped in accordance will all applicable Department of Transportation (DOT) regulations. For example, DOT promulgated a final rule in March 2016 on the reverse logistics of hazardous materials. This rule includes provisions to help ensure that items, including consumer grade fireworks, are in original packaging when shipped from a retail store to a manufacturer, supplier, or distribution facility.[76]

There are six issues that came to EPA's attention when shaping this final reverse logistics policy. The first issue regards the ultimate disposition of unsold retail items moving through reverse logistics. The second issue regards unsold retail items that have expired. The third issue involves instances when retail items cannot be legitimately used/reused (e.g., lawfully redistributed for their intended purpose) because the items are subject to a "destroy disposition." The fourth issue regards the crediting process for unsold retail items. The fifth issue involves instances when nonprescription pharmaceuticals and other unsold retail items become subject to

[76] See 81 FR 18527; March 31, 2016.

a voluntary, federally mandated, or state mandated recall. The final issue involves instances when nonprescription pharmaceuticals and other unsold retail items cannot be sent through reverse logistics because they are broken, damaged, or leaking.

a. *Unsold retail items returned to the manufacturer or vendor*. The first issue regards the ultimate disposition of unsold retail items moving through reverse logistics. As noted previously, data from commenters suggests a majority of unsold retail items moving through reverse logistics are returned to the manufacturer or vendor.[77] EPA did not receive data on the ultimate disposition of retail items that are returned to a manufacturer or vendor from a reverse logistics center. For this final action, EPA assumes the items are not wastes if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed. However, if nonprescription pharmaceuticals or other retail items do not have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed after they are returned to a manufacturer or vendor, then the nonprescription pharmaceutical or other unsold retail item would be a solid and potentially hazardous waste at the reverse logistics center.

b. *Unsold retail items that have expired*. The second issue regards unsold retail items that have expired.[78] As mentioned previously, commenters noted that when an item is sent to a reverse logistics center because an expiration date has been exceeded, disposal is most often the required disposition, however the items may be returned to the manufacturer for further evaluation for potential liquidation.[79] Furthermore, nonprescription pharmaceuticals with "best by" dates (as opposed to expiration dates) often can still be donated or liquidated after the date has passed. In

[77] See comment number EPA-HQ-RCRA-2007-0932-0340 in the docket.
[78] EPA uses the term "expired" consistent with Food and Drug Administration regulations. See 21 CFR part 201.66, part 201.17, and 211.137.
[79] See comment number EPA-HQ-RCRA-2007-0932-0377 in the docket.

addition to information received from commenters suggesting that expired products might be considered eligible for redistribution, FDA occasionally allows the donation of drugs that are past the expiration date shown on the label when provided sufficient information to show the expired pharmaceuticals are safe and effective and other specific criteria have been met.[80] Thus, for this final action, EPA assumes that nonprescription pharmaceuticals and other unsold retail items that have expired are not wastes if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed. These items are in their original, intact packaging and do not pose a high risk of release to the environment. Further, this position is consistent with the goal of the RCRA statute to reduce waste, as EPA is concerned that considering unsold retail items that have expired to be wastes at the retail store could introduce an unintended incentive for retailers to remove those items from shelves in advance of expiration dates, resulting in an unnecessary increase in overall waste generation.

c. *Unsold retail items subject to a destroy disposition*. The third issue involves instances when retail items cannot be legitimately used/reused (e.g., lawfully redistributed for their intended purpose) because the items are subject to a "destroy disposition." A destroy disposition is when a manufacturer has established "business rules" that prohibit unsold retail items from being redistributed for their intended purpose (i.e., liquidated or donated). The term "business rules" (i.e., manufacturer return policies) refers to the rules that govern the disposition of retail items agreed to by the manufacturer, retailer, and reverse distributor or reverse logistics center.[81] The Agency's understanding is that manufacturers adopt destroy dispositions over concerns related to

[80] See U.S. Food and Drug Administration "Question and Answers for the Public: Donating Drugs to International Humanitarian Relief Efforts" available at: https://www.fda.gov/downloads/NewsEvents/PublicHealthFocus/UCM249617.pdf.

[81] This definition is derived from the definition of "business rules" in the "Surplus Household Consumer Products and Wastes: Report to the Legislature." Available at: http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.

liability and brand protection and that assigning a destroy disposition is not a common practice because it precludes income from potential redistribution and results in disposal costs.[82] For this final action, if a manufacturer has established business rules that prohibit unsold retail items from being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) because the items are subject to a "destroy disposition," and that prohibit the unsold retail items from being reclaimed, the items are considered solid waste at the retail store or healthcare facility. However, if a manufacturer has established business rules that do not imply that disposal is the ultimate disposition for unsold retail items, and there is a reasonable expectation the items will be reclaimed, these items would not be solid wastes at the retail store when they are sent through reverse logistics. Thus, a manufacturer can adopt business rules that prohibit the lawful redistribution of retail items for their intended purpose (i.e., liquidation or donation), but allow for the items to be sent through reverse logistics for reclamation. These items would not be wastes at the retail store if there is a reasonable expectation the items will be reclaimed.

d. *Crediting process for unsold retail items*. The fourth issue regards the crediting process for unsold retail items. It is the Agency's understanding that there are two primary credit models. The first is the "traditional approach" whereby credit is awarded after unsold retail items are returned to a reverse logistics center for processing. The second is the adjustable rate policy, which is also commonly referred to as a "swell allowance," whereby credit is awarded up-front based on an assumption that a certain percentage of items will become unsalable for various reasons at the primary retailer.[83] EPA's understanding is that one of the goals of the adjustable

[82] See discussion of "destroy dispositions" in the "Surplus Household Consumer Products and Wastes: Report to the Legislature." Available at: http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.

[83] Additional information on the Adjustable Rate Policy and other reimbursement policies for unsalable items can be found in the publication entitled, 2008 Joint Industry Unsaleables Management Study: The Real Causes and Actionable Solutions. This publication is available at http://www.gmaonline.org/downloads/research-and-reports/UnsaleablesFINAL091108.pdf.

rate policy is to reduce the amount of unsold items sent through to reverse logistics centers and to encourage sale at the primary retailer – even if this means discounting those items. EPA's understanding is that under such an approach, retailers are responsible for managing unsold retail items and determining the ultimate disposition since the manufacturer is not involved in the disposition decision. That being said, retailers can utilize reverse logistics to assist in the management and disposition of unsold retail items sold under an adjustable rate policy. More importantly, under EPA's final policy, although the potential exists for a manufacturer to issue credit for an unsold retail item, the "decision point" on whether a retail item is a solid waste is when the decision has been made to discard the material. In other words, a pharmaceutical is a solid waste when the decision has been made to discard regardless of whether the pharmaceutical has value. Thus, for this final action, the credit model is not relevant to the waste status of unsold retail items. EPA assumes that nonprescription pharmaceuticals and other unsold retail items that receive credit up-front through an adjustable rate policy are not wastes if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed.

e. *Unsold retail items subject to a recall*. The fifth issue involves instances when nonprescription pharmaceuticals and other unsold retail items become subject to a voluntary, federally mandated, or state mandated recall. Almost all pharmaceutical recalls are overseen by FDA. However, under the Poison Prevention Packaging Act, the U.S. Consumer Product Safety Commission (CPSC) has authority regarding special packaging (sometimes called child resistant packaging) of certain household products, including drugs (as that term is defined in the Federal Food, Drug,

and Cosmetic Act).[84] Similarly, under the child Nicotine Poisoning Prevention Act of 2015, CPSC has authority for administering special packaging requirements for liquid nicotine containers.[85] Thus, CPSC oversees a recall if there is a problem with a pharmaceutical's special packaging or containers for liquid nicotine. Additionally, CPSC has jurisdiction over recalls of many other consumer products sold at retail stores.[86] EPA is choosing not to apply RCRA regulations to nonprescription pharmaceuticals and other unsold retail items while they are subject to a recall, provided the recall is regulated and overseen by FDA or CPSC. This is true whether they become subject to a recall at a reverse logistics center, healthcare facility, or retail store. It is possible that recalled nonprescription pharmaceuticals and other unsold retail items are not a solid waste if they are legitimately used/reused or reclaimed. For example, if CPSC oversees a recall if there is a problem with a pharmaceutical's packaging (e.g., an item's packaging poses a threat because it is not sufficiently child resistant), it is possible the pharmaceutical could still be sent for reclamation. Although it is difficult for EPA to make a blanket determination on whether all recalled nonprescription pharmaceuticals and other unsold retail items are or are not solid wastes, EPA is choosing not to apply RCRA regulations to recalled nonprescription pharmaceuticals and other unsold retail items provided the recall is overseen by FDA or CPSC. When FDA directs the destruction of some or all of the recalled retail items, or CPSC grants permission to dispose or destroy some or all of the recalled items, the materials that are hazardous waste must be managed in accordance with RCRA, including the hazardous waste generator regulations standards in 40 CFR part 262.

[84] See 15 U.S.C. 1471-1477 for the Poison Prevention Packaging Act.
[85] Public Law No. 114-116 (January 28, 2016).
[86] The CPSC has jurisdiction over more than 15,000 kinds of consumer products used in and around the home, in sports, recreation and schools. See https://www.recalls.gov/cpsc.html for more information.

Although FDA and CPSC are the federal agencies that primarily regulate recalled nonprescription pharmaceuticals and other unsold retail items, other federal agencies regulate some recalled retail items. For example, the National Highway Traffic Safety Administration oversees motor vehicle defects and safety recalls. Although other federal agencies may occasionally regulate recalled retail items, EPA is only choosing not to apply RCRA regulations to recalled nonprescription pharmaceuticals and other unsold retail items when the recall is overseen by FDA or CPSC. CPSC requires manufacturers to develop a recall strategy that outlines all of the actions to be taken on behalf of the manufacturer from start to finish. FDA requires firms that initiate a recall to develop a recall strategy and recommends that firms that initiate a FDA-requested recall develop a recall strategy.[87] Included as a required component of a comprehensive recall strategy is a requirement that FDA or CPSC approves a manufacturer's decision to take the action to discard some or all of the recalled items. Thus, EPA believes it is reasonable not to apply RCRA regulations to recalled nonprescription pharmaceuticals and other unsold retail items when the recall is overseen by FDA or CPSC. However, the Agency will continue to evaluate recalled nonprescription pharmaceuticals and other unsold retail items managed by other federal agencies on a case-by-case basis. As an example, see the memo that EPA released in 2017 that describes how RCRA regulations apply to recalled Takata airbag inflators while they are being held under the 2015 DOT preservation order.[88] EPA's policy does not apply to unused pesticides that are suspended or canceled under the Federal Insecticide, Fungicide, and Rodenticide Act and recalled, as these can be managed as universal waste under 40 CFR part 273. Finally, while EPA is not applying RCRA regulations in these situations, we note that if recalled nonprescription pharmaceuticals and other unsold retail items are not

[87] See 21 CFR 7.46(a)(8) and 21 CFR 7.45(b), respectively.
[88] See RCRA Online #14893 for the June 23, 2017 memo titled "Recalled Takata Airbag Inflators."

managed and stored in a manner that prevents release to the environment, they may be considered a solid waste and a hazardous waste under sections 3007, 3013, and 7003 of RCRA.

f. *Unsold retail items that are broken, damaged, or leaking*. The sixth issue involves instances when nonprescription pharmaceuticals and other unsold retail items cannot be sent through reverse logistics because they are broken, damaged, or leaking. In recent years, EPA took multiple enforcement actions against national retailers for sending hazardous waste, in the form of broken and/or leaking items with hazardous contents, to unpermitted TSDFs (in the form of reverse distributors and reverse logistics centers), among other RCRA violations.[89] The resulting settlements specify that unsold retail items with broken and/or leaking packaging are waste at the retailer and, if they are hazardous, cannot be sent to a reverse distributor or reverse logistics center. CVS commented on the proposed rulemaking and asked that EPA clarify that when pharmaceutical packaging is in sufficiently poor condition that it is broken, leaking, or otherwise unable to be used for its intended purpose, that those pharmaceuticals become solid waste at the healthcare facility.[90] CVS noted that this is consistent with their current practice, whereby broken and leaking items are managed as waste at their facilities and are not sent through reverse distribution or reverse logistics.

Although EPA affirms the resulting settlements and agrees that nonprescription pharmaceuticals and other retail items cannot be sent through reverse logistics when they are broken, damaged, or leaking, the Agency is aware that there is inherent uncertainty surrounding when these items are considered broken, damaged, or leaking. For example, a nonprescription pharmaceutical could experience damage to the outer packaging while the inner container remains intact. For this final action, unsold retail items, including nonprescription

[89] Walmart Consent Agreement and Final Order, Docket Nos. RCRA-HQ-2013-4001 and FIFRA-HQ-2013-5056.
[90] See comment number EPA-HQ-RCRA-2007-0932-0312 in the docket.

pharmaceuticals, are not considered waste at the retail store if their packaging is in good condition, with no leaks or other continuing or intermittent unpermitted releases of the materials to the environment,[91] and they are contained to prevent releases to the environment,[92] and they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed. Thus, the Agency intends that nonprescription pharmaceuticals and other unsold retail items can be sent to a reverse logistics center and are not considered wastes at the retail store if they meet this standard. For example, if an outer cardboard box containing vials of nonprescription pharmaceuticals is damaged, but the vials are intact and not damaged or leaking, EPA does not consider the item to be damaged such that it cannot go through reverse logistics.

In order to prevent exposures to personnel, the public, and the environment, if items are not in good condition, or are leaking or releasing to the environment, these items must be managed as wastes at the stores in accordance with the applicable hazardous waste regulations. Specifically, if the broken, damaged, or leaking item is a hazardous waste pharmaceutical, the retail store must manage it under the streamlined standards of part 266 subpart P (unless it is a VSQG for all its hazardous waste). Otherwise, the retail store would manage hazardous wastes under the applicable RCRA regulations, including part 262 generator regulations.

E. Applicability of the Household Hazardous Waste Exemption to Retail Items

One commenter suggested that the "household hazardous waste" exclusion at 40 CFR 261.4(b)(1) apply to retail items purchased by a customer and subsequently returned to the

[91] As defined in §260.10, unpermitted releases are releases that are not covered by a permit (such as a permit to discharge to water or air) and may include, but are not limited to, releases through surface transport by precipitation runoff, releases to soil and groundwater, wind-blown dust, fugitive air emissions, and catastrophic unit failures.
[92] These conditions are derived from the definition of contained as defined in §260.10.

retailer.[93] The Agency has already addressed the issue of retail wastes as part of a previous rulemaking that responded to a petition from the American Retail Federation. As explained in a November 13, 1984, final rule[94], EPA excluded household hazardous waste because the legislative history of RCRA indicated an intent to exclude such wastes and not because these wastes can never pose the risks associated with hazardous wastes. Additionally, consistent with legislative history, when evaluating the American Retail Federation's petition, EPA determined that it was necessary to establish two criteria that must be met to qualify for this exclusion. First, the waste must be generated by individuals on the premises of a temporary or permanent residence and, second, the waste stream must be composed primarily of materials found in wastes generated by consumers in their homes. In this final rule, EPA denied the American Retail Federation's petition to exempt consumer household hazardous waste generated by retail sources because these wastes fail to meet both criteria. The Agency reaffirmed this position in the Retail Strategy, arguing that retail goods, including those that could become wastes when discarded, do not satisfy the criteria for this exclusion.

The Agency believes that this interpretation extends to retail items purchased by a customer and subsequently returned to a retail store. Hazardous waste generated at retail stores, including retail items purchased by a customer that are subsequently returned, does not meet the first criterion for the household hazardous waste exemption. Specifically, the decision to discard does not occur at the residence, it occurs at the retail store. In fact, many retail items that are returned are restocked and sold at the store (e.g. lawfully redistributed for their intended purpose) and are not solid wastes.

[93] See comment number EPA-HQ-RCRA-2007-0932-0277 in the docket for this rulemaking.
[94] See 49 FR 44978; November 13, 1984.

On the other hand, the Agency notes that a household pharmaceutical that is collected from individuals by a healthcare facility (e.g., retail store) as part of a DEA pharmaceutical take-back program maintains the household hazardous waste exemption as long as it is not sewered, and is destroyed by a method that DEA has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the types of combustors identified in § 266.506(b). For more discussion on DEA take-backs of household pharmaceuticals, please see section XIV of this preamble.

VII. Scope of the Final Rule

A. *What Facilities Are Subject to the Final Rule?*

This final rule is a sector-based rule that applies to the management of hazardous waste pharmaceuticals that are generated and managed by healthcare facilities and reverse distributors. Subsequent sections of the preamble will discuss in detail the definitions of these terms, as well as what provisions of the rule apply to each type of facility (see section VIII for a discussion of each definition and section IX for Applicability). Healthcare facilities and reverse distributors will use the regulations finalized under 40 CFR part 266 subpart P in lieu of the RCRA generator regulations in 40 CFR part 262 to which they were previously subject.

B. *What Facilities Are Not Subject to the Final Rule?*

1. Pharmaceutical Manufacturers

Part 266 subpart P does not apply to the management of hazardous waste pharmaceuticals that are generated by pharmaceutical manufacturers. A pharmaceutical manufacturer remains subject to part 262 and all applicable RCRA subtitle C regulations for the management of its hazardous waste, including its hazardous waste pharmaceuticals. Pharmaceutical manufacturers do not face the same challenges that healthcare facilities experience when managing hazardous

waste pharmaceuticals in accordance with the federal RCRA subtitle C regulations (for an explanation of the challenges healthcare facilities face, see discussion in section III of the preamble). The types of hazardous waste pharmaceuticals generated by manufacturers are less variable and therefore more predictable, and the staff have the necessary expertise to determine which pharmaceutical waste is hazardous waste. However, when any facility, including a pharmaceutical manufacturer, meets the definition found in this proposal for a reverse distributor, it would be subject to the final regulations for reverse distributors with respect to those operations.

2. Households

The Agency emphasizes that the regulatory requirements in this final rule do not apply to households that discard pharmaceuticals. Pharmaceuticals that are discarded by households are not regulated as hazardous waste and are generally considered municipal solid waste. While a small percentage of these household waste pharmaceuticals meet the definition of hazardous waste under RCRA, the federal RCRA hazardous waste regulations include an exclusion for all hazardous wastes generated by households.[95] Thus household hazardous waste pharmaceuticals—like other household hazardous wastes—are not subject to the federal RCRA hazardous waste regulations.

Despite the fact that household hazardous wastes are not regulated as hazardous wastes, it is important to note that "EPA excluded household wastes because the legislative history of RCRA indicated an intent to exclude such wastes, though *not* because they necessarily pose no

[95] See the household waste exclusion at § 261.4(b)(1), which is often referred to as the household hazardous waste or HHW exclusion.

hazard."[96] Some household products, including pharmaceuticals, contain ignitable, corrosive, reactive, or toxic ingredients. As a result, for household hazardous waste collected at a household hazardous waste collection program, the Agency has historically recommended that communities operating the collection programs manage the collected household hazardous waste as hazardous waste, even though it is not required by RCRA.[97]

Similarly, the Agency recommends that, whenever possible, households utilize pharmaceutical collection events as the preferred disposal option for their unwanted pharmaceuticals.[98] For consumers without access to a pharmaceutical take-back event, FDA provides information on the disposal of unused pharmaceuticals and step-by-step guidance for disposing of pharmaceuticals in the household trash.[99]

In a 2012 memo, the Agency recommended that collected household waste pharmaceuticals be incinerated— preferably at a permitted hazardous waste incinerator, but when that is not feasible, at a large or small municipal waste combustor.[100] The Agency believes that this practice is already common among collection programs since one goal of many collection programs is to divert pharmaceuticals from municipal landfills. Additionally, incineration is commonly used to meet the non-retrievable standard of destruction required by DEA for controlled substances collected from consumers ("ultimate users," as DEA refers to them). The Agency included this recommendation as a requirement for household waste

[96] See 49 FR 44978; November 13, 1984
[97] See memo November 1, 1988, from Porter to Regions (RCRA Online #11377).
[98] For pharmaceuticals, these collection events are often referred to as pharmaceutical take-back events. As used in this preamble, a take-back event refers to one-day collection events, such as the DEA bi-annual pharmaceutical take back days, while a take-back program refers to an ongoing collection program, such as a DEA-approved collection receptacle at a retail store.
[99] For more information on the safe disposal of household waste pharmaceuticals, please see: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm.
[100] See memo September 26, 2012, Rudzinski to the Regional RCRA Division Directors (RCRA Online# 14833).

pharmaceuticals that have been collected (see § 266.506).[101] See section XIV of this preamble for a detailed discussion of this provision.

3. Farmers, Ranchers and Fisheries

This final rule is a sector-specific rulemaking that applies to healthcare facilities and reverse distributors. As such, this final rule does not apply other generators of hazardous waste pharmaceuticals such as farmers, ranchers, and fisheries. Although these businesses might administer pharmaceuticals to their animals in the regular course of their business, they would not fall within the definition of a healthcare facility or a reverse distributor. The Agency designed this final rule to address the unique needs of the healthcare sector and concluded that it would not be appropriate to apply it to all sectors that generate hazardous waste pharmaceuticals. Other generators of hazardous waste pharmaceuticals, such as farmers, ranchers and fisheries, remain subject to the part 262 generator regulations. As discussed in detail in section VIII of this preamble, the definition of healthcare facility does include veterinary clinics and veterinary hospitals.

4. RCRA-Permitted or Interim Status Treatment, Storage and Disposal Facilities

This final rule does not affect how RCRA-permitted or interim status TSDFs manage hazardous waste pharmaceuticals at their facilities, except indirectly when they treat hazardous waste pharmaceuticals to meet the land disposal restrictions (LDRs). See section X.H. of this preamble for additional detail.

C. *Scope of Hazardous Wastes Addressed by This Final Rule*

1. Hazardous Waste Pharmaceuticals

[101] Since pharmaceutical collection programs typically commingle DEA controlled substances with non-controlled substances, this requirement is included in a section of the regulations that pertains to controlled substances.

These final regulations pertain only to those pharmaceutical wastes that are RCRA hazardous wastes that are generated by healthcare facilities or managed by reverse distributors. Under this rulemaking, EPA has not added additional pharmaceuticals to the hazardous waste listings or expanded the hazardous waste characteristics to include additional pharmaceuticals. Although we solicited ideas from commenters for possible methods or approaches for regulating additional pharmaceuticals as hazardous waste, any action taken to address the comments we received in response to this request would be a separate action taken by the Agency in the future and is not part of this final rulemaking.

2. Related Federal or State Regulations

The generation, accumulation, transportation, treatment, storage, and disposal of hazardous waste pharmaceuticals are regulated under RCRA Subtitle C. However, hazardous waste pharmaceuticals may also be subject to a number of other statutes and implementing regulations administered by state or other federal agencies. Examples include pharmaceuticals that are subject to the Controlled Substances Act and DEA regulations; infectious pharmaceutical wastes that are subject to state and local medical waste regulations; pharmaceuticals with a radioactive component that are subject to the Atomic Energy Act (AEA) and pharmaceuticals that are hazardous waste as defined in 40 CFR 261.3 that are subject to OSHA's Hazardous Waste Operations and Emergency Response standard. These potentially overlapping requirements make the appropriate management of pharmaceutical wastes a complex matter. The following discusses the impact of this final rule on various dually regulated hazardous waste pharmaceuticals.

a. *Controlled substances.* Under prior regulations, any healthcare facility generating or managing a RCRA hazardous waste pharmaceutical that is also a DEA controlled substance listed in

Schedule II-V[102] had to comply with the RCRA hazardous waste requirements, as well as the requirements of the Controlled Substances Act and DEA regulations. DEA regulations from 2014 to implement the Secure and Responsible Drug Disposal Act of 2010 require that controlled substances be destroyed so that they are "non-retrievable."[103] In the preamble to both the proposed and final DEA rules, DEA stated that flushing alone will not meet DEA's new non-retrievable standard.[104] Due to difficulties associated with managing these hazardous waste pharmaceuticals that are also controlled substances, the Agency is finalizing a conditional exemption from the RCRA regulatory requirements for the handful of pharmaceuticals that are both a RCRA hazardous waste and a DEA controlled substance. That is, this final rule eliminates the dual regulation for RCRA hazardous waste pharmaceuticals that are also DEA controlled substances. A more detailed discussion of this conditional exemption is found in section XIV of this final rule.

b. *Medical wastes.* There are instances when a hazardous waste pharmaceutical will also pose a biological hazard. The healthcare industry often refers to pharmaceutical wastes that are both RCRA hazardous and a biological hazard as "dual wastes," and such wastes must be managed in accordance with RCRA and state and/or local medical waste regulations. As a result, the healthcare facility must send these dual wastes to a hazardous waste TSDF that is also permitted by their state to accept medical wastes. Some examples of dual wastes include partially administered syringes containing hazardous waste pharmaceuticals (e.g., physostigmine) or intravenous (IV) bags containing residues of a hazardous waste pharmaceutical that are attached to the tubing and needles used to administer the pharmaceutical. The RCRA hazardous waste

[102] See 21 CFR part 1308 for a complete list of controlled substances.
[103] Final rule: September 9, 2014; 79 FR 53520.
[104] Proposed rule: December 21, 2012; 77 FR 75784, see page 75803; and final rule: September 9, 2014; 79 FR 53520, see page 53548).

pharmaceutical component of these dual wastes are included within these final subpart P management standards so that healthcare facilities can obtain the benefits of this new subpart, while ensuring the hazardous waste component of the waste is managed appropriately and ultimately delivered to RCRA-permitted TSDFs. Healthcare facilities must still manage the biological hazard in accordance with state and/or local medical waste requirements. EPA notes that autoclaving alone is not an acceptable method of treating hazardous wastes (pharmaceutical or non-pharmaceutical) that are also medical waste. In addition, as discussed in section XV of this preamble, EPA is exempting from RCRA regulation the residues of hazardous waste pharmaceuticals remaining in empty (i.e., fully administered) syringes.

c. *Hazardous waste pharmaceuticals with a radioactive component*. Hazardous waste pharmaceuticals that also contain a radioactive component subject to the Atomic Energy Act of 1954 (AEA) (which are often referred to as "mixed waste") are also regulated by multiple agencies. The hazardous waste component is regulated under EPA or the authorized state RCRA Subtitle C programs, while either the Nuclear Regulatory Commission (NRC) or the Department of Energy (DOE) regulates the radioactive component of the waste under the AEA.[105] Healthcare facilities can use this final rule to meet the obligation of complying with the RCRA Subtitle C hazardous waste regulations for hazardous waste pharmaceuticals while also complying with the appropriate AEA regulations. Although we do not believe that anything in this subpart is inconsistent with the AEA, § 1006(a) of RCRA states that if the RCRA requirements are inconsistent with the AEA requirements, then the RCRA requirements do not apply. Therefore, if a healthcare facility that manages hazardous waste pharmaceuticals encounters specific RCRA

[105] The NRC regulates radioactive wastes generated by commercial or non-DOE facilities, whereas DOE regulates radioactive wastes generated by DOE facilities.

requirements that are inconsistent with specific AEA requirements, only the AEA requirements would apply.

As is discussed in the Joint NRC/EPA Guidance on Testing Requirements for Mixed Radioactive and Hazardous Waste an inconsistency occurs when compliance with one statute or set of regulations would necessarily cause non-compliance with the other statute or set of regulations.[106] Relief from the regulatory inconsistency would be provided by the AEA requirement overriding the specific RCRA requirement. It is important to note, however, that the determination of an inconsistency would relieve the healthcare facility only from compliance with the specific RCRA requirement(s) that is deemed inconsistent with the AEA requirement(s); the healthcare facility would still be required to comply with all of the other hazardous waste pharmaceutical management standards.

d. *Clean Air Act*. The combustion of hazardous waste pharmaceuticals is subject to both RCRA and to § 112 of the Clean Air Act. In general, the Clean Air Act protects human health and the environment from the harmful effects of air pollution by requiring reductions in the emissions of air pollutants. These pollutants, which are known or suspected to cause serious health problems, such as cancer or birth defects, are referred to as hazardous air pollutants (HAPs) and include several metals that are found in pharmaceuticals, such as selenium, mercury, and chromium compounds. Under § 112 of the Clean Air Act, EPA is required to list categories of major and area sources of HAPs; EPA has listed Hazardous Waste Combustors as one of these categories.

EPA is also required to establish National Emission Standards for Hazardous Air Pollutants (NESHAPs) for the control of HAP emissions from listed sources. The NESHAPs are to reflect the maximum degree of reduction in emissions of HAPs that is achievable. This is

[106] 62 FR 62079, 62085; November 20, 1997.

known as "maximum achievable control technology" (MACT) and is based on emission levels that are achieved by the best-performing sources within a source category. On October 12, 2005, EPA promulgated NESHAP for Hazardous Waste Combustors that set MACT standards for HAPs from this source category.[107] The owner or operator of a hazardous waste combustor is required to comply with specific emission standards that control HAPs to levels that reflect MACT. These standards vary based on the type of hazardous waste combustion source (e.g., incinerator, cement kiln, boiler), and in some instances based on the amount of HAPs that are emitted by the facility (e.g., boilers that are area sources can elect to comply with fewer HAP emission standards). Generally speaking; however, hazardous waste combustors are required to comply with emission standards for chlorinated dioxins and furans, mercury, lead, cadmium, arsenic, beryllium, chromium, hydrochloric acid/chlorine gas, as well as particulate matter as a surrogate to control five additional metals, and carbon monoxide, hydrocarbon, and destruction removal efficiency as surrogates to control nondioxin/furan organic HAPs.

Hazardous waste combustors may be subject to more stringent emission limitations issued under the RCRA omnibus authority provisions (§ 3005(c)(3)). This is usually where site-specific circumstances indicate that a MACT standard is not protective of health and the environment. In other words, some hazardous waste combustors also have a RCRA permit limit that further reduces emissions of certain HAPs (e.g., mercury) beyond that which is required by the Clean Air Act MACT standard.

The combustion of pharmaceuticals that meet the definition of a RCRA solid waste but do not meet the definition of RCRA hazardous waste (i.e., non-hazardous waste pharmaceuticals) is regulated by § 129 of the Clean Air Act and implementing regulations. These

[107] 70 FR 59402; October 12, 2005.

regulations established emission limits for nine substances or mixtures (i.e., particulate matter, carbon monoxide, dioxins/furans, sulfur dioxide, nitrogen oxides, hydrogen chloride, lead, mercury, and cadmium, as well as opacity where appropriate) from several categories incineration units, including: municipal waste combustors (MWCs); hospital, medical and infectious waste incinerators (HMIWIs); commercial and industrial solid waste incinerators (CISWIs); and other solid waste incinerators (OSWIs). The emission limits are based on the application of MACT and reflect the emission levels achieved by the best performers in each category.

3. Drug Supply Chain Security Act

On November 27, 2013, the Drug Quality and Security Act was signed into law, amending the Federal Food, Drug and Cosmetic Act (FD&C Act).[108] The Drug Quality and Security Act consists of two titles: Title I is known as the Compounding Quality Act and Title II is known as the Drug Supply Chain Security Act (DSCSA). The FDA was given the responsibility of developing the implementing regulations for both titles of the Drug Quality and Security Act. In a summary of the DSCSA written by the Congressional Research Service, a nonpartisan division of the Library of Congress, it states that the Act "Establishes requirements to facilitate the tracing of prescription drug products through the pharmaceutical supply distribution chain."[109] Prior to enactment of this federal law, several states had passed similar laws to ensure the pedigree of the drug supply chain. Because each state law was slightly different, it made compliance difficult for companies operating in multiple states. As a result, Congress amended the FD&C Act to add § 585, entitled Uniform National Policy, which moots

[108] Public Law 113-54.
[109] https://www.congress.gov/bill/113th-congress/house-bill/3204/summary/49; accessed September 13, 2017.

the pedigree laws already in effect (to the extent they are inconsistent with the DSCSA) and prevents states (and others) from enacting inconsistent pedigree laws in the future. This section, which was added by the DSCSA, includes sub-sections that are sometimes referred to as "preemption clauses."[110]

Since the DSCSA was signed into law, some have argued to EPA and RCRA-authorized states that § 585 of the FD&C Act (as amended by the DSCSA) preempts all state hazardous waste regulatory authority as it may relate to the documentation of the disposition of hazardous waste pharmaceuticals. EPA disagrees with this interpretation of the DSCSA. Section 585 specifically avoids preempting state requirements, such as RCRA hazardous waste laws, that are unrelated to the tracing of products within the prescription drug distribution supply chain and other issues expressly addressed by the DSCSA. As stated in § 585(c), "Nothing in this section shall be construed to preempt State Requirements related to the distribution of prescription drugs *if such requirements are not related to product tracing* as described in subsection (a) or wholesale distributor and third-party logistics provider licensure as described in subsection (b) applicable under § 503(e) (as amended by the Drug Supply Chain Security Act) or this subchapter (or regulations issued thereunder)" (emphasis added).

This provision makes clear that § 585 applies only to state requirements related to distribution of prescription drugs and only to the extent that these requirements are related to product tracing or other issues specifically addressed by the DSCSA, such as licensure. Thus, as EPA interprets § 585, it would not apply to state requirements related to documentation of RCRA hazardous waste management activities, including disposal, because those activities are distinct and unrelated to the product tracing and other requirements of the DSCSA.

[110] See sections 585(a) and 585(b)(1) of the FD&C Act, as amended by the DSCSA.

And indeed, in EPA's consultation with FDA on this issue, FDA agreed with EPA's conclusion that § 585 does not preempt state hazardous waste regulations related to the documentation of the management of hazardous waste pharmaceuticals. EPA's position is based upon our review of both the direct language and intent of the statute.[111]

To understand the connection between state hazardous waste regulations and the DSCSA, it is important to understand the relationship between the federal and state hazardous waste regulations. The federal RCRA program is implemented by state RCRA programs that are authorized by EPA under RCRA section 3006, 42 U.S.C. 6926. Authorized state hazardous waste regulations must, at a minimum, be equivalent to federal RCRA hazardous waste regulations. Under RCRA, EPA authorizes state hazardous waste programs to operate in lieu of the federal hazardous waste program.[112] Authorized state requirements are federally enforceable as requirements under RCRA Subtitle C.

Nothing in the DSCSA indicates that Congress intended to impliedly repeal federal RCRA requirements. Such an implied repeal would leave gaps in RCRA coverage and result in no hazardous waste regulations of any kind—federal or state—applying to the documentation of the management of hazardous waste pharmaceuticals. Given that (i) there is no indication of Congressional intent to repeal hazardous waste documentation regulations via the DSCSA (indeed, there is no mention of hazardous waste in the DSCSA at all), and (ii) § 585(c) of the FD&C Act, as added by the DSCSA, expressly notes the limits of the statute's preemptive effect, we believe it is clear that Congress did not intend to impliedly repeal RCRA authorized state hazardous waste requirements as they apply to the documentation of the management, including

[111] For a more thorough legal analysis of this issue, see EPA's letter to the Minnesota Pollution Control Agency, dated April 9, 2015, in the docket for this rulemaking EPA-HQ-RCRA-2007-0932. EPA consulted with FDA in the development of this letter and FDA agrees with the analysis and conclusions set forth in the letter.
[112] RCRA section 3006(b), 42 U.S.C. 6926(b).

disposal, of hazardous waste pharmaceuticals. The general rule enunciated by the U.S. Supreme Court is that "when two [federal] statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective."[113] Here, both RCRA and the DSCSA coexist easily, because neither the language nor the purpose of the DSCSA is in conflict with RCRA.

In addition, some commenters have argued that, in the case of nonsaleable pharmaceutical products, DSCSA requirements preempt RCRA requirements and that nonsaleable pharmaceutical products are regulated exclusively by the FDA pursuant to the provisions of the DSCSA.[114] Commenters have also argued that under the DSCSA, nonsaleable pharmaceutical products that are sent from wholesale distributors, dispensers, and repackagers as nonsaleable may be sent to a returns processor reverse logistics provider for handling as products. These commenters believed that, at a minimum, the mere fact that a pharmaceutical product becomes nonsaleable does not mean that such pharmaceutical product is now a solid waste under the RCRA hazardous waste regulations.

EPA does not agree with these comments. The preemption provisions added to the FD&C Act by the DSCSA – both § 585(a) and § 585(b) − only apply to the protection of the drug supply chain and do not apply to waste management requirements under RCRA. [115] Under RCRA, EPA regulates pharmaceuticals differently than FDA does under the DSCSA since the goals of the statutes serve different purposes. The purpose of the DSCSA is to protect the security, pedigree, and quality of pharmaceutical products in the drug supply chain. One of the

[113] Morton v. Macari, 417 U.S. 535, 551(1974).
[114] The DSCSA uses the term "drug product."
[115] Section 585(a) of the DSCSA contains a preemption provision for state requirements for tracing drug products through the distribution system. Section 585(b) of the DSCSA contains a preemption provision for state requirements for wholesale prescription drug distributors and third-party logistics providers.

many purposes of RCRA is to ensure that any waste that is generated is "treated, stored or disposed of so as to minimize the present and future threat to human health and the environment."[116] In addition, we note that the DSCSA applies only to prescription drug products (not to OTC drug products), so there can be no conflict between DSCSA and RCRA for nonsaleable OTC drug products.

As explained in further detail throughout this preamble, whether a pharmaceutical has monetary value (such as when it receives manufacturer credit) is not determinative of whether it is a waste under RCRA. Under RCRA, one considers whether a material is discarded—and not whether it receives credit, or holds value or no value—to determine whether it is waste. Thus, prescription pharmaceuticals that are sent by healthcare facilities to reverse distributors and that will be discarded (even if these pharmaceuticals receive credit) will first be considered wastes at the healthcare facility when the decision is made by the healthcare facility to send them to a reverse distributor.

Furthermore, EPA disagrees with commenters that a nonsaleable pharmaceutical product sent to reverse distributors should not be considered a waste. Nonsaleable pharmaceutical products sent to reverse distributors are not sent for reuse or donation, but are sent for disposal, and thus would be considered wastes at the healthcare facility. In its comments to the FDA on the Draft Guidance for Industry, Identifying Trading Partners Under the Drug Supply Chain Security Act,[117] an industry trade association appears to confirm this point when it says, "Most fundamentally, returns processors are unlike the trading partners described in the DSCSA. Trading partners are dedicated to moving products forward for dispensing and administration to patients. Returns processors' activities come at the end, when the product is no longer retained

[116] See 42 U.S.C. 6902(b)
[117] August 2017, docket number FDA-2017-D-1956.

for distribution or dispensing and is safely removed from the supply chain."[118] The commenter goes on to say that "the assumptions that product is being distributed for further use, rather than only for credit assessment and/or disposition" do not appear to apply to returns processors (known as reverse distributors in this final rule.[119] Similarly, a reverse distributor also submitted comments to the FDA on the same draft guidance, stating that "once these products reach the returns processors for creditability assessment and final disposition management, they are forever removed from commerce."[120] Furthermore, during a site visit to a large reverse distributor, EPA was told that none of the pharmaceuticals on site would be donated or redistributed or otherwise returned to commerce.[121] After they are evaluated for manufacturer credit, the pharmaceuticals are sent for incineration. Under § 261.2(b)(3) of the RCRA regulations, "Materials are solid waste if they are abandoned by being…Accumulated, stored, or treated (but not recycled) before or in lieu of being abandoned by being disposed of, burned, or incinerated." The pharmaceuticals at reverse distributors are being accumulated prior to being incinerated and therefore are solid wastes. Additionally, in a 2013 memo EPA includes a series of questions to help determine whether a commercial chemical product is a solid and hazardous waste. One set of questions relates to whether the facility appears to be selling into commerce the material being evaluated. If the facility has no customers or market for the material, it can be an indication that the material is a solid waste.[122]

[118] See page 6 of comment FDA-2017-D-1956-0013.
[119] See page 7 of comment FDA-2017-D-1956-0013.
[120] See page 14 of comment FDA-2017-D-1956-0011.
[121] See notes from site visit to Med-Turn, October 10, 2017 in the docket for this rulemaking EPA-HQ-RCRA-2007-0932. Med-Turn is a subsidiary of Inmar.
[122] See Section 3 of Attachment A of memo entitled Checklist to Assist in Evaluating Whether Commercial Chemical Products or Solid and Hazardous Waste Under the Resource Conservation and Recovery Act, May 14, 2013, Devlin to RCRA Division Directors, RCRA Online #14837.

As explained elsewhere in the preamble, EPA distinguishes between reverse distributors (as defined in this rule) and reverse logistics centers. Reverse distributors do not reuse or donate, but in fact, dispose of the pharmaceuticals they receive. In sum, what DSCSA would consider to be a nonsaleable product is still considered to be a solid waste under RCRA when it is discarded according to the RCRA regulations, and the DSCSA does not preclude pharmaceuticals from being waste under RCRA.

EPA notes that many of the implementing regulations for the DSCSA are still under development by the FDA and the FDA has announced that it is delaying enforcement of certain requirements.[123] Section 584(d) of the FD&C Act, as added by the DSCSA, directs the FDA to issue licensing regulations for third party logistics providers (3PLs) within two years of the date of enactment of the DSCSA.[124] Draft FDA guidance issued in August 2017 indicates that FDA plans to consider a returns processor or reverse logistics provider to be a type of 3PL.[125] However, FDA has not yet finalized this guidance or issued proposed or final regulations for licensing 3PLs. The listing for the relevant regulation in the most recent version of the public list of planned federal rulemaking (the Unified Agenda of Regulatory and Deregulatory Actions, or "Unified Agenda") indicates that FDA plans to issue a *proposed* DSCSA licensing regulation within the next year.[126]

Furthermore, since 3PLs, such as reverse logistics providers, do not take ownership of the drugs that they manage at their facilities, the DSCSA requirements related to tracing drugs

[123] On June 30, 2017, FDA issued a draft guidance, Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf.
[124] The DSCSA was enacted on November 27, 2013; therefore, the 3PL licensing regulations were scheduled to be issued by FDA by November 27, 2015.
[125] August 2017, Identifying Trading Partners Under the Drug Supply Chain Security Act - Guidance for Industry. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM572252.pdf.
[126] See the Spring 2018 Unified Agenda, available at https://www.reginfo.gov/public/do/eAgendaMain.

through the supply chain, including transaction information (TI), transaction history (TH), and transaction statements (TS), do not apply to them. In the absence of relevant FDA regulations, it is difficult for EPA to consider the possibility of deferring to FDA for the regulation of reverse distributors, who we consider to be managing hazardous wastes. In the future, if there are duplicative regulations, EPA may need to revisit the regulation of reverse distributors after the FDA issues proposed and final licensing regulations for 3PLs in accordance with the DSCSA.

D. *Wastes Generated at Healthcare Facilities That Are Not Included in the Scope of this Final Rule*

Wastes that are not included in the scope of this proposed rulemaking include non-hazardous wastes and non-pharmaceutical hazardous wastes. Pharmaceutical wastes that are not listed or characteristic hazardous wastes under RCRA Subtitle C may nonetheless pose some risks to public health and the environment. These wastes are discussed further below.

1. How Should Non-hazardous Waste Pharmaceuticals Be Disposed?

A large portion of the pharmaceutical wastes generated at healthcare facilities will not meet the definition of a RCRA hazardous waste under RCRA Subtitle C. This final rule, therefore, does not require that healthcare facilities manage these waste pharmaceuticals under the RCRA Subtitle C hazardous waste regulations, including this final rule. However, a healthcare facility may choose to manage its non-hazardous and hazardous waste pharmaceuticals together (as hazardous waste pharmaceuticals) under the new subpart P regulations. Because all healthcare facilities operating under this subpart are regulated in the same way regardless of quantity of hazardous waste pharmaceuticals generated, managing non-hazardous waste pharmaceuticals as hazardous waste under this subpart would not affect the

facility's hazardous waste generator category. While not regulated by the federal RCRA hazardous waste requirements, non-hazardous waste pharmaceuticals that are not managed under subpart P are still considered solid wastes under the federal regulations and must be managed in accordance with applicable federal, state, and/or local regulatory requirements. Moreover, some waste pharmaceuticals that do not qualify as "hazardous wastes" under RCRA can nonetheless be extraordinarily hazardous thus, extreme care may be warranted.[127] These are discussed below in section VII.D.1.a.

If a healthcare facility decides to segregate its hazardous and non-hazardous waste pharmaceuticals, EPA recommends that healthcare facilities follow the best management practices (BMPs) outlined in "Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States," (Blueprint)[128] an EPA guidance document for the management, treatment, storage and disposal of non-hazardous waste pharmaceuticals. The following summarizes the recommended BMPs found in the Blueprint for various categories of pharmaceutical wastes, including those wastes that possess hazardous waste-like qualities yet are not regulated as hazardous waste under RCRA Subtitle C.

a. *Recommended best management practices for healthcare facilities managing non-hazardous waste pharmaceuticals possessing hazardous waste-like qualities.* Currently, most pharmaceuticals are not regulated as RCRA hazardous wastes when discarded by healthcare facilities. These "non-RCRA-hazardous" pharmaceuticals can be divided into two categories:

[127] See, for example, https://www.cdc.gov/niosh/review/peer/isi/hazdrug2018-pr.html or NIOSH [2016]. NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016-161 (Supersedes 2014-138). https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf.

[128] Practice Greenhealth, Revised August 2008. Published in 2006, the development of the original Blueprint was funded by the Office of Solid Waste and Emergency Response and managed by EPA Region 1. The 2008 revision of the Blueprint was funded by the Healthcare Environmental Resource Center. http://practicegreenhealth.org/sites/default/files/upload-files/pharmwasteblueprint.pdf

those that possess hazardous waste-like qualities and those that do not. As outlined in the Blueprint, there are pharmaceuticals that possess hazardous waste-like qualities, but for various reasons, are not regulated by the RCRA Subtitle C hazardous waste regulations. The Agency supports the Blueprint's recommendation of hazardous waste incineration as the BMP for healthcare facilities and reverse distributors discarding pharmaceuticals that may possess hazardous waste-like qualities, but are not regulated as RCRA hazardous waste. This recommendation would apply to pharmaceuticals with more than one active ingredient listed on the P- or U-lists,[129] chemotherapeutic agents characterized as bulk wastes,[130] pharmaceuticals which meet the hazardous drug criteria set by the National Institute for Occupational Safety and Health (NIOSH),[131] pharmaceuticals with LD50s $\leq$ 50 mg/kg, pharmaceuticals that are carcinogenic or endocrine disrupting compounds, and vitamin/mineral preparations containing heavy metals.

b. *Recommended best management practices for other non-hazardous waste pharmaceuticals (not possessing hazardous waste-like qualities).* As far as other non-hazardous waste pharmaceuticals (i.e., those not possessing hazardous waste-like qualities), disposing of non-hazardous waste pharmaceuticals at healthcare facilities via drain disposal is strongly discouraged and not recommended by EPA. Therefore, EPA endorses the Blueprint's recommendation of municipal solid waste incineration or medical waste incineration for any

[129] As noted in the comment after § 261.33(d), the phrase "commercial chemical product" includes formulations in which the P- or U-listed chemical is the sole active ingredient. Therefore, formulations with more than one active ingredient do not meet the specifications of the P- and U-listings even if one, two or all of the active ingredients are listed on the P- and/or U-lists.

[130] The descriptions "bulk" and "trace" when applied to chemotherapeutic wastes are industry terms and are not defined by the federal RCRA regulations.

[131] See NIOSH list of antineoplastic and other hazardous drugs in healthcare settings, 2016. By Connor TH, MacKenzie BA, DeBord DG, Trout DB, O'Callaghan JP. Cincinnati, OH: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication Number 2016-161 (Supersedes 2014-138). https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf.

non-hazardous waste pharmaceuticals, even when they do not possess hazardous waste-like qualities. The potential risk remains for active pharmaceutical ingredients (APIs) to be released into the environment if medical waste autoclaves or municipal solid waste landfills are used for the purposes of pharmaceutical waste treatment and disposal. For example, autoclaves are designed to kill pathogens and do not achieve the temperatures required to destroy most APIs during the autoclaving process. As a result, when wastewater is generated either by cleaning an autoclave, or during automatic blow down from autoclaves equipped with steam generators, there is the potential for wastewater containing APIs to be generated and discharged into the sewer. In addition, some limited studies have shown APIs present in landfill leachate collected in municipal solid waste landfill leachate systems.[132,133] Typically, the collected landfill leachate is subsequently sent to wastewater treatment plants for treatment, but their treatment technologies are not designed to remove all APIs from the wastewater (See section XIII for more information regarding the prohibition on sewering hazardous waste pharmaceuticals).

2. How Should Non-pharmaceutical Hazardous Waste Be Disposed?

These newly promulgated subpart P regulations will pertain only to hazardous waste pharmaceuticals. Therefore, other types of hazardous wastes generated at healthcare facilities and reverse distributors that do not meet the definition of a hazardous waste pharmaceutical cannot be managed in accordance with this new subpart (as previously discussed, non-hazardous waste pharmaceuticals may be managed under this new subpart). For example, hazardous wastes generated in hospital laboratories or during cleaning and maintenance of the facility are not

[132] Barnes, K. K., Christenson, S. C., Kolpin, D. W., Focazio, M. J., Furlong, E. T., Zaugg, S. D., Meyer, M. T. and Barber, L. B. (2004), Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill. Groundwater Monitoring & Remediation, 24: 119–126

[133] Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (June 2009), Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002. Bulletin of Environmental Contamination and Toxicology, V82.6 :635-659

considered hazardous waste pharmaceuticals and are not included within the scope of this final rule. The generation of non-pharmaceutical hazardous wastes is often more routine and does not trigger the same concerns that healthcare facilities experience when managing hazardous waste pharmaceuticals. Also note that the 2016 Hazardous Waste Generator Improvements final rule added new flexibility for episodic generators of non-pharmaceutical hazardous waste under part 262 subpart L.

VIII. What Terms Are Defined in this Final Rule? (§ 266.500)

A. *Definition of Pharmaceutical*

1. Summary of Proposal

EPA proposed to define "pharmaceutical" as any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition included, but was not limited to dietary supplements as defined by the Federal Food, Drug, and Cosmetic Act (FD&C Act), prescription drugs, OTC drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from the spills of pharmaceuticals. This proposed definition of "pharmaceutical" was intended to include all dose forms, including, but not limited to, tablets, capsules, medicinal gums or lozenges, medicinal liquids, ointments and lotions, IV or other compound solutions, chemotherapy pharmaceuticals, vaccines, allergenics, medicinal shampoos, antiseptics, and any delivery device, including medicinal dermal patches, with the primary purpose to deliver or dispense the pharmaceutical.

EPA relied on the FD&C Act's definition of "drug" to develop the proposed definition of "pharmaceutical" but expanded on the definition based on comments to the 2008 Universal Waste proposed rulemaking. In particular, stakeholders requested that the Agency take a broad view in delineating what items are included in the definition of pharmaceutical so that the proposed standards applied broadly. Thus, the proposed definition of "pharmaceutical" did not exclude pharmaceuticals with a radioactive component and included items not specifically recognized by the FDA as drugs, such as dietary supplements, pharmaceutical residues in non-empty containers (including delivery devices), personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from spills of pharmaceuticals.

2. Summary of Comments

The most frequent comment EPA received on the definition of "pharmaceutical" was on the inclusion of personal protective equipment and clean-up material in the definition of pharmaceutical. Many commenters argued that personal protective equipment and clean-up material should not be included in the final definition. One commenter suggested that loose tablets be included in the definition of pharmaceutical but that personal protective equipment should not be included. Waste Management National Services, Inc. suggested that only "overtly contaminated" personal protective equipment or clean-up materials be included in the definition, but not personal protective equipment and clean-up materials with trace contamination.[134] Two commenters asked EPA to clarify which personal protective equipment is included in the definition of "pharmaceutical."

One state expressed concern that EPA proposed to take a broad view in delineating what items are included in the definition of "pharmaceutical." The New Jersey Department of

[134] See comment number 0257 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

Environmental Protection pointed out that although "sharps" did not meet the proposed definition of "pharmaceutical" that IV bags, tubing and syringes that come in contact with blood or pathogens could fall under the definition of "pharmaceutical." They asked that EPA exclude these items from the definition.[135]

EPA requested comment on the Agency's decision to include dietary supplements in the definition of "pharmaceutical" under the final rule. Four states and one industry association supported the Agency's proposal to include dietary supplements under the definition of "pharmaceutical." One state and five industry associations did not support including dietary supplements in the definition of "pharmaceutical." Multiple commenters requested that EPA only include dietary supplements that are regulated as drugs and exclude supplements regulated as foods.

EPA requested comment on the possibility of including low-concentration nicotine products, such as electronic nicotine delivery systems (e-cigarettes), in the definition of "pharmaceuticals" under the final rule. EPA received multiple comments on whether to include e-cigarettes and liquid nicotine (e-liquids) in the final definition. Hawaii State Department of Health and the Hematology/Oncology Pharmacy Association did not support including e-cigarettes or e-liquids in the final definition of "pharmaceutical."[136] RILA requested that EPA exempt all low-concentration nicotine products from the P075 listing, including e-cigarettes and e-liquids, but agreed that if EPA did not exempt these products from the P075 listing, that e-cigarette products should fall under the definition of "pharmaceutical."[137]

[135] See comment number 0235 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).
[136] See comment numbers 0238 and 0264 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).
[137] See comment number 0295 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

The American Dental Association asked that EPA specifically exclude dental amalgam from the final definition of "pharmaceutical."[138]

Multiple commenters pointed out that the same chemical may have a pharmaceutical and non-pharmaceutical use (e.g., isopropyl alcohol is used to clean wounds and to clean instruments and surfaces). [139] Commenters asked EPA to clarify that they are regulated differently.

Stericycle, Inc. requested that investigational or research drugs be considered pharmaceuticals because they are difficult to characterize.[140]

3. Final Rule Provisions

In this final rule, "pharmaceutical" means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen), or any liquid nicotine (e-liquid) packaged for retail for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials). This definition includes, but is not limited to dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 CFR 203.3(y); OTC drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

The final definition of pharmaceutical includes both prescription drugs, as defined by 21 CFR 203.3(y) and OTC drugs. As previously mentioned, commenters pointed out that the same chemical may have a pharmaceutical and non-pharmaceutical use.[141] If an OTC product is required by the FDA to include "Drug Facts" on the label, it would be considered a

[138] See comment number 0294 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).
[139] See comment numbers 0246, 0280, 0296 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).
[140] See comment number 0280 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).
[141] See comment numbers 0246, 0280, 0296 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

pharmaceutical for the purposes of this rule.[142] In rare cases, some items that are OTC pharmaceuticals may not be labeled appropriately with a "Drug Facts" label. It is the Agency's understanding, however, that all OTC drugs must contain a Drug Facts label. Therefore, if an item meets the criteria to be considered a pharmaceutical under subpart P but is not labeled with Drug Facts, it should still be managed as a pharmaceutical. Any non-pharmaceutical hazardous wastes must be managed pursuant to all other applicable RCRA regulations. The final definition of "pharmaceutical" also includes any pharmaceutical residuals remaining in non-empty containers, such as the pharmaceutical residuals remaining in dispensing bottles, IV bags and tubing, vials, unit dose packages, and delivery devises, such as syringes and patches. However, the final definition does not include sharps (e.g., needles from IV bags or syringes). Used sharps, such as needles or syringes with needles, are not included under the final definition of pharmaceutical because sharps are considered medical wastes, presently regulated at both the state and local level. Further, as discussed in section XV of this preamble, EPA is finalizing regulations for when pharmaceutical containers are considered empty.

The final definition of "pharmaceutical" also includes items contaminated with or containing pharmaceuticals, such as personal protective equipment contaminated with pharmaceuticals or related spill clean-up materials (including loose tablets accumulated during pharmacy floor sweepings). EPA's decision to include contaminated personal protective equipment under the definition of "pharmaceutical" reflects the Agency's interest in promoting a similar management scheme for the personal protective equipment containing pharmaceuticals and other types of pharmaceuticals. Only personal protective equipment that is already considered hazardous waste under the "contained in" policy because it is contaminated with

[142] See 21 CFR 201.66

pharmaceuticals will fall under the definition of pharmaceutical. [143] These items are included in the definition so that facilities can manage more types of hazardous waste commonly found in healthcare settings under the same standards. For example, the contained in policy would not apply to gloves that have touched a warfarin pill during the course of patient care. However, if a healthcare worker spills a hazardous waste pharmaceutical on their personal protective equipment and it cannot be removed from the personal protective equipment, the personal protective equipment would be considered a hazardous waste pharmaceutical. If the personal protective equipment only has trace amounts of contamination it would not be considered a hazardous waste and therefore not be considered a hazardous waste pharmaceutical.

The final definition of "pharmaceutical" includes dietary supplements for the same reason—in order to promote a consistent management scheme for similar waste streams. Dietary supplements are commonly found in various healthcare settings because they are recommended or prescribed by healthcare providers to patients.[144] Further, retail pharmacies routinely sell vitamins and other medicinal minerals and supplements. When EPA uses the term "dietary supplements" in the definition of "pharmaceutical," EPA is referencing the definition for dietary supplement used by the FD&C Act, as amended by the Dietary Supplement Health and Education Act of 1994 (21 U.S.C. 321 (ff)).[145] If a dietary supplement is required by the FDA to include a "Supplement Facts" panel on the label, it would be considered a pharmaceutical for the

[143] See memo from Lowrance to Fields, January 3, 1989 (RCRA Online #11387).
[144] Including dietary supplements under the definition of "pharmaceutical" does not supersede the requirements of the Dietary Supplement Health and Education Act of 1994, the Federal Food, Drug and Cosmetic Act, or FDA regulations.
[145] The substance of the definition is: a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A): a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E); For the complete definition of dietary supplement, please see: https://www.gpo.gov/fdsys/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21-chap9-subchapII.pdf.

purposes of this rule.[146] The FD&C Act categorizes dietary ingredients and dietary supplements under the general umbrella of foods and therefore does not review them before being marketed. In fact, several commenters suggested that because the FD&C Act does not regulate supplements as drugs, EPA does not have the authority to regulate them as pharmaceuticals under RCRA. EPA disagrees with the commenters, noting that any waste that is listed or exhibits a characteristic is regulated as a hazardous waste when discarded, including supplements. This final rule does not newly apply RCRA to the disposal of supplements that meet the definition of hazardous waste, as some commenters suggest; it changes which regulations apply when discarding supplements that are hazardous waste. EPA recognizes that healthcare facilities may benefit from managing dietary supplements along with drugs under the final regulation, and thus, is including it in the final definition of "pharmaceutical." Although dietary supplements are considered pharmaceuticals under this definition, only the dietary supplements that meet the definition of hazardous waste (e.g., exhibits the toxicity characteristic for metal content) would be regulated under part 266 subpart P as hazardous waste pharmaceuticals (see the definition of "hazardous waste pharmaceutical").

The final rule specifically excludes dental amalgam from the final definition of pharmaceutical. EPA promulgated new pretreatment standards in June 2017 to reduce discharges of mercury from dental offices into publicly owned treatment works. [147] If EPA included dental amalgam in the final definition of pharmaceutical, it would subject dentists to duplicative regulatory requirements.

The final definition of "pharmaceutical" includes electronic nicotine delivery systems and liquid nicotine (e-liquid) packaged for retail for use in electronic nicotine delivery systems.

[146] See 21 CFR 101.36.
[147] 82 FR 27154; June 14, 2017.

These items are included in the definition "pharmaceutical" so that facilities can manage more types of hazardous waste commonly found in healthcare settings under part 266 subpart P. The final definition of "pharmaceutical" applies to finished product electronic nicotine delivery systems, including components and parts, sealed in final packaging intended for consumer use (e.g., electronic cigarettes and vaping pens) and e-liquid that is packaged for retail for use in the electronic nicotine delivery systems (e.g., pre-filled cartridges and vials that are sold separately to consumers or as part of kits). EPA intends that e-liquid used by manufacturers of tobacco products (as defined by the FD&C Act) not be included in the final definition of "pharmaceutical."[148] That is, a pre-filled e-liquid cartridge sealed in final packaging that is to be sold or distributed to a consumer for use is included in the definition, but in contrast, an e-liquid that is sold or distributed for further manufacturing, mixing, or packaging into a finished electronic nicotine delivery system is not included.[149] EPA believes that finished products sealed in packaging intended for consumer use pose a lower risk for leaks and other releases to the environment than e-liquid that is sold or distributed for further manufacturing. E-liquid that is packaged for retail for use in electronic nicotine delivery systems, such as e-liquid that is in pre-filled cartridges and vials, is typically sold at lower concentrations and smaller quantities than e-liquid that is sold or distributed for further manufacturing.

The final definition of "pharmaceutical" includes investigational drugs. One commenter asked EPA to include investigational drugs in the definition because these drugs are difficult to characterize. The investigational drugs might have proprietary ingredients that the manufacturer might not be willing to divulge during trials. The final definition includes investigational drugs

[148] 26 U.S.C. 5702 (d)
[149] This distinction is adapted from the term "finished tobacco product" used by FDA in its regulations for e-cigarettes, cigars, and all other tobacco products. 81 FR 28973; May 10, 2016.

in order to provide clarity on how to manage these items when discarded. See section IX.B.2.e regarding the applicability of subpart P to discarded investigational drugs.

B. *Definition of Hazardous Waste Pharmaceutical*

1. Summary of Proposal

EPA proposed to define "hazardous waste pharmaceutical" as a pharmaceutical that is a solid waste, as defined in § 261.2, and is listed in part 261 subpart D, or exhibits one or more characteristics identified in part 261 subpart C. The Agency proposed to define the term "hazardous waste pharmaceutical" in order to clarify its intent that only pharmaceuticals that meet the definition of hazardous waste when disposed or discarded need to be managed under the new subpart P management standards.

2. Summary of Comments

EPA requested comment on the proposed definition of "hazardous waste pharmaceutical" and specifically on whether any dietary supplements currently on the market meet or could potentially meet RCRA's definition of hazardous waste.

The New Mexico Environment Department requested that EPA broaden the definition of "hazardous waste pharmaceutical" to include antineoplastic agents. The New Mexico Environment Department argued that EPA has not updated the P- and U- hazardous waste lists even though new pharmaceuticals have been developed that should be considered hazardous waste.[150] Public Employees for Environmental Responsibility also argued that the definition of "hazardous waste pharmaceutical" is too narrow because not enough pharmaceuticals meet the

[150] See comment number 0211 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

definition.[151] American Pharmacists Association expressed concern that the definition is difficult to understand because the P- and U- hazardous waste lists are not comprehensive.[152]

Waste Management National Services Inc., supported the proposed definition of "hazardous waste pharmaceutical" and pointed out that there are dietary supplements on the market that meet the RCRA definition of hazardous waste because the supplements contain selenium or chromium.[153]

3. Final Rule Provisions and Response to Comments

In this final rule, "hazardous waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C, or is listed in part 261 subpart D. A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed. An OTC pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

The Agency is including in the final definition of "hazardous waste pharmaceutical" that a pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical if it is lawfully donated. The Agency included this language to clarify that pharmaceuticals are not solid waste if they are donated for use (see section IX.B for more discussion).

[151] See comment number 0247 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).
[152] See comment number 0321 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).
[153] See comment number 0257 in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

The Agency is defining the term "hazardous waste pharmaceutical" in order to clarify its intent that only pharmaceuticals (as defined in this final rule) that are hazardous waste when disposed or discarded need to be managed under the final subpart P management standards. For example, warfarin (brand name Coumadin) is a listed hazardous waste and when discarded meets the definition of hazardous waste pharmaceutical. The Agency notes that hazardous waste pharmaceuticals are hazardous wastes; more specifically, they are a subset of hazardous waste. The term hazardous waste is defined in § 260.10 as "a hazardous waste as defined in § 261.3." Therefore, even though we do not reference § 261.3 in the definition of hazardous waste pharmaceutical, a hazardous waste pharmaceutical is also hazardous waste as defined in § 261.3. This is relevant to the OSHA Hazardous Waste Operations and Emergency Response standard (29 CFR 1910.120), which apply to hazardous wastes, as defined by § 261.3. This final rule does not impact the applicability of the OSHA Hazardous Waste Operations and Emergency Response standards.

Multiple commenters suggested that the proposed definition of "hazardous waste pharmaceutical" was too narrow because the P- and U- hazardous waste lists have not been updated even though new pharmaceuticals have been developed. Although we solicited ideas from commenters for possible methods or approaches for regulating additional pharmaceuticals as hazardous waste, any action taken to address the comments we received in response to this request would have to be a separate action taken by the Agency in the future and is not part of this final rulemaking. Therefore, these comments are considered to be out of the scope of this final action and we do not plan to address them at this time. That said, we do anticipate that because subpart P lowers regulatory barriers to over-managing non-hazardous waste pharmaceuticals, some healthcare facilities will choose to over-manage non-hazardous waste

pharmaceuticals as hazardous waste pharmaceuticals even if they do not meet a current listing or exhibit a hazardous waste characteristic.

C. Definition of Reverse Distributor[154]

1. Summary of Proposal

EPA proposed to define reverse distributor as any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. EPA proposed that any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer credit would be considered a reverse distributor. Pharmaceutical manufacturers often offer credit to healthcare facilities for unused and/or expired pharmaceuticals.[155] Manufacturers issue credit for a variety of reasons: it can be a marketing incentive tool, it helps protect against illicit diversion[156] or improper disposal, and it allows manufacturers to collect data on the returned items, which then can be used to help plan for future pharmaceutical production. Reverse distributors contract with both manufacturers and healthcare facilities to act as an intermediary to facilitate the crediting process.

EPA proposed new standards for shipping potentially creditable hazardous waste pharmaceuticals to reverse distributors and management standards of potentially creditable hazardous waste pharmaceuticals by reverse distributors. Thus, EPA proposed to define "reverse distributor" to clearly delineate which types of facilities were subject to the proposed

[154] The proposed rule used the term "pharmaceutical reverse distributor" but the final rule uses the term "reverse distributor." To avoid confusion, we use the term "reverse distributor" in this preamble, even when discussing the proposed rulemaking.
[155] As noted in the definition of "potentially creditable hazardous waste pharmaceutical," manufacturers provide credit for those pharmaceuticals that are less than one year past the expiration date.
[156] Through the return of pharmaceuticals by a pharmacy for manufacturer credit, manufacturers are able to maintain control of the pharmaceutical up to the point of its disposal, thereby, decreasing the risk of diversion of the pharmaceutical.

rulemaking. The agency solicited public comment on its proposed definition of "reverse distributor." Specifically, EPA asked for comment on whether the definition of "reverse distributor" captures the universe of facilities acting as reverse distributors for pharmaceuticals.

2. Summary of Comments

Commenters requested that EPA clarify who would be considered a reverse distributor and what the functions of a reverse distributor are. States and industry, including manufacturers, wholesalers, and waste management companies, wanted to know if any facility that performed reverse distribution functions would be encompassed in this definition. Reverse distributors asked for clarification in how 3PLs fit into the definition of reverse distributor and whether all functions performed by their business would fall under the definition.

3. Final Rule Provision

Under the final rule, reverse distributor means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

In response to comments, EPA made two changes to the definition of "reverse distributor" for the final rule. First, EPA proposed to use the term "pharmaceutical reverse distributor" but the final rule uses the term "reverse distributor." EPA dropped the word "pharmaceutical" from reverse distributor because the definition of pharmaceutical is overly broad given that it refers to both prescription and nonprescription pharmaceuticals. EPA received comments from stakeholders pointing out that in the terminology of the industry, reverse

distributors receive prescription pharmaceuticals, while reverse logistics centers receive nonprescription pharmaceuticals and other unsold retail items. This distinction is useful to EPA in making the same distinction in these regulations and EPA has adopted it.

The second change EPA made was to add the word prescription to the definition to further clarify that the definition does not include reverse logistics centers that receive nonprescription pharmaceuticals or other unsold retail items that are evaluated for legitimate use/reuse or reclamation. EPA's definition of "reverse distributor" only includes prescription hazardous waste pharmaceuticals that are evaluated for credit and then disposed. EPA made this clarification to be consistent with the policy for the reverse logistics of nonprescription pharmaceuticals and other unsold retail items. See section VI of this preamble for discussion of the regulations for the reverse distribution of prescription hazardous waste pharmaceuticals and the policy for the reverse logistics of other unsold retail items, including nonprescription pharmaceuticals.

EPA incorporated the changes to the final definition of "reverse distributor" in response to the comments summarized below.

4. Comments and Responses

EPA received comments from states and industry, including manufacturers, wholesalers and waste management companies, asking for clarification on who would be considered a reverse distributor. For example, commenters asked whether wholesalers, forward distributors and 3PLs meet the definition of "reverse distributor" even if reverse distribution is only a part of their business. For example, a facility might act as a sorting and shipping facility or a pharmacy might act as a consolidation center but not evaluate for manufacturer credit. The definition of "reverse distributor" specifically states that any person, including forward distributors (e.g.,

wholesalers), 3PLs, or pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor. Any person that is performing the function of a reverse distributor, even if it is a small part of their business, would need to operate under the reverse distributor standards. If a facility is not processing any hazardous waste prescription pharmaceuticals for facilitating or verifying manufacturer credit, then it would not meet the definition of "reverse distributor."

The retail industry was especially concerned with need to differentiate between reverse distributors and reverse logistics centers. Reverse logistics centers that receive nonprescription pharmaceuticals (such as OTC pharmaceuticals) would not fall under this definition. Likewise, wholesale distributors receiving returns from their customers would not be considered reverse distributors. This is because wholesale distributors do not facilitate manufacturer credit. Further, according to comments received from Healthcare Distribution Management Association, in 2013, approximately 94% of the returns to wholesale distributors, were saleable.[157,158] As saleable products, the pharmaceuticals returned to wholesale distributors would remain subject to the track and trace requirements of the DSCSA. Reverse logistics centers, which evaluate nonprescription pharmaceuticals for legitimate use/reuse and reclamation do not fit this definition.

EPA is also finalizing the definitions for potentially creditable and non-creditable hazardous waste pharmaceuticals (in parts D and E of this section) to differentiate between reverse distributors' function in evaluation of credit versus the traditional TSDF role in waste disposal. It is the Agency's intent that potentially creditable hazardous waste pharmaceuticals can be sent to reverse distributors for the determination of credit under subpart P. It is not the

[157] Healthcare Distribution Management Association has since been renamed Healthcare Distribution Alliance.
[158] See comment #EPA-HQ-RCRA-2007-0932-0276.

Agency's intent, however, for reverse distributors to serve in the capacity as storage facilities or TSDFs for other hazardous waste.

Multiple state commenters asked EPA to clarify what is meant by "facilitate." The facilitation of credit encompasses the role that reverse distributors serve between healthcare facilities and manufacturers. A reverse distributor receives potentially creditable hazardous waste pharmaceuticals for evaluation of manufacturer credit. Once the evaluation is complete and it is determined that credit can be given, reverse distributors will issue the manufacturer credit on behalf of the manufacturer to the healthcare facility.

Reverse distributors wanted to add all the other functions performed by reverse distributors to the regulatory definition to more fully define their role. EPA did not add reverse distributors' other functions to the definition of "reverse distributor" in the final rule. While a reverse distributor may continue to perform other lawful activities, they are not relevant for the purpose of defining a reverse distributor under this final rule. EPA's definition of reverse distribution focuses on issuing of manufacturer credit because although the pharmaceuticals are hazardous waste, they have value to the healthcare facility and the reverse distributor. Since these hazardous waste pharmaceuticals have value, there is a greater economic incentive to manage them with more care than typical hazardous waste. The final definition captures the handling of prescription hazardous waste pharmaceuticals that fall under RCRA and the rest of the functions can be regulated, as needed, under local, state and other federal regulations.

The waste management industry requested clarification on the intersection of DEA reverse distributors and RCRA reverse distributors and how a reverse distributor that receives a DEA controlled substance as a waste would determine if they are also subject to subpart P. A hazardous waste pharmaceutical that is also a DEA controlled substance is not subject to subpart

P, provided they meet the terms of the conditional exemption in § 266.506. The conditional exemption for DEA controlled substances that are also RCRA hazardous waste is covered in section XIV of the preamble.

The Agency also wants to clarify the difference between what is defined as a reverse distributor under this final rule and how DEA regulations define "reverse distribute." The recently amended DEA regulatory definition of "reverse distribute" is to "acquire controlled substances from another registrant or law enforcement for the purposes of: (1) Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or (2) Destruction."[159]

Under DEA's definition, a reverse distributor does not necessarily process pharmaceuticals for the purpose of determining manufacturer credit: often a reverse distributor's main function under DEA's definition is to destroy the controlled substances. Under EPA's definition, however, a reverse distributor is defined as a facility that accepts potentially creditable pharmaceuticals for the purposes of evaluating manufacturer credit. These potentially creditable hazardous waste pharmaceuticals may or may not be identified as controlled substances by DEA.[160] Therefore, a DEA-registered reverse distributor may or may not meet EPA's definition of a reverse distributor and vice versa. For example, a reverse distributor that accepts DEA controlled substances that are also hazardous waste pharmaceuticals for the purpose of destruction (e.g., incineration) would be regulated as a DEA-registered reverse distributor and as a RCRA TSDF (or other regulated incinerator, depending on what other wastes

[159] See 21 CFR 1300.01. On September 9, 2014, DEA finalized new definitions for "reverse distribute" and "reverse distributor." Please see 79 FR 53520. The term "reverse distributor" is defined as "a person registered with the Administration [DEA] as a reverse distributor."

[160] In order for a reverse distributor to be able to accept controlled substances, the reverse distributor must be a DEA registrant. See 21 CFR part 1308 for a complete list of controlled substances.

it combusts), but not as a reverse distributor under part 266 subpart P. Conversely, a reverse distributor that processes pharmaceuticals for manufacturer credit, but is not a DEA registrant and therefore, cannot accept controlled substances, would meet the subpart P reverse distributor definition, but not DEA's reverse distributor definition. However, EPA has heard from stakeholders that most, if not all, entities that facilitate manufacturer credit are also DEA-registered reverse distributors. Therefore, such reverse distributors would meet both EPA's definition of reverse distributor and the DEA's definition of reverse distributor. Lastly, EPA's definition for reverse distribution does not alter or supersede the requirements of the Controlled Substances Act and DEA regulations.

In addition, the DOT's Pipeline and Hazardous Materials Safety Administration has defined the closely related term, "reverse logistics," in a recent rulemaking.[161] EPA coordinated with the Pipeline and Hazardous Materials Safety Administration to ensure that our rules are compatible, even if the definitions differ. It is important to note that their final rule does not supersede EPA's RCRA Subtitle C regulations for solid or hazardous waste determinations or hazardous waste management.

D. Definition of Potentially Creditable Hazardous Waste Pharmaceutical

1. Summary of Proposal

In order to distinguish hazardous waste pharmaceuticals that are sent by a healthcare facility to RCRA TSDFs from those hazardous waste pharmaceuticals that are sent by a healthcare facility to a reverse distributor for a determination or verification of manufacturer

[161] 79 FR 46748; August 11, 2014. The Pipeline and Hazardous Material Safety Administration's definition of reverse logistics "is the process of moving goods from their final destination for the purpose of capturing value, recall, replacement, proper disposal, or similar reason."

credit, the Agency proposed a definition for "potentially creditable hazardous waste pharmaceutical."

EPA proposed to define "potentially creditable hazardous waste pharmaceutical" to mean a hazardous waste pharmaceutical that has the potential to receive manufacturer credit and is

(1) unused or un-administered; and

(2) unexpired or less than one year past expiration date.

The proposed term did not include evaluated hazardous waste pharmaceuticals, residues of pharmaceuticals remaining in containers, contaminated personal protective equipment, and clean-up material from the spills of pharmaceuticals. These pharmaceuticals are typically unopened and in their original packaging and include both generic and name brand pharmaceuticals.

Whether a pharmaceutical is eligible for manufacturer credit is determined solely by the manufacturer's return policy. Based on comments received for the 2008 Universal Waste proposed rulemaking and through discussions with various stakeholders, the Agency understands that the return policies of manufacturers change regularly. As a result, healthcare facilities are not always aware if a particular pharmaceutical will be creditable at the time that it is pulled from the shelves. However, the Agency also understands that there are instances where it is well known that a pharmaceutical will not be creditable. Examples of these instances include the following: if the pharmaceutical has been removed from the original container and repackaged for dispensing purposes; if an attempt was made to administer a pharmaceutical, but the patient refused to take it; if the hazardous waste pharmaceutical was generated during patient care; if the pharmacy receives a return of a dispensed pharmaceutical for which they had already received compensation by a third-party payer; or if the pharmaceutical is more than one year past its

expiration date. In these instances, as well as others, the healthcare facility knows that it will not receive manufacturer credit. It is the Agency's intent for the proposed definition of "potentially creditable hazardous waste pharmaceutical" to allow the return of hazardous waste pharmaceuticals to reverse distributors for the determination of credit. It is not the Agency's intent, however, for reverse distributors to serve in the capacity as TSDFs when it is well known that the manufacturer will not give credit for those hazardous waste pharmaceuticals.

Also, based on communication with stakeholders and the public comments received on the 2008 Universal Pharmaceutical Waste proposal, EPA understands that pharmaceutical manufacturers' policies often allow for credit to be issued on the return of "partials." "Partials" is a term used in the industry to refer to opened containers that have had some contents removed. Under the proposed definition, the Agency considered partials to be potentially creditable hazardous waste pharmaceuticals.

2. Summary of Comments

States, manufacturers and waste management companies commented that word changes to this definition would clarify which hazardous waste pharmaceuticals could or could not be returned to reverse distributors. Manufacturers, some states and healthcare facilities argued that all pharmaceuticals should go to reverse distributors to relieve the burden on healthcare facilities to make these individual determinations. Pharmacists and reverse distributors wanted further clarification on what distinguishes a potentially creditable hazardous waste pharmaceutical and how it relates to credit.

3. Final Rule Provision

In response to comments, EPA has made five changes to the definition of "potentially creditable hazardous waste pharmaceutical" from the proposal. First, the final definition

specifically includes prescription pharmaceuticals only. Second, we added the phrase "reasonable expectation" to clarify that the healthcare facility does not have to definitively know whether something will receive manufacturer credit but rather indicates that they should have a reasonable expectation that it will. We also note that EPA could have proposed to use the term "creditable hazardous waste pharmaceuticals," but chose to use the term "potentially creditable hazardous waste pharmaceutical" to convey the same concept (i.e., that a healthcare facility does not have to definitively know whether a specific item will receive manufacturer credit.) Third, we replaced "unadministered" with the term "undispensed" to make clear that it is not just that a patient refused to take a prescription pharmaceutical, but rather that it was never dispensed to a patient at all. Fourth, we removed the word "unused" from the definition since the use of this term could introduce some confusion given that "partials" can get manufacturer credit. Fifth, we specified that the pharmaceuticals be in the "original manufacturer's packaging" since repackaged prescription pharmaceuticals are not typically eligible for credit.[162]

For the final rule, a potentially creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is (1) in original manufacturer's packaging (except pharmaceuticals that were subject to 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, OTC drugs, homeopathic drugs, and dietary supplements.

4. Comments and Responses

[162] See email correspondence from Nicole Wilkinson of CVS dated February 21, 2018and Erica Burwell of Inmar dated February 22, 2018, both in the docket for this rulemaking EPA-HQ-RCRA-2007-0932.

a. Definitional Wording. EPA received many comments from states and industry on revising the definition to clarify which hazardous waste pharmaceuticals could and could not be returned to reverse distributors. States especially stressed that "potentially creditable" should be changed to "reasonable expectation of credit" or that EPA should define potentially creditable hazardous waste pharmaceuticals as those that are accepted by reverse distributors for evaluation, as compared to those that are not. Manufacturers and states asked us to clarify whether we mean "unadministered" or "undispensed" or whether the term "unopened" should be added to the definition. The waste management industry had some concern that adding expiration dates to the definition might prevent potentially creditable hazardous waste pharmaceuticals from being returned to the reverse distributor.

In the final definition of potentially creditable hazardous waste pharmaceuticals, EPA has added some new phrases such as "reasonable expectation of credit" to the definition to be clear that not all hazardous waste pharmaceuticals should be going back to reverse distributors. We have also changed words like "unadministered" to "undispensed" since the expectation of credit ends once a pharmaceutical has been dispensed to a patient regardless of whether the patient takes the pharmaceutical and deleted "unused" since that could imply it has been dispensed but not used and/or that it was never opened.

We are specifically not adding the word "unopened" to the definition as some commenters had suggested, since it is EPA's understanding that "partials" can be given credit under certain circumstances and some pharmaceuticals may be repackaged. Although the definition does not include the word "intact" when describing original manufacturer's packaging, the definition of "potentially creditable hazardous waste pharmaceutical" does not include anything that is leaking or damaged.

Some commenters also argued that EPA was limiting manufacturers from changing policies by defining potentially creditable hazardous waste pharmaceuticals and giving examples of what those are. EPA recognizes that special circumstances may arise where a prescription hazardous waste pharmaceutical may be given credit but not fit squarely within this definition. We have added an example of this in our definition by noting that a recalled pharmaceutical may be given credit although it is not in original packaging. This definition is meant to give examples of what is commonly done and to aid healthcare facilities in being able to more easily identify a potentially creditable from a non-creditable hazardous waste pharmaceutical. It is not intended to prevent a manufacturer from changing its credit policies.

b. Evaluation of Hazardous Waste Pharmaceuticals and Credit. In their comments regarding potentially creditable hazardous waste pharmaceuticals received by reverse distributors, manufacturers and reverse distributors expressed concern about the burden being added to healthcare facilities by not allowing them to send all the hazardous waste pharmaceuticals together and putting the onus on them to determine if something is "potentially creditable". Healthcare facilities were concerned that credit policies are frequently updated by manufacturers and that a healthcare facility would not know if credit would be issued for any given pharmaceutical or not.

Commenters also addressed the question of a bright line as to what is and what is not potentially creditable hazardous waste pharmaceuticals. Commenters asked whether generics were considered "potentially creditable." The waste management industry commenters asked how many times credit must be rejected before a type of pharmaceutical is no longer considered potentially creditable.

It is the Agency's intent in our definition of "potentially creditable hazardous waste pharmaceutical" to allow the return of hazardous waste pharmaceuticals to reverse distributors for the determination of manufacturer credit. It is not the Agency's intent, however, for reverse distributors to serve in the capacity as TSDFs when it is well known that the manufacturer will not give credit for certain hazardous waste pharmaceuticals.

EPA recognizes that in some cases a healthcare facility may not know if the hazardous waste pharmaceuticals will be given credit. We do not want to deter healthcare facilities from sending their hazardous waste pharmaceuticals to a reverse distributor if there is a reasonable expectation of credit. Whether or not credit is actually given is not a defining factor and it is not within EPA's expertise to know how many times a potentially creditable hazardous waste pharmaceutical needs to be rejected before it is considered "non-creditable." Each pharmaceutical is different and is or is not creditable for various reasons as dictated by the manufacturer. EPA has learned since the proposal that generic prescription drugs can have a reasonable expectation of receiving manufacturer credit. EPA also agrees with commenters that "partials" can be given credit.

EPA's intent is to prevent hazardous waste pharmaceuticals that are clearly ineligible for credit and are ready for disposal, due to their condition, previous use with a patient, or other reason, from being sent to the reverse distributor. Hazardous waste pharmaceuticals that are in original packaging and have not been dispensed to a patient would fit under this definition of "potentially creditable hazardous waste pharmaceutical."

E. Definition of Non-Creditable Hazardous Waste Pharmaceutical

1. Summary of Proposal

In order to distinguish hazardous waste pharmaceuticals that have the potential for credit from those that have no expectation of receiving credit, the Agency proposed to define the term "non-creditable hazardous waste pharmaceutical." The proposed definition of a "non-creditable hazardous waste pharmaceutical" is a hazardous waste pharmaceutical that is not expected to be eligible for manufacturer credit. Examples include, but are not limited to pharmaceuticals that have been removed from the original container and repackaged for dispensing purposes; a pharmaceutical refused by a patient after an attempt to administer it; hazardous waste pharmaceuticals generated during patient care; dispensed pharmaceuticals returned to a pharmacy after the pharmacy had already received compensation by a third-party payer (e.g., health insurance company); or pharmaceuticals that are more than one year past their expiration dates. Non-creditable hazardous waste pharmaceuticals are typically opened and not in their original packaging and have been dispensed (though not administered) to a patient. These conditions of the non-creditable pharmaceutical are what makes them not creditable rather than the manufacturer's policy on the specific type of pharmaceutical.

2. Summary of Comments

Commenters expressed a variety of opinions on EPA's proposed definition of "non-creditable hazardous waste pharmaceutical." Some states, manufacturers and the waste management industry stated that they were satisfied with the proposed definition of "non-creditable hazardous waste pharmaceutical." Wholesalers argued that the definition should be struck and the regulations should allow all intact hazardous waste pharmaceuticals to go back to a reverse distributor. Pharmacists, some states, and the retail industry argued that EPA should define "non-creditable hazardous waste pharmaceuticals" as those hazardous waste pharmaceuticals that are not accepted by reverse distributors for manufacturer credit.

3. Final Rule Provision

For the final rule, EPA made three major changes to the definition of "non-creditable hazardous waste pharmaceutical" to address comments. First, EPA has added the word "prescription" to the first portion of the definition to be consistent with the use of terminology in the final rule that reverse distribution is the reverse flow of prescription hazardous waste pharmaceuticals. Second, the Agency has added new language to the definition to reflect the fact that nonprescription hazardous waste pharmaceuticals can also be considered non-creditable hazardous waste pharmaceuticals that must be managed under the healthcare facility standards in § 266.502 when they do not have a reasonable expectation to be legitimately used/reused or reclaimed. For purposes of this definition, the determination is being made that at the healthcare facility, prescriptions that have already been dispensed to a patient, and free samples given to healthcare facilities do not have a reasonable expectation of receiving manufacturers credit. Third, EPA has also added examples of non-creditable hazardous waste pharmaceuticals.

Under the final rule, non-creditable hazardous waste pharmaceutical means 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.

While not specifically laid out in the definition, other examples of non-creditable hazardous waste pharmaceuticals can be pharmaceuticals that have been removed from the

original container and repackaged for dispensing purposes; pharmaceuticals in their original packaging when the packaging is leaking or otherwise damaged; a pharmaceutical refused by a patient after an attempt was made to administer it; pharmaceuticals generated during patient care; dispensed pharmaceuticals returned to a pharmacy after the pharmacy already received compensation by a third-party payer (e.g., health insurance company); or pharmaceuticals at are more than one year past their expiration date.

4. Comments and Responses

Wholesalers and some reverse distributors recommended that we do not differentiate between potentially creditable and non-creditable hazardous waste pharmaceuticals and allow all hazardous waste pharmaceuticals that are intact and in original packaging to go to the reverse distributors. EPA disagrees with the commenters. EPA proposed this differentiation between potentially creditable and non-creditable hazardous waste pharmaceuticals to distinguish between a traditional TSDF and the function served by a reverse distributor. A reverse distributor should not act as a hazardous waste disposal facility for healthcare facilities. It is serving as the manufacturer's agent for determination of credit. If a reverse distributor is not determining credit, EPA views it as managing hazardous waste pharmaceuticals that do not have monetary value and thus would be subject to TSDF regulations. If a reverse distributor begins to routinely receive non-creditable hazardous waste pharmaceuticals, then it is serving as a TSDF. EPA has made this differentiation to correctly represent the reverse distributor role as a manufacturer's agent for facilitating credit and not like a more traditional hazardous waste management facility.

Pharmacists, the retail industry and some states recommended that we define non-creditable hazardous waste pharmaceuticals as those hazardous waste pharmaceuticals that do not receive credit. There are some situations in which pharmaceuticals are well known to not be

eligible for credit, such as leaky containers, samples or when pharmaceuticals were already dispensed to patients. The Agency did not finalize the commenters' recommendation, however, because it could potentially lead to situations where a healthcare facility sends a hazardous waste pharmaceutical to a reverse distributor in good faith that manufacturer credit is forthcoming, but credit is not issued. If EPA accepted this recommendation, the reverse distributor could be determined to unlawfully be in possession of non-creditable hazardous waste pharmaceuticals. For this reason, the Agency added into the definition that non-creditable hazardous waste pharmaceuticals are prescription pharmaceuticals that do not have a reasonable expectation of receiving manufacture credit, or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. It should be clear to healthcare personnel that leaking containers, for example, are not eligible for credit and should be sent to a designated facility for disposal (e.g., a TSDF). However, it is often not clear to the healthcare facility personnel making the determination which hazardous waste pharmaceuticals will receive manufacturer credit if they were not dispensed and/or are in their original packaging (i.e., potentially creditable). The Agency does find it reasonable that healthcare personnel may not know if a manufacturer credit policy for a particular pharmaceutical has changed.

Because it is not always clear that all hazardous waste pharmaceuticals will be eligible for credit due to frequent changes in manufacturers' policies, it is inappropriate to create a bright line in the definition solely based on whether the hazardous waste pharmaceutical would or would not receive manufacturer credit. Instead, this final definition takes into account this uncertainty and the difficulty it poses for healthcare facilities and allows for instances where a potentially creditable hazardous waste pharmaceutical can be correctly sent to a reverse distributor under the subpart P regulations despite not actually receiving manufacturer credit.

F. Definition of Evaluated Hazardous Waste Pharmaceutical

1. Summary of Proposal

EPA proposed a definition for evaluated hazardous waste pharmaceuticals. After potentially creditable hazardous waste pharmaceuticals arrive at a reverse distributor, they are evaluated by the reverse distributor to determine whether they are eligible for manufacturer credit or whether they need to be transferred to another reverse distributor for additional verification of manufacturer credit. Hazardous waste pharmaceuticals that need to be transferred to another reverse distributor for additional verification of manufacturer credit will continue to be considered potentially creditable hazardous waste pharmaceuticals. EPA proposed that hazardous waste pharmaceuticals for which manufacturer credit has been issued (and no further verification of credit is required), as well as those that do not receive credit, be referred to as "evaluated hazardous waste pharmaceuticals."

EPA proposed to define an "evaluated hazardous waste pharmaceutical" as a hazardous waste pharmaceutical that was a potentially creditable hazardous waste pharmaceutical but has been evaluated by a reverse distributor to establish whether it is eligible for manufacturer credit and will not be sent to another reverse distributor for further evaluation or verification.

It is important to define this term since the proposed management and shipping standards for potentially creditable hazardous waste pharmaceuticals differ from the proposed management and shipping standards for evaluated hazardous waste pharmaceuticals and the regulations must therefore distinguish between them. For a discussion of the proposed shipping and management standards for potentially creditable hazardous waste pharmaceuticals, see section XVI.D. and for a discussion of the proposed shipping and management standards for evaluated hazardous waste pharmaceuticals, see section XVI.B.

2. Summary of Comments

There were few comments pertaining to this definition. One state sought clarification on whether under this definition, an evaluated pharmaceutical could be sent on to another reverse distributor. Pharmacists wanted further clarification that evaluated hazardous waste pharmaceuticals are not eligible for credit.

3. Final Rule Provision

For the final rule, EPA made two changes to the definition of "evaluated hazardous waste pharmaceuticals": (1) adding the word "prescription" to be consistent with our decision to distinguish between reverse distribution and reverse logistics and (2) focusing the definition on the evaluation process and does not rely as heavily on manufacturer credit.

EPA is finalizing that "evaluated hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with §266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit.

Under the definition of evaluated hazardous waste pharmaceutical, if credit has been determined and no other verification is needed, then the waste would be considered evaluated. If the prescription hazardous waste pharmaceutical needs further evaluation for credit, it can be sent on to another reverse distributor for that determination. It will not be considered evaluated until the credit is verified.

The Agency notes that an evaluated pharmaceutical still at the reverse distributor is not precluded from ever being awarded manufacturer credit. A manufacturer may change a credit policy while an evaluated pharmaceutical is being accumulated at a reverse distributor. However, as an evaluated pharmaceutical, it is no longer managed as a potentially creditable

pharmaceutical at the reverse distributor, then it must be managed as an evaluated hazardous waste pharmaceutical even if credit is awarded after the initial evaluation. Please refer to section XVII.C of this preamble for a detailed discussion of the reverse distributor standards.

G. *Definition of Household Waste Pharmaceutical*

1. Summary of Proposal

EPA proposed to define the term "household waste pharmaceutical" as a solid waste, as defined in § 261.2, that also meets the definition of pharmaceutical, but is not a hazardous waste because it is exempt from RCRA Subtitle C regulation by the household waste exclusion in § 261.4(b)(1).

We proposed this term to distinguish this type of waste pharmaceutical from the hazardous waste pharmaceuticals that are proposed to be regulated under this new subpart.

2. Summary of Comments

Commenters generally agreed with EPA's definition of "household waste pharmaceutical" as proposed but were concerned with applicability of this definition and where the household waste exclusion can be used. For example, one commenter asked if it extended to schools. A few commenters wanted to know if this applied to all DEA take back programs and requested that the words "including those generated by DEA regulations" be added. Lastly, commenters asked us to clarify the significance of the household waste pharmaceutical definition with respect to long-term care facilities (LTCFs).

3. Final Rule Provisions

EPA is finalizing the definition of "household waste pharmaceutical" as proposed with one minor change. EPA changed the word "exempt" to "excluded" to be consistent with the title

of § 261.4(b). In the final rule, "household waste pharmaceutical" means a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1).

4. Comments and Responses

In response to some of the commenters' concerns, EPA is defining the term "household waste pharmaceutical" as a matter of convenience in crafting the regulatory language as well as the preamble. By defining the term, we do not alter the criteria we have consistently relied on for determining whether a waste is considered a household hazardous waste. The two criteria that must be met to be a household hazardous waste are (1) the waste must be generated by individuals on the premise of a temporary or permanent residence and (2) the waste stream must be composed primarily of materials found in wastes generated by consumers in their homes. Section 261.4(b)(1) defines household to include single and multiple residences, hotels and motels, bunkhouses, ranger stations, crew quarters, campgrounds, picnic grounds and day-use recreation areas. This exclusion does not include schools. Schools generate hazardous waste from various sources throughout the school grounds such as chemicals from labs, cleaning supplies and hazardous waste pharmaceuticals from medical clinics. These wastes are not being generated at a temporary or permanent residence and are not the types of wastes that would ordinarily be generated by a consumer at their home. Pharmaceuticals generated at schools would not be considered household waste pharmaceuticals. However, hazardous waste pharmaceuticals generated at dormitories at schools would be considered household waste pharmaceuticals and thus excluded, because the dormitories are residences.

Some types of healthcare facilities could be considered households. This final rule defines the term LTCF in § 266.500. LTCF means a licensed entity that provides assistance with

activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities. The types of healthcare facilities listed at the end of this definition that are not considered to be LTCFs are not subject to subpart P requirements and hazardous waste pharmaceuticals generated there continue to be excluded from RCRA as household hazardous wastes. For a more thorough discussion of the applicability of the household hazardous waste exclusion at LTCFs, see section VIII.K of this preamble.

While DEA controlled substances can sometimes be household waste pharmaceuticals, once these wastes are collected at a take back event or by law enforcement, DEA regulations require that any proper disposal must meet the DEA non-retrievable standards of destruction. Furthermore, this EPA rule finalizes specific requirements for the destruction of collected household waste pharmaceuticals, see section XIV of this preamble for details. Therefore, it could have been confusing to add "including waste under DEA regulations" to the definition of household waste pharmaceutical.

H. Definition of Non-hazardous Waste Pharmaceutical

1. Summary of Proposal

EPA proposed to define the term "non-hazardous waste pharmaceutical." While hazardous waste pharmaceuticals are regulated under this new subpart, non-hazardous waste pharmaceuticals are not regulated under RCRA Subtitle C, including this new subpart. The

Agency proposed this definition since we believed it was important to clearly delineate what is and is not regulated under this new subpart.

The Agency proposed to define the term "non-hazardous waste pharmaceutical" as a pharmaceutical that is a solid waste, as defined in § 261.2, but is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C. The characteristics of hazardous waste are ignitability, corrosivity, reactivity, and toxicity.

2. Summary of Comments

Most commenters agreed with the definition of "non-hazardous waste pharmaceutical" as proposed. There were some comments concerning commingling of hazardous and non-hazardous waste. These comments are addressed in detail in section X.C. and XI.A. of this preamble.

3. Final Rule Provision

The Agency is finalizing the definition of "non-hazardous waste pharmaceutical" as proposed, with no changes. In this rule, a "non-hazardous waste pharmaceutical" is a pharmaceutical that is a solid waste, as defined in § 261.2, but is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C.

I. Definition of Non-pharmaceutical Hazardous Waste

1. Summary of Proposal

Like the previous definition, we proposed to define non-pharmaceutical hazardous waste to help delineate what is and what is not regulated under this new subpart. We proposed to define the term ''non-pharmaceutical hazardous waste'' as a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical as defined in this section.

The proposed definition was needed because the management of non-pharmaceutical hazardous wastes is not regulated under subpart P; rather, generators of non-pharmaceutical hazardous wastes, including healthcare facilities and reverse distributors, remain subject to part 262 and other applicable Subtitle C hazardous waste regulations for the management of those hazardous wastes.

2. Summary of Comments

There were only a few comments on the proposed definition of "non-pharmaceutical hazardous waste." Commenters generally agreed with the definition, but two commenters wanted EPA to clarify how to classify a waste with an ingredient that is used in both pharmaceutical and non-pharmaceutical items.

3. Final Rule Provisions

EPA is finalizing the definition of non-pharmaceutical hazardous waste, as proposed, with no changes. In this final rule, "non-pharmaceutical hazardous waste" is a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical as defined in §266.500.

4. Comments and Responses

Multiple commenters asked EPA to clarify how a hazardous waste should be managed when it is used as an ingredient in both pharmaceuticals and non-pharmaceutical, e.g., isopropyl alcohol, which can be used both as an antiseptic and a degreaser. Please see the definition in section VIII.A. for discussion about what meets the definition of pharmaceutical, including how to apply the definition in this type of scenario. Any hazardous waste not meeting the definition of

pharmaceutical is considered a non-pharmaceutical hazardous waste and should be managed under all applicable RCRA standards.

J. Definition of Healthcare Facility

1. Summary of Proposal

EPA proposed to define "healthcare facility" as any person that provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or sells or dispenses OTC or prescription pharmaceuticals. The proposed definition was adapted from the definition of "health care" that the Department of Health and Human Services promulgated as a result of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (45 CFR part 160.103).[163] The proposed definition of "healthcare facility" included, but was not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, LTCFs, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of OTC medications; and veterinary clinics and hospitals.

EPA proposed to include coroners and medical examiners in the definition of "healthcare facility" despite the fact that the services coroners provide occur after life. Coroners will often inventory, and then dispose of, any pharmaceuticals that may be found at the scene of a death, and commonly sewer dispose of pharmaceuticals by putting them down the drain.[164] In order to reduce sewer disposal of pharmaceuticals and provide these facilities with the same management

[163] 45 CFR part 160 http://aspe.hhs.gov/admnsimp/final/pvctxt01.htm

[164] For more information on the disposal process, please see: Ruhoy, I.S. and Daughton, C.G. "Types and Quantities of Leftover Drugs Entering the Environment via Disposal to Sewage – Revealed by Coroner Records," Sci. Total Environ., 2007, 388(1-3):137-148. https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryID=168384

options that are available to other healthcare facilities, EPA included coroners in the proposed definition of healthcare facility.

The proposed definition of healthcare facility did not include pharmaceutical manufacturers and their representatives, wholesalers, or any other entity that is involved in the manufacturing, processing, or wholesale distribution of pharmaceuticals. EPA proposed to exclude manufacturing facilities from the definition of healthcare facility because the Agency did not anticipate that manufacturing facilities, which predictably generate a known range of hazardous wastes, face the same issues as healthcare facilities.

2. Summary of Comments

EPA requested comment on including coroners in the definition of "healthcare facility." EPA received three comments supporting the inclusion of coroners in the definition of "healthcare facility." One stakeholder was aware of coroner facilities that sewer dispose of pharmaceuticals and argued to include them in the definition in order to reduce the sewer disposal of pharmaceuticals. Two commenters expressed concern about including coroners in the definition of "healthcare facility." One commenter stated that including coroners in the definition could discourage coroners from promoting take-back programs.

EPA also took comment on including compounding pharmacies in the definition of "healthcare facility." Three commenters supported the inclusion of compounding pharmacies in the definition. One commenter stated that compounding pharmacies should be included because they do not predictably generate a known range of hazardous wastes and face problems similar to that of a healthcare facility.

The most frequent comment the Agency received on the definition of "healthcare facility" was that EPA should define wholesale distributors and third-party logistics providers as

healthcare facilities or to create a separate definition for wholesale distributors and third-party logistics providers, but allow them to operate under the same standards as healthcare facilities.

3. Final Rule Provisions

EPA is finalizing a definition for "healthcare facility" so that it is clear to whom these final regulations apply. EPA is finalizing that "healthcare facility" means any person that is lawfully authorized to (1) provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) distribute, sell, or dispense pharmaceuticals, including OTC pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, LTCFs, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, and veterinary clinics and hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Although EPA uses the term "person," in the definition of healthcare facility, the definition of healthcare facility does not necessarily apply to individual healthcare providers at a site. As defined in § 260.10, "person" means "an individual, trust, firm, joint stock company, Federal Agency, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or any interstate body." Accordingly, a healthcare facility can have multiple healthcare providers or a sole

healthcare provider. For example, an individual healthcare provider who works at a hospital with multiple healthcare providers is not considered a healthcare facility, but the hospital is considered a healthcare facility, under the final definition. Additionally, a doctor's office with a sole healthcare provider would also be considered a healthcare facility under this final rule.

The proposed definition of "healthcare facility" did not apply to pharmaceutical manufacturers' representatives, wholesale distributors, third-party logistics providers, or any other entity that is involved in the wholesale distribution of prescription or OTC pharmaceuticals. Commenters argued that excluding wholesale distributors and third-party logistics providers from the definition of "healthcare facility," in combination with the revised interpretation that the point of generation for potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, could hinder wholesale distributors' and third-party logistics providers' ability to send potentially creditable pharmaceuticals through reverse distribution. These commenters were concerned that if they were not included in the definition of "healthcare facility" they would be precluded from using reverse distributors. Commenters also pointed out that wholesale distributors and third-party logistics facilities are likely to generate hazardous waste pharmaceuticals unpredictably and that their workers typically do not have the expertise to make hazardous waste determinations. Due to these comments, the Agency anticipates that wholesale distributors and third-party logistics facilities face similar issues as healthcare facilities and therefore is including them in the final definition of "healthcare facility."

The final definition of "healthcare facility" includes wholesale distributors, third-party logistics providers that engage in forward distribution, and military medical logistics facilities. Including wholesale distributors and third-party logistics facilities in the definition of "healthcare facility" ensures that these facilities can continue sending potentially creditable hazardous waste

pharmaceuticals through reverse distribution. EPA recognizes that wholesale distributors and third-part logistics providers are not accustomed to referring to themselves as healthcare facilities. However, it is helpful to have a single, umbrella term when discussing who is subject to this subpart.

The final definition of "healthcare facility" does not apply to pharmaceutical manufacturers or any other entity that is involved in the manufacturing of OTC or prescription pharmaceuticals. The purpose for these sector-based regulations is to address the various issues that healthcare facilities and reverse distributors face when managing hazardous waste pharmaceuticals. The Agency does not anticipate that manufacturing facilities, which predictably generate a known range of hazardous wastes, face the same issues as healthcare facilities, and therefore are excluded from the definition of "healthcare facility" under this rule.

The final definition of "healthcare facility" includes locations that sell pharmaceuticals over the internet, through the mail, or through other distribution mechanisms. A pharmacy does not necessarily have to have a "brick and mortar" or "store front" presence to be considered a healthcare facility for the purposes of this final rule. The final definition of a "healthcare facility" also applies to entities that engage in drug compounding. In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. EPA solicited comment on including compounding pharmacies in the definition of healthcare facility and received three comments supporting and no comments opposing the inclusion of compounders in the definition. The final definition of "healthcare facility" applies to state-licensed pharmacies, federal facilities, and licensed physicians that compound drugs in accordance with section 503A of the

FD&C Act, and to outsourcing facilities that compound drugs in accordance with section 503B of the FD&C Act.

4. Comments and Responses

The final definition does not include independently located coroners and medical examiners. EPA made this change in response to commenter concern that including coroners and medical examiners in the definition could discourage coroners and medical examiners from promoting take-back programs for household pharmaceuticals. However, coroners and medical examiners that are co-located with healthcare facilities, such as hospitals, will fall under the definition of "healthcare facility," because they are physically part the healthcare facility.

K. *Definition of Long-term Care Facility*

1. Summary of Proposal

The proposed definition of healthcare facility specifically included LTCFs as an example of a type of healthcare facility. Since the term "long-term care facility" does not have a standardized, industry definition, EPA proposed to define the term for purposes of this rule. We proposed to define a LTCF as a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, assisted living, hospices, nursing homes, skilled nursing facilities, and the assisted living and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, and the independent living portions of continuing care retirement communities.

The facilities we proposed to include as LTCFs are licensed care facilities that are more similar to hospitals than to standard residences. Although group homes may be licensed care

facilities, they are typically very small (fewer than 10 beds) and therefore were not included within the proposed definition. Similarly, independent living communities are not licensed care facilities, but rather are residences made up of individual units such as townhomes or apartments and therefore were not included within the proposed definition. Finally, we clarified in the preamble to the proposed rulemaking that private residences with visiting nurses would not be considered long-term care facilities.

By proposing to define a LTCF as a type of healthcare facility, EPA was proposing to revise its policy regarding the regulatory status of hazardous waste from long-term care facilities. We proposed that hazardous waste from LTCFs would no longer be excluded as household hazardous waste; rather, it would be regulated as hazardous waste, subject to the appropriate RCRA Subtitle C management standards, including the standards proposed for hazardous waste pharmaceuticals under part 266 subpart P. In other words, the proposed revision to our policy regarding long-term care facilities pertained to all of the facilities' hazardous waste, not just the hazardous waste pharmaceuticals.

The Agency proposed revising its interpretation with regard to hazardous wastes generated at LTCFs based on a reevaluation of how such facilities operate. Specifically, in order to qualify for the household hazardous waste exclusion of § 261.4(b)(1), waste must meet two criteria: (1) the hazardous waste must be generated by individuals on the premises of a household, and (2) the hazardous waste must be composed primarily of materials found in the wastes generated by consumers in their homes.[165] In the preamble to the proposed rulemaking, EPA explained that hazardous waste generated at LTCFs, even those pharmaceuticals that are

[165] See November 13, 1984; 49 FR 44978.

under the control of the patient or resident, does not meet either criterion for the household hazardous waste exemption.

In brief, the explanation provided in the preamble to the proposed rulemaking was two-fold. First, a LTCF is more similar to a hospital than it is a typical residence and EPA does not consider a hospital to be a household. LTCFs are licensed, residential care settings that offer their residents a wide range of services, many of which are centered on administering medications and providing healthcare by various professional healthcare providers, such as medical technicians, nurse's aides, nurses, and doctors. Other services provided involve assistance in performing activities of daily living, such as bathing and eating. Given that LTCFs are licensed settings for the care of their residents and routinely provide healthcare services, EPA believes that LTCFs more closely resemble hospitals than typical residences.

Second, we explained, the hazardous wastes generated by LTCFs do not meet the second criteria for the waste to be considered household hazardous waste. This is primarily due to the quantity and breadth of pharmaceutical wastes that are often generated on the premises of LTCFs when compared to a typical residence. This distinction about volume and breadth of waste is analogous to the distinction that EPA has made in the past about contractor or do-it-yourself waste from households: waste from ''routine residential maintenance'' is exempt as household hazardous waste, while waste from ''building construction, renovation, demolition'' is not excluded.[166]

2. Summary of Comments

EPA received a number of comments requesting changes to the proposed definition of "LTCF" that were instrumental in the final definition in the rule. We also received a number of

[166] Memo from Petruska to McNally, February 28, 1995; RCRA Online #11897 that discusses the distinction about what renovation waste is household hazardous waste and what is not.

comments related to whether hazardous waste from LTCFs should be excluded from RCRA Subtitle C regulations as household hazardous waste.

3. Final Rule Provisions

Based on comments, we have made some changes to the proposed definition of LTCF. The final definition retains the descriptive portion of the definition, but the list of types of facilities included as a LTCF has been revised to be more consistent with how the term is used by DEA and the Centers for Medicare and Medicaid Services (CMS). This final rule defines "LTCF" as a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

The primary change we have made to the proposed definition relates to assisted living facilities. Under the proposed definition, an assisted living facility was considered a type of LTCF. Under the final definition, an assisted living facility is not considered a type of LTCF. This change is responsive to commenter's concerns and will make EPA's definition more consistent with how the term is used by both DEA and CMS. The DEA's definition of "long term care facility" is "a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients."[167] DEA does not consider assisted living facilities to be long-term care facilities. CMS also does not consider assisted living

[167] See 21 CFR 1300.01.

facilities to be long-term care facilities. One commenter pointed out that "As primary regulatory oversight of [assisted living] resides at the state level, regulatory requirements and applicable definitions differ state by state. This is why the Centers for Medicare and Medicaid Services (CMS) excluded [assisted living] in its definition of Long Term Care Facilities."[168]

Furthermore, commenters argued, and EPA agrees, that assisted living facilities differ from LTCFs in at least two ways. First, some assisted living facilities do not provide medication management.[169] In some cases, assisted living facilities are actually prohibited from managing medications.[170] Second, many assisted living facilities do not have on-site nursing or other medical staff.[171] EPA believes it is easier for implementation of this rule, to make a determination about assisted living facilities as a category, rather than on the basis of whether they provide medication management of have on-site medical staff. Therefore, for ease of implementation as well as consistency with DEA and CMS, EPA is not considering assisted living facilities to be long-term care facilities for purposes of subpart P.

4. Comments and Responses

a. *Long-term care facilities and the household hazardous waste exclusion*. Aside from the comments about what types of facilities should and should not be considered LTCFs, we received many comments about whether LTCFs should be eligible to use the household hazardous waste exclusion of § 261.4(b)(1). Three states, the Hematology/Oncology Pharmacy Association, Stericycle, Inc., Healthcare Waste Institute, National Waste and Recycling

[168] Medicare Prescription Drug Benefit Manual – Chapter 5, §10.2, as cited by commenter EPA-HQ-RCRA-2007-0932-0289.
[169] See comment EPA-HQ-RCRA-2007-0932-0242.
[170] See comment EPA-HQ-RCRA-2007-0932-0289.
[171] Overview of Assisted Living, 2009, A collaborative research project of American Association of Homes and Services for the Aging (AAHSA), American Seniors Housing Association (ASHA), Assisted Living Federation of American (ALFA), National Center for Assisted Living (NCAL), and National Investment Center for the Seniors Housing and Care Industry (NIC).

Association, and Public Employees for Environmental Responsibility agreed that LTCFs should be considered healthcare facilities and therefore not eligible to use the household hazardous waste exemption. The American Society of Consultant Pharmacists and the National Community Pharmacists Association disagreed with EPA's proposed change of interpretation that hazardous waste (including pharmaceuticals) generated at LTCFs will no longer be considered exempt as household hazardous waste. The American Society of Consultant Pharmacists expressed concern that this change would be a substantial learning curve for LTCFs and the costs may be significant. Covanta Energy LLC expressed concern that the impacted facilities do not have robust financials and would pass the costs on to consumers. An assisted living community commented that the facility does not have the authority to compel residents to surrender their medications for disposal and therefore the new requirement would cause the assisted living community to be perpetually in noncompliance. One state opposed classifying group homes as healthcare facilities rather than as households. Waste Management National Services, Inc. suggested that self-administered pharmaceuticals that are under residents' control should be considered household waste.

EPA is finalizing that LTCFs are included within the final definition of healthcare facility. Accordingly, EPA is also finalizing that hazardous waste (including pharmaceuticals) generated at LTCFs will no longer be excluded as household hazardous waste: it will be regulated as hazardous waste, subject to the appropriate RCRA Subtitle C management standards, including the final subpart P management standards for hazardous waste pharmaceuticals. EPA is revising its interpretation with regard to hazardous wastes generated at LTCFs based on a reevaluation of how such facilities operate. Specifically, in order for hazardous waste to qualify for the household hazardous waste exclusion of § 261.4(b)(1), it must

meet the two criteria. EPA continues to believe that hazardous waste generated at LTCFs, does not meet either criterion for the household waste exclusion.

In summary, EPA is finalizing that LTCFs may no longer use the household hazardous waste exclusion. LTCFs need to manage their hazardous waste pharmaceuticals in accordance with the healthcare facility specific management standards in this final rule and their non-pharmaceutical hazardous wastes in accordance with the applicable RCRA hazardous waste generator regulations in § 262.14 (for VSQGs), § 262.16 (for SQGs), or § 262.17 (for LQGs), as well as § 262.15 (for satellite accumulation areas (SAAs)). However, even though LTCFs will no longer be eligible to use the household hazardous waste exclusion, EPA estimates that there are between 2,875 and 4,770 LTCFs that generate hazardous waste and that 98–99 percent of the facilities are VSQGs regulated under § 262.14 and therefore not subject to part 266 subpart P (except the sewer prohibition, the empty container provisions and the optional provisions of § 266.504).[172] This means that this change in policy will primarily affect the larger long-term care facilities, which are far fewer in number (1–2 percent of LTCFs).

It is also important to note that, because of the change to the definition of LTCF, this change in policy regarding the household hazardous waste exclusion and LTCFs will not impact residents in assisted living facilities. As discussed previously, assisted living facilities will not be considered healthcare facilities and therefore will continue to be considered residences that are eligible to use the household hazardous waste exclusion in 40 CFR 261.4(b)(1). Under the household hazardous waste exclusion, assisted living facilities are not required to manage their residents' hazardous waste, including their hazardous waste pharmaceuticals, under the RCRA regulations. Commenters confirmed our data that two-thirds of assisted living facilities are small

[172] Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

facilities with 25 residents or less, many of whom would presumably be VSQGs.[173] Therefore, we believe that this revised interpretation will have minimal environmental impact: instead of assisted living facilities being exempt as VSQGs, residential waste from assisted living facilities will be exempt as household hazardous waste. That said, under RCRA, states may be more stringent than the federal government and we are aware that some states already have a more stringent interpretation and do not consider assisted living facilities to be exempt from RCRA as households.

As noted previously, EPA's household hazardous waste exclusion in 40 CFR 261.4(b)(1) exempts hazardous waste that meets two criteria: (1) it is generated on the premises of a temporary or permanent residence for individuals and (2) the waste stream is composed primarily of materials found in the waste generated by consumers in their homes.[174] Therefore, only hazardous wastes that are generated in the residential areas of an assisted living facility would be excluded as household hazardous waste. On the other hand, hazardous wastes that are generated by an assisted living facility outside of the residential areas would not be considered excluded as household hazardous waste. This interpretation regarding non-residential hazardous waste generated at assisted living is consistent with our interpretation regarding dry cleaning wastes generated at hotels. Specifically, our interpretation has been that while hazardous waste generated in hotel rooms is excluded as household waste, "dry cleaning wastes produced by the hotel do not meet both criteria for household waste and will not qualify for the household waste exclusion."[175] Similarly, when it comes to assisted living facilities, this final rule will rely on the interpretation that we initially expressed in the preamble to the proposed rulemaking to add

[173] See commenter EPA-HQ-RCRA-2007-0932-0289.
[174] 49 FR 44978; November 13, 1984.
[175] See RCRA Online #13736, March 1995.

pharmaceuticals to Universal Waste: "the [long-term care] facility itself may generate hazardous waste as a result of its central management of pharmaceuticals in its pharmacy or pharmacy-like area. These hazardous pharmaceutical wastes would be subject to the RCRA hazardous waste generator regulations since the pharmaceuticals are under the control of the facility, and thus, the resulting wastes are generated by the facility. However, patients and residents in long-term care facilities may generate hazardous wastes. Those pharmaceuticals that are under the control of the patient or resident of this LTCF, when discarded, would be subject to RCRA's household hazardous waste exclusion (§ 261.4(b)(1)). Hazardous pharmaceutical wastes generated by the resident are excluded from regulation because they are considered to be derived from the household."[176]

Under the final rule, group homes and independent living communities are also not defined as LTCFs but rather are considered residences that are eligible to use the household hazardous waste exclusion. An assisted living facility, group home and independent living facility are eligible for the household hazardous waste exclusion whether they are stand-alone facilities, or whether they are part of a continuing care retirement community. Conversely, a nursing facility or skilled nursing facility is considered a LTCF, and hence a healthcare facility, whether it is a stand-alone facility or part of a continuing care retirement community. Therefore, a continuing care retirement community will likely have portions of the facility that are excluded from RCRA regulation as households, while other portions of the facility will be regulated under RCRA for their hazardous waste generation and management, including hazardous waste pharmaceuticals.

[176] See 73 FR 73525, December 2, 2008. Note that while the Universal Waste proposal used the term "hazardous pharmaceutical wastes," this final rule uses the term "hazardous waste pharmaceuticals"

b. *Other comments.* Commenters asked us to clarify the difference in regulatory status between in-home hospice care and in-patient hospice facilities. One commenter points out that "Most hospice care is provided in the private residence of a patient."[177] Hazardous waste pharmaceuticals that are generated by in-home medical care, such as in-home hospice care, would be eligible for the household hazardous waste exclusion. On the other hand, hospice *facilities* are not considered residences and are not eligible for the household hazardous waste exclusion. Nevertheless, as discussed in section XII.D. of this preamble, long-term care facilities, including hospice facilities, that have 20 beds or fewer will be presumed to be VSQGs. Healthcare facilities that are VSQGs are subject to the sewer prohibition for hazardous waste pharmaceuticals under this final rule, the empty container standards in § 266.507, and the optional provisions of § 266.504, but otherwise are regulated by the reduced regulations of 40 CFR 262.14 for the generation and accumulation of hazardous waste, including hazardous waste pharmaceuticals.

IX. Applicability (§ 266.501)

Part 266 subpart P was proposed to replace the standard RCRA generator regulations in part 262 for the management of hazardous waste pharmaceuticals by healthcare facilities and reverse distributors. We proposed separate regulations for healthcare facilities and reverse distributors. Further, we proposed separate regulations for the management of the two types of hazardous waste pharmaceuticals — potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals. When a healthcare facility disposes hazardous waste pharmaceuticals directly by sending it to a hazardous waste treatment, storage, or disposal facility, we proposed that these would be considered non-creditable hazardous waste

[177] CareFirst, Commenter EPA-HQ-RCRA-2007-0932-0239

pharmaceuticals. On the other hand, when a healthcare facility disposes of hazardous waste pharmaceuticals indirectly through a reverse distributor that facilitates manufacturer credit, we proposed that these would be considered potentially creditable hazardous waste pharmaceuticals. We proposed that when a reverse distributor receives the potentially creditable pharmaceuticals, it must evaluate them to determine whether they need to go onto another reverse distributor, in which case the pharmaceuticals would still be considered potentially creditable, or whether they will go to a TSDF, in which case they will be considered evaluated hazardous waste pharmaceuticals. Although EPA proposed that potentially creditable pharmaceuticals destined for reverse distributors would be considered hazardous wastes, we also recognized that due to the considerable value they retain in the form of potential credit from manufacturers, there was a strong incentive to manage them appropriately and we did not need to apply the standard RCRA regulations to them or to the reverse distributors that manage them. In contrast, once the credit has been established for the evaluated hazardous waste pharmaceuticals, the incentive to manage them appropriately no longer exists and we needed to apply more rigorous regulations. This section of the preamble discusses the types of facilities and pharmaceuticals that are and are not subject to this rulemaking. Subsequent sections of the preamble discuss the details of the regulations for healthcare facilities managing non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals as well as the regulations that pertain to reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated pharmaceuticals.

A. *What Facilities Are Subject to the Final Rule?*

1. Healthcare Facilities (§§ 262.10(n) and 266.501(d))

a. *Summary of proposal.* The Agency proposed that healthcare facilities that are not VSQGs will be required to manage all hazardous waste pharmaceuticals generated at their facilities in

accordance with the new part 266 subpart P (see § 262.10(n)) in lieu of the part 262 generator regulations. In other words, we proposed that these new management standards apply to any healthcare facility that generates more than 100 kg of hazardous waste per calendar month *or* more than 1 kg of acute hazardous waste per calendar month (e.g., P-listed hazardous waste) *or* more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31, or 261.33(e) per calendar month. We proposed that part 266 subpart P applies to all healthcare facilities that generate above the VSQG monthly quantity limits, including LTCFs.

Further, we proposed that subpart P is not optional for healthcare facilities that generate above the VSQG monthly quantity limits. EPA proposed to make subpart P mandatory to promote national consistency, a goal championed by stakeholder comments as well as EPA. We reasoned that having one set of standards applicable to hazardous waste pharmaceuticals would be less confusing to the regulated community, which should lead to better compliance.

We also proposed that any healthcare facility that generates hazardous waste above VSQG limits is subject to the same set of standards for the management of its hazardous waste pharmaceuticals. That is, unlike under part 262, the stringency of the proposed regulations for healthcare facilities operating under part 266 subpart P does not increase as the amount of hazardous waste generated increases. Put another way, we proposed that there is no generator category for hazardous waste pharmaceuticals under part 266 subpart P. The SQG and LQG categories under the part 262 RCRA requirements will only be relevant for the healthcare facilities' non-pharmaceutical hazardous waste because non-pharmaceutical hazardous waste remains subject to those 40 CFR part 262 generator regulations (along with other applicable sections of the subtitle C regulations).

We proposed that healthcare facilities generating non-creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.502, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.508.

We proposed that healthcare facilities generating potentially creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.503, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.509.

We expect that most potentially creditable hazardous waste pharmaceuticals will be sent to reverse distributors; however, that may not always be the case. For example, in some cases, manufacturer credit can get awarded without having to physically send the potentially creditable hazardous waste pharmaceuticals to a reverse distributor. In such cases, we proposed that if they are not destined for a reverse distributor, then they must be managed by the healthcare facility as non-creditable hazardous waste pharmaceuticals.

b. *Summary of comments.* Comments on the applicability section addressed several main areas of concern. First, commenters weighed in on whether the VSQGs should be subject to part 266 subpart P in its entirety, as opposed to just the sewer prohibition. Second, commenters weighed in on whether the new subpart should be mandatory. Third, commenters weighed in on our proposed revision to our policy related to the reverse distribution of pharmaceuticals. While some commenters agreed with our proposed revised position that pharmaceuticals going through reverse distribution would be considered solid waste, many commenters strongly objected to our

proposed revised position. We have made several changes to the final regulations that affect applicability, although several of these changes are to definitions, rather than to the applicability section of § 266.501. The primary focus of this section is to discuss changes made to the applicability section of § 266.501, although changes to definitions that affect applicability are also noted.

c. *Final rule provisions.* The final rule applies to all healthcare facilities that generate above any of the VSQG monthly quantity thresholds. Healthcare facilities that are not VSQGs do not have the choice of opting into part 266 subpart P in lieu of part 262. Further, all healthcare facilities that are subject to part 266 subpart P are regulated the same with respect to their hazardous waste pharmaceuticals, regardless of how much hazardous waste pharmaceuticals they generate. Note that we have made two changes to § 262.10(n). First, we have revised the regulations so that only a healthcare facility that *generates* above the VSQG quantity thresholds are subject to part 266 subpart P. A healthcare facility that *accumulates* above the VSQG quantity thresholds would not be subject to part 266 subpart P; it would remain subject to part 262 (although as with any VSQG, it would be allowed to opt into subpart P). The 2016 Hazardous Waste Generator Improvements final rule amended the part 262 regulations to make it clear that a VSQG that accumulates above the quantity thresholds must manage its hazardous waste in accordance with the conditions of either the SQG or LQG regulations, but the generator would remain a VSQG.[178] Second, in response to comments, we have added the following clarifying sentence at the end of the paragraph: A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its

[178] See § 262.14(a)(3) for accumulating > 1 kg of acute hazardous waste and § 262.14(a)(4) for accumulating > 1000 kg non-acute hazardous waste.

non-pharmaceutical hazardous waste, remains subject to § 262.14 and is not subject to part 266 subpart P, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.[179]

We have made four changes to the proposed regulatory language of § 266.501(d). First, we have made a conforming change to reflect the change in terminology in this final rule. That is, in § 266.501(d)(1)(ii), "pharmaceutical reverse distributor" has now been replaced by "reverse distributor." The second change we made is to omit the reference to § 266.504 in both § 266.501(d)(1) and (2). Section 266.504 only applies to healthcare facilities that are VSQGs and should not have been referenced when discussing the requirements for other healthcare facilities. The third change is to clarify in § 266.501(d)(2), that healthcare facilities managing potentially creditable hazardous waste pharmaceuticals are also subject to the notification and withdrawal standards of § 266.502(a). While EPA believes it is extremely unlikely that a healthcare facility would only manage potentially creditable hazardous waste pharmaceuticals, as proposed, in this situation a healthcare facility would not need to notify as a healthcare facility. EPA is clarifying in the final rule, that should this situation arise, a healthcare facility only managing potentially creditable hazardous waste pharmaceuticals and no non-creditable hazardous waste pharmaceuticals is subject to notification.

The fourth, and far more substantive change we made is to § 266.501(d)(2). This paragraph has been revised to reflect our decision that healthcare facilities are regulated under part 266 subpart P for the management of prescription hazardous waste pharmaceuticals going through reverse distribution but healthcare facilities are not regulated under part 266 subpart P for the management of nonprescription pharmaceuticals, such as OTCs, homeopathic drugs, and dietary supplements, going through reverse logistics because they are not considered solid or

[179] See comment number EPA-HQ-RCRA-2007-0932-0341.

hazardous wastes, provided they have the potential to be lawfully redistributed or legitimately reused or reclaimed. To summarize, part 266 subpart P applies to healthcare facilities managing *non-creditable* hazardous waste pharmaceuticals, whether the pharmaceuticals are prescription or nonprescription. But part 266 subpart P applies to healthcare facilities managing *potentially creditable* hazardous waste pharmaceuticals only if they are prescription hazardous waste pharmaceuticals. The comments we received in this area and the reasoning for our decision have been discussed at length in section VI of the preamble to this final rule.

Due to changes in the definition of healthcare facility and LTCF, there are effectively additional substantial changes to the applicability of the final rule. These two definitional changes have already been discussed, but are summarized here. In short, due to changes to the definition of "healthcare facility," wholesale distributors will now be regulated under part 266 subpart P as healthcare facilities for the management of their hazardous waste pharmaceuticals. This includes 3PLs when they perform the function of a wholesale distributor. Unlike wholesale distributors, 3PLs do not take ownership of the pharmaceuticals; however, both wholesale distributors and 3PLs take physical custody of pharmaceuticals. Under RCRA, a 3PL would meet the definition of a hazardous waste generator, regardless of whether they own the hazardous waste pharmaceuticals.

The final rule still applies to long-term care facilities, because they are still considered healthcare facilities. However, we have amended the proposed definition of LTCF such that assisted living facilities will not be considered long-term care facilities. Further, we have finalized a rebuttable presumption that long-term care facilities with 20 beds or fewer will be presumed to be VSQGs. The combined impact of these changes is that this final rule will apply to far fewer long-term care facilities than the when the rule was proposed.

In other respects, § 266.501(d) of the final rule remains the same as the proposal. That is, healthcare facilities generating non-creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.502, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.508. And healthcare facilities generating potentially creditable hazardous waste pharmaceuticals would be subject to the management standards in § 266.503, the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, and the shipping standards in § 266.509. Finally, if potentially creditable hazardous wastes are not destined for a reverse distributor, then they must be managed by the healthcare facility as non-creditable hazardous waste pharmaceuticals. For example, if a healthcare facility receives manufacturer credit for a prescription pharmaceutical without shipping it to a reverse distributor, then the healthcare facility is required to manage the hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals.

d. *Comments and responses.* Several commenters asked us to consider making part 266 subpart P an optional alternative to part 262, instead of mandatory. They argued that EPA's previous sector- or waste- specific regulations, such as the Academic Laboratories Rule or Universal Waste, are not mandatory and that generators have the option to use them in lieu of the standard RCRA generator regulations under part 262. On the other hand, several states agreed that having "one set of standards will be less confusing to the regulated community."[180]

[180] See comment numbers: EPA-HQ-RCRA-2007-0932-0242 and EPA-HQ-RCRA-2007-0932-0304.

As discussed previously, part 266 subpart P will be mandatory for all healthcare facilities generating above VSQG monthly quantity thresholds. Previous sector or waste specific regulations have all been considered either less stringent (Universal Waste) or equally stringent (Academic Laboratories rule) as the standard RCRA generator regulations. In contrast, part 266 subpart P is considered, on the whole, more stringent than the standard RCRA regulations. EPA has never made a more stringent RCRA regulation optional. In part, this is because it seems unlikely that anyone would opt into a more stringent regulatory scheme. If healthcare facilities chose to remain operating under part 262, they would not be subject to the sewer prohibition, which is a cornerstone of this new subpart.

Further, if part 266 subpart P were not mandatory, another result would be that healthcare facilities would not be able to use the new provisions for empty containers or the conditional exemptions for hazardous waste pharmaceuticals that are also DEA controlled substances. But the most important consideration is that this final rule revises our previous policy regarding pharmaceuticals being sent to reverse distributors for manufacturer credit such that they are now considered solid, and possibly hazardous, wastes. Under part 262, a generator can only send its hazardous waste to an off-site facility that has a RCRA permit or interim status. This would require reverse distributors to get RCRA storage permits to be able to accept hazardous waste from off-site. In light of all these considerations, with the exception of VSQG healthcare facilities, EPA has concluded that it is not feasible to make part 266 subpart P an optional alternative to part 262.

That said, we recognize that some commenters are concerned that this final rule will impact their established programs for managing hazardous waste pharmaceuticals. In response, we would point out that, in some cases, compliant practices by healthcare facilities under part 262

would also meet the standards under part 266 subpart P. For example, the training provisions for SQGs (§ 262.16(a)(9)(iii)) and LQGs (§ 262.17(a)(7)) would meet the training provisions for healthcare facilities under part 266 subpart P (§ 266.502(b)). In fact, the subpart P regulatory language for training personnel at healthcare facilities in managing non-creditable hazardous waste pharmaceuticals is identical to the regulatory language in part 262 for SQGs. For labeling, under part 266 subpart P, containers of non-creditable hazardous waste pharmaceuticals part 266 subpart must be labeled with the words "hazardous waste pharmaceuticals," but nothing would prohibit additional labeling by the healthcare facility. Likewise, under part 266 subpart P, healthcare facilities are not required to accumulate their non-creditable hazardous waste pharmaceuticals in a central accumulation area (CAA), but nothing would prohibit them from being accumulated in a CAA. Furthermore, healthcare facilities have up to one year to accumulate non-creditable hazardous waste pharmaceuticals on site under part 266 subpart P, but nothing would prohibit a healthcare facility from accumulating for the shorter time-frames dictated by the SQG (180 days) or LQG (90 days) regulations in part 262.

2. Reverse Distributors (§§ 262.10(m), 264.1, 265.1, 266.501(e), and 270.1)

a. *Summary of proposal*. The proposed rulemaking responded to stakeholders who have asked EPA to clarify how reverse distributors are regulated under RCRA, as states have applied varied hazardous waste regulatory approaches to reverse distributors.[181] EPA proposed specific standards in 40 CFR part 266 subpart P for reverse distributors (as defined in this proposed rulemaking) that incorporated various generator standards, as well as some TSDF standards. EPA proposed that reverse distributors that accumulate potentially creditable hazardous waste

[181] Note that the proposed rule used the term "pharmaceutical reverse distributor" but final rule uses the term "reverse distributor;" therefore, the preamble will use the term "reverse distributor," even when discussing the proposed rule.

pharmaceuticals or evaluated hazardous waste pharmaceuticals are subject to this new subpart. We proposed that reverse distributors are only subject to part 266 subpart P for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals; if a reverse distributor also treats and/or disposes of hazardous waste pharmaceuticals, we proposed that it would be subject to the applicable RCRA Subtitle C TSDF regulations, including the requirement to have a permit or interim status. We proposed that all reverse distributors would be regulated the same for the accumulation of hazardous waste pharmaceuticals under part 266 subpart P, including any reverse distributors that would be considered VSQGs under part 262 (see § 262.10(m)). Under the applicability section in § 266.501(e), we proposed that reverse distributors would be subject to the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, the shipping standards in § 266.508 and § 266.509, and the reverse distributor standards in § 266.510, for the management of hazardous waste pharmaceuticals. As with healthcare facilities, if a reverse distributor generates other, non-pharmaceutical hazardous waste, it remains subject to part 262 and all other applicable portions of the Subtitle C regulations (see § 266.501(c)).

b. *Summary of comments*. We received a large number of comments regarding the foundational question of whether the pharmaceuticals going through reverse distribution should be considered solid or hazardous wastes. In section VI of the preamble we have responded thoroughly to that threshold question; therefore, we do not elaborate here. We received a few comments on other areas related to the applicability of part 266 subpart P to reverse distributors, which have led to some conforming changes in the final rule.

c. *Final rule provisions.* Other than changing the term "pharmaceutical reverse distributor" to "reverse distributor," we are finalizing the regulatory text of § 262.10(m) and § 266.501(e), as proposed. As a result, all reverse distributors will be subject to part 266 subpart P for the management of their hazardous waste pharmaceuticals instead of part 262. This includes any reverse distributors that would have been considered VSQGs under part 262. This also includes third-party logistics providers (3PLs) when they perform the function of a revere distributor. Reverse distributors and 3PLs acting as reverse distributors do not take ownership of the pharmaceuticals; however, both take physical custody of hazardous waste pharmaceuticals from off-site healthcare facilities and both facilitate the awarding of manufacturer credit for potentially creditable hazardous waste pharmaceuticals.

Under part 266 subpart P, there are no generator categories for the accumulation of hazardous waste pharmaceuticals; all reverse distributors will be regulated the same with respect to the management of their hazardous waste pharmaceuticals, regardless of the quantity. All reverse distributors will be subject to the sewer prohibition in § 266.505, the conditional exemption for hazardous waste pharmaceuticals that are also controlled substances in § 266.506, the empty container standards in § 266.507, the shipping standards in § 266.508 and § 266.509, and the reverse distributor standards in § 266.510, for the management of hazardous waste pharmaceuticals.

d. *Comments and responses.* It is important to note that, although we have not made any substantive changes to the applicability section of the regulations pertaining to reverse distributors, a change we have made to the definition of reverse distributor has effectively made a change to the applicability of the final rule. Under the final rule, the term "reverse distributor" has been narrowed considerably, so that it only includes reverse distributors of prescription

pharmaceuticals. This change has been described and explained thoroughly in previous sections of the preamble and will be discussed here only briefly. In short, under the proposed rulemaking, the term "pharmaceutical reverse distributor" included facilities that facilitated manufacturer credit for both prescription and nonprescription pharmaceuticals (e.g., OTCs and dietary supplements). In this final rule, we have adopted the distinction drawn by commenters between reverse distributors, who manage prescription pharmaceuticals, and reverse logistics centers, who manage nonprescription pharmaceuticals (and all other, non-pharmaceutical retail items). While reverse distributors are regulated by part 266 subpart P, reverse logistics centers are not regulated by part 266 subpart P.

Additionally, we have made several conforming changes to §§ 264.1, 265.1 and 270.1. Specifically, we added paragraphs §§ 264.1(g)(13), 265.1(c)(16), and 270.1(c)(2)(x). Together, these paragraphs make it clear that reverse distributors complying with the conditions for accumulating hazardous waste pharmaceuticals under part 266 subpart P are not required to operate under the regulations for permitted TSDFs in part 264 or interim status TSDFs in part 265; nor are they required to get a RCRA permit under part 270.

3. Very Small Quantity Generators (§§ 266.501(a) and (b))

a. *Summary of proposal.* VSQGs are subject to a limited set of federal RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 262.14.[182] We proposed that subpart P would preserve this current regulatory structure for the most part, such that healthcare facilities that generate hazardous waste pharmaceuticals and qualify as VSQGs would maintain their conditional exemption under § 262.14 and would not be

[182] Not all authorized states recognize the VSQG (or CESGQ) category and may have more stringent regulatory requirements for VSQGs. Therefore, as noted previously, EPA recommends that facilities that qualify as VSQGs under the federal regulations contact their state and/or local environmental regulatory agencies to determine whether more stringent regulatory requirements apply to VSQGs in their state.

subject to *most* aspects of the proposal. However, as part of this rulemaking, EPA proposed a prohibition on sewer disposal of hazardous waste pharmaceuticals by all healthcare facilities, including VSQG healthcare facilities (and all reverse distributors). (See section XIII of this preamble for a more detailed discussion on the sewer prohibition.) We also proposed that healthcare facilities that are VSQGs would be able to use the standards in § 266.504 for the management of their hazardous waste pharmaceuticals, as well as the standards in § 266.507 for determining when their containers of pharmaceutical are considered empty (See sections XII and XV for detailed discussion of those sections of the regulations). We also proposed that VSQG healthcare facilities would have the ability to opt into using part 266 subpart P in lieu of the conditional exemption in § 262.14.

b. *Summary of comments.* Many of the comments on the applicability section for VSQG healthcare facilities were related to whether EPA should maintain the conditional exemption for VSQG healthcare facilities or whether we should make them fully subject to subpart P. Several commenters urged us to be clearer in our regulatory language and preamble about how a healthcare facility determines whether it is a VSQG or not. Although this section will address this area of confusion, see section IX.C of the preamble for additional information about not counting hazardous waste pharmaceuticals toward generator category when they are managed under subpart P.

c. *Final rule provisions.* In the final rule, healthcare facilities that are VSQGs (when counting all their hazardous waste, both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste) remain mostly exempt from part 266 subpart P. Note that all healthcare facilities, including healthcare facilities that are VSQGs, and all reverse distributors are subject to the sewer prohibition of § 266.505.

Healthcare facilities that are VSQGs are also subject to § 266.504 which includes optional provisions specifically for healthcare facilities that are VSQGs for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste. We note that although § 266.501(a) states that VSQGs are subject to § 266.504, all of the provisions in § 266.504 are optional. For example, a healthcare facility that is a VSQG operating under § 262.14 for all of its hazardous waste is not required to send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Rather, we are providing a regulatory mechanism that allows a VSQG healthcare facility to use a reverse distributor to obtain manufacturer credit. Nor is a VSQG healthcare facility required to send its hazardous waste pharmaceuticals off site to be consolidated at another healthcare facility that is operating under subpart P. Again, subpart P provides a regulatory mechanism for those VSQG healthcare facilities that wish to manage their hazardous waste pharmaceuticals in a more environmentally protective manner. A VSQG that elects to use any of the optional provisions of § 266.504 will not be considered to be opting into subpart P. See section XII of the preamble for a further discussion of § 266.504.

Several states asked us to expand the applicability of the final rule so that all of the healthcare facility standards in part 266 subpart P would be mandatory for all healthcare facilities, including VSQGs. For example, Colorado wrote that "…healthcare professionals can be highly mobile across the healthcare industry. As a result, professionals that leave a hospital setting and move to the [long-term care] setting have to relearn a new process for waste management, adding opportunity for more confusion and mismanagement. Colorado strongly encourages EPA to consider regulating all healthcare facilities (including CESQGs) that generate hazardous waste pharmaceuticals under the proposed regulations to minimize confusion and

promote consistency across the entire spectrum of the healthcare industry settings."[183] Although we agree with Colorado, we also believe that it would pose a burden on the large number of small healthcare facilities and divert resources from regulatory agencies to expand the applicability of the final rule to include healthcare facilities that are VSQGs. We have concluded that it would be best to let the individual states that adopt this new subpart to decide whether to expand the applicability to healthcare facilities that are VSQGs.

Additionally, in the final rule we have retained the ability for healthcare facilities that are VSQGs to opt into part 266 subpart P in lieu of operating under § 262.14. A VSQG healthcare facility may choose this option if it does not want to have to keep track of how much hazardous waste pharmaceuticals and acute hazardous waste pharmaceuticals it is generating on a monthly basis or if it generates an unpredictable or fluctuating amount of hazardous waste pharmaceuticals each month that might exceed one or more of the VSGQ monthly quantity thresholds. If a healthcare facility that is a VSQG (counting all of its hazardous waste, including pharmaceuticals and non-pharmaceuticals) chooses to opt into subpart P, it must comply with all the standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals, including notification as a healthcare facility.[184] The VSQG healthcare facility may not selectively pick which provisions of part 266 subpart P it chooses to comply with; it would be treated the same as any other healthcare facility that is subject to part 266 subpart P. More specifically, if a VSQG healthcare facility chooses to opt into subpart P, then it would be subject to all the provisions identified in §

[183] See comment number: EPA-RCRA-HQ-2007-0932-0242.

[184] A VSQG healthcare facility that opts into part 266 subpart P for managing its hazardous waste pharmaceuticals would still have to keep track of its monthly generation of non-pharmaceutical hazardous waste to verify that it is, in fact, a VSQG. Assuming it is a VSQG, the healthcare facility could manage its non-pharmaceutical hazardous waste under § 262.14.

266.501(d) rather than the optional provisions of § 266.504 for VSQGs or § 262.14. The final regulatory language has been amended to be more specific in this regard. That is, rather than saying a healthcare facility has the option of complying with "this subpart," we have changed the regulations to say that a healthcare facility has the option of complying with "§ 266.501(d)," which identifies the specific sections of the regulations that non-VSQG healthcare facilities must comply with. Further, the final regulatory language clarifies that a VSQG healthcare facility that opts into part 266 subpart P would no longer be able to use the optional provisions for VSQG healthcare facilities in § 266.504.

We have made four additional changes to the applicability section of the regulations pertaining to healthcare facilities that are VSQGs. The first two changes are conforming changes to reflect the 2016 Hazardous Waste Generator Improvements final rule; this includes changing the term "conditionally exempt small quantity generator" to "very small quantity generator" and changing the regulatory citation for VSQGs from § 261.5 to § 262.14.

The third change was made to address commenters' concerns that the use of the term VSQG in § 266.501(a) and (b) was confusing. The Generator Improvements final rule has now defined the term VSQG in 260.10, which should help reduce confusion. Nevertheless, in response to the comments, we also have added language to § 266.501(a) and (b) to make it clearer that we are referring to VSQGs that are below the VSQG quantity thresholds for all of their hazardous waste combined—including both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste. Such VSQGs are VSQGs for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste. In large part, VSQGs are not subject to subpart P for the management of their hazardous waste pharmaceuticals (except the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional

standards of § 266.504). This type of VSQG stands in contrast to what might be referred to as a "subpart P VSQG," meaning a healthcare facility that generates over one or more of the VSQG quantity thresholds and is therefore subject to subpart P for its hazardous waste pharmaceuticals but becomes a VSQG for its non-pharmaceutical hazardous waste after complying with subpart P because it is no longer required to count its hazardous waste pharmaceuticals toward its generator category.

The fourth change to § 266.501(a) is to the reference to the new empty container regulations of § 266.507. We proposed in § 266.501(a) that a VSQG would be subject to § 266.507(a) and (b). In both the proposed and final rules, these two paragraphs of § 266.507 define when unit dose containers and dispensing vials, and syringes, respectively, are empty. The purpose of the reference was to allow a healthcare facility to use the new empty container provisions in determining how much hazardous waste pharmaceuticals it generates and therefore whether it is subject to subpart P. Under the final rule, a healthcare facility is still able to use the new empty container provisions in § 266.507 when determining how much hazardous waste pharmaceuticals it generates, but we have concluded that this reference should include all of §266.507, rather than just paragraphs (a) and (b) because § 266.507 (c) and (d) include provisions for determining whether IV bags and other types of containers of hazardous waste pharmaceuticals are empty. Additionally, we have also amended the associated language in § 261.7 which defines when a container of hazardous waste is considered empty. We had already proposed to add a new paragraph (c) to § 261.7 to direct healthcare facilities and reverse distributors to § 266.507. The final rule modifies the proposed paragraph such that the new empty container regulations in § 266.507 are no longer limited to healthcare facilities and reverse distributors operating under part 266 subpart P. Section 266.507 defines when containers of

hazardous waste pharmaceuticals are empty and apply regardless of whether they are being managed by a healthcare facility, a reverse distributor, or another entity. Generators, including healthcare facilities, can use the new provisions in § 266.507 in determining when the containers of hazardous waste pharmaceuticals are empty and the residues are no longer regulated as hazardous waste. In turn, this will help generators determine how much hazardous waste they generate and; therefore, whether they are subject to part 266 subpart P and/or part 262. See section XV of this preamble for further information about § 266.507.

d. *Comments and responses.* A few commenters had suggestions for alternative organization or placement of the applicability section pertaining to healthcare facilities that are VSQGs. One commenter suggested that we combine all of the subpart P regulations that pertain to VSQG healthcare facilities in one place, under § 266.504, rather than have some in § 266.501 and others in § 266.504.[185] We generally agree with the commenter and have included all substantive standards for VSQG healthcare facilities in § 266.504 (see section XII of the preamble for a further discussion of § 266.504). However, we believe that, when discussing the central question of who the subpart applies to, it is best to keep together in § 266.501 all the regulations that address applicability. And since the applicability section of § 266.501 appears before the VSQG healthcare facility standards of § 266.504, we believe that it is more helpful to the reader to know, up front in the regulations, whether the subpart applies. Another commenter thought we should move the entire applicability section so that it appears before the definitions section in the regulations, in order to allow "the reader to determine if [s]ubpart P applies to his facility before reviewing any of its requirements."[186] Although we agree that the applicability section is critical to the reader, we believe that the reader must have a full understanding of terms used in the

[185] See comment number: EPA-HQ-RCRA-2007-0932-0280.
[186] See comment number: EPA-HQ-RCRA-2007-0932-0231.

applicability section in order to accurately determine whether the subpart applies. As a result, we have declined to make this suggested change. We requested comment on whether the applicability section for VSQG healthcare facilities should appear in § 262.14 (formerly § 261.5) rather than in subpart P and a couple of commenters responded that we should.[187] Although that would have been an acceptable option for crafting the new regulations, we have concluded that we prefer the option of keeping the regulatory language related to hazardous waste pharmaceuticals contained within the same subpart when possible. As a result, we have declined to make this suggested change, as well.

B. *What Facilities or Pharmaceuticals Are Not Subject to the Final Rule?* (§§ 266.501(c) and 266.501(f) and 266.501(g))

1. Summary of Proposal

EPA proposed that the new part 266 subpart P management standards would apply only to hazardous waste pharmaceuticals generated or managed by healthcare facilities and reverse distributors. This new subpart was designed as a sector-specific rulemaking to address the unique circumstances of the healthcare sector and the reverse distribution of their hazardous waste pharmaceuticals. In § 266.501(f), we proposed that other entities that generate or manage hazardous waste pharmaceuticals would not be subject to part 266 subpart P, but would remain subject to the standard generator regulations in part 262, along with other applicable Subtitle C regulations. For example, in the preamble to the proposed rulemaking we stated that pharmaceutical manufacturers and wholesalers would remain subject to part 262 generator regulations because they do not face the same challenges that healthcare facilities experience when managing hazardous waste pharmaceuticals. We reasoned that manufacturers and

[187] See comment numbers: EPA-HQ-RCRA-2007-0932-0231 and 0280.

wholesalers generate hazardous waste pharmaceuticals that are more predictable and the staff have the necessary expertise to determine which pharmaceuticals are considered hazardous waste. However, we noted in the proposal that when any facility, including a pharmaceutical manufacturer, meets the definition of a reverse distributor, it would be subject to the new regulations for reverse distributors with respect to those operations.

In § 266.501(c), we also proposed that this new subpart would only apply to the management of hazardous waste pharmaceuticals. The proposed new subpart was sector-specific as well as waste stream-specific. We proposed that other, non-pharmaceutical hazardous wastes generated or managed by healthcare facilities and reverse distributors would remain subject to all applicable hazardous waste regulations.

2. Final Rule Provisions and Comments and Responses

This final rule remains a sector-specific rule as well as a waste stream-specific rule. Accordingly, § 266.501(c) of the final rule remains as proposed. That is, a healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste. Likewise, as discussed previously, a number of commenters requested that we include wholesale distributors in part 266 subpart P as healthcare facilities and in response we have amended the definition of healthcare facility to include wholesale distributors. This, of course, affects which entities are subject to the rule, but as we have made this change through amending the definition of healthcare facility, it does not necessitate a change to § 266.501 of the regulations, which is entitled Applicability. Therefore, the final rule applies to the generation and management of hazardous waste pharmaceuticals only by healthcare facilities and reverse distributors and not to others that might generate or manage hazardous waste pharmaceuticals, such as pharmaceutical manufacturers.

We have added paragraph (g) to § 266.501 of the final rule, substantially expanding the list of types of wastes that are not subject to part 266 subpart P or to RCRA regulation in general. In some cases, the additions grew out of comments and in some cases, the additions grew out the need for additional clarity. Each of the types of waste that are not subject to this subpart are discussed individually below.

a. *Donations.* As discussed previously, we have amended the definition of hazardous waste pharmaceutical to make it clear that a pharmaceutical is not a solid waste, as defined in § 261.2, and therefore, not a hazardous waste, if it is lawfully donated for its intended purpose. We have made the same change to the applicability section of this subpart to similarly indicate that pharmaceuticals are not subject to subpart P when they are lawfully donated for their intended purpose.[188] In fact, because pharmaceuticals that are lawfully donated or are otherwise legitimately used/reused or reclaimed are not solid wastes, as defined by § 261.2, they would not be subject to RCRA at all. Although this is common for nonprescription pharmaceuticals, it is rare for prescription pharmaceuticals. Sirum, a commenter that is a non-profit organization that "helps implement State-based programs to recycle unused medication to indigent patients" in four states, concurred that "repurposing pharmaceuticals happens under narrow circumstances" and that "in most cases, pharmaceuticals transported back to a reverse distributor are discarded by the reverse distributor."[189] State donation and repository laws dictate the conditions under which pharmaceuticals may be donated. These laws are tracked by the National Conference of State Legislatures.[190] EPA would note that, in addition to the state regulations, the FDA has

[188] See 40 CFR 266.501(g)(1).
[189] See comment number EPA-HQ-RCRA-2007-0932-0353.
[190] http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx.

guidelines for the donation of pharmaceuticals for international relief efforts,[191] as does the World Health Organization (WHO).[192]

Sirum is providing a valuable and commendable service and EPA does not wish to impede their operations, which support the waste minimization goal of RCRA. We have amended both the definition of hazardous waste pharmaceutical and the applicability section to clarify that pharmaceuticals that are lawfully donated are not solid or hazardous wastes and therefore are not subject to RCRA, including this subpart. This would include donations to a charity, non-governmental organization, or to a healthcare facility that is participating in a donation or repository program that is authorized by the state. EPA concurs with Sirum that this should act "as an incentive and path forward for socially responsible reverse distributors [and others] to donate rather than destroy pharmaceuticals within the safety of existing state laws that allow for these practices."[193]

b. *Over-the-counter pharmaceuticals going through reverse logistics.* As discussed at length in section VI of the preamble, OTC pharmaceuticals, and other items meeting our definition of pharmaceutical that do not require a prescription, such as dietary supplements, or homeopathic drugs, will only be subject to this subpart when they are discarded by a healthcare facility. OTCs and other nonprescription pharmaceuticals are not considered solid or hazardous wastes when they are sent through reverse logistics for the purpose of determining whether they can be redistributed for their intended purpose or legitimately reused or reclaimed. We have added § 266.501(g)(2) to the applicability section to codify this position regarding OTC pharmaceuticals, dietary supplements and homeopathic drugs.

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[191] See Questions and Answers for the Public Donating Drugs to International Humanitarian Relief Efforts https://www.fda.gov/downloads/newsevents/publichealthfocus/ucm249617.pdf.
[192] http://www.who.int/selection_medicines/emergencies/guidelines_medicine_donations/en/.
[193] See comment number EPA-HQ-RCRA-2007-0932-0353.

c. *Recalled hazardous waste pharmaceuticals.* The Agency initially proposed standards for recalled non-creditable hazardous waste pharmaceuticals at healthcare facilities in § 266.502(g)(3), and for potentially creditable and evaluated hazardous waste pharmaceuticals at reverse distributors in § 266.510(a)(5). The finalized recall provisions for all hazardous waste pharmaceuticals are now in the applicability section in § 266.501(g)(3) and (4).

The Agency proposed that healthcare facilities managing recalled non-creditable hazardous waste pharmaceuticals could request an extension from the EPA Regional Administrator should they need to accumulate them for longer than the allotted one-year period. Likewise, the Agency proposed that reverse distributors managing recalled potentially creditable hazardous waste pharmaceuticals could request an extension from the EPA Regional Administrator should they need to accumulate them for longer than the allotted 90-day period. In the proposed regulations, the reasons for requesting an extension were characterized as "any unforeseen circumstances beyond the control" of the healthcare facility or reverse distributor. In the proposed preamble, we gave the specific examples of recalls and litigation as circumstances that are the beyond the control of the healthcare facility or reverse distributor, which could require longer accumulation than the proposed time frames. The proposed provision in both sections required that an extension request be sent in writing (electronic or paper) to the EPA Regional Administrator explaining the need for the extension, the approximate amount of hazardous waste pharmaceuticals accumulated beyond the corresponding time period, and the amount of extra time requested. The Agency also proposed to allow the Regional Administrator discretion to grant, modify, or deny extension requests on a case-by-case basis. Lastly, the Agency solicited comment on the proposed mechanism to request a time extension.

The proposed recall provisions only applied to hazardous waste pharmaceuticals that had limited accumulation times, i.e., non-creditable hazardous waste pharmaceuticals at healthcare facilities, and potentially creditable and evaluated hazardous waste pharmaceuticals at reverse distributors. The finalized recall provisions, however, apply to all recalled hazardous waste pharmaceuticals.

These proposed extension provisions were opposed by many commenters from both industry and state governments. Industry commenters were concerned about the additional burden that would arise from having to generate, transmit, and maintain an additional set of records every time they would need to request an extension of the accumulation time period. The commenters suggested that these situations occur more often than EPA indicated in the proposal. Similarly, many state agencies were concerned about the added burden imposed on them by requiring notifications that must be processed, analyzed, afforded appropriate consideration, and responded to. In addition, many commenters mentioned the possibility that these provisions would conflict with other federal oversight authorities, in particular, recalls overseen by the FDA and CPSC. Commenters were also wary of the discretion these proposed provisions afforded the Regional Administrator to grant extensions, primarily due to the lack of a mechanism to coordinate those extensions with other agencies that might require longer accumulation times. Commenters were concerned this would likely lead to a scenario in which the EPA Regional Administrator does not grant sufficient accumulation time needed to comply with other federal requirements for recalls.

To address these adverse comments, the Agency has modified the final rule. The modifications also address the fact that the duration of a recall is highly variable, making it unreasonable to prescribe a specific time frame for accumulation. The Agency is finalizing

provisions to ensure that recalled hazardous waste pharmaceuticals are properly managed without imposing requirements that are superfluous or conflict with other federal regulations and procedures.

In an effort to avoid overreach and potentially overlapping regulations, the Agency consulted with FDA and CPSC to better understand their procedures and policies in regulating and overseeing recalls of OTC and prescription pharmaceuticals. We learned that almost all pharmaceutical recalls are overseen by FDA, however, CPSC occasionally oversees a recall if an item's packaging does not comply with special (also called child resistant) packaging requirements. We also learned that third-party companies (typically reverse distributors, as defined in subpart P) serve as recall facilitators contracted by the manufacturer of the recalled item, to provide recall logistics such as aggregating recalled items, tracking recall progress, and making disposition determinations. Nearly all pharmaceuticals sent to a recall facilitator as part of a recall are ultimately destroyed. However, in some cases, the content of a recalled item is reclaimed and put back into commerce. For example, if the outer packaging has incorrect information, the manufacturer may choose to place the contents in updated packaging so they can be lawfully sold.

Although retailers are not permitted to sell a pharmaceutical that is subject to a CPSC recall, participation in a recall is not compulsory on the part of every consignee (entity that has purchased those items), which means that there is no way to compel participation, whether the recall is voluntary or federally mandated. The Agency had considered taking the position that all pharmaceuticals subject to a recall are waste when the recall is issued. However, because some recalled pharmaceuticals have the potential to be legitimately used/reused or reclaimed, combined with the fact that they sometimes can be lawfully dispensed by the consignee (but not

sold by a retailer), we concluded that pharmaceuticals subject to a recall do not necessarily become waste simply by virtue of being subject to that recall.

Although many pharmaceuticals being sent by a healthcare facility to a recall facilitator as part of a recall could be considered solid waste, the Agency has determined that the combination of regulations, guidance and/or oversight provided by FDA and CPSC is sufficiently protective of human health and the environment while pharmaceuticals are subject to a recall. Therefore, EPA is choosing not to apply RCRA regulations on hazardous waste pharmaceuticals that are subject to a voluntary or federally-mandated recall until the decision is made to send some or all items for destruction (see below for further discussion).

EPA is not attaching any requirements to recalled hazardous waste pharmaceuticals while subject to a recall. In the final rule, healthcare facilities and reverse distributors will not be required to request an extension of the accumulation time period for recalled non-creditable hazardous waste pharmaceuticals or potentially creditable hazardous waste pharmaceuticals as proposed. This decision is also responsive to commenters who were concerned about having to operate under multiple and possibly conflicting federal regulatory schemes. It is also worth noting again that FDA and CPSC are the only federal agencies that regulate recalled pharmaceuticals and special packaging for pharmaceuticals, respectively.

When a pharmaceutical recall is initiated, the manufacturer must develop, and the corresponding agency must accept, a recall strategy which outlines all of the actions to be taken on behalf of the manufacturer from start to finish. A disposition determination is a required component of a comprehensive recall strategy. It is EPA's understanding that items being managed under an FDA or CPSC recall may be periodically sent for destruction as part of the disposition strategy (other disposition options allowed by FDA and CPSC can include

redirection, and in rare circumstances, reconditioning). It is at this point (upon the decision to send some or all of the recalled pharmaceuticals for destruction) that the Agency will apply RCRA regulations these hazardous waste pharmaceuticals.

Any recalled pharmaceutical that is sent for destruction as part of the disposition strategy and is a RCRA hazardous waste, must be managed according to RCRA Subtitle C and any applicable provisions of this new subpart. This strategy is also in line with FDA and CPSC recall procedures in that they both specify that items being sent for destruction must comply with other applicable state, local and federal regulations, which may include DOT's Hazardous Material Regulations (HMR) and RCRA. In other words, this rule maintains the framework that any entity sending recalled items for destruction under a FDA or CPSC recall must comply with RCRA regulations but imposes these new subpart P regulations at the point at which RCRA regulations already applied in lieu of the generator regulations in 40 CFR part 262.

d. *Preservation orders, investigations, and judicial proceedings.* In addition to recalls, the proposed rulemaking included litigation holds as an example of a circumstance that is beyond the control of a healthcare facility or reverse distributor, which would be a valid reason to request an extension of the accumulation period. Similar to the proposed standards for recalled hazardous waste pharmaceuticals, the standards for hazardous waste pharmaceuticals under litigation holds were also included in § 266.502(f)(3) for non-creditable hazardous waste pharmaceuticals at healthcare facilities, and in § 266.510(a)(5) for potentially creditable and evaluated hazardous waste pharmaceuticals at reverse distributors. As with recalls, we have moved the section of the regulations that addressed accumulation time extensions for litigation holds out of the healthcare facility standards and reverse distributor standards and into the applicability section of § 266.501(g)(5). The final rule also uses terminology that is more encompassing than just litigation

holds, such that we are choosing not to apply RCRA regulations on hazardous waste pharmaceuticals that are being held pursuant to preservation orders, investigations, and judicial proceedings (which would include litigation holds).[194] Accordingly, the hazardous waste pharmaceuticals under a preservation order, investigation, or judicial proceeding are not subject to part 266 subpart P until after the preservation order, investigation or judicial proceeding has concluded and/or a decision is made to discard the hazardous waste pharmaceuticals. As with recalled hazardous waste pharmaceuticals, the final rule no longer requires healthcare facilities and reverse distributors to request an extension of the accumulation time period for hazardous waste pharmaceuticals under a preservation order, investigation, or judicial proceeding, as was originally proposed.

Some commenters were concerned that the Agency had proposed that any item under a preservation order, investigation, or judicial proceeding would be considered waste. We would like to emphasize that non-waste hazardous pharmaceuticals do not automatically become a waste upon being directed to participate in a preservation order.

The Agency has determined that any pharmaceuticals that were, prior to a preservation order, investigation, or judicial proceeding, determined to be waste, are not subject to RCRA when under the preservation order, investigation, or judicial proceeding. The Agency believes that sufficient protections are in place to be duly protective of human health and the environment while the preservation order, investigation, or judicial proceeding is ongoing. In addition, the extreme variability and multijurisdictional nature of judicial actions and Agency investigations make it impractical to impose RCRA standards while a corresponding preservation order,

[194] See the following three memos: (1) June 23, 2017, from Johnson to Regional RCRA Division Directors, RCRA Online #14893; (2) August 11, 1988, from Lowrance to McGuire, RCRA Online #11363; and (3) January 6, 2014, from Devlin to Mitlo, RCRA Online #14881.

investigation, or judicial proceeding is ongoing. When lifted—for any portion or the entire complement of items—a new waste determination must be made. The location at which the waste determination is made will be the new point of generation. If the items are ultimately determined to be hazardous waste pharmaceuticals, all applicable standards in this subpart apply and the time frames for accumulation, inventory, etc., begin anew.

e. *Investigational drugs.* Similar to recalls, FDA has specific regulations pertaining to investigational new drugs, including that an investigational new drug application must be developed and approved by FDA, in accordance with 21 CFR part 312. These regulations include a requirement that "The sponsor shall assure the return of all unused supplies of the investigational drug from each individual investigator whose participation in the investigation is discontinued or terminated. The sponsor may authorize alternative disposition of unused supplies of the investigational drug provided this alternative disposition does not expose humans to risks from the drug."[195] Because FDA requires these investigational drugs to be returned to the sponsor of the new drug application, EPA would not consider these returned investigational new drugs to be solid wastes and therefore, they would not be subject to RCRA, including this subpart. However, when a decision is made to discard the investigational new drug, or when the FDA approves the destruction of the investigational new drug, at that point it would be considered a solid waste, and if it is a hazardous waste, then it would be subject to subpart P, if the investigational new drug is discarded by a healthcare facility or a reverse distributor. However, typically, investigational new drugs that are part of a clinical trial are returned to the manufacturer at the conclusion of the clinical trial. In that case, if the investigational new drug is discarded by a manufacturer, then it would be subject to part 262, not part 266 subpart P. We

[195] See 21 CFR 312.59.

have added § 266.501(g)(6) to carve out investigational new drugs for which an investigational new drug application is in effect in accordance with the FDA regulations in 21 CFR part 312. But we have also included a sentence to make it clear that, when the decision of discard has been made, the investigational new drug is subject to subpart P, if it meets the definition of hazardous waste and it is discarded by a healthcare facility or a reverse distributor.

f. *Household pharmaceuticals.* In the proposed rulemaking, we indicated that pharmaceuticals from households would continue to be excluded as household hazardous waste under § 261.4(b)(1). However, this was only a discussion in the preamble, we did not include regulatory language in part 266 subpart P. Additionally, we proposed a conditional exemption for collected household pharmaceuticals in § 266.507. For added clarity in the final rule, we have included in the applicability section a new paragraph § 266.501(g)(7). This paragraph indicates that household waste pharmaceuticals are not regulated under part 266 subpart P or other RCRA regulations. A household waste pharmaceutical is defined as a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1). This exclusion is for the residential generator of the household waste pharmaceuticals, as well as the collection and disposal of the residential trash as municipal solid waste.

As discussed later in this preamble, we are finalizing a conditional exemption in § 266.506(a)(2) for household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration). To remain exempt as household waste pharmaceuticals, these collected pharmaceuticals may not be sewered and have to be

destroyed by a method that the Drug Enforcement Administration has publicly deemed in writing to meet their non-retrievable standard of destruction, or combusted at one of the types of combustors identified in § 266.506(b). We have included in the applicability section in § 266.501(g)(7) references to the conditional exemption in § 266.506(a)(2) and the conditions in § 266.506(b) to clarify that household waste pharmaceuticals that are collected as part of a take-back event or program are distinct and different from those that are not part of a collection program. That is, when discarded directly at a residence, the household waste pharmaceuticals remain excluded as household hazardous waste, without any conditions; however, when the household waste pharmaceuticals are collected in a take-back event or program, they must be destroyed in accordance with the conditions in § 266.506 to remain exempt. See section XIV of this preamble for a more detailed discussion of the conditional exemption for household waste pharmaceuticals that are collected in a take-back event or program.

C. *Do Not Count Hazardous Waste Pharmaceuticals Managed Under Subpart P Toward Determining Generator Category* (§§ 262.13(c)(9))

1. Summary of Proposal

EPA proposed that hazardous waste pharmaceuticals that are managed under part 266 subpart P are not required to be counted in determining a facility's hazardous waste generator category under part 262. There were two primary reasons this provision was proposed. First, we received support for this provision when we initially proposed it as part of the 2008 proposal to add pharmaceuticals to the Universal Waste program. Second, and more importantly, under part 266 subpart P, there are no generator categories; therefore, it is not necessary to know the quantity of hazardous waste pharmaceuticals being generated. EPA emphasized that a healthcare facility must be managing its hazardous waste pharmaceuticals under subpart P in order to have

the benefit of not counting them towards its generator category (see section XIX for further discussion).

2. Summary of Comments

There was widespread support among commenters for this proposed provision. However, a number of the commenters expressed some confusion and asked for further explanation and clarity regarding the effect this may have on determining a facility's hazardous waste generator category.

3. Final Rule Provisions

We are finalizing this provision with a minor edit. Additionally, the provision is now in a different place in the final regulations. First, the minor edit was made in response to Connecticut Depart of Energy and Environmental Protection's (CT DEEP) objection to the phrasing of the proposed regulatory language. Specifically, CT DEEP thought the phrase "managed under 40 CFR part 266 subpart P" could lead to confusion if a healthcare facility was operating under part 266 subpart P, but was not in full compliance with part 266 subpart P and whether that would be considered to be "managed under 40 CFR part 266 subpart P."[196] In response, and to avoid this potential area of confusion, we have changed the regulatory language so that "a hazardous waste pharmaceutical *subject to* or managed in accordance with 40 CFR part 266 subpart P" does not have to be counted toward determining a facility's generator category. The second change is a conforming change necessitated by the reorganization of the generator regulations in the 2016 Hazardous Waste Generator Improvements final rule. The list of hazardous wastes that do not have to be counted toward generator category had been listed in § 261.5(c), but when the Hazardous Waste Generator Improvements final rule reorganized the generator regulations, this

[196] See comment number: EPA-HQ-RCRA-2007-0932-0341.

list was moved to § 262.13(c). Under this final rule, hazardous waste pharmaceuticals that are subject to part 266 subpart P do not have to be counted toward determining a facility's generator category. This provision now appears in § 262.13(c)(9). Finally, for clarity we have added that the hazardous waste pharmaceuticals that are also DEA controlled substances and are conditionally exempt under § 266.506, do not have to be counted toward determining generator category.

4. Comments and Responses

Several commenters asked us to clarify when a healthcare facility does and does not count its hazardous waste pharmaceuticals toward determining a facility's generator category. A healthcare facility must count all of its hazardous waste—including hazardous waste pharmaceuticals—to determine whether it is subject to part 266 subpart P. If a healthcare facility generates below all of the VSQG monthly quantity limits, then it remains subject to § 262.14 for all of its hazardous waste and it is not subject to subpart P for its hazardous waste pharmaceutical, except for the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional provisions of § 266.504. On the other hand, if a healthcare facility generates above any of the VSQG monthly quantity limits, then the healthcare facility is subject to subpart P for its hazardous waste pharmaceuticals. But since subpart P is only for the management of hazardous waste pharmaceuticals, the healthcare facility remains subject to part 262 for its non-pharmaceutical hazardous waste.

The next step is for the healthcare facility to determine its new generator category under part 262 so it knows how to manage its non-pharmaceutical hazardous waste. At this point, a healthcare facility does not need to count its hazardous waste pharmaceuticals in determining its generator category for its non-pharmaceutical hazardous waste. EPA continues to emphasize that

a healthcare facility must be managing its hazardous waste pharmaceuticals under subpart P in order to have the benefit of not counting them towards its generator category. Put another way, a healthcare facility managing its hazardous waste pharmaceuticals under subpart P does not have a generator category for the hazardous waste pharmaceuticals, but it will be a VSQG, SQG or LQG for its non-pharmaceutical hazardous waste.

When a healthcare facility that manages its hazardous waste pharmaceuticals under subpart P no longer counts the hazardous waste pharmaceuticals to determine its part 262 generator category, the healthcare facility may experience a change in RCRA generator category for its non-pharmaceutical hazardous waste. For example, a healthcare facility may shift from being an LQG to an SQG or even VSQG by not counting its hazardous waste pharmaceuticals toward its generator category, especially when acute hazardous waste pharmaceuticals such as warfarin (brand name: Coumadin) no longer need to be counted. A shift in generator category, should it occur, would allow a healthcare facility to manage its non-pharmaceutical hazardous waste, such as hazardous waste from laboratories, according to the reduced part 262 generator regulations for a smaller category.

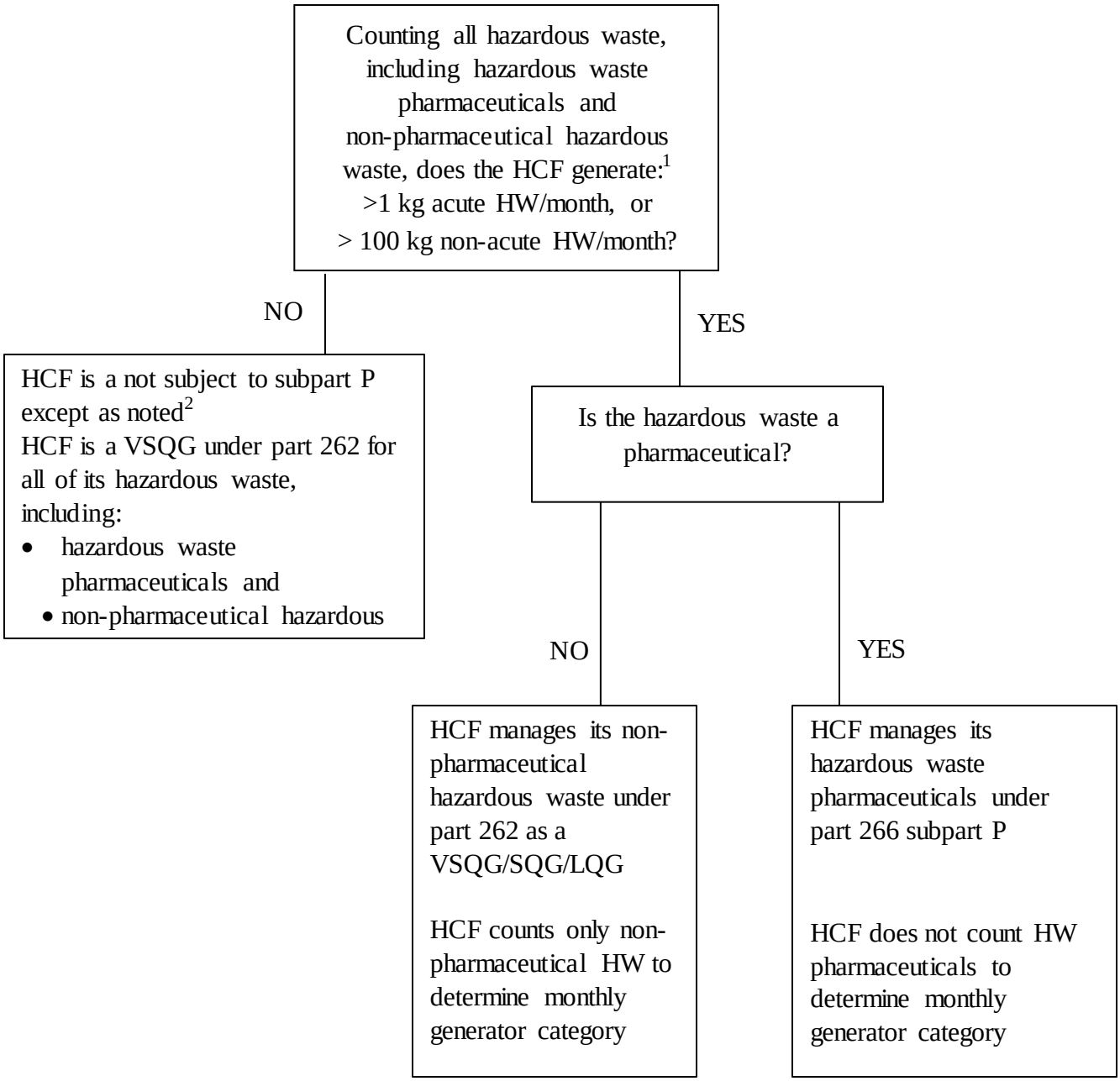
For reverse distributors, it works somewhat differently than with healthcare facilities, because all reverse distributors are subject to part 266 subpart P for the management of their hazardous waste pharmaceuticals, including reverse distributors that are VSQGs. In other respects, the regulations work the same, because reverse distributors also are not required to count their hazardous waste pharmaceuticals when determining their part 262 generator category for their non-pharmaceutical hazardous waste.

Again, we emphasize, such dropping down in generator category only pertains to non-pharmaceutical hazardous waste and is only possible when the hazardous waste pharmaceuticals

are being managed under subpart P. Further, EPA points out that universal wastes also are not counted toward a facility's generator category and what we are finalizing for hazardous waste pharmaceuticals has been implemented successfully for years within the universal waste program for facilities that generate both universal waste and other hazardous waste.

Below are a diagram and a table to help summarize the preceding sections of the preamble related to the applicability of the final rule and the provision that allows a healthcare facility or a reverse distributor to not count hazardous waste pharmaceuticals when determining the facility's generator category for its non-pharmaceutical hazardous waste.

Diagram 1: When is a Healthcare Facility Subject to Part 266 Subpart P?



HW = Hazardous Waste HCF = Healthcare Facility RD = Reverse Distributor Rx = Prescription

[1] Non-Rx pharmaceuticals are not solid or hazardous waste if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed. Reverse logistics facilities are subject to the generator standards in part 262.

[2] All VSQGs are subject to the sewer prohibition of § 266.505 and the empty container standards of § 266.507, and can use the optional provisions of § 266.504.

Table 2: Applicability of Subpart P and Part 262 Generator Category for Healthcare Facilities

Hazardous Waste Pharmaceutical			Non-Pharmaceutical Hazardous Waste		Total Hazardous Waste		Part 266 Subpart P?	Part 262 Generator Category of Healthcare Facility		
Acute	**Non-Acute**		**Acute**	**Non-Acute**	**Acute**	**Non-Acute**		**LQG**	**SQG**	**VSQG**
Any amount		and	>1 kg and/or ≥1000 kg		>1 kg and/or ≥1000 kg		Yes	✓		
Any amount		and	≤1 kg and >100 and <1000 kg		≤1 kg and >100 and <1000 kg		Yes		✓	
>1 kg and/or >100 kg		and	≤1 kg and ≤100 kg		>1 kg and/or >100 kg		Yes			✓[2]
≤1 kg and ≤100 kg		and	≤1 kg and ≤100 kg		>1 kg and/or >100 kg		Yes			✓[2]
≤1 kg and ≤100 kg		and	≤1 kg and ≤100 kg		≤1 kg and ≤100 kg		No[1]			✓[3]
Long-Term Care Facilities with ≤ 20 beds							No[1]			✓[4]

[1] All VSQGs healthcare facilities are subject to the sewer prohibition of § 266.505, and the empty container standards of § 266.507, and can use the optional provisions in § 266.504

[2] VSQGs for non-pharmaceutical hazardous waste only ("subpart P VSQG")

[3] VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste

[4] Presumed to be a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste

X. Standards for Healthcare Facilities that Manage Non-creditable Hazardous Waste Pharmaceuticals (§ 266.502)

A. Notification/Withdrawal Requirements for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals (§ 266.502(a))

1. Summary of Proposal

To address commenters' concerns from the 2008 Pharmaceutical Universal Waste proposal that regulatory agencies are unaware of hazardous waste pharmaceutical management activities, EPA proposed to require that a healthcare facility that does not qualify as a VSQG to submit a one-time notification as a ''healthcare facility'' to the appropriate EPA Regional Administrator. EPA proposed that healthcare facilities subject to 40 CFR part 266 subpart P will have to submit a notification even if the healthcare facility has previously obtained an EPA identification number. The required notification was meant to enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals subject to the 40 CFR part 266 subpart P requirements.

At any point, a healthcare facility's hazardous waste pharmaceutical generation may change due to waste minimization efforts or other reasons, causing the facility to legitimately decrease its total monthly hazardous waste generation enough to qualify as a VSQG. In this case, if the healthcare facility withdraws from the 40 CFR part 266 subpart P requirements due to qualifying as a VSQG, EPA proposed that the healthcare facility must re-notify EPA of its choice to withdraw.

Alternatively, if a healthcare facility determines that it is a VSQG, but does not want to keep track of the amount of hazardous waste pharmaceuticals it generates and whether it is above or below the VSQG threshold, we proposed that it can choose to operate under subpart P. By

choosing to operate under subpart P, the VSQG healthcare facility must comply with all of the requirements, including the one-time notification that it is operating under 40 CFR part 266 subpart P. We proposed that healthcare facilities that are not VSQGs, however, are required to operate under 40 CFR part 266 subpart P for the management of their hazardous waste pharmaceuticals.

The Agency proposed that this notification occur using the RCRA Subtitle C Site Identification Form (EPA Form 8700-12; or Site Identification Form). EPA believes that notification via the Site Identification Form is the preferred approach for notification purposes for several reasons. First, both state environmental regulatory agencies and hazardous waste generators are familiar with the form, as it is the form currently used by hazardous waste generators to notify regulators of their RCRA Subtitle C activities. Second, as stated previously, the use of the Site Identification Form will allow for EPA and state regulatory agencies to monitor the healthcare facilities utilizing the new regulatory requirements. Lastly, public comments received on previous EPA actions (e.g., Academic Laboratories Rulemaking (73 FR 72912; December 1, 2008)) have indicated that notification via the Site Identification Form is the notification approach typically preferred by the regulated community. We proposed that healthcare facilities can submit their notification as part of the Biennial Report, if the healthcare facility will be required to submit a Biennial Report due to its non-pharmaceutical hazardous waste. This was intended to take advantage of an existing reporting mechanism for LQGs or other generators already required to submit the Biennial Report and avoid duplicative notification requirements. Otherwise, healthcare facilities are required to notify within 60 days of this new subpart becoming effective, or within 60 days of becoming subject to this new subpart.

We also proposed that a healthcare facility would have to keep a record of its notification as long as it is subject to this subpart.

The Agency did not anticipate that the proposed notification requirement would place any undue economic burden upon healthcare facilities or the environmental regulatory agencies that process these notifications (see the Regulatory Impact Analysis for the proposed rulemaking in the rulemaking docket EPA–HQ–RCRA–2007–0932). In fact, under the proposed regulations, healthcare facilities would no longer need to count the hazardous waste pharmaceuticals managed under 40 CFR part 266 subpart P towards a healthcare facility's generator category. As a result, EPA anticipates that many healthcare facilities will reduce their generator category to either an SQG or VSQG for their other non-pharmaceutical hazardous wastes. So, while the notification requirement ensures that the environmental regulatory agencies are informed of all hazardous waste pharmaceutical management activities subject to the 40 CFR part 266 subpart P requirements, the fact that some healthcare facilities will no longer qualify as LQGs will reduce the number of healthcare facilities in the LQG universe.

The Agency solicited comment on the notification requirement for healthcare facilities, the method of notification via the Site Identification Form, and whether this notification requirement will result in any undue burden to either healthcare facilities or state environmental regulatory agencies.

2. Summary of Comments

While there was general support for requiring healthcare facilities to notify the EPA Regional Administrator that they are operating under this subpart, a number of states and industry commenters provided opposition to the proposed 60-day time frame. States supported notification but were concerned that they would not be able to process all of the notifications in a

timely manner given that all VSQG and SQG facilities operating under subpart P would have to notify within 60 days of the effective date of this rule. One suggestion was to instead require notification on a rolling or staggered basis to give resource-limited states enough time to process the notices within a timely manner.

States also voiced concern about the provision allowing healthcare facilities that are LQGs because of their non-pharmaceutical waste to notify as part of their normal Biennial Reporting schedule.[197] Depending on the timing of the Final Rule, states were concerned about the possibility that LQGs would not have to notify that they are operating under this subpart for up to two years, during the course of which they could be generating large amounts of pharmaceutical waste and managing it under the reduced restrictions of this subpart unbeknownst to the state or EPA. Meanwhile VSQGs and SQGs would have to notify within 60 days.[198] Another state recommended that healthcare facilities be required to list on the notification what their generator category would be if they were to count their pharmaceutical waste. The state was concerned that a healthcare facility could be generating LQG amounts of pharmaceutical waste but because they are now VSQGs, would be a much lower inspection priority.[199]

There was, however, no opposition to the provision that a healthcare facility be required to maintain a copy of its notification on file as long as it is subject to this subpart.

3. Final Rule Provisions

EPA is finalizing the notification provisions for healthcare facilities managing non-creditable hazardous waste pharmaceuticals as proposed, with no changes.

[197] §262.18(d)(2) requires LQGs to renotify EPA by March 1 of each even-numbered year thereafter using EPA Form 8700–12. An LQG may submit this renotification as part of its Biennial Report required under § 262.41.
[198] EPA-HQ-RCRA-2007-0932-0341
[199] EPA-HQ-RCRA-2007-0932-0235

All healthcare facilities as defined in § 266.500 that are subject to the requirements of this subpart (all healthcare facilities that generate above the VSQG thresholds and healthcare facilities that are VSQGs choosing to operate under this subpart) will have to submit a notification to the EPA Regional Administrator using the Site ID Form (EPA Form 8700-12) stating that they are a healthcare facility and will be operating under this subpart. A healthcare facility that already has an EPA Identification Number must re-notify the EPA Regional Administrator that it will be operating under this subpart within 60 days of becoming subject to subpart P. Healthcare facilities that do not have an EPA Identification Number will be required to obtain one by submitting the Site Identification Form (EPA Form 8700-12) within 60 days from the effective date of this rule if they are not otherwise required to submit Biennial Reports. A healthcare facility that undergoes a change in generator category causing them to become subject to the requirements of this subpart must notify the EPA Regional Administrator within 60 days of the event that triggered the change in generator category.

Healthcare facilities that are LQGs for their non-pharmaceutical hazardous waste, and therefore must submit a Biennial Report, may notify the EPA Regional Administrator according to their normal reporting cycle. SQGs that are required by their state to submit a Biennial Report may also notify EPA that they are operating under subpart P on their normal reporting cycle. Healthcare facilities that are required to submit a Biennial Report are not, however, required to wait to notify EPA that they are operating under subpart P on their Biennial Report, and may notify EPA at any point prior to submitting the Biennial Report. The Agency notes that any healthcare facility that is required to operate under subpart P must begin complying with its requirements as soon as the final rule becomes effective. VSQGs that opt into subpart P may notify the EPA whenever they choose, but they become subject to the requirements of this

subpart on the date they submit the notification. All healthcare facilities must retain a copy of the notification as long as they are operating under this subpart.

4. Comments and Responses

Some states were concerned about their ability to process notifications in a timely manner given the 60-day time frame after the effective date of this rule within which all non-LQG healthcare facilities must notify EPA that they are operating under this subpart. The Agency reasserts, however, that the added burden is reasonable and necessary for the Agency and implementing states to gain a timely understanding of the facilities within the universe of this rule.

The Agency also notes that this final rule goes into effect six months from the date it is published in the Federal Register in EPA Territories and states that do not have an authorized RCRA program. That time frame could be even longer in authorized states which must first adopt this rule for it to become effective. Therefore, healthcare facilities in all states have a minimum of six months from the day this rule is published in the federal register, plus the 60 days in this requirement, to notify their state that they are operating under this subpart.

One commenter suggested that the agency implement a staggered roll-out of this notification provision to prevent them from becoming inundated with incoming notifications, preventing them from processing notifications in a timely manner. The Agency would note, however, that there is no provision requiring a healthcare facility to receive approval before it can operate under this subpart and states and regions can process the notifications by whatever time frames and methods they choose. All healthcare facilities must operate under this subpart immediately upon becoming subject to this rule. Therefore, as long as a healthcare facility that does not submit a BR notifies its state within 60 days that it is operating under this subpart, it

will be in compliance. In addition, we did not propose and are not finalizing any time frames within which regional or state offices must process notifications, therefore, we defer to those agencies to develop their own best practices.

Another state suggested that EPA develop a "smart-form" tool for RCRAInfo—EPA's database of RCRA-related information from required reporting— that would allow healthcare facilities to notify the state electronically that they are operating under subpart P, directly input their own information, and update their information on a regular basis. EPA notes that it has developed an online tool called myRCRAid which allows generators to complete and submit the Site Identification Form electronically, which the Agency expects will reduce states' administrative burden by reducing the number of notifications that have to be manually input, while simultaneously reducing the potential for error while transferring data.

In addition, the Site Identification Form will be modified by EPA in a separate action to add a section for a healthcare facility to indicate that it generates hazardous waste pharmaceuticals. The healthcare facility will no longer be required to identify on the Site Identification Form the specific types of hazardous waste pharmaceuticals it generates. The Agency also intends to add a checkbox to the new section which will allow a healthcare facility to indicate that its generator category is changing to a VSQG and it is no longer managing its hazardous waste pharmaceuticals according to 40 CFR part 266 subpart P.

Some states disagreed with the provision that allows healthcare facilities that file a BR to notify EPA that they are operating under subpart P on their normal reporting schedule, as opposed to notifying within 60 days of this rule becoming effective, or becoming subject to subpart P. This means that healthcare facilities that file a BR could potentially operate under this subpart for up to two years without having to notifying the Agency, depending on when their

normal BR date falls in relation to the effective date of this rule. They recommended that all facilities, regardless of generator category, be required to notify within 60 days. While the Agency agrees that the possibility for a healthcare facility to operate for up to two years under this subpart without notifying EPA does, in fact, exist, we do not wish to impose duplicative notification requirements.

One state requested that a healthcare facility be required to list on the notification what its generator category would be if it were required to count its hazardous waste pharmaceuticals. They were concerned that some facilities that are LQGs because of their hazardous waste pharmaceuticals would reduce their generator category as a result of this rule, making them a low priority for inspections, even though they could still be generating LQG quantities of pharmaceutical waste. We understand the state's concern, however, making a change like this would not be in line with the goals of this rule to provide streamlined standards. However, options available to the states with similar concerns are adopting more stringent requirements or using historical notifications and Biennial Report data.

B. Personnel Training Requirements for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals (§ 266.502(b))

1. Summary of Proposal

a. Performance-based training standards. EPA believes that the part 262 LQG training regulations are excessive for healthcare personnel who sporadically generate hazardous waste pharmaceuticals at healthcare facilities, but believes it is necessary to have some familiarity with the dangers that hazardous waste pharmaceuticals can pose, making the VSQG training standards insufficient. Therefore, the Agency proposed healthcare facility-specific personnel training requirements that are akin to the training requirements for SQGs and small quantity universal

waste handlers, for all healthcare facilities subject to subpart P. Specifically, we proposed that healthcare facilities managing hazardous waste pharmaceuticals in accordance with subpart P must inform all employees that handle or have responsibility for generating and/or managing hazardous waste pharmaceuticals of the proper handling and emergency procedures appropriate to their responsibilities during normal facility operations and emergencies. We indicated in the preamble to the proposed rulemaking that this training information can be disseminated through verbal communication or through distribution of pamphlets or other documentation. However, a healthcare facility that is an LQG due to its non-pharmaceutical hazardous wastes may choose to continue to use its existing training program as an LQG so as not to have different training programs.

Under part 262 regulations, an LQG healthcare facility had to provide full RCRA training to its personnel involved in the generation and/or management of hazardous waste according to the standards in § 262.17(a)(7). These personnel training requirements include either classroom instruction, on-line training, or on-the-job training in RCRA and require the facility to maintain documentation of that training. On the other hand, before this rule was finalized, under the part 262 regulations, an SQG healthcare facility had to meet a performance-based standard when training personnel involved in the generation and/or management of hazardous waste pharmaceuticals. Specifically, this entailed ensuring ''that all employees are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.''[200] For comparative purposes, healthcare facilities that are considered VSQGs did not have any personnel training requirements under the part 262 regulations. Similarly, SQGs and LQGs, including healthcare facilities, were not required to

[200] § 262.16(b)(9)(iii)

provide RCRA training to personnel that only work in SAAs regulated under § 262.15. That said, healthcare personnel that are involved in the generation of hazardous waste pharmaceuticals must be familiar enough with the pharmaceuticals with which they work to know when they have generated a hazardous waste so that it will be managed in accordance with the RCRA regulations.

b. Documentation of training. Although no regulations were proposed, EPA also sought comment in the preamble to the proposed rulemaking on whether documentation of training is necessary in order to verify compliance with the training requirement.

2. Summary of Comments

a. Performance-based training standards. There were a variety of comments on the proposed training standards, both in support and opposition. Although most states agreed with the assessment that standard LQG regulations would be excessive if applied to healthcare facilities, some wanted EPA to provide more stringent and prescriptive language. Commenters from the waste management industry were also opposed to the proposed performance-based standards for similar reasons.

Pharmacy trade groups generally agreed with the proposed standards, citing the same rationale provided in the preamble of the proposed rulemaking, which states that the variability in waste generated and turnover in employees warrants a performance-based standard, and any subsequent training should be left up the healthcare facility. They stated that most pharmacy staff are trained on proper handling and management of radiation and other pharmaceuticals that can pose significant risks as required by other accreditation and standard-setting agencies and any prescriptive training standards under subpart P would be duplicative.

b. Documentation of training. There were mixed comments on whether to require that a healthcare facility document that its personnel have been trained according to the standards set forth in 40 CFR 266.502(b). All of the states that commented on this issue were supportive of the requirement to document training. These states were mostly concerned with their ability to cite specific violations of the training provisions during inspections. Another state mentioned that many facilities already maintain documentation of training as a best management practice.

Waste management companies also wanted EPA to require healthcare facilities to document that employees have been trained. They argued that the training standards will not have their intended effect if there is no requirement for documentation because healthcare facilities will not feel compelled to comply with them.

Pharmacy trade groups were concerned that requiring documentation of training would result in added burden and generally opposed this provision. They argued that there are a number of standard-setting and accreditation agencies that already require documentation that employees have been trained, and as such, this requirement would be redundant and overly burdensome.

3. Final Rule Provisions

a. Performance-based training standards. EPA is finalizing the performance-based training standards as proposed. A healthcare facility must train employees to the extent that they are thoroughly familiar with the proper handling and emergency procedures relevant to their responsibilities during normal operations and emergencies. The information can be disseminated verbally, via printed materials, or other means. These standards are similar to the training standards for SQGs and small quantity handlers of universal waste.[201,202] The agency feels that these standards provide consistency across generator types and do not impose any added burden

[201] 40 CFR part 262.16 (a)(9)(iii)
[202] 40 CFR part 273.16

on inspection and enforcement actions beyond what is already in place within the Universal Waste program.

b. Documentation of training. EPA has decided not to finalize a standard that would have required healthcare facilities to document that the performance-based training standards have been met. The Agency thinks this requirement would have resulted in an undue increase in the regulatory burden for healthcare facilities. Also, there is no such requirement in the part 262 SQG training requirements or for small quantity handlers of universal waste. The agency feels this approach is consistent with other RCRA regulations and would improve consistency with the Universal Waste program, especially since the requirements for healthcare facilities managing hazardous waste pharmaceuticals were purposefully modeled after the requirements for small quantity handlers of universal waste. The Agency ultimately concluded that, because this approach is sufficient for universal waste, it is also acceptable for hazardous waste pharmaceuticals.

4. Comments and Responses

a. Performance-based training standard. There were a number of commenters from states and the waste management industry that recommended more rigorous and prescriptive training standards such as more specific minimum requirements, recurring training, and that the Agency specify the job titles subject to the training requirements. The Agency is not finalizing any of these recommendations, however, because we believe that the proposed performance-based standards are protective of human health and the environment without imposing undue burden either on states or industry. These standards strike an appropriate balance between ensuring proper management of hazardous waste pharmaceuticals and reducing the regulatory burden on

healthcare facilities and healthcare personnel in a manner that also encourages compliance with these new regulations.

One commenter mentioned that prescriptive RCRA training requirements would be duplicative given the training requirements of the various accreditation entities. The Agency responds that any waste management training for healthcare personnel would not be duplicative because accreditation training typically focusses on managing pharmaceuticals prior to becoming a waste, whereas the training required in subpart P is targeted specifically at management practices after the pharmaceuticals have become waste. As mentioned previously, the Agency is not finalizing prescriptive training standards in an effort to minimize regulatory burden and allow healthcare facilities to tailor their training programs in a way that best fits their circumstances.

These training standards apply only to healthcare personnel. Healthcare personnel includes any person that manages hazardous waste pharmaceuticals at a healthcare facility (e.g., employees, volunteers, students). Environmental health and safety personnel are likely to manage hazardous wastes other than just hazardous waste pharmaceuticals at a healthcare facility, in which case, they would be subject to other RCRA Subtitle C training requirements.

The Agency acknowledges that there are many pharmaceuticals that pose significant risk to human health and the environment, yet are not RCRA hazardous when they become waste. We in no way intend to imply that these items pose any less of a risk by virtue of being considered non-hazardous under RCRA and encourage healthcare facilities to provide all relevant training to healthcare personnel and observe industry best management practices.

b. Documentation of training. After requesting comment on documentation of training, the Agency decided not to finalize any requirements for healthcare facilities to document and

maintain records verifying that healthcare personnel have met the training requirements. We considered the many adverse comments and ultimately agreed that such requirements would be overly burdensome and more stringent than the training requirements in the Universal Waste rule, which were largely emulated in this rule. Many comments that advocated for a requirement to document training were from states. Although such a requirement is not being finalized at the federal level, any authorized state has the ability to impose more stringent regulations. If a state chooses to require documentation of training, that would be considered more stringent and permissible under RCRA.

C. Healthcare Facilities Making a Hazardous Waste Determination for Non-creditable Pharmaceuticals (§ 266.502(c))

1. Summary of Proposal

EPA proposed that, similar to the current part 262 generator requirements, healthcare facilities operating under subpart P would be required to make hazardous waste determinations on pharmaceutical wastes in order to determine the applicable management standards. Specifically, we proposed that when a healthcare facility generates a solid waste pharmaceutical, the healthcare facility must determine if the discarded pharmaceutical is listed in 40 CFR part 261 subpart D and/or if it exhibits one or more of the four characteristics of hazardous waste identified in 40 CFR part 261 subpart C. We proposed that, if the non-creditable pharmaceutical waste is determined to be a hazardous waste, then the healthcare facility must manage the non-creditable hazardous waste pharmaceuticals in accordance with part 266 subpart P instead of 40 CFR part 262. Pharmaceutical wastes—both potentially creditable and non-creditable—not meeting the definition of a hazardous waste (i.e., non-hazardous waste pharmaceuticals) must be managed in compliance with applicable federal, state and local regulations.

EPA understands that healthcare facilities utilize various approaches when making hazardous waste determinations. For example, healthcare facilities may hire consultants to review their formularies and identify those pharmaceuticals that are hazardous wastes when discarded. These facilities may then identify hazardous waste pharmaceuticals at the pharmacy level, marking these pharmaceuticals with a special label so that healthcare personnel know how to properly dispose of the pharmaceutical when it becomes a waste. Other healthcare facilities may instruct personnel to dispose of all pharmaceutical wastes into one RCRA hazardous waste collection container. These healthcare facilities may then choose to manage all of the contents of the container as hazardous waste or they may choose to sort the hazardous waste portion from the non-hazardous waste pharmaceutical portion in an on-site hazardous waste accumulation area, also known as a CAA. Due to the various ways that healthcare facilities make the hazardous waste determination, the Agency did not propose that a specific approach be utilized when making the hazardous waste determination, only that the facility performs the hazardous waste determination.

We also proposed that healthcare facilities have the option to manage all of their pharmaceutical wastes as hazardous, and thus, if a healthcare facility chooses this approach, they would not need to make individual hazardous waste determinations. Instead, they would have made a generic decision that all of their discarded pharmaceuticals are hazardous and manage them as hazardous waste pharmaceuticals in accordance with the requirements in 40 CFR part 266 subpart P. Accumulating all non-creditable waste pharmaceuticals in one container (except for those that are incompatible or cannot be incinerated according to the dilution prohibition)[203]

[203] § 268.3(c) Dilution prohibited as a substitute for treatment. See appendix XI of part 268 for a full list of hazardous wastes that are prohibited from being combusted.

and managing them under subpart P would relieve healthcare facilities from the burden associated with making individual hazardous waste determinations.

2. Summary of Comments

There were a wide variety of comments on this provision. Many in the regulated community requested some sort of a reference or compendium containing a comprehensive and up-to-date list of the waste pharmaceuticals that would be considered RCRA hazardous.

Commenters from states were generally supportive of the provision allowing all waste pharmaceuticals to be managed as hazardous waste pharmaceuticals. They believe the provision will encourage healthcare facilities to manage all of their waste pharmaceuticals in an environmentally protective manner. One commenter did suggest that healthcare facilities be required to choose whether they will make individual hazardous waste determinations for their waste pharmaceuticals or manage all of them as hazardous waste pharmaceuticals under this subpart and maintain documentation reflecting their decision.

Retail industry commenters were opposed to what they believe are contrary requirements, specifically, allowing a healthcare facility to manage all of its waste pharmaceuticals as hazardous but still require them to segregate incompatible hazardous waste and those prohibited from combustion as required by § 266.502(d)(4). They believe having to segregate incompatible and non-combustible waste significantly diminishes the intended relief.

3. Final Rule Provisions

EPA has finalized the provisions of this section with minor edits that further clarify that this section applies only to non-creditable pharmaceuticals. A healthcare facility that generates solid waste that is a non-creditable pharmaceutical has two options for hazardous waste determination. It may choose to either; (1) determine if each non-creditable pharmaceutical is a

listed or characteristic hazardous waste to determine whether it is subject to the subpart P requirements, or (2) manage all of its non-creditable waste pharmaceuticals under the subpart P requirements as non-creditable hazardous waste pharmaceuticals. A healthcare facility that chooses the latter option, instead of making individual hazardous waste determinations at the point of generation, would have made a generic decision that all of their non-creditable pharmaceutical waste is hazardous and place it into a container or containers that are managed under part 266 subpart P.

The Agency wanted to provide maximum flexibility to healthcare facilities managing non-creditable waste pharmaceuticals while ensuring protection of human health and the environment, which is why we are finalizing the provision to allow healthcare facilities the option of managing all of their waste pharmaceuticals under subpart P. If a healthcare facility chooses to manage all of its non-creditable waste pharmaceuticals under the subpart P requirements, healthcare personnel are relieved from having to make individual hazardous waste determinations which might otherwise distract from their efforts in providing patient care.

4. Comments and Responses

A number of commenters asked if a third party can come on site and make individual hazardous waste determinations for commingled non-creditable waste pharmaceuticals. If a healthcare facility chooses to use a third party, typically a hazardous waste transport company, to come on site and make hazardous waste determinations at any time (typically in preparation for transport off site), that would also be permissible under this subpart.

Many comments were focused on the lack of an EPA-provided reference guide of which pharmaceuticals are hazardous waste when discarded. The RCRA generator regulations have always placed the onus on the generator of a waste to determine whether it is solid and hazardous

waste. Nevertheless, EPA has made efforts to aid healthcare facilities in making hazardous waste determinations by developing the Hazardous Waste Pharmaceuticals wiki.[204] The website has served as a central location where users (e.g., healthcare facilities, states) can share their knowledge about which pharmaceuticals are listed or characteristic hazardous waste, and other related information. EPA has also funded a compliance assistance center for healthcare facilities, which provides information on which pharmaceuticals are hazardous waste as well as other hazardous wastes found in a healthcare setting.[205,206]

D. No Central Accumulation Area and Satellite Accumulation Area Requirements for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals

1. Summary of Proposal

Hazardous waste pharmaceuticals are generated at numerous locations across a healthcare facility. Under the part 262 generator regulations, each location at the healthcare facility with a RCRA hazardous waste receptacle for the disposal of hazardous waste pharmaceuticals is considered an SAA and is subject to volume accumulation limits and other provisions. Of particular concern regarding the SAA regulations for healthcare facilities is the one-quart accumulation limit for acute hazardous wastes (i.e., P-listed wastes) and the requirement that hazardous waste must be accumulated at or near the point of generation. In particular, hospitals have noted that their difficulties are with having an SAA in each hospital room. As a result, the proposed December 2008 Pharmaceutical Universal Waste rule did not require the establishment of any accumulation areas (neither central nor satellite) for hazardous waste pharmaceuticals.

[204] Hazardous Waste Pharmaceuticals Wiki. http://hwpharms.wikispaces.com. Wikispaces is phasing out its business of hosting wiki pages. The Agency plans to preserve the information that has been contributed to the wiki on EPA's website, but the content will be static.
[205] Healthcare Environmental Resource Center. http://www.hercenter.org.
[206] EPA makes no claims, promises, or guarantees about the accuracy, completeness, or adequacy of the contents of these sites.

This proposed approach was consistent with the current federal universal waste program, since facilities are not required to designate a special centralized area for the accumulation of universal wastes, nor are they required to have SAAs for universal wastes. Nevertheless, EPA understands that healthcare facilities will often accumulate their universal wastes within their 90- or 180-day hazardous waste accumulation areas. The part 262 generator regulations, including the SAA and CAA regulations, were designed more for industrial and manufacturing operations. Part 266 subpart P is a sector-based regulatory approach designed to work better with how the healthcare sector operates. Therefore, consistent with the approach initially taken in the Universal Waste proposed rulemaking, the Agency designed the proposed standards for healthcare facilities accumulating hazardous waste pharmaceuticals under subpart P to operate in lieu of the SAA regulations or the CAA regulations (also sometimes called "less than 90- or 180-day areas").

2. Summary of Comments

The majority of commenters on this provision were states. All but one state and all other commenters agreed with the proposal to eliminate requirements for SAAs and CAAs for healthcare facilities managing non-creditable hazardous waste pharmaceuticals. The lone dissenting state agreed with eliminating requirements for SAAs but expressed concern about not requiring CAAs. They recommended that hazardous waste pharmaceuticals be accumulated in or near a 90-day or 180-day accumulation area for LQGs and SQGs respectively.

3. Final Rule Provisions

The agency is finalizing the approach for part 266 subpart P to operate in lieu of requiring CAAs and SAAs for healthcare facilities managing non-creditable hazardous waste pharmaceuticals. The SAA regulations, in particular, were not a good fit for how healthcare facilities operate. Additionally, there was near-unanimous agreement among commenters that

SAAs and CAAs are not necessary to accumulate hazardous waste pharmaceuticals, further supporting the agency's decision.

Although there is no requirement that a healthcare facility accumulate its hazardous waste pharmaceuticals in a CAA, doing so is, nonetheless, acceptable. A healthcare facility may choose to accumulate hazardous waste pharmaceuticals within its 90-day or 180-day CAA if it has one established for its other hazardous wastes, as long as it maintains compliance with the accumulation time limit and container requirements of 40 CFR part 266 subpart P. If a healthcare facility chooses to accumulate its hazardous waste pharmaceuticals in a CAA, those hazardous waste pharmaceuticals will only be subject to the requirements of part 266 subpart P and not the part 262 hazardous waste generator standards.

E. Container Standards for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals (§ 266.502(d))

1. Summary of Proposal

The container standards discussed in this section apply to those containers used by healthcare facilities to accumulate non-creditable hazardous waste pharmaceuticals. First, we would note that due to the relatively small quantities of hazardous waste pharmaceuticals that are typically accumulated and stored at a healthcare facility, the Agency understands that other types of waste management units, such as tanks, are not used for the management of waste pharmaceuticals. Therefore, we only proposed standards for containers as defined in 40 CFR 260.10. However, the Agency solicited comment as to whether other types of waste management units are also used by healthcare facilities to accumulate and store hazardous waste pharmaceuticals and whether EPA should establish technical standards for other types of waste management units.

The Agency proposed to require that healthcare facilities place hazardous waste pharmaceuticals into containers that are structurally sound and that are compatible with the hazardous waste pharmaceuticals that will be contained within them. EPA intends this requirement to mean that containers used for holding non-creditable hazardous waste pharmaceuticals must be in good condition, with no severe rusting, apparent structural defects, nor deterioration. EPA also proposed that containers also must not have any evidence of leakage, spillage, or damage that could result in the release of waste under reasonably foreseeable circumstances. Furthermore, the Agency proposed to require that incompatible wastes not be placed in the same container, unless the commingling of incompatible hazardous wastes is conducted in such a way that it does not have the potential to (1) generate extreme heat or pressure, fire or explosion, or violent reaction; (2) produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health; (3) produce uncontrollable flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions; (4) damage the structural integrity of the facility or container containing the hazardous waste pharmaceuticals; or (5) through other like means threaten human health or the environment. For example, the majority of a healthcare facility's non-creditable hazardous waste pharmaceuticals are likely organic in nature, and thus, compatible with each other and can be accumulated together, especially since they will most likely be incinerated once they are transported to a TSDF.

The Agency believes that these technical standards, like similar technical standards that EPA has promulgated in § 265.17(b) for interim status TSDFs,[207] would ensure that hazardous waste pharmaceuticals are properly managed and would not be released into the environment,

[207] § 265.17 General requirements for ignitable, reactive, or incompatible wastes is available. https://www.gpo.gov/fdsys/pkg/CFR-2017-title40-vol28/pdf/CFR-2017-title40-vol28-part265.pdf.

while at the same time providing flexibility to the healthcare facility in selecting those containers that are most appropriate for their situation.

In addition to the proposed container standards, the Agency also proposed that accumulation containers for hazardous waste pharmaceuticals be secured in a manner that prevents unauthorized access to the contents in order to prevent the diversion of hazardous waste pharmaceuticals or inadvertent exposures to them. Unlike most other hazardous wastes, some hazardous waste pharmaceuticals might still retain considerable value to individuals or on the black market, which can increase the likelihood of diversion for illicit purposes.

Some non-creditable hazardous waste pharmaceuticals, such as metal-bearing wastes not containing sufficient organics (e.g., P012, arsenic trioxide), are prohibited from being incinerated under the dilution prohibition.[208] Dilution is not a substitute for treatment of certain restricted wastes because the hazardous constituents are not destroyed, removed, or immobilized before being disposed of on the land.[209] EPA proposed that the hazardous waste pharmaceuticals that cannot be incinerated must be accumulated separately from organic wastes destined for incineration.

2. Summary of Comments

There was considerable interest in this section with a broad range of comments in support, in opposition, and suggesting modifications. While some states were in support of the proposed standards, others were concerned that they would not be easily understood by healthcare facility workers, and that we should provide more detail about what constitutes a

[208] § 268.3(c) Dilution prohibited as a substitute for treatment. See appendix XI of part 268 for a full list of hazardous wastes that are prohibited from being combusted.
[209] See RCRA Policy Statement: Clarification of the Land Disposal Restrictions' Dilution Prohibition and the Combustion of Inorganic Metal-Bearing Hazardous Waste. https://www.epa.gov/hw/policy-statement-clarification-dilution-prohibition-and-combustion-inorganic-metal-bearing

closed container. There was also a comment that recommended we clarify that hazardous waste pharmaceuticals can only be accumulated in containers, and not tanks or other accumulation units, and also what would constitute an acceptable container. For example, the commenter asked if re-sealable plastic storage bags or plastic pill bottles are considered a container under this subpart.

Commenters from the waste management industry were generally in support of the proposed container standards although one commenter took issue with the security standards in 40 CFR 266.502(d)(3), stating that they are not adequate and recommending that we incorporate existing DEA guidance on container security standards. The commenter also suggested the final regulations incorporate an additional security provision stating that hazardous waste pharmaceuticals be put into a "product or container that is specifically designed to render them inaccessible, non-consumable, and/or irretrievable prior to final disposal." A different waste management company echoed the concerns shared by the previously mentioned state that the final rule should specify that hazardous waste pharmaceuticals can only be accumulated in containers and not in other types of waste accumulation units.[210] No commenters indicated that any other types of waste management units are used to accumulate hazardous waste pharmaceuticals.

Trade associations representing a range of stakeholders also generally supported the proposed provisions but were concerned about the requirements to segregate hazardous waste pharmaceuticals that cannot be incinerated. One waste treatment trade association recommended that the regulatory language that allows the incineration of certain mercury-bearing hazardous waste pharmaceuticals be changed to discourage the incineration of such wastes even though it is

[210] See comment number EPA-HQ-RCRA-2007-0932-0257.

permissible. They believe that the proposed language may be interpreted as advocating for their incineration. A state association was concerned about the possible subjectivity of the language in 40 CFR 262.502(d)(2), which contains standards for facilities that manage ignitable or hazardous waste pharmaceuticals or that mix or commingle incompatible wastes in the same container. They recommend instead, that the final rule employ the "traditional prohibition" on incompatibility.[211]

3. Final Rule Provisions

The Agency is finalizing the container standards for non-creditable hazardous waste pharmaceuticals as proposed. A healthcare facility must place its non-creditable hazardous waste pharmaceuticals in containers that are structurally sound, compatible with the contents, and that would prevent any leaks or spills under reasonably foreseeable conditions. If incompatible hazardous waste pharmaceuticals are commingled in a container, the healthcare facility must manage the container such that it does not have the potential to generate dangerous heat and/or pressure, emit any toxic substances (e.g., mists, fumes, dust), produce flammable fumes or gases, damage the structural integrity of the container, or otherwise endanger human health and the environment.

To address the concerns of commenters, EPA would like to emphasize that, while it is permissible for hazardous waste pharmaceuticals containing metals such as mercury to be incinerated if the total organic carbon is greater than 1%,[212] we strongly recommend that they be segregated out and treated via other acceptable methods that comply with the land disposal restrictions.

[211] See comment number EPA-HQ-RCRA-2007-0932-0216.
[212] § 268.3 (c) Dilution prohibited as a substitute for treatment

EPA is clarifying that the container standards like the other standards for non-creditable hazardous waste pharmaceuticals do not apply to hazardous waste pharmaceuticals that are also DEA controlled substances because these DEA controlled substances are conditionally exempt from RCRA.[213] Section XIV further discusses hazardous waste pharmaceuticals that are also DEA controlled substances.

To reduce the risk of illicit diversion, the Agency is finalizing the requirement preventing unauthorized access to the contents of containers used to accumulate non-creditable hazardous waste pharmaceuticals. EPA intended this requirement to be performance-based and did not finalize prescriptive regulatory requirements for this standard. Healthcare facilities may choose to utilize containers that are designed to prevent unauthorized access to their contents when located in areas with uncontrolled access or store containers in areas with controlled access, such as locked storage lockers, locked closets, or locked rooms, to prevent unauthorized access to the contents of the containers. Containers used to accumulate non-creditable hazardous waste pharmaceuticals may also be kept behind a pharmacy counter because of the restricted access to those areas.

The Agency received no comments indicating that non-creditable hazardous waste pharmaceuticals are accumulated in any waste management units other than containers. Therefore, these standards apply only to containers used to accumulate non-creditable hazardous waste pharmaceuticals. Other types of hazardous waste accumulation units are not permitted for the accumulation of non-creditable hazardous waste pharmaceuticals.

4. Comments and Responses

[213] § 266.506

Section (d)(4) of this provision regarding the requirement to segregate certain metal-bearing non-creditable hazardous waste pharmaceuticals was added as a reminder that, due to existing LDR regulations, a few hazardous waste pharmaceuticals cannot be incinerated and therefore must be segregated. This is not a new requirement for healthcare facilities and does not represent a change in the regulatory burden.

One commenter asked if plastic bags are considered a container as defined in § 260.10. If hazardous waste is placed inside a plastic bag, it meets the definition of a RCRA container and is subject to all applicable standards in 40 CFR 264 subpart I and 40 CFR 265 subpart I. Specifically, to be in compliance, a plastic bag must be compatible with the waste, able to prevent the contents from leaking, kept closed during storage except when it is necessary to add or remove waste, and handled or stored in a manner that prevents rupture and/or causes leaking. EPA would also note that, even though this commenter did not mention other types of containers, that cups, pill bottles, vials, etc. are also considered a container under RCRA.[214]

Regarding the state association that suggested EPA apply the "traditional prohibition" on mixing or commingling incompatible wastes in the same container because they were concerned about the possible subjectivity of the five specified conditions in 40 CFR 262.502(d)(2), that regulatory language was taken directly from the general requirements for ignitable, reactive, or incompatible wastes, in the General Facility Standards at 40 CFR 265.17(b). This is not a newly designed requirement. Healthcare facilities that manage hazardous waste pharmaceuticals are already required to comply with this provision.

F. Labeling Standards on Containers for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals (§ 266.502(e))

[214] See memo November 11, 2011, Rudzinski to the Regional RCRA Division Directors (RCRA Online# 14827).

1. Summary of Proposal

During the period of accumulation, the Agency proposed that containers of hazardous waste pharmaceuticals be marked with the words ''Hazardous Waste Pharmaceuticals.'' The Agency did not propose to require that the hazardous waste numbers (often referred to as hazardous waste codes) of the container's contents be listed on the label. Healthcare personnel (e.g., nurses) typically generate the hazardous waste pharmaceuticals. Healthcare personnel are not usually intimately familiar with RCRA and its regulations and are primarily focused on patients and their health. In addition, while a healthcare facility may have an environmental compliance manager or environmental consultant that is knowledgeable about RCRA and its regulations and can make hazardous waste determinations, this individual cannot be present to assign a hazardous waste code and label the collection receptacle each time a hazardous waste pharmaceutical is generated. For these reasons, EPA did not believe it would be practical to require individual hazardous waste codes on the hazardous waste pharmaceutical collection container at the healthcare facility.

The Agency solicited comment on the appropriateness of the proposed general labeling requirement. The Agency also requested comment on security concerns regarding having the word ''pharmaceutical'' marked on the containers.

2. Summary of Comments

The issues of determining waste codes and whether they should be required on labels and/or manifests cuts across a number of provisions in this rule. Many commenters intertwined their opinions on container labeling standards with manifest requirements, waste code determinations by healthcare workers, and LDRs. While the Agency understands the inter-relatedness of these issues, this section pertains specifically to the proposed standards of

requiring the words "Hazardous Waste Pharmaceuticals" on containers used to accumulate hazardous waste pharmaceuticals, and whether having the word "Pharmaceutical" displayed on those containers increases the risk of illicit diversion. Many of the comments alluded to these container labeling requirements during on-site accumulation, but did not address them directly, instead focusing on how the proposed labeling standards to not require hazardous waste codes on containers will affect the manifesting, shipping, and LDR processes. We will address those comments in subsequent sections as appropriate.

States had mixed views with a few voicing support for the proposed labeling standards, while another asked that the Agency provide more leeway in the required wording on the container label. Another state agreed with not requiring individual waste codes, but recommended that EPA require some sort of identification of potentially incompatible wastes to help prevent their inadvertent mixing. Two states were opposed to the proposed standards and recommended requiring individual hazardous waste codes on container labels to reduce the risk of mismanagement and incorrect treatment.

One reverse logistics company tacitly agreed with the proposal to not require hazardous waste codes on containers (or manifests) and instead, write "Hazardous Waste Pharmaceuticals" on the container and comply with DOT requirements. They expressed agreement with the agency's proposal to not require hazardous waste codes on the manifest, which leads the Agency to conclude that not requiring hazardous waste codes on containers is acceptable to them as well.

Comments from the waste treatment sector were mixed as well. One commenter agreed with the proposal to not require hazardous waste codes on container labels but wanted more flexibility in labeling. Other commenters from the waste treatment industry were wholly opposed

to the proposed labeling requirements citing the need for waste codes by TSDFs to meet LDR standards.[215]

One medical waste trade association did not explicitly agree that hazardous waste codes should not be required on container labels, but they did request that, at a minimum, hazardous waste codes should be included on the manifest.

Stericycle initially disagreed with the proposal to require the word "pharmaceutical" on labels in addition to "Hazardous Waste" when it commented on the 2008 proposal to add pharmaceuticals to the Universal Waste rule. It has subsequently, through first-hand experience, determined that including the word "pharmaceutical" on containers does not increase the risk for illicit diversion. Therefore, in its comments to this proposed rulemaking, it is now in support of labeling containers of hazardous waste pharmaceuticals with the words "Hazardous Waste Pharmaceuticals."

Multiple commenters representing regional and national healthcare systems currently label their containers with the word "pharmaceuticals" and feel it is appropriate.[216] A commenter from the healthcare waste association also agrees that including the word "pharmaceutical" on containers is current practice and does not present any additional risk of diversion.[217]

3. Final Rule Provisions

EPA is finalizing the container labeling requirements as proposed. Specifically, containers of non-creditable hazardous waste pharmaceuticals must be marked with the words "Hazardous Waste Pharmaceuticals" when accumulating on-site. This final rule provision is consistent with the container labeling requirements in the Hazardous Waste Generator

[215] See comment numbers EPA-HQ-RCRA-2007-0932-0333 and EPA-HQ-RCRA-2007-0932-0297.
[216] See comment number EPA-HQ-RCRA-2007-0932-0297.
[217] See comment number EPA-HQ-RCRA-2007-0932-0296.

Improvements rule,[218] in that generators are not required to label containers with hazardous waste codes during on-site accumulation. Previously, the regulations did not specify when hazardous waste codes needed to be added to container labels.

The Agency was concerned about increasing the risk of diversion resulting from displaying the word "pharmaceutical" on a container. However, given the general support from commenters, in this final rule, EPA is comfortable including the word "pharmaceutical" on the label of containers used to accumulate hazardous waste pharmaceuticals. There was no opposition from commenters representing healthcare systems and pharmacy trade groups. In fact, many commented that this is has been standard practice for some time and has not resulted in any increased diversion.

4. Comments and Responses

One state was concerned that allowing the commingling of hazardous waste pharmaceuticals could inadvertently lead to incompatible hazardous waste pharmaceuticals being mixed together, and suggested that EPA add a requirement to label containers with potentially incompatible wastes. It is the Agency's understanding that there are only a few pharmaceuticals that are incompatible according to DOT. Pressurized aerosols are the most common, although both DOT and EPA are considering relaxing their management requirements in the near future. Other DOT incompatible wastes include oxidizers, acids, and bases, yet they occur infrequently in dosage form.[219] In addition, there are a limited number of cases in which commingled incompatible pharmaceutical waste has caused a problem. Therefore, the Agency has determined

[218] Final rule: November 28, 2016; 81 FR 85808.
[219] Smith, Charlotte A. "Managing Pharmaceutical Waste: A New Implementation Blueprint." Pharmacy Practice News, Special Edition, 2011.

that the risk does not rise to the level of requiring a specific provision and is not finalizing any additional labeling requirement for incompatible hazardous waste pharmaceuticals.

One commenter from the waste management industry suggested that EPA add the flexibility to label containers of hazardous waste pharmaceuticals with the words "hazardous waste" or other words that communicate the hazards per § 262.34(c)(1)(ii).[220] The Agency is not finalizing this suggestion. EPA recently revisited these provisions in the 2016 Hazardous Waste Generator Improvements rule to require that generators label containers with both the words "hazardous waste" and other words that indicate the nature of the hazard partially because the Agency felt that the previous requirements were too vague. In addition, § 262.34 applied only to containers in SAAs whereas there are no SAAs in a subpart P healthcare facility.

G. Accumulation Time Limits for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals (§ 266.502(f))

1. Summary of Proposal

a. One-year accumulation time limit. A few hazardous waste pharmaceuticals are P-listed acute hazardous wastes, the most common being warfarin. Under the part 262 generator regulations, if a generator generates more than 1 kg of acute hazardous waste per calendar month, the generator is regulated as an LQG and subject to a 90-day limit on accumulation. Due to this low generation/accumulation threshold associated with P-listed wastes, healthcare facilities are often LQGs. However, while healthcare facilities can generate enough P-listed waste to become LQGs, they often do not generate sufficient total amounts of hazardous waste pharmaceuticals

[220] See comment number EPA-HQ-RCRA-2007-0932-0280 in the docket for this rulemaking. The regulation cited by the commenter has been since moved to 262.16(b)(6) as part of the 2016 Hazardous Waste Generator Improvements Final Rule.

within the allowed accumulation period of 90 days to make off-site shipments using a hazardous waste transporter cost-effective.

Under the 2008 proposed amendment to add pharmaceuticals to the Universal Waste program, handlers of pharmaceutical universal waste would have had one year to accumulate their hazardous waste pharmaceuticals in order to facilitate proper treatment and disposal. Commenters on the proposed 2008 Pharmaceutical Universal Waste rule indicated support for the one-year accumulation time limit. Thus, under part 266 subpart P, the Agency proposed to allow healthcare facilities to accumulate non-creditable hazardous waste pharmaceuticals for up to one year without triggering interim status or the need to obtain a RCRA permit. EPA proposed one year as an appropriate time frame because it strikes a balance between allowing healthcare facilities enough time to accumulate enough non-creditable hazardous waste pharmaceuticals to make it economically viable to transport their hazardous waste pharmaceuticals off site while ensuring that the hazardous wastes are not accumulated beyond the one-year storage limit under the LDR program (see § 268.50). Under the LDR storage prohibition, the Agency assumes that any accumulation for up to one year is for the purpose of facilitating proper treatment and disposal.

EPA proposed that healthcare facilities could use various approaches to demonstrate the length of time that non-creditable hazardous waste pharmaceuticals are accumulated on site. For example, EPA proposed that a healthcare facility can choose to mark the container label with the date that accumulation first began, maintain an inventory system that identifies dates when the hazardous waste pharmaceuticals were first accumulated, identify in the accumulation area the earliest date that a hazardous waste pharmaceutical became a hazardous waste, or any other

method that clearly demonstrates the length of time that the hazardous waste pharmaceutical has been accumulated from the date it became a hazardous waste.

b. Extensions to accumulation time limits. In the proposed time frames to accumulate non-creditable hazardous waste pharmaceuticals, EPA included a provision that allowed any healthcare facility needing longer than the one-year accumulation time frame to request an extension from the appropriate EPA Regional Administrator. The Agency provided several examples of situations when a healthcare facility might request an extension. The reasons included litigation (now referred to as preservation orders, investigations or judicial proceedings),[221] recalls, and circumstances that are beyond the control of the healthcare facility. The proposed extension provision required that healthcare facilities send a request in writing (electronic or paper) to the Regional EPA Administrator explaining the need for the extension, the approximate amount of hazardous waste pharmaceuticals to be accumulated beyond the one year, and the amount of extra time requested. The Agency then proposed to allow the Regional Administrator the discretion to grant, modify, or deny the requested extension on a case-by-case basis. Lastly, the Agency solicited comment on the proposed mechanism to request a time extension.

2. Summary of Comments

a. One-year accumulation time limit. One commenter from industry agreed with the proposed time limits, but expressed concern about the ability of a healthcare facility to track accumulation times of their waste, and recommended that there be an additional requirement to inventory

[221] Subsequent to the proposal, the Agency became aware that the term "litigation" was not sufficiently broad to encompass all of the legal actions that might require a hazardous waste pharmaceutical to be preserved. To maintain consistency throughout the final rule, all instances where the term "litigation" or "litigation holds" appeared in the proposed rule have been changed to "preservation order, investigation, or judicial proceeding," except in this section which discusses what was proposed.

container contents in a manner that will ensure that the 1-year limit is not exceeded. Another state commenter also recommended that § 266.502(f)(2)(iv), which would have allowed containers to be marked in "any other method which clearly demonstrates the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating from the date it first became a waste," be eliminated because it is too vague.

b. Extensions to accumulation time limits. The proposed extension provisions were opposed by a majority of commenters from both industry and state governments. Industry commenters were concerned about the additional burden that would likely arise from having to generate, transmit, and maintain an additional set of records for a scenario (the need to accumulate hazardous waste pharmaceuticals beyond the one-year allotment) that they say occurs more often than EPA seems to have been aware of at the time of proposal. Similarly, many state agencies were concerned about the added burden that would be imposed by a novel source of administrative workload in the form of written requests that must be processed, analyzed, afforded appropriate consideration/discretion, and responded to. In addition, many commenters mentioned the possibility that these provisions would conflict with existing federal regulations, those of FDA for recalls, in particular. Other commenters brought up similar concerns about pharmaceuticals being stored pursuant to a litigation hold because of their protracted and unpredictable nature.

3. Final Rule Provisions

a. One-year accumulation time limit. The Agency is finalizing a one-year accumulation time limit for healthcare facilities accumulating non-creditable hazardous waste pharmaceuticals. Healthcare facilities may use one of three approaches to demonstrate the length of time that non-creditable hazardous waste pharmaceuticals are accumulated on site. A healthcare facility can choose to mark the container label with the date that accumulation first began, maintain an

inventory system that identifies dates when the hazardous waste pharmaceuticals were first accumulated, or identify in the accumulation area the earliest date that a hazardous waste pharmaceutical became a hazardous waste.

The Agency reiterates that the one-year accumulation time limit only applies to a healthcare facility's non-creditable hazardous waste pharmaceuticals and does not apply to any other types of non-pharmaceutical hazardous waste generated on-site nor to potentially creditable hazardous waste pharmaceuticals.

The provision in § 266.502(f)(2)(iv) has been eliminated. It would have allowed for the accumulation start date to be labeled in any manner that clearly indicates the length of time that it first began accumulating non-creditable hazardous waste pharmaceuticals. One commenter argued that the provision was overly broad and EPA agreed.

b. Extensions to accumulation time limits. The Agency is not finalizing any of the proposed provisions in § 266.502(f)(3) that would have allowed a healthcare facility to request an extension of the one-year accumulation period for non-creditable hazardous waste pharmaceuticals and has addressed commenter concerns in other areas of the rule.

Recalls and preservation orders, investigations, or judicial proceedings (formerly referred to as litigation in the proposed rulemaking) were the two specific situations that the Agency attempted to address in the proposal as examples of unforeseen circumstances beyond the control of the healthcare facility. Pharmaceuticals that are subject to a voluntary or federally-mandated recall (most likely overseen by FDA, rarely CPSC) must be managed according to the requirements of either one or both agencies, as appropriate. Although many of these items could likely be considered RCRA solid waste, EPA is choosing not to apply RCRA regulations upon recalled pharmaceuticals that are managed under a voluntary or federally-mandated recall until a

decision is made to destroy those items either in part or in whole. Similarly, the agency also determined that pharmaceuticals being stored pursuant to a preservation order, investigation, or judicial proceeding are not RCRA hazardous waste. Both scenarios are addressed in the Applicability section of the final rule in the preamble and regulations (see §§ 266.501(g)(4) and 266.501(g)(5)). Because pharmaceuticals that have been recalled and/or are being stored pursuant to a preservation order, investigation, or judicial proceeding are not subject to this subpart, the Agency does not see the need to include a provision for extending accumulation time. Recall managers (likely reverse distributors) and states will not be burdened by producing and responding to such requests.

The proposed rulemaking also discussed other unforeseen circumstances (other than a recall or preservation order, investigation, or judicial proceeding) as a legitimate reason for requesting an extension of the one-year period to accumulation of non-creditable hazardous waste pharmaceuticals. However, the only circumstances mentioned by commenters that would necessitate an extension were recalls and litigation (preservation orders, investigations, or judicial actions). Because both of those scenarios are now addressed individually in the finalized Applicability section of the preamble and regulations, and have no associated accumulation time limits, the Agency saw no need to codify a provision to allow a healthcare facility to request an extension of the accumulation time limit for other reasons beyond their control. Therefore, the EPA is not finalizing the proposal to allow healthcare facilities to request an extension of the one-year accumulation time frame from the Regional Administrator for any reason.

H. Land Disposal Restrictions for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals (§ 266.502(g) and § 266.502(d)(4))

1. Summary of Proposal

As required by HSWA and consistent with part 262 generator requirements, EPA proposed that healthcare facilities must comply with the LDR requirements prior to land disposal of the hazardous waste pharmaceuticals they generate. Since healthcare facilities are generators, even though they are not subject to the 40 CFR part 262 requirements for the management of hazardous waste pharmaceuticals, we proposed that they must comply with the LDR requirements found at 40 CFR part 268. The LDRs required by HSWA are in place to ensure that toxic constituents present in hazardous waste are properly treated to reduce their mobility or toxicity before hazardous waste is placed into or onto the land (i.e., land disposed). With limited exceptions, hazardous waste must be treated by a RCRA-permitted or interim status TSDF.

In general, generators of hazardous waste assign the appropriate hazardous waste numbers (commonly called hazardous waste codes) to allow TSDFs to determine the specific treatment standard(s) for each prohibited waste. The Agency proposed that healthcare facilities generating non-creditable hazardous waste pharmaceuticals do not have to label the containers with the words "hazardous waste" or the hazardous waste codes when transporting them off site, but rather must label the containers with the words "hazardous waste pharmaceuticals." Healthcare facilities do, however, need to make determinations as to whether wastes must be treated to meet LDR treatment standards. While most hazardous waste pharmaceuticals are likely organic in nature and may be incinerated, some hazardous waste pharmaceuticals may not be suitable for incineration and, therefore, must be segregated from the organic wastes. The hazardous waste pharmaceuticals not suitable for incineration include characteristic metal wastes (i.e. D004–D043) prohibited from being combusted because of the dilution prohibition of § 268.3(c), as well as the listed wastes U151 (mercury), U205 (selenium sulfide), and P012 (arsenic trioxide), unless they contain greater than 1% total organic carbon. Put another way,

hazardous waste pharmaceuticals with these metals that also contain greater than 1% total organic carbon may be incinerated. In order to comply with the LDRs, healthcare facilities will need to segregate these wastes from the organic hazardous waste pharmaceuticals so that they can be properly treated by the TSDF. Although the Agency did include a requirement to segregate these metal-bearing low total organic carbon hazardous waste pharmaceuticals in proposed § 266.502(d)(4), the Agency requested comment on whether it is necessary to incorporate into the regulations at § 266.502(g) a requirement to segregate these wastes and whether additional labeling requirements are necessary to identify the hazardous waste pharmaceuticals that are not suitable for incineration.

Because EPA proposed that containers of non-creditable hazardous waste pharmaceuticals would not be required to list the hazardous waste codes on the label, we also proposed that waste codes are not required on the LDR notification.

2. Summary of Comments

There were a variety of comments on this provision, primarily regarding four issues: (1) the segregation of hazardous waste pharmaceuticals unsuitable for incineration, (2) the incineration of hazardous waste pharmaceuticals with numeric treatment standards, (3) the LDR notification, and (4) the need for hazardous waste pharmaceuticals-specific waste code and treatment standard.

Commenters from both states and the waste management industry requested that the agency add a requirement for healthcare facilities to segregate any hazardous waste pharmaceuticals that are unsuitable for incineration into separate containers and label them with the appropriate waste codes. They argued that there would be an increased likelihood that

pharmaceuticals containing metals subject to the dilution prohibition would be inadvertently incinerated, resulting in noncompliance with LDR standards.

Many waste management companies expressed concern about their ability to meet LDR standards without knowing specific waste codes and the added burden they would incur from having to test their ash for the seven hazardous waste pharmaceuticals with numeric treatment standards—lindane, chloroform, m-cresol, dichlorodifluoromethane, trichloromonofluoromethane, phenacetin and phenol.[222] They did, however, agree that healthcare workers should not have to make hazardous waste determinations. They stated that they would have to alter or augment their testing protocols for residual ash which would add undue burden. One commenter suggested that, at a minimum, segregation be performed before a shipment of hazardous waste pharmaceuticals are transported off site for disposal, but having waste codes either on a label or the manifest would be preferable. They generally stated that they do not feel waste management should bear all of the added burden of LDR compliance under this rule.

Another common theme among commenters, from the waste management industry in particular, was a recommendation for a new, single hazardous waste code for all hazardous waste pharmaceuticals with a corresponding alternate treatment of standard of combustion (CMBST). One commenter representing the retail industry expressed concern that the relief provided by this rule will be negated by the requirement to list waste codes on the LDR notice.

3. Final Rule Provisions

The Agency is finalizing the LDRs for non-creditable hazardous waste pharmaceuticals as proposed. The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the LDRs of 40 CFR part 268. A healthcare facility that generates

[222] See 40 CFR 268.40 table "Treatment Standards for Hazardous Wastes," which identifies maximum concentration values for all hazardous constituents in the waste/treatment residue prior to land disposal.

hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with § 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (i.e., hazardous waste codes) on the LDR notification.

To address commenters' concerns about whether hazardous waste codes are required on the LDR notification, the Agency has added clarifying language to specify that waste codes are, in fact, not required on the LDR notification. The Agency would note, however, that the proposed regulatory language did, in fact, specify in § 266.502(g) that waste codes are not required on the LDR notice. Due to the number of commenters who were under the impression that waste codes would still be required on the LDR notice, we added an additional clarification to make it more obvious that waste codes are not required on the LDR notice.

The final rule requires healthcare facilities that generate non-creditable hazardous waste pharmaceuticals to comply with the LDRs. In response to comments, we have made one minor change for added clarity. The Agency has added a requirement to § 266.502(d)(4) for healthcare facilities that generate non-creditable hazardous waste pharmaceuticals that are unsuitable for incineration to segregate them into separate containers from those containing commingled non-creditable hazardous waste pharmaceuticals, and label them with the appropriate hazardous waste codes. We would note, however, that the dilution prohibition of § 268.3 already necessitates such segregation, therefore, this addition in § 266.502 (d)(4) is for the purposes of clarity and does not substantially change any of the proposed LDR requirements for hazardous waste pharmaceuticals.

4. Comments and Responses

Waste management companies opposed the provision to not require healthcare facilities to label containers with hazardous waste codes because of the added burden they argue would

result from having to conduct additional testing for pharmaceuticals with numeric treatment standards. Nevertheless, the Agency is not finalizing a requirement for healthcare facilities to label containers of non-creditable hazardous waste pharmaceuticals with hazardous waste codes, nor is the Agency finalizing any additional requirements for healthcare facility personnel to segregate the seven pharmaceuticals that have numeric treatment standards, although a vendor could include such a requirement in its contract with a healthcare facility.

Unlike metal-bearing hazardous waste pharmaceuticals that may not be incinerated, the seven hazardous waste pharmaceuticals with numerical treatment standards may be incinerated or treated using any other treatment method to meet LDR values. Therefore, the Agency thinks it would cause confusion and add burden to require healthcare facilities to segregate the hazardous waste pharmaceuticals with numeric treatment standards. Further, the Agency has determined that several of the seven organics with numeric treatment standards also appear in non-pharmaceutical hazardous waste, which means that hazardous waste combustors are already required to test their ash to ensure compliance with LDRs for those constituents.

Because this rule does not require that healthcare facilities label their waste with the hazardous waste codes, TSDFs will now have to analyze their incinerator residue (ash) for the seven organics that have numerical treatment standards according to the conditions established in the facility waste analysis plan, as they could possibly be present in any shipment of organic hazardous waste pharmaceuticals or treatment residues. Organic hazardous waste pharmaceuticals (other than arsenic trioxide) may all be incinerated at RCRA-permitted or interim status hazardous waste combustors. Most organic wastes have a specified treatment standard of combustion (CMBST). The remaining seven organics have numerical treatment standards, such that no particular treatment technology is required to achieve the numerical LDR

treatment standards. While these wastes may be incinerated, the ash must be analyzed for these seven organic constituents to demonstrate compliance with the LDR treatment standards before that ash can be land disposed. The Agency is not finalizing any standards that would affect the frequency of testing, simply that TSDFs test their ash for these seven constituents as part of their existing protocol.

EPA is not finalizing recommendations from commenters that the Agency implement a new waste code or alternative treatment standards specifically for hazardous waste pharmaceuticals. Because the Agency did not propose any new waste codes or treatment standards for hazardous waste pharmaceuticals, the recommendation is outside the scope of this rule. The Agency does agree that implementing an alternative treatment standard of combustion for hazardous waste pharmaceuticals that currently have numeric treatment standards would be a viable solution to mitigate any added burden imposed on TSDFs that will have to modify their testing protocol; however, we did not receive the necessary data to propose such a change prior to proposal, and therefore cannot finalize an alternative treatment standard in this rule. The Agency is, however, open to considering alternative treatment standards for hazardous waste pharmaceuticals in possible future rulemakings.

In their comments on this rule and the 2008 Universal Waste proposal, Environmental Technology Council (ETC) suggested revising the treatment standards for the organic hazardous waste pharmaceuticals that have numerical treatment standards to the specified treatment standard of combustion. Specifying combustion would relieve the TSDFs from demonstrating compliance with the numerical treatment standards. [223] EPA explored the feasibility of making

[223] Prohibited waste may be land disposed if it is treated using the technology specified in the table (e.g., CMBST:''), which are described in detail in § 268.42, Table 1—Technology Codes and Description of Technology-Based Standards.

combustion an alternative treatment standard for the seven organic hazardous waste pharmaceuticals that currently have numeric LDR treatment standards. In fact, EPA notes that the numerical treatment standards were developed based on levels achieved through combustion. However, EPA has indicated a preference for numerical treatment standards over specifying treatment standards whenever possible, to allow maximum flexibility. Furthermore, it is not clear that pharmaceuticals would be the sole source of the seven organic constituents in question. Therefore, even if we proposed an alternative treatment standard of combustion for the seven organic pharmaceuticals, hazardous waste combustors would still be required to test their ash for these constituents to demonstrate compliance with numeric treatment standards if they received the organics from another, non-pharmaceutical source.

Again, EPA notes that autoclaving is not an acceptable method of treating hazardous waste.[224]

I. Procedures for Healthcare Facilities Managing Rejected Shipments of Non-creditable Hazardous Waste Pharmaceuticals (§ 266.502(h))

1. Summary of Proposal

In rare circumstances, a healthcare facility may send its non-creditable hazardous waste pharmaceuticals to a designated facility that is unable to manage the hazardous waste. For such situations, we proposed that healthcare facilities follow the same procedures listed in 40 CFR part 262 (see § 262.23(f)). EPA believes that it is appropriate to continue current practices for rejected shipments that are part of the generator regulations of 40 CFR part 262 because rejected shipments are relatively rare and the procedures currently used for rejected shipments is

[224] See section VII.D.1.b for further discussion.

relatively straightforward. In addition, healthcare facilities should be familiar with these procedures already.

2. Summary of Comments

There were relatively few comments on this section of the proposed rulemaking. One state and one waste management company agreed with the standards as proposed. Another state suggested that, as written, the regulatory language contradicts itself. Specifically, the commenter said that proposed § 266.502(h)(4) implies that a healthcare facility that receives a rejected shipment of non-creditable hazardous waste pharmaceuticals (a shipment that it initiated) must offer it for shipment to a new designated facility upon receipt, as opposed to the 90-day additional accumulation period mentioned in § 266.502(h). They reason that, because there are no time frames in the requirement, the Agency intended to mean upon receipt.

3. Final Rule Provisions

The agency is finalizing the provisions in this section as proposed with the added clarification that a healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility must have an understanding that the designated facility can accept and manage the waste. However, if the healthcare facility later receives the shipment back as a rejected load, the healthcare facility must sign the manifest that was used to return the shipment, provide the transporter a copy of the manifest, send a copy of the manifest within 30 days to the designated facility that returned the shipment and ship the non-creditable hazardous waste pharmaceuticals to a new designated facility. The Agency also added additional clarification to § 266.502(h)(4), to respond to comments, specifying that a healthcare facility has up to 90 days to ship the rejected shipment to a new designated facility.

J. Reporting Requirements for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals (§ 266.502(i))

1. Summary of Proposal

We proposed that healthcare facilities that are required to submit a BR would no longer be required to include their non-creditable hazardous waste pharmaceuticals in the report. In addition, the Agency proposed that healthcare facilities managing non-creditable hazardous waste pharmaceuticals have reporting requirements similar to generators regulated under 40 CFR part 262—that is, the exception reporting requirement under § 262.44(b) and the additional reporting requirement under § 262.44(c).

We proposed to incorporate and adapt the generator exception reporting procedures of 262.44(b) for this new subpart. Specifically, we proposed that if a healthcare facility does not receive a copy of the hazardous waste manifest from the designated facility within 60 days, the healthcare facility must submit to the EPA Regional Administrator a copy of the manifest with a statement that the healthcare facility did not receive confirmation of the non-creditable hazardous waste pharmaceuticals' delivery, along with an explanation of the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts. Likewise, we proposed that if a shipment of non-creditable hazardous waste pharmaceuticals from a healthcare facility is rejected by the designated facility and it is shipped to an alternate facility and if the healthcare facility does not receive a signed copy of the hazardous waste manifest from the alternate facility within 60 days, it must submit to the EPA Regional Administrator a copy of the hazardous waste manifest with a statement that the healthcare facility did not receive confirmation of the non-creditable hazardous waste pharmaceuticals' delivery along with an

explanation of the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

Finally, the Agency proposed that the Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of hazardous waste pharmaceuticals. This is already the case for generators operating under the 40 CFR part 262. As with 40 CFR part 262, it is a codification of statutory authority under §§ 2002(a) and 3002(a)(6) that provides the Agency some flexibility in what reports may be required.

2. Summary of Comments

The Agency received few comments on this subsection. Comments primarily addressed there being no requirement to include hazardous waste pharmaceuticals on the BR, and opinions were mixed. All pharmacy trade groups that commented were in favor of the proposal to not require hazardous waste pharmaceuticals managed under part 266 to be reported on the BR. States that commented were split. One state opposed the proposal and argued it would hinder the state's ability to reconcile what is treated at a TSDF with what is generated at a healthcare facility. Another state disagreed with the proposed provision and argued states will be forced to establish their own reporting requirements at the state level, leading to inconsistency in the way states determine their reporting fees. Another state was in agreement with the proposed provision, stating that information regarding amounts of non-creditable hazardous waste pharmaceuticals generated and treated can be captured from reverse distributor and TSDF reporting. One other state pointed out that the lack of a requirement for healthcare facilities to determine waste codes would make reporting in the BR difficult, if not impossible.

Regarding the exception reporting requirements, one state suggested that § 266.502(i)(2)(ii)(A) and (B) are unnecessary because the requirements in § 266.502 (i)(2)(i)(A)

and (B) for a healthcare facility that does not receive a signed copy of the manifest within 60 days of being accepted by the initial transporter are the same, whether the shipment is lost or rejected and transferred to a new designated facility. The state suggested that § 266.502(i)(2) should be rewritten to simply state that an exception report is only necessary if the healthcare facility has not received the signed manifest from the TSDF within 60 days. One healthcare provider suggested that the proposed 60-day period for a healthcare facility to receive the manifest from the TSDF should be shortened to 45 days because shipments of other non-pharmaceutical hazardous waste require receipt of the manifest from the TSDF within 45 days.

3. Final Rule Provisions

The reporting requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals are being finalized as proposed. That is, non-creditable hazardous waste pharmaceuticals managed under this subpart at a healthcare facility are not required to be reported on the BR, healthcare facilities must submit an exception report to the Regional Administrator if they have not received a signed copy of the manifest within 60 days of the initial transporter accepting the shipment, and the Agency may require a healthcare facility to furnish additional reports regarding the quantity and disposition of non-creditable hazardous waste pharmaceuticals. When managing rejected shipments, the Agency believes it is advantageous to use established procedures that should be familiar to healthcare facilities, especially given that rejected shipments are relatively rare.

To clarify, the exception reporting regulations for healthcare facilities differ from the exception reporting regulations for reverse distributors because they were based on the differing § 262.42 exception reporting for LQGs and SQGs. The exception reporting regulations for healthcare facilities were based on the corresponding § 262.42(b) SQG regulations, whereas the

reverse distributor exception reporting regulations were based on the § 262.42(a) LQG regulations.

Although commenters voiced some concern about not knowing the volume of non-creditable hazardous waste pharmaceuticals being generated at healthcare facilities, the Agency believes it is unnecessary to require healthcare facilities generating non-creditable hazardous waste pharmaceuticals to report this information. If a state or region wants to obtain such information, it can examine hazardous waste received forms in the BR submission from TSDFs. Further, one of the goals of this final rule is to reduce burden on healthcare facilities so that they will be encouraged to manage all of their waste pharmaceuticals under part 266 subpart P. Requiring a healthcare facility to report hazardous waste pharmaceuticals on its BR would discourage them from managing non-hazardous waste pharmaceuticals as hazardous. Finally, we would note that this approach is consistent with the Universal Waste program upon which the healthcare facility standards are based. Universal wastes managed under part 273 are not reported on the BR.

4. Comments and Responses

As part of the part 262 generator regulations, healthcare facilities that are LQGs must submit a BR to the Regional Administrator by March 1st of every even numbered year (see § 262.41). Among other requirements, the BR must include a description (EPA hazardous waste number and DOT hazard class) and quantity of each hazardous waste shipped off-site to a TSDF during each odd numbered year. If a healthcare facility is an LQG due to its non-pharmaceutical hazardous waste, it will continue to be required to submit a BR under part 262. However, it need not include in its BR hazardous waste pharmaceuticals managed under part 266. As discussed previously, the Agency is no longer requiring healthcare facilities to count hazardous waste

pharmaceuticals managed under part 266 when determining their generator category under part 262. Instead, all healthcare facilities, with the exception of VSQGs, will be subject to this final rule for the management of hazardous waste pharmaceuticals. The Agency has determined that it does not need the information to be included in the BR because this final rule will bring a consistent approach to managing hazardous waste pharmaceuticals.

One commenter suggested that the time frame within which a healthcare facility must receive a signed manifest be shortened from 60 days to 45. The Agency did not finalize that request because many standards in this final rule were based upon SQG and universal waste standards. Since no manifest is required for transport and there is no exception reporting standard in the Universal Waste program, the Agency used the 60-day time frame in the part 262 SQG standards. LQGs have a 45-day time frame to receive a signed manifest from a designated facility. Therefore, shortening the exception reporting time frame from 60 days to 45 would not be consistent with the goals of this rule to relieve the burden of LQG standards on healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

The Agency is not finalizing the suggestion to unify the language in § 266.502(i)(2) to cover both missing and rejected shipments. The proposed language was taken from the generator requirements in § 262.42, which addresses both situations separately. The Agency is not aware of the existing approach creating any problems for generators and is finalizing the regulatory language as proposed.

K. Recordkeeping Requirements for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals (§ 266.502(j))

1. Summary of Proposal

The Agency proposed that healthcare facilities managing non-creditable hazardous waste pharmaceuticals maintain records similar to the records that must be kept by generators regulated under 40 CFR part 262 (see § 262.40). Specifically, we proposed that healthcare facilities must keep a signed copy of each hazardous waste manifest as a record for three years from the date that the non-creditable hazardous waste pharmaceutical was accepted by the initial hazardous waste transporter. If the healthcare facility is required to file an exception report because it does not receive a signed copy of the manifest from the designated facility within 60 days of the date that the hazardous waste pharmaceutical was accepted by the initial transporter, then the healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report. In addition, EPA proposed that a healthcare facility must keep records of any test results, waste analyses or other determinations made on hazardous waste pharmaceuticals regarding which pharmaceuticals are hazardous wastes for three years from the date of the test, analysis, or other determination. The Agency also proposed that any of the retention periods be automatically extended during the course of ongoing enforcement actions against any activity associated with hazardous waste pharmaceutical management or as requested by the Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

2. Summary of Comments

There were very few comments on this proposed provision. All but one of the commenters were states, all of which agreed with the proposed standard. One commenter suggested that we specify that all three types of records (manifest, exception reports, and test results/analysis/waste determinations) be kept on site.

3. Final Rule Provisions

The recordkeeping requirement is being finalized as proposed, with two changes. First, the Agency added a fifth provision in § 266.502(j)(5) to address comments requesting that all records be kept on site. The added provision also requires that all records must be readily available upon request by an inspector. The Agency understands that some records may be kept at off-site locations (e.g., headquarters), which is acceptable as long as those records are able to be produced in a timely manner upon the request of an inspector.

The second change was an addition to § 266.502(j)(3) that relieves a healthcare facility from the requirement to retain documentation of hazardous waste determinations in § 266.502(c) if it chooses to manage all of its non-creditable waste pharmaceuticals as hazardous waste under subpart P. As discussed elsewhere, a goal of this rule is to encourage healthcare facilities to manage all of their waste pharmaceuticals under subpart P to reduce the amount of pharmaceuticals entering surface and groundwater via sewering and landfill leachate. The relief provided in § 266.502(j)(3) provides additional incentive for healthcare facilities to manage their non-creditable non-hazardous pharmaceutical waste under subpart P.

A healthcare facility must keep a copy of the signed manifest for a period of at least three years from the date the shipment was accepted by the initial transporter. A healthcare facility must also keep a copy of any exception report for a period of at least three years from the date of the report. To make the recordkeeping consistent with the 2016 Generator Improvements final rule, a healthcare facility must keep any information used to support its hazardous waste determination for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal, unless it chooses to manage all of its non-creditable pharmaceutical waste as hazardous waste under subpart P. The periods of retention will be

automatically extended in the event of any enforcement activity or as requested by the Regional Administrator.

L. Response to Spills for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals (§ 266.502(k))

1. Summary of Proposal

For non-creditable hazardous waste pharmaceuticals generated and managed by healthcare facilities under this subpart, the Agency proposed basic spill response requirements, including the requirement that healthcare facilities immediately contain all spills of, and other residues from, hazardous waste pharmaceuticals. In addition, we proposed that healthcare facilities determine whether any material (e.g., residue, contaminated clean-up materials, or debris resulting from the spill) is or contains a hazardous waste pharmaceutical and, if so, that the healthcare facility manage it under the management standards for non-creditable hazardous waste pharmaceuticals. Commenters to the original 1993 proposed rulemaking for establishing the Universal Waste program overwhelmingly supported these release response measures (60 FR 25528; May 11, 1995). Thus, we believe it was appropriate to include them again in this proposal for healthcare facilities managing non-creditable hazardous waste pharmaceuticals since it was based on the Universal Waste program.

2. Summary of Comments

One waste management company was in support of the proposed standards while another voiced its concern with the proposed preamble language discussing the requirement to report releases into the environment greater than the reportable quantity without knowing the waste codes of the wastes that had been spilled. They recommended that the Agency establish a reportable quantity for hazardous waste pharmaceuticals so large releases are appropriately

reported to EPA. Similarly, one pharmacist trade association recommended that the Agency define what constitutes a release because the proposed regulatory language and preamble are unclear, and therefore it is also unclear when a release needs to be reported to the Agency.

One state commenter pointed out that these standards should also apply to healthcare facilities that accumulate potentially creditable hazardous waste pharmaceuticals. They recommend that this standard apply to all hazardous waste pharmaceuticals and that after a spill is cleaned up, the determination of credit potential must be made again. All other states agreed with the proposed standards for responding to spills.

3. Final Rule Provisions

The standards in this subsection are being substantially finalized as proposed with two changes.

First, we changed the word "release" to "spill" in the regulations in response to a commenter that expressed concern about having to comply with CERCLA requirements for spills of non-creditable hazardous waste pharmaceuticals. It was not the Agency's intent to imply that spills occurring inside a healthcare facility are automatically subject to CERCLA. The proposed preamble language was intended to differentiate between three scenarios: spills that are cleaned up immediately, spills that are not cleaned up immediately, and releases to the environment. Spills that are cleaned up immediately must be managed under this subpart. Spills that are not cleaned up immediately would generally constitute illegal disposal, which may result in further action by EPA or an authorized state. The proposal also mentioned that hazardous waste is included in the definition of hazardous substance under CERCLA, and any release to the environment would trigger CERCLA authority in addition to RCRA. In many cases, a spill of a hazardous waste pharmaceuticals that occurs inside a healthcare facility does not constitute a

release to the environment under CERCLA.[225] Therefore, this standard applies to spills that do not constitute a release to the environment, and there are no reporting requirements for spills unless they result in a release to the environment. This requirement makes no assertions about when or how CERCLA applies to spills of both non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals. The new terminology is also consistent with the term used in the definition of non-creditable hazardous waste pharmaceuticals in § 266.500, which refers to spills as opposed to releases.

Second, we addressed the comment from the state that requested a clarification regarding whether the spill response requirements apply to potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals. The Agency agrees that the applicability of this proposed provision—whether it applies only to non-creditable hazardous waste pharmaceuticals or to both potentially creditable hazardous waste pharmaceuticals and non-creditable hazardous waste pharmaceuticals—was unclear. The regulatory language has been changed to reflect that the standards in this subsection apply only to spilled non-creditable hazardous waste pharmaceuticals. Further, the proposed regulations required that a healthcare facility determine whether, after being cleaned up, spilled non-creditable hazardous waste pharmaceuticals are potentially creditable or non-creditable, implying that non-creditable hazardous waste pharmaceuticals could become potentially creditable. The Agency did not intend to imply that spilled non-creditable hazardous waste pharmaceuticals could become potentially creditable. The regulatory language has been modified to simply require that spilled non-creditable hazardous waste pharmaceuticals and clean-up material be contained and

[225] Spills are likely to occur upon impermeable surfaces both inside of and outside of a healthcare facility which limits the potential for release into the environment. Under CERCLA, a release to the environment also includes releases into the atmosphere. Since many pharmaceuticals are in pill form, spilled pharmaceuticals would rarely, constitute a release to the environment under CERCLA.

managed as non-creditable hazardous waste pharmaceuticals. To address this regulatory gap that commenters identified regarding spilled potentially creditable hazardous waste pharmaceuticals, the Agency has added a corresponding subsection containing standards for response to spills of potentially creditable hazardous waste pharmaceuticals at a healthcare facility to the regulatory language at § 266.503(f).

M. Management of Non-creditable Hazardous Waste Pharmaceuticals by Long-term Care Facilities that Collect Them from Individuals Who Self-administer

1. Summary of Proposal

The Agency proposed that a LTCF must collect hazardous waste pharmaceuticals from its residents that self-administer their medication and manage them under this subpart. This provision was proposed in order to require the proper management of all hazardous waste pharmaceuticals at LTCFs. LTCFs are similar to hospitals in that they are both healthcare providers, but they differ with respect to who owns the pharmaceuticals dispensed to patients. While hospitals own the pharmaceuticals they dispense, the pharmaceuticals dispensed at long-term care facilities belong to the residents of the facility. EPA understands that, while long-term care facilities often maintain each individual's pharmaceuticals in a centralized location, such as a pharmaceutical cart, there are instances where some individuals at some types of LTCFs may keep and self-administer their own pharmaceuticals. Under the proposal, long-term care facilities would have had to collect and manage all hazardous waste pharmaceuticals generated on site, regardless of ownership, in accordance with these same proposed subpart P management standards for healthcare facilities. EPA believed this approach would prohibit and prevent sewering of hazardous waste pharmaceuticals at these locations.

2. Summary of Comments

There was very little agreement with the proposed requirement for LTCFs to collect hazardous waste pharmaceuticals from patients that self-administer their medication. Most commenters argued that hazardous waste pharmaceuticals generated by residents who self-administer are household hazardous waste and that LTCFs are not allowed by law to perform any mandatory collection actions and have no authority to compel residents to surrender their unused medications. In addition, they commented that medication prescribed under Medicare Subpart D is considered the property of the resident. One commenter also pointed out that this provision would be unlawful and even dangerous to enforce because it would entail inspectors having to enter private residences, which is prohibited by many state statutes, and search through garbage bags and dumpsters to ensure that hazardous waste pharmaceuticals have not been illegally disposed.

Also, one commenter mentioned that this provision would add significant cost to the residents because waste management expenses are not covered under Medicare and pharmacies are not allowed to offer waste collection services for less than cost and would therefore be required to pass the full cost onto the residents.

3. Final Rule Provisions

The Agency is not finalizing the proposed provisions in this subsection. As discussed previously, after consideration of the comments, the Agency modified the definition of LTCF to specifically exclude assisted living facilities, group homes, independent living communities, and the independent/assisted living portions of continuing care retirement communities. The Agency agrees that the hazardous waste pharmaceuticals generated at these types of facilities meet the criteria for the household hazardous waste exclusion in § 261.4(b)(1) and are therefore not under the purview of RCRA regulations. Accordingly, we have also deleted proposed § 266.502(l) and

the final rule does not require LTCFs to collect hazardous waste pharmaceuticals for their residents that have custody of and self-administer their medication. The Agency does, however, reiterate that this definition of LTCFs classified them as a type of healthcare facility. As such, LTCFs are subject to all the provisions being finalized for hazardous waste pharmaceuticals that are present in an LTCF's central pharmacy, because the hazardous waste being generated is not the property of the residents. Additionally, hazardous waste pharmaceuticals that are in the custody of the LTCF on behalf of the resident must be managed under this subpart. That said, the Agency expects that most LTCFs will be VSQGs and therefore only subject to a limited subset of the regulations in this rule, including the sewer prohibition of § 266.505, the empty container standards of § 266.507, and the optional provisions of § 266.504. In fact, § 266.504(d) of the final rule includes a presumption that an LTCF with fewer than 20 beds is a VSQG.

Although not regulated under this subpart, the Agency recommends that assisted living facilities, group homes, independent living communities, and the independent and assisted living portions of continuing care retirement communities develop voluntary pharmaceutical collection programs for both hazardous and non-hazardous waste pharmaceuticals as a best management practice, as allowed by DEA regulations, to ensure proper management, avoid flushing, and minimize the potential for accidental poisonings, misuse or abuse.

N. Healthcare Facilities that Accept Hazardous Waste Pharmaceuticals from Off-site Very Small Quantity Generator Healthcare Facilities (§ 266.502(l))

1. Summary of Proposal

Typically, hazardous waste pharmaceuticals from healthcare facilities are transported either to a reverse distributor, if it is potentially creditable, or to a permitted or interim status hazardous waste TSDF, if it is not. However, stakeholders have informed EPA that in some

cases, hazardous waste pharmaceuticals are transported to another healthcare facility.

Until EPA finalized the Hazardous Waste Generator Improvements rule on November 28, 2016, CESQG regulations of § 261.5 did not allow a generator to send its hazardous waste off site to another generator, unless the receiving generator was one of the seven types of facilities listed in § 261.5(f)(3)(i)–(vii) or § 261.5(g)(i)–(vii), which included landfills permitted by state law.[226] The 2016 Hazardous Waste Generator Improvements final rule added a new provision for the consolidation of hazardous waste from VSQGs to LQGs under the control of the same person.[227] Person is defined under RCRA in § 260.10 and control is defined as "the power to direct policies at the facility under RCRA in §260.10." [228,229] This provision now allows the same company to consolidate its VSQG hazardous waste at its LQG sites.

Specific to healthcare facilities, EPA is aware of two situations in which VSQGs would like to consolidate their hazardous waste pharmaceuticals at other healthcare facilities. The first situation is LTCFs that are VSQGs that return their hazardous waste pharmaceuticals to long-term care pharmacies that they contract with. The second situation involves military bases, where the off-post clinics that are generally VSQGs would like to send their hazardous waste pharmaceuticals back to the base clinics or pharmacies on the nearby base.[230]

Since long-term care pharmacies are not generally under the control of the same person as the LTCF, the proposed healthcare facility consolidation provision was broader than what was

[226] The Hazardous Waste Generator Improvements final rule renamed CESGGs as VSQGs, moved the regulations from § 261.5 to § 262.14 and added an eighth type of facility.
[227] 40 CFR 262.14(a)(5)(viii).
[228] *Person* means an individual, trust, firm, joint stock company, Federal Agency, corporation (including a government corporation), partnership, association, State, municipality, commission, political subdivision of a State, or any interstate body.
[229] For purposes of this provision, "control" means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate facilities on behalf of a different person shall not be deemed to control such healthcare facility.
[230] See notes from 11-28-12 meeting with U.S. Army Institute of Public Health in the docket for this rule (EPA-HQ-RCRA-2007-0932-0209).

finalized in the 2016 Hazardous Waste Generator Improvements rule to accommodate the contractual relationship between long-term care facilities and long-term care pharmacies. The Agency proposed this consolidation provision to allow healthcare facilities that are VSQGs to send their hazardous waste pharmaceuticals to another healthcare facility rather than send it to a municipal solid waste landfill.

Specifically, EPA proposed to allow VSQG healthcare facilities to send their hazardous waste pharmaceuticals to an off-site healthcare facility without a hazardous waste manifest, provided the receiving healthcare facility meets four conditions. First, the receiving healthcare facility must be contracted to supply pharmaceutical products to the VSQG LTCF, or the VSQG healthcare facility and the receiving healthcare facility must both be under the control of the same person, as defined by § 260.10. [231] Second, the receiving healthcare facility must be managing its hazardous waste pharmaceuticals in accordance with subpart P. Third, the hazardous waste pharmaceuticals from the VSQG must be managed by the receiving healthcare facility as hazardous waste pharmaceuticals in accordance with subpart P once it arrives at the receiving healthcare facility. Fourth, the receiving healthcare facility must keep and maintain records of the hazardous waste pharmaceuticals received from the off-site VSQG healthcare facilities for three years from receipt of shipment.

As proposed, these conditions would ensure the proper management of the hazardous waste pharmaceuticals: once they are received by the healthcare facility, they are subject to the

[231] For purposes of this provision, "control" means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate facilities on behalf of a different person shall not be deemed to control such healthcare facility.

same management standards EPA proposed for hazardous waste pharmaceuticals managed by healthcare facilities.

EPA took comment on two aspects of this exclusion: (1) whether any additional conditions should be imposed in this provision and (2) whether to expand the scope of the provision to facilities that do not meet the proposed definition of a healthcare facility in this rule.

2. Summary of Comments

Overall, states, waste management and the healthcare industry were supportive of the proposal to allow VSQG healthcare facilities to consolidate their hazardous waste pharmaceuticals at another healthcare facility, provided the four conditions outlined above are met. One state, however, did oppose this provision unless the receiving healthcare facility is subject to all of the LQG requirements under part 262. They recommended that hazardous waste pharmaceuticals from VSQGs be consolidated at larger healthcare facilities under the 2016 Hazardous Waste Generator Improvements final rule to ensure more stringent standards are met by the receiving facility. Some states and pharmacists raised concerns that some of the language within the conditions was too narrow to serve the purpose that the language was trying to achieve.

3. Final Rule Provision

EPA is finalizing the provision to allow healthcare facilities that are operating under subpart P to receive hazardous waste pharmaceuticals from VSQGs with minor changes. Healthcare facilities that are VSQGs for their pharmaceutical and non-pharmaceutical waste may send their potentially creditable and non-creditable hazardous waste pharmaceuticals to an off-site healthcare facility operating under subpart P, without a hazardous waste manifest, provided

the receiving healthcare facility meets the four conditions in § 266.502(l)(1)–(4) or § 266.503(b)(1)–(4), as applicable.

Several conforming changes were made to reflect the change in terminology from CESQG to VSQG and to reflect the reorganization of the VSQG regulations from § 261.5 to § 262.14. There are three more substantive changes from the proposal. First, under § 266.502(l)(1) where we proposed that one way a healthcare facility could receive hazardous waste pharmaceuticals from an off-site VSQG healthcare facility was to have a contractual relationship to provide the pharmaceutical products to the LTCF, we broadened the language to allow cases in which a "business relationship" between the LTCF and long-term care pharmacy exists.

Under the final rule, a healthcare facility under subpart P may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the VSQG healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility;

(2) Is operating under subpart P for the management of its non-creditable hazardous waste pharmaceuticals;

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with subpart P; and

(4) Keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

It is important to note that a VSQG healthcare facility that chooses to send their waste for consolidation to an off-site healthcare facility is not considered to be operating under subpart P and does not need to notify as a VSQG operating under subpart P.

The second substantive change was to include a parallel provision in § 266.503 for potentially creditable hazardous waste pharmaceuticals. This addition allows healthcare facilities that are VSGQs two options for where to send their potentially creditable hazardous waste pharmaceuticals. The first option is to send them directly to a reverse distributor.[232] The second option is to send them to a healthcare facility operating under part 266 subpart P, provided the receiving facility meets the conditions of 266.503(b)(1)-(4).

The third change related to off-site consolidation of hazardous waste pharmaceuticals is to add paragraph § 262.14(a)(5)(x). Section 262.14(a)(5) of the VSQG regulations consists of a list of types of facilities to which VSQGs can send their hazardous waste. Section 262.14(a)(5)(viii) allows VSQGs to send their hazardous waste to large quantity generators under the control of the same person as the VSQG, provided certain conditions are met. This provision is similar to the provision we are finalizing in this rule for healthcare facilities that are VSQGs. Therefore, for consistency, we have added paragraph (x) to the list of facilities in § 262.14(a)(5) such that a healthcare facility that is a VSQG can send its non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals to an off-site healthcare facility (as defined in § 266.500) that meets the conditions in § 266.502(l) and § 266.503(b), as applicable.

4. Comments and Responses

[232] As allowed by 40 CFR 266.504(a).

Some states and pharmacists noted that language in the first condition may have the unintended consequence of prohibiting healthcare facilities from consolidating their hazardous waste pharmaceuticals due to their relationship with the consolidating facility. The first condition that a receiving healthcare facility must be under the control of the same person or contracted to supply pharmaceutical products to the VSQG's LTCF might prevent some long-term care facilities from taking advantage of this provision. Long-term care facilities that would otherwise be eligible to take advantage of this exclusion might not use it since CMS does not prevent long-term care facilities and/or their residents from using more than one long-term care pharmacy. This allows the long-term care facilities and the residents to shop for the "best and most competitive" pricing for medications and to change as needed.[233] Commenters believed that adding "business relationship" in addition to a contractual relationship for the healthcare facility and receiving facility to both be under the control of the same person would relieve this concern.

Furthermore, pharmacists raised the concern that a long-term care pharmacy would not want to take responsibility for returned pharmaceuticals under this condition as proposed unless they could confirm that they were the ones that distributed the pharmaceuticals in the first place (a receipt of purchase or similar documentation), since the management of these wastes is costly and may not be covered by the various healthcare programs. According to the CMS website, the managing of returned pharmaceuticals at long-term care pharmacies varies from state to state and is not a specific requirement of the Medicare/Medicaid program.[234] This consolidation provision was created so that VSQGs could consolidate their hazardous waste pharmaceuticals for proper management. If the provision as written is preventing long-term care facilities from potentially consolidating their hazardous waste, then it is thwarting the intended outcome of this provision

[233] https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html
[234] https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html

and that is why EPA decided to add "business relationship" to the first condition for VSQG consolidation.

One state commenter recommended that the receiving healthcare facilities must either be an LQG or comply with the LQG requirements under part 262, since LQGs have more protective management standards during accumulation. First, under part 266 subpart P, healthcare facilities do not have a generator category for their hazardous waste pharmaceuticals; all healthcare facilities are regulated the same under part 266 subpart P. Second, if EPA limited this consolidation provision to LQGs, then there would be a very small subset of receiving healthcare facilities that would be able to take advantage of this provision. Since subpart P allows healthcare facilities operating under this subpart to not count their hazardous waste pharmaceuticals towards their generator category, some healthcare facilities may no longer be LQGs for their other hazardous waste. It is highly unlikely that a long-term care pharmacy would remain an LQG under this rule since the majority of the hazardous waste that would be handled at these pharmacies would be pharmaceuticals. If we were to limit this provision to only LQG receiving facilities, then we would be preventing LTCFs from consolidating at long-term care pharmacies. Therefore, we determined that requiring the receiving facilities to be LQGs or to comply with LQG standards as a condition of the consolidation provision would severely limit the value of this provision.

In addition, the Agency is not finalizing a requirement for healthcare facilities that receive hazardous waste pharmaceuticals from VSQG healthcare facilities to manage the received pharmaceutical waste under the part 262 LQG standards. The Agency does not see the necessity in having more stringent management standards for healthcare facilities that receive pharmaceutical waste, because subpart P management standards are the same for all non-VSQG

healthcare facilities, regardless of the amount of hazardous waste pharmaceuticals they generate. The Agency has determined that the subpart P standards are sufficiently protective of human health and the environment since all pharmaceuticals at a receiving healthcare facility must be managed under the same subpart P standards, regardless of whether they were generated on site or received from off site. If a state determines that the standards being finalized for healthcare facilities that receive hazardous waste pharmaceuticals from off-site are not adequate, that state may implement its own standards, provided they are more stringent.

The waste management industry, as well as some states, recommended that EPA require a notification when a facility was receiving hazardous waste pharmaceuticals and at least some minimal requirements for labeling, recordkeeping, and documentation of shipments. One state also recommended that we issue licenses to facilities that were receiving hazardous waste pharmaceuticals in order to track who was taking advantage of this provision. Consistent with our rationale for the limited shipping requirements for "potentially creditable hazardous waste pharmaceuticals" in this rule, the Agency believes that the shipping of hazardous waste pharmaceuticals poses a relatively low risk of release to the environment but a high risk for diversion of the pharmaceuticals when labeled "pharmaceuticals." The hazardous waste that are being shipped often are in pill form or blister packs and not fifty-gallon drums of liquids that can be easily spilled. They are not likely to pose the same risks that typical hazardous waste could cause during shipping and transport, but there is a real risk to them being stolen if attention is brought to the contents of the containers. If the four conditions are met, the Agency believes this ensures the proper management of hazardous waste pharmaceuticals and adding new labeling and shipping requirements is unnecessary to accomplish that goal. Furthermore, the part 262 VSQG regulations do not require labeling or recordkeeping, and VSQGs might not take

advantage of this consolidation provision if the requirements are too onerous, thus continuing to put their hazardous waste pharmaceuticals in municipal solid waste landfills.

The waste management industry asked for clarification on hazardous waste pharmaceuticals consolidation across state lines that have different requirements for VSQGs. There is nothing in this section that prevents a healthcare facility from sending their hazardous waste pharmaceuticals to a healthcare facility in another state provided both states have adopted this provision. Each state has their own requirements, so it would be prudent for VSQG healthcare facilities to make sure that the state in which they are consolidating has adopted this provision and does not impose any additional requirements on the receiving healthcare facility that accepts this waste.

EPA also received comments on what types of facilities could take advantage of this provision, specifically whether this provision will include wholesale drug distribution centers. In the final rule, EPA has defined wholesale distributors as a type of healthcare facility under § 266.500. Wholesale distributors were not an example that was given to us at proposal for this consolidation provision, but if all four conditions were met and there was a contractual or business relationship between the VSQG healthcare facility and the wholesale distributor, they would not be precluded from using this provision. However, we would note that when a wholesale distributor receives hazardous waste pharmaceutical return from a healthcare facility, the pharmaceuticals are usually restocked, which means they are pharmaceutical products and not hazardous waste pharmaceuticals.

Lastly, a non-profit organization asked us to clarify if these consolidated hazardous waste pharmaceuticals would be eligible for redistribution or evaluation for donation once consolidated to the receiving facility. In regard to redistribution or evaluation for donation, if the receiving

healthcare facility can lawfully donate or redistribute the consolidated hazardous waste pharmaceuticals, there is nothing in this provision that prevents that from occurring, but those shipments would not fall under the consolidation provision in subpart P. If a VSQG is sending products to another facility, then the receiving facility should evaluate the received pharmaceuticals as they would any other products they receive for continued use, redistribution to secondary markets, donation and/or any other lawful possibilities. At this point, they are not a solid or hazardous waste and not subject to the requirements in § 266.502(l) or § 266.503(b).

EPA would also note that this provision is optional and it is not meant to impose undue burden on healthcare facilities. This section does not require a VSQG healthcare facility to ship their hazardous waste pharmaceuticals to a receiving healthcare facility. VSQG healthcare facilities continue to have the option, unless the state regulations are more stringent, of sending their hazardous waste pharmaceuticals to any of the types of facilities specified in § 262.14, including a municipal solid waste landfill.

XI. Standards for Healthcare Facilities that Accumulate Potentially Creditable Hazardous Waste Pharmaceuticals Prior to Shipment to Reverse Distributors (§ 266.503)

A. Healthcare Facilities Making a Hazardous Waste Determination for Potentially Creditable Pharmaceuticals (§ 266.503(a))

1. Summary of Proposal

EPA proposed standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals in § 266.503 of subpart P. As with non-creditable hazardous waste pharmaceuticals, a healthcare facility must determine which potentially creditable pharmaceuticals are listed or characteristic hazardous wastes, in order to determine which potentially creditable pharmaceuticals are subject to regulation under this subpart.

Accordingly, we proposed that a healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable solid waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical (i.e., is listed in 40 CFR part 261 subpart D or exhibits a characteristic identified in 40 CFR part 261 subpart C).

We also proposed that a healthcare facility may choose to manage all of its potentially creditable waste pharmaceuticals (both hazardous and non-hazardous) together as potentially creditable hazardous waste pharmaceuticals while accumulating on site and when shipping off site under § 266.509. If a healthcare facility chooses this approach of commingling its hazardous and non-hazardous potentially creditable waste pharmaceuticals, it would not need to make individual hazardous waste determinations, but would have made a generic decision that all of its potentially creditable waste pharmaceuticals are hazardous and would manage them as potentially creditable hazardous waste pharmaceuticals in accordance with the requirements in 40 CFR part 266 subpart P.

We proposed that healthcare facilities may choose to manage potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under the shipping standards of § 266.509. Additionally, EPA proposed that healthcare facilities would be prohibited from sending hazardous waste other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor. This was in keeping with our position that a reverse distributor's function in managing hazardous waste should be limited to managing hazardous waste pharmaceuticals that have a reasonable expectation of receiving manufacturer credit and not non-creditable hazardous waste pharmaceuticals or other non-pharmaceutical hazardous waste.

2. Summary of Comments

Pharmacists, some wholesalers, and manufacturers expressed concern that making hazardous waste determinations at their facilities would require additional staff, additional training on making hazardous waste determination, as well as more storage space in which to hold the hazardous waste as the determinations are being made.

We received mixed comments on commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals. Healthcare facilities and pharmacists were in favor of EPA allowing commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals, and the benefit it offers in handling their pharmaceutical waste or continuing the common practice of commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals when sent to reverse distributors. On the other hand, waste management and states raised concerns that commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals may prevent healthcare facilities from sending their waste across state lines or to certain reverse distributors, due to state regulations and/or reverse distributors' policies.

3. Final Rule Provisions

EPA is finalizing the standards as proposed, with some minor changes. Under this section, a healthcare facility has two choices: (1) make a hazardous waste determination on each potentially creditable waste pharmaceutical and determine individually which are hazardous waste and thus subject to regulation under this subpart or, 2) commingle all potentially creditable pharmaceutical waste whether or not it is hazardous waste and manage the commingled pharmaceuticals under this subpart and thereby not have to make individual hazardous waste determinations.

EPA removed "even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261 subpart C and are not listed in 40 CFR part 261 subpart D" from the non-hazardous waste provision of this section since it was redundant with determinations of solid waste pharmaceuticals and whether they are potentially creditable or not.

EPA has also modified the regulatory language in the final rule to make clear that when a healthcare facility commingles potentially creditable non-hazardous and hazardous waste pharmaceuticals, the healthcare facility is choosing to subject the potentially creditable non-hazardous waste pharmaceuticals to all of subpart P while being managed at a healthcare facility and in preparation for shipping off-site. Once potentially creditable non-hazardous and hazardous waste pharmaceuticals are commingled they are subject to all applicable subpart P management standards while they remain commingled. As a practical matter, however, we expect that the primary impact to healthcare facilities will be that potentially creditable non-hazardous waste pharmaceuticals are subject to the shipping standards of § 266.509. Once potentially creditable non-hazardous waste pharmaceuticals are shipped off site to a reverse distributor, a reverse distributor may choose to segregate the non-hazardous waste pharmaceuticals from the hazardous waste pharmaceuticals. This process of segregation by the reverse distributor would require the reverse distributor to make new hazardous waste determinations on the commingled pharmaceuticals.

4. Comments and Responses

We received many comments on making hazardous waste determinations and commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals. While the commenters raised valid concerns on why making hazardous waste determinations can be burdensome on a healthcare facility, or why commingling potentially creditable non-hazardous

and hazardous waste pharmaceuticals may not work for all facilities, EPA made only minor editorial changes to this section of the final rule. The Agency determined that more substantive changes were unnecessary because this provision contains sufficient flexibility by providing healthcare facilities with two options.

a. *Making hazardous waste determinations.* Pharmacists, some wholesalers, and manufacturers expressed concern that being required to make hazardous waste determinations at their facilities would impose undue burden because they would have to hire additional staff and train them to make accurate waste determination. They argue that they would also need to allocate more space in which to store waste as the determinations are being made. Some commenters stated that making hazardous waste determinations may prevent healthcare facilities from sending their hazardous waste pharmaceuticals to reverse distributors at all. In support of the comments above, manufacturers and wholesalers argued that reverse distributors have the appropriate RCRA expertise to make accurate waste determinations, that they have served as a consolidation point for unused and hazardous waste pharmaceuticals for many years, and that the process has been effective and successful. The Agency notes, however, that allowing potentially creditable pharmaceuticals to be sent to a reverse distributor without a hazardous waste determination being made at the point of generation violates a basic tenet of RCRA, because the decision to send them to a reverse distributor is effectively a decision to discard. In addition, the burden mentioned by commenters associated with making individual waste determinations would likely be significantly mitigated by exercising the option to manage all potentially creditable waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals.

b. *Commingled waste stream*. As previously noted, we received mixed comments on commingling potentially creditable non-hazardous hazardous waste pharmaceuticals.

EPA proposed the option of commingling potentially creditable non-hazardous and hazardous waste pharmaceuticals to mitigate the burden of complying with the management standards, particularly for healthcare personnel making hazardous waste determinations. Given that many healthcare facilities currently commingle their potentially creditable non-hazardous and hazardous waste pharmaceuticals, we expect the practice to continue. However, if commingling causes undue burden on a facility due to state regulations, reverse distributor policies, or other reasons, then the healthcare facility does not have to utilize this option and can make individual hazardous waste determinations in accordance with § 266.503(a). This is an individual decision for each healthcare facility and each healthcare facility may choose what works best for managing its potentially creditable pharmaceutical waste.

Retailers and reverse distributors recommended that healthcare facilities should be allowed to make a determination about whether the item will be managed as hazardous when it becomes a waste at the time of arrival at the retail store or healthcare facility. They believe this practice would be impeded if all pharmaceuticals must be managed as potentially creditable hazardous waste pharmaceuticals when they become waste. If this is common practice among healthcare facilities, then the need to commingle their waste may not be something that is important. Allowing the commingling of all solid waste pharmaceuticals is meant to ease the burden on healthcare facilities that are not currently making hazardous waste determinations, or do not wish to make them, by allowing them to manage and ship all of their potentially creditable waste pharmaceuticals together.

B. Accepting Potentially Creditable Hazardous Waste Pharmaceuticals from an Off-site Healthcare Facility that is a Very Small Quantity Generator (§ 266.503(b))

1. Summary of Proposal

EPA proposed to allow healthcare facilities operating under subpart P to accept potentially creditable and non-creditable hazardous waste pharmaceuticals from an off-site VSQG healthcare facility without a hazardous waste manifest, provided four conditions are met. We proposed this provision in § 266.502(m) under the standards for managing non-creditable hazardous waste pharmaceuticals.[235] We proposed that healthcare facilities operating under subpart P could accept both potentially creditable and non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG. Previously, the part 262 VSQG regulations did not allow a healthcare facility to send its hazardous waste off-site to another healthcare facility, unless the receiving healthcare facility is one of the eight types of facilities listed in § 262.14(a)(5)(i–viii). For more detailed information on our proposal, please refer to section X.N.

2. Summary of Comments

EPA only received one comment in this section concerning changes to the generator category of the receiving facility. A trade association of pharmacists was concerned that allowing VSQG consolidation would affect the generator category of the receiving healthcare facility, and that it would need to report as an LQG.

3. Final Rule Provision

In the proposed rulemaking, EPA intended to allow healthcare facilities to accept both potentially creditable and non-creditable (including commingled) hazardous waste pharmaceuticals from an off-site VSQG healthcare facility, provided the receiving healthcare facility complies with the four conditions of § 266.502(m) (now in § 266.502(l)). In the final

[235] This provision is now found at § 266.502(l).

rule, we clarified our intention to allow healthcare facilities to accept both potentially creditable and non-creditable (including commingled) hazardous waste pharmaceuticals from an off-site VSQG healthcare facility by placing similar standards in § 266.503(b) under the standards for managing potentially creditable hazardous waste pharmaceuticals. This does not reflect a change from what was proposed, only that the consolidation standards apply to healthcare facilities receiving both non-creditable and potentially creditable hazardous waste pharmaceuticals.

Under the final rule, a healthcare facility that is a VSQG can send both its potentially creditable hazardous waste pharmaceuticals and non-creditable (including commingled) hazardous waste pharmaceuticals to an off-site healthcare facility operating under subpart P, provided the receiving healthcare facility complies with the four requirements of the respective sections. Regulations for the receiving healthcare facilities now appear in § 266.502(l) for non-creditable hazardous waste pharmaceuticals and in § 266.503(b) for potentially creditable hazardous waste pharmaceuticals. VSQG healthcare facilities that send their hazardous waste pharmaceuticals to an off-site healthcare facility are subject to the regulations in § 266.504(b), with further discussion in section XII.B of the preamble.

Under § 266.503(b) of the final rule, a healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the VSQG healthcare facility that is sending potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility;

(2) Is operating under subpart P for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with subpart P; and

(4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

It is important to note that a VSQG healthcare facility that chooses to consolidate its hazardous waste pharmaceuticals at an off-site healthcare facility is not considered to be operating under subpart P, and does not need to notify as a VSQG operating under subpart P.

4. Comments and Responses

A pharmacists' association was concerned that allowing for VSQG consolidation would change the generator category of the receiving healthcare facilities and that the consolidating facility would need to report as an LQG. All healthcare facilities operating under part 266 subpart P are regulated the same, regardless of the amount of hazardous waste pharmaceuticals they generate. Further, healthcare facilities managing their hazardous waste pharmaceuticals under this subpart do not count their hazardous waste pharmaceuticals toward their generator category so consolidation of this additional hazardous waste pharmaceuticals at their facilities would not change the generator category of the receiving healthcare facility.

C. Accumulation Time, Container Management and Labeling for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals

Under the hazardous waste generator regulations in part 262, EPA requires specific management standards for containers that hold hazardous waste. However, potentially creditable

hazardous waste pharmaceuticals pose a lower risk of release into the environment than traditional industrial hazardous waste. The risk of release is lower for several reasons.

First, potentially creditable hazardous waste pharmaceuticals must be in original manufacturers' packaging by definition and are often in their outer packaging as well, providing two layers of protection from leaks or spills.[236] Second, potentially creditable hazardous waste pharmaceuticals are typically generated in the pharmacy area of a healthcare facility where there is restricted access, creating a layer of security for these pharmaceuticals. Third, EPA has been informed that it is common practice at healthcare facilities for potentially creditable waste pharmaceuticals that are destined for a reverse distributor to be taken from the shelves of the pharmacy periodically and promptly boxed for off-site shipment.

For the reasons listed above, EPA did not propose specific standards for managing and labeling containers of potentially creditable hazardous waste pharmaceuticals at healthcare facilities. For the same reasons, we also did not propose a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals.

This is not to say that all potentially creditable hazardous waste pharmaceuticals waste pharmaceuticals are safe and pose no risk of spill or release into the environment. It is important to note that the accumulation of some potentially creditable hazardous waste pharmaceuticals, such as liquids and aerosols, may pose more of a risk due to possible spills or leaks than solid pills. However, EPA believes that the small quantities in which liquid and aerosol potentially creditable hazardous waste pharmaceuticals are generated, along with the DOT packaging requirements (49 CFR parts 173, 178, and 180), significantly reduces the risks of spills or releases to the environment.

[236] See 73 FR 73529; December 2, 2008.

In addition, to further mitigate the potential for spills or leaks, as a best management practice, EPA encourages healthcare facilities to place the original containers, and packaging containing liquids and aerosols pharmaceuticals, in separate individual containers (e.g., sealed storage bag) before placing them in the accumulation container.

1. Accumulation Time and Container Management of Potentially Creditable Hazardous Waste Pharmaceuticals.

a. Summary of proposal. EPA did not propose a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals or specific standards for how the containers must be managed during accumulation.

b. Summary of comments. Most commenters were in favor of adding some guidelines for accumulation time and container management. Some states commented that the proposed standards for non-creditable hazardous waste pharmaceuticals should be applied to both non-creditable and potentially creditable hazardous waste pharmaceuticals to prevent confusion from having multiple accumulation standards, and to provide extra protection of human health and the environment.

c. Final rule provisions. EPA is not finalizing a time limit for accumulating containers of potentially creditable hazardous waste pharmaceuticals. EPA is also not finalizing specific container management standards for healthcare facilities that accumulate containers of potentially creditable hazardous waste pharmaceuticals

d. Comments and responses. Several states expressed concern about the security of potentially creditable hazardous waste pharmaceuticals during accumulation. These commenters agreed that potentially creditable hazardous waste pharmaceuticals should be accumulated in a designated area that is labeled and kept locked or sealed according to best management practices for that

facility as an additional deterrent to illicit diversion. Commenters also expressed concerned that not having designated accumulation areas could lead to situations where healthcare facility personnel may misplace or forget the locations of accumulation containers. States were concerned that the potential for healthcare facilities to receive manufacturer credit does not sufficiently encourage proper management.

As previously discussed, potentially creditable hazardous waste pharmaceuticals do not pose the same risks as other hazardous wastes. We received many comments, especially from the retail industry, about the condition of packages being important for being eligible and receiving manufacturer credit. For example, broken and/or leaking containers cannot be sent to a reverse distributor per the definition of "potentially creditable hazardous waste pharmaceuticals," so there is an incentive to manage these items carefully. There is also an incentive to not overaccumulate wastes in healthcare facilities since manufacturer credit is only issued by reverse distributors and in many cases, cannot be collected by a healthcare facility until the reverse distributor receives them.

It is also important to note that many of these potentially creditable hazardous waste pharmaceuticals are already being generated and stored in secure areas, such as pharmacies, and being handled by personnel that have pharmaceutical expertise. EPA is also recommending that liquids and aerosols be put in sealed plastic bags, containers, or other management practices during accumulation to reduce the risk of spills and releases.

As for labeling the accumulation area with the words pharmaceutical waste, the concern still remains for increasing the potential for illicit diversion of these potentially creditable hazardous waste pharmaceuticals by bringing attention to the fact that it contains

pharmaceuticals. Therefore, the Agency is not finalizing a requirement for healthcare facilities to label accumulation areas for potentially creditable hazardous waste pharmaceuticals.

Finally, if a state is uncomfortable with our approach to the accumulation of potentially creditable hazardous waste pharmaceuticals, it may choose to be more stringent in this regard when it adopts the rule.

2. Labeling Requirements for Containers of Potentially Creditable Hazardous Waste Pharmaceuticals.

a. Summary of proposal. EPA did not propose specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals while they are accumulated on-site at a healthcare facility because they are in original manufacturer packaging, they are already labeled, and any additional labeling would be duplicative or apply to secondary containers, such as boxes used to ship to reverse distributors.

In addition, due to concerns regarding illicit diversion of pharmaceuticals, EPA believes that it is safer not to call attention to the fact that these containers hold pharmaceuticals. Unlike floor or patient care pharmaceutical waste, the potentially creditable hazardous waste pharmaceuticals returned to a reverse distributor often have high black-market value that makes them susceptible to diversion. Thus, EPA did not propose to require a label for containers used to accumulate potentially creditable hazardous waste pharmaceuticals.

b. Summary of comments. Many states believe that labeling should be required for all containers of hazardous waste to ensure proper management and disposal. Proper management, according to comments, includes accumulation in designated locations with individual containers labeled for inspection.

Other commenters expressed concerns that containers that are not labeled are subject to inaccurate waste determinations and will be mishandled and treated as non-creditable hazardous waste pharmaceuticals and sent to a TSDF rather than as potentially creditable which could ultimately be destined for a reverse distributor.

c. Final rule provision. EPA is not finalizing labeling standards for containers of potentially creditable hazardous waste pharmaceuticals accumulated by healthcare facilities.

d. Comments and responses. While the commenter's concerns apply to hazardous waste in general and for hazardous waste going to a TSDF, we do not believe they are equally applicable to containers of potentially creditable hazardous waste pharmaceuticals. First, containers of potentially creditable hazardous waste pharmaceuticals are in original manufacturer's packaging (or have been repackaged for use in a LTCF) and thus the contents are easily identifiable. Second, if a healthcare facility does not label an accumulation container on site and then forgets about it or misidentifies where it needs to go, then no manufacturer credit will be issued for those potentially creditable hazardous waste pharmaceuticals. Likewise, if a healthcare facility does label the containers on site and the contents are illicitly diverted, then the healthcare facility will not receive the manufacturer credit for those items. Healthcare facilities have a monetary incentive to keep track of what is in these containers, regardless of whether they are labeled, and to make sure they arrive unmolested at the reverse distributor.

Additionally, by imposing labeling requirements, EPA does not want to deter the practice of commingling potentially creditable hazardous waste pharmaceuticals with potentially creditable non-hazardous waste pharmaceuticals since both are typically transported together to a reverse distributor.

Therefore, EPA concludes that it is not necessary to require any labeling standards for potentially creditable hazardous waste pharmaceuticals.

D. No Biennial Reporting for Potentially Creditable Hazardous Waste Pharmaceuticals Generated at Healthcare Facilities (§ 266.503(d))

1. Summary of Proposal

The Agency proposed that healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

2. Summary of Comments

One state commented that it would prefer to be notified about who is handling this waste to ensure that healthcare facilities are adhering to the prohibition on sewering, since they will not know who is handling this waste.

3. Final Rule Provision

The Agency is finalizing as proposed that healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart. Potentially creditable hazardous waste pharmaceutical quantities will be captured by the reverse distributors' required biennial reports,[237] therefore, a requirement for healthcare facilities to report quantities of potentially creditable hazardous waste pharmaceuticals generated would be duplicative.

4. Comments and Responses

[237] This provision is found at § 266.510(c)(9)(i)

One state was concerned that they would not know which healthcare facilities are generating potentially creditable hazardous waste pharmaceuticals. All healthcare facilities operating under this subpart will be required to submit a one-time notification that they are subject to subpart P (§ 266.502(a)(1)). States will, therefore, be informed of what healthcare facilities are operating under subpart P and can inspect accordingly.

E. Recordkeeping Requirements for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.503(e))

1. Summary of Proposal

EPA proposed to require healthcare facilities to keep records of the shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors.

Specifically, we proposed that healthcare facilities that initiate a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor keep (1) records of advance notification, (2) shipping papers or bills of lading, and (3) records of delivery confirmation. We proposed that a healthcare facility must retain these records for three years after the shipment was initiated. These records document that shipments of potentially creditable hazardous waste pharmaceuticals have been taken into the control and custody of the receiving reverse distributor and have not been diverted. In most cases, retaining records for three years should be sufficient for inspection purposes; however, we proposed that the periods of retention are automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator.

2. Summary of Comments

One state agreed that three years was a sufficient retention period to enable inspectors to identify issues upon inspection. State and local governments requested clarification about what

types of documentation (e.g., shipping papers/bills of lading) satisfies the requirement. One commenter argued that the receiving facility should document efforts made to locate shipments that did not arrive.

3. Final Rule Provision

EPA is finalizing the proposed recordkeeping provision for potentially creditable hazardous waste pharmaceuticals for healthcare facilities and reverse distributors that initiate a shipment to another reverse distributor with two changes. First, as we discuss later in the shipping standards, we have eliminated the requirement for healthcare facilities to provide advance notification of shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Thus, we have removed the requirement to keep a record of the advance notification. Second, EPA removed the reference to bills of lading from the recordkeeping requirement while keeping shipping papers since bills of lading are a type of shipping papers under DOT regulations. This is also responsive to comments asking for clarification. Healthcare facilities initiating shipments of potentially creditable hazardous waste pharmaceuticals must keep, (1) delivery confirmation for each shipment and (2) shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable. EPA is finalizing that these records must be retained for three years unless there is an unresolved enforcement activity or a request by the EPA Regional Administrator to keep them longer. In that case, the period of retention is automatically extended. EPA is finalizing this requirement as proposed despite input from commenters, as this is standard practice with enforcement activity. At the request of commenters, we have added a requirement that all records must be readily available upon request by an inspector.

F. Response to Spills for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.503(f))

1. Summary of Proposal

EPA proposed response requirements for spills of non-creditable hazardous waste pharmaceuticals but did not propose similar response requirements for releases of potentially creditable hazardous waste pharmaceuticals.

2. Summary of Comments

A commenter suggested that spills of potentially creditable hazardous waste pharmaceuticals should also be subject to the same containment and cleanup requirements as non-creditable hazardous waste pharmaceuticals. The commenter also asked whether EPA intended that all spills of potentially creditable hazardous waste pharmaceuticals render them non-creditable.

3. Final Rule Provision

EPA agrees with comments that all spills of hazardous waste pharmaceuticals, both potentially creditable and non-creditable, must be contained, and that all spills of potentially creditable hazardous waste pharmaceuticals renders them non-creditable. Therefore, in response to this comment, we have added a similar provision to the healthcare facility standards of § 266.503(f) for responding to releases of potentially creditable hazardous waste pharmaceuticals.

The standards in this section are based upon what is being finalized in the standards for response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities in § 266.502(k). The final rule requires that a healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with subpart P.

It is EPA's understanding that unused/undispensed pharmaceuticals that remain in original manufacturer's packaging often receive manufacturer credit even if the packaging has been opened. In the event of a spill, a healthcare facility should reevaluate whether any pharmaceuticals that remain in their containers (not spilled) are still eligible to receive manufacturer credit per the definition of potentially creditable hazardous waste pharmaceutical in § 266.500. The healthcare facility must determine whether the pharmaceuticals that remain in the containers are potentially creditable and manage them according to subpart P. Even if a healthcare facility determines that the remaining pharmaceuticals are potentially creditable, it must also ensure that the decision is consistent with the manufacturer's policies. It is important to note that this only applies to whatever might be left in the container and was not spilled.

XII. How Does this Rule Apply to Healthcare Facilities that are Very Small Quantity Generators for Both Their Hazardous Waste Pharmaceuticals and Their Non-pharmaceutical Hazardous Waste? (§ 266.504)

A. *Very Small Quantity Generators Using Reverse Distributors (§ 266.504(a))*

1. Summary of Proposal

VSQGs are subject to a limited set of federal RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 262.14.[238] Under § 262.14, VSQGs are limited in where they may send their hazardous waste for treatment and disposal.[239] In § 266.504(a), we proposed to allow VSQG healthcare facilities to send their potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Without this

[238] Since the hazardous waste pharmaceutical rule was proposed, § 261.5 has been renumbered to § 262.14 as part of the reorganization of the generator regulations in the Generator Improvements final rule and this will be referenced later in this section.

[239] Since the Pharmaceutical rule was proposed § 261.5(f)(3)(i)-(vii) for acute hazardous waste and § 261.5(g)(3)(i)-(vii) for non-acute hazardous waste has been combined and renumbered to § 262.14(a)(5)(i)-(vii) for acute and non-acute hazardous waste in the Hazardous Waste Generator Improvements final rule.

change, VSQGs would have been required to send all their hazardous waste pharmaceuticals, including those that are potentially creditable, to one of the types of facilities in § 262.14, which does not include a reverse distributor. Although we proposed to make this change within part 266 subpart P, we requested comment on whether stakeholders would prefer this change to be made within the VSQG regulations in § 262.14 (formerly the CESQG regulations in § 261.5) instead. VSQGs are still required to send their non-pharmaceutical hazardous waste and their non-creditable hazardous waste pharmaceuticals to one of the types of facilities listed in § 262.14.[240]

2. Summary of Comments

States, waste management and reverse distributors supported allowing VSQG healthcare facilities to send their potentially creditable hazardous waste to reverse distributors. These same commenters were also in favor of including their change in both this rule and § 262.14 to ensure that all healthcare facilities that might have potentially creditable hazardous waste pharmaceuticals would be aware of this provision and be able to take advantage of it.

3. Final Rule Provision

We are finalizing this provision as proposed, with minor edits. In general, this final rulemaking will preserve the current regulatory scheme for VSQGs: healthcare facilities that qualify as VSQGs for their total count of hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste will maintain their conditional exemption under § 262.14 and will not be subject to most aspects of this proposal. Healthcare facilities that are VSQGs are subject to three provisions of part 266 subpart P: the sewer ban in § 266.505, the empty container standards in § 266.507, and the optional provisions in § 266.504.

[240] A VSQG healthcare facility may be able to send its hazardous waste pharmaceuticals for consolidation at another healthcare facility operating under subpart P as allowed by § 266.504(b), or a large quantity generator and 262.14(a)(5)(viii), see section X of the preamble for further discussion.

In response to commenter's request for clarity, the final rule makes it clear that § 266.504 applies to VSQG healthcare facilities that are VSQGs when counting both its hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste. Section 266.504 does not apply to healthcare facilities that become VSQGs under this rule as a result of not having to count their hazardous waste pharmaceuticals. Such healthcare facilities are VSQGs with respect to their non-pharmaceutical hazardous waste only and must operate under subpart P for their hazardous waste pharmaceuticals.

Under the final rule, a healthcare facility that is a VSQG when counting both its hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may choose to send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor. In response to comments, EPA has added a conforming change to the VQSG generator provision in § 262.14(a)(5)(ix) for added clarity on this point. It is a restatement of § 266.504(a) which allows VSQG healthcare facilities to send their potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

A healthcare facility that is a VSQG for both their hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste is given a choice. The healthcare facility may

- Operate as a standard VSQG under part 262 rules, and can use the optional provisions in § 266.504, or
- Operate under as a healthcare facility under part 266 subpart P.

4. Comments and Responses

The waste management industry requested that EPA regulate all healthcare facilities under the proposed subpart P requirements regardless of generator category. While this rule's requirements are meant to create uniformity for healthcare facilities managing hazardous waste

pharmaceuticals, we want to avoid creating undue burden on VSQGs and have declined to make them subject to part 266 subpart P except for the sewer prohibition in § 266.505, the empty container provisions in § 266.507 and the optional provisions in § 266.504..

B. Off-site Collection of Hazardous Waste Pharmaceuticals Generated by Healthcare Facilities (§ 266.504(b))

1. Summary of Proposal

EPA proposed that a healthcare facility that is a VSQG may send its hazardous waste pharmaceuticals to another healthcare facility provided the receiving healthcare facility meets certain conditions. These conditions were proposed in § 266.502(m) of this subpart.

2. Summary of Comments

One state was concerned about how consolidation might affect the generator category of the receiving facility. The commenter also raised concerns about the receiving facility performing some functions of a reverse distributor.

3. Final Rule Provision

EPA is finalizing the proposed provision with conforming changes that correspond with other sections within this rule and one additional change. The first conforming change added the words "hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste" to clarify that only healthcare facilities that are VSQGs for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste may take advantage of this provision. The second conforming change converted the term CESQG to VSQG according to the 2016 Hazardous Waste Generator Improvements final rule. EPA notes that the consolidation provisions for healthcare facilities that receive both non-creditable hazardous waste pharmaceuticals and

potentially creditable hazardous waste pharmaceuticals from off-site were added to the regulations in §§ 266.502(l) and 266.503(b) (sections X.N and XI.B of the preamble), respectively. The final change added flexibility for VSQGs to meet the consolidation provisions that were added as part of the 2016 Hazardous Waste Generator Improvements final rule in lieu of the subpart P off-site consolidation provisions. In this case, the receiving LQG would have to meet the conditions in § 262.17(f) while the VSQG healthcare facility would have to meet the conditions in § 262.14(a)(5)(viii).

The final rule provision allows a healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste to send its hazardous waste pharmaceuticals off-site provided either of the following is met: (1) the receiving healthcare facility meets the conditions in § 266.502(1) and § 266.503(b) of this subpart, as applicable, or (2) the VSQG healthcare facility meets the conditions in § 262.14(a)(5)(viii), and the receiving large quantity generator meets the conditions in § 262.17(f).

4. Comments and Responses

One commenter asked for clarification about whether EPA will allow consolidation of a healthcare facility's potentially creditable or non-creditable hazardous waste pharmaceuticals at a reverse distributor. In response, the Agency is clarifying that subpart P does not allow healthcare facilities to consolidate any pharmaceutical waste at a reverse distributor. Healthcare facilities may only consolidate their waste at another facility that meets the definition of a healthcare facility as defined in § 266.500. See sections X.N and XI.B, respectively, for further discussion about healthcare facilities that receive non-creditable and potentially creditable hazardous waste pharmaceuticals from off-site healthcare facilities.

C. Long-Term Care Facilities that are Very Small Quantity Generators Can Dispose Hazardous Waste Pharmaceuticals in Drug Enforcement Administration Collection Receptacles (§ 266.504(c))

1. Summary of Proposal

We proposed that a LTCF that is a VSQG that has an on-site DEA collection receptacle could use the collection receptacle for its hazardous waste pharmaceuticals, even if they are not controlled substances. We reasoned that since DEA already allows controlled substances to be commingled with non-controlled substances, it was consistent to allow VSQG hazardous waste pharmaceuticals that are not controlled substances to be placed in DEA authorized collection receptacles along with controlled substances. Further, we reasoned that the management of VSQG hazardous waste pharmaceuticals as DEA controlled substances is preferable to management as municipal solid waste because it provides greater protection to patients, visitors, and workers at LTCFs to have the hazardous waste pharmaceuticals in DEA authorized collection receptacles than down the sewer or in the facility's regular trash.

2. Summary of Comments

The few comments we received on this specific provision of the proposed rulemaking were mostly supportive.

3. Final Rule Provisions

We are finalizing the provision that allows an LTCF that is a VSQG to use a DEA authorized collection receptacle to dispose of its hazardous waste pharmaceuticals with three minor changes. The first change is to clarify again that this provision only applies to LTCFs that are VSQGs for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and are therefore not subject to subpart P (except the sewer prohibition of § 266.505, the empty

container standards of § 266.507, and the optional provisions of § 266.504). The second change is to clarify that the DEA authorized collection receptacle that the VSQG LTCF uses to dispose of its hazardous waste pharmaceuticals must be on-site. The third change is to exclude items such as contaminated personal protective equipment or clean-up residues from being placed into the DEA authorized collection receptacle. Although these items meet our new definition of pharmaceutical, a DEA authorized collection receptacle is designed for the collection of the pharmaceuticals themselves and not larger items that might be contaminated by the pharmaceuticals, such as contaminated PPE or clean-up residues. For instance, they are required to have small openings and limited volumes, making their use for contaminated PPE and clean-up residues impractical.

4. Comments and Responses

One commenter thought that this proposed provision was "not feasible" because "take-back kiosks for controlled substances are intended to be used by end users and not the DEA registrant."[241] In many, if not most, cases at an LTCF, the hazardous waste pharmaceuticals will be from an ultimate user and the DEA regulations permit the collection receptacles to be used for collecting both controlled and non-controlled substances from ultimate users. There are more limited cases where an LTCF may have its own inventory of non-controlled hazardous waste pharmaceuticals.

Although EPA concurs with the commenters that the DEA authorized collection receptacles are only for controlled substances from ultimate users, EPA does not believe that the same limitation needs to be placed on the pharmaceuticals from VSQGs that are hazardous waste but not controlled substances. In fact, it could be argued that long-term care facilities that are

[241] See comment number EPA-HQ-RCRA-2007-0932-0280.

VSQGs would be allowed to use DEA authorized collection receptacles for their hazardous waste pharmaceuticals even without this new provision, provided the waste from the DEA authorized collection receptacles is treated or disposed at one of the types of facilities identified in § 262.14(a)(5) (e.g., facilities that are permitted or have interim status to manage hazardous waste and facilities that are permitted, licensed or registered by a state to manage hazardous waste, municipal waste or non-municipal waste). Nevertheless, we did propose, and are finalizing the provision in § 266.504(c) making it clear that an LTCF that is a VSQG can place its hazardous waste pharmaceuticals in an on-site DEA collection receptacle.

However, as the commenter pointed out, it is important to note that the DEA regulations for controlled substances are much narrower in what may be placed in a collection receptacle; DEA only allows controlled substances from ultimate users (patients) to be placed in collection receptacles that are at long-term care facilities. As a result, if a LTCF (or any other healthcare facility) is a DEA registrant, it may not place its inventory of controlled substances in a collection receptacle, even if it is a VSQG.

D. Long-Term Care Facilities with 20 Beds or Fewer are Presumed to be Very Small Quantity Generators (§ 266.504(d))

1. Summary of Proposal

EPA took comment on whether we should provide a rebuttable presumption that LTCFs with fewer than 10 beds are assumed to be VSQGs and thus would not be required to keep track of the amount of hazardous waste generated each month. The Agency did not propose regulatory language for this provision. EPA asked commenters to submit data to support a 10-bed cutoff to show that LTCFs with fewer than 10 beds are generally VSQGs. Alternatively, if commenters

supported a different cutoff for the rebuttable assumption, EPA asked that the commenters submit information to support their suggested cutoff.

2. Summary of Comments

Comments on the rebuttable presumption for LTCFs with fewer than 10 beds varied. One state did not support providing a rebuttable presumption for LTCFs with fewer than 10 beds and argued that all generators should be required to count the hazardous waste they generate.[242] One state expressed support for providing a rebuttable presumption and requested that EPA keep the cutoff at 10 beds.[243] One state did not support providing the rebuttable presumption because most healthcare facilities in their state, including LTCFs, have more than 10 beds but generate only VSQG quantities of hazardous waste.[244]

Two healthcare industry commenters that supported the rebuttable presumption asked that EPA increase the cutoff from 10 beds to 20 beds.[245] One healthcare industry commenter supported the rebuttable presumption and asked that EPA increase the bed cutoff from 10 beds to 15 beds.[246]

3. Final Rule Provisions

Under the final rule, EPA is finalizing a rebuttable presumption in § 266.504(d) that LTCFs with 20 beds or fewer are assumed to be VSQGs and thus are not required to demonstrate the amount of hazardous waste generated each month. Under this presumption, LTCFs are only subject to the requirements for VSQG healthcare facilities as described elsewhere in this proposal, including the requirement not to sewer hazardous waste pharmaceuticals (§ 266.505),

[242] See comment number EPA–HQ–RCRA–2007–0932-0238 in the docket for this rulemaking.
[243] See comment number EPA–HQ–RCRA–2007–0932-0242 in the docket for this rulemaking.
[244] See comment number EPA–HQ–RCRA–2007–0932-0332 in the docket for this rulemaking.
[245] See comment numbers EPA–HQ–RCRA–2007–0932-0239 and EPA–HQ–RCRA–2007–0932-0282 in the docket for this rulemaking.
[246] See comment number EPA–HQ–RCRA–2007–0932-0328 in the docket for this rulemaking.

the empty container standards (§266.507), and the optional provisions of § 266.504. Under the final rule, the EPA Regional Administrator has the responsibility to demonstrate that a LTCF with 20 beds or fewer generates quantities of hazardous waste that are in excess of the VSQG limits as defined in § 260.10 if the EPA Regional Administrator wishes to mandate that the LTCF operate under subpart P. A LTCF with more than 20 beds that operates as a VSQG under § 262.14 must demonstrate that it generates quantities of hazardous waste that are within the VSQG limits as defined by § 260.10.

Based on available data, EPA believes it is reasonable to be responsive to the healthcare industry commenters who supported the rebuttable presumption and to increase the cutoff to 20 beds. The available information on hazardous waste generation at LTCFs suggests that LTCFs with 20 beds or fewer are generally VSQGs. Although EPA did not receive any data from the healthcare industry commenters, one state commented that most healthcare facilities in their state, including LTCFs, have many more than 10 beds but generate only VSQG quantities of hazardous waste.[247] Additionally, EPA estimates that there are between 2,875 and 4,770 long-term care facilities that generate hazardous waste and that 98 to 99 percent of the facilities are VSQGs.[248] Although EPA estimates that there are few LTCF hazardous waste generators that are SQGs or LQGs, EPA does not have data on the number of beds at each facility, making it difficult to estimate a facility size threshold at which a LTCF becomes an SQG or an LQG. EPA conducted additional analysis using data on the average size of LTCFs in the United States and data on the average volume of hazardous waste generated annually at LTCFs that submitted a biennial hazardous waste report between 2001 and 2015 in order to estimate the average size at

[247] See comment number EPA–HQ–RCRA–2007–0932-0332 in the docket for this rulemaking.
[248] Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

which a LTCFs become SQGs or LQGs.[249] The estimates suggest that LTCFs with fewer than 20 beds will generally be VSQGs. Therefore, EPA concludes that it is reasonable to provide a rebuttable presumption that LTCFs with 20 beds or fewer are assumed to be VSQGs and thus are not required to demonstrate the amount of hazardous waste generated each month.

XIII. Sewer Disposal Prohibition (§ 266.505)

A. *Regulatory Background on the Domestic Sewage Exclusion*

Under RCRA and the Subtitle C hazardous wastes regulations, if a material is not a solid waste, then it cannot be considered a hazardous waste. Under § 261.4(a)(1)(ii) of the RCRA regulations, "Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment" is not a solid waste for purposes of Subtitle C regulation. This exclusion was finalized by EPA on May 19, 1980, based on the reasoning that "Mixed waste streams that pass through sewer systems to publicly-owned treatment works (POTWs) will be subject to controls under the Clean Water Act (CWA). The Agency's construction grants program provides financial assistance for the proper treatment of these wastes. In addition, the Agency's pretreatment program provides a basis for EPA and the local communities to ensure that users of sewer and treatment systems do not dump wastes in the system that will present environmental problems."[250]

In 1984, Congress enacted the Hazardous and Solid Waste Amendments (HSWA) to the Solid Waste Disposal Act (SWDA), as amended by RCRA. HSWA included a new Section 3018, entitled Domestic Sewage. This section directed EPA to do two things with respect to the § 261.4(a)(1)(ii) exclusion for mixtures of domestic sewage and other wastes: (1) submit a Report

[249] See memorandum "Long-Term Care Facility Summary Data and Hazardous Waste Generation Data" in the docket for this rulemaking (EPA-HQ–RCRA–2007–0932).
[250] May 19, 1980; 45 FR 33097.

to Congress (RTC) that describes the types, size and number of generators which dispose of such wastes in this manner, the types and quantities of wastes disposed of in this manner, and identify significant generators, wastes and waste constituents not regulated under existing Federal law or regulated in a manner sufficient to protect human health and the environment; and (2) based on the report, revise the appropriate existing regulations to "ensure that substances…which pass through a sewer system to a publicly owned treatment works are adequately controlled to protect human health and the environment."

EPA submitted its Report to Congress on February 7, 1986 (Domestic Sewage Study). Subsequent to the Report to Congress, EPA issued an advance notice of proposed rulemaking on August 22, 1986;[251] a response to comments on the advanced notice of proposed rulemaking on June 22, 1987;[252] a notice of proposed rulemaking (NPR) on November 23, 1988;[253] and a final rule on July 24, 1990.[254] That final rule expanded an existing prohibition on the discharge of pollutants which create a fire or explosion hazard in the POTW, so that it included, but was not limited to, "waste streams with a closed cup flashpoint of less than 140 degrees Fahrenheit or 60 degrees Centigrade using the test methods specified in 40 CFR 261.21."[255] Although the RCRA characteristic of reactivity (D003) was not specifically mentioned in the CWA regulations, discharges of some D003 reactive hazardous wastes are also prohibited by this section of the CWA regulations: (1) chemicals that react violently with water[256] and (2) chemicals that form potentially explosive mixtures with water.[257]

[251] See the advance notice of proposed rulemaking in August 22, 1986; 51 FR 30166.
[252] See the response to comments in June 22, 1987; 52 FR 23477.
[253] See the proposed rule November 23, 1988; 53 FR 47632.
[254] See the final rule in July 24, 1990; 55 FR 30082.
[255] See the prohibition in 40 CFR 403.5(b)(1).
[256] See 40 CFR 261.23(a)(2).
[257] See 40 CFR 261.23(a)(3).

The 1990 CWA final rule added a new prohibition such that no discharge shall "result in the presence of toxic gases, vapors or fumes within the POTW in a quantity that may cause acute worker health and safety problems."[258] Similarly, although the RCRA characteristic of reactivity (D003) was not specifically mentioned in this section of the CWA regulations, discharges of some D003 reactive hazardous wastes are also prohibited by this section: (1) chemicals that, when mixed with water, generate toxic gases, vapors or fumes in quantity sufficient to present a danger to human health or the environment[259] or (2) cyanide or sulfide bearing waste which, when exposed to pH conditions between 2 and 12.5, can generate toxic gases, vapors or fumes in a quantity sufficient to present a danger to human health or the environment.[260]

In addition, some D002 corrosive hazardous wastes were prohibited prior to the 1990 CWA final rule and remain prohibited. Under RCRA, a waste is considered D002 for corrosivity if it has a pH of less than or equal to 2 (strongly acidic) or greater than or equal to 12.5 (strongly basic). Section 403.5(b)(2) of the CWA regulations prohibits discharges with a pH of less than 5.0, except under limited circumstances. Therefore, acidic D002 hazardous waste is prohibited from being discharged under the CWA regulations.

Note that although the exclusion for mixtures of domestic sewage and other wastes is found under the RCRA regulations in § 261.4(a)(1)(ii), and it was HSWA, which is an amendment to RCRA, that directed the review of and amendments to that exclusion, the sewer ban of liquid ignitable D001 hazardous wastes and some D002 and D003 hazardous wastes was established under 40 CFR 403.5(b), which is under the CWA regulations. Also note that EPA left open the possibility of additional future action when it stated in the preamble to the July 24,

[258] See 40 CFR 403.5(b)(7).
[259] See 40 CFR 261.23(a)(4).
[260] See 40 CFR 261.23(a)(5).

1990, final rule, its intent "to carefully review the effect of this rule and promulgate in the future any additional regulations that experience reveals are necessary to improve control over hazardous waste and other industrial user discharges to POTWs."[261]

B. *Summary of Proposal*

In 2015, EPA proposed to impose a sewer ban on all hazardous waste pharmaceuticals managed by healthcare facilities and reverse distributors. That is, healthcare facilities and reverse distributors subject to part 266 subpart P would not be able to use the RCRA domestic sewage exclusion in § 261.4(a)(1)(ii) any longer for their hazardous waste pharmaceuticals. They would be prohibited from disposing of pharmaceuticals that are listed hazardous waste and/or exhibit one or more of the four hazardous waste characteristics (i.e., ignitability, corrosivity, reactivity, or toxicity) by putting them down a drain (e.g., sink, toilet, or floor drain).

EPA proposed this sewer prohibition of hazardous waste pharmaceuticals for several reasons. First, as described in detail in the preamble to the proposed rulemaking, a number of studies had shown that flushing of leftover medications had become a prevalent practice used in lieu of proper hazardous waste management and that experience had, indeed, revealed that additional regulations were "necessary to improve control over hazardous waste and other industrial user discharges to POTWs."[262]

Second, although EPA establishes national regulations under the CWA (called effluent limitations guidelines and pretreatment standards) to reduce discharges of pollutants from industries to surface waters and POTWs, currently there are no national effluent limitations or pretreatment standards that apply to healthcare facilities discharging pharmaceuticals to POTWs.

[261] July 24, 1990 Federal Register; 55 FR 30084.
[262] July 24, 1990 Federal Register; 55 FR 30084.

Furthermore, traditional wastewater treatment operations implemented at POTWs are designed to remove conventional pollutants, such as suspended solids and biodegradable organic compounds. They are not designed to remove pharmaceuticals that are present in discharges from medical and veterinary facilities. While some POTWs may have implemented advanced treatment technologies, these technologies are not designed to remove pharmaceuticals. EPA released a study in 2009 in which over 100 chemicals (including some pharmaceuticals) were analyzed in the influent and effluent at nine POTWs.[263] Although it was a limited study and difficult to generalize the results to all POTWs, it does indicate that the capabilities of treatment technologies currently employed by POTWs does not include treatment to remove active pharmaceutical ingredients (APIs).[264] In a more recent study, EPA measured concentrations of 56 APIs in effluent samples from 50 large POTWs across the country and discovered at least one API in each sample.[265] In addition, as stated in EPA's Health Services Industry study, "synthetic compounds, such as pharmaceuticals, are often manufactured to be resistant to metabolic transformation. As a result, some pharmaceutical compounds that are present in the influent to POTWs may pass through treatment systems at conventional POTWs and discharge to receiving waters." [266]

Third, the pharmaceuticals entering the environment, through flushing or other means, are having a negative effect on aquatic ecosystems and on fish and animal populations. A recent

[263] EPA, Occurrence of Contaminants of Emerging Concern in Wastewater from Nine Publicly Owned Treatment Works, August 2009; EPA-821-R-09-009.
[264] Eggen RI, Hollender J, Joss A, Schärer M, Stamm C, "Reducing the Discharge of Micropollutants in the Aquatic Environment: The Benefits of Upgrading Wastewater Treatment Plant." Environmental Science and Technology 2014, 48(14) 7683-7689.
[265] Kostich MS, Batt AL, Lazorchak JM, "Concentrations of prioritized pharmaceuticals in effluents from 50 large wastewater treatment plants in the US and implications for risk estimation" Environmental Pollution 2014, 184:354-9.
[266] Health Services Industry Study: Management and Disposal of Unused Pharmaceuticals (Interim Technical Report) August 2008; EPA-821-R-08-013.

article highlighted the scientific literature that examines the effect of pharmaceuticals on freshwater ecosystems, particularly the effect of pharmaceuticals on key ecological processes.[267] The RIA for the proposed rulemaking more fully summarized the scientific literature with regard to ecological effects.[268] The scientific research with regard to human health effects due to pharmaceuticals in the environment is still ongoing. Nevertheless, the important features and risks of the problem can be summarized as follows:[269]

(1) Pharmaceuticals are intrinsically bioactive compounds; therefore, they can potentially impact living systems.

(2) There is a continuous and worldwide increase in their use and, thus, on their subsequent input into the environment.

(3) Many of the hundreds of frequently prescribed pharmaceuticals are known for targeted effects and adverse off-target side effects, a problem that can be exacerbated by interactive effects during therapy involving co-administration and disposal.

While healthcare facilities that are VSQGs were generally not subject to the proposed rulemaking, EPA proposed that the sewer ban of hazardous waste pharmaceuticals also apply to healthcare facilities that are VSQGs. The RIA for the rule projects that the vast majority of healthcare facilities are VSQGs (81–86 percent).[270] Some particular types of healthcare facilities have an even larger proportion of VSQGs: for example, the RIA estimates that of the LTCFs that

[267] Richmond EK, Grace MR, Kelly JJ, Reisinger AJ, Rosi EJ, Walters, DM. "Pharmaceuticals and personal care products (PPCPs) are ecological disrupting compounds (EcoDC). Elem Sci Anth 2017, 5:66.
[268] see page 147 of the Regulatory Impact Analysis for the proposed rule in the docket EPA-HQ-RCRA-2007-0932-0151.
[269] A. Ginebreda et al, Environmental risk assessment of pharmaceuticals in rivers: Relationships between hazard indexes and aquatic macroinvertebrate diversity indexes in the Llobregat River (NE Sapin). Environ Int. (2009), doi:10.1016/j.envint.2009.10.003.
[270] See the Regulatory Impact Analysis for the final rule in the docket EPA-HQ-RCRA-2007-0932

generate hazardous waste, 98–99 percent of LTCFs are VSQGs.[271] EPA was and remains concerned that these smaller healthcare facilities are more likely to dispose of their hazardous waste pharmaceuticals via the sewer. EPA estimates that there are between 50,900 and 84,800 healthcare facilities that are VSQGs.[272] Given this large number, the combined impact of sewer disposal by healthcare facilities that are VSQGs has an even greater potential to provide a substantial impact on the environment, as well as human health. EPA solicited comment on whether it was appropriate to apply the proposed ban on the sewer disposal of hazardous waste pharmaceuticals to all healthcare facilities, including healthcare facilities that are VSQGs. Comments submitted to the Agency in response to this request are discussed in the next section.

We note that EPA's proposed ban on sewering hazardous waste pharmaceuticals is consistent with other federal state, and local actions. For example, the DEA has finalized regulations to implement the Secure and Responsible Drug Disposal Act of 2010.[273] DEA's regulations require a "non-retrievable" method of destruction of controlled substances. The preamble to DEA's proposed and final rules state that flushing does not meet the non-retrievable standard for destruction.[274] According to the preamble of the DEA final rule, DEA received 20 comments supporting their position against flushing controlled substances.[275] The comments supporting the prohibition against sewering came from states, regional, and local hazardous waste management programs, recycling associations, non-governmental organizations (NGOs), trade associations and environmental organizations. Many of these commenters noted that wastewater treatment systems do not eliminate many of the drugs that are flushed into the sewers

[271] Ibid.
[272] Ibid.
[273] September 9, 2014; 79 FR 53520.
[274] Proposed rule: December 21, 2012; 77 FR 75784 (see page 75803); and Final rule: September 9, 2014; 79 FR 53520 (see page 53548).
[275] September 9, 2014; 79 FR 53520 (see page 53548).

and requested that DEA clearly state in the regulatory language, not just preamble, that sewering is not allowable as a means of destruction.

In addition, four states, the District of Columbia, and local California jurisdictions have taken action to limit the sewering of pharmaceuticals and another state has introduced a bill. "Colorado has prohibited the discharging of solid/hazardous waste down the drain since the adoption of RCRA in the 1980s."[276] In 2009, Illinois passed the Safe Pharmaceutical Disposal Act, which prohibits healthcare facilities from flushing any solid dosage form other than DEA schedule II drugs into public sewers or septic systems.[277] In 2012, New Jersey passed a similar law that prohibits healthcare facilities from discharging prescription medications into public sewers or septic systems.[278] In 2002, California banned the use of lindane in pharmaceuticals after it found that lindane was adversely impacting wastewater quality. The authors of the paper "Outcomes of the California Ban on Pharmaceutical Lindane: Clinical and Ecologic Impacts state that "This is the first time that a pharmaceutical has been outlawed to protect water quality."[279] After researching and documenting environmental benefits of the ban, the authors conclude, "This ban serves as a model for governing bodies considering limits on the use of lindane or other pharmaceuticals." Also in California, some county departments, such as Sacramento County and Contra Costa County, prohibit sewering of hazardous waste pharmaceuticals.[280] And the District of Columbia has promulgated municipal regulations, effective January 1, 2011, that prohibits healthcare facilities from flushing pharmaceutical

[276] See comment number: EPA-HQ-RCRA-2007-0932-0242.
[277] Illinois Public Act 096-0221.
[278] Nicknamed Bateman's Law, after Senator Christopher "Kip" Bateman (R-Somerset) that sponsored the legislation.
[279] Humphreys, et al. Environmental Health Perspectives. 2008 March; 116(3) 297-302.
[280] See comment number: EPA-HQ-RCRA-2007-0932-0378.

products.[281] The Connecticut legislature has also considered a bill to ban the discharge of medication into public or private wastewater collection systems or septic systems, although it has not yet become law.[282] Nevertheless, the Connecticut Department of Energy and Environmental Protection's (CT DEEP) "current hazardous waste management regulations essentially ban sewer disposal of RCRA waste by requiring all generators in Connecticut, including [VSQGs], to ensure delivery by a licensed waste transporter with an EPA ID Number to a facility authorized to receive the waste."[283]

The Agency sought comment on several areas related to the prohibition on sewering hazardous waste pharmaceuticals. First, the Agency requested comment on whether the sewer ban should apply to healthcare facilities that are VSQGs. Second, we requested comment on the trade-offs inherent in prohibiting sewer disposal; that is, would the benefit of the reduction in aquatic risk be outweighed by additional opportunities for diversion and the possibility of inadvertent exposures for certain workers? Third, we sought comment on whether it would be appropriate to allow any exceptions to the sewer ban, such as for leftover portions of hazardous wastes that are also controlled substances.[284] Finally, the Agency sought comment on whether it would be helpful to incorporate in 40 CFR 261.4(a)(1)(ii), a cross-reference to the CWA regulations that prohibit the sewering of certain hazardous wastes.

C. *Summary of Comments*

Nearly a third of the commenters to the proposed rulemaking commented on the proposed prohibition of sewering hazardous waste pharmaceuticals. Commenters were nearly

[281] DCMR Title 22-B Chapter 5 Safe Disposal of Unused Pharmaceuticals in Health Care Facilities
[282] State of Connecticut General Assembly, January Session 2013, Raised Bill No. 6439. An Act Concerning the Disposal and Collection of Unused Medication.
[283] See comment number EPA-HQ-RCRA-2007-0932-0341.
[284] In a DEA letter dated October 17, 2014, DEA refers to leftover, partially administered drugs as "pharmaceutical wastage." https://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf

unanimous in their support for the prohibition on sewering of hazardous waste pharmaceuticals. Support was expressed by a broad and diverse set of commenters, including state and local governments, sewer districts, environmental groups, and waste management companies. Although some commenters had suggestions for minor exceptions, few commenters expressed complete opposition to the prohibition on sewering. Furthermore, there was widespread support from commenters for applying the prohibition on sewering hazardous waste pharmaceuticals to healthcare facilities that are VSQGs. As one commenter noted, "given the large number of small generators…If each of these small generators were allowed to discharge even a small amount of pharmaceuticals, the overall volume would be significant."[285]

D. *Final Rule Provisions*

Given the environmental concerns described above combined with the overwhelming support that we received from commenters, we are finalizing the prohibition of sewering hazardous waste pharmaceuticals. The prohibition on sewering hazardous waste pharmaceuticals applies to all reverse distributors and all healthcare facilities, including healthcare facilities that are VSQGs. Furthermore, EPA is not providing any exceptions to the prohibition on sewering. Therefore, the prohibition on sewering hazardous waste pharmaceuticals applies to all hazardous waste pharmaceuticals that are generated by any healthcare facilities and reverse distributors, including hazardous waste pharmaceuticals that are also controlled substances and any pharmaceutical wastage from partial administration of hazardous waste pharmaceuticals. How the sewer prohibition intersects with the disposal of pharmaceutical wastage will be discussed in greater detail in section XIV.D.2. rather than this section.

[285] See comment number EPA-HQ-RCRA-2007-0932-0337.

In response to commenters' suggestions, we are making some minor editorial changes, including adding two cross references to the CWA prohibitions on sewering hazardous wastes in § 403.5(b). One cross reference will be added to § 261.4(a)(1)(ii) and the other cross reference will be added to § 266.505. We also eliminated the second sentence of the proposed prohibition, which read: The exclusion in § 261.4(a)(1)(ii) for mixtures of domestic sewage and other wastes that pass through a sewer system to a publicly owned treatment works does not apply to hazardous waste pharmaceuticals.

Oklahoma Department of Environmental Quality (OK DEQ) expressed concern that this "second sentence could be interpreted that EPA is exerting RCRA authority over domestic sewage if it contains [hazardous waste pharmaceuticals] – an area that has been exclusively under Clean Water Act jurisdiction since the first regulations were promulgated in 1980."[286] EPA had proposed the second sentence in an attempt to be abundantly clear that the proposed prohibition on sewering hazardous waste pharmaceuticals supersedes the exclusion in § 261.4(a)(1)(ii). We did not intend to assert RCRA jurisdiction over domestic sewage; therefore, we have concluded that it is better to remove the sentence in order to avoid the concern expressed by OK DEQ. Nevertheless, we wish to emphasize that the prohibition on sewering hazardous waste pharmaceuticals being finalized in § 266.505 does, in fact, supersede the exclusion in § 261.4(a)(1)(ii). To make that point clear, we are amending § 261.4(a)(1)(ii) to state that any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, *except as prohibited by §§ 266.505 and Clean Water Act requirements at 40 CFR 403.5(b),* is not a solid waste.

E. *Comments and Responses*

[286] See commenter number EPA-HQ-RCRA-2007-0932-0231.

Many comments suggested various ways in which we should broaden the applicability of the prohibition on sewering hazardous waste pharmaceuticals. In some cases, commenters urged us to apply the prohibition to all pharmaceuticals, not just hazardous waste pharmaceuticals. Subtitle D of RCRA, which governs the management of non-hazardous (solid) waste, does not provide EPA the statutory authority to apply the prohibition to non-hazardous waste pharmaceuticals. Nevertheless, EPA strongly recommends against sewering any pharmaceuticals. The American Water Works Association asked us to extend the prohibition to prevent the sewering of pharmaceuticals that are radioactive and patient waste containing radioactive pharmaceuticals. As discussed previously, hazardous waste pharmaceuticals that also contain a radioactive component subject to the Atomic Energy Act of 1954 (i.e., "mixed waste") are regulated by multiple agencies. The hazardous waste component is regulated under EPA or the authorized state RCRA programs, while either the NRC or the Department of Energy regulates the radioactive component of the waste under the Atomic Energy Act.[287] Therefore, a "mixed waste" pharmaceutical that is both radioactive and RCRA hazardous waste is prohibited from being discharged to the sewer. We strongly recommend against sewering other radioactive pharmaceuticals and patient waste containing radioactive pharmaceuticals.

Other commenters suggested that the prohibition should not be limited to discharges to POTWs; rather, it should also apply to discharges to septic tanks, privately owned treatment works and federally owned treatment works. Section 261.4(a)(1)(ii) allows the discharge of what would otherwise be a hazardous waste to POTWs, without being considered a solid or hazardous waste. The prohibition on discharges of hazardous waste pharmaceuticals being finalized today is intended to reduce the scope of that exclusion in the existing regulations. Discharges of

[287] The NRC regulates radioactive wastes generated by commercial or non-DOE facilities, whereas DOE regulates radioactive wastes generated by DOE facilities.

hazardous waste to other types of sewage systems, such as septic tanks, privately owned treatment works and federally owned treatment works are not allowed by exclusion in § 261.4(a)(1)(ii). Therefore, the discharge of hazardous wastes to septic tanks, privately owned treatment works and federally owned treatment works is already prohibited, even though it is not explicitly stated.

We note that although our RCRA statutory authority limits us to apply the prohibition on sewering narrowly to pharmaceuticals that are RCRA hazardous wastes, EPA strongly recommends as a best management practice to not sewer any waste pharmaceutical (i.e., hazardous or non-hazardous) from any source or location. This recommendation against sewering pharmaceuticals includes households and assisted living facilities, except in the relatively rare situation when households and assisted living facilities are specifically directed by FDA guidance to flush certain potentially dangerous drugs down the toilet (as noted on pharmaceutical packaging), when a drug take-back option is not readily available, to help ensure that they are not misused or accidentally ingested or touched.[288] In lieu of sewering, we recommend that households, including residents of assisted living facilities, follow the guidelines developed by the U.S. Office of National Drug Control Policy (ONDCP), the FDA, and EPA for the disposal of unwanted household pharmaceuticals. In summary, the guidelines for households disposing of pharmaceuticals are as follows (in order of preference):

(1) Use a drug take-back event or program, when available;

(2) Dispose in household trash, after mixing the unwanted medicines with an unpalatable substance such as dirt, cat litter, or used coffee grounds and placing in a sealed container; and

[288] https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM337803.pdf.

(3) Only if the drug label specifically instructs you to, flush the unwanted medicine down the toilet.[289]

We also note that the CWA prohibitions on discharges of hazardous waste in § 403.5(b) are broader than just pharmaceuticals and apply beyond healthcare facilities and reverse distributors. Like all of the prohibited discharges under the CWA regulations, the prohibitions of hazardous waste discharges apply to any industrial user. Additionally, the CWA prohibitions on hazardous waste discharges apply to all D001 ignitable liquids, acidic D002 hazardous wastes, and D003 reactive hazardous wastes that (1) react violently with water,[290] (2) form potentially explosive mixtures with water,[291] or (3) result in the presence of toxic gases, vapors or fumes within the POTW in a quantity that may cause acute worker health and safety problems,[292] not just pharmaceuticals that exhibit those characteristics.

Some commenters asked us to include some exceptions to the prohibition on discharges of hazardous waste pharmaceuticals. Specifically, one commenter who supported our proposed ban on sewering of hazardous waste pharmaceuticals, and even supported extending it to non-hazardous waste pharmaceuticals, suggested that we allow exceptions "for those that do not contain active pharmaceutical ingredients, such as sterile water and 0.9% sodium chloride for injection and irrigation."[293] First, as a point of clarification, because sterile water and 0.9% sodium chloride are not hazardous waste, they would not be subject to the prohibition of discharging hazardous waste pharmaceuticals to the sewer. And even though, as a general rule, we strongly recommend against sewering any pharmaceutical, regardless of whether it meets our

[289] https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm.
[290] See 40 CFR 261.23(a)(2).
[291] See 40 CFR 261.23(a)(3).
[292] See 40 CFR 403.5(b)(7).
[293] See comment number EPA-HQ-RCRA-2007-0932-0230.

definition of hazardous waste, we agree with the commenter that it seems unnecessary to prohibit the sewering of sterile water and 0.9% sodium chloride.

Other commenters asked us to make other exceptions to the prohibition on discharging hazardous waste pharmaceuticals. For example, the Healthcare Waste Institute suggested that we allow the discharge of hazardous waste pharmaceuticals that are specifically allowed by the local wastewater treatment agency or POTW.[294] CT DEEP made a similar suggestion, saying that we should allow discharges if they are "explicitly authorized by a National Pollutant Discharge Elimination System (NPDES) or State pretreatment permit."[295] We have concluded that such an allowance is unnecessary because no known pretreatment standards or local limits have been established that specifically allow for the discharge of any pharmaceuticals. Note that 40 CFR part 439 separately regulates discharges from pharmaceutical manufacturers to POTWs and waters of the U.S. Furthermore, in the absence of water quality standards for specific drugs, we would like to avoid a situation where local wastewater treatment agencies might feel pressured to make judgments on which discharges would be acceptable without knowing the effects on aquatic life or the synergistic effects of multiple drugs.

We received few comments related to our inquiry about trade-offs inherent in prohibiting sewer disposal. Sharps Compliance did note that as "our experience as a DEA authorized collector has shown, regulations that ban the sewering in conjunction with a proactive collection and destruction program offer the best protection against both environmental harm and the risk

[294] See comment number EPA-HQ-RCRA-2007-0932-0296.
[295] See comment number EPA-HQ-RCRA-2007-0932-0341.

of diversion." [296] In addition, CT DEEP commented they do "not believe there is an unfavorable risk trade-off inherent in prohibiting sewer disposal," indicating both risks are manageable.[297]

Eli Lilly was one of the few commenters that opposed the prohibition on sewering hazardous waste pharmaceuticals, even though, as a manufacturer, they are not subject to the prohibition.[298] They expressed two reasons for their opposition: (1) they do not believe that a total prohibition is based on sound risk management decisions and should be more flexible to exclude pharmaceuticals which FDA says should be disposed of down the drain, and (2) they believe that an effluent guideline under the CWA regulations is more appropriate and that EPA's Office of Water has decided not to promulgate an effluent guideline for the healthcare industry. As discussed previously, the prohibition on sewering hazardous waste pharmaceuticals and the FDA flush list do not conflict with one another. The prohibition applies to healthcare facilities (which does not include assisted living facilities) and reverse distributors, while the FDA flush list is directed to households and assisted living facilities and includes the caveat that flushing takes place only when a drug take-back option is not readily available. As to the commenter's second point, while it is true that the Office of Water has not yet promulgated an effluent guideline for the healthcare industry, this should not be taken as a sign that a decision has been made affirmatively that an effluent guideline is not appropriate at some time in the future. Rather, the Office of Water has preferred that the Office of Resource Conservation and Recovery (ORCR) first focus on preventing intentional discharges of hazardous waste pharmaceuticals. We firmly believe that the prohibition of sewering hazardous waste pharmaceuticals would

[296] See comment number EPA-HQ-RCRA-2007-0932-0248.
[297] See comment number EPA-HQ-RCRA-2007-0932-0341.
[298] See comment number EPA-HQ-RCRA-2007-0932-0249.

complement any future action taken by the Office of Water to issue effluent guidelines for the healthcare industry.

XIV. Conditional Exemptions for Hazardous Waste Pharmaceuticals that are Also Drug Enforcement Administration Controlled Substances and Household Waste Pharmaceuticals Collected in Take-Back Programs (§ 266.506)

A. *Summary of Proposal*

Prior to this final rulemaking, the management and disposal of a pharmaceutical that was both a RCRA hazardous waste and a DEA controlled substance was regulated under both the RCRA Subtitle C hazardous waste regulations, which is under EPA's or the authorized state's purview, and the Controlled Substances Act and its implementing regulations, which is under DEA's purview. At the time of the proposal, EPA was aware of only a handful of pharmaceuticals in common usage that are both hazardous waste and controlled substances and therefore subject to regulation by both EPA and the DEA. These are identified in Table 3:

Table 3: Pharmaceuticals Still Used in Healthcare that Are DEA Controlled Substances & RCRA Hazardous Wastes

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Chloral; chloral hydrate	Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supprettes	Sedative	U034 toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics
Fentanyl sublingual spray	Subsys	Analgesic	D001 ignitable	II	Ignitable due to alcohol content
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001 ignitable	IV	Ignitable due to alcohol content

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Testosterone gels	Androgel, Fortesta, Testim	Hormone	D001 ignitable	III	Ignitable due to gel base
Valium injectable	Diazepam	Anti-anxiety	D001 ignitable	IV	Ignitable due to alcohol content

Chloral hydrate (U034), which is listed for toxicity, is the only dually regulated hazardous waste/controlled substance that is a listed hazardous waste.[299] The other four dually regulated hazardous wastes/controlled substances in common use are considered hazardous because they exhibit the characteristic of ignitibility (D001). While the active ingredient is not ignitable, these particular forms of the pharmaceuticals are ignitable because they are prepared in ignitable solutions, such as alcohol.

EPA is aware of three additional hazardous waste pharmaceuticals that are DEA controlled substances, but it is our understanding that they are no longer in common usage, although there may be legacy supplies remaining in healthcare facilities. See Table 4.

Table 4: DEA Controlled Substances & RCRA Hazardous Wastes Pharmaceuticals that Are Not in Common Use

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Paraldehyde	1,3,5-Trioxane, 2,4,6-trimethyl-; Paral	Anticonvulsant	U182 toxic	IV	No longer in common use
Paregoric	camphorated tincture of opium	Analgesic, expectorant, antidiarrheal	D001 ignitable	III	No longer in common use

[299] Note that EPA's U034 listing includes chloral hydrate, see memo dated April 6, 1998; Brandes to Knauss, RCRA Online #14175

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Opium Tincture	Laudanam	Analgesic, antidiarrheal	D001 ignitable	II	No longer in common use

Similarly, as noted in Table 5, phentermine is a controlled substance, but the medical form is a phentermine salt, and the salts are no longer considered to be within the scope of the P046 listing.[300]

Table 5: Pharmaceuticals that are DEA Controlled Substances & RCRA Hazardous Wastes Salt(s) No Longer Considered Hazardous Waste

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Phentermine	alpha, alpha-Dimethylphenethyl amine; Benzeneethanamine, alpha,alpha-dimethyl-; Adipex-P, Atti Plex P, Fastin, Ionamin, Kraftobese, Panshape M, Obe-Nix, Pentercot, Phentride, Pro-Fast, Raphtre, Supramine, Tara-8, Termene, Termine, Zantryl	Appetite suppressant	P046 Acutely toxic	IV	If in salt form, it does not meet the P046 listing and medical dosage forms are salts

[300] See memo dated February 17, 2012; from Devlin to RCRA Division Directors, RCRA Online #14831.

EPA requested comment on whether these are, indeed, the only pharmaceuticals in common usage that are regulated both as DEA controlled substances, and when discarded, as RCRA hazardous waste.

To eliminate duplicative regulation for these handful of hazardous wastes that are also controlled substances, EPA proposed to conditionally exempt from RCRA Subtitle C regulation those hazardous wastes that are also DEA controlled substances. Specifically, EPA proposed that hazardous wastes that are also controlled substances will be exempt from all RCRA Subtitle C requirements, including 40 CFR part 266 subpart P, provided they meet two conditions: (1) they are combusted at a permitted large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln) and (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances.

The first condition we proposed was to ensure that the controlled substances are destroyed in an environmentally protective manner by a high-temperature combustor, such as a large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln). At the time of proposal, DEA had not specified or endorsed a method by which the controlled substances should be destroyed to meet the non-retrievable standard. Although many hazardous wastes/controlled substances were being destroyed by incineration, it was not required by DEA. At the time, EPA was concerned that in the future DEA might allow a technology that lacks environmental controls and permits. Therefore, combustion of the hazardous wastes/controlled substances, which requires permitting, operating and monitoring standards, was proposed as a condition of the exemption. However, EPA requested comment on whether there are additional technologies that would be appropriate

to include for the destruction of hazardous waste pharmaceuticals that are also controlled substances.

The second condition we proposed was to ensure that dually regulated hazardous wastes/controlled substances are managed under another rigorous regulatory program since they will not be managed in accordance with the RCRA Subtitle C regulations. Although developed for different reasons, both EPA's hazardous waste and DEA's controlled substance regulatory programs are designed to track the regulated material from cradle to grave. EPA requested comment on whether the tracking that DEA requires for controlled substances is sufficient to act in lieu of the RCRA manifest.

We considered proposing a third condition that the hazardous waste pharmaceuticals that are also DEA controlled substances would be subject to the sewer prohibition of § 266.505. At the time of proposal, however, we concluded that because combustion in specific units was a condition of the exemption, that it was unnecessary to state that the hazardous waste/controlled substances may not be sewered.

EPA also proposed a related conditional exemption for household pharmaceuticals, including those that are collected in DEA authorized collection receptacles and commingled with DEA controlled substances. Specifically, we proposed that collected household pharmaceuticals will continue to be excluded from RCRA regulation as household hazardous waste, provided they comply with the same two conditions. The Agency has a long-standing recommendation that household hazardous waste collection programs manage the collected waste as hazardous waste.[301] As such, the Agency recommends that collected household waste pharmaceuticals be incinerated— preferably at a permitted hazardous waste incinerator, but when that is not feasible,

[301] See memo from J. Winston Porter to Regions, dated November 1, 1988; RCRA Online # 11377.

at a large or small municipal waste combustor.[302] The Agency believes that this practice is already common among collection programs since one goal of many collection programs is to divert pharmaceuticals from municipal landfills. Additionally, incineration is commonly used to meet the "non-retrievable" standard of destruction required by DEA for controlled substances collected from consumers (ultimate users, as DEA refers to them). Nevertheless, the Agency proposed to make this recommendation a requirement for collected household waste pharmaceuticals in § 266.506.[303] We strongly believe that if a program goes to the expense of collecting the waste, including waste pharmaceuticals, it should manage the waste as hazardous waste, rather than manage it as municipal solid waste, which the household could do absent the collection program. However, the current household waste exemption does not *require* an entity that hosts a household hazardous waste collection event to manage the collected waste as hazardous waste. Typically, the parties conducting household hazardous waste collection events have been government entities—municipalities and counties. It is relatively new that retail pharmacies and others are becoming interested in performing this function. To encourage this practice, while at the same time ensuring that collection programs are managing the collected waste properly, we proposed to codify our policy that pharmaceuticals that are household hazardous waste (i.e., "household waste pharmaceuticals") and are collected in DEA authorized collection receptacles where they may be commingled[304] with controlled substances continue to be excluded from RCRA regulation, provided they are (1) combusted at a municipal solid waste

[302] See memo September 26, 2012, Rudzinski to the Regional RCRA Division Directors (RCRA Online# 14833) and memo October 2, 2015, Johnson to RCRA Division Directors (RCRA Online #14853).
[303] Since pharmaceutical collection programs typically commingle DEA controlled substances with non-controlled substances, this requirement is included in a section of the regulations that pertains to controlled substances.
[304] DEA does not prohibit co-mingling of controlled substances with non-controlled substances provided they are all then managed as controlled substances.

or hazardous waste combustor, and (2) managed in accordance with all applicable DEA regulations.[305]

B. *Summary of Comments*

Many of the commenters, including states, healthcare facilities, and waste management companies, supported both conditional exemptions as a way to eliminate the duplicative regulation by DEA and EPA and commenters thought that the DEA tracking, shipping and recordkeeping are sufficient to operate in lieu of RCRA. Several commenters suggested that we expand the types of treatment that are allowed to destroy the hazardous waste pharmaceuticals that are also controlled substances. In some cases, commenters suggested that we allow additional combustion units such as hospital, medical, infectious waste incinerators (HMIWIs); commercial, industrial solid waste incinerators (CISWIs); and other solid waste incinerators (OSWIs) to combust hazardous waste pharmaceuticals that are also controlled substances. Other commenters suggested that we allow forms of destruction beyond combustion, such as oxidation treatment[306] or chemical digestion,[307] or any technology that achieves DEA's standard of non-retrievable.[308]

C. *Final Rule Provisions*

We are finalizing both conditional exemptions for hazardous wastes that are also controlled substances, with some changes. First, we have amended the regulatory language in § 266.506(a)(2) to be more consistent with the preamble to the proposed rulemaking and to be more consistent with how the conditional exemption in § 266.506(a)(1) was crafted. In the preamble to the proposed rulemaking, we discussed the conditional exemption in terms of the

[305] See 40 CFR 26.506(a)(2).
[306] See Comment number EPA-HQ-RCRA-2007-0932-0287.
[307] See Comment number EPA-HQ-RCRA-2007-0932-0375.
[308] See Comment number EPA-HQ-RCRA-2007-0932-0333.

waste pharmaceuticals from take-back events and programs, while in the proposed regulatory language, the conditional exemption was focused on the collector of the waste pharmaceuticals. We revised the regulatory language in § 266.506(a)(2) to conditionally exempt the collected household waste pharmaceuticals, as opposed to the collector of the household waste pharmaceuticals. Additionally, one commenter pointed out that the proposed regulatory language could be read to mean that if the household waste pharmaceuticals were not commingled with DEA controlled substances, then the requirement to combust them would not apply.[309] EPA did not intend to make this distinction. Although we understand that most, if not all, take-back events and programs do, in fact, commingle controlled substances with non-controlled substances, EPA proposed to place conditions on collectors of household waste pharmaceuticals with the understanding that this proposed regulatory language would capture all pharmaceuticals collected at take-back events and programs. The revised regulatory language in this final rule makes it clearer that the household waste pharmaceuticals collected during a take-back event or program must be destroyed by combustion or other DEA-approved method, whether or not the household waste pharmaceuticals are commingled with DEA controlled substances.

Also in response to comments, we are expanding the types of combustors that are allowed to destroy the conditionally exempt hazardous waste pharmaceuticals. Under the final rule, five types of combustors will be allowed to destroy hazardous waste pharmaceuticals that are also DEA controlled substances and the pharmaceuticals from take-back events and programs: (1) permitted large municipal waste combustors (MWCs), (2) permitted small MWCs, (3) permitted HMIWIs, (4) permitted CISWIs and (5) permitted hazardous waste combustors (either an incinerator or other combustor, such as a cement kiln).

[309] See comment number EPA-HQ-RCRA-2007-0932-0261.

In addition to the five types of permitted combustors allowed to destroy the conditionally exempt pharmaceuticals, EPA is building in flexibility to the final regulation to allow for the possibility that future technologies might be developed that meet the DEA non-retrievable standard. Specifically, we are allowing any method of destruction for the conditional exemption that DEA has publicly approved in writing as able to meet its non-retrievable standard. While it is reasonable to defer to the DEA's judgement in this matter to approve methods of destruction that are environmentally protective, we feel it is necessary to limit future allowable destruction technologies for the conditionally exempt pharmaceuticals to those that are publicly approved by the DEA as meeting the non-retrievable standard. This is intended to avoid a situation where parties might make unsubstantiated claims that their product is capable of meeting the DEA non-retrievable standard in order to qualify for the conditional exemption. Furthermore, any method that DEA might specify must not conflict with federal environmental laws or regulations. Also, because combustion is no longer specified as the only allowable method of destruction, we have concluded that an additional change to the regulations is needed to make it clear that the hazardous waste pharmaceuticals that are also DEA controlled substances are subject to § 266.505, and therefore, may not be sewered.

Both types of conditionally exempt hazardous waste pharmaceuticals (i.e., those that are DEA controlled substances and those that are collected household waste pharmaceuticals) will be able to take advantage of the expanded list of allowable types of combustors. For healthcare facilities and reverse distributors that generate and manage the handful of hazardous waste pharmaceuticals that are also controlled substances, we think it will be helpful to have additional destruction methods for these previously dually regulated wastes. Also, the expanded list of allowable types of combustors will be helpful for those operating take-back programs and events.

The Agency is a strong supporter of take-back programs and events for household pharmaceuticals as an alternative to disposing of leftover, unwanted medications in the trash or in the toilet or down the sink (except in cases where the FDA-approved labeling instructs patients to immediately flush the unneeded medication down the toilet if a take-back option is not readily available). In expanding the types of combustors that are allowed to burn the pharmaceuticals from take-back events, we strive to strike a balance between maximizing flexibility while still being protective of human health and the environment. Under the revised list in the final rule, the universe of allowable combustors will substantially increase in number. There are 77 municipal solid waste combustion facilities (also referred to as waste-to-energy facilities) in 22 states,[310] and 21 commercial hazardous waste combustion facilities (i.e., those that accept waste from off-site) in 12 states.[311] There are currently 33 HMIWIs units in the US: 11 of the 33 are commercial HMIWIs, while the other 22 HMIWI units only combust their own waste.[312] There are approximately 75 CISWIs facilities in the US.[313] We note that the types of combustors we are allowing to accept the conditionally exempt pharmaceuticals are not obligated to accept the conditionally exempt pharmaceuticals. Of course, we strongly encourage all the various types of allowable combustors to work with their communities and regulators in developing viable options for destroying the pharmaceuticals from take-back events. In particular, we encourage the "captive" combustors that currently only combust their own waste to consider amending their permits to allow them to accept pharmaceuticals from take-back events and programs.

[310] Energy Recovery Council, 2016 Directory of Waste-to-Energy Facilities; http://energyrecoverycouncil.org/wp-content/uploads/2016/06/ERC-2016-directory.pdf.
[311] Memo from Rudzinski to Regions, dated September 26, 2012; RCRA Online # 14833.
[312] See comment number EPA-HQ-RCRA-2007-0932-0280.
[313] See CISWI inventory EPA-HQ-OAR-2016-0664-0002.

We have concluded that it is reasonable to expand the list of allowable combustors able to accept the conditionally exempt pharmaceuticals because the combustion of pharmaceuticals that meet the definition of a RCRA solid waste but do not meet the definition of RCRA hazardous waste (i.e., non-hazardous waste pharmaceuticals) is regulated by § 129 of the Clean Air Act. The statute requires EPA to establish emission limits for nine air pollutants (i.e., particulate matter, carbon monoxide, dioxins/furans, sulfur dioxide, nitrogen oxides, hydrogen chloride, lead, mercury, and cadmium) from several categories of solid waste incineration units, including MWCs; HMIWIs; and CISWIs. EPA has established emission limits for each of the categories based on the application of maximum available control technology (MACT) which reflect the emission levels achieved by the best performers in each category.

In addition to complying with emission limitations, solid waste incineration units are also subject to comprehensive operating, monitoring and reporting requirements. In light of the common framework used to develop emission limits and requirements for MWC, CISWI, and HMIWI units, we believe that it is appropriate to include HMIWIs and CISWIs as types of combustors that are allowed to burn the pharmaceuticals from take-back events.

While the Agency has expanded the list of allowable combustors to include HMIWIs and CISWIs, we have not expanded the list to include other solid waste incinerators (OSWIs). OSWIs are small units that have fewer emission controls than other types of combustors. Further, there are only a handful of new OSWIs in operation and the legal status of existing OSWIs is uncertain due to litigation. EPA is also not expanding the list of allowable combustors to include human and pet crematoriums. Crematoriums are not regulated under the Clean Air Act and typically do not use air pollution control devices to limit toxic air pollutants such as mercury and dioxins and furans. We believe that crematoriums would not provide adequate public health and

environmental protection when burning non-hazardous waste pharmaceuticals. If solid or hazardous wastes are burned in a crematorium, it would make the crematorium subject to the Clean Air Act.

D. *Comments and Responses*

In its comment, Cardinal Health included a list of pharmaceuticals that it manages as both RCRA hazardous waste and DEA controlled substances.[314] In most cases, their comments reinforced the list that we included in the proposed rulemaking. In two cases, Cardinal Health identified additional forms of drugs that were included in the table of DEA controlled substances and hazardous wastes in the preamble to the proposed rulemaking. First, Cardinal Health identified Axiron as the brand name of an additional form of testosterone that is a solution applied to the underarms that is also ignitable. Second, Cardinal Health identified Diastat as the brand name of an additional form of valium that is a gel intended for rectal administration that is also ignitable. We have amended our list of DEA controlled substances and RCRA hazardous wastes by including Axiron and Diastat in Table 6 below to be more complete and accurate. However, there is no corresponding regulatory change being made. The regulations conditionally exempt all RCRA hazardous wastes that are also DEA controlled substances; the table identifying which drugs are both is included in the preamble for informational purposes:

Table 6: Pharmaceuticals Still Used in Healthcare that are DEA Controlled Substances & RCRA Hazardous Wastes (Amendments in bold based on comments)

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Chloral;	Acetaldehyde,	Sedative	U034	IV	Used in hospital

[314] See comment number EPA-HQ-RCRA-2007-0932-0250.

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
chloral hydrate	trichloro-; Aquachloral, Noctec, Somnote, Supprettes		toxic		pediatric units; common ingredient in vet anesthetics
Fentanyl sublingual spray	Subsys	Analgesic	D001 ignitable	II	Ignitable due to alcohol content
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001 ignitable	IV	Ignitable due to alcohol content
Testosterone gels/solutions	Androgel, **Axiron,** Fortesta, Testim	Hormone	D001 ignitable	III	Ignitable due to alcohol content
Valium injectable/gel	Diazepam, **Diastat**	Anti-anxiety	D001 ignitable	IV	Ignitable due to alcohol content

Cardinal Health's comment also indicated that the company manages Somatropin (brand names Humatrope and Genotropin) as a DEA controlled substance and a RCRA hazardous waste. M-cresol, which is a contaminant identified on the toxicity characteristic list in § 261.24 (D024), is used as a preservative in Somatropin. Per legislations, all anabolic steroids are considered controlled substances;[315] however, Somatropin is considered a human growth hormone, not an anabolic steroid.[316] Therefore, although Somatropin may be a RCRA hazardous waste for its m-Cresol content, it is not a DEA controlled substance.

The two conditional exemptions we are finalizing in this rule are intended to eliminate any duplicative regulations for pharmaceuticals that are RCRA hazardous wastes and DEA controlled substances. Nevertheless, there are several remaining areas where DEA and EPA

[315] The Anabolic Steroids Control Act of 1990 placed anabolic steroids into Schedule III of the Controlled Substances Act (CSA) as of February 27, 1991.
[316] https://www.fda.gov/Drugs/DrugSafety/ucm237839.htm; accessed 8/24/2017.

regulations intersect, even if they are not duplicative. The Agency would like to address these intersecting areas in effort to reduce confusion and aid compliance.

1. Only Household (Ultimate User) Waste May Be Collected in DEA Authorized Collection Receptacles

It is important to note that in order to qualify for the conditional exemption, a retail pharmacy (or other DEA authorized collector pharmacy) can use the DEA authorized collection receptacle to collect waste generated only at households (DEA refers to this as waste from "ultimate users") and brought to the store for collection. The hazardous waste generated by the retail pharmacy and store, including hazardous waste pharmaceuticals, are not excluded household wastes under RCRA and may not be placed in the DEA authorized receptacle.[317] Depending on the amount generated, the hazardous waste pharmaceuticals generated by the retail pharmacy and store must be managed under either § 262.14 (as a VSQG) or under part 266 subpart P. Furthermore, states generally regulate non-hazardous waste and it is possible that they may have licensing or permitting requirements for the collection of solid waste. Because EPA would like to see the use of DEA authorized collection receptacles become widespread, we encourage states to streamline any requirements that may create a barrier to the use of the DEA authorized collection receptacles.

2. Sewer Prohibition, Conditional Exemption and Pharmaceutical Wastage

In response to comments, EPA has decided against making any exceptions to the sewer prohibition. Some commenters suggested that EPA should allow RCRA hazardous wastes that are also DEA controlled substances to be sewered. On the other hand, many commenters

[317] DEA also prohibits retail pharmacy stock/inventory from being placed in the collection receptacle or mail-back envelopes (see 21 CFR 1317.05(a)).

suggested, and EPA agrees, that it would be inappropriate to make exceptions to the sewer prohibition, even for the handful of hazardous wastes that are also controlled substances. In part, commenters thought it was bad environmental policy to allow sewering of any hazardous waste pharmaceuticals. Commenters were also concerned that it would send a mixed message to the regulated community about our goals and lead to confusion about which hazardous waste pharmaceuticals could and could not be sewered. As a result, all hazardous waste pharmaceuticals are prohibited from being sewered, including the handful that are also DEA controlled substances.

Under the DEA regulations, a registrant's inventory of controlled substances is already prohibited from being sewered as a means of meeting the non-retrievable standard.[318] Likewise, under the CWA regulations, RCRA ignitable hazardous wastes (D001) are prohibited from being discharged to the sewer.[319] As noted in Table 6, four out of the five RCRA hazardous wastes that are also DEA controlled substances are hazardous waste due to being ignitable and hence are already prohibited from being sewered by the CWA regulations. In effect, this new RCRA regulation only prohibits the sewering of one additional DEA controlled substance that is also a RCRA hazardous waste: chloral hydrate, which is listed for toxicity. In summary, a RCRA hazardous waste that is also DEA controlled substance that is part of a DEA registrant's inventory may not be sewered.

DEA does allow controlled substance "pharmaceutical wastage" to be disposed of in accordance with applicable federal, state, and local laws, regulations, and healthcare facility

[318] See the preamble to DEA's final rule 79 FR 53548; September 9, 2014 and the preamble to DEA's proposed rule 77 FR 75803; December 21, 2012.
[319] See the Clean Water Act regulations at 40 CFR 403.5(b)(1).

policies, including sewering or putting down the drain.[320] DEA uses the term "pharmaceutical wastage" to refer to leftover, unadministered pharmaceuticals ("e.g., some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized"[321]). While DEA allows pharmaceutical wastage of controlled substances to be sewered, the CWA regulations already prohibit the discharge of any RCRA ignitable hazardous waste and, under this RCRA rule, EPA is not creating any exceptions to the sewer prohibition. As a result, neither inventory nor pharmaceutical wastage of DEA controlled substances that are also RCRA hazardous wastes may be sewered.

Even though inventory and pharmaceutical wastage are prohibited from being sewered, both inventory and pharmaceutical wastage would be eligible for the conditional exemption being finalized in this rule in § 266.506 for RCRA hazardous wastes that are also DEA controlled substances. As discussed previously, EPA is finalizing the conditional exemption that the few RCRA hazardous waste pharmaceuticals that are also DEA controlled substances would be exempt from RCRA regulation, on the condition that they are (1) managed in accordance with DEA regulations and (2) incinerated by one of five types of permitted combustors or destroyed by another method that has been publicly approved by DEA, and (3) are not sewered.

Therefore, if inventory or pharmaceutical wastage is both a RCRA hazardous waste and a DEA controlled substance it would not be allowed to be sewered, it would have to be incinerated (or destroyed by another method publicly approved by DEA). Prior to incineration, however, the inventory and pharmaceutical wastage, both of which are conditionally exempt under RCRA, are regulated differently by DEA. The leftover inventory of DEA controlled substances remains

[320] See DEA letter to registrants re: clarifying disposal of pharmaceutical wastage dated Oct 17, 2014; http://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf

[321] Ibid.

fully subject to DEA regulations, which includes tracking and witnessed destruction. On the other hand, controlled substance pharmaceutical wastage is no longer regulated by DEA. Therefore, only pharmaceutical wastage could be collected in a container at the healthcare facility prior to incineration. If this container were used to collect only conditionally exempt pharmaceutical wastage prior to incineration, it would not be subject to the subpart P container standards. It is more likely, however, that a container used to collect the conditionally exempt pharmaceutical wastage would also be used to collect regulated hazardous waste, in which case the container would be subject to subpart P container standards. In either case, as DEA states in its guidance, "Although Part 1317 does not apply to pharmaceutical wastage, the DEA strongly encourages all practitioners to continue to adhere to security controls and procedures that ensure pharmaceutical wastage is not diverted. For example, most institutional practitioners have implemented policies that require two persons to witness and record destruction of pharmaceutical wastage."[322] In support of DEA's guidance, EPA strongly recommends that any container that is used to collect pharmaceutical wastage that will include DEA controlled substances contain some sort of absorbent or chemical reactant in order to bind or chemically alter the contents and thus deter the diversion of the collection container for controlled substance recovery.

3. Long-Term Care Facilities and The DEA Regulations

This section will discuss the intersection of the DEA regulations and the RCRA hazardous waste regulations that pertain to LTCFs.

Under the DEA regulations, most LTCFs are not registrants and until recently have had few options for properly and securely disposing of the controlled substances from its patients

[322] Ibid.

(ultimate users). DEA's 2014 final regulations to implement the Secure and Responsible Drug Disposal Act of 2010 are designed to help alleviate the problem that LTCFs face when discarding their patients' controlled substances. DEA's 2014 final rule allows, but does not require, retail pharmacies and hospital/clinics with an on-site pharmacy that are DEA registrants to modify their registrations to become "collectors" and to place collection receptacles at LTCFs (or at the retail pharmacy or hospital/clinic with an on-site pharmacy) for the collection of controlled substances from ultimate users. Per the DEA regulations, if a DEA authorized collection receptacle is placed in a LTCF, only the ultimate users' controlled substances may be placed in the DEA collection receptacle. If an LTCF is a DEA registrant and discards DEA controlled substances from its inventory, they may not be placed in the DEA authorized collection receptacle and must be otherwise destroyed to meet the non-retrievable standard.

Under the 2014 DEA final rule, LTCFs now have three options for managing their patients' controlled substances. First, if a DEA registered retail pharmacy or hospital/clinic with an on-site pharmacy places a collection container at an LTCF, the staff from the LTCF may place the patients' controlled substances in the collection receptacles. Second, although LTCFs are not allowed to conduct a facility-wide collection event for their patients' controlled substances for mail-back programs, they are allowed to assist patients who choose to use a mail-back program for their own controlled substances, on an individual-by-individual basis. And third, law enforcement can pick up patients' controlled substances for disposal. With these changes to DEA's regulation, LTCFs can now dispose of patients' controlled substances in a more environmentally protective way and EPA strongly encourages the use of any of these three collection methods. It should be noted that the 2014 DEA regulations do not mandate the

placement of collection receptacles at long-term care facilities or patient participation in mail-back programs or take-back events.

As for the RCRA regulations, this rule finalizes the provision that hazardous waste from LTCFs will no longer be considered exempt as household hazardous waste. Instead, it will need to be managed as regulated hazardous waste. This interpretation will apply to all the hazardous waste generated by a LTCF, not just its hazardous waste pharmaceuticals (although the Agency expects that much of the hazardous waste generated by LTCFs consists of hazardous waste pharmaceuticals). Notwithstanding this revised interpretation, there are four other regulatory provisions that might affect how a LTCF will actually have to manage its hazardous waste pharmaceuticals under this final rule

First, we have added to the final rule a presumption that LTCFs with 20 beds or fewer will be VSQGs.[323] And those LTCFs that have more than 20 beds may still qualify as VSQGs (for all of their hazardous waste) if they generate less than 100 kg of hazardous waste and less than 1 kg of acute hazardous waste per calendar month. In fact, based on the RIA for the final rule, EPA estimates that 98–99 percent of LTCFs that generate hazardous waste are VSQGs.[324] As VSQGs, the long-term care facilities will be subject to the reduced regulatory provisions of 40 CFR 262.14 for all of their hazardous waste (including those that are controlled substances), and only the sewer prohibition provision of this new subpart for their hazardous waste pharmaceuticals. Only the other 1–2 percent of LTCFs that generate hazardous waste will be subject to part 266 subpart P.

[323] See 40 CFR § 266.504(d).
[324] See the Regulatory Impact Analysis for this final rule in the docket EPA-HQ-RCRA-2007-0932.

Second, this final rule allows an LTCF that is a VSQG (for all of its hazardous waste) to send its hazardous waste pharmaceuticals to an off-site healthcare facility that either supplies the LTCF with its pharmaceuticals (e.g., a long-term care pharmacy) or is under the control of the same person and that is operating under subpart P.[325] Note that this provision is limited to hazardous waste pharmaceuticals and not to those that are also controlled substances because the DEA allows controlled substances to be returned to a long-term care pharmacy only when they are subject to a recall.

Third, this final rule also allows a healthcare facility, including a LTCF that is a VSQG, to use an on-site DEA authorized collection receptacle to dispose of its hazardous waste pharmaceuticals (see § 266.504(c)). It could be argued that VSQGs would already be allowed to use DEA authorized collection receptacles for their hazardous waste pharmaceuticals even without this new provision, provided the waste from the DEA authorized collection receptacles is treated or disposed at one of the types of facilities identified in § 262.14(a)(5) (e.g., facilities that are permitted or have interim status to manage hazardous waste and facilities that are permitted, licensed or registered by a state to manage hazardous waste, municipal waste or non-municipal waste). Nevertheless, we did propose, and are finalizing the provision in § 266.504(c) making it clear that healthcare facilities that are VSQGs can place their hazardous waste pharmaceuticals in an on-site DEA collection receptacle. DEA already allows controlled substances to be commingled with non-controlled substances. Therefore, EPA believes it is consistent to allow VSQG hazardous waste pharmaceuticals that are not controlled substances to be placed in DEA collection receptacles with controlled substances. EPA believes that management of VSQGs'

[325] See 40 CFR 266.502(l) and 266.503(b) for non-creditable and creditable hazardous waste pharmaceuticals, respectively.

hazardous waste pharmaceuticals as DEA controlled substances is preferable because it provides greater protection to patients, visitors, and workers at healthcare facilities to have the hazardous waste pharmaceuticals accumulating in DEA-authorized collection receptacles rather than in the regular trash. However, it is important to note that the DEA regulations for controlled substances are much narrower in what may be placed in a collection receptacle; DEA only allows controlled substances from patients to be placed in collection receptacles that are at LTCFs. To reiterate, under the DEA regulations, if a LTCF, or any other healthcare facility, is a DEA registrant it may not place its own inventory of controlled substances in a collection receptacle, even if it is a VSQG under RCRA.

Fourth, for the LTCFs that are not VSQGs, the handful of RCRA hazardous waste pharmaceuticals that are also DEA controlled substances will not be subject to RCRA, provided they meet three conditions: (1) they are combusted at a small or large MWC, a HMIWI, a CISWI or a hazardous waste combustor (or destroyed by another method publicly approved by DEA), (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances, and (3) they are not sewered. DEA allows LTCFs to put their patients' controlled substances into an on-site collection receptacle; therefore, an LTCF could also place its patients' controlled substances that are also RCRA hazardous waste into a DEA authorized collection receptacle (alternatively, patients could use another allowable take-back method, such as mail-back envelopes) in order to meet the conditional exemption. However, we must stress that only LTCFs would be able to use collection receptacles (or another allowable take-back method) to meet the conditional exemption for RCRA hazardous wastes that are also DEA controlled substances, because they are the only type of facility that DEA allows to place their patients' wastes into an on-site collection container. Other healthcare facilities, such as hospitals,

could not meet the conditional exemption by placing their DEA controlled substances that are also RCRA hazardous wastes in a collection receptacle because DEA does not allow patients at hospitals to use on-site collection receptacles. No registrant healthcare facility, including an LTCF, would be able to use the collection receptacle to meet the terms of the conditional exemption for any of its own inventory of DEA controlled substances that are also RCRA hazardous wastes because DEA does not allow registrants to use collection receptacles for their own inventory.

For those LTCFs that are not VSQGs, the hazardous waste pharmaceuticals that are not controlled substances (and therefore not conditionally exempt) will be subject to part 266 subpart P, while the other hazardous wastes will be subject to the SQG or LQG regulations, as applicable, in part 262.

See Table 7 for a summary of the intersection of RCRA and DEA regulations for the disposal of hazardous waste pharmaceuticals at LTCFs:

Table 7: Intersection of RCRA & DEA Regulations at Long-Term Care Facilities

Types of Pharmaceutical Waste at Long-Term Care Facilities	**RCRA Regulatory Requirements**		
	How RCRA Applies	**DEA Authorized Collection Methods Allowed for HW Pharmaceuticals?**	**Can be returned to an off-site HCF owned by the same person or LTC Pharmacy?**
Hazardous Waste Pharmaceuticals that are NOT Controlled Substances			
if LTCF is a VSQG	§ 262.14 and sewer prohibition	Yes § 266.504(c)	Yes

if LTCF is **not** a VSQG	part 266 subpart P	No	No
Hazardous Waste Pharmaceuticals that are also Controlled Substances			
if LTCF is a VSQG	§ 262.14 and sewer prohibition	Yes Only from patients	Only if subject to a recall
if LTCF is **not** a VSQG	Conditionally exempt from RCRA (§ 266.506) if: • Combusted (or other DEA approved destruction method) • Comply with DEA regulations	Yes Only from patients (DEA collection methods meet the terms of the RCRA conditional exemption)	Only if subject to a recall

XV. Management of Residues in Pharmaceutical Containers (§ 266.507)

A. *Regulatory Background*

Over the years, EPA has received numerous inquiries regarding the regulatory status of residues in various types of containers that once held pharmaceuticals that are considered hazardous waste when discarded. Stakeholders have been particularly concerned about residues in containers that once held pharmaceuticals that are on the "P-list" of acutely hazardous commercial chemical products in § 261.33(e) because a generator becomes an LQG if it generates more than 1 kg of acute hazardous waste per calendar month.[326] The regulatory status of acute and non-acute commercial chemical product residues remaining in a container are specifically addressed in § 261.33:

"The following materials or items are hazardous wastes if and when they are discarded or intended to be discarded… (c) Any *residue* remaining in a container or in an inner liner removed

[326] Additionally, acute hazardous wastes are included on the F-list of § 261.31; however, none of those acute hazardous wastes are pharmaceuticals.

from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is *empty* as defined in § 261.7(b)."

In § 261.7(b)(1), there are two ways a container that held a non-acute hazardous waste can be considered "empty." The container is considered empty if all wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, e.g., pouring, pumping, aspirating, *and* (1) no more than 2.5 centimeters (one inch) of residue remain on the bottom of the container or inner liner, *or* (2) No more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size; or no more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size.

Therefore, it is important to note that if the container that held the non-acute hazardous waste pharmaceutical does not have its contents removed by a commonly employed practice even though it has one inch or less of residue remaining or has 3 percent or less by weight of the total capacity of the container remaining,[327] the container is still *not* considered "RCRA empty." If the container is not "RCRA empty," then the residues are regulated as hazardous waste (since the residues are within the container, the container must be managed as hazardous waste, as well, even if it is not itself hazardous waste).

According to § 261.7(b)(3), there are three ways that a container that held an acute hazardous waste can be considered empty:

[327] We are assuming that containers that hold pharmaceuticals are in containers less than 119 gallons in size.

(1) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;
(2) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or
(3) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed.

According to these requirements, if the container that held the P-listed pharmaceutical is not triple rinsed, or cleaned by another method that has been demonstrated to achieve equivalent removal, or had the inner liner removed, the container is not considered "RCRA empty," even though the pharmaceutical may have been fully removed. If the container is not "RCRA empty," then the residues are regulated as acute hazardous waste.

In November 2011, EPA issued guidance about containers that once held P-listed pharmaceuticals[328] that provides three possible regulatory approaches for generators:

(1) Count only the weight of the hazardous waste residues toward generator category
(2) Demonstrate an equivalent removal method to render containers RCRA empty
(3) In the case of warfarin, show that the concentration in the residue is below the P-listed concentration.

This guidance was intended as a short-term solution that worked within the confines of the existing RCRA hazardous waste regulations. In 2015, we proposed to amend the regulations that pertain to residues in containers that once held pharmaceuticals that are RCRA hazardous wastes. EPA proposed different regulatory solutions for different types of containers found in healthcare settings. Specifically, the proposal addressed the following three categories of containers: (1)

[328] Rudzinski to RCRA Division Directors, November 11, 2011, RCRA Online #14827.

unit-dose containers (e.g., packets, cups, wrappers, blister packs, and delivery devices) and dispensing bottles and vials; (2) dispensed syringes; and (3) other containers, including delivery devices. Generally, commenters were supportive of the need for these new empty container standards specifically developed for the types of small containers used in the healthcare setting, although they did have suggestions for changes. Each category of container is discussed separately below. Today's new "empty container" regulations in § 266.507 will replace the November 2011 guidance as it pertained to residues of hazardous waste pharmaceuticals in containers, although the memo will remain in effect for non-pharmaceutical hazardous wastes.

B. Stock, Dispensing and Unit-dose Containers (§ 266.507(a))

1. Summary of Proposal

We proposed that a dispensing bottle, vial, or ampule (not to exceed 1 liter or 1,000 pills) or a unit-dose container (e.g., a unit-dose packet, cup, wrapper, blister pack or delivery device) would be considered empty and the residues would not be regulated as hazardous waste if the hazardous waste pharmaceuticals have been removed from the dispensing or unit-dose container by commonly employed methods.

This proposal applied to containers that once held acute or non-acute hazardous waste pharmaceuticals. Under the proposal, for containers that once held non-acute hazardous waste pharmaceuticals, it would not be necessary to measure the remaining contents. Likewise, under the proposal, for containers that once held acute hazardous waste pharmaceuticals, it would not be necessary to triple rinse the containers or demonstrate an equivalent removal method. Rather, we proposed that a dispensing or unit-dose container would be considered empty if all pharmaceuticals have been removed using the practices commonly employed to remove

materials from that type of container—thus, the residues (and therefore the container as well) may be disposed of as non-hazardous waste.

We proposed this new "RCRA empty" standard for containers used within a healthcare setting for two reasons. First, this approach will help eliminate the sewering of pharmaceuticals. In a healthcare setting, if containers are triple rinsed, the rinsate will likely be poured down the drain, which is not a good environmental practice. We think it is important that the residues be managed in a more controlled manner—such as in municipal solid waste landfills— rather than poured down the drain. Second, although the "empty container" regulations of § 261.7 apply to all sizes of containers, they were developed with larger, industrial-sized containers in mind. For the most part, the containers that hold pharmaceuticals are smaller in size than a 55-gallon drum; therefore, the amount of residue will likely be much less in these containers. In the preamble to the proposed rulemaking, we explained that we selected the 1,000-pill/1-liter limit because, in our observation, EPA had rarely seen dispensing bottles larger than that. We specifically sought comment on whether larger containers are used for dispensing pharmaceuticals and, if so, which pharmaceuticals they are used for and what RCRA hazardous waste codes would apply.

In the proposal, EPA presented data from three stakeholders helping to confirm the assumption that very little residue remains in containers after the pharmaceuticals (e.g., pills) have been removed. In addition, EPA's Office of Research and Development conducted similar research.[329] A summary of the results is in the preamble to the proposed rulemaking, while the

[329] Tolaymat, T. and A. El Badawy. Evaluation of P-Listed Pharmaceutical Residues in Empty Pharmaceutical Containers. U.S. Environmental Protection Agency, Washington, DC, EPA/600/R-14/167, 2015.

full results from each of the four sources are included in the docket for the proposed rulemaking.[330, 331]

EPA is aware that there are certain limitations with the data from the four sources. For instance, in one of the studies, no replicate samples were tested. In another study, only warfarin residues were tested. However, given the size of the containers involved and the nominal quantities of residues involved, the Agency proposed to allow the residues in dispensing bottles, vials and ampules, and single-unit dose containers that once held hazardous waste pharmaceuticals to be managed as non-hazardous waste provided the pharmaceutical product has been removed (e.g., all pills have been removed).

As part of the proposal, EPA raised the concern of potential diversion of the pharmaceutical containers that may occur when the pharmaceutical residues and containers are discarded in the municipal waste stream. The Agency proposed that RCRA-empty pharmaceutical containers that are original pharmaceutical packages (and therefore susceptible to diversion) should be destroyed prior to placing them in the trash. These types of containers would include dispensing bottles, vials, or ampules typically used in pharmacies, but would not include paper or plastic cups, or blister packs used for dispensing singles doses to patients. In the preamble to the proposal, we explained that the means of destruction could include crushing or shredding the container.

2. Summary of Comments

The comments for this section can be broken into two major groups. One group of comments expressed concern with the 1,000-pill/1-liter size limit to pharmaceutical dispensing

[330] September 25, 2018; 80 FR 58052.
[331] EPA-HQ-RCRA-2007-0932-0153 through 0156.

containers and commenters asked EPA to consider allowing the new RCRA-empty standard for pharmaceutical dispensing containers to apply to larger pharmaceutical containers or even to all dispensing containers, regardless of size.

As part of its comments, CVS Health included results from an analysis conducted on containers that held warfarin.[332] Their tests included brand name and generic warfarin stock bottles, testing the largest stock bottles with the highest prescription strength warfarin typically found in a CVS Health Pharmacy, although their comments do not specify the size of the largest stock bottle, nor do they specify the highest prescription strength of warfarin. That said, their results do offer similar results as the studies used in support of the proposal, indicating the range of total residues detected was 0.0–19.8 mg (excluding outliers).

Another group of comments objected to the proposed requirement to destroy the containers before disposing of them in municipal solid waste landfills. Commenters objected to this proposed provision for several reasons. First, the most common reason given by commenters that objected to this provision was they disagreed with EPA that diversion of these containers is occurring. Many states commented that this has never been a problem in their state and that the issues with these types of containers arise from purchase of empty vials on the internet and counterfeit labels made on home computers, not from dumpster diving. Second, there was concern that this would be a costly option since many healthcare facilities would now need to hire someone or buy equipment to destroy the containers. Many commenters thought the same goals could be reached through more cost-effective means such as defacing the label to render the containers unusable for illicit purposes. Third, a few commenters were also concerned with the release of the residues in these containers upon destruction and the effect that could have on

[332] See comment number EPA-HQ-RCRA-2007-0932-0312.

the workers. This set of commenters included the one state that favored destruction of the containers. Finally, some commenters noted that these empty containers are already being disposed of in locked dumpsters and there are adequate institutional controls to address any public health risk from use of discarded containers in counterfeit drug sales.

3. Final Rule Provisions

In response to comments, we have made three substantive changes to the regulations proposed in § 266.507(a) that define when a dispensing or unit-dose container is empty. First, based on comments, we now recognize that we used the term "dispensing" bottle, vial, or ampule incorrectly. Dispensing bottles are those that are provided to patients when they get a prescription filled. Although a healthcare facility such as a pharmacy may dispose of some dispensing bottles, they are more likely to dispose of the stock bottles that they use to fill the dispensing bottles provided to the patients. As a result, we have modified the regulatory language to include stock bottles in addition to dispensing bottles, vials or ampules, and unit-dose containers.

Second, after reviewing comments and asking for additional support and clarification from commenters, including the Army Public Health Center, CVS Health and the Department of Veterans Affairs, the Agency has increased the size of the dispensing containers from 1,000 pills to 10,000 pills.[333] The Army Public Health Center states that they "routinely procure containers containing 1K, 2K, and even 5K or 10K pill counts" for refilling the automated dispensing machines at their facilities.[334] This exceeds the size of dispensing containers that we and others

[333] See the email correspondence from Lisa Strutz (APHC); Donald Dempsey (CVS Health); and Peter Carbrey (VA) in the supporting materials of the docket for this final rulemaking (EPA-HQ-RCRA-2007-0932).
[334] See the email correspondence from Lisa Strutz (APHC) to Kristin Fitzgerald (EPA), dated February 9, 2017, in the supporting materials of the docket for this final rulemaking (EPA-HQ-RCRA-2007-0932).

tested, but given that the contents are solid pills, capsules and tablets, and that the residues we and others detected are very small, we determined that it is appropriate to increase the size of the stock or dispensing container to 10,000 pills.

However, we have kept the maximum volume for stock and dispensing containers at a maximum of 1 liter since this volume limit would apply to liquids (and other non-pill formulations), which are harder to fully remove, and commenters did not provide sufficient information to support increasing the volume limit. Further, it is not clear from comments or subsequent correspondence whether any containers larger than 1 liter are in use for pharmaceuticals that would be hazardous waste when discarded. Stock or dispensing containers that exceed 1 liter would be considered "other containers" under § 266.507(d). As such, under the final rule, if they held pharmaceuticals that are non-acute hazardous waste, then they would be able to use § 261.7(b)(1) to show that they are empty.

The third substantive change is that we have removed the proposed requirement to destroy the empty pharmaceutical containers prior to disposal. We share commenters' concerns about possible worker exposure during the process of crushing or shredding the containers. However, EPA remains concerned about the diversion of the empty containers for illicit purposes. Therefore, we strongly encourage healthcare facilities to use best management practices, such as locked dumpsters and defacing labels, to prevent the diversion of these containers, but the extra step of destroying these containers will not be required.

Thus, under the final rule, a stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (e.g., a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle,

vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

In § 261.33(c), we have also added a reference to the new empty container provisions for hazardous waste pharmaceuticals in § 266.507 as a conforming change. Previously, § 261.33(c) referenced only the empty container provisions of § 261.7(b).

4. Comments and Responses

One commenter asked us to add an explicit reference to acute/P-listed hazardous waste in this section of the regulations. We believe this is unnecessary since § 261.7(c) indicates that containers of hazardous waste pharmaceuticals (which includes acute and non-acute hazardous waste pharmaceuticals) are subject to § 266.507 in lieu of § 261.7 for determining when they are empty. Nevertheless, we agree with the commenter that all of the new empty container provisions in § 266.507 apply to containers that held either non-acute or acute hazardous waste pharmaceuticals. Under the new subpart P provisions, for containers that once held non-acute waste pharmaceuticals to be considered empty, it will not be necessary to measure the remaining contents, and for containers that once held acute hazardous waste pharmaceuticals, it will not be necessary to triple-rinse the containers or demonstrate an equivalent removal method.

C. Syringes (§ 266.507(b))

1. Summary of Proposal

EPA proposed that the residues remaining in a syringe would not be regulated as hazardous waste provided the syringe had been used to administer a pharmaceutical to a patient, the syringe is placed in a sharps container (if appropriate), and is managed in accordance with all applicable federal, state, and local medical waste or regulated waste regulations. As with all of the new empty container standards proposed in § 266.507, this proposed provision applied to

syringes used to administer pharmaceuticals that are acute or non-acute hazardous waste when discarded.

Prior to the proposal, EPA issued guidance regarding the regulatory status of residues in syringes in December 1994 and April 2008.[335,336] In the December 1994 RCRA/Superfund Hotline Q&A about whether epinephrine residues in a discarded syringe would be P042, EPA stated, "Drug residues often remain in a dispensing instrument after the instrument is used to administer medication. EPA considers such residues remaining in a dispensing instrument to have been used for their intended purpose. The epinephrine remaining in the syringe, therefore, is not a commercial chemical product and not a P042 hazardous waste. The epinephrine could be a RCRA hazardous waste, however, if it exhibits a characteristic of hazardous waste."[337] In the April 2008 memo, EPA clarified that the 1994 interpretation extends to other P- and U-listed pharmaceuticals that have been used to administer the pharmaceutical by syringe.

EPA thinks that it is important to clarify in regulation when syringes are considered RCRA empty as this has been a source of many questions over the years. As part of the decision making, EPA is aware of the need to minimize the potential for exposures of healthcare workers to the sharps, which may be contaminated with bloodborne pathogens, as well as to the contents of the syringes.

The preamble to the proposed rulemaking also noted that sharps containers containing syringes are typically autoclaved prior to disposal. EPA expressed concern that the residues remaining in the syringes could be aerosolized during autoclaving and inadvertently expose

[335] December 1994, RCRA Online #13718.
[336] Memo from Dellinger to Chilcott, April 14, 2008, RCRA Online #14788.
[337] Note that since this Q&A was issued, EPA issued guidance indicating that epinephrine salts are not included in the scope of the P042 listing and therefore, most, if not all, medical applications of epinephrine are not P042 (October 15, 2007; RCRA Online #14778).

workers to the aerosolized hazardous waste residues, posing risks via pulmonary exposure to those present during venting of the autoclave. Research suggests that autoclaving may even increase the toxicity of certain drugs.[338] As a result, EPA requested comment on whether it is necessary to place a limit on the volume of residue or the volume of the syringe to which this new provision would apply or whether any other conditions would be appropriate.

2. Summary of Comments

As noted above, commenters generally supported EPA's goal of codifying new standards for defining when containers are considered empty, including syringes. EPA received many comments requesting that the Agency clarify what it means when it uses the term "dispensed." Further, they noted that although the proposed regulations used the term "dispensed," in several cases in the preamble, we used the term "fully dispensed" and they requested clarification about which was correct. Commenters also noted that EPA used the term "dispensed" inappropriately and stated that the term "administered" was more appropriate. The Agency received mixed comments on whether any residues or contents should be left in the syringes when disposing of the syringe. In the case of autoclaving residues in syringes, almost all commenters agreed that the hazardous waste pharmaceutical residues should not be autoclaved. Some commenters believed that the contents should be disposed of in a gauze pad or equivalent while others argued that this was in contradiction to NIOSH recommendations for minimizing exposure to hazardous drugs. Some commenters were comfortable with leaving contents in the syringes, suggesting that would be in compliance with OSHA[339] and DOT.[340]

[338] Daughton CG, Drugs and the Environment: Stewardship & Sustainability, National Exposure Research Laboratory, Environmental Sciences Division, US EPA, Las Vegas, NV; NERL-LV-ES 10/081, EPA/600/R-10/106; September 2010 (https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryID=228503).
[339] OSHA Title 29 CFR 1910.1030 Bloodborne Pathogens.

3. Final Rule Provisions

We have made two substantive changes to this section of the regulations that define when syringes are considered empty for the sake of RCRA regulation. First, EPA agrees with commenters that we used the term "dispensed" inappropriately in the proposed rulemaking. FDA defines "dispense to patients to mean the act of delivering a prescription drug product to a patient or an agent of the patient."[341] Dispensed pharmaceuticals are then administered directly to the patient. EPA has revised the regulations to address commenters' concerns. In the final rule, to avoid confusion, when discussing syringes we do not use the term dispensed, fully dispensed, or administered. Instead, under the final rule, a syringe is considered empty and the residues are not regulated as hazardous waste provided the contents have been removed by fully depressing the plunger of the syringe. Thus, the final regulations convey an intent that is more similar to the proposed preamble use of the term "fully dispensed." This reflects commenters' and EPA's desire to avoid the possibility of autoclaving syringes that may have a large portion of their hazardous waste pharmaceutical contents remaining.

Commenters affirmed EPA's concerns about aerosolizing the autoclaved hazardous waste in sharps containers and we have concluded that hazardous waste incineration of hazardous waste pharmaceuticals remaining in non-empty syringes is more appropriate. A recent literature search also supports this position. The NIOSH and the American Society of Hospital Pharmacists (ASHP) have both published articles regarding autoclaving of sharps. The 2004 NIOSH alert states, "Do not place hazardous drug-contaminated sharps in red sharps containers that are used

[340] DOT Title 49 CFR 172.343 Subpart D – Marking; 172 Subpart E – Labeling Standards; 172.432 Subpart E.
[341] See 21 CFR 208.3.

for infectious wastes, since these are often autoclaved or microwaved."[342] The ASHP article states, "Sharps used in the preparation of hazardous drugs should not be placed in red sharps containers or needle boxes, since these are most frequently disinfected by autoclaving or microwaving, not by incineration, and pose a risk of aerosolization to waste-handling employees."[343]

A syringe with a fully depressed plunger will have a minute amount of residue and the syringe can be considered empty under the final rule. Thus the residue in the empty syringe (as well as the syringe) will not be regulated as hazardous waste. A syringe that does not have a fully depressed plunger could have anything from a small amount to 99% of hazardous waste pharmaceutical contents still left in it. Therefore, we have concluded that it is impracticable to impose an alternate bright line for determining whether a partially administered syringe is empty. Further, we concur with ASHP and NIOSH regarding concerns about the safety of autoclave operators and believe the standard in this final rule will help prevent exposing workers to volatilized hazardous waste pharmaceutical residues during the autoclaving process.

The second substantive change we made in the final rule is to clarify that if a syringe contains a pharmaceutical that is a hazardous waste and it is not empty because the plunger is not fully depressed, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart as well as any applicable federal, state, and local requirements for sharps containers and medical or regulated waste. We note that the new empty syringe

[342] NIOSH. "Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings." Publication Number 2004-165, Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH), Cincinnati, OH, 2004. 58 pp; http://www.cdc.gov/niosh/docs/2004-165/pdfs/2004-165.pdf.

[343] ASHP. "ASHP guidelines on handling hazardous drugs." American Journal of Health-System Pharmacy 2006, 63:1172-1193; http://dx.doi.org/10.2146/ajhp050529.

provisions being finalized today supersedes the previous EPA interpretations expressed in guidance memos in December 1994 and April 2008.[344,345]

We note that a syringe can become empty in three ways: (1) fully depressing the plunger of the syringe by administering the contents of the syringes to a patient, or (2) fully depressing the plunger by injecting the contents of the syringe into another delivery device such as an IV bag, or (3) fully depressing the plunger of the syringe by emptying the remaining contents into a hazardous waste collection container.

4. Consultation with OSHA

As part of the final rule process, EPA consulted with OSHA to gain a better understanding of its Bloodborne Pathogens standard and how it interacts with other regulations for the disposal of sharps and the contents within the syringes. The Bloodborne Pathogens standard states that "[u]niversal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials."[346] It also states that disposal of a sharp shall be done "immediately or as soon as feasible."[347] Further, OSHA requires that containers for contaminated sharps shall be "easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can reasonably anticipated to be found."[348] When workers travel to a remote location to discard a sharp, it increases the possibility of an accidental needlestick, increases the chances that needles and other sharps will be improperly discarded, and creates potential hazards

[344] December 1994, RCRA Online #13718.
[345] Memo from Dellinger to Chilcott, April 14, 2008, RCRA Online #14788.
[346] See 29 CFR 1910.1030(d)(1).
[347] See 29 CFR 1910.1030(d)(4)(iii)(A)(*1*).
[348] See 29 CFR 1910.1030(d)(4)(iii)(A)(*2*)(*i*).

for other staff members. The determination of whether or not a sharps disposal container is as close as feasible should be made on a case-by-case basis by OSHA.[349]

Therefore, the practice of emptying the contents of the syringe would not violate the OSHA standard if the containers are as close as feasible. Any related work practices must also be such that they do not create additional hazards to workers (e.g., containers are located in close proximity to the work area to avoid employees travelling with used sharps to disposal receptacles located outside the point of use). Furthermore, nothing in this new subpart requires workers to recap needles or other sharps, or otherwise manually manipulate the sharp or needle during emptying, such as unscrewing the needle from the syringe.

As part of this consultation, OSHA addressed the issue of waste disposal. OSHA's Bloodborne Pathogens compliance directive states: "[W]hile OSHA specifies certain features of the regulated waste containers, including appropriate tagging, the ultimate disposal method (landfilling, incinerating, and so forth) for medical waste falls under the purview of the EPA and possibly State and local regulations" ("Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories" (1910.1030(d)(4)(iii)(C))).[350]

The Agency also received comment that we should recommend the extra protective step that all syringes/sharps be incinerated. Any sharps container that contains hazardous waste must be treated to meet the LDR requirements in part 268. In most cases, the LDR treatment standard for hazardous waste pharmaceuticals is incineration. On the other hand, if a sharps container

[349]OSHA Compliance Directive CPL 02-02-069 Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens https://www.osha.gov/OshDoc/Directive_pdf/CPL_02-02-069.pdf.

[350] Ibid.

does not contain hazardous waste pharmaceuticals because all the syringes have been emptied by fully depressing the plunger, then the RCRA hazardous waste regulations would not apply to these sharps containers (although these sharps containers are still solid wastes).

Regardless of whether sharps containers have regulated hazardous waste pharmaceutical residues, they could contain bloodborne pathogens or other infectious materials. Thus, OSHA's Bloodborne Pathogens standard requires that "disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories."[351] Many states have medical waste regulations that require the treatment of regulated medical waste, including sharps containers, to render it non-infectious, which is often achieved by autoclaving, prior to disposal as solid waste.

D. Other Containers, Including Delivery Devices (§ 266.507(c) & (d))

1. Summary of Proposal

EPA proposed that the residues remaining in other types of unused or used containers, including delivery devices, such as IV bags and tubing, inhalers, aerosols, nebulizers, tubes of ointments, gels, or creams, would be regulated as hazardous waste if the residues are acute or non-acute hazardous waste. In some cases, such as with IV bags, the volume of hazardous waste being disposed is much larger than with residues contained in syringes or unit-dose containers. It is extremely difficult to determine how much residue remains in tubes of ointments, gel, or cream. In the case of aerosols, it would be inadvisable to remove the contents of the container. Since EPA proposed that hazardous waste pharmaceuticals managed under subpart P would not be counted towards a facility's generator category, we argued that managing these residues and containers as hazardous waste under the proposed provisions should not pose the same burden

[351] See 29 CFR 1910.1030(d)(4)(iii)(C).

that generators had been facing in with keeping track of the monthly amount of residues in containers that are not "RCRA empty."

2. Summary of Comments

Comments were mixed in this section. Some commenters agreed with EPA that it is difficult to determine if containers such as inhalers, aerosol cans, tubes of ointments, gels, or creams meet the RCRA empty standards within § 261.7 and, therefore, managing them under the streamlined requirements of subpart P would be protective. Other commenters wanted EPA to allow these other containers to continue to meet the definition of empty within § 261.7 or develop specific empty container standards for them within subpart P. One commenter recommended that EPA revise the regulations to state that IV bags and their tubing, inhalers, aerosols, nebulizers, tubes of ointments, and gels or creams are RCRA empty and not subject to hazardous waste regulations if they contain non-acute hazardous waste and their contents are fully administered.

3. Final Rule Provision

In response to comments, the final rule contains an empty container standard for IV bags separate from other containers, including delivery devices. The Agency stated in the proposal that it is very hard to determine if aerosols, tubes of ointments, gels and creams, inhalers, and nebulizers are empty due to their containers and contents. As commenters pointed out, this is not the case for IV bags and tubing since they are transparent and the liquids inside can be easily observed.

Taking approaches suggested from commenters, EPA is finalizing in § 266.507(c) that an IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. In cases where the IV

bag has not been fully administered and the IV bag held non-acute hazardous waste pharmaceuticals, then IV bag can be shown to be empty and the remaining residues not regulated as hazardous waste per § 261.7(b)(1). If an IV bag is not empty through either of these means because it either has not been fully administered or cannot meet the requirements of § 261.7(b)(1) or because it contained an acute hazardous waste pharmaceutical, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart.

In the final rule, EPA has also altered the requirements for other types of containers including delivery devices. Commenters pointed out that a healthcare facility should not be precluded from proving that these containers meet the RCRA-empty standards in § 261.7 simply due to the type of container or contents. EPA agrees with the commenters that these types of containers which held non-acute hazardous waste pharmaceuticals should be able to use the RCRA empty container standards under § 261.7 and has changed the final rule to allow this. If the containers meet the RCRA empty standard under § 261.7 then the non-acute hazardous waste pharmaceutical residues (and the container) are not regulated as hazardous waste and can be managed as solid waste.

If these other containers, a category that includes but is not limited to inhalers, aerosols, nebulizers, tubes of ointments, gels or creams, once held an acute hazardous waste pharmaceutical or if they held a non-acute hazardous waste pharmaceutical but cannot meet the RCRA empty container standard of § 261.7, then the residues of these hazardous waste pharmaceuticals (and their containers) must be managed as non-creditable hazardous waste pharmaceuticals under this subpart.

4. Comments and Responses

One commenter was concerned that managing all other containers that held hazardous waste pharmaceuticals as non-empty could cause a VSQG healthcare facility to bump up in generator category to an LQG. This will no longer be a concern since a healthcare facility now has the option to prove that their other containers that held non-acute hazardous waste pharmaceuticals meet the RCRA empty container standards in § 261.7 and they can manage the residues (and containers) as non-hazardous waste. Otherwise, if these other containers are not considered empty, then the residues (and containers) must be managed as non-creditable hazardous waste pharmaceuticals under subpart P and hazardous waste pharmaceuticals managed under subpart P do not count towards determining the generator category. Further, we note that a healthcare facility can use the new empty container provisions in § 266.507 when determining whether they generate enough hazardous waste to become subject to part 266 subpart P.

XVI. Shipping Standards for Hazardous Waste Pharmaceuticals (§§ 266.508 and 266.509)

A. Shipping Non-creditable Hazardous Waste Pharmaceuticals from Healthcare Facilities to Treatment, Storage, and Disposal Facilities (§ 266.508(a))

1. Summary of Proposal

Under part 266 subpart P, hazardous waste pharmaceuticals generated in a healthcare facility fall into two categories: (1) Non-creditable hazardous waste pharmaceuticals (e.g., partially administered for patient care), and (2) potentially creditable hazardous waste pharmaceuticals (e.g., unused, unadministered). This section discusses the proposed requirements for shipping non-creditable hazardous waste pharmaceuticals. For information regarding the shipment of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and reverse distributors, see section XVI.D. of this preamble.

Generally, non-creditable hazardous waste pharmaceuticals differ from potentially creditable hazardous waste pharmaceuticals in that they have been partially administered and often are not in their original packaging. In addition, since there is not a reasonable expectation that prescription non-creditable hazardous waste pharmaceuticals are eligible to receive manufacturer credit, they are shipped off site to a TSDF rather than a reverse distributor. Due to concerns that a healthcare facility might send all of its hazardous waste pharmaceuticals to a reverse distributor even if there is not a reasonable expectation of receiving manufacturer credit—essentially using the reverse distributor as a TSDF—EPA proposed that non-creditable hazardous waste pharmaceuticals generated at healthcare facilities, when shipped off site, must be shipped to a designated facility (e.g., an interim status or permitted hazardous waste TSDF), as was required under part 262 (unless the healthcare facility has interim status or a RCRA permit to store or treat hazardous waste and chooses to store or treat the non-creditable hazardous waste pharmaceuticals on site instead of shipping them to a designated facility).

Specifically, EPA proposed that healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a designated facility for treatment or disposal must continue to comply with the existing Department of Transportation (DOT) pre-transport requirements for packaging, labeling and marking, and that the non-creditable hazardous waste pharmaceuticals must continue to be shipped using a hazardous waste transporter and be tracked with a hazardous waste manifest. However, to avoid unnecessarily burdening the healthcare facility staff, who the Agency assumes are typically unfamiliar with RCRA, EPA proposed that the hazardous waste numbers (often called hazardous waste codes) are not required to be entered into the hazardous waste manifest for non-creditable hazardous waste pharmaceuticals. In lieu of hazardous waste codes, EPA proposed that the words, ‘‘hazardous waste pharmaceuticals’’ must be entered in the

‘‘special handling and additional information’’ box on the manifest (this box was called Item 14 at the time of the proposal).

We also proposed that all existing RCRA recordkeeping requirements regarding hazardous waste manifesting as well as all applicable DOT shipping requirements continue to apply to healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF for treatment or disposal (see section X.K).

2. Summary of Comments

Comments on this section of the proposed rulemaking were mixed. Commenters generally agreed with the proposed standards for packaging, labeling, marking, placarding, and shipping papers. Adverse comments were mostly in regard to the decision to not require individual waste codes on the manifest for a healthcare facility sending non-creditable hazardous waste pharmaceuticals to a TSDF for disposal. In fact, commenters were generally concerned about the proposal to not require individual waste codes anywhere in the management standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals. Whether the comments were regarding waste code determinations, labeling containers with waste codes, or including waste codes on the manifest, the overarching concern was that TSDFs would not know the specific contents of shipments received, resulting in an increase to their burden, and possibly would be detrimental to human health and the environment. Therefore, the adverse comments regarding the lack of a proposed requirement to input individual waste codes on the manifest are applicable more broadly to the subject of whether or not the information that individual waste codes convey should somehow be provided to a TSDF by the healthcare facility shipping non-creditable hazardous waste pharmaceuticals.

Some states agreed with the proposal to not require individual waste codes on the manifest, while others commented that it is important to have waste codes at all steps where they would otherwise be required under previous RCRA regulations. Comments from waste management companies were also mixed, with some supporting the proposal to not require individual hazardous waste codes on the manifest, while others agreed with the proposal but suggested including a profile of likely constituents to alert TSDFs of potential waste contents to aid in LDR compliance.

Those waste management companies that disagreed with the proposed standards cited the added burden imposed by not knowing the specific waste constituents included in a shipment, which would make compliance with LDR standards more difficult. They were primarily concerned about the added burden of having to either begin testing their ash for wastes that have a numeric treatment standard, or modify existing testing protocols. One commenter from the healthcare industry disagreed with the elimination of individual hazardous waste codes on manifests from healthcare facilities shipping non-creditable hazardous waste pharmaceuticals, arguing that healthcare workers are capable of making accurate hazardous waste determinations. They also stated that hazardous waste codes are integral to properly managing hazardous waste. One waste management commenter stated that continuing to require waste codes on LDR notices altogether negates any actual relief because healthcare facilities will have to determine appropriate waste codes before sending hazardous waste pharmaceuticals off site to a TSDF whether or not they are required on the container label or manifest.

One reverse distributor also agreed with the proposed standards under the condition that the Agency agree that pharmaceuticals being sent to a reverse distributor are not waste.

3. Final Rule Provisions

The agency is finalizing the majority of the proposed requirements in this section. Before being shipped off site, all shipments of non-creditable hazardous waste pharmaceuticals must comply with applicable DOT pre-transport requirements for packaging (49 CFR parts 173, 178, and 180), labeling (49 CFR part 172 subpart E), and marking (49 CFR part 172 subpart D). There are, however, three notable changes being finalized.

First, § 266.508(a)(1)(v) has been removed and a healthcare facility shipping hazardous waste pharmaceuticals to a TSDF for disposal must instead comply with § 266.508(a)(2)'s manifest requirement to meet DOT's shipping papers requirement.

Second, the agency has decided to modify the proposal to not require any hazardous waste codes in Item 13 (Waste Codes) of the hazardous waste manifest for shipments of non-creditable hazardous waste pharmaceuticals being sent to a TSDF, and write the words "Hazardous Waste Pharmaceuticals" in Item 14 (Special Handling Instructions and Additional Information). The Agency is instead finalizing a requirement to write only one waste code—"PHARMS"—in Item 13, and not impose any requirements for what must be written in Item 14. After further consideration of the impacts this proposed requirement would impose on implementation and data collection, the Agency decided it had to be modified. During the development of this rule, the Agency has also been developing the electronic manifest system (e-Manifest) which requires that some code be written in Item 13. We chose the PHARMS code because it both meets the required number of characters and communicates the nature of the waste. Since the waste will now be sufficiently characterized in Item 13, the Agency feels there is no longer the need to require the words "hazardous waste pharmaceuticals" in Item 14.

This new PHARMS code is for manifesting and reporting purposes only and is not an official EPA hazardous waste code. Because it will be written in the same place as other official

EPA hazardous waste codes, it may also be referred to colloquially as a "hazardous waste code." However, it does not modify any existing LDR treatment standards, nor does it enact any new or alternate LDR treatment standards for hazardous waste pharmaceuticals. Many commenters throughout the proposed rulemaking suggested that EPA promulgate an alternative treatment standard of the "CMBST" code specifically for hazardous waste pharmaceuticals with numeric treatment standards. The agency considered incorporating these suggestions into the proposed rulemaking, but did not receive the necessary data to support such an action. The Agency does, however, generally agree that implementing a new alternative treatment standard for hazardous waste pharmaceuticals might help mitigate burden on the regulated community while remaining protective of human health and the environment. The Agency remains open to considering the addition of an alternative treatment standard for hazardous waste pharmaceuticals in future rulemakings.

Although the Agency is now requiring the PHARMS code in Item 13 for shipments of non-creditable hazardous waste pharmaceuticals from a healthcare facility to a TSDF, hazardous waste codes are not required on the manifest, which was preferred by some commenters. As a result, TSDFs treating hazardous waste pharmaceuticals will have to assume that shipments of hazardous waste pharmaceuticals contain the few that have numeric treatment standards in order to demonstrate compliance with LDRs.

The third change made to the regulations was to modify the regulatory language in § 266.508(a) slightly to clarify that shipments of non-creditable hazardous waste pharmaceuticals being sent from a healthcare facility for disposal must be sent to a designated facility and accompanied by a hazardous waste manifest. As part of the manifest requirements in 40 CFR part 262 subpart B, shipments of non-creditable and evaluated hazardous waste pharmaceuticals

must be sent to a designated facility via a hazardous waste transporter. One commenter noted that the proposed language could have been interpreted to mean that such shipments are also allowed to go elsewhere, which was not the Agency's intent.

Another substantive change to the regulatory language that resulted from incorporating commenters' concerns was to remove the requirements for shipping papers in § 266.508(a)(1)(v). A commenter pointed out that the requirement is unnecessary given the requirements in § 266.508(a)(2) and the Agency agreed. Section 266.508(a)(1)(v) would have required a healthcare facility shipping non-creditable hazardous waste pharmaceuticals to a TSDF to prepare shipping papers in accordance with 49 CFR 172 subpart C; however, the subsequent paragraph (§ 266.508(a)(2)) outlines the requirements for manifesting a shipment of non-creditable hazardous waste pharmaceuticals. Requiring both shipping papers and a manifest is redundant and could have possibly resulted in confusion and contradictory requirements. The hazardous waste manifest requirements, if complied with, duly satisfy DOT's shipping paper requirements.

The wording in § 266.508(a) was modified slightly to clarify that healthcare facilities and reverse distributors that ship non-creditable and evaluated hazardous waste pharmaceuticals off site, respectively, are required to send them to a designated facility.

Finally, to be consistent with the Hazardous Waste Generator Improvements final rule, we have added paragraph 266.508(a)(1)(iii)(C) to mirror § 262.32(d), which addresses marking for lab packs. Specifically, lab packs of hazardous waste pharmaceuticals that will be treated using the alternative treatment standard of incineration, as allowed by § 268.42(c), do not have to marked or labeled with EPA hazardous waste numbers. However, lab packs that contain D004 (arsenic), D005 (barium), D006 (cadmium), D007 (chromium), D008 (lead), D010 (selenium) or D011 (silver), the EPA hazardous waste number must be marked or labeled with the EPA

hazardous waste numbers (or electronic means may be used). These specific metals must be identified because § 268.42(c)(4) requires any incinerator residues from lab packs that contain any of these specific metals to undergo further treatment prior to land disposal.

B. Shipping Evaluated Hazardous Waste Pharmaceuticals from Reverse Distributors to Treatment, Storage, and Disposal Facilities (§ 266.508(a))

1. Summary of Proposal

For reverse distributors, once a potentially creditable hazardous waste pharmaceutical has been evaluated and it has been determined that it is not destined for another reverse distributor for further evaluation or verification of credit, EPA proposed that the hazardous waste pharmaceuticals be referred to as ''evaluated hazardous waste pharmaceuticals.'' As with shipping non-creditable hazardous waste pharmaceuticals, when evaluated hazardous waste pharmaceuticals are shipped off-site, EPA proposed that they must be shipped in accordance with the existing DOT pre-transport requirements under 49 CFR parts 172–80 for packaging, labeling, marking, placarding, and shipping papers. We also proposed that they must be shipped in accordance with the existing RCRA manifest requirements of 40 CFR part 262 subpart B, which requires all relevant waste codes be listed in Item 13 and that they be shipped via a hazardous waste transporter to a designated facility. This continues current practices under existing regulations for this type of hazardous waste pharmaceutical and does not represent an increase in burden. EPA argued that the use of a hazardous waste manifest and a hazardous waste transporter are appropriate at this point for two reasons. First, once credit for the hazardous waste pharmaceuticals has been verified, the potential for mismanagement is greater because evaluated pharmaceuticals no longer retain any value and will cost the reverse distributor money to dispose. Second, TSDFs are accustomed to receiving hazardous waste via a hazardous waste

transporter with a hazardous waste manifest and it would place administrative and compliance burdens on the receiving TSDF to accept shipments of hazardous waste with alternative tracking.

EPA proposed that a reverse distributor must list all appropriate hazardous waste codes on the manifest when shipping evaluated hazardous waste pharmaceuticals to a TSDF. This differs from the requirements for a healthcare facility shipping non-creditable hazardous waste pharmaceuticals to a TSDF. Unlike non-creditable hazardous waste pharmaceuticals generated at a healthcare facility, hazardous waste pharmaceuticals received by reverse distributors are typically in the manufacturer's original, intact, and labeled packaging (if not, they are likely non-creditable hazardous waste pharmaceuticals and should be sent to a TSDF), so the information needed to determine the appropriate hazardous waste codes once evaluated should be readily available to the reverse distributor. Also, reverse distributors are currently required to include hazardous waste codes on the manifest and it is expected that they have the necessary expertise in the management of these hazardous wastes that healthcare personnel lack. Under the reverse distributor standards in § 266.510(c)(10)(ii), EPA also proposed that reverse distributors must keep copies of hazardous waste manifests for three years from the date evaluated hazardous waste pharmaceuticals are shipped to a TSDF.

2. Summary of Comments

Comments in this section were mixed. Many commenters addressed the standards for healthcare facilities sending shipments of non-creditable hazardous waste pharmaceuticals to a TSDF but did not specifically mention the standards for shipping evaluated hazardous waste pharmaceuticals to a TSDF. Nevertheless, many of the concerns expressed by commenters with the standards for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF are relevant because the standards in § 266.508 are the same for healthcare facilities

shipping non-creditable hazardous waste pharmaceuticals as they are for reverse distributors shipping evaluated hazardous waste pharmaceuticals, with the exception of § 266.508(a)(2)(i) and (ii). The few that commented directly on the proposed shipping standards for evaluated hazardous waste pharmaceuticals being shipped from a reverse distributor to a TSDF agreed with the standards as proposed.

Reverse distributor and waste management industry commenters were in agreement with the proposed standards for shipping evaluated hazardous waste pharmaceuticals to a TSDF, but to reiterate, did not agree with the standards for shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility to a TSDF (no waste codes on the manifest). Many commenters on this section simply stated that waste codes should be included on a manifest, referring to the requirements in § 266.508(a)(2)(i) and (ii) which do not require waste codes on the manifest for healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF. Since those standards only apply to healthcare facilities shipping non-creditable hazardous waste pharmaceuticals to a TSDF and not reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF, the agency assumes that those same commenters are generally in agreement with the requirement for reverse distributors shipping evaluated hazardous waste pharmaceuticals to a TSDF to comply with all of the manifest standards in 40 CFR part 262 subpart B, which includes a requirement to list all applicable EPA hazardous waste codes on the manifest.

3. Final Rule Provisions

The Agency is finalizing the standards for shipping evaluated hazardous waste pharmaceuticals from a reverse distributor to a TSDF with minor changes. First, § 266.508(a)(1)(v) has been removed. The standards for shipping papers for reverse distributors

sending evaluated hazardous waste pharmaceuticals to a TSDF are contained instead in subparagraph § 266.508(a)(2) (i.e., the manifest).

Second, the clarification to the regulatory language mentioned previously, which specifies that non-creditable hazardous waste pharmaceuticals must go only to a TSDF, also applies to evaluated hazardous waste pharmaceuticals. As mentioned above, commenters were concerned that the proposed regulatory language appeared to make it optional for a reverse distributor to ship evaluated hazardous waste pharmaceuticals to a TSDF for disposal, although it was not intended to read that way. The finalized regulatory language was modified to clarify that a reverse distributor shipping evaluated hazardous waste pharmaceuticals must send them to a TSDF for treatment and disposal. This change pertains to both evaluated pharmaceuticals being shipped from a reverse distributor as well as non-creditable hazardous waste pharmaceuticals being shipped from a healthcare facility.

To summarize, reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF for disposal are required to comply with all standards in § 266.508(a), which includes a requirement to list all applicable waste codes in Item 13 of the manifest, even though healthcare facilities sending non-creditable hazardous waste pharmaceuticals to a TSDF do not. They are not, however, required to write the word PHARMS in Item 13 or on the container label in addition to all other applicable waste codes.

C. Shipping Non-creditable or Evaluated Hazardous Waste Pharmaceuticals for Import or Export (§§ 266.508(b) and 266.508(c))

1. Summary of Proposal

Under part 262, a healthcare facility or reverse distributor may not import hazardous waste pharmaceuticals unless it has a RCRA permit or interim status that allows it to accept

hazardous waste from off site and complies with the requirements for importing hazardous waste in 40 CFR part 262 subpart H. Under part 266, EPA did not propose to change the regulations as they apply to the import of non-creditable or evaluated hazardous waste pharmaceuticals. Likewise, under part 262, a healthcare facility or reverse distributor may not export (non-creditable nor evaluated) hazardous waste pharmaceuticals unless it complies with requirements for exporting hazardous waste in 40 CFR part 262 subpart H. Under part 266, EPA did not propose to change the regulations as they apply to the export of (non-creditable or evaluated) hazardous waste pharmaceuticals.[352]

EPA requested comment on the likelihood that non-creditable hazardous waste pharmaceuticals that are shipped from a healthcare facility to a domestic TSDF, would then be exported to a TSDF in a foreign country. In addition, EPA did not anticipate that hazardous waste pharmaceuticals would be destined for transboundary shipments for purposes of recovery operations and therefore potentially subject to 40 CFR part 262 subpart H; however, we also requested comment on whether this is the case.

2. Summary of Comments

We received no comments on the proposed standards for importing and exporting non-creditable or evaluated hazardous waste pharmaceuticals.

3. Final Rule Provisions

Since part 266 subpart P was proposed, the hazardous waste import and export regulations under part 262 have been revised.[353] The export regulations which had been in part 262 subpart E are now in part 262 subpart H. Likewise, the import regulations which had been in

[352] In the proposed rule we referenced part 262 subparts E and F when discussing this provision. Part 262 subparts E and F have since been replaced by part 262 subpart H; see the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

[353] See the final Hazardous Waste Export-Import Revisions rule, 81 FR 85696; December 31, 2016.

part 262 subpart F are also now in part 262 subpart H. The requirements for both importing and exporting non-creditable hazardous waste pharmaceuticals are being substantially finalized as proposed. The only change being made from the proposed requirements is to update the reference to the revised part 262 regulations, in order to conform to the changes implemented in the Hazardous Waste Imports and Exports Improvement Rule. Whereas the proposed § 266.508(b) and (c) refer to the standards in 40 CFR part 262 subpart E and F, they now refer to 40 CFR part 262 subpart H.

D. Shipping Potentially Creditable Hazardous Waste Pharmaceuticals (§ 266.509)

1. Summary of Proposal

This section discusses the proposed requirements for shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility to a reverse distributor and between reverse distributors. The return of potentially creditable waste pharmaceuticals (hazardous and non-hazardous) to a reverse distributor can involve multiple shipping steps before the pharmaceuticals are transported for ultimate treatment and disposal. In comments on the 2008 Pharmaceutical Universal Waste proposal and in response to EPA's request for information,[354] reverse distributors described various scenarios. For example, a healthcare facility typically sends waste pharmaceuticals to the reverse distributor with which it has a contract. However, some manufacturers will only provide manufacturer credit after the pharmaceuticals have been returned to the reverse distributor with which the manufacturer has a contract. Thus, if the reverse distributor with which the healthcare facility has a contract differs from the reverse distributor with which the manufacturer has a contract, then the healthcare facility's reverse distributor must send the pharmaceuticals on to the manufacturer's reverse distributor for the

[354] See the survey of reverse distributors in docket number: EPA-HQ-RCRA-2007-0932-0158 through 0160.

manufacturer credit to be given to the healthcare facility. In some cases, a pharmaceutical manufacturer may require the reverse distributor to ship the pharmaceuticals back to them so they can perform the verification and issue credit themselves. The estimated amount of pharmaceuticals transported from reverse distributors to manufacturers for verification varies. Based on our request for information, reverse distributors indicated that the percent of potentially creditable hazardous waste pharmaceuticals transported to manufacturers ranged from an estimated 25 percent to 93 percent of total volume, depending on the contractual agreement between the reverse distributor and the manufacturer. The scenarios described previously occur routinely and are an integral part of the process by which manufacturers issue credit.

As explained in section IV.A, EPA proposed that all pharmaceuticals transported to reverse distributors for manufacturer credit are solid wastes, some of which would also be considered hazardous wastes. The finalized regulations have been modified, however, such that only prescription pharmaceuticals going through reverse distribution for manufacturer credit are solid wastes, while OTC pharmaceuticals going through reverse logistics are outside of this rule. Under the part 262 regulations, hazardous waste, including hazardous waste pharmaceuticals, must be manifested to a permitted or interim status TSDF and shipped using a hazardous waste transporter to ensure the cradle-to-grave system of RCRA is maintained. However, compared to other hazardous wastes, EPA believes that the risk of environmental release posed by most potentially creditable hazardous waste pharmaceuticals during accumulation and transport is relatively low. The risk is low because of the form and packaging of most potentially creditable hazardous waste pharmaceuticals, which is typically in small, individually packaged doses (such as with many tablets and capsules) or small vials. These small volumes of individually wrapped or packaged pharmaceuticals, when aggregated in a larger container, are unlikely to spill or be

released into the environment since they are essentially double-packed when transported to a reverse distributor. Potentially creditable hazardous waste pharmaceuticals that are in liquid and aerosol forms may pose more of a risk during accumulation and transport due to possible spillage or leakage, but the small quantities in which they are generated, along with the DOT packaging requirements of 49 CFR parts 173, 178, and 180, would likely mitigate this risk (see EPA's recommendation regarding liquids and aerosols in section XI.C.1). Further, the 2008 Pharmaceutical Universal Waste proposal specifically sought comment regarding the risks of transportation of hazardous waste pharmaceuticals and no commenters identified environmental risks.

Due to the low risk to human health and release to the environment, EPA proposed to allow potentially creditable hazardous waste pharmaceuticals to be shipped without a hazardous waste manifest and without the use of hazardous waste transporters when the healthcare facility is sending potentially creditable hazardous waste pharmaceuticals to a reverse distributor or when a reverse distributor is sending potentially creditable hazardous waste pharmaceuticals to another reverse distributor. The same DOT shipping requirements would continue to apply to shipments of potentially creditable hazardous waste pharmaceuticals (provided they are classified as DOT hazardous materials) that applied prior to this final rule. Nothing in this final rule changes how DOT shipping requirements apply to shipments of prescription pharmaceuticals to reverse distributors.

EPA proposed an alternate tracking method for potentially creditable hazardous waste pharmaceuticals—with two requirements in lieu of requiring a hazardous waste manifest and the use of hazardous waste transporters. First, EPA proposed that for each shipment, healthcare facilities and reverse distributors must provide in writing (via letter or electronic

communication), advance notice of the intent to send a shipment to the receiving reverse distributor. We also proposed that the receiving reverse distributor must provide acknowledgement to the shipper that they received the advance notice. This requirement was intended to function like a manifest, tracking the potentially creditable hazardous waste pharmaceuticals en route to the reverse distributor. Second, EPA proposed that for each shipment, the receiving reverse distributor must provide confirmation to the healthcare facility or reverse distributor that initiated the shipment, that the shipment of potentially creditable hazardous waste pharmaceuticals has been received. The Agency proposed this requirement in direct response to concerns expressed by commenters over the lack of tracking of pharmaceutical waste in the 2008 Pharmaceutical Universal Waste proposal.

The Agency proposed that, if a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within seven calendar days, that the healthcare facility or reverse distributor that initiated the shipment must contact the shipper and the intended recipient promptly to (1) report that the confirmation was not received, and (2) to determine the status and whereabouts of the potentially creditable hazardous waste pharmaceuticals that were shipped.

The Agency proposed that if a healthcare facility or reverse distributor exports potentially creditable hazardous waste pharmaceuticals, it must generally comply with 40 CFR part 262 subpart E, except that it is not required to manifest the potentially creditable hazardous waste pharmaceuticals. The Agency also proposed that any person that imports potentially creditable hazardous waste pharmaceuticals, must comply with the proposed requirements for the shipment

of potentially creditable hazardous waste pharmaceuticals, in lieu of the requirements for hazardous waste imports found at 40 CFR part 262 subpart F.[355]

EPA proposed to require healthcare facilities (§ 266.503(d)) and reverse distributors (§ 266.510(b)(4)) to keep records of the shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Specifically, we proposed that healthcare facilities and reverse distributors that initiate a shipment to a reverse distributor must keep (1) records of advance notification regarding shipments of potentially creditable hazardous waste pharmaceuticals, (2) delivery confirmation for three years after the shipment was initiated, and (3) shipping papers or bills of lading. The Agency argued that these records are necessary to ensure that potentially creditable hazardous waste pharmaceuticals reach their intended destination and are not diverted.

In most cases, retaining records for three years should be sufficient for inspection purposes; however, we proposed that the periods of retention would be automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator. The Agency sought comment on whether additional recordkeeping is necessary to document the cases when the reverse distributor does not receive a shipment of potentially creditable pharmaceuticals within seven calendar days and the steps must be taken to locate the shipment.

2. Summary of Comments

The majority of comments focused on the provision to allow shipments of potentially creditable hazardous waste pharmaceuticals to be sent via carrier (i.e., not by hazardous waste transporter), the requirements for advance notice of shipment and delivery confirmation, and the

[355] Part 262 subparts E and F have since been replaced by part 262 subpart H; see the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

time frame within which delivery confirmation is received before the shipper must take action to locate a missing shipment.

Comments on whether the Agency should allow shipments of potentially creditable hazardous waste pharmaceuticals to be sent via carriers such as USPS, UPS, and FedEx without a manifest were mixed. Only a few states commented on this provision specifically. The majority of states agreed that shipping via carriers provides sufficiently low risk of release or illicit diversion. However, one state was concerned that we did not propose a requirement to reconcile the contents of what was shipped with what was received. That same commenter, as well as a handful of others, also voiced concern about whether DOT regulations would permit hazardous waste pharmaceuticals to be lawfully shipped via carrier in the first place. Manufacturers, waste management companies, healthcare industry groups, and pharmacy trade associations were all generally in agreement with the proposed shipping standards for potentially creditable hazardous waste pharmaceuticals.

One of the primary points of contention in this subsection was the proposed standard that would require a shipper to provide advance notice of its intent to ship potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Reverse distributors objected, arguing it would impart undue financial and administrative burden, which would require them to hire additional staff to adequately process advance notices, track, and confirm the delivery of thousands of shipments per year. A national trade association of retailers expressed similar concerns. They did not support the proposed advance notice and delivery confirmation requirements and argued the requirements would add undue burden due to the high volume of shipments large retailers send per year. The commenters suggested that the proposed notification and delivery standards either be removed or modified to match current inventory and accounting

practices.[356] One pharmaceutical manufacturer also disagreed with the proposed standard, but gave no reasoning as to why, other than they thought it was unnecessary. States generally agreed with the proposed standard and a few suggested the Agency finalize additional requirements like reconciling what was in the notice with the contents of the package after delivery which would also require an inventory of each container. One state was concerned about its ability to confirm that a shipment has reached its final destination (TSDF) in scenarios where a shipment is sent to an out-of-state reverse distributor or a second reverse distributor. Healthcare facilities and pharmacist trade groups either agreed with the proposed standards or did not mention these standards specifically. One pharmacist trade group said they want some clarification about what constitutes advance notice.[357]

There were numerous comments both in agreement with and opposition to the proposed requirement to take action to locate a shipment of potentially creditable hazardous waste pharmaceuticals if no delivery confirmation is received within seven days from the day the shipment leaves the shipper's facility. Most comments were related to the time frame within which the shipper must receive delivery confirmation, but a few commenters from the retail and reverse distribution industries opposed the requirement altogether because of the added financial, procedural, and administrative burden they argue it would impose. Many commenters were concerned that the proposed time frame was too short and would result in frequent situations in which the shipper would be required to undertake efforts to locate a shipment that eventually arrives without intervention sometime after the seven days. Some commenters noted that seven days is the minimum transit time for a standard cross-country shipment under ideal conditions, which provides no buffer for unforeseen circumstances that may cause delays such as inclement

[356] See comment number EPA-HQ-RCRA-2007-0932-0295.
[357] See comment number EPA-HQ-RCRA-2007-0932-0284.

weather or some other service disruption. One state suggested a 35-day time frame as an alternative because it would be the same as the time frame specified for delivery confirmation of universal waste shipped via carrier per the universal waste rule.[358]

There were limited comments regarding the proposed standards for healthcare facilities and reverse distributors importing and/or exporting potentially creditable hazardous waste pharmaceuticals. The only concern raised was whether shipments sent to or received from U.S. territories (e.g., Puerto Rico, Guam) are considered exports/imports, and if so, they recommended that the Agency confer with other appropriate federal agencies and their reverse distributor contractors.

3. Final Rule Provisions

In response to comments, the Agency has made several changes to the proposed standards for shipping potentially creditable hazardous waste pharmaceuticals. First, we have made a minor change to make our regulatory language more consistent with DOT's terminology and clarify to whom the regulations refer. Specifically, in § 266.509(c), we changed the word shipper to carrier. As originally proposed, the word shipper could have been interpreted to refer to the party that prepares and offers a shipment of potentially creditable hazardous waste pharmaceuticals, whereas the regulations apply to the company providing transportation of a shipment of potentially creditable hazardous waste pharmaceuticals. To clarify, a shipper is the party that prepares and offers a shipment to be transported by a carrier.

Second, we have eliminated the requirement in § 266.509(a)(1) for a healthcare facility or reverse distributor that ships potentially creditable hazardous waste pharmaceuticals to provide advance notice of the shipment. The Agency believes that the proposed advance notice

[358] See comment number EPA-HQ-RCRA-2007-0932-0238.

requirement goes beyond the manifest requirements and would have resulted in undue burden on both the shippers and the receiving reverse distributors while only nominally more protective of human health and the environment. We would, however, recommend that, as a best practice, shippers of potentially creditable hazardous waste pharmaceuticals provide advance notice to the recipients to the extent practicable. Conforming changes have been made throughout the regulations that reflect the elimination of the requirement to provide advance notice of shipments of potentially creditable hazardous waste pharmaceuticals.

Third, the proposed requirement that a reverse distributor that receives a shipment of potentially creditable hazardous waste pharmaceuticals must provide delivery confirmation to the facility that initiated the shipment is being finalized as proposed, with the added clarification that the shipment is not considered delivered until it is under the custody and control of the receiving reverse distributor. Requiring delivery confirmation provides assurance that the shipment was actively received by the reverse distributor and the chain of custody maintained. Without this confirmation from the receiving reverse distributor personnel, it is possible for a shipment to be delivered to the destination location but not necessarily taken into their custody and control (e.g., left unattended outside the building).

Under this final rule, healthcare facilities and reverse distributors may use carriers, such as USPS, UPS, and FedEx for shipments of potentially creditable hazardous waste pharmaceuticals to and between reverse distributors, as long as personnel are present to receive and take control of the shipments upon arrival. EPA believes that carriers are able to provide safe shipment since these potentially creditable hazardous waste pharmaceuticals present low risk of release during transport.

In addition, all of the carriers EPA is aware of offer services that meet the delivery confirmation requirement. Delivery confirmation can be paper-based or electronic and must indicate that personnel from the receiving reverse distributor have taken the shipment into their custody and control. One way for healthcare facilities and reverse distributors sending shipments of potentially creditable hazardous waste pharmaceuticals to a reverse distributor via carrier may comply with the delivery confirmation requirement would be to utilize the delivery confirmation service provided by most carriers (e.g. Return Receipt from USPS, Delivery Confirmation from UPS, or Signature Proof of Delivery from FedEx). Typically, personnel at the receiving reverse distributor will sign for a shipment confirming that it is now in their custody and control. That signature will then be made available to the shipper, which satisfies the delivery confirmation requirement.

EPA has learned that some stakeholders use alternative electronic tracking methods outside of those offered by carriers. One alternative electronic tracking method is to apply barcoding on pharmaceutical packaging or on containers containing multiple pharmaceutical packages. A barcode is a unique identifier that links the container to a database with detailed information about its contents and includes the exact quantities of each item included in the shipment (inventories). Typically, when a reverse distributor receives a barcoded shipment, it will scan the barcodes upon receipt, and the sender will receive electronic notification that the shipment has arrived at its destination and is in the custody and control of the reverse distributor. This type of barcode tracking would meet the delivery confirmation requirement of this final rule. Another type of alternative electronic tracking that would satisfy the delivery confirmation requirement is radio frequency identification (RFID). Similar to barcodes, RFID tags are placed inside a container, or integrated into the container itself, and linked to inventories and other

detailed information. The RFID tags are read when they arrive at the receiving facility and that information is made available to the shipper, confirming that the shipment has been taken into the custody and control of the receiving reverse distributor.[359]

Fourth, we have eliminated the regulatory language that was proposed in § 266.509(a)(2). We had referenced the DOT pre-transport regulations that apply to shipments of non-creditable hazardous waste pharmaceuticals. However, in 2016, DOT revised the Hazardous Materials Regulations (HMR) as they apply to shipments of items in reverse logistics.[360] As a result, many of the DOT pre-transport requirements we had referenced no longer apply to shipments of hazardous materials in reverse logistics. In response, we have eliminated the reference to the DOT pre-transport requirements and instead modified our final regulations in § 266.509(a) to refer to the entire HMR, rather than specific provisions within the HMR. Healthcare facilities and reverse distributors that send shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors need only comply with the applicable sections of DOT's HMR for shipments in reverse logistics.

We note that healthcare facilities and reverse distributors must meet the applicable DOT hazardous material shipping requirements only when shipping potentially creditable hazardous waste pharmaceuticals that meet the definition of DOT hazardous material. Under the DOT regulations, a RCRA hazardous waste that requires a manifest is considered a Class 9 hazardous material. Potentially creditable hazardous waste pharmaceuticals do not require a manifest; therefore, the DOT shipping requirements will apply when potentially creditable hazardous waste pharmaceuticals are shipped to reverse distributors only when the hazardous wastes are

[359] See comment number EPA-HQ-RCRA-2007-0932-0268
[360] March 31, 2016; 62 FR 18527.

otherwise classified as DOT hazardous materials (i.e., DOT hazard class 1-8). We added regulatory language (that was adapted from the Universal Waste regulations) to reflect this.

Fifth, the Agency has finalized the requirement that the shipper of potentially creditable hazardous waste pharmaceuticals must receive a delivery confirmation from the reverse distributor, however, the Agency has extended the time frame within which the shipper must receive the delivery confirmation from the reverse distributor from the proposed seven days to 35 days, after which the shipper must begin taking actions to locate a shipment if the delivery confirmation is not received. Many commenters suggested 14 days as an alternative to the proposed seven-day time frame, while others suggested far longer or to eliminate the time frame altogether. Upon reconsideration of the issue and how it pertains more generally to other RCRA hazardous waste programs, the Agency decided that 35 days was more appropriate, while remaining duly protective of human health and the environment and reducing burden on the regulated community. The time frame to receive delivery confirmation for shipments of potentially creditable hazardous waste pharmaceuticals is also now in line with the standard for delivery confirmation under universal waste, which is also 35 days. In addition, one of the overarching goals of this rule was to enact universal waste-like standards for hazardous waste pharmaceuticals, to which this provision conforms. Some states wanted the Agency to go further and require that the EPA Regional Administrator be notified whenever a shipment has not been received within the allotted time frame. Although the Agency understands the utility of such a provision, it is not being adopted because of the added burden it would impose on both states and the regulated community. In addition, the Agency prefers, in this instance, to allow states the flexibility to implement more stringent reporting standards for missing shipments of potentially

creditable hazardous waste pharmaceuticals according to their individual circumstances and preferences.

After considering these comments, the Agency determined that it is necessary to require a delivery confirmation in order to ensure shipments of potentially creditable hazardous waste pharmaceuticals have been received and taken into the custody and control of the destination facility as a way to approximate the manifest system without requiring the use of hazardous waste transporters or manifests. In response to comments, we have reconsidered the proposed seven-day time frame for the shipper to receive delivery confirmation; the Agency decided that 35 days is more appropriate. It strikes a balance between being duly protective of human health and the environment, reducing burden, and is now in line with universal waste standards.

Sixth, we have made several changes to the pre-transport requirements that we proposed in § 266.509(a)(1) and (2). Because of the removal of the requirement for advance notice of shipments of potentially creditable hazardous waste pharmaceuticals, we renumbered the section such that it all appears in § 266.509(a) now. What was proposed in § 266.509(a)(2) and is now in § 266.509(a), has been modified to reflect the removal of § 266.508(a)(1)(v) which previously contained a requirement that DOT shipping papers be generated. The Agency believes that the shipping papers requirement—although duplicative for shipments of non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor—is appropriate for shipments of potentially creditable hazardous waste pharmaceuticals given that they are not manifested. Therefore, the requirement for DOT shipping papers has been added to § 266.509(a). Language was also added to clarify that shipments of potentially creditable hazardous waste pharmaceuticals from a healthcare facility or reverse distributor to a reverse distributor do not require a manifest. This language was taken

from the universal waste standards in § 273.52(a) which is consistent with the goal of developing universal waste-like shipping standards for potentially creditable hazardous waste pharmaceuticals.

As with the export of non-creditable hazardous waste pharmaceuticals, the proposed standards for healthcare facilities or reverse distributors that export potentially creditable hazardous waste pharmaceuticals to a foreign destination have also been modified to reflect the changes made to the import/export rules of part 262. Specifically, the Agency is finalizing requirements that exporters of potentially creditable hazardous waste pharmaceuticals must comply will all applicable sections of 40 CFR part 262 subpart H, except for the manifest requirements of § 262.83(c), in addition to the requirements for shipping potentially creditable hazardous waste pharmaceuticals in § 266.509(a) through (c).

Subsequent to when this rule was proposed in September 2015, the Hazardous Waste Import-Export Revisions rule was finalized in 2016.[361] As a result, the Agency has had to make conforming changes to this final rule to reflect the changes made by the Import-Export Revisions final rule. Because the regulations for importing and exporting hazardous waste were previously located in separate subparts – exports in subpart E and imports in subpart F – the proposed requirements in this rule were also separated into discreet subsections and referred to their respective subparts (exporting and importing) of 40 CFR part 262. A significant change enacted by the Import-Export Revisions Rule was to consolidate into subpart H the multiple related subparts in 40 CFR 262 regarding import, export, and transboundary movements of hazardous waste that had been in subparts E and F.

[361] See the Hazardous Waste Export-Import Revisions final rule, 81 FR 85696; December 31, 2016.

The essence of the proposed regulations has not changed in the finalized requirements. That is, a healthcare facility or reverse distributor exporting potentially creditable hazardous waste pharmaceuticals is still subject to the same or similar provisions as were proposed, only now they must comply with 40 CFR part 262 subpart H instead, except for the manifesting requirements, and paragraphs (a) through (c) of § 266.509.

For healthcare facilities and reverse distributors that import potentially creditable hazardous waste pharmaceuticals, the requirements are being finalized as proposed, except that due to the conforming changes necessitated by the Hazardous Waste Export-Import Revisions Final Rule, they must now comply with the shipping standards for potentially creditable hazardous waste pharmaceuticals in lieu of 40 CFR part 262 subpart H (instead of part 262 subpart F). One other clarification was added to the regulatory language specifying that potentially creditable hazardous waste pharmaceuticals are subject to all applicable provisions in this subpart immediately after entering the United States.

4. Comments and Responses

The commenter that requested an official definition of advance notice also requested an official definition for delivery confirmation.[362] The Agency is purposely leaving this standard sufficiently broad as to allow the implementing agencies discretion to determine the best implementation strategies on a case-by-case basis.

EPA notes that a reverse distributor is not required to segregate the potentially creditable hazardous waste pharmaceuticals from the potentially creditable non-hazardous waste pharmaceuticals when they are destined for another reverse distributor. However, if the potentially creditable pharmaceuticals are not segregated, the reverse distributor must follow the

[362] See comment number EPA-HQ-RCRA-2007-0932-0284.

tracking procedures for the entire shipment. On the other hand, if a reverse distributor chooses to segregate the potentially creditable hazardous waste pharmaceuticals from the non-hazardous waste pharmaceuticals prior to shipping to another reverse distributor, only the potentially creditable hazardous waste pharmaceutical portion would have to be shipped according to these standards.

XVII. Standards for Reverse Distributors (§ 266.510)

A. Background on Reverse Distributor Operations

Reverse distributors act as intermediaries between healthcare facilities and pharmaceutical manufacturers. They receive shipments of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and, on behalf of manufacturers, facilitate the process of crediting healthcare facilities for these pharmaceuticals. From stakeholder input, EPA site visits, and comments on the proposed rulemaking, EPA's understanding is that when a reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its computer system. Based on manufacturers' "business rules" (i.e., manufacturers' return policies), the reverse distributors determine which potentially creditable hazardous waste pharmaceuticals can receive manufacturer credit, as well as which must be sent on to another reverse distributor for completion of the crediting process. "Business rules" (i.e. manufacturers' return policies) refers to the rules that govern the disposition of retail items agreed to by the manufacturer, retailer, and reverse distributor or reverse logistics center.[363]

[363] This definition is derived from the definition of "business rules" in the "Surplus Household Consumer Products and Wastes: Report to the Legislature." Available at: http://www.dtsc.ca.gov/HazardousWaste/Retail_Industry/upload/SB423_Final-Rpt.pdf.

In many cases, there is more than one reverse distributor involved in establishing and verifying manufacturer credit for a particular potentially creditable hazardous waste pharmaceutical. For instance, reverse distributors may have contracts with specific pharmaceutical manufacturers such that only a specific reverse distributor may facilitate credit for a particular manufacturer's pharmaceuticals. If the receiving reverse distributor has a contract with the healthcare facility, but not with the pharmaceutical manufacturer, then the receiving reverse distributor sends the returned pharmaceutical on to the reverse distributor that has a contract with the pharmaceutical manufacturer in order to facilitate the manufacturer credit process.

Because manufacturers' business rules change over time, sometimes a reverse distributor receives a potentially creditable hazardous waste pharmaceutical that is not eligible for credit immediately, and the reverse distributor retains the potentially creditable hazardous waste pharmaceutical on site until it is credit eligible (often called "aging" a pharmaceutical). For example, manufacturers only issue credit for expired pharmaceuticals. As a result, sometimes a reverse distributor receives an unexpired hazardous waste pharmaceutical that is otherwise creditable but awaiting its expiration date. The reverse distributor then retains the potentially creditable hazardous waste pharmaceutical on site until after it has expired and thus becomes eligible for manufacturer credit. In some cases, even after the reverse distributor has awarded manufacturer credit, a pharmaceutical manufacturer may request that the hazardous waste pharmaceuticals be transported back to the manufacturer to verify the amount of pharmaceuticals and manufacturer credit.

On the other hand, if the potentially creditable hazardous waste pharmaceuticals are not sent on to another reverse distributor and the reverse distributor awards the manufacturer credit

to the healthcare facility itself, it then manages the hazardous waste pharmaceuticals on site until they are sent off site for treatment and disposal. As discussed previously, after a potentially creditable hazardous waste pharmaceutical has been evaluated and no additional reverse distributors will be involved in the manufacturer's crediting process, EPA uses the term ''evaluated hazardous waste pharmaceutical.'' This is to distinguish between the potentially creditable hazardous waste pharmaceuticals awaiting determination within the reverse distribution system versus the evaluated hazardous waste pharmaceuticals that will not be sent to another reverse distributor for evaluation. Both are considered hazardous waste pharmaceuticals, but they are managed differently under this subpart.

EPA is not aware of any reverse distributor that facilitates manufacturer credit that also has interim status or a permit to treat or dispose of hazardous waste on-site.[364] Therefore, EPA anticipates that reverse distributors eventually send all evaluated hazardous waste pharmaceuticals off site for treatment and disposal.

B. EPA's Rationale for Finalizing New RCRA Management Standards for Reverse Distributors

This final rule establishes standards for the management of both potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that reverse distributors receive and manage. The management standards discussed in this section apply only to reverse distributors of prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. The management standards discussed in this section do not apply to the reverse logistics systems that may exist for other retail items. In response to comments, EPA is codifying our existing interpretation that nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the

[364] Several DEA reverse distributors have RCRA interim status or a permit to treat or dispose of hazardous waste, but these DEA reverse distributors do not facilitate manufacturer credit.

retail store if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed (see the definition of hazardous waste pharmaceutical under section VIII and section IX, the applicability section). Additionally, EPA is establishing a policy that other retail items that are sent through reverse logistics are not solid waste at the retail store if they have a reasonable expectation of being legitimately used/reused or reclaimed (see section VI). Therefore, reverse logistics centers that receive and manage nonprescription pharmaceuticals will not be regulated under this subpart and will not be subject to the standards for reverse distributors.

The current federal RCRA hazardous waste generation regulations at 40 CFR part 262 provide that only designated facilities, such as RCRA-permitted and interim status TSDFs, may receive hazardous waste from off site for treatment, storage, or disposal. However, the Agency does not believe it is necessary for reverse distributors to obtain permits or have interim status to store hazardous waste pharmaceuticals in order to protect human health and the environment. Thus, EPA is finalizing a new category of hazardous waste management facilities under RCRA called a ''reverse distributor,'' which is defined as any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. The definition specifies that any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription hazardous waste pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor. EPA is finalizing that reverse distributors are not required to have interim status or a RCRA permit to accumulate hazardous waste pharmaceuticals and they may only accept potentially creditable hazardous waste pharmaceuticals from off site provided they comply with the standards in this final rule.

Reverse distributors may not treat or dispose of hazardous waste on-site unless authorized to do so as a RCRA-permitted or interim status TSDF.

As discussed earlier in this document, EPA's previous interpretation allows reverse distributors to be generators of hazardous waste pharmaceuticals after a decision is made about whether the pharmaceuticals will be repurposed. As a hazardous waste generator, a reverse distributor had to comply with the LQG, SQG, or VSQG generator regulations, depending on the total volume of hazardous waste generated in a calendar month. Some smaller reverse distributors might have stayed under the hazardous waste quantity limits for VSQGs, which would mean that under the federal RCRA regulations, these VSQG reverse distributors would not have had to notify EPA as a generator and their hazardous waste pharmaceuticals could be disposed of with municipal and non-municipal solid waste (see § 262.14). However, the Agency has concerns with VSQG reverse distributors not notifying EPA that they are managing hazardous waste. EPA is even more concerned about reverse distributors that currently qualify as VSQGs placing the hazardous waste pharmaceuticals into the municipal and non-municipal solid waste stream and sending them to non-hazardous waste landfills. Some studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems.[365,366] Landfill leachate is generally transported to a wastewater treatment plant to be treated before discharge; however, some pharmaceutical compounds pass through treatment and are discharged, becoming a potential contributor of the pharmaceutical compounds detected in our nation's waters.

[365] Barnes, K. K., Christenson, S. C., Kolpin, D. W., Focazio, M. J., Furlong, E. T., Zaugg, S. D., Meyer, M. T. and Barber, L. B. (2004), Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill. Groundwater Monitoring & Remediation, 24: 119– 126.
[366] Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (2009), Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002. Bulletin of Environmental Contamination and Toxicology, 82.6:635–659.

In this final rule, EPA is revising its position regarding prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals, such that they will be considered discarded at the healthcare facilities, not at the reverse distributors. This revision is based on new information demonstrating to EPA that prescription pharmaceuticals returned to a reverse distributor are rarely, if ever, recycled or reused, and therefore the decision to send a potentially creditable hazardous waste pharmaceutical to a reverse distributor is a decision to discard the pharmaceutical (as discussed previously in section VI). Comments on the December 2008 Pharmaceutical Universal Waste proposal indicated that notification to EPA by reverse distributors and tracking of shipments of potentially creditable hazardous waste pharmaceuticals are critical and must be included in any regulatory scheme to ensure the safe management of potentially creditable hazardous waste pharmaceuticals.

Although EPA maintains its position as stated in the proposed rulemaking preamble that hazardous waste pharmaceuticals going to reverse distributors are solid wastes at the healthcare facility, there are important differences between reverse distributors and traditional TSDFs. Only between 2–6 percent of the potentially creditable pharmaceuticals that are received by reverse distributors are listed or characteristic hazardous wastes.[367] Therefore, the vast majority of the potentially creditable pharmaceutical waste that a reverse distributor receives is not considered a characteristic or listed hazardous waste pharmaceutical under the existing definition of hazardous waste. This stands in contrast to a typical TSDF, whose primary function is to manage hazardous waste. As a result, a reverse distributor generally manages a smaller volume of hazardous waste than a typical permitted TSDF.

[367] See EPA's request of information from reverse distributors, as well as their responses to EPA in the docket for this rulemaking: EPA–HQ–RCRA–2007–0932-0157, EPA–HQ–RCRA–2007–0932-0158, EPA–HQ–RCRA–2007–0932-0159, EPA–HQ–RCRA–2007–0932-0160, EPA–HQ–RCRA–2007–0932-0161, EPA–HQ–RCRA–2007–0932-0162, EPA–HQ–RCRA–2007–0932-0163, EPA–HQ–RCRA–2007–0932-0164.

In addition, because the pharmaceuticals in the reverse distribution system are receiving manufacturer credit, they are moved through the system efficiently. In fact, one national pharmacy retail chain informed EPA that the value of the credit they receive from manufacturers for returned pharmaceuticals is approximately $1 billion a year.[368] Healthcare facilities and reverse distributors have a vested interest in having potentially creditable hazardous waste pharmaceuticals processed and credited quickly and managed appropriately so money is not lost in the process.

Furthermore, potentially creditable hazardous waste pharmaceuticals generally present a low risk of release to the environment as they typically are still in the manufacturer's packaging, which in some cases includes inner and outer packaging (e.g., plastic bottle inside a box). Since there is a relatively low human health and environmental risk of release associated with the low volumes of potentially creditable hazardous waste pharmaceuticals shipped to reverse distributors for crediting purposes, and because EPA is not aware of any incidents of mismanagement resulting in environmental harm or releases of hazardous waste pharmaceuticals by reverse distributors, EPA believes that it is not necessary to require reverse distributors to obtain RCRA hazardous waste storage permits with respect to typical reverse distribution operations, such as receiving, sorting, consolidating, and reshipping potentially creditable hazardous waste pharmaceuticals.

Thus, EPA is taking a tailored approach to regulating reverse distributors by regarding them as a new type of RCRA hazardous waste entity — a reverse distributor. This approach balances EPA's revised interpretation that the point of generation for prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals is at the

[368] Meeting with representatives from CVS (August 11, 2012); see the docket for meeting notes (EPA–HQ–RCRA–2007–0932-0188).

healthcare facility, not the reverse distributor, with the fact that potentially creditable hazardous waste pharmaceuticals have value which provides an incentive for proper management.

EPA is establishing new management standards for reverse distributors in 40 CFR part 266 subpart P. These entities will not be subject to 40 CFR parts 262, 264, 265, or 270. Generally, EPA is finalizing that reverse distributors comply with standards that are similar to the current federal LQG standards, in combination with certain requirements that permitted or interim status hazardous waste TSDFs must meet. We are establishing one set of requirements for all reverse distributors, regardless of the amount of potentially creditable hazardous waste pharmaceuticals they receive. EPA believes this uniform set of standards will make it easier for reverse distributors to comply with the new subpart, in part because the burden of having to count hazardous waste pharmaceuticals on a monthly basis, especially the 1 kg of acute hazardous waste pharmaceuticals, will be removed.

EPA is finalizing that a reverse distributor will not be required to have a hazardous waste permit or interim status for on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals provided it follows the final reverse distributor standards. As mentioned previously, the on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals generally presents low risk of release to the environment because they are typically in the manufacturer's packaging. However, for activities such as treatment or disposal of hazardous waste pharmaceuticals or other hazardous waste, a reverse distributor must either obtain a RCRA permit or have interim status, as these activities pose a higher risk of release. EPA has determined that requirements similar to LQG standards for on-site accumulation of hazardous waste that are found in § 262.17 are appropriate. As discussed previously, the value of the potentially creditable pharmaceuticals creates an incentive for proper management and the

risk of release is low. Furthermore, many reverse distributors are already LQGs and, therefore, this final rule should not represent a large shift in current practices or increased burden.[369] However, once credit is provided, the value of the pharmaceuticals is eliminated and therefore the evaluated hazardous waste pharmaceuticals have a greater potential for mismanagement. As a result, EPA is finalizing additional standards for the management of evaluated hazardous waste pharmaceuticals at reverse distributors.

EPA received numerous comments that expressed concern that the standards for reverse distributors would be burdensome for reverse logistics centers that handle nonprescription pharmaceuticals. For example, one commenter expressed concern that the reverse distributor inventory requirements for both potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals would be burdensome for facilities that receive and manage nonprescription pharmaceuticals because these reverse logistics centers do not currently maintain an inventory for these retail items.[370] EPA is codifying our existing interpretation that nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed (see section VI for more discussion). Therefore, reverse logistics centers will not be regulated under part 266 subpart P and will not be subject to the standards for reverse distributors. As a result, comments received on the impact of the reverse distributor standards on reverse logistics centers that receive and manage nonprescription pharmaceuticals are outside the scope of the final rule and are not discussed in this section. EPA also received numerous general comments expressing concern that finalizing new RCRA management standards for reverse distributors would be burdensome. However,

[369] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).
[370] See comment number EPA–HQ–RCRA–2007–0932-0377 in the docket for this rulemaking.

some specific provisions included in the proposed reverse distributor standards received few comments.

C. Detailed Discussion of Final Reverse Distributor Standards

The final standards for reverse distributors are organized into three sections. The first section applies to the reverse distributor for the management of all potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals (§ 266.510(a)). The second section includes additional standards that would apply to the management of the potentially creditable hazardous waste pharmaceuticals that will be sent to another reverse distributor for further evaluation or verification of credit and therefore continue to be regulated as potentially creditable hazardous waste pharmaceuticals (§ 266.510(b)). The third section includes additional standards that apply to the management of the evaluated hazardous waste pharmaceuticals that will not be sent to another reverse distributor, but instead will be sent to a permitted or interim status TSDF (§ 266.510(c)).

1. Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals (§ 266.510(a))

This portion of the preamble discusses the standards that apply to reverse distributors for the management of all hazardous waste pharmaceuticals on site, including potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. Unlike the following two sections, the standards discussed in this section apply to all prescription hazardous waste pharmaceuticals at a reverse distributor, regardless of the subsequent destination of the hazardous waste pharmaceuticals. We note that a reverse distributor must follow these standards for the management of hazardous waste pharmaceuticals even if it generates other, non-pharmaceutical hazardous waste that is managed under 40 CFR part 262. Note that we have

reorganized § 266.510(a) since the proposal to more accurately reflect the flow of hazardous waste pharmaceuticals at a reverse distributor. The subsequent preamble section follows the organization of the final regulations.

a. *Notification.*

Summary of Proposal EPA proposed that a reverse distributor must notify EPA of its hazardous waste pharmaceutical activities using the Site ID Form (EPA Form 8700–12). Under the RCRA Subtitle C program, SQGs, LQGs, and TSDFs must submit a Site ID Form to EPA. EPA proposed that a reverse distributor that does not have an EPA ID number will be required to submit the Site ID Form to obtain one and that a reverse distributor that already has an EPA ID number will need to notify EPA as a reverse distributor.

Summary of Comments EPA received two comments in support of the proposed notification requirements. One state supported all of the proposed notification requirements.[371] Inmar, Inc. supported the requirement that reverse distributors must notify EPA using EPA Form 8700-12.[372]

Final Rule Provisions EPA is finalizing in § 266.510(a)(1) that a reverse distributor must notify EPA of its hazardous waste pharmaceutical activities using the Site ID Form (EPA Form 8700–12). The Agency will revise the Site ID Form to include a box to allow notifications by reverse distributors. EPA believes it is appropriate, and in line with comments received on the proposal, to require reverse distributors to notify EPA. Under the final rule, a reverse distributor that does not have an EPA ID number will be required to submit the Site ID Form to obtain one. A reverse distributor that already has an EPA ID number will need to notify EPA as a reverse distributor. The time frame in both cases is within 60 days of the effective date of this subpart or within 60 days of becoming subject to this subpart. Some reverse distributors may also be generators of

[371] See comment number EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.
[372] See comment number EPA–HQ–RCRA–2007–0932-0377 in the docket for this rulemaking.

other types of hazardous waste (e.g., from cleaning and maintenance operations). Therefore, it is possible that a reverse distributor may notify on the same notification form as both a generator of hazardous waste and as a reverse distributor.

b. *Inventory*.

Summary of Proposal EPA proposed that reverse distributors must keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on site. EPA proposed that the inventory must include the identity (e.g., name or National Drug Code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical. EPA also proposed that a reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the reverse distributor.

Summary of Comments EPA received comments from states and industry in support of the proposed inventory requirement.[373] One state suggested that EPA also require reverse distributors to include the name of the healthcare facility that shipped the potentially creditable hazardous waste pharmaceuticals to the reverse distributor.[374]

Retail Industry Leaders Association argued that the inventory requirements for reverse distributors should be reduced.[375] Inmar, Inc. did not support the inventory requirements and argued that they are duplicative because reverse distributors must already inventory and track prescription pharmaceuticals.[376] Inmar, Inc. wrote that at least four states currently require the

[373] See comment numbers EPA–HQ–RCRA–2007–0932-0235, EPA–HQ–RCRA–2007–0932-0257, EPA–HQ–RCRA–2007–0932-0280, EPA–HQ–RCRA–2007–0932-0296, EPA–HQ–RCRA–2007–0932-0300, and EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.
[374] See comment number EPA–HQ–RCRA–2007–0932-0235 in the docket for this rulemaking.
[375] See comment number EPA–HQ–RCRA–2007–0932-0295 in the docket for this rulemaking.
[376] See comment number EPA–HQ–RCRA–2007–0932-0377 in the docket for this rulemaking.

maintenance of drug inventories by law.[377] Both Inmar, Inc. and RILA expressed concern that the inventory requirements would be particularly burdensome for their facilities that handle nonprescription pharmaceuticals. Inmar, Inc. pointed out that their reverse logistics centers do not maintain an inventory for nonprescription pharmaceuticals.[378]

EPA received multiple comments from industry that expressed concern that the reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival.[379] One commenter expressed concern that the reverse distributor must complete an inventory upon arrival because packages of potentially creditable hazardous waste pharmaceuticals can remain unopened for up to 5 business days.[380] Healthcare Distribution Management Association[381] pointed out that reverse distributors sometimes receive tens of thousands of products in a day and do individual product accounting when the credit determination is made.[382]

Commenters on the proposed rulemaking also pointed out that reverse distributors are already required to inventory and track prescription pharmaceuticals under licensing and accreditation programs overseen by the National Association of Boards of Pharmacy.[383]

Final Rule Provisions EPA is finalizing in § 266.510(a)(2) that reverse distributors must keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on site. In response to comments, we have made several changes to what was proposed but have determined that an inventory is a key requirement to protect

[377] See the EPA correspondence with Inmar dated March 29, 2017 in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.
[378] See comment number EPA–HQ–RCRA–2007–0932-0377 in the docket for this rulemaking.
[379] See comment numbers EPA–HQ–RCRA–2007–0932-0295, EPA–HQ–RCRA–2007–0932-0276, EPA–HQ–RCRA–2007–0932-0352, and EPA–HQ–RCRA–2007–0932-0340 in the docket for this rulemaking.
[380] See comment number EPA–HQ–RCRA–2007–0932-0278 in the docket for this rulemaking.
[381] Now renamed Heathcare Distribution Alliance.
[382] See comment number EPA–HQ–RCRA–2007–0932-0276 in the docket for this rulemaking.
[383] See comment number EPA–HQ–RCRA–2007–0932-0377 in the docket for this rulemaking.

public health by helping to prevent the diversion of hazardous waste pharmaceuticals. An inventory will allow the reverse distributor to know which hazardous waste pharmaceuticals they have on-site at any time. Based on stakeholder input and site visits, the Agency believes that in many cases, reverse distributors already maintain inventories of pharmaceuticals and this requirement is not expected to be burdensome for the reverse distributors to implement. According to responses from reverse distributors to a 2011 request for information, four out of eight of them indicated that they already keep inventories as best management practices or because it is required by the Board of Pharmacy in their state.[384] The inventory must include the identity (e.g., name or National Drug Code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceuticals. In response to commenter concern that the inventory requirement would be duplicative, EPA clarified in the regulatory language of the final rule that if the reverse distributor already meets the inventory requirements because of other regulatory requirements, such as State Board of Pharmacy regulations, the facility is not required to provide a separate inventory.

EPA proposed that a reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the reverse distributor. The final rule has been revised to state that reverse distributors must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of arriving at the reverse distributor. EPA made this change in response to commenter concern that the Agency did not provide enough time for reverse distributors to inventory potentially creditable hazardous waste pharmaceuticals. As previously mentioned, comments pointed out that reverse distributors sometimes receive tens of

[384] See EPA's request of information from reverse distributors, as well as their responses to EPA in the docket for this rulemaking: EPA–HQ–RCRA–2007–0932-0157, EPA–HQ–RCRA–2007–0932-0158, EPA–HQ–RCRA–2007–0932-0159, EPA–HQ–RCRA–2007–0932-0160, EPA–HQ–RCRA–2007–0932-0161, EPA–HQ–RCRA–2007–0932-0162, EPA–HQ–RCRA–2007–0932-0163, EPA–HQ–RCRA–2007–0932-0164.

thousands of products in one day and need additional time to inventory each potentially creditable hazardous waste pharmaceutical.[385] EPA is also aware that many reverse distributors inventory the potentially creditable hazardous waste pharmaceutical at the same time that they evaluate the potentially creditable hazardous waste pharmaceutical to determine if it will receive manufacturer credit. When a reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its system and make a credit determination. EPA believes that 30 days is an adequate amount of time for the reverse distributor to sort through shipments of hazardous waste pharmaceuticals and inventory the potentially creditable hazardous waste pharmaceuticals. The Agency has determined that because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, increasing the amount of time reverse distributors have to complete the inventory will not increase risk of release to the environment.

c. *Evaluating potentially creditable hazardous waste pharmaceuticals within 30 days.*

Summary of Proposal The key role the reverse distributor plays in managing the issuing of credit from a manufacturer to a healthcare facility is sorting through shipments of potentially creditable hazardous waste pharmaceuticals and evaluating them to determine which must be transported to another reverse distributor for further evaluation of manufacturer credit and which will be sent off site for treatment and disposal. The reverse distributors often use barcodes to scan items into their systems.

EPA proposed that this evaluation process must be completed within 21 days of arriving at the reverse distributor. Likewise, EPA proposed that if the reverse distributor is a

[385] See comment number EPA–HQ–RCRA–2007–0932-0276 in the docket for this rulemaking.

manufacturer, the manufacturer must finish verifying the appropriate credit within 21 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals. The Agency proposed that the 21 calendar days for evaluating the potentially creditable hazardous pharmaceuticals counts as part of the total 90 calendar days that each reverse distributor is allowed to accumulate hazardous waste pharmaceuticals on site.

Summary of Comments The most frequent comment EPA received on the proposed requirement that reverse distributors complete the evaluation process within 21 days of arriving at the reverse distributor is that the proposed time frame was too short. Waste Management National Services, Inc. requested that EPA allow additional time for reverse distributors to evaluate potentially creditable hazardous waste pharmaceuticals.[386] One state requested that EPA allow reverse distributors to have 30 days to complete the evaluation process.[387] RILA and PharmaLink, Inc. requested that EPA allow reverse distributors to have 60 days to complete the evaluation process.[388] GENCO, Qualanex, LLC, and Healthcare Waste Institute of the National Waste and Recycling Association requested that there be no time limit set for reverse distributors to complete the evaluation process.[389] One state suggested that it is not critical to require the evaluation to take place in a certain number of days if the days count toward the total number of days that hazardous waste pharmaceuticals are allowed to accumulate on site.[390]

EPA also received multiple comments in support of the requirement that reverse distributors complete the evaluation process in a short time frame. One state supported the

[386] See comment number EPA–HQ–RCRA–2007–0932-0257 in the docket for this rulemaking.
[387] See comment number EPA–HQ–RCRA–2007–0932-0313 in the docket for this rulemaking.
[388] See comment numbers EPA–HQ–RCRA–2007–0932-0295 and EPA–HQ–RCRA–2007–0932-0349 in the docket for this rulemaking.
[389] See comment numbers EPA–HQ–RCRA–2007–0932-0336, EPA–HQ–RCRA–2007–0932-0352, and EPA–HQ–RCRA–2007–0932-0296 in the docket for this rulemaking.
[390] See comment number EPA–HQ–RCRA–2007–0932-0235 in the docket for this rulemaking.

requirement that reverse distributors complete the evaluation process in a short time frame.[391] Clean Harbors Environmental Services argued that 21 days is more than adequate for a reverse distributor to evaluate potentially creditable hazardous waste pharmaceuticals.[392]

Final Rule Provisions Under the final rule, EPA is requiring in § 266.510(a)(3) that reverse distributors evaluate potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor. Likewise, EPA is finalizing in § 266.510(a)(4) that if the reverse distributor is a manufacturer, the manufacturer must finish verifying the appropriate credit within 30 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals.

EPA is now aware that reverse distributors sometimes receive tens of thousands of products in one day and that sometimes reverse distributors need more than 21 days to evaluate the potentially creditable hazardous waste pharmaceuticals.[393] As mentioned previously, commenters pointed out that many reverse distributors inventory the potentially creditable hazardous waste pharmaceuticals at the same time that they evaluate the potentially creditable hazardous waste pharmaceuticals to determine if they will be credited.[394] Therefore, the Agency is finalizing that both the inventory and the evaluation process must be completed in 30 days to ensure that reverse distributors have adequate time to sort through shipments of potentially creditable hazardous waste pharmaceuticals.[395] In the case where healthcare facilities do not

[391] See comment number EPA–HQ–RCRA–2007–0932-0315 in the docket for this rulemaking.
[392] See comment number EPA–HQ–RCRA–2007–0932-0333 in the docket for this rulemaking.
[393] See comment numbers EPA–HQ–RCRA–2007–0932-0276 and EPA–HQ–RCRA–2007–0932-0257 in the docket for this rulemaking.
[394] See comment number EPA–HQ–RCRA–2007–0932-0276 in the docket for this rulemaking.
[395] Although RILA requested that EPA allow reverse distributors to have 60 days to complete the evaluation process, RILA was primarily concerned that it would be difficult for reverse distributors to sort through over-the-counter pharmaceuticals and dietary supplements within the proposed time frame (see comment number EPA–HQ–RCRA–2007–0932-0295 in the docket for this rulemaking). However, the Agency thinks that 30 days is a sufficient amount of time for reverse distributors to sort through shipments of potentially creditable hazardous waste pharmaceuticals,

segregate hazardous waste pharmaceuticals from non-hazardous waste pharmaceuticals as part of the evaluation process, reverse distributors will effectively make a hazardous waste determination in order to determine which pharmaceuticals are hazardous waste pharmaceuticals and thus subject to this subpart.

The Agency is finalizing that the 30 calendar days for evaluating the potentially creditable hazardous pharmaceuticals do not count as part of the total 180 calendar days that the hazardous waste pharmaceuticals are allowed to accumulate on site at the reverse distributor. The Agency has determined that because of the value of the potentially creditable hazardous waste pharmaceuticals and the low risk these materials present, increasing the amount of time reverse distributors have to evaluate shipments of potentially creditable hazardous waste pharmaceuticals will not increase risk of release to the environment. Additionally, because most potentially creditable hazardous waste pharmaceuticals are in their original packaging, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (e.g., for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container standard, and therefore EPA has determined that having a longer accumulation time is not a hazard to human health and the environment.[396]

EPA is finalizing that once an evaluation is made on the incoming potentially creditable hazardous waste pharmaceuticals, if they are destined for another reverse distributor, they are still considered potentially creditable hazardous waste pharmaceuticals. There are additional regulations in this subpart at § 266.510(b) that pertain to these potentially creditable hazardous waste pharmaceuticals. If, however, they are destined for an interim status or permitted TSDF,

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which does not include over-the-counter pharmaceuticals and dietary supplements under the final regulations (see the definition of "potentially creditable hazardous waste pharmaceuticals" in 266.500).

[396] For more discussion of the closed container standard see memo from Devlin to RCRA Division Directors, November 3, 2011, (RCRA Online #14826)

they are considered ‘‘evaluated hazardous waste pharmaceuticals.’’ There are additional regulations in this rule at § 266.510(c) that pertain to these evaluated hazardous waste pharmaceuticals.

d. *Accumulation time limit*.

Summary of Proposal EPA proposed that, like LQGs, reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for up to 90 calendar days without having interim status or a permit. However, because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present because they are in original manufacturer's packaging that would meet our typical requirement for closed containers, the Agency decided not to propose specific container management standards.

The Agency proposed that the 90-day time limit begin when the potentially creditable hazardous waste pharmaceuticals initially arrive at the reverse distributor. The Agency also proposed that there is a 90-day accumulation limit for the hazardous waste pharmaceuticals at each reverse distributor. Some potentially creditable hazardous waste pharmaceuticals travel through more than one reverse distributor to receive manufacturer credit. The Agency proposed that in such cases, each reverse distributor that receives the potentially creditable hazardous waste pharmaceuticals has a 90-day accumulation limit.

EPA did not propose a specific method that reverse distributors must use to document that accumulation does not exceed 90 calendar days. EPA anticipated that most reverse distributors would use the inventory system to verify the 90-calendar day time frame rather than taking the extra step of labeling containers with dates for verification. EPA also proposed to allow a reverse distributor to request from EPA an extension of the 90-day accumulation time

limit for situations when the hazardous waste pharmaceuticals are involved in litigation, a recall, or in unforeseen circumstances beyond the control of the reverse distributor. Under the part 262 generator regulations, the extension of time typically allowed is limited to an extra 30 days for LQGs. However, due to the complex nature of pharmaceutical litigation and recalls, EPA proposed to allow the EPA Regional Administrator to grant a time extension at their discretion on a case-by-case basis.

Summary of Comments The most frequent comment EPA received on the proposed on-site accumulation time limit was that the 90-day accumulation limit was too short. Waste Management National Services, Inc. did not support the 90-day accumulation limit, arguing that there are many reasons why a reverse distributor would experience significant changes in the volumes of returns it receives, including recalls.[397] Inmar, Inc. did not support the 90-day accumulation limit, arguing that its facilities receive thousands of shipments every day and it would be impractical to ensure a 90-day accumulation limit.[398] Healthcare Distribution Management Association pointed out that the 90-day accumulation limit is too short because manufacturers frequently take longer than 90 days to make credit determinations.[399] Waste Management National Services, Inc., Qualanex, LLC, and PharmaLink, Inc. requested that EPA not require the 90-day accumulation to begin until the potentially creditable hazardous waste pharmaceuticals become evaluated hazardous waste pharmaceuticals.[400] Stericycle, Inc. requested that EPA extend the accumulation time limit from 90 days to 180 days and suggested that there should not be an accumulation time limit for hazardous waste pharmaceuticals being

[397] See comment number EPA–HQ–RCRA–2007–0932-0257 in the docket for this rulemaking.
[398] See comment number EPA–HQ–RCRA–2007–0932-0377 in the docket for this rulemaking.
[399] See comment number EPA–HQ–RCRA–2007–0932-0276 in the docket for this rulemaking.
[400] See comment numbers EPA–HQ–RCRA–2007–0932-0257, EPA–HQ–RCRA–2007–0932-0352, and EPA–HQ–RCRA–2007–0932-0349 in the docket for this rulemaking.

held due to recall.[401] GENCO and Healthcare Waste Institute of the National Waste and Recycling Association also requested that EPA extend the accumulation time limit from 90 days to 180 days.[402] RILA Association requested that EPA extend the accumulation time limit from 90 days to one year.[403] National Pharmaceutical Returns requested that EPA place no accumulation time limit on potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.[404]

EPA received multiple comments suggesting that the accumulation time limits did not accommodate situations where reverse distributors receive unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date or situations where reverse distributors "age" potentially creditable pharmaceuticals until they are eligible for manufacturer credit.[405]

One state supported the 90-day accumulation limit.[406] One state agreed that the 90-day accumulation limit is reasonable but did not support allowing each reverse distributor to have a 90-day accumulation period because it increases the potential for mismanagement.[407]

Final Rule Provisions In response to comments, EPA is providing additional time for reverse distributors accumulating hazardous waste pharmaceuticals. Specifically, EPA is finalizing in § 266.510(a)(5) that reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for up to 180 calendar days without having interim status or a permit as long as they meet the conditions of this subpart. The Agency is finalizing that the 180-day time limit begins once the reverse distributor evaluates

[401] See comment number EPA–HQ–RCRA–2007–0932-0280 in the docket for this rulemaking.
[402] See comment numbers EPA–HQ–RCRA–2007–0932-0336 and EPA–HQ–RCRA–2007–0932-0296 in the docket for this rulemaking.
[403] See comment number EPA–HQ–RCRA–2007–0932-0295 in the docket for this rulemaking.
[404] See comment number EPA–HQ–RCRA–2007–0932-0310 in the docket for this rulemaking.
[405] See comment number EPA–HQ–RCRA–2007–0932-0377 in the docket for this rulemaking.
[406] See comment number EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.
[407] See comment number EPA–HQ–RCRA–2007–0932-0300 in the docket for this rulemaking.

the potentially creditable hazardous waste pharmaceutical and determines if the potentially creditable hazardous waste pharmaceuticals must be transported to another reverse distributor for further evaluation of manufacturer credit or if it will be sent off site for treatment and disposal. As mentioned in the previous section, reverse distributors are required to inventory and evaluate potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor. Therefore, the potentially creditable hazardous waste pharmaceuticals can be accumulated at each reverse distributor for no more than 210 days in total after arrival.

The Agency is finalizing that there is a 180-day accumulation limit for the hazardous waste pharmaceutical at each reverse distributor. Some potentially creditable hazardous waste pharmaceuticals travel through more than one reverse distributor to receive manufacturer credit. Under the final rule, each reverse distributor that receives the potentially creditable hazardous waste pharmaceuticals has a new 180-day accumulation limit. Under the final rule, the 180-day time limit begins when the reverse distributor evaluates potentially creditable hazardous waste pharmaceuticals and to determine which potentially creditable hazardous waste pharmaceuticals must be transported to another reverse distributor and which ones will be sent off site for treatment and disposal.

Under the final rule, EPA is not requiring a specific method that reverse distributors must use to document that accumulation does not exceed 180 calendar days. EPA anticipates that most reverse distributors will use the inventory system to verify the 180-calendar day time frame rather than taking an addition step of labeling containers with dates for verification. As discussed previously, EPA is finalizing that a reverse distributor must inventory potentially creditable hazardous waste pharmaceuticals within 30 calendar days of arriving at the reverse distributor.

Many reverse distributors utilize barcoding and scanners to log potentially creditable pharmaceuticals into a database upon arrival or soon after a shipment arrives.

Because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, the Agency is not requiring specific container management standards in the final rule. Furthermore, potentially creditable hazardous waste pharmaceuticals are typically still in the manufacturer's packaging, which would meet our typical requirement for closed containers.

Under the final rule, EPA has eliminated the proposed provision allowing reverse distributors to request an extension of the accumulation time limit. In order to accommodate situations where hazardous waste pharmaceuticals are involved in unforeseen circumstances beyond the control of the reverse distributor, the Agency increased the accumulation time limit from 90 days to 180 days. As discussed previously, the Agency also increased the amount of time reverse distributors can take to evaluate potentially creditable hazardous waste pharmaceuticals from 21 to 30 days. Additionally, in order to accommodate situations when hazardous waste pharmaceuticals are involved in litigation or a recall, under the final rule, the Agency decided that hazardous waste pharmaceuticals that are either involved in an investigation or judicial proceeding or are subject to a voluntary or federally-mandated recall are not required to be managed under subpart P (see section IX for a detailed discussion). As a result, we do not anticipate the need for reverse distributors to seek accumulation time extensions and therefore we have deleted proposed § 266.510(a)(5).

In order to accommodate situations when reverse distributors receive unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (i.e., aging in a holding morgue), EPA has added a provision in § 266.510(a)(5)(ii) to allow reverse distributors

to accumulate these unexpired pharmaceuticals for up to 180 days after the expiration date provided that the unexpired pharmaceuticals are managed in accordance with the container labeling and management standards for evaluated hazardous waste pharmaceuticals found at § 266.510(c)(4)(i)–(vi) while they are aging. This includes labeling containers with the words "hazardous waste pharmaceuticals;" ensuring the containers are in good condition, managed to prevent leaks and compatible with the contents; and keeping containers closed.

Once a reverse distributor evaluates a hazardous waste pharmaceutical and determines that it is not destined for another reverse distributor, the reverse distributor must manage that hazardous waste pharmaceutical according to the standards for evaluated hazardous waste pharmaceuticals (unless, as previously mentioned, the hazardous waste pharmaceuticals are unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date). The evaluated hazardous waste pharmaceuticals can be accumulated for up to 180 calendar days without having interim status or permits and they must be managed in accordance with the standards for evaluated hazardous waste pharmaceuticals in § 266.510(c). Although reverse distributors must manage the hazardous waste pharmaceuticals that are not destined for another reverse distributor in accordance with the standards for evaluated hazardous waste pharmaceuticals, the reverse distributor can decide at any point during the accumulation time that the evaluated hazardous waste pharmaceuticals have become eligible for manufacturer credit. If the evaluated hazardous waste pharmaceuticals become eligible for manufacturer credit, the reverse distributor does not get additional calendar days beyond the 180-day accumulation time limit to accumulate the hazardous waste pharmaceuticals. If the evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit, and the hazardous waste pharmaceutical will still not be sent to another reverse distributor for further evaluation, the

reverse distributor must continue to manage the hazardous waste pharmaceutical in accordance with the standards for evaluated hazardous waste pharmaceuticals.

EPA does not anticipate a scenario where an evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit and the reverse distributor needs to send the hazardous waste pharmaceutical to another reverse distributor for further evaluation. A reverse distributor is unlikely to utilize resources to accumulate a pharmaceutical that another reverse distributor is required to evaluate due to contractual arrangements with pharmaceutical manufacturers. Although EPA does not anticipate this scenario, if an evaluated hazardous waste pharmaceutical becomes eligible for manufacturer credit and the reverse distributor determines that it should go to another reverse distributor to be further evaluated for manufacturer credit, the reverse distributor can then resume managing the hazardous waste pharmaceutical pursuant to the standards for potentially creditable hazardous waste pharmaceuticals that are going on to another reverse distributor (§ 266.510(b)). However, the reverse distributor does not get additional time to accumulate the hazardous waste pharmaceuticals. That is, the reverse distributor can only accumulate the hazardous waste pharmaceuticals for a total of 180 days after the initial evaluation process is complete. Overall, this approach balances the requests from commenters to accommodate situations where reverse anticipate that a manufacturer's policy might change and that evaluated hazardous waste pharmaceuticals might become eligible for manufacturer credit with EPA's belief that it is necessary to limit total accumulation time to 180 days.

e. *Security*.

Summary of Proposal EPA proposed that reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. Due to increased thefts of pharmaceuticals from pharmacies reported in recent

years in major media outlets, EPA was concerned that reverse distributors could face such thefts since they accumulate unused pharmaceuticals.[408] Further, commenters on the 2008 Pharmaceutical Universal Waste proposal suggested that pharmaceutical universal waste handlers should meet the TSDF facility security requirement. EPA agreed with the commenters that the requirements in the interim status TSDF security regulations would be appropriate to adopt and apply to reverse distributors to prevent the illicit use of these pharmaceuticals, thereby safeguarding human health. EPA's proposal required that they must prevent unknowing entry, and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (e.g., a receiving area and accumulation area).

Summary of Comments Inmar, Inc. and RILA did not support the proposed security requirements and argued that they are duplicative because protective security measures are already required by other state and federal laws.[409] One state and two industry commenters expressed support that reverse distributors must meet a performance-based security standard.[410] One industry commenter pointed out that this requirement should not be an added burden since reverse distributors should already have significant security systems in place and one industry commenter pointed out that the requirements are consistent with the way that reverse distributors operate.[411,412]

[408] "Pharmacies Besieged by Addicted Thieves" by Abby Goodnough Published: February 6, 2011 http://www.nytimes.com/2011/02/07/us/07pharmacies.html.
[409] See comment numbers EPA–HQ–RCRA–2007–0932-0377 and EPA–HQ–RCRA–2007–0932-0295 in the docket for this rulemaking.
[410] See comment numbers EPA–HQ–RCRA–2007–0932-0257, EPA–HQ–RCRA–2007–0932-0280, and EPA–HQ–RCRA–2007–0932-0315 in the docket for this rulemaking.
[411] See comment number EPA–HQ–RCRA–2007–0932-0257 in the docket for this rulemaking.
[412] See comment number EPA–HQ–RCRA–2007–0932-0280 in the docket for this rulemaking.

Final Rule Provisions EPA is finalizing in § 266.510(a)(6) that reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. EPA believes that the requirements that appear in the interim status TSDF security regulations are appropriate to adopt and apply to reverse distributors to prevent the illicit use of these pharmaceuticals thereby safeguarding human health. The security requirement of § 265.14(a) requires a facility to ''prevent the unknowing entry, and minimize the possibility for the unauthorized entry, of persons or livestock onto the active portion of his facility.'' EPA is finalizing a similar requirement for reverse distributors: they must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (e.g., a receiving area and accumulation area).

Based on site visits and comments received on the proposed rulemaking, EPA recognizes that many reverse distributors may already meet the proposed security standard through the use of key cards that allow only authorized personnel into specific areas of the reverse distributor, camera surveillance systems, and cages for storing pharmaceuticals. Some reverse distributors may use fences and signs. EPA is including several examples of acceptable security measures in the regulatory text, but reverse distributors are not limited to the examples provided. Further, EPA does not believe this requirement is duplicative because we included a provision in the regulations that if a reverse distributor already meets the performance-based security standard by complying with other regulations, such as DEA's regulations, then the reverse distributor would not need to install additional security. Furthermore, in response to comments we added a reference to the State Board of Pharmacy regulations as a second example of other regulations that could be used to fulfill the performance based security requirement.

f. *Contingency plan and emergency procedures.*

Summary of Proposal The Agency proposed to require that reverse distributors meet standards that are the same as those that appear in the federal LQG regulations for developing a contingency plan and emergency procedures at 40 CFR part 265 subpart D. EPA noted in the proposal that a reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Since many reverse distributors are already LQGs, they should already have contingency plans to address the hazards on site. It may be possible that the reverse distributors would have to amend their contingency plans to include the potentially creditable hazardous waste pharmaceuticals, which have been considered products, not hazardous waste, but the Agency pointed out in the proposal that such modifications should not impose much burden.

Summary of Comments One state and two industry commenters supported the requirement that reverse distributors meet the same contingency planning standards as LQGs at 40 CFR part 265 subpart D.[413] Inmar, Inc. supported the proposed contingency plan and emergency procedures requirements and pointed out that most of their facilities are LQGs and already follow these requirements.[414] RILA argued that the contingency planning and emergency procedures requirements should not apply to reverse distributors that handle lower volumes of hazardous waste than an SQG generates because the nature of the waste does not warrant the more stringent requirements.[415]

Final Rule Provisions EPA is finalizing in §266.510(a)(7) that reverse distributors meet standards that are the same as those that appear in the federal LQG regulations for developing a

[413] See comment numbers EPA–HQ–RCRA–2007–0932-0257, EPA–HQ–RCRA–2007–0932-0341, and EPA–HQ–RCRA–2007–0932-0377 in the docket for this rulemaking.
[414] See comment number EPA–HQ–RCRA–2007–0932-0377 in the docket for this rulemaking.
[415] See comment number EPA–HQ–RCRA–2007–0932-0295 in the docket for this rulemaking.

contingency plan and emergency procedures. Since this rule was proposed, the 2016 Hazardous Waste Generator Improvements rule has been finalized and has placed the contingency plan and emergency procedures for LQGs in part 262 subpart M, entitled "Preparedness, Prevention and Emergency Procedures for Large Quantity Generators." As a result, this final rule now references the LQG standards in part 262 subpart M rather than the interim status TSDF standards part 265 subpart D. EPA believes that a reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Reverse distributors that are LQGs should already have contingency plans to address the hazards on-site. Commenters pointed out that reverse distributors that currently operate as SQGs will face a burden under this requirement, but EPA's data shows that most reverse distributors are already LQGs.[416] It is possible that the reverse distributors will have to amend their contingency plans to include the potentially creditable hazardous waste pharmaceuticals, which have been considered products, not hazardous waste, but EPA does not believe that such modifications will impose much burden.

Comments and Responses One state recommended that EPA establish a similar requirement to 40 CFR 264.31 (failure of a facility owner or operator to maintain or operate facility to minimize possibility of fire, explosion or releases of hazardous waste or hazardous waste constituents) for reverse distributors.[417] EPA included similar language in the regulations at § 266.510(c)(4)(v).

g. *Closure*.

Summary of Proposal Due to the generally low risk of release to the environment of the hazardous waste pharmaceuticals that reverse distributors will accumulate on site, as well as the value of the hazardous waste pharmaceuticals, EPA proposed a performance-based closure standard for reverse distributors that incorporated the federal LQG closure standard found at §

[416] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).
[417] See comment number EPA–HQ–RCRA–2007–0932-0235 in the docket for this rulemaking.

265.111. Specifically, when a reverse distributor closes its operations related to hazardous waste pharmaceuticals, EPA proposed that it must control or minimize post-closure releases of hazardous waste into the environment. EPA expected that this would entail removing the containers of both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste pharmaceuticals from the facility before closure.

Summary of Comments Waste Management National Services, Inc., the California Department of Toxic Substances Control, and the Connecticut Department of Energy and Environmental Protection support the requirement for a performance-based closure standard that is based on the federal LQG closure standard.[418] Inmar, Inc. requested that EPA clarify that the reverse distributor closure requirement only apply to the closure of the facility and not to the closure of accumulation areas.[419]

Final Rule Provisions Under the final rule at § 266.510(a)(8), EPA is requiring a performance-based closure standard that is based on the federal LQG closure standard. Since the rule was proposed, the 2016 Hazardous Waste Generator Improvements rule has been finalized and has incorporated the LQG closure standards into the new LQG regulations in § 262.17. As a result, this final rule now references the LQG closure standard in §§ 262.17(a)(8)(ii) and (iii) rather than incorporating the regulatory language of § 265.111. The LQG closure standards are substantially the same as before. Therefore, when a reverse distributor closes its operations related to hazardous waste pharmaceuticals, it must control or minimize post-closure releases of hazardous waste constituents into the environment. This will entail removing the containers of both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste

[418] See comment numbers EPA–HQ–RCRA–2007–0932-0257, EPA–HQ–RCRA–2007–0932-0315, and EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.
[419] See comment number EPA–HQ–RCRA–2007–0932-0377 in the docket for this rulemaking.

pharmaceuticals from the facility before closure. The closure standards apply when the reverse distributor closes its operations related to hazardous waste pharmaceuticals rather than when the reverse distributor closes an accumulation area.

h. *Reporting*.

Summary of Proposal In some instances, a shipment arriving at a reverse distributor may inadvertently include items that are not potentially creditable pharmaceuticals. These shipments can include wastes that are clearly not eligible to receive credit, such as patient care waste (e.g., IV bags and tubing), contaminated personal protective equipment (PPE), medical waste, or other inappropriate wastes. Reverse distributors are not the appropriate waste management facility for medical or infectious wastes and these wastes must be managed and transported from the healthcare facility to an appropriate waste disposal facility. In some cases, these non-creditable wastes may be hazardous waste. These non-creditable hazardous wastes are prohibited from being transported from a healthcare facility to a reverse distributor and should have been manifested from the healthcare facility to a designated facility, such as a permitted or interim status TSDF.

EPA proposed that if a shipment including these unauthorized wastes arrives at a reverse distributor from a healthcare facility, the reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 15 days. EPA adapted the existing requirement for situations when permitted and interim status TSDFs receive unmanifested hazardous waste (§ 264.76 and § 265.76, respectively) to make it appropriate for situations when unauthorized waste arrives at a reverse distributor. EPA also proposed additional requirements for when inappropriate hazardous waste arrives at a reverse distributor.

First, EPA proposed that the reverse distributor must send a copy of the unauthorized waste report to the healthcare facility that sent the unauthorized waste. This requirement was intended to alert the healthcare facility of its mistake in order to prevent further shipments of non-creditable hazardous waste or non-pharmaceutical hazardous waste.

Second, EPA proposed that the reverse distributor must manage the unauthorized waste that it receives in accordance with all applicable regulations. Third, the Agency proposed that the EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

Summary of Comments The most frequent comment that EPA received on the proposed reporting requirements is that 15 days is not enough time to submit an unauthorized waste report to the EPA Regional Administrator. Four commenters argued that 15 days is not enough time to submit an unauthorized waste report to the EPA Regional Administrator.[420] Two industry commenters pointed out that it may take up to 30 days for shipments to be processed.[421] Healthcare Waste Institute of the National Waste and Recycling Association suggested that reverse distributors be required to submit an unauthorized waste report within 15 days of processing a shipment of hazardous waste rather than within 15 days of receiving the hazardous waste.[422]

CT DEEP supported the reporting requirements and wrote that the requirement might incentivize healthcare facilities not to ship unauthorized wastes to reverse distributors.[423] RILA

[420] See comment numbers EPA–HQ–RCRA–2007–0932-0257, EPA–HQ–RCRA–2007–0932-0278, EPA–HQ–RCRA–2007–0932-0296, and EPA–HQ–RCRA–2007–0932-0352 in the docket for this rulemaking.
[421] See comment numbers EPA–HQ–RCRA–2007–0932-0257 and EPA–HQ–RCRA–2007–0932-0352 in the docket for this rulemaking.
[422] See comment number EPA–HQ–RCRA–2007–0932-0296 in the docket for this rulemaking.
[423] See comment number EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.

did not support the reporting requirements and wrote that reverse distributors should not be required to submit an unauthorized waste report when shipments of non-creditable hazardous waste pharmaceuticals arrive at the reverse distributors because the healthcare facilities are not capable of evaluating creditworthiness.[424] Waste Management National Services, Inc. requested that EPA only require reverse distributors to send a copy of the unauthorized waste report to a specific healthcare facility three times, arguing that it is not the reverse distributor's responsibility to continue this reporting.[425] National Pharmaceutical Returns pointed out that reverse distributors receive a large amount of unauthorized waste pharmaceuticals that healthcare facilities think are potentially creditable and therefore the reporting requirements will be time consuming.[426] One state requested the EPA clarify if a reverse distributor may refuse to take a shipment. [427]

Final Rule Provisions In response to comments, EPA is finalizing at § 266.510(a)(9) that if a shipment from a healthcare facility arrives at a reverse distributor that includes hazardous waste that it is not authorized to receive, the reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 45 days of receiving the hazardous waste rather than the proposed 15 days. However, EPA is finalizing, as proposed, the additional requirements for when shipments of unauthorized waste arrive at reverse distributors. First, the reverse distributor must send a copy of the unauthorized waste report to the healthcare facility that sent the unauthorized waste. Second, the reverse distributor cannot reject the shipment of non-creditable hazardous waste and must manage the unauthorized waste in accordance with all applicable regulations (e.g., part 262 or medical waste regulations). Healthcare facilities are not

[424] See comment number EPA–HQ–RCRA–2007–0932-0295 in the docket for this rulemaking.
[425] See comment number EPA–HQ–RCRA–2007–0932-0257 in the docket for this rulemaking.
[426] See comment number EPA–HQ–RCRA–2007–0932-0310 in the docket for this rulemaking.
[427] See comment number EPA–HQ–RCRA–2007–0932- 0259 in the docket for this rulemaking.

equipped as well as reverse distributors to manage the hazardous waste and EPA is concerned that rejecting shipments of non-creditable hazardous waste will prolong mismanagement. Third, the Agency is finalizing as proposed that the EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. This provides the Agency with some flexibility in what reports may be required.

Comments and Responses The Agency believes that commenters understood this provision to apply more broadly than we intended. We are aware that healthcare facilities often do not know whether a hazardous waste pharmaceutical will receive manufacturer credit at the reverse distributor. EPA did not intend for a reverse distributor to generate an unauthorized waste report each time a hazardous waste does not receive credit. Rather, a reverse distributor must generate an unauthorized waste report when it receives waste that it is not authorized to receive or manage. EPA reworded the regulations to include better examples of unauthorized waste, which includes, but is not limited to, non-pharmaceutical hazardous waste and medical or infectious waste.

In order to prevent exposing employees to unnecessary risk, EPA recommends as a best management practice that reverse distributors keep to a minimum the sorting of shipments that contain unauthorized waste since the shipment may include hazardous waste, including infectious or radioactive healthcare waste. As a result, it is possible that a reverse distributor that receives a shipment that includes non-creditable waste may be unsure whether the shipment includes hazardous waste. In such cases, EPA recommends that the reverse distributor assume the shipment includes hazardous waste and submit an unauthorized waste report. Further, we

recommend that reverse distributors work with their clients to reduce the occurrence of further inappropriate shipments.

i. *Recordkeeping*.

Summary of Proposal EPA proposed three recordkeeping requirements to provide transparency for the movement of potentially creditable hazardous waste pharmaceuticals and as a means of verification upon inspection. First, EPA proposed that a reverse distributor must keep a copy of its notification (EPA Form 8700–12) to EPA to indicate that it is a reverse distributor operating under 40 CFR part 266 subpart P. EPA proposed that a reverse distributor must keep the record of notification for as long as it is subject to these requirements. Second, EPA proposed that a reverse distributor must keep copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives. This included a copy of the proposed advance notification from the healthcare facility or other reverse distributor, a copy of delivery confirmation, shipping papers or bills of loading, and any unauthorized waste reports. The Agency proposed that these shipping records must be kept for three years from the date the reverse distributor receives the shipment. Third, EPA proposed that a reverse distributor must keep a copy of its inventory at all times as long as the reverse distributor remains subject to this subpart. Finally, EPA proposed that periods of record retention indicated previously for a reverse distributor will be automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

Summary of Comments EPA received multiple comments on the recordkeeping requirements. GENCO did not support the recordkeeping requirements, arguing the requirements would

impose burden.[428] Inmar, Inc. argued that reverse distributors are already required to keep records under other regulatory requirements related to receipt, storage, duration, and shipping of controlled and uncontrolled substances.[429]

Stericycle, Inc., the Healthcare Waste Institute of the National Waste and Recycling Association, and Waste Management National Services, Inc. expressed concern about the requirement that a reverse distributor must keep a copy of its inventory for as long as the facility is subject to this subpart.[430] Stericycle, Inc. argued that it is not reasonable to require the inventory be maintained for the life of the facility.[431] The Illinois Council of Health-System Pharmacists requested that EPA clarify whether reverse distributors must maintain only a current inventory or that all inventories as they change must be maintained.[432]

Final Rule Provisions EPA is finalizing the proposed recordkeeping requirements at § 266.510(a)(10) with some minor changes in order to provide transparency for the movement of potentially creditable hazardous waste pharmaceuticals and as a means of verification upon inspection. First, EPA is finalizing that a reverse distributor must keep a copy of its notification (EPA Form 8700–12) to EPA to indicate that it is a reverse distributor operating under 40 CFR part 266 subpart P. A reverse distributor must keep the record of notification for as long as it is subject to these requirements.

Second, EPA is finalizing that a reverse distributor must keep copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives. This includes a copy of delivery confirmation, shipping papers or bills of lading, and

[428] See comment number EPA–HQ–RCRA–2007–0932-0336 in the docket for this rulemaking.
[429] See comment number EPA–HQ–RCRA–2007–0932-0377 in the docket for this rulemaking.
[430] See comment numbers EPA–HQ–RCRA–2007–0932-0280, EPA–HQ–RCRA–2007–0932-0296, and EPA–HQ–RCRA–2007–0932-0257 in the docket for this rulemaking.
[431] See comment number EPA–HQ–RCRA–2007–0932-0280 in the docket for this rulemaking.
[432] See comment number EPA–HQ–RCRA–2007–0932-0228 in the docket for this rulemaking.

any unauthorized waste reports. We have revised the regulation language such that these shipping records must be kept for three years from the date the shipment arrives at the reverse distributor rather than when the reverse distributor "receives" the shipment since this standard is more precise.

Third, EPA is finalizing that a reverse distributor must keep a copy of its current inventory at all times as long as the reverse distributor remains subject to this subpart. The inventory is a living document that will constantly be updated and must be available for inspection. In order to clarify that a reverse distributor must maintain only a current inventory rather than all inventories even if they have changed, EPA revised the final regulatory language in § 266.510(a)(2) such that a reverse distributor must keep a copy of its current inventory. This recordkeeping change is being made to be consistent with that change in § 266.510(a)(2).

Finally, EPA is finalizing that periods of record retention referred to in this section are automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action. The Agency recommends reverse distributors keep electronic versions of these records rather than paper or hard copy versions of these records.

Note that additional recordkeeping requirements may also pertain to reverse distributors. For example, a reverse distributor that manifests its non-pharmaceutical hazardous waste is subject to the manifest recordkeeping requirements of § 262.40. Further, as discussed in subsequent sections, there are additional recordkeeping requirements that apply to reverse distributors for the management of potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor (§ 266.510(b)) and others that apply to reverse distributors for the management of evaluated hazardous waste pharmaceuticals (§ 266.510(c)).

2. Additional Standards for Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals Destined for Another Reverse Distributor (§ 266.510(b))

This section discusses the additional standards that apply to a reverse distributor for the management of potentially creditable hazardous waste pharmaceuticals that require further evaluation or verification of manufacturer credit at another reverse distributor. Since these pharmaceuticals retain their value and there is greater incentive to manage them carefully in order to receive full manufacturer credit, EPA is requiring few regulatory standards for the management of the potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor.

a. *Where potentially creditable hazardous waste pharmaceuticals can be sent.*

Summary of Proposal EPA proposed a limit of three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceuticals are ultimately transported to a permitted or interim status TSDF. The Agency proposed that the three possible types of transfers were:[433]

(1) a healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a reverse distributor, which may or may not be a manufacturer;

(2) the first reverse distributor may send the potentially creditable hazardous waste pharmaceuticals to another reverse distributor, which may or may not be a manufacturer;

(3) the second reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals on to a reverse distributor that is a manufacturer.

Because EPA proposed that each reverse distributor could accumulate hazardous waste pharmaceuticals up to 90 days after arriving at the reverse distributor, this proposed chain of

[433] A healthcare facility or reverse distributor also has the option of sending its hazardous waste pharmaceuticals to a RCRA-permitted or interim status TSDF.

transfers ensured that the potentially creditable hazardous waste pharmaceuticals would be accumulated for no more than 270 days in total after leaving a healthcare facility and before being transported to a RCRA-permitted or interim status TSDF for treatment and disposal.[434] As described previously, this is consistent with current practice among reverse distributors because of the contractual arrangements that reverse distributors have with specific manufacturers.

Summary of Comments One state did not support allowing three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceuticals are required to be transported to a TSDF and requested that EPA consider a maximum of two transfers prior to transportation to a TSDF.[435] Two industry commenters opposed EPA's proposed limit on the number of times a potentially creditable hazardous waste pharmaceutical may be transferred before it must be transported to a TSDF.[436] One of the industry commenters argued that reverse distributors have no knowledge about the pedigree of products prior to receipt and as such cannot be held accountable as to how many times a product is handled before transport to a TSDF.[437]

Final Rule Provisions The final regulations for reverse distributors continue to be structured so that there is a limit to the number of transfers of potentially creditable hazardous waste pharmaceuticals that may occur before they are ultimately transported to a TSDF for treatment and disposal. Stakeholders expressed concern that the 2008 Pharmaceutical Universal Waste proposal would have allowed hazardous waste pharmaceuticals to be shipped repeatedly and indefinitely from one universal waste handler to another. From discussions with reverse

[434] Although the proposal did allow for the possibility to request an accumulation time limit, the final rule does not.
[435] See comment number EPA–HQ–RCRA–2007–0932-0261 in the docket for this rulemaking.
[436] See comment numbers EPA–HQ–RCRA–2007–0932-0349 and EPA–HQ–RCRA–2007–0932-0377 in the docket for this rulemaking.
[437] See comment number EPA–HQ–RCRA–2007–0932-0349 in the docket for this rulemaking.

distributors and reviewing comments received on the proposed rulemaking, the Agency believes a reasonable limit is three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceutical is ultimately transported to a TSDF. The three possible types of transfers are:[438]

(1) a healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a reverse distributor, which may or may not be a manufacturer;

(2) the first reverse distributor may send the potentially creditable hazardous waste pharmaceuticals to another reverse distributor, which may or may not be a manufacturer (§ 266.510(b)(1)); and

(3) the second reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals on to a reverse distributor that is a manufacturer (§ 266.510(b)(2)).

Therefore, if a reverse distributor receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility, the reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor (which may or may not be a manufacturer) or must manage them as evaluated hazardous waste pharmaceuticals under § 266.510(c). However, a reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor is more limited in where it can send the potentially creditable hazardous waste pharmaceuticals. It can send potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is the manufacturer or else must manage them as evaluated hazardous waste pharmaceuticals under § 266.510(c).

The Agency disagrees with the commenter who argued that reverse distributors cannot be accountable for how many times a hazardous waste pharmaceutical is transferred because reverse

[438] A healthcare facility or reverse distributor also has the option of sending its hazardous waste pharmaceuticals to a RCRA-permitted or interim status TSDF.

distributors do not have a record of transfers of the potentially creditable hazardous waste pharmaceuticals prior to receipt.[439] It is not necessary for a reverse distributor to have a record of previous transfers. It is only necessary for a reverse distributor to know whether a shipment of potentially creditable hazardous waste pharmaceuticals originated from a healthcare facility or another reverse distributor. EPA believes it is reasonable for a reverse distributor to know the origin of a shipment that arrives at their facility.

Regardless of the origin or the destination of the potentially creditable hazardous waste pharmaceuticals, each reverse distributor must make an evaluation of them within 30 calendar days and may only accumulate the hazardous waste pharmaceuticals on site for no more than 180 calendar days after the evaluation before it ships them off-site to another reverse distributor or a RCRA-permitted or interim status TSDF (resulting in a maximum of 210 days). The 180 calendar day accumulation time starts after the 30 calendar days to make an evaluation. In the proposal, reverse distributors only had 90 days to accumulate hazardous waste pharmaceuticals on-site, including the 21 calendar days to make an evaluation. EPA made this conforming change to align with the change in § 266.510(a)(5) that allows reverse distributors to accumulate hazardous waste pharmaceuticals on-site for up to 180 calendar days without having interim status or a permit. In addition, all shipments of evaluated hazardous waste pharmaceuticals are subject to § 266.508 and shipments of all potentially creditable hazardous waste pharmaceuticals are subject to § 266.509.

Although this chain of transfers will allow potentially creditable hazardous waste pharmaceuticals to be accumulated for up to 630 days in total after leaving a healthcare facility and before being transported to a RCRA-permitted or interim status TSDF for treatment and

[439] See comment number EPA–HQ–RCRA–2007–0932-0349 in the docket for this rulemaking.

disposal, EPA does not expect that potentially creditable hazardous waste pharmaceuticals will be accumulated for this time period in practice. First, it is unlikely that a reverse distributor will expend resources to accumulate potentially creditable hazardous waste pharmaceuticals on site for the full 180 calendar days if the potentially creditable hazardous waste pharmaceuticals are destined for another reverse distributor. Second, the desire to receive manufacturer credit in a timely manner will also make it unlikely that reverse distributors will accumulate potentially creditable hazardous waste pharmaceuticals for the full 180 days.

EPA anticipated that some healthcare facilities that are VSQGs will send their potentially creditable hazardous waste pharmaceuticals directly to reverse distributors. We allow for this under § 266.504(a). On the other hand, healthcare facilities that are VSQGs may choose to consolidate all their hazardous waste pharmaceuticals (both creditable and non-creditable) at an off site healthcare facility, as allowed by § 266.504(b). In this later case, the consolidated potentially creditable hazardous waste pharmaceuticals at an off-site VSQG in § 266.504(b) are not counted as one of the 3 allowable transfers of potentially creditable hazardous waste pharmaceuticals under § 266.510(b).

Under the final rule, manufacturers cannot send hazardous waste pharmaceuticals to a reverse distributor because the hazardous waste pharmaceuticals are no longer considered potentially creditable hazardous waste pharmaceuticals. Since manufacturers are unable to issue credit to themselves, it is not possible for the hazardous waste pharmaceuticals to be considered potentially creditable hazardous waste pharmaceuticals.

b. *Recordkeeping for reverse distributors shipping potentially creditable hazardous waste pharmaceuticals to another reverse distributor.*

Summary of Proposal EPA proposed that reverse distributors must keep records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor (whether it is a manufacturer or not). This included a copy of the advance notification provided to the other reverse distributor, a copy of delivery confirmation, as well as shipping papers or bill of lading. EPA proposed that the reverse distributor must keep these shipping records for three years from the date it initiates the shipment.

Summary of Comments EPA received few comments on the recordkeeping requirements for reverse distributors that ship potentially creditable hazardous waste pharmaceuticals to another reverse distributor. One state asked EPA to clarify what it means by "shipping papers."[440]

Final Rule Provisions EPA is finalizing in § 266.510(b)(4) that reverse distributors must keep records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor (whether it is a manufacturer or not). This includes a copy of delivery confirmation, as well as DOT shipping papers. EPA has clarified in the regulations that it is the DOT shipping papers prepared in accordance with 49 CFR part 172 subpart C we are referring to as "shipping papers"; EPA is not adding a requirement for additional shipping papers. The regulations do not specifically mention that reverse distributors keep a copy of a bill of lading, as this is only one type of shipping paper that reverse distributors can use to comply with 49 CFR part 172 subpart C. EPA is finalizing that these shipping records must be kept for three years from the date of shipment.

[440] See comment number EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.

3. Additional Standards for Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals (§ 266.510(c))

This section discusses the additional standards that apply to a reverse distributor for the management of evaluated hazardous waste pharmaceuticals. In general, the term evaluated hazardous waste pharmaceuticals refers to hazardous waste pharmaceuticals that were potentially creditable hazardous waste pharmaceuticals but have been evaluated by a reverse distributor to establish whether they are eligible for manufacturer credit and will not be sent to another reverse distributor for further evaluation or verification. While potentially creditable hazardous waste pharmaceuticals have value in the form of manufacturer credit, evaluated hazardous waste pharmaceuticals do not. Therefore, in order to minimize the potential for their mismanagement, EPA believes it is necessary to have additional standards for the evaluated hazardous waste pharmaceuticals. These standards generally resemble the standards for LQG CAAs.

a. *Accumulation area.*

Summary of Proposal EPA proposed that once a reverse distributor completes its evaluation of a potentially creditable hazardous waste pharmaceutical and the reverse distributor knows that the hazardous waste pharmaceutical is destined for treatment and disposal at a RCRA-permitted or interim status TSDF, rather than another reverse distributor, the pharmaceutical is considered an evaluated hazardous waste pharmaceutical. EPA proposed that a reverse distributor must establish an on-site accumulation area where it will accumulate these evaluated hazardous waste pharmaceuticals. An on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the potentially creditable hazardous waste pharmaceuticals.

Summary of Comments One state supported the requirement for reverse distributors to establish on-site accumulation areas for evaluated hazardous waste pharmaceuticals.[441]

Final Rule Provisions EPA is finalizing as proposed that a reverse distributor must establish an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals in § 266.510(c)(1). An on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the potentially creditable hazardous waste pharmaceuticals that have fewer requirements and are destined for another reverse distributor.

b. *Weekly inspections.*

Summary of Proposal EPA proposed that the accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at least weekly to ensure containers are not leaking and that diversion of the evaluated hazardous waste pharmaceuticals is not occurring. Under the recordkeeping requirements for reverse distributors, the Agency proposed that a reverse distributor must keep a log of the weekly inspections of the on-site accumulation area and that the log must be retained for at least three years from the date of inspection. The log is necessary to validate the weekly inspections.

Summary of Comments One state commented that weekly inspections are not sufficient to determine whether or not diversion of evaluated hazardous waste pharmaceuticals is occurring and requested EPA require additional security provisions.[442] Washington State Department of Ecology requested that EPA clarify the intent of "at least weekly" and argued that they interpret "at least weekly" to mean once within every seven days.[443]

[441] See comment number EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.
[442] See comment number EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.
[443] See comment number EPA–HQ–RCRA–2007–0932-0272 in the docket for this rulemaking.

Final Rule Provisions In response to comments, EPA is finalizing that the accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at least once every seven days to ensure containers are not leaking and that diversion of the hazardous waste pharmaceuticals is not occurring. We agree with the commenter that phrasing the standard as "at least once every seven days" is more precise than "at least weekly" and will avoid the situation where a reverse distributor could inspect early in one week and late the following week and still claim it is inspecting weekly. Under the recordkeeping requirements for reverse distributors in § 266.510(c)(10), the Agency is finalizing that a reverse distributor must keep a log of the weekly inspections of the on-site accumulation area and that the log must be retained for at least three years from the date of inspection. The log is necessary to validate the weekly inspections.

c. *Personnel training.*

Summary of Proposal EPA proposed to require that reverse distributors meet the same federal classroom or on-the-job personnel training regulations that LQGs must meet (§ 265.16). However, the Agency specified in the proposal that the personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals in the on-site accumulation area. EPA argues that these personnel are the individuals handling and managing the evaluated hazardous waste pharmaceuticals and must have appropriate hazardous waste training.

Summary of Comments Two industry commenters and one state supported the personnel training criteria for reverse distributors.[444] One state argued that the training requirements should be applied to the personnel who handle potentially creditable hazardous waste pharmaceuticals in

[444] See comment numbers EPA–HQ–RCRA–2007–0932-0280, EPA–HQ–RCRA–2007–0932-0296, and EPA–HQ–RCRA–2007–0932-0304 in the docket for this rulemaking.

addition to the personnel who handle evaluated hazardous waste pharmaceuticals on site.[445] Inmar, Inc. pointed out that personnel at reverse distributors are already required to receive training under other regulatory requirements.[446]

Final Rule Provisions Under the final rule, reverse distributors must meet the same classroom or on-the-job personnel training requirements that LQGs must meet. EPA is finalizing that the personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals. Since these personnel are the individuals handling and managing the hazardous waste pharmaceuticals, they must have appropriate hazardous waste training. As mentioned previously, EPA received multiple comments in support of the training requirements for reverse distributors. Additionally, EPA does not believe the training requirements will add burden because EPA believes most reverse distributors currently operate as LQGs.[447] Since the proposed rulemaking, the 2016 Hazardous Waste Generator Improvement rule was finalized. As part of its reorganization, the personnel training regulations for LQGs are now incorporated into § 262.17(a)(7) and no longer refer to § 265.16. As a result, the § 266.510(c)(3) training requirements for personnel managing evaluated hazardous waste pharmaceuticals at reverse distributors now reference § 262.17(a)(7) instead of § 265.16.

d. *Labeling and management of containers in on-site accumulation area.*

Summary of Proposal EPA proposed that while containers of evaluated hazardous waste pharmaceuticals are in the on-site accumulation area, they must be marked with the words, ''hazardous waste pharmaceuticals.'' EPA proposed this term in order to distinguish them from the non-hazardous waste pharmaceuticals and from the hazardous waste pharmaceuticals that are

[445] See comment number EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.
[446] See comment number EPA–HQ–RCRA–2007–0932-0377 in the docket for this rulemaking.
[447] See the Regulatory Impact Analysis in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

still considered potentially creditable. The Agency did not propose to require an accumulation start date on the label for the containers of evaluated hazardous waste pharmaceuticals.

In terms of container management standards, the Agency proposed requirements that are similar to the container management standards for LQGs, but the Agency proposed to include some requirements specific to evaluated hazardous waste pharmaceuticals. For example, LQGs must keep all containers of hazardous waste closed. However, EPA proposed to require that only containers with hazardous waste pharmaceuticals that are liquids or gels be kept closed during accumulation due to the low potential for release to the environment for those hazardous waste pharmaceuticals that are in a solid form. The Agency did not propose to require other containers of evaluated hazardous waste pharmaceuticals to be closed during accumulation, although we expect that reverse distributors would choose to do so as a best management practice. Further, because most evaluated hazardous waste pharmaceuticals are in their original packaging, we proposed that if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (e.g., for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the proposed closed container standard.

As with LQGs, EPA proposed that containers of evaluated hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the evaluated hazardous waste pharmaceuticals placed in the container. Another requirement that was tailored to reverse distributors was the proposal that reverse distributors that accumulate evaluated hazardous waste pharmaceuticals must segregate the pharmaceuticals that are prohibited from being combusted because of the dilution prohibition

of § 268.3(c) and accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals.

The LQG regulations in part 262 include management standards for several types of accumulation units that EPA did not propose to include for the management of evaluated hazardous waste pharmaceuticals. For instance, the proposal only set standards for the accumulation of evaluated hazardous waste pharmaceuticals in containers. EPA did not think it was necessary to include standards for accumulation units such as tanks, containment buildings, or drip pads because reverse distributors do not currently use these types of accumulation units. In addition, the Agency did not propose to require reverse distributors to meet the air emission standards found in 40 CFR part 265 subpart CC as required in § 262.34(a)(1)(i) for LQGs because the Agency anticipated that they will not be applicable. Additionally, 40 CFR part 265 subpart AA— air emissions standards for process vents—and subpart BB—air emission standards for equipment leaks—are not applicable to the activities of a reverse distributor.

Summary of Comments EPA received numerous comments on the proposed requirements for labeling and management of containers of evaluated hazardous waste pharmaceuticals in on-site accumulation areas at reverse distributors. One state supported that containers be marked with the words "hazardous waste pharmaceuticals," but three states and one industry commenter requested that EPA require reverse distributors to label containers with the accumulation start date.[448] Stericycle, Inc. agreed that there is not a need to include standards for accumulation units such as tanks, containment buildings, or drip pads.[449] Clean Harbors argued that the only way to prevent diversion of hazardous waste pharmaceuticals is for all containers to be closed and

[448] See comment numbers EPA–HQ–RCRA–2007–0932-0211, EPA–HQ–RCRA–2007–0932-0235, EPA–HQ–RCRA–2007–0932-0341, and EPA–HQ–RCRA–2007–0932-0257 in the docket for this rulemaking.
[449] See comment number EPA–HQ–RCRA–2007–0932-0280 in the docket for this rulemaking.

sealed.[450] One state requested that EPA prohibit reverse distributors from mixing or commingling incompatible hazardous waste pharmaceuticals in the same container rather than only requiring reverse distributors to manage containers to prevent dangerous situations, such as fire explosion or release of toxic fumes.[451] One commenter agreed that the 40 CFR part 265 subpart AA— air emissions standards for process vents—and subpart BB—air emission standards for equipment leaks—are not applicable to the activities of a reverse distributor and its management of hazardous waste pharmaceuticals.[452]

Final Rule Provisions Final standards for labeling and management of containers at an on-site accumulation area are found at § 266.510(c)(4). EPA is finalizing that while containers of evaluated hazardous waste pharmaceuticals are in the accumulation area, they must be marked with the words, ''hazardous waste pharmaceuticals.'' Under the final rule, reverse distributors are not required to mark an accumulation start date on the label for the containers, because the reverse distributor's inventory will likely be used to verify the accumulation start date. However, a reverse distributor may choose an alternate method, such as marking the date on each container, to ensure that the containers of evaluated hazardous waste pharmaceuticals are not accumulated at the reverse distributor for more than 180 days. As explained previously, EPA prefers to allow a performance-based standard that allows flexibility to verify the 180-day accumulation time rather than require dating on the container labels. Most of the commenters that requested accumulation start dates on labels were states. Although the requirement is not being finalized at the federal level, any authorized state has the ability to impose more stringent

[450] See comment number EPA–HQ–RCRA–2007–0932-0333 in the docket for this rulemaking.
[451] See comment number EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.
[452] See comment number EPA–HQ–RCRA–2007–0932-0296 in the docket for this rulemaking.

regulations. If a state chooses to require the accumulation start date on the container label, that would be considered more stringent and permissible under RCRA.

In terms of container management standards, the Agency is finalizing the proposed requirements that are similar to the container management standards for LQGs as well as the additional management requirements specific to evaluated hazardous waste pharmaceuticals. Specifically, only containers with evaluated hazardous waste pharmaceuticals that are liquids or gels must be kept closed during accumulation, although EPA expects that all containers of evaluated hazardous waste pharmaceuticals will be closed given that evaluated hazardous waste pharmaceuticals are in their original packaging. As with the proposal, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (e.g., for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container standard.

EPA is also finalizing that containers of evaluated hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the hazardous waste pharmaceuticals placed in the container. In addition, a reverse distributor that manages any container of ignitable or reactive evaluated hazardous waste pharmaceuticals or any container of commingled incompatible evaluated hazardous waste pharmaceuticals must manage the container to prevent dangerous situations, such as fire, explosion, or release of toxic fumes. These regulations are consistent with the LQG container management regulations in part 262 and already apply to LQG reverse distributors accumulating hazardous waste on site. The Agency is also finalizing that reverse distributors that accumulate evaluated hazardous waste pharmaceuticals must segregate the pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) and

accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals. The dilution prohibition of § 268.3(c) already prohibits the incineration of some hazardous waste pharmaceuticals. This new provision highlights this prohibition to the reverse distributors accumulating the hazardous waste pharmaceuticals prior to sending off site for treatment and disposal.

Comments and Responses EPA is finalizing management standards only for containers used to accumulate evaluated hazardous waste pharmaceuticals because commenters confirmed that reverse distributors do not use other types of hazardous waste accumulation units, such as tanks, containment buildings, or drip pads.

In addition, the Agency is not requiring reverse distributors to meet the air emission standards found in 40 CFR part 265 subpart CC as required for LQGs in § 262.17(a)(1)(i) because the Agency anticipates that they will not be applicable. Specifically, § 265.1083(c) of subpart CC exempts tanks, surface impoundments, and containers from the organic air emission standards if the hazardous waste entering the accumulation unit has an average volatile organic concentration of less than 500 parts per million by weight, while § 265.1080(b)(2) of subpart CC exempts containers with a capacity of less than 0.1 m^3 (26 gallons) from the standards. EPA understands that the only evaluated hazardous waste pharmaceuticals that have the potential for air emissions are liquids and gels, but they generally do not contain volatile organics. Thus, they do not release organic air emissions, which is what the 40 CFR part 265 subpart CC air emission standards for tanks, surface impoundments, and containers were promulgated to control. Moreover, because evaluated hazardous waste pharmaceuticals are often in their original packaging, and EPA is requiring that liquid and gel evaluated hazardous waste pharmaceuticals must be in intact, sealed packaging or otherwise in closed containers, EPA believes that the

container air emission standards are unnecessary. In addition, the Agency anticipates that the packaging and containers for hazardous waste pharmaceuticals will have a capacity of less than 0.1 m^3 (26 gallons) further limiting the applicability of the container air emission standards. Similarly, EPA does not anticipate that the 40 CFR part 265 subpart AA (air emissions standards for process vents) and subpart BB (air emission standards for equipment leaks) are applicable to the activities of a reverse distributor and its management of evaluated hazardous waste pharmaceuticals. Therefore, like 40 CFR part 265 subpart CC discussed previously, EPA is not requiring that 40 CFR part 265 subparts AA and BB apply to reverse distributors.

e. *Hazardous waste numbers (codes).*

Summary of Proposal EPA proposed that RCRA hazardous waste numbers (commonly called "hazardous waste codes") must be marked on the container label in order to ensure that they are readily visible and cannot be separated from the hazardous waste. In the proposal, the Agency did not require that the reverse distributor be the party that adds the hazardous waste codes to the containers. The proposed regulations allowed a vendor to perform this duty on behalf of the reverse distributor.

Summary of Comments Two states supported the requirement that hazardous waste codes be placed on containers of evaluated hazardous waste pharmaceuticals.[453] Waste Management National Services, Inc. argued that it is not practical to include all hazardous waste codes on each container label and instead suggested that codes be listed on the hazardous waste profile developed with the TSDF and on the manifest.[454]

[453] See comment numbers EPA–HQ–RCRA–2007–0932-0300 and EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.
[454] See comment number EPA–HQ–RCRA–2007–0932-0257 in the docket for this rulemaking.

Final Rule Provisions Under the final rule, EPA is requiring that the containers of evaluated hazardous waste pharmaceuticals be marked with the applicable RCRA hazardous waste numbers (codes) at § 266.510(c)(5). The hazardous waste codes must be added prior to shipping evaluated hazardous waste pharmaceuticals off site, although they may be placed on the container label at any time during on-site accumulation. The hazardous waste numbers must be marked on the container label in order to ensure that it is readily visible and cannot be separated from the hazardous waste. It is necessary that the hazardous waste numbers are on the containers so that transporters, transfer facilities, and TSDFs know how to properly transport, consolidate, treat, store and dispose of the hazardous waste in compliance with the applicable RCRA regulations. In the final rule, the Agency is not requiring that the reverse distributor be the party that adds the hazardous waste numbers to the containers. The regulations allow a vendor to perform this duty on behalf of the reverse distributor. In practice, however, if a vendor is responsible for assigning hazardous waste numbers, personnel from the reverse distributor may need to assist in the process. To be consistent with the Hazardous Waste Generator Improvements final rule, we have added a sentence to § 266.510(c)(5) indicating that a nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste number(s).

f. *Shipping evaluated hazardous waste pharmaceuticals.*

Summary of Proposal Although it is already stated in § 266.508(a) under the section of the regulations that pertains to shipping standards, for clarity, EPA proposed to repeat in the § 266.510 the reverse distributor regulations that reverse distributors that ship evaluated hazardous waste pharmaceuticals off site must do so in accordance with the proposed shipping requirements in § 266.508(a). This includes the applicable DOT packaging, marking and labeling

requirements, as well as the requirement to utilize the hazardous waste manifest when shipping the evaluated hazardous waste to a designated facility.

Summary of Comments Two states generally supported the shipping requirements for evaluated hazardous waste pharmaceuticals.[455] One state supported that EPA repeat in § 266.510 the requirements pertaining to shipping standards although it is already stated in § 266.508(a).[456]

Final Rule Provisions For clarity, the final reverse distributor regulations state that a reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in § 266.508(a) or (b). This includes the applicable DOT packaging, marking and labeling requirements, as well as the requirement to utilize the hazardous waste manifest when shipping the evaluated hazardous waste to a permitted or interim status TSDF.

g. *Procedures for managing rejected shipments*.

Summary of Proposal The Agency proposed to require that reverse distributors meet the same procedures that LQGs must meet for rejected shipments in § 262.42(c). Specifically, if a designated permitted or interim status TSDF identified on the hazardous waste manifest cannot accept a shipment of evaluated hazardous waste pharmaceuticals from a reverse distributor and the TSDF returns the shipment to the reverse distributor, EPA proposed that the reverse distributor must sign either item 18c of the original manifest or item 20 of a new manifest. In addition, the proposal allowed the reverse distributor to consolidate the rejected hazardous waste pharmaceuticals on site for up to 90 days provided they were managed in the on-site accumulation area and in accordance with the reverse distributor standards for evaluated

[455] See comment numbers EPA–HQ–RCRA–2007–0932-0261 and EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.
[456] See comment number EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.

hazardous waste pharmaceuticals. EPA also proposed that reverse distributors send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor within 30 days of delivery.

Summary of Comments One state requested the EPA clarify that a reverse distributor that receives a rejected shipment does not have to transport it off site upon receipt by the reverse distributor.[457] One state argued that a reverse distributor does not need 90 days to accumulate rejected hazardous waste pharmaceuticals in the on-site accumulation area and argued that 30 days is sufficient.[458]

Final Rule Provisions The Agency is finalizing in §266.510(c)(7) that reverse distributors must meet the same procedures that LQGs must meet for rejected shipments in § 262.42(c). Under part 262, these rejected shipment procedures already apply to LQG reverse distributors. Furthermore, EPA anticipates that a rejected shipment is a relatively infrequent occurrence and therefore should not be a burden to reverse distributors. In addition, the final rule allows the reverse distributor to consolidate the rejected hazardous waste pharmaceuticals on site for up to 90 days provided they are managed in the on-site accumulation area and in accordance with the reverse distributor standards for evaluated hazardous waste pharmaceuticals. Although one state requested EPA only allow accumulation for 30 days, any authorized state has the ability to impose more stringent regulations. If a state chooses to shorten the accumulation time, that would be considered more stringent and permissible under RCRA.

h. *Land disposal restrictions.*

Summary of Proposal EPA proposed that reverse distributors are subject to the same LDRs that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals. In addition,

[457] See comment number EPA–HQ–RCRA–2007–0932-0231 in the docket for this rulemaking.
[458] See comment number EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.

EPA proposed to amend the testing, tracking, and recordkeeping requirements for generators, treaters and disposal facilities at § 268.7 to add the words, "pharmaceutical reverse distributors" to the title of that section to make the applicability of the treatment standards clear.

Summary of Comments EPA received multiple comments in support of the requirement that reverse distributors meet the same LDRs that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals, including two states.[459] The Oregon Association of Clean Water Agencies wrote that applying the LDRs will reduce mobility of pharmaceutical constituents in landfill leachate, which is frequently routed to POTWs in Oregon.[460]

Final Rule Provisions As required by HSWA, EPA is finalizing that reverse distributors are subject to the same land disposal restrictions that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals. In addition, EPA is amending the titles at §§ 268.7 and 268.7(a) to add the words, ''reverse distributors'' to make the applicability of the land disposal restrictions clear. SQG and LQG reverse distributors are already subject to LDRs for their hazardous waste pharmaceuticals. Therefore, this provision does not impose additional burden on reverse distributors.

i. *Reporting*.

Summary of Proposal EPA proposed that reverse distributors submit a biennial report (BR) for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF in order for the Agency to have as complete a picture of the amount of hazardous waste generated, treated, stored, or disposed of annually. The Agency proposed that the BR should only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste

[459] See comment numbers EPA–HQ–RCRA–2007–0932-0315 and EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.
[460] See comment number EPA–HQ–RCRA–2007–0932-0288 in the docket for this rulemaking.

pharmaceuticals that a reverse distributor sends to another reverse distributor. Specifically, EPA proposed that a reverse distributor comply with the LQG BR requirements in § 262.41, except for § 262.41(a)(7), which included the requirement to report changes in volume and toxicity of waste achieved during the year in comparison to previous years. The Agency did not propose that a reverse distributor provide such information because it does not have control of the volume or toxicity of the hazardous waste pharmaceuticals it receives from healthcare facilities, and thus has no ability to reduce the volume or toxicity of the hazardous waste pharmaceuticals.

EPA proposed that reverse distributors provide an exception report when a TSDF does not return the hazardous waste manifest to the reverse distributor for shipments of evaluated hazardous waste pharmaceuticals. Likewise, EPA proposed that reverse distributors meet LQG exception reporting when a shipment from a reverse distributor is rejected by the designated facility and forwarded onto an alternate facility. These proposed standards were adapted from the exception reporting for LQGs in §262.42(a).

Summary of Comments One state supported both of the proposed reporting requirements for reverse distributors managing evaluated hazardous waste pharmaceuticals that are transported to a TSDF.[461] RILA argued that the requirement that reverse distributors submit a BR for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF is effectively more stringent than current generator requirements that only require generators to submit a biennial report if they generate over 1000 kg of hazardous waste in a month.[462]

Final Rule Provisions EPA is finalizing at § 266.510(c)(9)(i) that reverse distributors submit a BR for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF in order for the Agency to have as complete a picture of the amount of hazardous waste generated,

[461] See comment number EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.
[462] See comment number EPA–HQ–RCRA–2007–0932-0295 in the docket for this rulemaking.

treated, stored, or disposed of annually. The BR should only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste pharmaceuticals that a reverse distributor sends to another reverse distributor. EPA does not expect that requiring reverse distributors to submit a BR for evaluated hazardous waste pharmaceuticals will be burdensome because most reverse distributors currently operate as LQGs and already submit a BR.[463] Specifically, under the final rule, reverse distributors must comply with the LQG BR requirements in § 262.41. EPA proposed that reverse distributors had to comply with the LQG BR requirements in § 262.41 except § 262.41(a)(7), which included the requirement to report changes in volume and toxicity of waste achieved during the year in comparison to previous years. However, since the proposed rulemaking, the 2016 Hazardous Waste Generator Improvement rule was finalized. As part of that final rule, § 262.41(a)(7) was removed from the generator requirements. Thus, the final rule only states that reverse distributors must comply with the LQG BR requirements in § 262.41.

Consistent with the LQG regulations in part 262, EPA is finalizing at § 266.510(c)(9)(ii) that reverse distributors must provide an exception report when a TSDF does not return the signed hazardous waste manifest to the reverse distributor for shipments of hazardous waste pharmaceuticals to a designated facility within 45 days of shipment. Likewise, EPA is finalizing that reverse distributors must provide an exception report when a shipment from a reverse distributor is rejected by the designated facility and forwarded onto an alternate facility and the reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days. These standards were adapted from the exception reporting for LQGs in §262.42(a), while the standards for healthcare facilities

[463] See the Regulatory Impact Analysis in the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

managing non-creditable hazardous waste pharmaceuticals were adapted from the exception reporting for SQGs §262.42(b). EPA is finalizing that a reverse distributor that does not receive a copy of the manifest within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or TSDF to determinate the status of the evaluated hazardous waste pharmaceuticals. EPA is also finalizing that a reverse distributor must submit a copy of an exception report if it has not received a copy of the manifest within 45 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The exception report must include a legible copy of the manifest for which the reverse distributor does not have confirmation of delivery and a cover letter explaining efforts taken to locate the evaluated hazardous waste pharmaceuticals.

j. *Recordkeeping*.

Summary of Proposal In total, EPA proposed five recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals at reverse distributors. First, EPA proposed that a reverse distributor keep a log (written or electronic) of its weekly inspections of the on-site accumulation area. The other four recordkeeping requirements that EPA proposed for reverse distributors are the same as the LQG recordkeeping requirements that appear in §§ 262.17(a)(7)(iv) and (v), 262.40, and 262.42; these include training documentation, hazardous waste manifest records, records of biennial reports, and exception reporting.

Summary of Comments Hennepin County supported the requirement for reverse distributors to document training.[464]

Final Rule Provisions Many of the final recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals have been discussed in the sections previously, but for clarity,

[464] See comment number EPA–HQ–RCRA–2007–0932-0386 in the docket for this rulemaking.

it is useful to restate them in this recordkeeping section, so that reverse distributors can refer to one section to determine their recordkeeping requirements related to evaluated hazardous waste pharmaceuticals. In total, EPA is finalizing five recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals at reverse distributors that can be found listed at § 266.510(c)(10). First, EPA is requiring that a reverse distributor keep a log (written or electronic) of its inspections of the on-site accumulation area. The other four recordkeeping requirements that EPA is requiring under the final rule for reverse distributors are the same as the LQG recordkeeping requirements in part 262. These include hazardous waste manifest records, records of biennial reports, exception reporting and training documentation.

4. When a Reverse Distributor Must Have a RCRA Hazardous Waste Permit (§ 266.510(d))

a. *Summary of proposal.* In the proposed rulemaking, EPA did not require that a reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the reverse distributor follows all the conditions of the permitting exemption in § 266.510. However, EPA proposed that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site.

b. *Summary of comments.* One state supported the proposed requirement that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site.[465] Clean Harbors argued that EPA's rationale for not requiring a hazardous waste storage permit is flawed and argued that the requirement for obtaining a full RCRA permit be based on the amount of time a potentially

[465] See comment number EPA–HQ–RCRA–2007–0932-0341 in the docket for this rulemaking.

creditable hazardous waste pharmaceutical is stored.[466] The Environmental Technology Council argued that reverse distributors should be required to obtain permits or interim status for storage.[467]

c. *Final rule provisions*. Under the final rule, EPA is not requiring that a reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the reverse distributor follows all the conditions of the permitting exemption in § 266.510. In other words, a reverse distributor will be subject to regulation as a TSDF and require a RCRA permit (or interim status) if it does not meet the conditions of § 266.510. In addition, EPA is finalizing that a reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site. A reverse distributor is required to reject shipments of manifested hazardous waste that it may inadvertently receive from off site because a reverse distributor is not a designated facility and therefore is not eligible to receive hazardous waste shipped with a manifest. EPA believes that this approach to regulation of reverse distributors that accumulate potentially creditable and evaluated hazardous waste pharmaceuticals strikes an appropriate balance because it recognizes that reverse distributors are different from typical hazardous waste TSDFs for permitting purposes, while it still imposes certain conditions for exemption from permitting requirements that provide the necessary environmental protection.

XVIII. Amendments to the Part 268 Prohibitions on Storage

The Agency is finalizing conforming changes that we proposed to the prohibitions on storage of restricted waste in § 268.50. We are finalizing two new subparagraphs in § 268.50(a)

[466] See comment number EPA–HQ–RCRA–2007–0932-0333 in the docket for this rulemaking.
[467] See comment number EPA–HQ–RCRA–2007–0932-0297 in the docket for this rulemaking.

to make it clear that the storage prohibitions apply to both healthcare facilities and reverse distributors operating under part 266 subpart P. Specifically, we are adding paragraph (4) for healthcare facilities and paragraph (5) for reverse distributors to extend the application of the existing storage prohibition to facilities operating under subpart P. Under the LDR storage prohibition the storage of restricted hazardous wastes is prohibited unless certain conditions are met. Healthcare facilities must comply with the applicable requirements in §§ 266.502 and 266.503 and reverse distributors must comply with § 266.510 when accumulating hazardous waste pharmaceuticals on site.

XIX. Implementation and Enforcement

A. Healthcare Facilities

1. Determining Whether a Healthcare Facility is Subject to Part 266 Subpart P

EPA is finalizing that healthcare facilities that are currently considered LQGs or SQGs are subject to the final 40 CFR part 266 subpart P requirements for the management of hazardous waste pharmaceuticals. Thus, a healthcare facility that generates more than 100 kg of hazardous waste per month, or more than 1 kg of acute hazardous waste per calendar month, or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute wastes listed in § § 261.31, or 261.33(e), must manage its hazardous waste pharmaceuticals in compliance with the 40 CFR part 266 subpart P requirements. In addition, healthcare facilities that are VSQGs are subject to the prohibition on sewering hazardous waste pharmaceuticals in § 266.505, the empty container standards in § 266.507, and the optional standards of § 266.504.

To determine whether a healthcare facility is subject to 40 CFR part 266 subpart P or is a VSQG regulated under § 262.14, a healthcare facility must count all the hazardous waste—

pharmaceutical and non-pharmaceutical—it generates in a calendar month. Note that in the final rule EPA has revised which pharmaceuticals are considered hazardous wastes. Specifically, EPA is finalizing that potentially creditable hazardous waste pharmaceuticals transported to a reverse distributor are considered a solid and hazardous waste from the point of generation at the healthcare facility and therefore must be counted when determining whether the healthcare facility is a VSQG regulated under § 262.14 or whether it is regulated under 40 CFR part 266 subpart P for its hazardous waste pharmaceuticals. This differs from previous healthcare facility practice of not counting the potentially creditable hazardous waste pharmaceuticals it sends to a reverse distributor towards its hazardous waste generator category. Therefore, although a healthcare facility may have been considered a VSQG under that previous practice, when it begins counting its potentially creditable hazardous waste pharmaceuticals, it may no longer be a VSQG. In that case, the healthcare facility would be subject to the 40 CFR part 266 subpart P requirements for its hazardous waste pharmaceuticals.

2. Healthcare Facilities Managing Hazardous Waste Pharmaceuticals under Part 266 Subpart P

EPA is finalizing that all healthcare facilities operating under part 266 subpart P will be subject to the same regulations for the management of their hazardous waste pharmaceuticals, regardless of the quantity of hazardous waste pharmaceuticals generated. A healthcare facility that generates both pharmaceutical and non-pharmaceutical hazardous waste must manage the non-pharmaceutical hazardous waste pursuant to part 262, but need not count its hazardous waste pharmaceuticals toward determining the facility's monthly hazardous waste generator category. Therefore, although a facility that previously may have been considered an LQG, once it no longer counts its hazardous waste pharmaceuticals towards its monthly hazardous waste generator category, it may no longer be an LQG. As a result, it is possible that the healthcare

facility may not need to manage its non-pharmaceutical hazardous waste pursuant to the LQG regulations in § 262.17, but rather can operate under the reduced regulations for SQGs in § 262.16 or for VSQGs in § 262.14. In addition, if a healthcare facility that is a VSQG does not want to keep track of the amount of hazardous waste pharmaceuticals it generates to ensure it does not exceed the VSQG quantity limits, it can choose to operate under this final rule. If it chooses to operate under this final rule, however, a healthcare facility must comply with all the requirements of this subpart for the management of its hazardous waste pharmaceuticals.

Following publication of the final rule, EPA plans extensive outreach to educate healthcare facilities and reverse distributors on the provisions of this final rule.

B. Reverse Distributors and Reverse Logistics Centers

1. Prescription Pharmaceuticals Sent to Reverse Distributors are Solid Wastes

EPA proposed to change how RCRA would apply to pharmaceuticals returned to reverse distributors to obtain manufacturers credit. EPA proposed that the decision by a healthcare facility to send a pharmaceutical to a reverse distributor is the decision to discard the pharmaceutical. Due to many comments on this proposed change, the Agency is now making a clear distinction in the final rule between reverse distribution, in the case of prescription pharmaceuticals, and reverse logistics in the case of all other pharmaceuticals—including over-the counter pharmaceuticals and dietary supplements, as well as other unsold consumer items (see section VI for a discussion of the comments). EPA is finalizing that the decision by a healthcare facility to send a prescription pharmaceutical to a reverse distributor is the decision to discard the prescription pharmaceutical. Therefore, under this final rule, once the healthcare facility makes the decision to send a prescription pharmaceutical to a reverse distributor for credit, it is a solid waste at the healthcare facility. A portion of the potentially creditable solid

waste prescription pharmaceuticals at healthcare facilities that are destined for a reverse distributor will also meet the definition of hazardous waste and as a result, these potentially creditable hazardous waste prescription pharmaceuticals would need to be managed in accordance with the final 40 CFR part 266 subpart P requirements.

In addition, the Agency notes that the change in EPA's position concerning reverse distribution and the management standards discussed in this final rule pertain only to the reverse distribution of prescription hazardous waste pharmaceuticals and does not apply to the reverse logistics of other pharmaceuticals or to the reverse logistics systems that may exist for other unsold consumer items.

2. Nonprescription Pharmaceuticals Sent to Reverse Logistics Centers are Not Solid Wastes

EPA proposed that the decision by a healthcare facility to send any pharmaceutical to a reverse distributor is the decision to discard the pharmaceutical, but is now making a clear distinction in the final rule between reverse distribution of prescription pharmaceuticals and reverse logistics of nonprescription pharmaceuticals and other unsold retail items. In response to comments, EPA is codifying our previous policy that the decision by a healthcare facility to send nonprescription pharmaceuticals to a reverse logistics center is not a decision to discard if the nonprescription pharmaceuticals have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed. In other words, EPA is finalizing that nonprescription pharmaceuticals are not solid wastes, and therefore not hazardous waste pharmaceuticals if they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed.

3. Reverse Distributors Managing Hazardous Waste Pharmaceuticals Under Part 266 Subpart P

EPA is finalizing that all reverse distributors are subject to 40 CFR part 266 subpart P and will be subject to the same standards with respect to their hazardous waste pharmaceuticals, regardless of the amount of hazardous waste pharmaceuticals they manage. Even reverse distributors that are currently VSQGs will be regulated under 40 CFR part 266 subpart P for the management of their hazardous waste pharmaceuticals. Therefore, a reverse distributor subject to 40 CFR part 266 subpart P will no longer have to keep track of the amount of hazardous waste pharmaceuticals that it generates on a monthly basis.

C. Healthcare Facilities and Reverse Distributors Managing Non-pharmaceutical Hazardous Waste in Accordance with 40 CFR Part 262 or Part 273 (i.e., Complying with "More Than One RCRA")

Most, if not all, healthcare facilities and reverse distributors generate at least some hazardous wastes other than pharmaceuticals. These non-pharmaceutical hazardous wastes will continue to be regulated under 40 CFR part 262 (and other applicable Subtitle C regulations). The standards established by this rulemaking apply only to the management of hazardous waste pharmaceuticals at healthcare facilities and reverse distributors. Healthcare facilities and reverse distributors likely generate or manage other types of hazardous wastes. For example, hospitals may generate non-pharmaceutical hazardous wastes, such as solvents in their diagnostic laboratories; those hazardous wastes must still be managed in accordance with the part 262 generator regulations (such as the RCRA SAA regulations (§ 262.15)), or if it is a teaching hospital, the Academic Laboratories Rule (if it has opted into part 262 subpart K). Retail stores, including pharmacies and grocery stores, may have non-pharmaceutical hazardous wastes on-site as well, which must be managed in accordance with the 40 CFR part 262 regulations and all other applicable RCRA Subtitle C regulations. For example, fluorescent bulbs may be managed under the universal waste program (40 CFR part 273). For reverse distributors, this rule only

applies to the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. Some reverse distributors may generate other non-pharmaceutical hazardous wastes from activities, such as cleaning and maintenance; other RCRA Subtitle C regulations will apply to those non-pharmaceutical hazardous wastes.

D. State Enforcement Activities and Interpretations

States have taken a variety of approaches regarding hazardous waste pharmaceuticals. One major goal of this final rule is to provide clarity on this topic, and thereby promote national consistency, which should promote better compliance among healthcare facilities, including pharmacies.

In 2012, Connecticut's Department of Energy and Environmental Protection (DEEP) took enforcement actions at seven CVS stores for violations of the RCRA hazardous waste regulations. Consent orders from CT DEEP direct CVS stores in the state to follow a set of best management practices.[468] A number of the practices developed in these consent orders mirror some of the practices EPA is finalizing in this rule, particularly with regard to pharmaceuticals destined for a reverse distributor. CT DEEP asserts RCRA jurisdiction over the pharmaceuticals destined for reverse distributors by applying specific management practices. For example, CVS must maintain records of each shipment of non-dispensable pharmaceuticals to a reverse distributor, including confirmation of receipt of the non-dispensable pharmaceuticals from the receiving reverse distributor. The best practices also include procedures for addressing situations when CVS does not receive delivery confirmation of shipment to a reverse distributor. Further, the consent order sets out separate, more comprehensive practices for the non-dispensable pharmaceuticals that are not suitable for reverse distribution.

[468] See the docket for this rulemaking EPA–HQ–RCRA–2007–0932-0173.

Aside from best management practices developed by Connecticut as part of a consent order, at least two other states have developed guidance documents that apply conditions to the management of hazardous wastes pharmaceuticals in exchange for enforcement discretion. In particular, in 2008, the Washington State Department of Ecology issued guidance titled, Interim Enforcement Policy: Pharmaceutical Waste in Healthcare.[469] This interim enforcement discretion policy had some elements in common with this final rule for hazardous waste pharmaceuticals. For instance, a healthcare facility was required to notify the Department of Ecology that it was operating under the policy and had to train its staff involved in pharmaceutical waste management. Only a time limit, rather than a quantity limit, applied to the accumulation of the hazardous waste pharmaceuticals on site. Of particular note is that Washington State prohibited disposing of most hazardous waste pharmaceuticals down the toilet or drain. In anticipation of this final rule, Washington State updated the interim policy in June 2017 to provide regulated facilities with the opportunity to use some of the provisions outlined in the proposed rulemaking, such as allowing facilities to send creditable pharmaceuticals to a reverse distributor for evaluation without providing hazardous waste codes.[470]

In 2011, Minnesota's Pollution Control Agency (MPCA) issued a fact sheet titled Reverse Distribution of Pharmaceuticals: Guidance for Minnesota Healthcare Providers.[471] In this guidance, Minnesota states, ''Whether a pharmaceutical is eligible for return credit does not affect its product or waste status. In Minnesota, if a pharmaceutical is not used or reused for its intended purpose, it is a waste. The MPCA considers health care practitioners and pharmacies to be generators of these pharmaceutical wastes. Nevertheless, the MPCA believes that the

[469] See the 2008 interim enforcement policy in the docket for this rulemaking EPA–HQ–RCRA–2007–0932-0181.
[470] See the 2017 interim enforcement policy at https://fortress.wa.gov/ecy/publications/documents/0704024.pdf or in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).
[471] See the guidance document in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932-0178).

established reverse distribution system provides an environmentally protective method for handling waste pharmaceuticals. Therefore, it will allow Minnesota health care practitioners and pharmacies to manage certain pharmaceuticals through reverse distribution, subject to additional requirements discussed in this fact sheet.'' This is similar to the approach that EPA is finalizing for potentially creditable hazardous waste pharmaceuticals. For example, like EPA's final rule, MPCA does not require hazardous waste pharmaceuticals destined for a reverse distributor to be counted toward determining a healthcare facility's generator category. In addition, MPCA does not require hazardous waste pharmaceuticals to be accompanied by a hazardous waste manifest when shipped to a reverse distributor. By finalizing a rule that is consistent with state approaches, EPA is bringing national consistency to the management of hazardous waste pharmaceuticals, while avoiding disruption to practices already in place.

E. Intersection of Part 266 Subpart P with the Hazardous Waste Generator Improvements Rule

The Hazardous Waste Generator Improvements rule was finalized on November 28, 2016.[472] This rule finalized a much-needed update to the hazardous waste generator regulations in part 262 to make the rules easier to understand, facilitate better compliance, provide greater flexibility in how hazardous waste is managed and close important gaps in the regulations. This section of preamble discusses three portions of the Hazardous Waste Generator Improvements final rule that might impact healthcare facilities and reverse distributors that are subject to part 266 subpart P.

1. Episodic Generation

One of the key provisions with which EPA added regulatory flexibility allows a hazardous waste generator to avoid increased burden of a higher generator category when

[472] See November 28, 2016; 81 FR 85732.

generating episodic waste provided the episodic waste is properly managed in accordance with part 262 subpart L. Healthcare facilities and reverse distributors will be able to take advantage of this added regulatory flexibility (assuming their state has adopted this provision).

A healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste can use the episodic generation provision of part 262 subpart L for all of its hazardous waste, including its hazardous waste pharmaceuticals. If a healthcare facility is generally operating under § 262.14 as a VSQG, but has an episodic event, it would be far less burdensome to comply with part 262 subpart L than to come into compliance with all the provisions of part 266 subpart P for the short duration of the episodic event. For example, if a VSQG healthcare facility is directed to dispose of recalled pharmaceuticals, it could use the episodic generator provisions of part 262 subpart L to avoid an increase in hazardous waste generator category. However, if a healthcare facility that is a VSQG generates hazardous waste in excess of the allowable amounts as a VSQG,[473] and it chooses not to use the episodic generator provisions in part 262 subpart L, it would become subject to part 266 subpart P for its hazardous waste pharmaceuticals.

As discussed previously, healthcare facilities and reverse distributors that are subject to part 266 subpart P for their hazardous waste pharmaceuticals may still be subject to part 262 for the management of their non-pharmaceutical hazardous waste. A healthcare facility or reverse distributor operating under part 266 subpart P for its hazardous waste pharmaceuticals may not use the episodic generator standards of part 262 subpart L with respect to its hazardous waste pharmaceuticals. Under part 266 subpart P, all healthcare facilities are regulated the same regardless of amounts of hazardous waste pharmaceuticals generated and all reverse distributors

[473] See the definition of very small quantity generator in 40 CFR 2601.10.

are regulated the same, regardless of amounts of hazardous waste pharmaceuticals managed, making the need for episodic generation provisions unnecessary. On the other hand, if a healthcare facility or reverse distributor is generally operating as a VSQG or SQG for its non-pharmaceutical hazardous waste, but has an episodic event, the healthcare facility may use the provisions in part 262 subpart L for its non-pharmaceutical hazardous waste.

2. Small Quantity Generator Re-notification

The 2016 Hazardous Waste Generator Improvements final rule added a new requirement for periodic re-notification by SQGs.[474] Under this new provision, SQGs must re-notify EPA starting in 2021 and every four years thereafter using EPA Form 8700-12. This re-notification must be submitted by September 1st of each year in which re-notifications are required.[475] Healthcare facilities and reverse distributors operating under part 266 subpart P may also be subject to part 262 for the management of its non-pharmaceutical hazardous waste. If a healthcare facility or reverse distributor is an SQG for its non-pharmaceutical hazardous waste, then it will be subject to this re-notification requirement under part 262. Therefore, in order to avoid duplicative notification requirements, under part 266 subpart P, EPA is not requiring re-notification by healthcare facilities and reverse distributors.

3. Very Small Quantity Generators that Accumulate More Than 1 Kg of Acute Hazardous Waste

The 2016 Hazardous Waste Generator Improvements final rule clarified in § 262.14(a)(3) that if a VSQG accumulates at any time greater than 1 kg of acute hazardous waste,[476] all quantities of that acute hazardous waste are subject to the additional conditions for exemption for LQGs. More specifically, the acute hazardous waste must be held on site for no more than 90

[474] See 40 CFR 262.18(d)(1).
[475] See 81 FR 85777-8; November 28, 2016 for the preamble discussion explaining the need for re-notification.
[476] Or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or 261.33(e).

days beginning on the date when more than 1 kg is exceeded, and the acute hazardous waste is subject to the LQG conditions for exemption in § 262.17(a) through (g). In other words, while the acute hazardous waste becomes subject to the stricter standards for LQGs when the accumulation limits are exceeded, the generator continues to be considered a VSQG, provided the generator continues to generate within the VSQG thresholds identified in the definition of VSQG in § 260.10.

If a healthcare facility that is a VSQG accumulates more than 1 kg of acute hazardous waste,[477] then it will remain subject to § 262.14(a)(3); the healthcare facility will not become subject to part 262 subpart P.

XX. State Authorization

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize states to administer the RCRA Subtitle C hazardous waste program. Following authorization, the authorized state program operates in lieu of the federal regulations. EPA retains authority to enforce the authorized state Subtitle C program, although authorized states have primary enforcement authority. EPA also retains its authority under RCRA sections 3007, 3008, 3013, and 7003. The standards and requirements for state authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a state with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the federal program in that state. EPA did not issue permits for any facilities in that state, since the state was now authorized to issue RCRA permits. When new, more stringent federal requirements were promulgated, the state was obligated to enact equivalent

[477] Or more than 100 kg of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or 261.33(e).

authorities within specified time frames. However, the new requirements did not take effect in an authorized state until the state adopted the equivalent state requirements.

In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized states at the same time that they take effect in unauthorized states. While states must still adopt HSWA-related provisions as state law to retain authorization, EPA implements the HSWA provisions in authorized states, including the issuance of any permits pertaining to HSWA requirements, until the state is granted authorization to do so.

Authorized states are required to modify their programs only when EPA promulgates federal requirements that are more stringent or broader in scope than existing federal requirements.[478] RCRA section 3009 allows the states to impose standards more stringent than those in the federal program (see 40 CFR 271.1). Therefore, authorized states may, but are not required to, adopt federal regulations, both HSWA and non-HSWA, that are considered less stringent than previous federal regulations.

B. Effect on State Authorization

This action adds a new subpart P to 40 CFR part 266, and it is being finalized in part under the authority of HSWA and in part under non-HSWA authority. The bulk of 40 CFR part 266 subpart P is being finalized under non-HSWA authority. Thus, the amendments promulgated under non-HSWA authority are applicable on the effective date only in those states that do not have final authorization of their base RCRA programs. Only the prohibition of sewering hazardous waste pharmaceuticals (§ 266.504) is being finalized under HSWA authority in section 3018 of RCRA. The amendments promulgated under the authority of HSWA (i.e., the

[478] EPA notes that decisions regarding whether a state rule is more stringent or broader in scope than the federal program are made when the Agency authorizes a state program for a particular rule.

prohibition on sewering hazardous waste pharmaceuticals) are applicable on the effective date of the final rule in all states. Moreover, authorized states are required to modify their programs only when EPA promulgates federal regulations that are more stringent or broader in scope than the authorized state regulations. For those changes that are less stringent, states are not required to modify their programs.

While some provisions of part 266 subpart P are considered less stringent than the current federal standards, other provisions of the final rule are considered more stringent than the current federal standards. Taken as a whole, we consider the entire new subpart P under 40 CFR part 266 entitled "Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities" (sections VIII–XVII of this preamble) to be more stringent than the current federal standards. Therefore, authorized states will be required to modify their programs to adopt these revisions. When a state adopts this new subpart, if elements of the state program are more stringent than this new subpart, the state has the option of retaining those more stringent elements. Likewise, when a state adopts this new subpart, the state has the option of adding elements that are more stringent or broader in scope than this new subpart.

On the other hand, one final revision is less stringent than the current hazardous waste regulations. The amendment to exempt from the P075 listing the nicotine patches, gums and lozenges that are FDA-approved OTC nicotine replacement therapies is less stringent that the current hazardous waste regulations (section V of this preamble). Thus, authorized states may, but are not required to, adopt the change to the P075 listing.

C. Effect on State Authorization in States that Have Added Pharmaceuticals to the Universal Waste Program

The Universal Waste program allows states to add waste streams to their own state program, even when the waste stream has not been added to the federal Universal Waste program, provided the state has adopted and been authorized for the petition process in §§ 260.20 and 260.23. Two states have added hazardous waste pharmaceuticals to their Universal Waste programs: Florida and Michigan. Because the added subpart P under CFR part 266 is considered more stringent than either the ''traditional RCRA'' standards or the Universal Waste program, both Florida and Michigan will be required to modify their programs to adopt an approach at least as stringent as the amendments. Furthermore, because the Agency has determined that it is not appropriate to add hazardous waste pharmaceuticals to the Universal Waste program, both Florida and Michigan must remove hazardous waste pharmaceuticals from their Universal Waste program when they adopt this new subpart, although they may continue to regulate non-hazardous waste pharmaceuticals under the Universal Waste program, to the extent allowed under state law. In addition, states may choose to add non-hazardous waste pharmaceuticals to their Universal Waste program or may regulate them more stringently as part of their hazardous waste program but states may not add hazardous waste pharmaceuticals to their Universal Waste program in the future. Accordingly, we have amended the regulations in § 273.80(a) and added §273.80(d) to reflect this decision that states may not add hazardous waste pharmaceuticals to their Universal Waste program.

XXI. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Pursuant to the terms of Executive Order 12866, as

affirmed in Executive Order 13563, the Agency has determined that this rule is a significant regulatory action because it contains novel policy issues, as defined under section 3(f)(4) of the Order. Any changes made in response to OMB recommendations have been documented in the docket.

As discussed in section I above, EPA prepared an economic analysis of the potential costs and benefits associated with this action. This analysis, *Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals*, indicates that the rule is projected to result in net annual cost savings of approximately $12.99 million to $14.96 million based on a discount rate of 7 percent or $12.98 to $14.95 million based on a discount rate of 3 percent. The full analysis is available in the docket for this rule.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this final rule can be found in EPA's analysis of the potential costs and benefits associated with this action.

C. Paperwork Reduction Act

The information collection activities in this rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR number 2486.02, OMB control number 0250-0212. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

EPA is finalizing in this rule, under a new subpart P to 40 CFR part 266, new and revised reporting and recordkeeping requirements for healthcare facilities and reverse distributors. These requirements, which are also identified in the ICR supporting this action, will enable EPA and

state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals. In addition, the requirements include provisions for tracking of hazardous waste pharmaceuticals that are sent to reverse distributors.

EPA will use the collected information to ensure that hazardous waste pharmaceuticals are being managed in a protective manner. The tracking requirements ensure that these wastes arrive at their intended destinations rather than diverted for illicit purposes or managed at facilities not equipped to manage these wastes. These tracking requirements will also help facilities identify shipments that do not arrive at their destination as planned, allowing generators to take corrective action that will ensure that future shipments are transported to the appropriate location. Information marked on containers of hazardous waste pharmaceuticals will assist handlers and transporters in ensuring proper management during storage and shipment.

Respondents/affected entities: Drug wholesalers, supermarkets and other grocery stores, pharmacies and drug stores, warehouse clubs and supercenters, veterinary clinics, physicians' offices, dentists' offices, other health practitioners, outpatient care centers, other ambulatory health care services, hospitals, nursing care facilities, continuing care retirement communities, and reverse distributors.

Respondent's obligation to respond: The recordkeeping and notification requirements are mandatory and are being promulgated under section 3001 of RCRA.

Estimated number of respondents: 13,373

Frequency of response: The frequency of response varies.

Total estimated burden: EPA estimated the total annual burden to respondents to be approximately 43,577 hours. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: EPA estimated the total estimated annual cost of this paperwork burden to respondents to be approximately $2,543,409.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the *Federal Register* and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

D. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule. As documented in the Regulatory Impact Analysis found in the docket for this proposal, EPA does not expect the rule to result in an adverse impact to a significant number of small entities. EPA estimates that there are at least 10,481 to 15,114 small entities that will be impacted by this rule. However, small entities are expected to experience a net cost savings under the final rule, and for the small entities that are expected to experience a net cost under the final rule, the RIA estimates the costs, at most, to represent 0.013 percent of annual revenues for small entities. We have therefore concluded that this action will either relieve regulatory burden or have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act

As documented in the Regulatory Impact Analysis found in the docket for this rule, this action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. As indicated previously, the annual net cost savings is estimated to be between approximately $13 million and $15 million (based on a discount rate of 7%). Thus, this rule is not subject to the requirements of sections 202 or 205 of UMRA.

This rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. While some hospitals are publicly owned, the requirements affecting those facilities are not unique in that they are the same as those affecting all facilities in the proposed rulemaking. Also, using data on revenues of hospitals owned by state and local governments, EPA estimated that the costs of the rule borne by state and local governments represent less than 0.001% of their revenues. Therefore, the costs incurred by small governments are not expected to be significant.

F. Executive Order 13132: Federalism

As documented in the Regulatory Impact Analysis found in the docket for this rule, this action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation with Tribal Governments

This action may have tribal implications as specified in Executive Order 13175. The final rule will neither impose substantial direct compliance costs on tribal government, not preempt

tribal law. Under the RCRA statute, the federal government implements hazardous waste regulations directly in Indian Country. Thus, the final rule would not impose any direct costs on tribal governments.

To assess the potential tribal implications of the action, EPA compiled data on the number of tribally run healthcare facilities in the U.S. and estimated the costs of this action for these facilities. As documented in the Regulatory Impact Analysis in the docket for this rule, the rule is not expected to impose a substantial burden on tribal governments.

EPA consulted with tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its development. A summary of that consultation is provided in the docket for this rule (see EPA-HQ-RCRA-2008-0932).

As required by section 7(a), the EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this action.

H. Executive Order 13045: Children's Health

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866 and because the EPA does not believe the environmental health or safety risks addressed by this proposed action present a disproportionate risk to children. This action's health and risk assessments are contained in the *Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals*, found in the docket for this action.

I. Executive Order 13211: Energy Supply

This action is not a "significant energy action" because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. The final rule does not directly regulate energy production or consumption. Changes in the management of hazardous waste pharmaceuticals stipulated in this action are not expected to impact energy production or distribution and will have minimal impact on energy consumptions.

J. National Technology Transfer and Advancement Act

This final rulemaking does not involve technical standards.

K. Executive Order 12898: Environmental Justice

EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation for this decision is contained in the Regulatory Impact Analysis, which can be found at regulations.gov under docket number EPA–HQ–RCRA–2007–0932.

To meet the requirements of Executive Order 12898, EPA analyzed potential environmental justice impacts associated with the diversion of hazardous waste pharmaceuticals from sewer disposal to hazardous waste combustion facilities. Populations living near and downstream from wastewater treatment plants may also benefit from the elimination of sewering of hazardous waste pharmaceuticals. To the extent that minority and/or low-income populations near or downstream from wastewater treatment plants make up a disproportionately high portion of the overall population, this final action may result in positive environmental justice impacts.

Overall, EPA expects that this action may positively affect U.S. environmental justice populations, although the size of the impact will vary by wastewater treatment plant. A reduction in sewering expected under the final rule may benefit relatively large minority and low-income

populations in close proximity to or downstream from wastewater treatment plants. The diversion of hazardous waste pharmaceuticals from wastewater treatment plants to combustion facilities, however, may increase the environmental burden borne by environmental justice populations near these combustion facilities. Although these effects offset each other to a certain degree, the number of minority and low-income individuals near wastewater treatment facilities exceeds the number near hazardous waste combustion facilities. This suggests that, on the whole, the final action may benefit environmental justice populations.

L. Congressional Review Act

EPA will submit a report containing this rule and other information required by the Congressional Review Act (5 U.S.C. 801 et seq.) to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the *Federal Register*. A major rule cannot take effect until sixty (60) days after it is published in the *Federal Register*. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This final authorization will be effective (insert date six months after publication).

List of Subjects

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

40 CFR Part 264

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds.

40 CFR Part 265

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Water supply.

40 CFR Part 266

Environmental protection, Energy, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 268

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 270

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements, Water pollution control, Water supply.

40 CFR Part 273

Environmental protection, Hazardous materials transportation, Hazardous waste.

Dated: December 11, 2018.

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Andrew R. Wheeler

Acting Administrator.

For the reasons stated in the preamble, Title 40, chapter I, of the Code of Federal Regulations is amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

2. Section 261.4 is amended by revising paragraph (a)(1)(ii) to read as follows:

§ 261.4 Exclusions.

(a) * * *

(1) * * *

(ii) Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment, except as prohibited by § 266.505 and Clean Water Act requirements at 40 CFR 403.5(b). "Domestic sewage" means untreated sanitary wastes that pass through a sewer system.

* * * * *

3. Section 261.7 is amended by adding paragraph (c) to read as follows:

§ 261.7 Residues of hazardous waste in empty containers.

* * * * *

(c) Containers of hazardous waste pharmaceuticals are subject to § 266.507 for determining when they are considered empty, in lieu of this section, except as provided by § 266.507(c) and (d).

4. Section 261.33 is amended by:

a. Revising paragraph (c); and

b. Revising the four entries for "P075" in the table in paragraph (e).

The revisions read as follows:

§ 261.33 Discarded commercial chemical products, off-specification species, container residues, and spill residues thereof.

* * * * *

(c) Any residue remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is empty as defined in § 261.7(b) or § 266.507 of this chapter.

[*Comment:* Unless the residue is being beneficially used or reused, or legitimately recycled or reclaimed; or being accumulated, stored, transported or treated prior to such use, re-use, recycling or reclamation, EPA considers the residue to be intended for discard, and thus, a hazardous waste. An example of a legitimate re-use of the residue would be where the residue remains in the container and the container is used to hold the same commercial chemical product or manufacturing chemical intermediate it previously held. An example of the discard of the residue would be where the drum is sent to a drum reconditioner who reconditions the drum but discards the residue.]

* * * * *

(e) * * *

Hazardous waste No.	Chemical abstracts No.	Substance

* * * * * * *		
P075	[1]54−11−5	Nicotine, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies)
* * * * * * *		
P075	[1]54-11-5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies)
* * * * * * *		
P075	[1]54−11−5	Nicotine, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies)
P075	[1]54−11−5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies)
* * * * * * *		

[1]CAS Number given for parent compound only.

* * * * *

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

5. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C 6906, 6912, 6922–6925, 6937, 6938, and 6939g.

6. Section 262.10 is amended by adding paragraphs (m) and (n) to read as follows:

§ 262.10 Purpose, scope and applicability.

* * * * *

(m) All reverse distributors (as defined in § 266.500) are subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

(n) Each healthcare facility (as defined in § 266.500) must determine whether it is subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month (including both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste). A healthcare facility that generates more than 100 kg (220 pounds) of hazardous waste per calendar month, or more than 1 kg (2.2 pounds) of acute hazardous waste per calendar month, or more than 100 kg (220 pounds) per calendar month of any residue or contaminated soil, water, or other debris, resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in § 261.31 or § 261.33(e), is subject to 40 CFR part 266 subpart P for the management of hazardous waste pharmaceuticals in lieu of this part. A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is not subject to part 266 subpart P, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.

7. Section 262.13 is amended by adding paragraph (c)(9) to read as follows:

§ 262.13 Generator category determination.

*** * * * ***

(c) * * *

(9) Is a hazardous waste pharmaceutical, as defined in § 266.500, that is subject to or managed in accordance with 40 CFR part 266 subpart P or is a hazardous waste pharmaceutical that is also a Drug Enforcement Administration controlled substance and is conditionally exempt under § 266.506.

*** * * * ***

8. Section 262.14 is amended by adding paragraphs (a)(5)(ix) and (x) to read as follows:

§ 262.14 Conditions for exemption for a very small quantity generator.

(a) * * *

(5) * * *

(ix) A reverse distributor (as defined in § 266.500), if the hazardous waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical generated by a healthcare facility (as defined in § 266.500).

(x) A healthcare facility (as defined in § 266.500) that meets the conditions in §§ 266.502(l) and 266.503(b), as applicable, to accept non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.

*** * * * ***

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

9. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, 6925, and 6939g.

10. Section 264.1 is amended by adding paragraph (g)(13) to read as follows:

§ 264.1 Purpose, scope and applicability.

*** * * * ***

(g) * * *

(13) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P in lieu of this part

for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

*** * * * ***

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

11. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, 6937, and 6939g.

12. Section 265.1 is amended by adding paragraph (c)(16) to read as follows:

§ 265.1 Purpose, scope, and applicability.

*** * * * ***

(c) * * *

(16) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P in lieu of this part for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

*** * * * ***

PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

13. The authority citation for part 266 continues to read as follows:

Authority: 42 U.S.C. 1006, 2002(a), 3001–3009, 3014, 3017, 6905, 6906, 6912, 6921, 6922, 6924–6927, 6934, and 6937.

Subpart O [Reserved]

14. Add reserved subpart O.

15. Add subpart P, consisting of §§ 266.500 through 266.510, to read as follows:

Subpart P—Hazardous Waste Pharmaceuticals

Sec.

266.500 Definitions for this subpart.
266.501 Applicability.
266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.
266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.
266.504 Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.
266.505 Prohibition of sewering hazardous waste pharmaceuticals.
266.506 Conditional exemption for hazardous waste pharmaceuticals that are also controlled substances and household hazardous waste pharmaceuticals collected in a take-back event or program.
266.507 Residues of hazardous waste pharmaceuticals in empty containers.
266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.
266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.
266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors.

Subpart P—Hazardous Waste Pharmaceuticals

§ 266.500 Definitions for this subpart.

The following definitions apply to this subpart:

Evaluated hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with §

266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.

Hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261 subpart D. A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

Healthcare facility means any person that is lawfully authorized to—

(1) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

(2) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and

veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Household waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1).

Long-term care facility means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

Non-creditable hazardous waste pharmaceutical means 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.

Non-hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C.

Non-pharmaceutical hazardous waste means a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical, as defined in this section.

Pharmaceutical means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials). This definition includes, but is not limited to, dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act; prescription drugs, as defined by 21 CFR 203.3(y); over-the-counter drugs; homeopathic drugs; compounded drugs; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

Potentially creditable hazardous waste pharmaceutical means 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.

Reverse distributor means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-

party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

§ 266.501 Applicability.

(a) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is *not* subject to this subpart, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.

(b) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, has the option of complying with § 266.501(d) for the management of its hazardous waste pharmaceuticals as an alternative to complying with § 262.14 and the optional provisions of § 266.504.

(c) A healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste.

(d) With the exception of healthcare facilities identified in paragraph (a) of this section, a healthcare facility is subject to the following in lieu of parts 262 through 265:

(1) Sections 266.502 and 266.505 through 266.508 of this subpart with respect to the management of:

(i) Non-creditable hazardous waste pharmaceuticals, and

(ii) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a reverse distributor.

(2) Sections 262.502(a), 266.503, 266.505 through 266.507, and 266.509 of this subpart with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor.

(e) A reverse distributor is subject to §§ 266.505 through 266.510 of this subpart in lieu of parts 262 through 265 with respect to the management of hazardous waste pharmaceuticals.

(f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (e.g., pharmaceutical manufacturers and reverse logistics centers) are not subject to this subpart. Other generators are subject to 40 CFR part 262 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

(g) The following are not subject to 40 CFR parts 260 through 273, except as specified:

(1) Pharmaceuticals that are not solid waste, as defined by § 261.2, because they are legitimately used/reused (e.g., lawfully donated for their intended purpose) or reclaimed.

(2) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as defined by § 261.2, because they have a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for their intended purpose) or reclaimed.

(3) Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with 21 CFR part 7 subpart C. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

(4) Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR part 1115. This subpart does apply to the management of the recalled hazardous waste

pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

(5) Pharmaceuticals stored according to a preservation order, or during an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded and/or a decision is made to discard the pharmaceuticals.

(6) Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR part 312. This subpart does apply to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

(7) Household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the Drug Enforcement Administration), provided the authorized collector complies with the conditional exemption in §§ 266.506(a)(2) and 266.506(b).

§ 266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

(a) *Notification and withdrawal from this subpart for healthcare facilities managing hazardous waste pharmaceuticals*—(1) *Notification.* A healthcare facility must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), that it is a healthcare facility operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each site or EPA identification number.

(i) A healthcare facility that already has an EPA identification number must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A healthcare facility that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(iii) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to this subpart.

(2) *Withdrawal.* A healthcare facility that operated under this subpart but is no longer subject to this subpart, because it is a very small quantity generator under § 262.14, and elects to withdraw from this subpart, must notify the appropriate EPA Regional Administrator using the Site Identification Form (EPA Form 8700-12) that it is no longer operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each EPA identification number.

(i) A healthcare facility must submit the Site Identification Form notifying that it is withdrawing from this subpart before it begins operating under the conditional exemption of § 262.14.

(ii) A healthcare facility must keep a copy of its withdrawal on file for three years from the date of signature on the notification of its withdrawal.

(b) *Training of personnel managing non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must ensure 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.

(c) *Hazardous waste determination for non-creditable pharmaceuticals.* A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical (i.e., it exhibits a characteristic identified in 40 CFR part 261 subpart C or is listed in 40 CFR part 261 subpart D) in order to determine whether the waste is subject to this subpart. A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under this subpart.

(d) *Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(2) A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or that mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(i) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(iv) Damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or

(v) Through other like means threaten human health or the environment.

(3) A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(4) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and non-hazardous non-creditable waste pharmaceuticals in the same container, except that non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of § 268.3(c) must be accumulated in separate containers and labeled with all applicable hazardous waste numbers (i.e., hazardous waste codes).

(e) *Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals."

(f) *Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on site for one year or less without a permit or having interim status.

(2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the non-creditable hazardous

waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(i) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that the non-creditable hazardous waste pharmaceuticals became a waste;

(ii) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste;

(iii) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

(g) *Land disposal restrictions for non-creditable hazardous waste pharmaceuticals*. The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of 40 CFR part 268. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with § 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (i.e., hazardous waste codes) on the land disposal restrictions notification.

(h) *Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals.* A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter may accumulate the returned non-creditable hazardous waste pharmaceuticals on site for up to an additional 90 days provided the rejected or returned shipment is managed in

accordance with paragraphs (d) and (e) of this section. Upon receipt of the returned shipment, the healthcare facility must:

(1) Sign either:

(i) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(2) Provide the transporter a copy of the manifest;

(3) Within 30 days of receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(4) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of § 266.508(a).

(i) *Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals*—(1) *Biennial reporting by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41, with respect to non-creditable hazardous waste pharmaceuticals managed under this subpart.

(2) *Exception reporting by healthcare facilities for a missing copy of the manifest*—(i) *For shipments from a healthcare facility to a designated facility*. (A) If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located; and

(*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) [Reserved]

(ii) *For shipments rejected by the designated facility and shipped to an alternate facility*. (A) If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within 60 days of the date the non-creditable hazardous waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located; and

(*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) [Reserved]

(3) *Additional reports.* The EPA Regional Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(j) *Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals.* (1) A healthcare facility must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

(2) A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

(3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) consistent with § 262.11(f), for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal. A healthcare facility that manages all of its non-creditable non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals is not required to keep documentation of hazardous waste determinations.

(4) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(5) All records must be readily available upon request by an inspector.

(k) *Response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must immediately contain all spills of non-creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with the requirements of this subpart.

(l) *Accepting non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.* A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person (as defined in § 260.10) as the very small quantity generator healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off-site ("control," for the purposes of this section, means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on behalf of a different person as defined in § 260.10 of this chapter shall not be deemed to "control" such healthcare facilities) or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) Is operating under this subpart for the management of its non-creditable hazardous waste pharmaceuticals;

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

§ 266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

(a) *Hazardous waste determination for potentially creditable pharmaceuticals.* A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical (i.e., it is listed in 40 CFR part 261 subpart D or exhibits a characteristic identified in 40 CFR part 261 subpart C). A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this subpart.

(b) *Accepting potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator.* A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the very small quantity generator healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the very small quantity generator healthcare facility;

(2) Is operating under this subpart for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

(c) *Prohibition.* Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(d) *Biennial Reporting by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

(e) *Recordkeeping by healthcare facilities.* (1) 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 of potentially creditable hazardous waste pharmaceuticals for three years from the date of shipment:

(i) The confirmation of delivery; and

(ii) The shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

(2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(3) All records must be readily available upon request by an inspector.

(f) *Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with this subpart.

§ 266.504 Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.

(a) *Potentially creditable hazardous waste pharmaceuticals.* A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(b) *Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a very small quantity generator.* A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided:

(1) The receiving healthcare facility meets the conditions in § 266.502(l) of this subpart and § 266.503(b), as applicable; or

(2) The very small quantity generator healthcare facility meets the conditions in § 262.14(a)(5)(viii) and the receiving large quantity generator meets the conditions in § 262.17(f).

(c) *Long-term care facilities that are very small quantity generators.* A long-term care facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

(d) *Long-term care facilities with 20 beds or fewer.* A long-term care facility with 20 beds or fewer is presumed to be a very small quantity generator subject to § 262.14 for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and *not* subject to

this subpart, except for §§ 266.505 and 266.507 and the other optional provisions of this section. The EPA Regional Administrator has the responsibility to demonstrate that a long-term care facility with 20 beds or fewer generates quantities of hazardous waste that are in excess of the very small quantity generator limits as defined in § 260.10. A long-term care facility with more than 20 beds that operates as a very small quantity generator under § 262.14 must demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by § 260.10.

§ 266.505 Prohibition of sewering hazardous waste pharmaceuticals.

All healthcare facilities—including very small quantity generators operating under § 262.14 in lieu of this subpart—and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b)(1).

§ 266.506 Conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected in a take-back event or program.

(a) *Conditional exemptions.* Provided the conditions of paragraph (b) of this section are met, the following are exempt from 40 CFR parts 262 through 273:

(1) Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308, and

(2) Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the

household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration).

(b) *Conditions for exemption.* The hazardous waste pharmaceuticals must be:

(1) Managed in compliance with the sewer prohibition of § 266.505; and

(2) Collected, stored, transported, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances; and

(3) Destroyed by a method that Drug Enforcement Administration has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the following:

(i) A permitted large municipal waste combustor, subject to 40 CFR part 62 subpart FFF or applicable state plan for existing large municipal waste combustors, or 40 CFR part 60 subparts Eb for new large municipal waste combustors; or

(ii) A permitted small municipal waste combustor, subject to 40 CFR part 62 subpart JJJ or applicable state plan for existing small municipal waste combustors, or 40 CFR part 60 subparts AAAA for new small municipal waste combustors; or

(iii) A permitted hospital, medical and infectious waste incinerator, subject to 40 CFR part 62 subpart HHH or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 CFR part 60 subpart Ec for new hospital, medical and infectious waste incinerators.

(iv) A permitted commercial and industrial solid waste incinerator, subject to 40 CFR part 62 subpart III or applicable state plan for existing commercial and industrial solid waste incinerators, or 40 CFR part 60 subpart CCCC for new commercial and industrial solid waste incinerators.

(v) A permitted hazardous waste combustor subject to 40 CFR part 63 subpart EEE.

§ 266.507 Residues of hazardous waste pharmaceuticals in empty containers.

(a) *Stock, dispensing and unit-dose containers.* A stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (e.g., a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

(b) *Syringes.* A syringe is considered empty and the residues are not regulated as hazardous waste under this subpart provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is not empty, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart and any applicable federal, state, and local requirements for sharps containers and medical waste.

(c) *Intravenous (IV) bags.* An IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. If an IV bag is not empty, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart, unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty as defined in § 261.7(b)(1).

(d) *Other containers, including delivery devices.* Hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable hazardous waste pharmaceuticals under this subpart, unless

the container held non-acute hazardous waste pharmaceuticals and is empty as defined in § 261.7(b)(1) or (2). This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

§ 266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.

(a) *Shipping non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* A healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with:

(1) The following pre-transport requirements, before transporting or offering for transport off-site:

(i) *Packaging.* Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR parts 173, 178, and 180.

(ii) *Labeling.* Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172 subpart E.

(iii) *Marking.* (A) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable Department of Transportation (DOT) regulations on hazardous materials under 49 CFR part 172 subpart D;

(B) Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Reverse distributor's Name and Address _____.

Healthcare Facility's or Reverse distributor's EPA Identification Number_____.

Manifest Tracking Number _____.

(C) Lab packs that will be incinerated in compliance with § 268.42(c) are not required to be marked with EPA Hazardous Waste Number(s), except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(iv) *Placarding.* Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR part 172 subpart F.

(2) The manifest requirements of 40 CFR part 262 subpart B, except that:

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable hazardous waste numbers (i.e., hazardous waste codes) in Item 13 of EPA Form 8700-22.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the word "PHARMS" in Item 13 of EPA Form 8700-22.

(b) *Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* A healthcare facility or reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262 subpart H.

(c) *Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262 subpart H. A healthcare facility or reverse distributor may not accept imported non-creditable hazardous waste

pharmaceuticals or evaluated hazardous waste pharmaceuticals unless they have a permit or interim status that allows them to accept hazardous waste from off site.

§ 266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.

(a) *Shipping potentially creditable hazardous waste pharmaceuticals.* A healthcare facility or a reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a reverse distributor must comply with all applicable U.S. Department of Transportation regulations in 49 CFR part 171 through 180 for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 CFR 171.8. For purposes of the Department of Transportation regulations, a material is considered a hazardous waste if it is subject to the Hazardous Waste Manifest Requirements of the U.S. Environmental Protection Agency specified in 40 CFR part 262. Because a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under the Department of Transportation regulations.

(b) *Delivery confirmation.* Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived at its destination and is under the custody and control of the reverse distributor.

(c) *Procedures for when delivery confirmation is not received within 35 calendar days.* If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within 35 calendar days from the date that the shipment of potentially creditable hazardous waste

pharmaceuticals was sent, the healthcare facility or reverse distributor that initiated the shipment must contact the carrier and the intended recipient (i.e., the reverse distributor) promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) *Exporting potentially creditable hazardous waste pharmaceuticals.* A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the applicable sections of 40 CFR part 262 subpart H, except the manifesting requirement of § 262.83(c), in addition to paragraphs (a) through (c) of this section.

(e) *Importing potentially creditable hazardous waste pharmaceuticals.* Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to paragraphs (a) through (c) of this section in lieu of 40 CFR part 262 subpart H. Immediately after the potentially creditable hazardous waste pharmaceuticals enter the United States, they are subject to all applicable requirements of this subpart.

§ 266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors.

A reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on site without a hazardous waste permit or without having interim status, provided that it complies with the following conditions:

(a) *Standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals*—(1) *Notification.* A reverse

distributor must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), that it is a reverse distributor operating under this subpart.

(i) A reverse distributor that already has an EPA identification number must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), that it is a reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A reverse distributor that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), that it is a reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(2) *Inventory by the reverse distributor.* A reverse distributor must maintain a current inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on site.

(i) A reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of each waste arriving at the reverse distributor.

(ii) The inventory must include the identity (e.g., name or national drug code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(iii) If the reverse distributor already meets the inventory requirements of this paragraph because of other regulatory requirements, such as State Board of Pharmacy regulations, the facility is not required to provide a separate inventory pursuant to this section.

(3) *Evaluation by a reverse distributor that is not a manufacturer.* A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste

pharmaceutical within 30 calendar days of the waste arriving at the reverse distributor to establish whether it is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

(i) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a "potentially creditable hazardous waste pharmaceutical" and must be managed in accordance with paragraph (b) of this section.

(ii) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim status treatment, storage or disposal facility is considered an "evaluated hazardous waste pharmaceutical" and must be managed in accordance with paragraph (c) of this section.

(4) *Evaluation by a reverse distributor that is a manufacturer.* A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 calendar days of the waste arriving at the facility and following the evaluation must manage the evaluated hazardous waste pharmaceuticals in accordance with paragraph (c) of this section.

(5) *Maximum accumulation time for hazardous waste pharmaceuticals at a reverse distributor.* (i) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for 180 calendar days or less. The 180 days start after the potentially creditable hazardous waste pharmaceutical has been evaluated and applies to all hazardous waste pharmaceuticals accumulated on site, regardless of whether they are destined for another reverse distributor (i.e., potentially creditable hazardous

waste pharmaceuticals) or a permitted or interim status treatment, storage, or disposal facility (i.e., evaluated hazardous waste pharmaceuticals).

(ii) *Aging pharmaceuticals.* Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (i.e., aging in a holding morgue) can be accumulated for up to 180 days after the expiration date, provided that the unexpired pharmaceuticals are managed in accordance with paragraph (a) of this section and the container labeling and management standards in 266.510(c)(4)(i) through (vi).

(6) *Security at the reverse distributor facility.* A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(i) Examples of methods that may be used to prevent unknowing entry and minimize the possibility for unauthorized entry include, but are not limited to:

(A) A 24-hour continuous monitoring surveillance system;

(B) An artificial barrier such as a fence; or

(C) A means to control entry, such as keycard access.

(ii) If the reverse distributor already meets the security requirements of this paragraph because of other regulatory requirements, such as Drug Enforcement Administration or State Board of Pharmacy regulations, the facility is not required to provide separate security measures pursuant to this section.

(7) *Contingency plan and emergency procedures at a reverse distributor*. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off site must

prepare a contingency plan and comply with the other requirements of 40 CFR part 262 subpart M.

(8) *Closure of a reverse distributor.* When closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor must comply with § 262.17(a)(8)(ii) and (iii).

(9) *Reporting by a reverse distributor*—(i) *Unauthorized waste report.* A reverse distributor must submit an unauthorized waste report if the reverse distributor receives waste from off site that it is not authorized to receive (e.g., non-pharmaceutical hazardous waste, regulated medical waste). The reverse distributor must prepare and submit an unauthorized waste report to the EPA Regional Administrator within 45 calendar days after the unauthorized waste arrives at the reverse distributor and must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor, or its authorized representative, and contain the following information:

(A) The EPA identification number, name and address of the reverse distributor;

(B) The date the reverse distributor received the unauthorized waste;

(C) The EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

(D) A description and the quantity of each unauthorized waste the reverse distributor received;

(E) The method of treatment, storage, or disposal for each unauthorized waste; and

(F) A brief explanation of why the waste was unauthorized, if known.

(ii) *Additional reports.* The EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(10) *Recordkeeping by reverse distributors.* A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(i) A copy of its notification on file for as long as the facility is subject to this subpart;

(ii) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years from the date the shipment arrives at the reverse distributor;

(iii) A copy of its current inventory for as long as the facility is subject to this subpart.

(b) *Additional standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor.* A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in paragraph (a) of this section, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

(1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 days after the potentially

creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(3) A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with § 266.509.

(4) *Recordkeeping by reverse distributors.* A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three years from the date of shipment. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(i) The confirmation of delivery; and

(ii) The DOT shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable

(c) *Additional standards for reverse distributors managing evaluated hazardous waste pharmaceuticals.* A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of paragraph (a) of this section, for the management of evaluated hazardous waste pharmaceuticals:

(1) *Accumulation area at the reverse distributor.* A reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

(2) *Inspections of on-site accumulation area.* A reverse distributor must inspect its on-site accumulation area at least once every seven days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

(3) *Personnel training at a reverse distributor.* Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of § 262.17(a)(7).

(4) *Labeling and management of containers at on-site accumulation areas.* A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must:

(i) Label the containers with the words, "hazardous waste pharmaceuticals";

(ii) Ensure the containers are in good condition and managed to prevent leaks;

(iii) Use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(iv) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(v) Manage any container of ignitable or reactive evaluated hazardous waste pharmaceuticals, or any container of commingled incompatible evaluated hazardous waste pharmaceuticals so that the container does not have the potential to:

(A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(E) Through other like means threaten human health or the environment; and

(vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) (e.g., arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

(5) *Hazardous waste numbers.* Prior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable hazardous waste numbers (i.e., hazardous waste codes). A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(6) *Shipments.* A reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in § 266.508(a) or (b).

(7) *Procedures for a reverse distributor for managing rejected shipments.* A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and

later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter, may accumulate the returned evaluated hazardous waste pharmaceuticals on site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with § 266.510(a) and (c). Upon receipt of the returned shipment, the reverse distributor must:

(i) Sign either:

(A) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(B) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within 30 days of receipt of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

(iv) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of § 266.508(a) or (b).

(8) *Land disposal restrictions*. Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of 40 CFR part 268. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off site must comply with the land disposal restrictions in accordance with § 268.7(a) requirements.

(9) *Reporting by a reverse distributor for evaluated hazardous waste pharmaceuticals*—

(i) *Biennial reporting by a reverse distributor*. A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of a biennial

report to the EPA Regional Administrator by March 1 of each even numbered year in accordance with § 262.41.

(ii) *Exception reporting by a reverse distributor for a missing copy of the manifest*.

(A) *For shipments from a reverse distributor to a designated facility*. (*1*) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(*2*) A reverse distributor must submit an exception report to the EPA Regional Administrator for the Region in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

(*i*) A legible copy of the manifest for which the reverse distributor does not have confirmation of delivery; and

(*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(B*) For shipments rejected by the designated facility and shipped to an alternate facility*. (*1*) A reverse distributor that does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or the

owner or operator of the alternate facility to determine the status of the hazardous waste. The 35-day time frame begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

(*2*) A reverse distributor must submit an Exception Report to the EPA Regional Administrator for the Region in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the alternate facility within 45 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The 45-day timeframe begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste pharmaceutical shipment from the designated facility to the alternate facility. The Exception Report must include:

(*i*) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(10) *Recordkeeping by a reverse distributor for evaluated hazardous waste pharmaceuticals.* (i) A reverse distributor must keep a log (written or electronic) of the inspections of the on-site accumulation area, required by paragraph (c)(2) of this section. This log must be retained as a record for at least three years from the date of the inspection.

(ii) A reverse distributor must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility that

received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(iii) A reverse distributor must keep a copy of each biennial report for at least three years from the due date of the report.

(iv) A reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(v) A reverse distributor must keep records to document personnel training, in accordance with § 262.17(a)(7)(iv).

(vi) All records must be readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(d) *When a reverse distributor must have a permit*. A reverse distributor is an operator of a hazardous waste treatment, storage, or disposal facility and is subject to the requirements of 40 CFR parts 264, 265, and 267 and the permit requirements of 40 CFR part 270, if the reverse distributor:

(1) Does not meet the conditions of this section;

(2) Accepts manifested hazardous waste from off site; or

(3) Treats or disposes of hazardous waste pharmaceuticals on site.

PART 268—LAND DISPOSAL RESTRICTIONS

16. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

17. Section 268.7 is amended by revising the section heading and the paragraph (a) subject heading to read as follows:

§ 268.7 Testing, tracking, and recordkeeping requirements for generators, reverse distributors, treaters, and disposal facilities.

(a) *Requirements for generators and reverse distributors*. * * *

* * * * *

18. Section 268.50 is amended by adding paragraphs (a)(4) and (5) to read as follows:

§ 268.50 Prohibitions on storage of restricted wastes.

(a) * * *

(4) A healthcare facility accumulates such wastes in containers on site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the healthcare facility complies with the applicable requirements in §§ 266.502 and 266.503 of this chapter.

(5) A reverse distributor accumulates such wastes in containers on site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the reverse distributor complies with § 266.510 of this chapter.

* * * * *

PART 270—EPA ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM

19. The authority citation for part 270 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974

20. Section 270.1 is amended by adding paragraph (c)(2)(x) to read as follows:

§ 270.1 Purpose and scope of these regulations.

*** * * * ***

(c) * * *

(2) * * *

(x) Reverse distributors accumulating potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals, as defined in § 266.500. Reverse distributors are subject to regulation under 40 CFR part 266 subpart P for the accumulation of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

*** * * * ***

PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT

21. The authority citation for part 273 continues to read as follows:

Authority: 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

22. Section 273.80 is amended by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 273.80 General.

(a) Except as provided in paragraph (d) of this section, any person seeking to add a hazardous waste or category of hazardous waste to this part may petition for a regulatory amendment under this subpart and 40 CFR 260.20 and 260.23.

* * * * *

(d) Hazardous waste pharmaceuticals are regulated by 40 CFR part 266 subpart P and may not be added as a category of hazardous waste for management under this part.

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