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 August 21, 2019.

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* website. 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.*

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SUPPLEMENTARY INFORMATION:

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The information presented in this preamble is organized as follows:

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

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.

[1] EPA–HQ–RCRA–2007–0932.

TABLE 1—NAICS CODES OF ENTITIES POTENTIALLY AFFECTED BY THIS FINAL RULE: HEALTHCARE FACILITIES AND REVERSE DISTRIBUTORS—Continued

NAICS codes	Description of NAICS code
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 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 $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
E.O. Executive Order
FDA Food and Drug Administration

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

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

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. 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 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

[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.

[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)).

[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.

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.

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 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

[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.

[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.*

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

creditable hazardous waste pharmaceuticals, EPA proposed flexibilities for some of the regulatory 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 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 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.

(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.

[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.

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

[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).

[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.*

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 *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."

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 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 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-

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

[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.

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

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

[24] *https://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf.*

[25] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3880486/.*

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. 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 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 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

[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*).

[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.*

[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.

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 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 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 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 reclassification or exemption of these

[31] See 78 FR 19718; April 2, 2013.

[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.

[35] See letter from Barnes Johnson, USEPA to Scott DeMuth, g2 Revolution, LLC., dated May 8, 2015, RCRAOnline #14851.

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

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 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.

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

[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.*

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

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

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 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 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 items,

[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.

[47] February 14, 2014 (79 FR 8926).

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 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 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 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

[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.

[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).

[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.

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 (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 precious 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 n.16 (D.C. 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 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, liquidate, or reclaim nonprescription pharmaceuticals that are sent through reverse logistics. However, commenters did confirm that prescription pharmaceuticals are in

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

[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.

[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.*

[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).

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 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 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.

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

[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.

[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 returned 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."

[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.

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 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 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 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

[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.*

[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.

[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.

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 1991 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 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

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

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

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 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 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 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 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

[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.

[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.*

[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.*

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.

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 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

[84] See 15 U.S.C. 1471–1477 for the Poison Prevention Packaging Act.

[85] Public Law 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.

[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."

[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.

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 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 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.

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

[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.

[93] See comment number EPA–HQ–RCRA–2007–0932–0277 in the docket for this rulemaking.

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

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 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 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

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

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

[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).

[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.

[102] See 21 CFR part 1308 for a complete list of controlled substances.

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 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 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 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

[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).

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

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

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

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 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 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 subsections 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.

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 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

[108] Public Law 113–54.

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

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

[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).

[113] Morton v. Macari, 417 U.S. 535, 551(1974).

[114] The DSCSA uses the term "drug product."

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 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 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]

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

[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.

[116] See 42 U.S.C. 6902(b).

[117] August 2017, docket number FDA–2017–D–1956.

[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.

[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: 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 ≤ 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 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

[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.*

[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.*

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 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 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]

The American Dental Association asked that EPA specifically exclude

[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.

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

[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).

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 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 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 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

[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).

[142] See 21 CFR 201.66

[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.*

[146] See 21 CFR 101.36.

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. 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 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 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).

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

[147] 82 FR 27154; June 14, 2017.

[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.

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

[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).

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 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

[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.

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 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 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

[157] Healthcare Distribution Management Association has since been renamed Healthcare Distribution Alliance.

[158] See comment #EPA–HQ–RCRA–2007–0932–0276.

[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.

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 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

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

[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."

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

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 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

[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.*

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 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 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.

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

[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.

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 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 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 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.

[167] See 21 CFR 1300.01.

[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).

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

[173] See commenter EPA–HQ–RCRA–2007–0932–0289.

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 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.

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 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

[174] 49 FR 44978; November 13, 1984.

[175] See RCRA Online #13736, March 1995.

[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".

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

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 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

[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.

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

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 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]

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

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

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 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 reverse 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

[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.

[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.

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 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 § 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.

[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.

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 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 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

[185] See comment number: EPA–HQ–RCRA–2007–0932–0280.

[186] See comment number: EPA–HQ–RCRA–2007–0932–0231.

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

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 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.

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

[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.*

[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.

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, 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 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

[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.

[195] See 21 CFR 312.59.

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 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

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

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.

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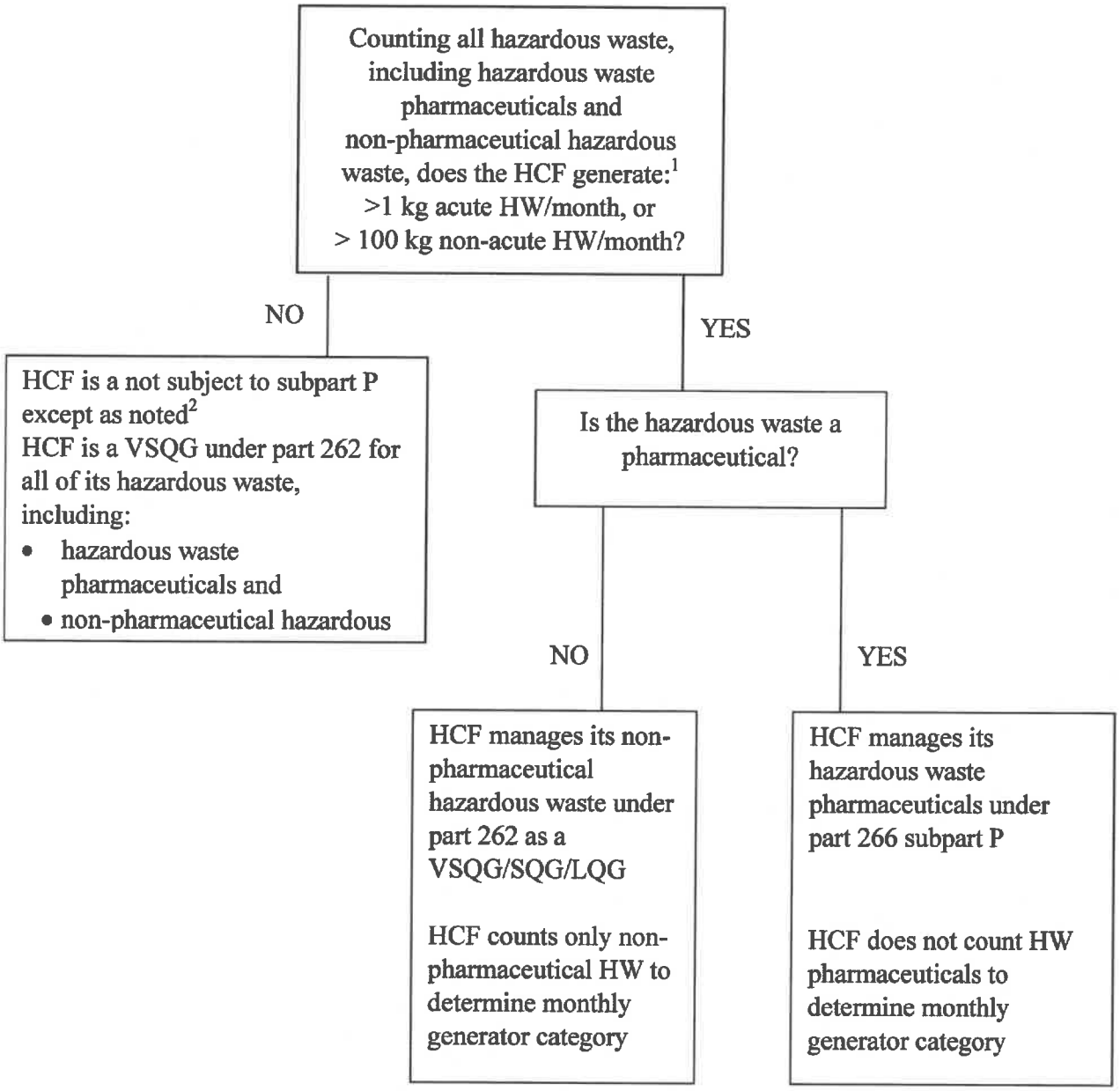
Diagram 1: When is a Healthcare Facility Subject to Part 266 Subpart P?



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

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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

[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.

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.

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 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 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.

[200] § 262.16(b)(9)(iii)

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

[202] 40 CFR part 273.16.

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] and

[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.

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]

[204] Hazardous Waste Pharmaceuticals Wiki. *http://hwpharms.wikispaces.com.* Wiki spaces 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.*

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. 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 are as").

[206] EPA makes no claims, promises, or guarantees about the accuracy, completeness, or adequacy of the contents of these sites.

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, 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 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.

[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.*

[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.*

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 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.

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

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.

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

[211] See comment number EPA–HQ–RCRA–2007–0932–0216.

[212] § 268.3 (c) Dilution prohibited as a substitute for treatment.

[213] § 266.506.

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

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

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 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

[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.

[218] Final rule: November 28, 2016; 81 FR 85808.

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 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 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 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

[219] Smith, Charlotte A. "Managing Pharmaceutical Waste: A New Implementation Blueprint." Pharmacy Practice News, Special Edition, 2011.

[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.

[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.

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 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

[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.

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 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 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

[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.

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

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 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

[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.

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 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 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

[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).

[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.

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

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 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

[232] As allowed by 40 CFR 266.504(a).

[233] *https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html.*

[234] *https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance.html.*