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40 CFR Parts 261, 262, 266, *et al.*
Management Standards for Hazardous Waste Pharmaceuticals; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 261, 262, 266, 268, and 273

[EPA–HQ–RCRA–2007–0932; FRL–9924–08–OSWER]

RIN 2050–AG39

Management Standards for Hazardous Waste Pharmaceuticals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Some pharmaceuticals are regulated as hazardous waste under the Resource Conservation and Recovery Act (RCRA) when discarded. Healthcare facilities that generate hazardous waste pharmaceuticals as well as associated facilities have reported difficulties complying with the Subtitle C hazardous waste regulations for a number of reasons. First, healthcare workers, whose primary focus is to provide care for patients, are not knowledgeable about the RCRA hazardous waste regulations, but are often involved in the implementation of the regulations. Second, a healthcare facility can have thousands of items in its formulary, making it difficult to ascertain which ones are hazardous wastes when disposed. Third, some active pharmaceutical ingredients are listed as acute hazardous wastes, which are regulated in small amounts. To facilitate compliance and to respond to these concerns, the U.S. Environmental Protection Agency (EPA or the Agency) is proposing to revise the regulations to improve the management and disposal of hazardous waste pharmaceuticals and tailor them to address the specific issues that hospitals, pharmacies and other healthcare-related facilities face. The revisions are also intended to clarify the regulation of the reverse distribution mechanism used by healthcare facilities for the management of unused and/or expired pharmaceuticals.

DATES: Comments must be received on or before November 24, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–RCRA–2007–0932, to the *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

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SUPPLEMENTARY INFORMATION:

I. General Information

Does this action apply to me?

This is a proposed rule. If finalized, this rule would apply to healthcare facilities, pharmaceutical reverse distributors, and owners or operators of treatment, storage, and disposal facilities engaged in the management of hazardous waste pharmaceuticals. The list of NAICS codes for the potentially affected entities, other than RCRA treatment, storage and disposal facilities (TSDFs), are presented in Table 1. More detailed information on the potentially affected entities is presented in Section V.A and Section V.B.1 of this preamble.

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

NAICS codes	Description of NAICS code
44611	Pharmacies.
54194	Veterinary Clinics.
6211	Physicians' Offices.
6212	Dentists' Offices.
6213	Other Health Practitioners (*e.g.,* chiropractors).
6214	Outpatient Care Centers.
6219	Other Ambulatory Health Care Services.
622	Hospitals.
6231	Nursing Care Facilities (*e.g.,* assisted living facilities, nursing homes, U.S. veterans domiciliary centers).
623311	Continuing Care Retirement Communities (*e.g.,* assisted living facilities with on-site nursing facilities).
Subset of 92219	Medical Examiners and Coroners' Offices.
Various NAICS	Pharmaceutical 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 of which EPA is aware that 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.

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G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act (NTTAA)
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

I. Statutory Authority

These regulations are proposed under the authority of §§ 2002, 3001, 3002, and 3004 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. 6921, 6922, 6923, and 6924.

II. List of Abbreviations and Acronyms

AARP American Association of Retired Persons
AEA Atomic Energy Act
API Active Pharmaceutical Ingredient
BDAT Best Demonstrated Available Technology
CERCLA Comprehensive Environmental Response, Compensation and Liability Act
CESQG Conditionally Exempt Small Quantity Generator
CFR Code of Federal Regulations
CSA Controlled Substances Act
CWA Clean Water Act
DEA Drug Enforcement Administration
DHHS Department of Health and Human Services
DOE Department of Energy
DOT Department of Transportation
EPA Environmental Protection Agency
EO Executive Order
FDA U.S. Food and Drug Administration
FR Federal Register
HIPAA Health Insurance Portability and Accountability Act
HSWA Hazardous and Solid Waste Amendments
LQG Large Quantity Generator
LQUWH Large Quantity Universal Waste Handler
LTCF Long-term Care Facility
LTCP Long-term Care Pharmacy
MSWLF Municipal Solid Waste Landfill
NIOSH National Institute for Occupational Safety and Health
NPRM Notice of Proposed Rulemaking
NRC Nuclear Regulatory Commission
OIG Office of Inspector General
OMB Office of Management and Budget
ONDCP Office of National Drug Control Policy
OSHA U.S. Department of Labor's 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
RQ Reportable Quantity
SQG Small Quantity Generator
SQUWH Small Quantity Universal Waste Handler
SWDA Solid Waste Disposal Act
TC Toxicity Characteristic
TCLP Toxicity Characteristic Leaching Procedure
TSDF Treatment, Storage and Disposal Facility

III. Summary of the Proposed Rule

EPA is proposing to add a subpart P under 40 CFR part 266. Part 266 is entitled, ''Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities.'' This new subpart P is a tailored, sector-specific regulatory framework for managing hazardous waste pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors. If finalized, healthcare facilities that are currently small quantity generators (SQGs) or large quantity generators (LQGs) and all pharmaceutical reverse distributors, regardless of their RCRA generator category, will be required to manage their hazardous waste pharmaceuticals under subpart P of 40 CFR part 266, instead of 40 CFR part 262. That is, the proposed standards are not an optional alternative to managing hazardous waste pharmaceuticals under 40 CFR part 262; they are mandatory standards.

Briefly, healthcare facilities will have different management standards for their non-creditable and creditable hazardous waste pharmaceuticals. Non-creditable hazardous waste pharmaceuticals (*i.e.,* those that are not expected to be eligible to receive manufacturer's credit) will be managed on-site similar to how they would have been under a previous proposal for managing these wastes: The 2008 Universal Waste proposal for pharmaceutical waste (73 FR 73520; December 2, 2008). When shipped off-site, they must be transported as hazardous wastes, including the use of the hazardous waste manifest, and sent to a RCRA interim status or permitted facility. On the other hand, healthcare facilities will continue to be allowed to send potentially creditable hazardous waste pharmaceuticals to pharmaceutical reverse distributors for processing manufacturers' credit. In response to comments received on the Universal Waste proposal, EPA is proposing standards to ensure the safe and secure delivery of the creditable

hazardous waste pharmaceuticals to pharmaceutical reverse distributors.

EPA is also proposing standards for the accumulation of the creditable hazardous waste pharmaceuticals at pharmaceutical reverse distributors. Like healthcare facilities, pharmaceutical reverse distributors will not be regulated under 40 CFR part 262 as hazardous waste generators, nor will they be regulated under 40 CFR parts 264, 265 and 270 as treatment, storage, and disposal facilities (TSDFs). Rather, the proposal establishes a new category of hazardous waste entity, called pharmaceutical reverse distributors. The proposed standards for pharmaceutical reverse distributors are, in many respects, similar to the LQGs standards, with supplementary standards added to respond to commenters' concerns.

For both healthcare facilities and reverse distributors, EPA is proposing to prohibit facilities from disposing of hazardous waste pharmaceuticals down the toilet or drain (*i.e*, flushed or sewered). Further, EPA proposes that hazardous waste pharmaceuticals managed under subpart P will not be counted toward calculating the site's generator category. Additionally, EPA is proposing a conditional exemption for hazardous waste pharmaceuticals that are also DEA controlled substances. Finally, EPA is proposing management standards for hazardous waste pharmaceutical residues remaining in containers.

IV. Background

A. What is the history of hazardous waste pharmaceutical management under RCRA?

1. What Is the Resource Conservation and Recovery Act?

The Resource Conservation and Recovery Act governs the management and disposal of hazardous wastes.[1] Under Subtitle C of RCRA, EPA has established a comprehensive set of regulations for hazardous waste management, generation, transportation, treatment, storage, and disposal. EPA can authorize an individual state hazardous waste program to operate in lieu of the federal program provided the authorized state's program is at least as stringent as, and consistent with, the federal program.[2] However, EPA maintains oversight of the authorized state's hazardous waste program and the authority to take independent enforcement actions. RCRA regulates pharmaceutical wastes that meet a listing of hazardous waste or exhibit one or more characteristics of hazardous waste. Accordingly, hospitals, pharmacies, reverse distributors and other healthcare-related establishments that generate hazardous wastes, including hazardous waste pharmaceuticals, are required to manage and dispose of their hazardous wastes in accordance with applicable federal, state, and/or local environmental regulations.

2. What are the current standards for generators of hazardous waste?

Currently, there are no RCRA Subtitle C regulations that focus specifically on the management of hazardous wastes from hospitals, pharmacies, reverse distributors and other healthcare-related facilities. Rather, healthcare facilities are currently required to comply with the same RCRA hazardous waste regulations as many other industries that generate hazardous waste. While the RCRA Subtitle C program has requirements for all aspects of hazardous waste management, including those generating (referred to as ''generators'' by RCRA), transporting, storing, treating, and disposing of hazardous wastes, it is the generator requirements found under 40 CFR part 262 that will typically be most pertinent to healthcare-related facilities.

Under the federal RCRA regulations, the standards for hazardous waste generators are divided into three categories—LQGs, SQGs, and Conditionally Exempt Small Quantity Generators (CESQGs) depending upon the total amount of hazardous waste a facility generates per calendar month. It is the facility's generator category that determines the applicable RCRA hazardous waste management requirements with which the generator must comply.[3]

A generator that generates a solid waste[4] is required by § 262.11 to determine whether such waste meets the definition of RCRA hazardous waste.[5] If the waste meets the RCRA definition of a hazardous waste, then the generator must manage the waste in accordance with the regulations that apply to its hazardous waste generator category (see § 261.5 and 40 CFR part 262 for the generator regulations). In particular:

- Facilities qualify as LQGs if in a calendar month they generate 1,000 kg or more of hazardous waste or more than 1 kg of acute hazardous waste (*i.e.,* P-listed waste), or more than 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31 or 261.33(e). Federal regulations for LQGs include, but are not limited to the following: Obtaining an EPA Identification number; a 90-day limit for accumulating hazardous waste on-site (with relevant standards for the accumulation of hazardous waste) without having to obtain a RCRA permit or comply with the interim status standards, provided that they comply with the conditions for exemption set forth in § 262.34(a) such as management and labeling standards specific to the type of accumulation unit (*e.g.,* container, tank); RCRA training of personnel; contingency planning; manifesting and recordkeeping and reporting (biennial report).

- Facilities qualify as SQGs if in a calendar month they generate more than 100 kg but less than 1,000 kg of hazardous waste. SQGs are subject to fewer requirements than LQGs and are given additional flexibility. For example, SQGs have a longer on-site accumulation time limit (180 or 270 days vs. 90 days for LQGs), with fewer standards for the accumulation of hazardous waste, without having to obtain a RCRA permit or comply with the interim status standards, provided that they comply with the conditions set forth in § 262.34(d) (which have fewer personnel training and contingency planning obligations than in the conditions for exemption for LQGs); and do not need to complete a biennial report (BR).

- Facilities qualify as CESQGs if in a calendar month they generate less than or equal to 100 kg of hazardous waste, and less than or equal to 1 kg of acutely hazardous waste (*i.e.,* P-listed), and less than or equal to 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in

[1] RCRA also governs the disposal of non-hazardous solid wastes; however, state and/or local environmental regulatory agencies predominantly administer the regulations pertaining to the management of non-hazardous wastes.

[2] For more information on RCRA State Authorization, see: *http://www.epa.gov/osw/laws-regs/state/index.htm.*

[3] For more information on hazardous waste generators, please see: *http://www.epa.gov/waste/hazard/generation/index.htm.*

[4] See 40 CFR 261.2 for the definition of solid waste.

[5] The waste determination process includes determining if the waste is specifically excluded or exempted from the RCRA hazardous waste regulations. If not, then the entity must determine if the waste is listed by EPA under the F-, K-, P- or U-lists of hazardous wastes (§§ 261.31–33). If the waste is not listed, then it must be determined if the waste exhibits a characteristic of a hazardous waste: Ignitability, corrosivity, reactivity, or toxicity (§§ 261.21–24).

§§ 261.31, or 261.33(e).[6] CESQGs are subject to very few of the RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 261.5(f)(3) and (g)(3).

Finally, under the household hazardous waste exemption in § 261.4(b)(1), hazardous wastes generated by households are not subject to the RCRA hazardous waste regulations. This exemption from the Subtitle C requirements extends to any household wastes collected during community-oriented take-back programs or events, as long as these collected household hazardous wastes are managed separately from regulated hazardous wastes.[7] However, while collected household hazardous wastes are not regulated under the federal standards, more stringent state standards may apply.

3. Are pharmaceuticals considered hazardous wastes under RCRA?

A portion of the pharmaceuticals currently on the market meets RCRA's definition of hazardous waste when discarded. As previously explained, it is the responsibility of the generator of a solid waste to determine if the waste is hazardous; this includes solid wastes that are pharmaceuticals. If the pharmaceutical waste meets RCRA's definition of hazardous waste, then the generator must manage it in accordance with all applicable federal, state, and/or local environmental regulations. A pharmaceutical is considered a hazardous waste under RCRA in one of two ways. First, a discarded pharmaceutical can be a listed hazardous waste if it is a commercial chemical product[8] that is listed under RCRA's P- or U-list, and the pharmaceutical has not been used for its intended purpose (§ 261.33 (e) and (f), respectively).[9] A few examples of pharmaceuticals that are considered P-listed wastes when discarded are arsenic trioxide (P012), smoking cessation products with nicotine as the sole active ingredient (P075), and pharmaceuticals with greater than 0.3% warfarin (and salts) as the sole active ingredient, such as Coumadin (P001). Some examples of pharmaceuticals that are considered U-listed wastes are: Cyclophosphamide (U058), mitomycin C (U010), streptozotocin (U206) and warfarin and salts (≤0.3%) as the sole active ingredient (U248).

Second, if the discarded pharmaceutical is not on the P- or U-list, then the pharmaceutical may be a hazardous waste if it exhibits one or more of the hazardous waste characteristics. Under the federal requirements (§ 261.21–24), a waste is a characteristic hazardous waste if it is ignitable (D001), corrosive (D002), reactive (D003) or toxic (D004–D043).[10] A number of pharmaceuticals are prepared in alcohol, which may cause the waste to be hazardous due to ignitability (D001), even if the active pharmaceutical ingredient itself is not considered hazardous waste. The Regulatory Impact Analysis for this proposed rule includes a list of pharmaceuticals that, to our knowledge, are hazardous waste when disposed, although this list should not be considered exhaustive (see the docket for this proposed rule EPA–HQ–RCRA–2007–0932).

Since the hazardous waste rules were initially promulgated, EPA has issued several clarifications regarding the regulatory status of certain commercial chemical products on the P- and U-lists, and these clarifications have affected the regulatory status of some active pharmaceutical ingredients.[11] For example, EPA recently clarified that phentermine hydrochloride and other phentermine salts are not included within the scope of the P046 (phentermine) listing.[12] Similarly, EPA has also clarified that epinephrine salts are not included in the epinephrine listing (P042).[13] In addition, medicinal nitroglycerin typically is not considered P081 since the medicinal form of this compound generally does not exhibit the characteristic of reactivity for which nitroglycerin was originally listed.[14] Furthermore, in a 1998 memo, EPA clarified that the U034 listing includes both anhydrous chloral and chloral hydrate.[15] And in a 2010 memo, EPA stated that unused nicotine patches, gums and lozenges are finished dosage forms of nicotine and therefore are regulated as P075 when discarded.[16]

Finally, EPA has developed a ''Hazardous Waste Pharmaceuticals Wiki'' as a platform to facilitate the sharing of expertise among the healthcare industry and other stakeholders in order to help make accurate hazardous waste determinations for waste pharmaceuticals and increase compliance with the hazardous waste regulations. The Hazardous Waste Pharmaceuticals Wiki will also help users find guidance documents, state-specific information, and manufacturers' information. The Hazardous Waste Pharmaceuticals Wiki can be viewed at: *http://hwpharms.wikispaces.com*. EPA encourages healthcare stakeholders to use the Wiki to share information regarding federal hazardous waste

[6] EPA recommends that facilities that qualify as CESQGs under the federal regulations contact their state and/or local environmental regulatory agencies, as authorized states can be more stringent than the federal regulations. As a result, not all authorized states recognize the CESQG category or they may have more stringent regulatory requirements for CESQGs.

[7] For clarification on household hazardous waste collection issues, please see the November 1, 1988 memo from Win Porter to the Regional Waste Management Division Directors (RCRA Online # 11377) at: *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2FD51915214EF63C8525670F006BDC88/$file/11377.pdf*.

[8] Commercial chemical product 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 (§ 261.33(d)).

[9] The P- and U-lists deem as hazardous certain commercial chemical products when they are discarded or intended to be discarded. These listings consist of commercial chemical products having the generic names listed, off-specification species, container residues, and spill residues. Chemicals on the P-list are identified as acute hazardous wastes and are regulated at lower amounts than those on the U-list.

[10] The toxicity characteristic (TC) indicates that the waste is likely to leach concentrations of contaminants that may be harmful, and TC waste is identified using the Toxicity Characteristic Leaching Procedure (see § 261.24). Examples of TC constituents that may be present in pharmaceuticals include, but are not limited to: Arsenic, barium, cadmium, selenium, silver, chloroform, lindane and m-cresol.

[11] In addition, in December 2008, the Agency proposed to regulate hazardous waste pharmaceuticals under the Universal Waste rule. However, based on the comments received, the Agency decided not to finalize that proposal and to proceed with a sector-based approach. (See section IV.C. of the preamble for further discussion of the Universal Waste proposal.)

[12] Memo from Devlin to RCRA Division Directors, February 17, 2012 (RCRA Online #14831) *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/A5C07D01188ECA59852579EA0067CDB1/$file/14831.pdf*.

[13] Memo December 1, 1994 (RCRA Online #13718) *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/1C1DEB3648A62A868525670F006BCCD2/$file/13718.pdf*.

[14] Memo from Dellinger to Smith, March 18, 2003 (RCRA Online #14654) *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/7ACFEC572DE8897F85256D1600748BCB/$file/14654.pdf*.

[15] Memo from Brandes to Knauss, April 6, 1998 (RCRA Online #14175) *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/7417D2556AD322FA852568E300468198/$file/14175.pdf*.

[16] Memo from Dellinger to Smith, August 23, 2010 (RCRA Online #14817) *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/209444BADDA4ECDC852577ED00624E8F/$file/14817.pdf*.

pharmaceuticals, as well as state-only hazardous waste pharmaceuticals.[17]

B. What are the rationale and goals for this proposed rule?

1. Sector-Based Approach

The impetus behind this proposal is to address the various concerns raised by stakeholders regarding the difficulty in implementing the 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 it has received input from stakeholders through more formal mechanisms. For instance, when EPA solicited stakeholder input in response to Executive Order 13563 (Improving Regulation and Regulatory Review), retailers submitted comments detailing compliance challenges with hazardous waste pharmaceuticals in their stores.[18] 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 both of these reports, see the next section). These two reports and input from healthcare (and associated) facilities 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 for generating and managing hazardous waste.

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

Second, under the current hazardous waste regulatory scheme, healthcare workers, 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 workers, such as nurses and doctors, do not typically have the expertise to make hazardous waste determinations.

Third, a healthcare facility can have thousands of items in its formulary at any one time and these may vary over time. In addition, pharmaceutical wastes come in many different forms, such as pills, 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 workers to make appropriate hazardous waste determinations when pharmaceuticals are disposed. This situation differs from manufacturing, where fewer, more predictable waste streams are generated.

Fourth, 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 at much smaller amounts. If a facility generates more than 1 kg of acute hazardous waste per calendar month or accumulates that amount at any time, it is regulated as an LQG. In addition to the pharmaceuticals, residues within pharmaceutical containers that contained P-listed commercial chemical products must be managed as acute hazardous waste even if the pharmaceutical was fully dispensed,[19] unless the container is RCRA-empty (*e.g.,* by triple-rinsing the container). Triple rinsing can be impractical with certain medical devices, such as syringes and paper cups, so healthcare facilities often end up managing these containers as hazardous waste, which can result in the facilities being subject to the most stringently regulated generator category (*i.e.,* LQG).[20]

To facilitate compliance among healthcare facilities and to respond to these concerns, EPA is proposing a new set of sector-specific regulations to improve the management and disposal of hazardous waste pharmaceuticals at healthcare facilities. This proposed rule also intends to clarify the regulatory status of a major practice used by healthcare facilities for management of unused and/or expired pharmaceuticals, known as reverse distribution (see Sections V.D.1 and V.G).

In addition to improving compliance and responding to stakeholder concerns, the Agency has two additional goals for this proposal. The first is to reduce the amount of pharmaceuticals that are disposed of ''down the drain.'' This is presently an allowable and common disposal practice among healthcare facilities (as long as the pharmaceutical waste is not ignitable (see the Clean Water Act regulations of 40 CFR 403.5(b)(1)) and provided certain conditions are met (see the Clean Water Act regulations of 40 CFR 403.12(p)). Studies have found that many healthcare facilities, particularly long term-care facilities, are using drain disposal as a routine disposal method for pharmaceutical wastes. Although pharmaceuticals are also entering the environment through excretion, reducing sewer disposal is one mechanism to help reduce the environmental loading of pharmaceuticals into our Nation's waters. For more information about sewer disposal and pharmaceuticals in water, see Section V.E.1.

The second goal is to address the overlap between EPA's RCRA hazardous waste regulations and the controlled substances regulations of the Drug Enforcement Administration (DEA). Stakeholders have indicated that hazardous waste pharmaceuticals that are also controlled substances are stringently regulated and expensive to dispose of in accordance with both sets of requirements when sent for incineration. In addition, stakeholders have indicated that those regulated hazardous waste pharmaceuticals that are also controlled substances are most likely to be sewer disposed to avoid the costs of compliant incineration. EPA plans to address this overlap in this proposed rule, as this is an unnecessary burden for healthcare facilities and revised requirements will help to reduce sewer disposal.

2. Executive Order 13563 for the Retrospective Review of Existing Regulations

On January 18, 2011, President Obama issued Executive Order 13563, which directed all federal agencies to perform periodic retrospective reviews of existing regulations to determine whether any should be modified,

[17] Anyone may view the Wiki. Those in the healthcare community who wish to contribute content or edit the Wiki can register by sending an email request to *HWPharmsWiki@epa.gov*.

[18] Executive Order 13563 was signed by President Obama on January 18, 2011 and published in the **Federal Register** on January 21, 2011 (76 FR 3821). In response to the Executive Order, EPA solicited comments on ''Improving EPA Regulations,'' in a **Federal Register** notice published on February 23, 2011 (76 FR 9988). See docket number EPA–HQ–OA–2011–0160 for public comments related to waste.

[19] 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)).

[20] 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) *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/57B21F2FE33735128525795F00610F0F/$file/14827.pdf*.

streamlined, expanded, or repealed.[21] EPA made its preliminary plan available for public review and comment during the spring of 2011 and released the final version of the plan in August 2011.[22] During the public comment process, EPA received requests to clarify and make more effective the hazardous waste regulations as they pertain to discarded retail products, including pharmaceutical wastes. In response to this specific issue, EPA agreed to review data and information currently in its possession as part of the development for a rulemaking to address pharmaceutical waste management issues.[23] This Notice of Proposed Rulemaking provides notice that EPA has completed its review and has satisfied this part of its obligation for retail hazardous waste pharmaceutical management issues.

3. Retail Notice of Data Availability

EPA published a Notice of Data Availability (NODA) for the Retail Sector on February 14, 2014 (79 FR 8926), 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/establishments face in complying with RCRA regulations. Many retail commenters mentioned that because nicotine is an acute hazardous waste (P075), they 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 them some regulatory relief with regard to nicotine-containing products. See Section VIII of this preamble for a discussion of EPA's potential future efforts to amend the acute hazardous waste listing for nicotine and salts (P075).

[21] For a copy of Executive Order 13563, please see: *http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf.*

[22] US EPA. Improving Our Regulations: Final Plan for Periodic Retrospective Reviews of Existing Regulations. *http://www.epa.gov/regdarrt/retrospective/documents/eparetroreviewplan-aug2011.pdf.*

[23] See page 45, item 2.2.17 of EPA's ''Improving Our Regulations: Final Plan for Periodic Retrospective Reviews of Existing Regulations'' at *http://www.epa.gov/regdarrt/retrospective/documents/eparetroreviewplan-aug2011.pdf.*

C. What was the 2008 Pharmaceutical Universal Waste proposal?

1. The 2008 Proposal To Add Hazardous Waste Pharmaceuticals to the Federal Universal Waste Program

On December 2, 2008, EPA proposed to add hazardous waste pharmaceuticals to the existing federal universal waste program, which would have provided a streamlined approach to facilitate the proper management and disposal of hazardous waste pharmaceuticals generated at pharmacies, hospitals, reverse distributors, and other healthcare-related facilities. Specifically, under the universal waste program, handlers and transporters who generate or manage items designated as a universal waste[24] are subject to the management standards under part 273, rather than the full RCRA subtitle C hazardous waste regulations. Universal waste handlers include universal waste generators and collection facilities. The regulations distinguish between ''large quantity handlers of universal waste'' (or those who handle more than 5,000 kilograms of total universal waste at any one time) and ''small quantity handlers of universal waste'' (or those who handle 5,000 kilograms or less of universal waste at any one time).[25] The streamlined requirements for all types of universal waste include modified requirements for storage, labeling and marking, preparing the waste for shipment off-site, employee training, response to releases and notification.

Transporters of universal waste are also subject to less stringent requirements than the full RCRA subtitle C hazardous waste transportation regulations. However, the primary difference between the universal waste transportation requirements and full RCRA subtitle C requirements is that no hazardous waste manifest is required for the transport of universal waste.

Destination facilities under the universal waste program are those facilities that treat, store, dispose of, or recycle universal wastes. Universal waste destination facilities are subject to all currently applicable requirements for hazardous waste treatment, storage, and disposal facilities (TSDFs), including the requirement to obtain a RCRA permit for such activities. (See 73 FR 73520, December 2, 2008, for a more detailed discussion of the proposed universal waste program for pharmaceutical wastes.)

[24] The current federal universal wastes include hazardous waste batteries, certain hazardous waste pesticides, mercury-containing equipment, and hazardous waste lamps.

[25] The 5,000 kilogram accumulation criterion applies to the quantity of all universal wastes accumulated.

2. What were the public comments to the 2008 Pharmaceutical Universal Waste proposal?

EPA received approximately 100 public comments on the 2008 proposal to add hazardous waste pharmaceuticals to the universal waste program.[26] Generally, public commenters supported the Agency's desire to address the issue of hazardous waste pharmaceutical management. However, although there were several aspects of the proposal that were well supported (*e.g.,* training requirements, accumulation times, and hazardous waste pharmaceuticals not being counted towards the generator category), public commenters expressed concern over the lack of notification and tracking requirements for small quantity handlers of universal waste and the reduced notification and tracking requirements for large quantity handlers. As a result, commenters, including state environmental regulatory agencies, expressed concern that they would not be informed of hazardous waste pharmaceutical generation, management, and transportation in their regulatory jurisdictions. Furthermore, public commenters expressed concern that because the universal waste program does not require a hazardous waste manifest or another tracking mechanism, the hazardous waste pharmaceuticals could be vulnerable to diversion. Public commenters argued that hazardous waste pharmaceuticals are different from the other federal universal wastes (batteries, mercury-containing equipment, lamps, and pesticides) in that the pharmaceuticals, as well as their containers, still retain considerable value upon disposal and can be easily diverted for illicit purposes. Therefore, tracking requirements beyond the requirements included in the current universal waste program were considered necessary by the majority of the public commenters.

In addition to the public comments about the strengths and weaknesses of using the universal waste program to address the disposal of hazardous waste pharmaceuticals, EPA received other comments expressing concern with the proposal, including the following: The point of generation of hazardous waste pharmaceuticals as it pertains to reverse distribution; the management of

[26] *See* docket EPA–HQ–RCRA–2007–0932 at *www.regulations.gov* for public comments: *http://www.regulations.gov/#!docketDetail;D=EPA-HQ-RCRA-2007-0932;dct=FR%252BPR%252BN%252BO%252BSR.*

containers that contain hazardous waste pharmaceutical residues; the variability in the land disposal restriction (LDR) treatment standards for hazardous waste pharmaceuticals; the overlap of EPA and DEA regulations for the management of hazardous waste pharmaceuticals that are also controlled substances; and the lack of activity to add pharmaceutical wastes to the hazardous waste listings. The Agency provides additional discussion on these specific comments within this preamble.

3. Why is EPA not finalizing the 2008 Pharmaceutical Universal Waste proposal?

Based on the adverse comments received on the 2008 Pharmaceutical Universal Waste proposal regarding the lack of notification and tracking requirements for small quantity universal waste handlers, the reduced notification and tracking requirements for large quantity universal waste handlers, as well as the other issues raised in public comments, the Agency has decided to not finalize the proposal to add hazardous waste pharmaceuticals to the Universal Waste program. In fact, EPA has concluded that the universal waste program is not appropriate for managing hazardous waste pharmaceuticals because, among other things, we are unable to adequately address the notification and tracking concerns raised by the public comments within the Universal Waste program.

Under the Universal Waste regulations, there are eight factors to consider when determining whether it is appropriate to add a new hazardous waste or category of hazardous waste to the Universal Waste program (§ 273.81). A hazardous waste does not need to meet every factor in order to be added to the Universal Waste program. Rather, the Agency's decision is ''based on the weight of evidence showing that regulation under part 273 is appropriate for the waste or category of waste, will improve management practices for the waste or category of waste, and will improve implementation of the hazardous waste program'' (§ 273.80(c)).

The Agency has concluded based on the comments received that the weight of evidence does not show that regulation under the Universal Waste program is appropriate for hazardous waste pharmaceuticals. Specifically, we find the Universal Waste program to be lacking with regard to the factor in § 273.81(e), which states that the risk posed by the waste being considered for universal waste be relatively low compared to other hazardous wastes and that the management standards would be protective of human health and the environment during accumulation and transport. Although we continue to believe that potentially creditable pharmaceuticals en route to reverse distributors pose a low risk for leaks and other releases to the environment, commenters urged us to consider the unique risk posed by the accumulation and transport of hazardous waste pharmaceuticals: the risk of diversion. Although it is rare that a hazardous waste is so valuable that it is sought for abuse or sale on the black market, EPA believes that the diversion of hazardous waste pharmaceuticals for illicit use is a risk to human health.

The Universal Waste program does not include sufficient tracking requirements to address the potential for diversion. Under part 273, tracking is not required for shipments by small quantity handlers of universal waste; certain tracking of shipments is required only for large quantity handlers of universal waste and destination facilities. More importantly, these basic tracking requirements consist only of recordkeeping of shipments sent and received and no tracking is required to ensure delivery. Commenters noted that these tracking requirements are not sufficient given the high value of many of the unused pharmaceuticals en route to reverse distribution and the potential for diversion.

Accordingly, the Agency is proposing to amend § 273.80 to state that hazardous waste pharmaceuticals may not be added as a category of hazardous waste for management under the Universal Waste program. See Section IX State Authorization of the preamble for a discussion on the effect on the two states that have adopted pharmaceuticals under the Universal Waste program (Michigan and Florida).

By proposing a new set of management standards outside the confines of the Universal Waste program, it allows us greater flexibility in addressing the tracking of such shipments, as well as additional pharmaceutical waste management issues raised by stakeholders, such as drain disposal, container residues, pharmaceutical reverse distribution, and the overlap with DEA regulation. This new action will address the original stakeholder concerns that resulted in the 2008 Pharmaceutical Universal Waste proposal, as well as the comments received on that proposal.

To reiterate, EPA is not adding hazardous waste pharmaceuticals to the federal Universal Waste program. Rather, we are proposing sector-specific regulations for the management of hazardous waste pharmaceuticals by healthcare facilities and pharmaceutical reverse distributors. If finalized, these regulations will be codified in 40 CFR part 266, separate from both the generator regulations (40 CFR part 262) and the Universal Waste program (40 CFR part 273). This new proposed rulemaking will pertain to those waste pharmaceuticals that meet the current definition of a RCRA hazardous waste *and* are generated by healthcare-related facilities and managed by pharmaceutical reverse distributors, as defined by this proposal. Finally, as this current proposal is a direct result of the comments received on the December 2, 2008, Pharmaceutical Universal Waste proposal, the Agency considers the 2008 Pharmaceutical Universal Waste proposal obsolete. Therefore, EPA is withdrawing the Universal Waste proposal for pharmaceutical waste, and does not seek comment on any provisions of the 2008 Pharmaceutical Universal Waste proposal or the current Universal Waste program. The Agency will only be accepting comments from the public on the provisions of this new proposed rulemaking.

D. EPA's Office of 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'' (Report No. 12–P–0508).[27] 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):

(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 HWPs [hazardous waste pharmaceuticals] (Report No. 12–P–0508).

As detailed in OSWER's response to OIG, this proposal fulfills our obligation

[27] For a copy of the report, please see: *http://www.epa.gov/oig/reports/2012/20120525-12-P-0508.pdf* or see the docket for this proposed rule: EPA–HQ–RCRA–2007–0932.

for addressing the third recommendation.[28] EPA does not address the OIG's first two recommendations as part of this proposed rulemaking; however, in Section VII of this preamble, we solicit comment on our ongoing efforts to identify additional pharmaceuticals as hazardous wastes.

V. Detailed Discussion of the Proposed Rule

EPA is proposing an entirely new set of regulations (40 CFR part 266, subpart P) for managing hazardous waste pharmaceuticals at both healthcare facilities and pharmaceutical reverse distributors. This section discusses in detail the major features of the proposal. The Agency also presents other options that it is considering or were considered in developing the proposed rule. EPA welcomes comments on all aspects of this proposed rule, and on options under consideration. Throughout this section, EPA requests comments on specific options and on specific issues, but comments are welcome on all provisions of this proposal.

A. What terms are defined in this proposed rule?

All the definitions that appear in this proposal are for the purposes of 40 CFR part 266, subpart P only. Therefore, the definitions are relevant only to healthcare facilities and pharmaceutical reverse distributors that are subject to these proposed standards. For the purposes of this regulation, the Agency is proposing and soliciting public comment on the following terms and their definitions presented below: ''evaluated hazardous waste pharmaceutical,'' ''hazardous waste pharmaceutical,'' ''healthcare facility,'' ''household waste pharmaceutical,'' ''long-term care facility,'' ''non-creditable hazardous waste pharmaceutical,'' ''non-hazardous waste pharmaceutical,'' ''non-pharmaceutical hazardous waste,'' ''pharmaceutical,'' ''pharmaceutical reverse distributor,'' and ''potentially creditable hazardous waste pharmaceutical.'' Although the proposed definitions appear in alphabetical order in the regulations, we have chosen to discuss the proposed definitions in a different order in the preamble.

1. What is the proposed definition of ''pharmaceutical''?

This proposed rule defines ''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 includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and Cosmetic Act (FD&C Act), prescription drugs, over-the-counter 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'' is intended to include all dose forms, including, but not limited to tablets, capsules, medicinal gums or lozenges, medicinal liquids, ointments and lotions, intravenous (IV) or other compounded 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. As a rule of thumb, if an over-the-counter 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. EPA asks for comment to identify additional types or forms of pharmaceuticals that are not adequately captured by the definition.

EPA previously proposed to define the term ''pharmaceutical'' in the December 2008 Pharmaceutical Universal Waste proposal to mean ''any chemical product, vaccine or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine or allergenic), not containing a radioactive component, that is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or injury in man or other animals; or any chemical product, vaccine, or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine, or allergenic), not containing a radioactive component, that is intended to affect the structure or function of the body in man or other animals. This definition includes products such as transdermal patches, and oral delivery devices such as gums or lozenges. This definition does not include sharps or other infectious or biohazard waste, dental amalgams, medical devices not used for delivery or dispensing purposes, equipment, contaminated personal protective equipment or contaminated cleaning materials.'' This definition was adapted from FD&C Act's definition for ''drug'' 21 U.S.C. 321(g).

Based on the comments received in response to the Pharmaceutical Universal Waste proposal, the Agency is continuing to rely primarily on the FD&C Act's definition for ''drug'' for the definition of pharmaceutical in this proposal and has preserved most of the definition proposed in the previous proposal. However, EPA is proposing to expand on its previous proposed definition of pharmaceutical based on stakeholder input. 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 apply broadly. Stakeholders indicated a preference for managing more items under the new standards than trying to determine how to apply the existing RCRA framework to pharmaceutical related items. Thus, the proposed definition of pharmaceutical no longer excludes pharmaceuticals with a radioactive component and includes items not specifically recognized by the U.S. Food and Drug Administration (FDA) as drugs, such as dietary supplements and pharmaceutical residues in containers (including delivery devices), personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from spills of pharmaceuticals.

EPA's decision to include dietary supplements under this rulemaking's proposed definition of hazardous waste pharmaceutical reflects our interest in promoting a management scheme for all types of pharmaceuticals, and is based upon our understanding that dietary supplements are commonly found in various healthcare settings because they are recommended or prescribed by healthcare providers to patients.[29] Further, retail pharmacies routinely sell vitamins and other medicinal minerals and supplements.

When EPA uses the term ''dietary supplements'' in our proposed 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)).[30] EPA understands that

[28] 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.*

[29] Including dietary supplements under the definition of pharmaceutical for this regulation 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.

[30] The substance of the definition is: a product (other than tobacco) intended to supplement the

Continued

the FDA does not recognize dietary ingredients or dietary supplements under its definition of ''drug,'' but rather categorizes such items under the general umbrella of foods and therefore, does not review them before being marketed.[31] [32] For the purposes of this proposed rule, however, EPA recognizes that healthcare facilities may benefit from managing dietary supplements along with other drugs under the regulatory scheme being proposed, and thus, is including it in the proposed definition of pharmaceutical. Although dietary supplements would be considered pharmaceuticals under this proposed 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''). We seek public comment on the Agency's decision to recognize dietary supplements as pharmaceuticals under this regulation.

The Agency also is clarifying that its proposed definition includes any items containing pharmaceutical residuals, such as dispensing bottles, IV bags and tubing, vials, unit dose packages, and delivery devices, such as syringes and patches. In addition, EPA is proposing that items contaminated with or containing residual pharmaceuticals, such as personal protective equipment containing trace amounts of pharmaceuticals or related spill clean-up materials (including loose tablets accumulated during pharmacy floor sweepings) also meet this proposed definition of pharmaceutical. However, this proposed definitions 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 proposed rule because sharps are considered medical wastes, presently regulated at the state and local level. In addition, sharps pose both an unreasonable physical danger and biohazard danger so have not been included in the definition of pharmaceutical under this proposed rule. OSHA's Technical Manual incorporates a recommendation from the American Society of Hospital Pharmacists that ''all syringes and needles used in the course of preparation be placed in ''sharps'' containers for disposal without being crushed, clipped or capped.'' [33] Further, as discussed in Section V.E.3.c of this preamble, EPA is proposing to conditionally exclude the residues of hazardous waste pharmaceuticals remaining in fully dispensed syringes from RCRA regulation. However, EPA is concerned about the possibility that some syringes may be disposed of in sharps containers that may contain significant amounts of undispensed pharmaceutical. EPA seeks comment on the prevalence of this situation.

The Agency solicits public comment on the proposed definition of ''pharmaceutical'' in its entirety, and particularly on EPA's decision to incorporate dietary supplements and items containing pharmaceutical residuals as part of the definition of pharmaceutical.

2. What is the proposed definition of a ''hazardous waste pharmaceutical''?

This proposed rule defines ''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. See Section IV.A.3. of this preamble for a discussion of pharmaceuticals that may be listed or characteristic hazardous wastes.[34]

The Agency is proposing to define the term ''hazardous waste pharmaceutical'' in order to clarify its intent that only pharmaceuticals (as defined in this proposal) that meet the definition of hazardous waste when disposed or discarded need to be managed under these proposed management standards. This means that any pharmaceutical waste that meets the definition of hazardous waste is a hazardous waste pharmaceutical for the purposes of this rule. For example, the prescription pharmaceutical warfarin (brand name Coumadin) is a listed hazardous waste and when discarded meets the definition of a hazardous waste pharmaceutical. EPA requests public comment on the proposed definition for ''hazardous waste pharmaceutical.'' The Agency also solicits information on whether any dietary supplements currently on the market meet or potentially could meet RCRA's definition of a hazardous waste.

3. What is the proposed definition of a ''potentially creditable hazardous waste pharmaceutical''?

In order to distinguish hazardous waste pharmaceuticals that are transported to RCRA treatment, storage and disposal facilities (TSDFs) from those hazardous waste pharmaceuticals being returned by a healthcare facility to a pharmaceutical reverse distributor for a determination or verification of manufacturer's credit, the Agency is proposing a definition for ''potentially creditable hazardous waste pharmaceutical.''

The proposed rule defines ''potentially creditable hazardous waste pharmaceutical'' to mean a hazardous waste pharmaceutical that has the potential to receive manufacturer's credit and is

(1) unused or un-administered; and

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

The term does 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.

Whether a pharmaceutical is eligible for manufacturer's credit is determined solely by the manufacturer's return policy. Based on comments received for the 2008 Universal Waste proposed rule and through discussions with various stakeholders, the Agency understands that the return policies of manufacturers change regularly. As a result, pharmacies 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 re-packaged 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

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 for dietary supplement, please see: *http://www.gpo.gov/fdsys/pkg/USCODE-2013-title21/pdf/USCODE-2013-title21-chap9-subchapII-sec321.pdf.*

[31] For more information regarding dietary supplements, please see: *http://www.fda.gov/Food/DietarySupplements/default.htm.*

[32] It is the responsibility of the manufacturers to ensure their dietary supplements are safe and that all claims on labels are true and accurate. Nevertheless, FDA has the authority to take action against any unsafe dietary supplements, as well as to take action against any products with false and misleading claims.

[33] See Section VI, Chapter 2 of OSHA's Technical Manual (paragraph V.C.1.b.) *https://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html.*

[34] For additional information about RCRA hazardous waste listings and characteristics, see: *http://www.epa.gov/osw/hazard/wastetypes/index.htm.*

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's credit. It is the Agency's intent for the proposed definition of potentially creditable hazardous waste pharmaceuticals 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 received 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 would consider partials to be potentially creditable hazardous waste pharmaceuticals.

The Agency is soliciting comment on the proposed definition of ''potentially creditable hazardous waste pharmaceutical'' and whether the definition is broad enough to encompass the various types of hazardous waste pharmaceuticals that are shipped to reverse distributors for manufacturer's credit, while also ensuring that non-creditable hazardous waste pharmaceuticals are not inappropriately shipped to reverse distributors solely for waste management purposes. Finally, the Agency is seeking comment on additional situations where it is well known that a returned pharmaceutical will or will not receive manufacturer's credit.

4. What is the proposed definition of ''non-creditable hazardous waste pharmaceutical''?

As discussed previously, there are instances when it is well known that credit will not be received for certain hazardous waste pharmaceuticals. In order to distinguish hazardous waste pharmaceuticals that have the potential for credit from those that have no expectation of receiving credit, the Agency is proposing 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's credit. Examples include, but are not limited to: if the pharmaceutical has been removed from the original container and re-packaged 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 (*e.g.* health insurance company); or if the pharmaceutical is more than one year past its expiration date. EPA requests comment on the proposed definition and seeks additional examples of hazardous waste pharmaceuticals that have no expectation of receiving manufacturer's credit.

5. What is the proposed definition of ''evaluated hazardous waste pharmaceutical''?

After potentially creditable hazardous waste pharmaceuticals arrive at a pharmaceutical reverse distributor, they are evaluated to determine whether they are eligible for manufacturer's credit, or whether they need to be transferred to another pharmaceutical reverse distributor for additional verification of manufacturer's credit. Hazardous waste pharmaceuticals that need to be transferred to another pharmaceutical reverse distributor for additional verification of manufacturer's credit will continue to be considered potentially creditable hazardous waste pharmaceuticals. EPA is proposing that hazardous waste pharmaceuticals for which manufacturer's credit has been issued (and no further verification of credit is required), as well as those that have been deemed non-creditable, be referred to as ''evaluated hazardous waste pharmaceuticals.'' EPA is proposing to define ''evaluated hazardous waste pharmaceutical'' as a hazardous waste pharmaceutical that was a potentially creditable hazardous waste pharmaceutical but has been evaluated by a pharmaceutical reverse distributor to establish whether it is eligible for manufacturer's credit and will not be sent to another pharmaceutical 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. For a discussion of the proposed management and shipping standards for potentially creditable hazardous waste pharmaceuticals, see Section V.F.2. For a discussion of the proposed management and shipping standards for evaluated hazardous waste pharmaceuticals, see Section V.F.1.b.

6. What is the proposed definition of ''household waste pharmaceutical''?

We are proposing to define the term ''household waste pharmaceutical'' as a solid waste, as defined in § 261.2, that also meets the definition of pharmaceutical, as defined in this proposed rule, 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 are proposing this term to distinguish this type of waste pharmaceutical from the hazardous waste pharmaceuticals that are proposed to be regulated under this new subpart. This proposed rule does not apply to pharmaceutical waste that is exempt due to the household waste exclusion.

7. What is the proposed definition of ''non-hazardous waste pharmaceutical''?

We are proposing to define the term ''non-hazardous waste pharmaceutical.'' While hazardous waste pharmaceuticals are proposed to be regulated under this new subpart, non-hazardous waste pharmaceuticals will not be regulated under this new subpart, nor the RCRA subtitle C hazardous waste regulations. The Agency is proposing to include this definition since we believe it important to delineate what is and is not regulated under this new subpart. We propose to define the term ''non-hazardous waste pharmaceutical'' to mean a pharmaceutical that is a solid waste, as defined in § 261.2, but that is not a listed hazardous waste and does not exhibit any characteristics of hazardous waste (*i.e.,* ignitable, corrosive, reactive, toxic).

8. What is the proposed definition of ''non-pharmaceutical hazardous waste''?

Like the previous definition, we are proposing a definition for non-pharmaceutical hazardous waste to help us delineate what is and what is not regulated under this new subpart. We are proposing to define the term ''non-pharmaceutical hazardous waste'' as a solid waste, as defined in § 261.2, that is either a listed hazardous waste or exhibits one or more characteristics of hazardous waste, but does not meet the definition of a pharmaceutical, as proposed under this new subpart. The management of non-pharmaceutical hazardous wastes is not regulated under this subpart; rather generators of non-

pharmaceutical hazardous wastes, including healthcare facilities and reverse distributors, remain subject to the existing Subtitle C hazardous waste regulations for the management of those hazardous wastes. Examples of non-pharmaceutical hazardous wastes that healthcare facilities may generate include cleaning solutions, solvents, and laboratory wastes. Some hazardous wastes exist in pharmaceutical form and non-pharmaceutical form. For example, warfarin, nicotine, and lindane were all originally listed as hazardous waste because they were pesticides, not medicines. If these products are not intended for human or animal use, they would be considered non-pharmaceutical hazardous wastes and remain subject to the existing RCRA hazardous waste regulations, not part 266, subpart P.

9. What is the proposed definition of a ''healthcare facility''?

These proposed regulations differ from those in the Pharmaceutical Universal Waste proposal in that they apply based not only on the type of hazardous waste generated, but also on the sector generating the waste. Accordingly, EPA is proposing a definition for ''healthcare facility'' so that it is clear to whom these proposed regulations apply. This proposed definition is adapted from the definition of ''health care'' that the Department of Health and Human Services (DHHS) promulgated as a result of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (45 CFR part 160.103).[35] Thus, for the purposes of these proposed regulations, EPA is proposing that ''healthcare facility'' means any person that (1) 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 (2) sells or dispenses over-the-counter or prescription pharmaceuticals. This definition includes, but is not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of over-the-counter medications; and veterinary clinics and hospitals. Thus, these proposed regulations will be applicable to any healthcare facility for human or animal which generates hazardous waste pharmaceuticals on its premises.

EPA proposes to include coroners in the definition of a 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. A common method of disposal is sewering. In order to reduce the sewer disposal practices of coroners, and to provide the same management options that are available to other healthcare facilities, EPA has decided to include ''coroners'' within the definition of healthcare facility, although the Agency solicits comment on including coroners within the definition of healthcare facility.[36]

Under the proposed definition, healthcare facilities include 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 proposed rule. The proposed 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. The proposed 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. The Agency is soliciting comment on the proposed definition of ''healthcare facility,'' including whether it is appropriate to consider these compounders as healthcare facilities within the scope of this proposed rule.

The proposed definition of ''healthcare facility'' does not apply to pharmaceutical manufacturers and their representatives, wholesalers, or any other entity that is involved in the manufacturing, processing or wholesale distribution of over-the-counter or prescription pharmaceuticals, unless they meet the definition of a ''reverse distributor'' as discussed in this section and in Section V.G. 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. As noted previously, the Agency does not anticipate that manufacturing facilities, which predictably generate a known range of hazardous wastes, face the same issues as healthcare facilities.

10. What is the proposed definition of a ''long-term care facility''?

The term ''long-term care facility'' does not have a standardized, industry definition. EPA is, therefore, proposing the following definition for ''long-term care facility'' (LTCF): 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 included facilities 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 (under 10 beds). Independent living communities are not licensed care facilities, but rather are residences made up of individual units such as townhomes or apartments. Finally, private residences with visiting nurses are not considered long-term care facilities. EPA requests public comment on the proposed definition of long-term care facility, and the inclusion of assisted living facilities, skilled nursing facilities and other LTCFs that administer their residents' pharmaceuticals as an integral part of their services within the definition of ''healthcare facility.''

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'' (21 CFR 1300.01). EPA's definition is more descriptive, and includes a list—which is not

[35] 45 CFR part 160 *http://aspe.hhs.gov/admnsimp/final/pvctxt01.htm.*

[36] 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. *http://www.epa.gov/nerlesd1/bios/daughton/SOTE2007.pdf.*

exhaustive—of examples of long-term care facilities. We feel this a more flexible way to define the universe. Although the definitions differ, they are not necessarily incompatible.

11. What is the proposed definition of a ''pharmaceutical reverse distributor''?

As more fully discussed in Section V.G.1 of this preamble, pharmaceutical manufacturers often offer credit to healthcare facilities on the return of unused and/or expired pharmaceuticals.[37] Stakeholders have informed the Agency that manufacturers issue credit for a variety of reasons. For example, it is a marketing incentive tool that helps ensure against illicit diversion [38] 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 are contracted by both pharmaceutical manufacturers and healthcare facilities to facilitate the crediting process.

Some of the pharmaceuticals returned for credit will meet RCRA's definition of a hazardous waste. Due to the fact that the vast majority of pharmaceuticals that are returned for manufacturer's credit are disposed of once credit eligibility is determined, EPA is proposing new standards for shipment of potentially creditable hazardous waste pharmaceuticals (see Section V.F.2.) and the management of potentially creditable hazardous waste pharmaceuticals by reverse distributors (see Section V.G). Thus, EPA is proposing to define pharmaceutical reverse distributor to clearly delineate which types of facilities are subject to this proposed rule. In keeping with how the term is commonly used in the healthcare sector, EPA is proposing to define a ''pharmaceutical reverse distributor'' as any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit. Any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer's credit is considered a pharmaceutical reverse distributor.

The Agency also needs to clarify the difference between what is defined as a pharmaceutical reverse distributor for the purpose of these proposed regulations 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 (21 CFR 1300.01).[39]

Under DEA's definition, a reverse distributor does not necessarily process pharmaceuticals for the purpose of determining manufacturer's credit; rather, their main function under DEA's definition is to destroy the controlled substances. Under EPA's proposed definition, however, a pharmaceutical reverse distributor is defined more broadly as a facility that can accept potentially creditable pharmaceuticals for the purposes of determining manufacturer's credit. These potentially creditable pharmaceuticals may or may not be identified as controlled substances by DEA.[40] Therefore, a DEA-registered reverse distributor may or may not meet EPA's definition of a pharmaceutical reverse distributor and vice versa. For example, a pharmaceutical reverse distributor that accepts controlled substances (that are also hazardous wastes) for the sole purpose of destruction (*e.g.,* incineration) would be regulated as a DEA-registered reverse distributor and as a RCRA TSDF, and not as a pharmaceutical reverse distributor under the RCRA hazardous waste regulations. Conversely, a pharmaceutical reverse distributor that processes pharmaceuticals for manufacturer's credit, but is not a DEA registrant and therefore, cannot accept controlled substances, would meet the RCRA pharmaceutical reverse distributor definition, but not DEA's reverse distributor definition. However, EPA has heard from stakeholders that many, if not all, entities that facilitate manufacturer's credit are also DEA-registered reverse distributors. Therefore, such pharmaceutical reverse distributors would meet both EPA's proposed definition of pharmaceutical reverse distributor, as well as the DEA's definition of reverse distributor. Lastly, we would note that EPA's definition for reverse distribution does not alter or supersede the requirements of the Controlled Substances Act and DEA regulations.

In addition, the Department of Transportation's Pipeline and Hazardous Materials Safety Administration (PHMSA) has defined the closely related term, ''reverse logistics,'' in a recent proposed rulemaking.[41] The EPA has been coordinating with the PHMSA to ensure that our rules are compatible, even if the definitions differ. It is important to note that, when finalized, the PHMSA rule will not supersede EPA's RCRA Subtitle C regulations for when something is considered a solid or hazardous waste or how a hazardous waste must be managed.

The Agency solicits public comment on its proposed definition of a ''pharmaceutical reverse distributor.'' Specifically, EPA asks for comment on whether the definition of ''pharmaceutical reverse distributor'' captures the universe of facilities acting as reverse distributors for pharmaceuticals. In addition, the Agency asks for comment regarding the intersection of DEA and EPA's definitions.

B. What is the scope of this proposed rule?

1. What facilities are subject to this rulemaking?

a. Healthcare facilities. The Agency is proposing that healthcare facilities that are currently considered either SQGs or LQGs will be required to manage all hazardous waste pharmaceuticals generated at their facilities in accordance with the standards proposed in this document. In other words, these management standards will apply to any healthcare facility that generates (or accumulates) 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, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31, or 261.33(e) per calendar month. All healthcare facilities

[37] As noted in the definition of ''potentially creditable hazardous waste pharmaceutical,'' credit is provided for those pharmaceuticals that are less than one year past the expiration date.

[38] Through the return of pharmaceuticals by a pharmacy for manufacturer's 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.

[39] 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.''

[40] 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.

[41] 79 FR 46748; August 11, 2014. The PHMSA's proposed 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.''

that meet these applicability criteria will be subject to the same set of standards for the management of their hazardous waste pharmaceuticals. That is, subpart P is not optional for healthcare facilities that generate above the CESQG monthly quantity limits (see Section V.B.1.c. of the preamble for a discussion of what regulations apply to CESQGs). EPA is proposing to make subpart P mandatory to promote national consistency, a goal championed by stakeholder comments as well as EPA. In addition, having one set of standards applicable to pharmaceutical waste will be less confusing to the regulated community, which should lead to better compliance. The stringency of the subpart P management standards for hazardous waste pharmaceuticals do not change if a healthcare facility generates more hazardous waste pharmaceuticals from one month to another. The generator categories—that is, LQG, SQG, and CESQG—under the part 262 RCRA requirements will only be relevant for the healthcare facilities' non-pharmaceutical hazardous waste because non-pharmaceutical hazardous waste remain subject to the 40 CFR part 262 generator regulations (see Section VI. *Implementation and Enforcement* for further discussion).

b. Long-term care facilities subject to this rule. Long-term care facilities are included within the proposed definition of healthcare facility. Further, EPA is proposing to change its policy regarding the management of hazardous waste and hazardous waste pharmaceuticals generated on the premises of long-term care facilities. Under current federal RCRA interpretation (see 73 FR 73525, December 2, 2008), hazardous wastes (including pharmaceuticals) generated on the premises of a long-term care facility can fall under two categories: (1) RCRA Subtitle C hazardous waste or (2) household hazardous waste that is exempt from RCRA Subtitle C regulation. As explained in the preamble to the proposal to add pharmaceuticals to the Universal Waste program, ''the [long-term care] facility itself may generate hazardous wastes 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 that 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 the long-term care facility, 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 a household'' (see December 2, 2008; 73 FR 73525).

The Agency is now providing notice that it intends to revise this interpretation. Specifically, hazardous waste (including pharmaceuticals) generated at long-term care facilities will no longer be considered exempt as household hazardous waste. It will be regulated as hazardous waste, subject to the appropriate RCRA Subtitle C management standards, including the standards being proposed. The Agency is revising its interpretation with regard to hazardous wastes generated at long-term care facilities based on a reevaluation of how such facilities operate. Specifically, in order for hazardous waste to qualify for the household hazardous waste exemption of § 261.4(b)(1), it 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.[42] EPA now believes that hazardous waste generated at long-term care facilities, even when those pharmaceuticals are under the control of the patient or resident, does not meet either criterion for the household hazardous waste exemption.

First, a long-term care facility is more akin to a hospital than it is a typical residence and EPA does not consider hospitals to be households. Long-term care facilities 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. A 2012 American Association of Retired Person (AARP) Public Policy Institute report indicates that there is an average of 24 beds per licensed residential care facilities (excluding nursing homes).[43] Based on another report prepared as a collaborative project of the American Association of Homes and Services for the Aging (AAHSA), American Seniors Housing Association (ASHA), Assisted Living Federation of America (ALFA), National Center for Assisted Living (NCAL) and National Investment Center for the Seniors Housing and Care Industry (NIC), there is an average of 54 units (*e.g.,* rooms) for all types of assisted living/dementia care properties.[44] Unlike other multiple dwellings, approximately 81 percent of these facilities store medications in a central location and 89 percent administer medications to their residents.[45] Given that long-term care facilities are licensed settings for the care of their residents and routinely provide healthcare services, we believe that long-term care facilities more closely resemble hospitals than typical residences.

Second, the hazardous wastes generated by long-term care facilities do not meet the second criteria for the waste to be considered household hazardous waste. This is primarily due to the quantity of pharmaceutical wastes that are often generated on the premises of long-term care facilities when compared to a typical residence. For example, the Colorado Department of Public Health and Environment estimates that a 100-bed nursing home might expect to generate approximately 120 to 336 pounds of pharmaceutical waste per year.[46] In addition, long-term care facilities, such as assisted living facilities and nursing homes, generate a greater variety of hazardous waste pharmaceuticals and a greater quantity of hazardous waste than a typical household generates. The AARP Public Policy Institute report indicates that ''residents take an average of seven or eight different prescriptions and two OTC [over-the-counter] medications daily.'' This number is larger than what we would expect a typical household to generate. This distinction about volume of waste is analogous to the distinction that EPA has made in the past about contractor or do-it-yourself waste from

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

[43] AARP Public Policy Institute, INSIGHT on the Issues 58, Assisted Living and Residential Care in the States in 2010, April 2012. *http://www.aarp.org/content/dam/aarp/research/public_policy_institute/ltc/2012/residential-care-insight-on-the-issues-july-2012-AARP-ppi-ltc.pdf* or see the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).

[44] 2009 Overview of Assisted Living; a collaborative research project of AAHSA, ASHA, ALFA, NCAL & NIC.

[45] Ibid.

[46] Net weight (without packaging) of types of pharmaceuticals wastes, including those that are RCRA hazardous, non-RCRA hazardous, DEA controlled, prescription and over-the-counter. Memo from Lillian Gonzalez, Colorado Department of Public Health and Environment to Kristin Fitzgerald, EPA; January 9, 2013, see the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).

households: waste from ''routine residential maintenance'' is exempt as household hazardous waste, while waste from ''building construction, renovation, demolition'' is not exempt.[47] Therefore, EPA is providing notice that if this rule is finalized, long-term care facilities may no longer use the household hazardous waste exemption. If this rule is finalized, long-term care facilities would need to manage their hazardous waste pharmaceuticals in accordance with the healthcare facility specific management standards in this proposal and their non-pharmaceutical hazardous wastes in accordance with the applicable RCRA hazardous waste generator requirements in § 261.5 (for CESQGs) or part 262 (for SQGS and LQGs). However, even though long-term care facilities will no longer be considered eligible to use the household hazardous waste exemption, our data show that only 28% of long-term care facilities generate hazardous waste pharmaceuticals, and of those, 85% are small enough to be considered CESQGs of hazardous waste (regulated under § 261.5) and therefore not subject to part 266, subpart P (except the sewer ban).[48] The Agency seeks comment on whether this proposed change to consider long-term care facilities to be healthcare facilities instead of households is appropriate. We also seeking comment on the extent to which long-term care facilities will pass the cost of compliance onto its customers. Until this rule is finalized, the current interpretation from the Universal Waste preamble will stand regarding hazardous waste from long-term care facilities.

c. Conditionally exempt small quantity generators (CESQGs). As discussed in the Background Section (Section IV.A.2), CESQGs are subject to a limited set of federal RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 261.5.[49] This proposed rulemaking will preserve this current regulatory structure for the most part; therefore, healthcare facilities that generate hazardous waste pharmaceuticals and qualify as CESQGs, will maintain their conditional exemption under § 261.5 and will not be subject to *most* aspects of this proposal. However, as part of this rulemaking, EPA is proposing a ban on sewer disposal of hazardous waste pharmaceuticals by all healthcare facilities and reverse distributors. EPA is proposing that the sewer ban would apply to all healthcare facilities, including CESQG healthcare facilities. Please see Section V.E.1 of this preamble for a more detailed discussion on this proposed sewer prohibition. EPA asks for comment on whether the proposed healthcare facility standards, in addition to the sewer ban, should apply to CESQG healthcare facilities.

EPA is proposing one additional change for CESQGs in order to allow them to continue to send their potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor. Currently, under § 261.5, CESQGs are limited in where they may send their hazardous waste for treatment and disposal (see § 261.5(f)(3)(i)-(vii) for acute hazardous waste and § 261.5(g)(3)(i)-(vii) for hazardous waste). However, in § 266.504(a) we are proposing to allow CESQGs to send their potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor. Without this change, CESQGs would be required to send all their hazardous waste pharmaceuticals, including those that are potentially creditable, to one of the types of facilities in § 261.5, which does not include a pharmaceutical reverse distributor. Although we are proposing to make this change within part 266, subpart P, we request comment on whether stakeholders would prefer this change to be made within § 261.5 instead. CESQGs will still be required to send their non-pharmaceutical hazardous waste and their non-creditable hazardous waste pharmaceuticals to one of the types of facilities listed in § 261.5.

In addition, it has been suggested that EPA seek comment on providing a rebuttable presumption that LTCFs with fewer than 10-beds are assumed to be CESQGs and thus would not be required to count the amount of hazardous waste generated each month. Under this presumption, they would be subject to all the requirements for CESQGs as described elsewhere in this proposal, including the requirement not to sewer hazardous waste pharmaceuticals. Therefore, EPA asks for comment on this rebuttable presumption and specifically whether the 10-bed cut off is appropriate or whether there are other criteria EPA should take into account. Further, EPA asks for commenters to submit data to support a 10-bed cut off to show that LTCFs with fewer than 10-beds are generally CESQGs. Alternatively, if comments wish to support a different cut-off for the rebuttable assumption, EPA also asks that the commenters submit information/data to support their suggested cut-off.

d. Pharmaceutical reverse distributors. EPA is proposing that pharmaceutical reverse distributors, including pharmaceutical manufacturers, which accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals are subject to this rule. Pharmaceutical reverse distributors are only subject to this proposed rule 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, it is subject to the applicable RCRA Subtitle C TSDF regulations, including the requirement to have a permit or interim status. Stakeholders have indicated a strong preference for EPA to clarify how pharmaceutical reverse distributors are regulated under RCRA, as states have applied varied hazardous waste regulatory approaches to pharmaceutical reverse distributors. EPA is proposing specific standards in 40 CFR part 266, subpart P for pharmaceutical reverse distributors (as defined in this proposed rule) that incorporate various generator standards, as well as some TSDF standards. See Section V.G for more information.

2. To what facilities does this rule not apply?

a. Pharmaceutical manufacturers. EPA does not intend for these proposed regulations to apply to hazardous waste pharmaceuticals that are generated by pharmaceutical manufacturers or wholesalers. Pharmaceutical manufacturers and wholesalers do not face the same challenges that healthcare facilities experience when managing hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals in accordance with the federal RCRA subtitle C requirements (for an explanation of the challenges healthcare facilities face, see discussion in section IV.B.1 of the preamble). These entities (*i.e.,* manufacturers and wholesalers) generate hazardous waste pharmaceuticals that are more predictable and the staff have the

[47] 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.

[48] See the docket for this rulemaking for data about long-term care facilities which was developed using data in the economic analysis: EPA–HQ–RCRA–2007–0932.

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

necessary expertise to determine which pharmaceutical waste is hazardous waste. However, as mentioned previously, when any facility, including a pharmaceutical manufacturer, meets the definition found in this proposal for a ''pharmaceutical reverse distributor,'' it would be subject to the proposed regulations for pharmaceutical reverse distributors with respect to those operations.

b. Households. The Agency would like to emphasize that the regulatory requirements in this proposed rule do not apply to households or to household pharmaceutical collection and take-back events and programs. (For information regarding collection programs, see Section V.E.2.) Pharmaceuticals that are unwanted by consumers (households) are not regulated as hazardous waste and are generally considered municipal solid wastes. While a small percentage of these household waste pharmaceuticals meet the definition of hazardous waste under RCRA, the federal RCRA hazardous waste regulations include an exclusion for all hazardous wastes generated by households (see the ''household hazardous waste'' exclusion at § 261.4(b)(1)). Thus household waste pharmaceuticals—like other household hazardous wastes—are not subject to the federal RCRA hazardous waste regulations.

''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.'' [50] Some household products, including pharmaceuticals, contain ignitable, corrosive, reactive, or toxic ingredients. As a result, for household hazardous waste collected at a take-back event or program, the Agency has historically recommended that communities operating the collection programs manage the collected household hazardous wastes as hazardous waste, even though it is not required by RCRA.[51] Furthermore, the Agency has recently 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.[52] 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. Nevertheless, the Agency is proposing to make this recommendation a requirement for collected household waste pharmaceuticals in § 266.506.[53] The Agency seeks comment on changing this recommendation to a requirement for pharmaceutical collection programs.

The Agency recommends that, whenever possible, households utilize pharmaceutical collection and take-back events as the disposal option for their unwanted pharmaceuticals. 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. For more information on the safe disposal of household pharmaceuticals, please see: *http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm.*

3. Which hazardous wastes are addressed by this proposed rule?

a. Hazardous waste pharmaceuticals. If finalized, these regulations will only pertain to those pharmaceutical wastes that are RCRA hazardous wastes generated by healthcare facilities or managed by pharmaceutical reverse distributors. Under this rulemaking, EPA is not proposing to add additional pharmaceuticals to the hazardous waste listings or to expand the hazardous waste characteristics to include additional pharmaceuticals. See Section VII of the preamble, *Request for Comment on EPA's Efforts to Identify Additional Pharmaceuticals as Hazardous Waste,* for a discussion of possible future actions by EPA to regulate additional pharmaceuticals as hazardous waste.

b. How does this proposal affect hazardous waste pharmaceuticals that are also regulated by other federal or state regulations? The management, 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; and pharmaceuticals with a radioactive component that are subject to the Atomic Energy Act (AEA). These potentially overlapping requirements make the appropriate management of pharmaceutical wastes a complex matter. The following discusses the impact of this proposed rule on various dually regulated hazardous waste pharmaceuticals.

i. *Hazardous waste pharmaceuticals that are also controlled substances.* Under current regulations, any healthcare facility generating or managing a RCRA hazardous waste pharmaceutical that is also a controlled substance listed in Schedule II–V [54] must comply with the RCRA hazardous waste requirements, as well as the requirements of the Controlled Substances Act and DEA regulations. Recently revised DEA regulations to implement the Secure and Responsible Drug Disposal Act of 2010 require that controlled substances be destroyed so that they are ''non-retrievable.'' [55] In the preamble to both the proposed and final rules, DEA has stated that flushing alone will not meet DEA's new non-retrievable standard.[56] Stakeholders have told EPA that it is expensive and difficult to incinerate controlled substances that are also hazardous wastes under both DEA and EPA regulatory schemes. As a result, healthcare facilities with hazardous waste pharmaceuticals that are also controlled substances have often sewered on-site in order to avoid the expense of complying with dual regulation that would apply if they were incinerated. Due to difficulties associated with managing these hazardous waste pharmaceuticals that are also controlled substances, the Agency is proposing to conditionally exempt from RCRA regulatory requirements those pharmaceuticals that are both a RCRA hazardous waste and a DEA controlled substance, provided the hazardous waste pharmaceuticals that are also DEA controlled substances are combusted at a permitted or interim

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

[51] See memo November 1, 1988, from Porter to Regions (RCRA Online #11377). *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2FD51915214EF63C8525670F006BDC88/$file/11377.pdf.*

[52] See memo September 26, 2012, Rudzinski to the Regional RCRA Division Directors (RCRA Online# 14833). *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/FCB11DD6F61D4B1685257AFE005EB5CE/$file/14833.pdf.*

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

[54] *See* 21 CFR 1308 for a complete list of controlled substances.

[55] Final rule: September 9, 2014; 79 FR 53520.

[56] Proposed rule: December 21, 2012; 77 FR 75784, see page 75803; and final rule: September 9, 2014; 79 FR 53520, see page 53548).

status hazardous waste incinerator, or a permitted municipal solid waste incinerator. A more detailed discussion of this exemption is found in Section V.E.2 of this proposal, *Conditional Exemption for Hazardous Waste Pharmaceuticals that are also Controlled Substances.*

ii. *Hazardous waste pharmaceuticals that are also medical wastes.* There are instances when a hazardous waste pharmaceutical will also exhibit 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 treatment, storage and disposal facility that is also permitted to accept medical wastes. Some examples of dual wastes include un-administered syringes containing hazardous waste pharmaceuticals (*e.g.,* physostigmine) or 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 portion of these ''dual'' wastes are included within these proposed management standards so that healthcare facilities can obtain the benefits of this proposal, while ensuring the hazardous waste portion of the waste is managed appropriately and ultimately delivered to RCRA-permitted TSDFs. In addition, healthcare facilities must still manage the biological hazard in accordance with state and/or local medical waste requirements. EPA notes that autoclaving is not an acceptable method of treating hazardous wastes that are also medical waste. In addition, as discussed in Section V.E.3.c of this preamble, EPA is proposing to conditionally exclude the residues of hazardous waste pharmaceuticals remaining in fully dispensed syringes from RCRA regulation.

iii. *Hazardous waste pharmaceuticals that contain a radioactive component.* Hazardous waste pharmaceuticals that also contain a radioactive component subject to the Atomic Energy Act of 1954 (AEA) (*i.e.,* ''mixed waste'') are regulated by multiple agencies. The hazardous waste component is regulated under EPA or the authorized state RCRA programs, while either the Nuclear Regulatory Commission (NRC) or the Department of Energy (DOE) regulates the radioactive component of the waste under the AEA.[57] Healthcare facilities would be able to use this rule (if finalized) to comply with the hazardous waste component for hazardous waste pharmaceuticals. Although we do not believe that anything in this proposal 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 (62 FR 62079, 62085; November 20, 1997), 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. 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); it would still be required to comply with all of the other hazardous waste pharmaceutical management standards.

4. Management of Wastes Generated at Healthcare Facilities That Are Not Included in the Scope of this Proposed Rule

Wastes that are not included in the scope of this proposed rule include non-hazardous wastes or 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.

a. How should non-hazardous waste pharmaceutical 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 proposal, therefore, does not require that healthcare facilities manage these waste pharmaceuticals under the RCRA subtitle C hazardous waste regulations, including this proposed rule. However, a healthcare facility may choose to manage its solid and hazardous waste pharmaceuticals together (as hazardous waste pharmaceuticals) under these new proposed regulations. Because all healthcare facilities operating under this subpart are regulated in the same way regardless of quantity of pharmaceutical hazardous waste 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 are still considered solid wastes under the federal regulations and must be managed in accordance with applicable federal, state and/or local regulatory requirements.

If a healthcare facility decides to segregate its hazardous and non-hazardous pharmaceuticals, EPA recommends that healthcare facilities follow the best management practices (BMPs) outlined in the ''Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States'' (Practice Greenhealth, Revised August 2008)[58] 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.

i. *Recommended BMPs 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

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

[58] 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*

recommendation of hazardous waste incineration as the BMP for healthcare facilities and pharmaceutical 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,[59] chemotherapeutic agents characterized as bulk wastes,[60] pharmaceuticals which meet the NIOSH Hazardous Drug Criteria,[61] pharmaceuticals listed in Appendix VI of the OSHA Technical Manual,[62] pharmaceuticals with LD50s ≤50 mg/kg, pharmaceuticals that are carcinogenic or endocrine disrupting compounds, and vitamin/mineral preparations containing heavy metals.

ii. *Recommended best management practices for other non-hazardous pharmaceutical wastes (*i.e., *those 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 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 municipal solid waste landfills or medical waste autoclaves 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, there is the potential for wastewater containing APIs to be generated and discharged into the sewer. In addition, some limited studies have shown APIs present in landfill leachate collected in municipal solid waste landfill leachate systems.[63] [64] 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 V.E.1 for more information regarding sewering and APIs).

b. Non-pharmaceutical hazardous wastes. These proposed regulations will only pertain to hazardous waste pharmaceuticals. Therefore, other types of hazardous wastes generated at healthcare facilities that do not meet the definition of a hazardous waste pharmaceutical cannot be managed in accordance with these proposed regulations. 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 proposal. 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.

After a healthcare facility determines it is subject to this proposed rule and manages its hazardous waste pharmaceuticals under part 266, subpart P, it is no longer required to count the hazardous waste pharmaceuticals that it generates towards its generator category. As a result, 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 a SQG or even CESQG 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 generator requirements. It is important to note that only when a healthcare facility is managing its hazardous waste pharmaceuticals under the new proposed subpart does it have the benefit of not counting them towards its generator category (see Section VI. *Implementation and Enforcement* for further discussion).

C. What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals?

This section discusses the proposed management standards for healthcare facilities (except CESQGs) that manage non-creditable hazardous waste pharmaceuticals, which include the following:

(1) Notification requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;

(2) personnel training requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;

(3) making a hazardous waste determination for non-creditable hazardous waste pharmaceuticals;

(4) elimination of central accumulation area and satellite accumulation area requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;

(5) container standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;

(6) labeling standards on containers for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;

(7) accumulation time limits for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;

(8) land disposal restrictions for non-creditable hazardous waste pharmaceuticals;

(9) procedures for shipping non-creditable hazardous waste pharmaceuticals off-site from healthcare facilities;

(10) procedures for managing rejected shipments of non-creditable hazardous waste pharmaceuticals from healthcare facilities;

(11) reporting requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;

(12) recordkeeping requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;

(13) procedures for responses to releases by healthcare facilities managing non-creditable hazardous waste pharmaceuticals;

[59] 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.

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

[61] *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012. http://www.cdc.gov/niosh/docs/2012-150/.*

[62] *OSHA Technical Manual, Section VI: Chapter 2, Appendix VI: 2–1. http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html.*

[63] 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.

[64] 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.

(14) special requirements for long-term care facilities managing non-creditable hazardous waste pharmaceuticals;

(15) conditions for healthcare facilities that accept hazardous waste pharmaceuticals from off-site CESQGs; and

(16) a prohibition of sewering hazardous waste pharmaceuticals for all healthcare facilities; (see section V.E.1. of the preamble, *Sewer Disposal Prohibition*).

The proposed management standards discussed in this section only apply to hazardous waste pharmaceuticals that are non-creditable hazardous waste pharmaceuticals (*i.e.,* they are destined for a RCRA permitted or interim status TSDF). They do not apply to those hazardous waste pharmaceuticals that meet the definition of a ''potentially creditable hazardous waste pharmaceutical.'' Please refer to Section V.D for the proposed healthcare facility management standards for potentially creditable hazardous waste pharmaceuticals that are transported to reverse distributors for the processing of manufacturer's credit.

1. Notification Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

In order to address commenters' concerns from the 2008 Pharmaceutical Universal Waste proposal that regulatory agencies are unaware of hazardous waste pharmaceutical management activities, EPA is proposing to require that a healthcare facility that does not qualify as a CESQG to submit a one-time notification as a ''healthcare facility'' to the appropriate EPA Regional Administrator. Healthcare facilities subject to 40 CFR part 266, subpart P will have to submit notification even if the healthcare facility has previously obtained an EPA identification number. The required notification will 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. In addition, having this information allows EPA and state environmental regulatory agencies to track healthcare facilities for enforcement and inspection purposes, ensuring the hazardous waste pharmaceuticals are managed in accordance with the regulations.

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 CESQG. In this case, if the healthcare facility plans to withdraw from the 40 CFR part 266, subpart P requirements due to qualifying as a CESQG, it will be required to re-notify EPA of its choice to withdraw.

Alternatively, if a healthcare facility determines that it is a CESQG,[65] but does not want to keep track of the amount of hazardous waste generated and whether it is above or below the CESQG threshold limit, it can choose to operate under this proposed rule. By choosing to operate under this proposed rule, the CESQG healthcare facility must comply with *all* of the requirements and must submit the one-time notification that it is operating under 40 CFR part 266, subpart P. Healthcare facilities that are not CESQGs, however, are required to operate under 40 CFR part 266, subpart P for the management of their hazardous waste pharmaceuticals.

The Agency is proposing that this notification occur via the RCRA Subtitle C Site Identification Form (EPA Form 8700–12; or Site Identification Form).[66] 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 are proposing 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. 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.

If this notification requirement is finalized, the Site Identification Form will be modified by EPA in a separate action.[67] Specifically, the Agency intends to amend the Site Identification Form by adding a section to the form for a healthcare facility to indicate the type of entity it is (*e.g.,* a hospital, a doctor's office, a veterinary clinic, a pharmacy, an assisted living facility, etc.) and 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 section in order to allow a healthcare facility to indicate that its generator category is changing to a CESQG and it is no longer managing its hazardous waste pharmaceuticals according to 40 CFR part 266, subpart P.

The Agency does not anticipate that this proposed notification requirement will 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 rule in the rulemaking docket EPA–HQ–RCRA–2007–0932). In fact, under these 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 change their generator category to either a SQG or CESQG 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 in their jurisdictions, the fact that some healthcare facilities will no longer qualify as LQGs will reduce the number of healthcare facilities in the LQG universe. Because LQGs are inspected more frequently than SQGs or CESQGs, EPA expects this could result in an overall decrease in burden for both

[65] A generator is a CESQG if it generates less than or equal to 100 kg of hazardous waste per calendar month, and less than or equal to 1 kg of acute hazardous waste per calendar month and <100 kg of any residue or contaminated soil, waste or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or § 261.33(e) per calendar month, provided it does not accumulate on-site at any time >1 kg of acute hazardous waste or >1000 kg of hazardous waste.

[66] For information on the current Site Identification Form, please *see: http://www.epa.gov/wastes/inforesources/data/form8700/8700-12.pdf.*

[67] The Information Collection Request (ICR) for the Site Identification Form (87000–12) is updated every three years and must be approved by the Office of Management and Budget (OMB). These updates and OMB approvals are published in the **Federal Register** and are subject to public comment.

the healthcare facilities and the environmental regulatory agencies.

The Agency is soliciting 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. Personnel Training Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Under the current RCRA Subtitle C regulations, an LQG healthcare facility must provide RCRA training to its healthcare workers involved in the generation and/or management of hazardous waste. Under § 262.34(a)(4), LQGs are required to comply with the personnel training requirements for interim status TSDFs (which are found in § 265.16). These personnel training requirements include either classroom instruction or on-the-job training in RCRA and state that the facility must maintain training documents and records for each trained staff person. On the other hand, under current regulation, healthcare facilities that are SQGs must meet a performance-based standard when training their healthcare workers. This entails ensuring ''that all employees are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies'' (§ 262.34(d)(5)(iii)). For comparative purposes, healthcare facilities that are considered CESQGs do not have any personnel training requirements under the current federal regulations. Similarly, generators, including healthcare facilities, are not required to provide RCRA training to personnel that only work in satellite accumulation areas regulated under § 262.34(c). However, healthcare personnel that are involved in the generation of pharmaceutical waste must be familiar enough with the pharmaceuticals with which they are working to know when they have generated a hazardous waste so that it will be managed in accordance with the RCRA regulations.

EPA believes that the LQG RCRA training requirement is excessive for healthcare workers who sporadically generate hazardous waste pharmaceuticals at healthcare facilities, but believe it is necessary to have some familiarity with the dangers that hazardous waste pharmaceuticals can pose. Therefore, the Agency is proposing healthcare facility-specific personnel training requirements that are akin to the training requirements for SQGs and small quantity universal waste handlers. Specifically, healthcare facilities managing their hazardous waste pharmaceuticals in accordance with the proposed healthcare facility standards 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. 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 and that would be acceptable, as well.

The Agency solicits comments on the personnel training requirements proposed in this document for healthcare facilities managing hazardous waste pharmaceuticals. Specifically, the Agency is seeking comment regarding the appropriateness of these personnel training requirements and if these requirements will be sufficient for communicating key procedures to healthcare workers that generate and/or manage hazardous waste pharmaceuticals.

EPA is seeking comment on whether documentation of training is necessary in order to verify compliance with the training requirement. Based on the comments received, we may include a requirement in the final rule for documenting and retaining records of healthcare personnel training. Finally, the Agency wants to reiterate that these proposed personnel training requirements only apply to staff generating and/or managing hazardous waste pharmaceuticals. The training requirements of 40 CFR part 262 will continue to apply to staff generating and/or managing other types of hazardous wastes at the healthcare facility.

3. Making a Hazardous Waste Determination for Non-Creditable Hazardous Waste Pharmaceuticals

Similar to the current RCRA Subtitle C generator requirements, healthcare facilities will still be required to make a hazardous waste determination on pharmaceutical wastes prior to managing them under the proposed cradle-to-grave standards. Therefore, when a healthcare facility generates a solid waste pharmaceutical, the healthcare facility must determine if the pharmaceutical waste is listed in 40 CFR part 261, subpart D and if it exhibits one or more of the four characteristics of hazardous waste identified in 40 CFR part 261, subpart C. However, unlike the existing generator requirements, the healthcare facility does not need to identify the specific waste codes applying to the pharmaceutical wastes. If the pharmaceutical waste is determined to be a hazardous waste, then the healthcare facility must manage the hazardous waste pharmaceuticals in accordance with these proposed requirements instead of 40 CFR part 262. Pharmaceutical wastes 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 contractors 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 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 the central accumulation area. Due to the various ways that healthcare facilities make the hazardous waste determination, the Agency is not proposing that a specific approach be utilized when making the determination, only that the facility performs the waste determination. However, healthcare facilities may choose 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, but would have made a generic decision that all of their waste pharmaceuticals are hazardous and manage them as hazardous waste pharmaceuticals in accordance with the proposed requirements in 40 CFR part 266, subpart P.

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

Hazardous waste pharmaceuticals are generated at numerous locations across a healthcare facility. Under the current RCRA Subtitle C requirements, each location at the healthcare facility with a RCRA hazardous waste receptacle for the disposal of hazardous waste pharmaceuticals is considered a satellite accumulation area and is subject to volume accumulation limits and other requirements.[68] Of particular concern regarding the satellite accumulation requirements for healthcare facilities is the one quart accumulation limit for acute hazardous wastes (*i.e.,* P-listed wastes). Under the December 2008 Pharmaceutical Universal Waste proposal, no accumulation areas, central or satellite, were proposed to be established 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 satellite accumulation areas for universal wastes. Nevertheless, EPA understands that facilities that handle universal wastes will often accumulate their universal wastes within their 90- or 180-day hazardous waste accumulation areas.

For the reasons articulated in the Pharmaceutical Universal Waste proposal, the Agency has decided that a healthcare facility accumulating hazardous waste pharmaceuticals will not be subject to the satellite accumulation area regulations or the central accumulation area regulations (also sometimes called less than 90- or 180-day areas), but rather to the proposed accumulation time limits and container standards.

A healthcare facility may choose to accumulate hazardous waste pharmaceuticals within its 90- or 180-day central accumulation area if it has one established for its other hazardous wastes as long as it maintains compliance with the proposed accumulation time limit and container requirements of 40 CFR part 266, subpart P. The Agency notes that even if the hazardous waste pharmaceuticals are accumulated in a 90- or 180-day central accumulation area, these hazardous waste pharmaceuticals are not subject to the 90- or 180-day requirements. EPA solicits public comment on its decision to not require hazardous waste pharmaceutical-specific central and satellite accumulation area requirements.

5. Container Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

The container standards discussed in this section apply to those containers used by healthcare facilities to accumulate, store and transport non-creditable hazardous waste pharmaceuticals.[69] 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 are only proposing standards for containers. However, the Agency solicits 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 is proposing to require that healthcare facilities pack 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 hazardous waste pharmaceuticals must be in good condition, with no severe rusting, apparent structural defects, or deterioration. 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 is proposing to require that incompatible wastes not be placed in the same container, unless the co-mingling 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 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. However, some non-creditable hazardous waste pharmaceuticals, such as metal bearing wastes not containing sufficient organics, are prohibited from being incinerated (*e.g.,* P012, arsenic trioxide). The hazardous waste pharmaceuticals that cannot be incinerated must be accumulated separately from organic wastes destined for incineration.

The Agency believes that these technical standards, like similar technical standards that EPA has promulgated in § 265.17 for interim status TSDFs, 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 is also proposing that accumulation containers for hazardous waste pharmaceuticals be secured in a manner that prevents unauthorized access to the contents in order to prevent the pilfering of hazardous waste pharmaceuticals or inadvertent exposures to them. As we have noted previously, hazardous waste pharmaceuticals still retain considerable value and can easily be diverted for illicit purposes. To ensure this does not occur, we believe it is important to propose a requirement that would prevent the unauthorized access to the contents of these containers. EPA intends this requirement to be performance-based and does not intend to propose prescriptive regulatory requirements for this standard. The Agency believes that healthcare facilities can choose to utilize containers that have built-in mechanisms to prevent access to their contents or can choose to store containers in locked storage lockers, closets or rooms where the public does not have access to the containers or their contents.

[68] See § 262.34(c) for the satellite accumulation requirements. For additional information on satellite accumulation areas, please see the memorandum from Robert Springer to the EPA Regional RCRA Directors, ''Frequently Asked Questions about Satellite Accumulation Areas'' (RCRA Online #14703) *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/0AC9E15424B2897D8525770600609793/$file/14703.pdf.*

[69] The container standards proposed do not apply to the various packaging, blister packs, bottles, vials, IV bags, etc., in which pharmaceuticals are stored prior to being dispensed or administered.

The Agency is seeking comment on the appropriateness of the proposed container management standards. In addition, the EPA is soliciting comment on the proposed requirement for ensuring that the hazardous waste pharmaceuticals contained in collection containers remain secure.

6. Labeling Standards on Containers for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

During the period of accumulation and storage, the Agency is proposing that containers of hazardous waste pharmaceuticals be marked with the words ''Hazardous Waste Pharmaceuticals.'' The Agency is not proposing to require that the hazardous waste numbers (often referred to as hazardous waste codes) of the container's contents be listed on the label. The personnel at healthcare facilities that typically generate the hazardous waste pharmaceuticals will be healthcare workers (*e.g.,* nurses). Healthcare workers 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 pharmaceutical waste is generated. For these reasons, EPA does not believe it is necessary to require individual waste codes on the hazardous waste pharmaceutical collection container at the healthcare facility. The Agency is soliciting comment on the appropriateness of the proposed general labeling requirement. The Agency also requests comment on security concerns regarding having the word ''pharmaceutical'' marked on the containers.

7. Accumulation Time Limits for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Several hazardous waste pharmaceuticals are P-listed, acute hazardous wastes (*e.g.,* nicotine, warfarin, etc.). Under current regulations, if a generator generates more than 1 kg of acute hazardous waste per calendar month or accumulates more than1 kg of acute hazardous waste at any time, the generator is regulated as an LQG. 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 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 Pharmaceutical Universal Waste proposal, universal waste handlers would have had one year for accumulation of its hazardous waste pharmaceuticals in order to facilitate proper treatment and disposal. Commenters on the 2008 Universal Waste proposed rule indicated support for the one-year accumulation time limit. Thus, the Agency is proposing to allow healthcare facilities to accumulate hazardous waste pharmaceuticals for up to one year, without having interim status or a RCRA permit. As with Universal Waste, one year is an appropriate timeframe because it strikes a balance between allowing healthcare facilities enough time to accumulate amounts of hazardous waste pharmaceuticals to make it economically viable for transporting their hazardous waste pharmaceuticals off-site while ensuring that the hazardous wastes are not accumulated beyond the one year storage limit under the land disposal restrictions programs (see § 268.50).[70]

Healthcare facilities will have various approaches to demonstrate the length of time that hazardous waste pharmaceuticals are accumulated on-site. For example, 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 central accumulation area[71] the earliest date that a hazardous waste pharmaceutical became a 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. The Agency assumes that any accumulation for up to one year is for the purpose of facilitating proper treatment and disposal. EPA proposes to require that any healthcare facility needing a longer accumulation time for any unforeseen circumstances beyond the control of the healthcare facility (*e.g.,* a recall or litigation) request an extension from the appropriate EPA Regional Administrator. This request must be sent in writing (electronic or paper) explaining the need for the extension, the approximate amount of hazardous waste pharmaceuticals accumulated beyond the one year, and the amount of extra time requested. An extension period will be granted at the discretion of the Regional Administrator on a case-by-case basis.

Finally, 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 hazardous waste generated on-site or to potentially creditable hazardous waste pharmaceuticals. EPA solicits comment on the proposed accumulation time limit of one year in order to allow healthcare facilities to generate enough non-creditable hazardous waste pharmaceuticals for cost-effective shipment, and solicits comment on the proposed mechanism to request a time extension.

8. Land Disposal Restrictions for Non-Creditable Hazardous Waste Pharmaceuticals

Similar to the current RCRA Subtitle C generator requirements, healthcare facilities must comply with the land disposal restrictions (LDR) 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, they must comply with the land disposal restrictions found at 40 CFR part 268. The land disposal restrictions 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. Again, EPA notes that autoclaving is not an acceptable method of treating hazardous waste.

In general, generators of hazardous waste assign the appropriate hazardous waste numbers codes to allow TSDFs to determine the specific treatment standard(s) for each prohibited waste. The Agency is proposing that healthcare facilities generating non-creditable hazardous waste pharmaceuticals do not have to assign hazardous waste codes to these wastes, but rather label them as ''hazardous waste pharmaceuticals''. They do, however, need to be aware that

[70] See the preamble to the Universal Waste final rule: May 11, 1995; 60 FR 25492 (page 25526).

[71] While the proposed rules do not require healthcare facilities to comply with the central accumulation requirements under 262.34, a healthcare facility may have a central accumulation area for the other hazardous wastes that it generates.

while most of the hazardous waste pharmaceuticals are likely organic in nature and will be incinerated, some of their hazardous waste pharmaceuticals may not be suitable for incineration and therefore must be segregated from the organic wastes. The pharmaceutical hazardous wastes not suitable for incineration include characteristic metal wastes 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. In order to comply with the LDRs, healthcare facilities will need to segregate these wastes from the organic pharmaceutical hazardous wastes so that they can be properly treated by the TSDF. The Agency seeks comment on whether it is necessary to incorporate into the regulations 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.

Tables 2 through 4 list the hazardous waste pharmaceuticals with their hazardous waste codes and their LDR treatment standards.

Table 2: Waste Codes of Characteristic Hazardous Waste Pharmaceuticals

Waste Code	Description	Non-Wastewater Treatment Standard
D001	Ignitable	
	Ignitable All D001, except high TOC D001 261.21(a)(1)	DEACT and UTS or RORGS or CMBST
	Ignitable High TOC D001 based on 261.21(a)(1)	RORGS or CMBST or POLYM
D002	Corrosivity	DEACT and UTS
D004 *	Arsenic	5.0 mg/L TCLP and UTS
D005 *	Barium	21 mg/L TCLP and UTS
D006 *	Cadmium	0.11 mg/L TCLP and UTS
D007 *	Chromium	0.60 mg/L TCLP and UTS
D008 *	Lead	0.75 mg/L TCLP and UTS
D009*	Mercury	
	Mercury ≥260 mg/kg total Hg (high mercury organics)	IMERC or RMERC
	Mercury < 260 mg/kg total Hg & are not residues from RMERC (low mercury)	**0.025 mg/L TCLP and UTS**
D010 *	Selenium	5.7 mg/L TCLP and UTS
D011 *	Silver	0.14 mg/L TCLP and UTS
D013	**Lindane**	
	Lindane alpha-BHC	**0.066 mg/kg and UTS**
	Lindane beta-BHC	**0.066 mg/kg and UTS**
	Lindane delta-BHC	**0.066 mg/kg and UTS**
	Lindane gamma-BHC	**0.066 mg/kg and UTS**
D022	**Chloroform**	**6.0 mg/kg and UTS**

Waste Code	Description	Non-Wastewater Treatment Standard
D024	**m-Cresol**	**5.6 mg/kg and UTS**

*Waste code may not be treated by combustion unless the waste meets one of the criteria in § 268.3(c) (e.g., has >1% total organic carbon)
BOLD indicates that the waste is an organic waste with a concentration-based treatment standard
UTS = Universal Treatment Standards in § 268.48

Table 3: P-listed Hazardous Waste Pharmaceuticals

Waste Code	Description	Non-Wastewater Treatment Standard
P001	Warfarin (concentration > 0.3%)	CMBST
P012 *	Arsenic trioxide	5.0 mg/L TCLP
P042	Epinephrine	CMBST
P046	Phentermine	CMBST
P075	Nicotine	CMBST
P081	Nitroglycerin	CMBST
P188	Physostigmine salicylate	1.4 mg/kg or CMBST
P204	Physostigmine	1.4 mg/kg or CMBST

*Waste code may not be treated by combustion unless the waste meets one of the criteria in § 268.3(c) (e.g., has >1% total organic carbon)

Table 4: U-listed Hazardous Waste Pharmaceuticals

Waste Code	Description	Non-Wastewater Treatment Standard
U010	Mitomycin	CMBST
U015	Azaserine	CMBST
U034	Chloral hydrate	CMBST
U035	Chlorambucil	CMBST
U044	**Chloroform**	**6.0 mg/kg**
U058	Cyclophosphamide	CMBST
U059	Daunomycin	CMBST
U075	**Dichlorodifluoromethane**	**7.2 mg/kg**

Waste Code	Description	Non-Wastewater Treatment Standard
U089	Diethylstilbestrol	CMBST
U121	**Trichloromonofluoromethane**	**30 mg/kg**
U122	Formaldehyde	CMBST
U129	**Lindane**	
	Lindane alpha-BHC	**0.066 mg/kg**
	Lindane beta-BHC	**0.066 mg/kg**
	Lindane delta-BHC	**0.066 mg/kg**
	Lindane gamma-BHC	**0.066 mg/kg**
U132	Hexachlorophene	CMBST
U150	Melphalan	CMBST
U151*	Mercury	
	Mercury ≥260 mg/kg total Hg (high mercury organics)	IMERC or RMERC
	Mercury < 260 mg/kg total Hg & are not residues from RMERC (low mercury)	**0.025 mg/L TCLP and UTS**
U182	Paraldehyde	CMBST
U187	**Phenacetin**	**16 mg/kg**
U188	**Phenol**	**6.2 mg/kg**
U200	Reserpine	CMBST
U201	Resorcinol	CMBST
U205 *	Selenium sulfide	5.7 mg/L TCLP
U206	Streptozotocin	CMBST
U237	Uracil mustard	CMBST
U248	Warfarin (Concentration ≤ 0.3%)	CMBST

*Waste code may not be treated by combustion unless the waste meets one of the criteria in § 268.3(c) (e.g., has >1% total organic carbon)

BOLD indicates that the waste is an organic waste with a concentration-based treatment standard

UTS = Universal Treatment Standards in § 268.48

The organic hazardous waste pharmaceuticals (other than arsenic trioxide) may all be incinerated at RCRA permitted or interim status hazardous waste combustors. As noted in Tables 2–4, most of the organic wastes have a specified treatment standard of combustion (CMBST). The remaining seven organics (lindane, chloroform, m-cresol, dichlorodifluoro methane, trichloromonofluoromethane, phenacetin and phenol) have numerical treatment standards, such that no particular treatment technology is specified or required in order to achieve the numerical treatment standards. While these wastes may be incinerated, the incinerator residue (ash) must be analyzed for these seven organic constituents to demonstrate compliance with the LDR treatment standards before that ash can be disposed.

As mentioned earlier, because this proposed rule does not require that healthcare facilities label their waste with the hazardous waste codes, the TSDF must always analyze the incinerator ash for these seven constituents—lindane, chloroform, m-cresol, dichlorodifluoro methane, trichloromonofluoromethane, phenacetin, and phenol—according to their waste analysis plan, as they could possibly be present in any shipment of organic hazardous waste pharmaceuticals.

a. Alternative treatment standards considered. In their comments to 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.[72] Specifying combustion would relieve the TSDFs from demonstrating compliance with the numerical treatment standards. EPA explored the feasibility of making combustion an alternative treatment standard for the seven organic hazardous waste pharmaceuticals that currently have numeric treatment standards. In fact, EPA notes that the numerical treatment standards were developed based on levels achieved through combustion. However, in order to allow maximum flexibility, EPA has indicated a preference for numerical treatment standards over specifying treatment standards whenever possible. 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 incinerators 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.

b. Incineration of mercury-containing hazardous waste pharmaceuticals. It is rare, but some pharmaceuticals contain mercury (*e.g.,* thimerosal, a mercury-containing preservative). When discarded, a mercury-containing pharmaceutical would be a D009 hazardous waste if the leachate generated by the toxicity characteristic leaching procedure (TCLP), or if the pharmaceutical itself (when the waste contains < 0.5% filterable solids), contains ≥ 0.2 mg/L mercury (see § 261.24).[73] As indicated in Table 2, a D009 hazardous waste with mercury content ≥ 260 mg/kg of total mercury and that also contains organics, must be treated by IMERC (incineration) or RMERC (mercury retorting). However, hazardous waste pharmaceuticals that are D009 are expected to have mercury content <260 mg/kg, in which case the treatment standards are numeric and treatment by RMERC or IMERC is not required. With numeric treatment standards, the generator has flexibility regarding which hazardous waste treatment method to use to meet the treatment standard. As explained previously, incineration of mercury-bearing hazardous waste with >1% total organic carbon is not considered impermissible dilution (see § 268.3(c)) and therefore is an allowable form of treatment.

Emissions from combustion units that burn hazardous waste[74] are regulated under RCRA and the Clean Air Act (CAA). The implementing regulations under these statutory authorities include emission limits for new and existing combustion units for mercury, semi-volatile metals (cadmium and lead), low volatility metals (arsenic, beryllium, and chromium), particulate matter, chlorinated dioxins and furans, other toxic organic compounds, hydrogen chloride and chlorine. The regulations also (1) specify when and how combustion sources must comply with the emission standards and operating requirements, (2) prescribe detailed monitoring requirements to show continuous compliance with the emission standards, and (3) prescribe performance testing requirements to demonstrate compliance with the emission standards (see 40 CFR part 63, subpart EEE).

To ensure continuous compliance with the emission limits, hazardous waste combustors are required to establish limits on (1) the feedrate of metals (including mercury), chlorine, and (for some types of hazardous waste combustors) ash; (2) combustor operating parameters such as minimum combustion chamber temperature; and (3) operating parameters of the air pollution control device. For mercury, continuous compliance requirements would generally include a limit on the total feedrate of mercury in all feedstreams to the combustion unit, limits on the operation of a wet scrubber (depending on the species of mercury in the combustion gases, wet scrubbers can be efficient at removing mercury), and operating limits on the activated carbon injection or carbon bed system, if such systems are used.

In addition, RCRA directs permitting authorities to impose additional terms and conditions on a site-specific basis as may be necessary to protect human health and the environment (see § 270.32(b)). Thus, if the mercury emission limits specified previously are not protective in an individual instance, the permit writer will establish permit limits that are protective.

Nevertheless, EPA is aware that some stakeholders are concerned about the risks associated with incinerating mercury-bearing hazardous wastes and we encourage healthcare facilities and pharmaceutical reverse distributors to consider the use of treatment technologies other than incineration for meeting the numeric treatment standards for mercury-bearing hazardous waste pharmaceuticals. Thimerosal-containing pharmaceuticals are expected to be non-wastewaters as defined by § 268.2, because they have more than 1% total organic carbon. For low mercury non-wastewaters, the numeric treatment standard can be achieved by stabilization/solidification, either with or without subsequent encapsulation.[75]

9. Shipments of Non-Creditable Hazardous Waste Pharmaceuticals Off-site From Healthcare Facilities

The Agency is proposing to maintain the current RCRA Subtitle C tracking requirement by requiring that a hazardous waste manifest be prepared for each off-site shipment of non-creditable hazardous waste pharmaceuticals from healthcare facilities. Accordingly, each off-site shipment of hazardous waste pharmaceuticals must be transported to an interim status or permitted TSDF via a hazardous waste transporter. However, the Agency is proposing that for hazardous waste pharmaceuticals shipped by healthcare facilities, the RCRA hazardous waste codes do not need to be listed on the manifest. This is intended to accommodate the fact that healthcare providers generating the hazardous waste pharmaceuticals are generally unfamiliar with RCRA and are focused on providing healthcare to patients. One function of the hazardous waste codes is to determine the appropriate hazardous waste treatment standards under the land disposal restrictions (part 268). However, virtually all hazardous waste pharmaceuticals sent for off-site treatment are sent to hazardous waste incinerators, even when the treatment standard does not require incineration. The fact that EPA is proposing to not require hazardous waste codes for shipping hazardous waste pharmaceuticals is not intended to alter or impact any Department of Transportation (DOT) requirements for the shipment of these hazardous wastes. For a more detailed discussion of these proposed requirements, as well as the basis for these requirements, please see Section V.F.1 of this document.

[72] See comment number 0125 in the docket for this rulemaking. EPA–HQ–RCRA–2007–0932.

[73] The Agency is not aware of any hazardous waste pharmaceuticals that would be considered U151 because mercury would have to be the sole active ingredient.

[74] Combustors that burn hazardous waste include the following types of combustion units: Incinerators, cement kilns, lightweight aggregate kilns, industrial boilers and process heaters, and hydrochloric acid production furnaces.

[75] EPA is not aware of any testing done to demonstrate the effectiveness of this treatment method specifically for thimerosal-containing hazardous wastes, so vendors performing such treatment may need to do treatability studies to identify optimal use of stabilization/solidification treatment technologies.

10. Rejected Shipment From Healthcare Facilities of Non-creditable Hazardous Waste Pharmaceuticals

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 are proposing that healthcare facilities follow the same procedures listed in 40 CFR part 262 (see § 262.23(f)). Specifically, if a designated facility is unable to accept the hazardous waste pharmaceuticals, and it returns the hazardous waste pharmaceuticals to the healthcare facility, 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 thirty days to the designated facility that returned the shipment and retain a copy of the manifest for three years from the date of delivery of the returned shipment. 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.

11. Reporting Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

The Agency is proposing that healthcare facilities managing non-creditable hazardous waste pharmaceuticals have reporting requirements similar to SQGs s 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). In addition, we are proposing that healthcare facilities that are LQGs would no longer be required to include their hazardous waste pharmaceuticals on their biennial report (BR). Each of these reporting requirements for healthcare facilities is discussed below.

First, as part of the current RCRA Subtitle C generator requirements, 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. However, it need not include its hazardous waste pharmaceuticals in its BR. As discussed previously, the Agency is no longer requiring healthcare facilities to count hazardous waste pharmaceuticals when determining their generator category. Instead, all healthcare facilities, with the exception of CESQGs, will be subject to this proposed rule. The Agency has determined that it does not need the information to be included in the BR because this proposed rule will bring a consistent approach to managing pharmaceutical hazardous wastes. Nevertheless, the Agency is soliciting public comment on whether the Agency should require healthcare facilities—that is, all healthcare facilities subject to the 40 CFR part 266, subpart P requirements—to submit a BR, and if so, the type of information that should be included.

Second, the Agency is proposing that healthcare facilities follow the same reporting procedures for exception reporting that generators operating under the 40 CFR part 262 must follow. We are proposing to incorporate the generator exception reporting procedures in this new subpart. Specifically, if a healthcare facility does not receive a copy of the hazardous waste manifest from the designated facility within 60 days, the healthcare facility must submit to the EPA Regional Administrator a copy of the manifest with a statement that the healthcare facility did not receive confirmation of the hazardous waste pharmaceuticals' delivery along with an explanation of the efforts taken to locate the hazardous waste pharmaceuticals and the results of those efforts. Likewise, if a shipment of 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 hazardous waste pharmaceuticals' delivery along with an explanation of the efforts taken to locate the hazardous waste pharmaceuticals and the results of those efforts. Again, 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.

Finally, the Agency proposes 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 requirements. 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. The Agency solicits public comment on the proposed reporting requirements for healthcare facilities managing their hazardous waste pharmaceuticals in accordance with the standards proposed in this document.

12. Recordkeeping Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

The Agency is proposing 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, 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 the each exception report for a period of at least three years from the due date of the report.[76] In addition, EPA is proposing 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.

[76] § 262.40 requires that generators keep a copy of each BR for a period of at least three years from the due date of the report. However, since we are not requiring a healthcare facility to include its hazardous waste pharmaceuticals on its a BR, the Agency is also not including in subpart P a requirement that a BR be kept at the healthcare facility. If healthcare facility must submit a BR due to its non-pharmaceutical hazardous waste, the § 262.40 recordkeeping requirements will apply (see the discussion under Reporting Requirement for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals for the Agency's basis of not requiring healthcare facilities to include hazardous waste pharmaceuticals on the BR.

The Agency is also proposing that any of the retention periods be extended during the course of enforcement actions against any activity associated with hazardous waste pharmaceutical management or as requested by the Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action. The Agency solicits public comment on the proposed recordkeeping requirements for healthcare facilities managing their non-creditable hazardous waste pharmaceuticals in accordance with the standards proposed in this document.

13. Response to Releases by Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

For hazardous waste pharmaceuticals generated and managed by healthcare facilities under the proposed standards, the Agency is proposing basic release responses, including the requirement that healthcare facilities immediately contain all releases of, and other residues from, hazardous waste pharmaceuticals. In addition, this proposal would require healthcare facilities to determine whether any material, residue, or debris resulting from the release is or contains a hazardous waste pharmaceutical and, if so, to manage it under the management standards for hazardous waste pharmaceuticals proposed in this document. These proposed release response procedures are the same as those under the Universal Waste program (see § 273.17 for small quantity universal waste handlers, and § 273.37 for large quantity universal waste handlers). Commenters to the 1993 proposed rule that established the Universal Waste program overwhelmingly supported the release response measures (60 FR 25528; May 11, 1995). Thus, we believe it is appropriate to include it again in this proposal.

Any releases of hazardous waste pharmaceuticals not cleaned up immediately would generally constitute illegal disposal, which may result in further action by EPA or an authorized state under RCRA. In addition, hazardous wastes under RCRA are included in the definition of hazardous substances for purposes of the Comprehensive Environmental Response Compensation, and Liability Act (CERCLA) (*see* CERCLA Section 101(14) [77]). Thus, any releases into the environment of hazardous substances above the reportable quantity (RQ) thresholds must be reported under CERCLA (*see* CERCLA Section 103). That is, since hazardous waste pharmaceuticals are hazardous wastes and, hazardous substances under CERCLA, reporting for hazardous waste pharmaceutical releases is required when RQs are exceeded (*see* 40 CFR 302.4 for a list of RQs and hazardous substances). Such reports provide notification to the Agency (through the National Response Center) concerning releases into the environment and help inform whether EPA should take action, if necessary, under either RCRA or CERCLA.

The Agency solicits comment regarding the proposed standard for the response to releases of hazardous waste pharmaceuticals at healthcare facilities.

14. Long-Term Care Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Long-term care facilities differ in one respect from other types of healthcare facilities subject to these proposed standards. Unlike hospitals, who own the pharmaceuticals they dispense to patients, many of the hazardous waste pharmaceuticals generated at long-term care facilities belong to the residents of the facility. That is, the pharmaceuticals are dispensed under the patient's name. However, as previously discussed in this preamble, EPA is proposing to no longer allow hazardous waste pharmaceuticals generated at long-term care facilities (as defined under this proposed regulation) to be eligible for the household hazardous waste exemption. As a result, long-term care facilities must manage all hazardous waste pharmaceuticals generated on-site, regardless of ownership, in accordance with these same proposed management standards for healthcare facilities. 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 may keep and self-administer their own pharmaceuticals. EPA is proposing that the long-term care facilities collect and manage all hazardous waste pharmaceuticals generated at their facilities in accordance with these proposed requirements. This requirement means that in addition to the hazardous waste pharmaceuticals kept in the centralized location, long-term care facilities will need to collect all other hazardous waste pharmaceuticals from individuals that self-administer these pharmaceuticals and manage them in accordance with these proposed standards, which, among other things, prohibits the sewering of hazardous waste pharmaceuticals. The Agency solicits comment on the extent to which long-term care facilities keep an inventory of the pharmaceuticals that individuals self-administer, as this would facilitate the collection of the hazardous waste pharmaceuticals for proper disposal.

Although long-term care facilities would not be required under this rule to collect non-hazardous waste pharmaceuticals, or hazardous waste pharmaceuticals from the independent living portion of a continuing care facility, EPA recommends that long-term care facilities collect all waste pharmaceuticals to ensure proper management, avoid flushing, and minimize the potential for accidental poisonings, misuse or abuse. As discussed later in this preamble, DEA regulations govern the management of controlled substances (see Section V.E.2.a of the preamble for a discussion of DEA's 2014 final rule for the disposal of controlled substances and the implications of that rule and this proposed rule for long-term care facilities.[78]) Also discussed later in more detail, EPA is proposing to exempt from RCRA those hazardous waste pharmaceuticals that are also controlled substances, provided they are combusted at a permitted or interim status hazardous waste incinerator or permitted municipal solid waste incinerator and managed in compliance with applicable DEA regulations (see Section V.E.2 of the preamble for a detailed discussion of the exemption).

The Agency solicits comment regarding this requirement, and specifically requests comment on the various approaches that long-term care facilities use, or could use in collecting hazardous waste pharmaceuticals from individuals that self-administer their pharmaceuticals.

15. Healthcare Facilities That Accept Hazardous Waste Pharmaceuticals From Off-Site Conditionally Exempt Small Quantity Generators (CESQGs) [79]

Typically, hazardous waste pharmaceuticals from healthcare facilities are transported either to a reverse distributor, if it is potentially creditable,[80] or to a permitted or interim

[77] *http://www.epw.senate.gov/cercla.pdf.*

[78] DEA's final rule for disposal of controlled substances: 79 FR 53520; September 9, 2104.

[79] Unlike other sub-sections of Section V.C., which discusses the proposed standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals, this sub-section addresses both non-creditable and creditable hazardous waste pharmaceuticals.

[80] Potentially creditable hazardous waste pharmaceuticals include pharmaceuticals that are: (1) Unused or un-administered, (2) unexpired or

Continued

status hazardous waste TSDF. However, stakeholders have informed EPA that in some cases, hazardous waste pharmaceuticals are transported to another healthcare facility. We are aware of at least two situations in which this is occurring. First, patients at long-term care facilities who receive their pharmaceuticals from an off-site long-term care pharmacy sometimes return their unused pharmaceuticals to the long-term care pharmacy.[81] Upon return, the long-term care pharmacy sorts through the returned pharmaceuticals to determine whether they will be disposed or restocked for reuse. Due to many factors, such as Medicare regulations and the cost of the pharmaceutical as compared to the cost of repackaging and restocking, only a small fraction of the returned pharmaceuticals are restocked for potential reuse. One long-term care pharmacy estimated that approximately 10 percent of the pharmaceuticals it sends to long-term care facilities come back as returns.[82] Some portion of the returns would be considered hazardous waste pharmaceuticals when discarded.[83] In the second situation, the Army has established off-post health clinics to provide easier access to healthcare for military personnel, including veterans. The pharmacies at the off-post clinics receive their pharmaceutical products via couriers that deliver the pharmaceuticals from the on-post, main pharmacy. The off-post pharmacies also return their unused pharmaceuticals to the on-post, main pharmacy via courier.

EPA data indicates that the majority of long-term care facilities are CESQGs[84] and the Army has informed EPA that their off-post clinics are generally CESQGs, as well.[85] The existing CESQG regulations do not allow a generator to send its hazardous waste off-site to another hazardous waste generator, unless the receiving generator is also one of the seven types of facilities listed in § 261.5(f)(3) for acute hazardous waste or § 261.5(g)(3) for hazardous waste, including municipal and non-municipal non-hazardous solid waste landfills. The Agency does not think that disposal in landfills is the best option for hazardous waste pharmaceuticals. Limited studies have shown active pharmaceutical ingredients are present in landfill leachate that is collected in municipal solid waste landfill leachate collection systems.[86] [87] Landfill leachate is then typically transported to a wastewater treatment plant for treatment; however, active pharmaceutical ingredients can pass through the treatment system and into our Nation's waters.

EPA thinks it would be preferable to allow healthcare facilities that are CESQGs to send their hazardous waste pharmaceuticals to another healthcare facility rather than send it to a municipal or non-municipal non-hazardous solid waste landfill. Therefore, EPA is proposing to allow healthcare facilities that are CESQGs operating under this subpart to send their hazardous waste pharmaceuticals to an off-site healthcare facility, without a hazardous waste manifest, provided four conditions are met. First, the receiving healthcare facility must be contracted to supply pharmaceutical products to the CESQG long-term care facility, or the CESQG healthcare facility and the receiving healthcare facility must both be under the control[88] of the same person, as defined by § 260.10 (*e.g.,* the Army). Second, the receiving healthcare facility must be managing its hazardous waste pharmaceuticals in accordance with the regulations of this proposed rule.[89] Third, the hazardous waste pharmaceuticals from the CEQSG must be managed by the receiving healthcare facility as hazardous waste pharmaceuticals in accordance with the regulations of this proposed rule 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 CESQG healthcare facilities for three years from receipt of shipment. These conditions should ensure the proper management of the hazardous waste pharmaceuticals, in that once they are received by the healthcare facility, they are subject to the same management standards EPA is proposing for hazardous waste pharmaceuticals managed by healthcare facilities, while at the same time would not impose an undue burden on healthcare facilities that are CESQGs, especially since these healthcare facilities always have the option of sending their hazardous waste pharmaceuticals to a municipal or non-municipal solid waste landfill.

The Agency solicits comment on this new provision under this subpart, including whether any additional conditions should be imposed. In recommending any additional conditions, the Agency requests that commenters provide their rationale for the additional condition(s), as well as why such additional condition(s) would not pose an undue burden on healthcare facilities that are CESQGs. In addition, the Agency solicits comment on whether it might be appropriate to allow facilities, other than those meeting the proposed definition of a healthcare facility, to accept hazardous waste pharmaceuticals from an off-site CESQG (*e.g.,* a military medical logistics facility).

D. How does this proposed rule address healthcare facilities that accumulate potentially creditable hazardous waste pharmaceuticals prior to shipment to pharmaceutical reverse distributors?

1. Potentially Creditable Hazardous Waste Pharmaceuticals Are Not Products

One difference between this proposal and the 2008 Pharmaceutical Universal Waste proposal is the proposed interpretation of how RCRA applies to pharmaceuticals that are returned to reverse distributors to obtain manufacturers' credit. Two previous agency policy memos set out EPA's existing understanding of the status of these ''creditable'' pharmaceuticals. The

less than one year past the expiration date; or (3) in unopened or opened packaging or containers.

[81] DEA controlled substances can be returned to a long-term care pharmacy only if they are subject to a recall (see 21 CFR 1317.85(a)).

[82] See notes from 11–15–12 site visit to Omnicare, Inc. in the docket for this proposed rule (EPA–HQ–RCRA–2007–0932).

[83] Due to the DEA regulations, a DEA registered long term care pharmacy may not accept returns of a controlled substances. DEA regulations define ''reverse distribute'' and reverse distributor'' in 21 CFR 1300.01. A pharmacy is not authorized to accept returns of controlled substances from patients or reverse distribute (see 21 CFR 1301.13(e)(1)(iv)).

[84] Under these proposed requirements, hazardous waste pharmaceuticals will not count towards a facility's generator category. Therefore, EPA expects that long-term care facilities will remain CESQGs, even though the Agency is proposing that all hazardous waste pharmaceuticals generated on the premises must be managed in accordance with these proposed requirements.

[85] See notes from 11–28–12 meeting with U.S. Army Institute of Public Health in the docket for this proposed rule (EPA–HQ–RCRA–2007–0932).

[86] 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.

[87] 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.

[88] 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.

[89] This condition is only applicable if the receiving healthcare facility is also a CESQG, since healthcare facilities that are SQGs and LQGs must comply with the requirements proposed in 40 CFR part 266 subpart P.

first, a letter to Merck Sharp & Dohme in 1981, explained that pharmaceuticals sent for credit may be reclaimed and are not wastes since the decision to discard a particular material does not occur until after the product has been returned to the manufacturing plant.[90] The second, a letter to BFI Pharmaceutical Services, Inc. in 1991 states, ''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.'' [91] In addition to these letters, EPA's 2008 Pharmaceutical Universal Waste proposal stated, ''Because unused or expired pharmaceuticals are returned (via the reverse distributor) for possible manufacturer's credit, they still have potential value to the pharmacy or hospital and are thus not considered wastes.'' [92]

In this action, we are proposing to modify EPA's position regarding the waste status of creditable pharmaceuticals. Because we understand that many participants in this sector have relied on the interpretations in the two letters and the 2008 Pharmaceutical Universal Waste preamble, we are providing notice of a change in EPA's position and providing an opportunity for public comment. Until this rule is final and effective, however, EPA's previous interpretations will continue to be in effect.

In terms of the concept that returned pharmaceuticals have value and are not waste, EPA confirms the general rule under RCRA that materials that are discarded are solid wastes, regardless of the economics of the system in which those discarded materials are handled. Therefore, the fact that a material may have monetary value (*e.g.,* through a manufacturer's credit) does not determine whether that material is a solid waste. Rather, the ''decision point'' on whether a pharmaceutical is a solid waste is when it has been discarded, or the decision has been made to discard the material. That is, a discarded pharmaceutical may retain value in the reverse distribution system, but still be considered a solid waste. Additionally, the economic value of hazardous waste can be one important consideration in determining whether a hazardous waste is legitimately recycled (see, for example, the discussion of *Useful Economic Information* in the 2008 Definition of Solid Waste final rule, 73 FR 84706–07, October 30, 2008) and therefore excluded from being a solid waste. The definition of legitimate recycling is codified at 40 CFR 260.43 and is discussed in the 2015 Definition of Solid Waste final rule (80 FR 1694, January 13, 2015).

Commenters to the 2008 Pharmaceutical Universal Waste proposal, the 2014 Retail Notice of Data Availability (NODA), stakeholders, and pharmaceutical reverse distributors themselves have informed EPA that pharmaceuticals transported to reverse distributors to receive credit are rarely, if ever, repurposed, recycled, or reused. One commenter wrote, ''. . . EPA's belief that reverse distributors first arrange to transport and receive the drugs, and then determine whether the drugs are useful products or wastes, is pure fiction.'' [93] Another commenter wrote, ''. . . the vast majority of the returned pharmaceuticals are to be collected for disposal or destruction once credit has been given.'' [94] A third commenter wrote, ''. . . drugs sent through reverse distribution are not reused or recycled due to economic and safety reasons.'' [95] Regulations pertaining to the repurposing of pharmaceuticals vary by state, as they are established by each state's Board of Pharmacy. However, stakeholders have overwhelmingly declared that state Boards of Pharmacy only allow pharmaceuticals to be repurposed under very narrow circumstances—that is, when a specific set of conditions are followed to ensure the viability and integrity of the pharmaceutical. The set of conditions vary by state; however, states have some restrictions in common when it comes to repurposing drugs. According to the National Conference of State Legislatures (NCSL), ''Virtually all [state] laws include some restrictions designed to assure purity, safety and freshness of the products. Unless otherwise noted, all programs require:

- All donated drugs must not be expired and must have a verified future expiration date.
- Controlled substances, defined by the federal Drug Enforcement Administration (DEA) usually be excluded and prohibited.
- A state-licensed pharmacist or pharmacy to be part of the verification and distribution process.
- Each patient who is to receive a drug must have a valid prescription form in his/her own name.'' [96]

Thus, in most, if not all cases, pharmaceuticals that are transported back to a reverse distributor for credit are discarded by the reverse distributor.[97] For that reason, the decision to send a pharmaceutical to a reverse distributor is essentially a decision to discard the pharmaceutical.

Therefore, EPA is proposing to reinterpret its position such 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. As a result, once the decision is made to send a hazardous waste pharmaceutical to a reverse distributor, it is a solid waste at the healthcare facility. In this document, EPA is proposing to define the term ''potentially creditable hazardous waste pharmaceutical.'' A portion of the potentially creditable pharmaceuticals at healthcare facilities that are transported to reverse distributors will likely meet the definition of hazardous waste. Of the set of pharmaceuticals that are hazardous wastes, only ''potentially creditable'' hazardous waste pharmaceuticals may be transported to a reverse distributor for manufacturer's credit (see definition Section V.A.3).

The Agency notes that the management standards discussed below pertain only to potentially creditable hazardous waste pharmaceuticals that are managed via reverse distribution and do not apply to the reverse distribution or reverse logistics systems that may exist for other consumer products. In addition to the standards discussed in this section, EPA is proposing standards for shipping potentially creditable hazardous waste pharmaceuticals to pharmaceutical reverse distributors as well as associated recordkeeping (see Section V.F.2. of the preamble).

2. Hazardous Waste Determination for Potentially Creditable Hazardous Waste Pharmaceuticals

As with non-creditable hazardous waste pharmaceuticals discussed

[90] Alan Corson to Steven Wittner on May 13, 1981 (RCRA Online #11012) *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/B630CD51DC85EDC58525670F006BCE84/$file/11012.pdf.*

[91] Sylvia Lowrance to Mark J. Schulz on May 16, 1991 (RCRA Online #11606) *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/A3A7A7A8F297438B8525670F006BE5D8/$file/11606.pdf.*

[92] 73 FR 73525; December 2, 2008.

[93] Comment EPA–HQ–RCRA–2007–0932–0125.

[94] Comment EPA–HQ–RCRA–2007–0932–0068.

[95] Comment EPA–HQ–RCRA–2012–0426–0025.

[96] Content is copied from *http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx* (accessed May 13, 2015).

[97] Any facility, including a pharmaceutical manufacturer engaged in processing pharmaceutical hazardous waste for facilitation or verification of manufacturer's credit would be considered a pharmaceutical reverse distributor under the proposed rule with respect to those operations, and would be subject to the proposed regulations for pharmaceutical reverse distributors.

previously, a healthcare facility must determine which potentially creditable pharmaceuticals are listed or characteristic hazardous wastes, in order to determine which potentially creditable pharmaceuticals are subject to regulation under this subpart. Potentially creditable hazardous waste pharmaceuticals must be managed under this subpart, while pharmaceuticals that do not meet the definition of hazardous waste but are potentially creditable, do not have to be managed under this subpart. However, a healthcare facility may choose to manage all of its potentially creditable pharmaceuticals (both hazardous and non-hazardous) as potentially creditable hazardous waste pharmaceuticals while accumulating on-site and when shipping off-site. If a healthcare facility chooses this approach, it would not need to make individual hazardous waste determinations, but would have made a generic decision that all of their potentially creditable waste pharmaceuticals are hazardous and manage them as potentially creditable hazardous waste pharmaceuticals in accordance with the proposed requirements in 40 CFR part 266, subpart P.

3. Accumulation Time, Container Management, and Labeling for Potentially Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities

Typically, EPA requires specific management standards for containers that hold hazardous waste. However, potentially creditable hazardous waste pharmaceuticals appear to pose lower environmental risk of release than patient care hazardous waste pharmaceuticals or traditional industrial hazardous waste. The risk of release is lower for several reasons. First, potentially creditable hazardous waste pharmaceuticals that are prepared for shipment to a reverse distributor are usually in their original containers as well as outer packaging, providing two layers of protection from leaks or spills.[98] Second, potentially creditable hazardous waste pharmaceuticals are typically generated in the pharmacy area of a healthcare facility where there is restricted access, creating a layer of security for these pharmaceuticals. Third, EPA has been informed that it is common practice at healthcare facilities for potentially creditable pharmaceuticals that are destined for a reverse distributor to be taken from the shelves of the pharmacy periodically and promptly boxed for off-site shipment. EPA anticipates that this relatively quick timing is largely driven by the economic value of the manufacturer's credit for the returned pharmaceuticals. Therefore, because of the lower risk these pharmaceuticals pose, EPA is not proposing specific management standards for healthcare facilities that accumulate containers of potentially creditable hazardous waste pharmaceuticals. For the same reasons, we also are not proposing a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals. EPA requests comment on the assumption that healthcare facilities promptly remove potentially creditable hazardous waste pharmaceuticals from pharmacy shelves and send them to reverse distributors. EPA asks for comment on whether the expectation of credit provides sufficient incentive to ensure that the hazardous waste pharmaceuticals will be managed appropriately or whether it is necessary to establish management standards and/or a maximum time limit for the accumulation of potentially creditable hazardous waste pharmaceuticals prior to off-site shipment.

In the 2008 Pharmaceutical Universal Waste proposal, EPA specifically solicited comment on whether stakeholders have knowledge of problems with mixing incompatible pharmaceuticals during accumulation. In response, one commenter indicated that there were no issues encountered with the compatibility of pharmaceuticals during storage.[99] Since then, a 2011 article by Charlotte Smith states, ''oxidizers, acids, and bases also are incompatible, but they occur infrequently as finished dosage forms.'' [100] It is important to note that the accumulation of some potentially creditable hazardous waste pharmaceuticals, such as liquids and aerosols, may pose more of a risk than solid pills due to possible spillage or leakage. However, EPA believes that the small quantities in which the liquid and aerosol potentially creditable hazardous waste pharmaceuticals are generated, along with the DOT packaging requirements (49 CFR parts 173, 178, and 180), would likely obviate these risks. In addition, to further mitigate the potential for spillage or leakages, as a best management practice, EPA encourages healthcare facilities to place the original containers and packaging containing liquids and aerosols pharmaceuticals in separate individual containers, such as a sealed storage bag before placing them in the container that will be shipped.

EPA also is proposing not to require specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals, while they accumulate on-site. EPA does not want to deter the practice of co-mingling potentially creditable hazardous waste pharmaceuticals with potentially creditable non-hazardous waste pharmaceuticals since both are typically transported to a reverse distributor together.

In addition, due to concerns regarding diversion of pharmaceuticals, EPA believes that it is safer not to call attention to the fact that these containers hold pharmaceuticals. Unlike floor waste or patient care pharmaceutical waste, or most hazardous waste, the hazardous waste pharmaceuticals returned to a reverse distributor often have high street value that makes them susceptible to diversion. Thus, EPA is not proposing to require a label for potentially creditable hazardous waste pharmaceuticals during accumulation at a healthcare facility. The Agency seeks comment on its proposal not to require specific accumulation, container management or labeling standards for potentially creditable hazardous waste pharmaceuticals that will be transported to a reverse distributor, including no specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals on-site prior to shipment off-site.

E. What are the proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals?

1. Sewer Disposal Prohibition

a. Regulatory background on the domestic sewage exclusion. Under RCRA and the Subtitle C hazardous wastes regulations, if a material is not a solid waste, then it cannot be considered a hazardous waste. Under § 261.4(a)(1)(ii) of the RCRA regulations, ''Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment'' is not a solid waste for purposes of Subtitle C regulation. This exclusion was finalized by EPA on May 19, 1980, based on the reasoning that ''Mixed waste streams that pass through sewer systems to publicly-owned treatment works (POTW's) will be subject to controls under the Clean

[98] See 73 FR 73529; December 2, 2008.

[99] Commenter #EPA–HQ–RCRA–2007–0932–0091.

[100] Charlotte Smith, RPH, MS; Managing Pharmaceutical Waste: A New Implementation Blueprint; Pharmacy Practice News, Special Edition, 2011.

Water Act. The Agency's construction grants program provides financial assistance for the proper treatment of these wastes. In addition, the Agency's pretreatment program provides a basis for EPA and the local communities to ensure that users of sewer and treatment systems do not dump wastes in the system that will present environmental problems'' (45 FR 33097).

In 1984, Congress enacted the Hazardous and Solid Waste Amendments (HSWA) to the Solid Waste Disposal Act (SWDA), as amended by RCRA. HSWA included a new Section 3018, entitled Domestic Sewage. This section directed EPA to do two things with respect to the 261.4(a)(1)(ii) exclusion for mixtures of domestic sewage and other wastes: (1) Submit a Report to Congress (RTC) that describes the types, size and number of generators which dispose of such wastes in this manner, the types and quantities of wastes disposed of in this manner, and identify significant generators, wastes and waste constituents not regulated under existing Federal law or regulated in a manner sufficient to protect human health and the environment; and (2) based on the report, revise the existing regulations that are necessary to ''ensure that substances . . . which pass through a sewer system to a publicly owned treatment works are adequately controlled to protect human health and the environment.''

EPA submitted its Report to Congress on February 7, 1986 (Domestic Sewage Study). Subsequent to the Report to Congress, EPA issued an advance notice of proposed rulemaking (ANPR) on August 22, 1986 (51 FR 30166); a response to comments on the ANPR on June 22, 1987 (52 FR 23477); a notice of proposed rulemaking (NPR) on November 23, 1988 (53 FR 47632); and a final rule on July 24, 1990 (55 FR 30082). That final rule prohibits the discharge of pollutants which create a fire or explosion hazard in the POTW, which includes, but is not limited to, wastestreams with a closed cup flashpoint of less than 140 degrees Fahrenheit or 60 degrees Celsius using the test methods specified in 40 CFR 261.21'' (55 FR 30087). Although the exclusion for mixtures of domestic sewage and other wastes is found under the RCRA regulations in § 261.4(a)(1)(ii), the sewer ban of liquid ignitable hazardous wastes (*i.e.,* with the hazardous waste code D001) was established under 40 CFR 403.5(b)(1), which is under the Clean Water Act (CWA) regulations. The Agency seeks comment on whether it would be helpful to incorporate in 40 CFR 261.4(a)(1)(ii), a cross-reference to the CWA regulations prohibiting the sewering of liquid ignitable hazardous wastes.

b. Prevalence of flushing in lieu of hazardous waste management. In the preamble to the July 1990 final rule, EPA stated its intent ''to carefully review the effect of this rule and promulgate in the future any additional regulations that experience reveals are necessary to improve control over hazardous waste and other industrial user discharges to POTWs'' (55 FR 30084). Since then, studies have found that many healthcare facilities, particularly long term-care facilities, use drain disposal as a routine disposal method for pharmaceutical wastes in lieu of collection and shipment off-site for management. For example,

- A 2008 study of 59 long-term care facilities showed that 46 percent of the long-term care facilities dispose of their pharmaceuticals by dumping them down the drain.[101]
- A 2003 King County, Washington survey of healthcare facilities showed that the vast majority of liquids, and nearly half of the pills, were disposed of down the drain.[102]
- In a study by The Albany Medical Center, funded by an EPA Pollution Prevention Grant, the author states, ''up to now, toilet wasting has been the common practice for drug wasting by patient care staff.'' [103]
- In a detailed study about the waste management practices within the healthcare industry, EPA's Office of Water also found that sewering of waste pharmaceuticals was common practice.[104]
- EPA staff from the Office of Research and Development (ORD) have published numerous articles on the subject of active pharmaceutical ingredients (APIs) in the environment. One such paper states that ''unit-packaged pills are probably not frequently disposed via toilets, whereas liquids are probably routinely poured down drains,'' although the authors acknowledge that ''gaining an understanding of the types and quantities of APIs introduced directly and purposefully to the environment by the disposal of unwanted, leftover drugs has been more problematic because of a dearth of comprehensive or reliable data.'' [105]

c. Inadequacy of POTW treatment to remove pharmaceuticals. Under the Clean Water Act (CWA), EPA establishes national regulations (called effluent limitations guidelines and pretreatment standards) to reduce discharges of pollutants from industries to surface waters and POTWs. However, there are currently no national effluent limitations or pretreatment standards that apply to discharges of pharmaceuticals by healthcare facilities to POTWs. Furthermore, traditional wastewater treatment operations implemented in the 1970s and 1980s at POTWs are designed to remove conventional pollutants, such as suspended solids and biodegradable organic compounds. They are not designed to remove pharmaceuticals that are present in discharges from medical and veterinary facilities. While some POTWs may have implemented advanced treatment technologies at their facilities, these technologies are also not designed to remove pharmaceuticals. EPA released a study in 2009 in which over 100 chemicals (including some pharmaceuticals) were analyzed in the influent and effluent at nine POTWs.[106] Although it was a limited study and difficult to generalize the results to all POTWs, it does indicate that the capabilities of treatment technologies currently employed by POTWs does not include treatment to remove APIs.[107] In addition, as stated in the Health Services Industry study, ''synthetic compounds, such as pharmaceuticals, are often manufactured to be resistant to metabolic transformation. As a result, some pharmaceutical compounds that are present in the influent to POTWs may pass through treatment systems at conventional POTWs and discharge to receiving waters.'' [108]

d. Adverse impacts to human health and the environment due to pharmaceuticals in the environment.

[101] Kansas State University. January 31, 2008. Nancy J. Larson. *Pharmaceutical Waste Outreach Project.*

[102] King County Pharmaceutical Waste Survey Final Report. King County, Washington. April 2003.

[103] The Albany Medical Center, October 29, 2009, Russell F. Mankes, Progress Report on the Source Reduction Demonstration Project, EPA Grant #X9–97256506–0.

[104] Health Services Industry Study: Management and Disposal of Unused Pharmaceuticals (Interim Technical Report) August 2008; EPA–821–R–08–013.

[105] Ruhoy and Daughton; Beyond the medicine cabinet: An analysis of where and why medications accumulate; Environment International 34(2008) 1157–1169.

[106] EPA, Occurrence of Contaminants of Emerging Concern in Wastewater from Nine Publicly Owned Treatment Works, August 2009; EPA–821–R–09–009.

[107] Eggen RI, Hollender J, Joss A, Schärer M, Stamm C, ''Reducing the Discharge of Micropollutants in the Aquatic Environment: The Benefits of Upgrading Wastewater Treatment Plant.'' Environmental Science and Technology 2014, 48(14) 7683–7689.

[108] Health Services Industry Study: Management and Disposal of Unused Pharmaceuticals (Interim Technical Report) August 2008; EPA–821–R–08–013.

The pharmaceuticals entering the environment, through flushing or other means, are having a negative effect on aquatic ecosystems and on fish and animal populations. The Regulatory Impact Analysis for this proposed rulemaking summarizes the scientific literature with regard to ecological effects (see the Regulatory Impact Analysis in the docket for this proposed rule EPA–HQ–RCRA–2007–0932). The scientific research with regard to human health effects due to pharmaceuticals in the environment is still ongoing. Nevertheless, the important features and risks of the problem can be summarized as follows: [109]

(1) Pharmaceuticals are intrinsically bioactive compounds; therefore, they are potentially able to impact living systems.

(2) There is a continuous and worldwide increase in their use and, thus, on their subsequent input into the environment.

(3) Many of the hundreds of frequently prescribed pharmaceuticals are known for targeted effects and adverse off-target side effects, a problem that can be exacerbated by interactive effects during therapy involving co-administration.

e. Banning sewering of hazardous waste pharmaceuticals. Given the demonstrated negative ecological effects and the potential for negative human health effects, EPA is proposing to impose a sewer ban on all hazardous waste pharmaceuticals managed by healthcare facilities and pharmaceutical reverse distributors that are subject to this proposed rule—that is, they are prohibited from disposing of pharmaceuticals that are listed hazardous waste and/or exhibit one or more of the four hazardous waste characteristics (*i.e.,* ignitability, corrosivity, reactivity, or toxicity) by putting them down a drain (*e.g.,* sink, toilet, or floor drain).

In addition, while healthcare facilities that are CESQGs are generally not subject to this proposed rule, EPA is proposing that the sewer ban of hazardous waste pharmaceuticals also apply to healthcare facilities that are CESQGs. The vast majority of healthcare facilities are CESQGs (84 percent). Some particular types of healthcare facilities have an even larger proportion of CESQGs: Over 94 percent of dental offices are CESQGs, and 94 percent of continuing care retirement communities are CESQGs (see the Regulatory Impact Analysis in the docket for this proposed rule EPA–HQ–RCRA–2007–0932.

EPA is concerned that these smaller healthcare facilities are more likely to dispose of their hazardous waste pharmaceuticals via the sewer. EPA estimates that there are more than 145,000 healthcare facilities that are CESQGs. Given this large number, the combined impact of sewer disposal by healthcare facilities that are CESQGs has an even greater potential to provide a substantial impact on the environment, as well as human health.

EPA solicits comment on EPA's proposal to ban the sewer disposal of hazardous waste pharmaceuticals at all healthcare facilities, including healthcare facilities that are CESQGs that generate such wastes. As part of its solicitation of comments, the Agency especially requests comment on the risk-risk tradeoffs inherent in prohibiting sewer disposal, which extends the life cycle of pharmaceutical waste, resulting in additional opportunities for diversion and increasing the possibility of inadvertent exposures for certain workers (and possibly even patients or visitors) as a tradeoff for a reduction in aquatic risks. EPA also solicits comment on whether the ban on sewer disposal should be limited to those healthcare facilities that are currently LQGs and SQGs, and not extended to CESQGs.

Under 40 CFR 403.12(p) of the CWA regulations, industrial users that discharge a substance to a POTW that, if otherwise disposed of, would be a hazardous waste, must notify in writing the POTW, the EPA Regional Waste Management Division Director and State hazardous waste authorities. POTWs should be made aware that under this proposal, if made final, the notifications they receive from healthcare facilities will no longer include hazardous waste pharmaceuticals since the healthcare facilities will be prohibited from sewering their hazardous waste pharmaceuticals.

We note that EPA's proposed ban on sewering hazardous waste pharmaceuticals is consistent with other federal and state actions. For example, the Drug Enforcement Administration (DEA) has finalized new regulations to implement the Secure and Responsible Drug Disposal Act of 2010 (September 9, 2014; 79 FR 53520). DEA's new regulations require a ''non-retrievable'' method of destruction of controlled substances. The preambles to DEA's proposed and final rules state that flushing does not meet the non-retrievable standard for destruction.[110] According to the preamble of the DEA final rule, DEA received 20 comments supporting their position against flushing controlled substances.[111] The comments supporting the prohibition against sewering came from states, regional and local hazardous waste management programs, recycling associations, non-governmental organizations (NGOs), trade associations and environmental organizations. Many of these commenters noted that wastewater treatment systems do not eliminate many of the drugs that are flushed into the sewers and requested that DEA clearly state in the regulatory language, not just preamble, that sewering is not allowable as a means of destruction.

In addition, three states and the District of Columbia have taken action to limit the sewering of pharmaceuticals and a third has introduced a bill. In 2009, Illinois passed the Safe Pharmaceutical Disposal Act, which prohibits healthcare facilities from flushing any unused medication into public sewers or septic systems.[112] In 2012, New Jersey passed a similar law that prohibits healthcare facilities from discharging prescription medications into public sewers or septic systems.[113] In 2002, California banned the use of lindane in pharmaceuticals after it found that lindane was adversely impacting wastewater quality. The authors of the paper ''Outcomes of the California Ban on Pharmaceutical Lindane: Clinical and Ecologic Impacts state that ''This is the first time that a pharmaceutical has been outlawed to protect water quality.'' [114] After researching and documenting environmental benefits of the ban, the authors conclude, ''This ban serves as a model for governing bodies considering limits on the use of lindane or other pharmaceuticals.'' And the District of Columbia has promulgated municipal regulations, effective January 1, 2011, that prohibits healthcare facilities from flushing pharmaceutical products.[115] The Connecticut legislature has also considered a bill to ban the discharge of medication into public or private waste water collection systems or septic

[109] A. Ginebreda et al, Environmental risk assessment of pharmaceuticals in rivers: Relationships between hazard indexes and aquatic macroinvertebrate diversity indexes in the Llobregat River (NE Sapin). Environ Int. (2009), doi:10.1016/j.envint.2009.10.003.

[110] Proposed rule: December 21, 2012; 77 FR 75784 (see page 75803) and Final rule: September 9, 2014; 79 FR 53520 (see page 53548).

[111] September 9, 2014; 79 FR 53520 (see page 53548).

[112] Illinois Public Act 096–0221.

[113] Nicknamed Bateman's Law, after Senator Christopher ''Kip'' Bateman (R-Somerset) that sponsored the legislation.

[114] Humphreys, *et al.* Environmental Health Perspectives. 2008 March; 116(3) 297–302.

[115] Title 22–B Chapter 5 Safe Disposal of Unused Pharmaceuticals in Health Care Facilities.

systems, although it has not yet become law.[116]

Finally, we would note that although the sewer ban is limited to pharmaceuticals that are RCRA hazardous wastes, EPA strongly recommends as a best management practice to not sewer any waste pharmaceutical (*i.e.,* hazardous or non-hazardous), except when sewering is specifically directed by FDA guidance (as noted on pharmaceutical packaging).[117]

For household pharmaceutical waste, we refer the public to the guidelines developed by the U.S. Office of National Drug Control Policy (ONDCP), the FDA, and EPA for the disposal of unwanted household pharmaceuticals. In summary, these guidelines are as follows:

(1) Use a drug take-back event or program, when available;

(2) Dispose in household trash, after mixing the unwanted medicines with an undesirable substance such as kitty litter or coffee grounds and placing in a sealed container; and

(3) Only if the drug label specifically instructs you to, flush the unwanted medicine down the toilet.[118]

2. Conditional Exemption for Hazardous Waste Pharmaceuticals That Are Also Controlled Substances

When a pharmaceutical that is discarded is both a hazardous waste and a controlled substance, its management and disposal is regulated under both the RCRA Subtitle C hazardous waste regulations, which is under EPA's or the authorized state's purview, and the Controlled Substances Act (CSA) and its implementing regulations, which is under DEA's purview. EPA understands that only a handful of pharmaceuticals are in common usage that are both hazardous waste and controlled substances and therefore subject to dual regulation by both EPA and the DEA. These are identified in Table 5:

Table 5: Pharmaceuticals Still Used in Healthcare that Are DEA Controlled Substances & RCRA Hazardous Wastes

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Chloral; chloral hydrate	Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supprettes	Sedative	U034 toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics
Fentanyl sublingual spray	Subsys	Analgesic	D001 ignitable	II	Ignitable due to alcohol content
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001 ignitable	IV	Ignitable due to alcohol content
Testosterone gels	Androgel, Fortesta, Testim	Hormone	D001 ignitable	III	Ignitable due to gel base
Valium injectable	Diazepam	Anti-anxiety	D001 ignitable	IV	Ignitable due to alcohol content

Chloral hydrate, U034, is the only dually regulated hazardous waste/controlled substance that is a listed hazardous waste. It is listed for toxicity (note that EPA's U034 listing includes chloral hydrate, see memo dated April 6, 1998; Brandes to Knauss, RCRA Online #14175). On the other hand, the remaining four dually regulated hazardous wastes/controlled substances in common use are considered hazardous because they exhibit the characteristic of ignitibility (D001). However, the active ingredient is not ignitable, but these particular forms of the pharmaceuticals are ignitable because they are prepared in ignitable solutions, such as alcohol.

EPA is aware of three additional hazardous waste pharmaceuticals that are DEA controlled substances, but it is our understanding that they are no longer in common usage, although there may be legacy supplies remaining in healthcare facilities. See Table 6.

[116] State of Connecticut General Assembly, January Session 2013, Raised Bill No. 6439. An Act Concerning the Disposal and Collection of Unused Medication.

[117] *http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM337803.pdf.*

[118] *http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM337803.pdf.*

Table 6: DEA Controlled Substances & RCRA Hazardous Wastes Pharmaceuticals that Are Not in Common Use

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Paraldehyde	1,3,5-Trioxane, 2,4,6-trimethyl-; Paral	Anticonvulsant	U182 toxic	IV	No longer in common use
Paregoric	camphorated tincture of opium	Analgesic, expectorant, antidiarrheal	D001 ignitable	III	No longer in common use
Opium Tincture	Laudanam	Analgesic, antidiarrheal	D001 ignitable	II	No longer in common use

Similarly, as noted in Table 7, phentermine is a controlled substance, but the medical form is a phentermine salt, and the salts are no longer considered to be within the scope of the P046 listing (see memo dated February 17, 2012; from Devlin to RCRA Division Directors, RCRA Online #14831).

Table 7: Pharmaceuticals that are DEA Controlled Substances & RCRA Hazardous Wastes Salt(s) No Longer Considered Hazardous Waste

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Phentermine	alpha, alpha-Dimethylphenethyl amine; Benzeneethanamine, alpha,alpha-dimethyl-; Adipex-P, Atti Plex P, Fastin, Ionamin, Kraftobese, Panshape M, Obe-Nix, Pentercot, Phentride, Pro-Fast, Raphtre, Supramine, Tara-8, Termene, Termine, Zantryl	Appetite suppressant	P046 Acutely toxic	IV	If in salt form, it does not meet the P046 listing and medical dosage forms are salts

EPA requests comment on whether these are, indeed, the only pharmaceuticals in common usage that are regulated both as DEA controlled substances, and when discarded, RCRA hazardous waste.

Common practices that healthcare facilities have used in the past in order to comply with the DEA regulations for destroying controlled substances include sewering and incineration. However, DEA's new regulation requires that controlled substances must be destroyed, such that they are ''non-retrievable.'' As discussed previously, the preambles for DEA's proposed and final rules state that flushing will not meet their new non-retrievable standard, a position which EPA fully supports. However, EPA is concerned that flushing will continue to be used by healthcare facilities for eliminating their controlled substances. In part, this concern is due to a 2009 EPA report which concluded, ''controlled substances are the pharmaceuticals most commonly poured down the drain, especially the partially-used IVs containing controlled substances.'' [119] In addition, stakeholders have informed EPA that it is expensive and difficult to manage controlled substances that are also hazardous wastes under both DEA and EPA regulatory schemes and therefore the unintended consequence is that they are often sewered on-site in order to avoid the expense of complying with dual regulation en route to incineration.

[119] Pathways for Environmental Releases of Unused Pharmaceuticals, October 12, 2009, Memo from ERG to EPA, EPA–HQ–OW–2008–0517–0518.

EPA wants to eliminate the flushing of pharmaceuticals in order to reduce potential environmental contamination. Sewering hazardous wastes that are ignitable (D001) is already banned and EPA is now proposing to eliminate the sewering of all other hazardous waste pharmaceuticals.[120] To eliminate duplicative regulation and thereby further reduce the incidence of flushing, EPA is proposing to conditionally exempt from RCRA Subtitle C regulation those hazardous wastes that are also DEA controlled substances. Specifically, EPA is proposing that hazardous wastes that are also controlled substances will be exempt from all RCRA Subtitle C requirements, including 40 CFR part 266, subpart P, provided they meet two conditions: (1) They are combusted at a permitted large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln), and (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances.

The first condition is to ensure that the controlled substances are destroyed in an environmentally protective manner by a high-temperature combustor, such as a large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln). The majority of the hazardous wastes that are also controlled substances are hazardous because they exhibit the characteristic of ignitability. The best demonstrated available technology (BDAT) developed for ignitable hazardous waste under the LDRs includes combustion (see § 268.40). In addition, although chloral hydrate (U034) is listed because of its toxicity, its BDAT is also combustion. Therefore, in an effort to eliminate the sewering of these dually regulated hazardous wastes/controlled substances, and because combustion of these pharmaceuticals is a suitable technology for destruction, EPA is proposing to allow the few hazardous wastes pharmaceuticals that are also controlled substances to be combusted at municipal solid waste combustors, although as noted previously, a hazardous waste incinerator (permitted or interim status) would also be allowed.

We realize that DEA may allow a technology other than combustion to be used to destroy controlled substances. However, if the RCRA hazardous waste pharmaceuticals that are DEA controlled substances are exempt from RCRA, the other destruction technologies may lack environmental controls and permits. Therefore, combustion of the hazardous wastes/controlled substances, which requires permitting, operating and monitoring standards, is a condition of the exemption. EPA requests comment on whether there are additional technologies that would be appropriate to include for the destruction of hazardous waste pharmaceuticals that are also controlled substances. Under this proposal, if DEA allows a technology other than incineration for the destruction of controlled substances, it would be allowed only for DEA controlled substances, but not for those that are also RCRA hazardous wastes.

The second condition is to ensure that dually regulated hazardous wastes/controlled substances are managed under another rigorous regulatory program since they will not be managed in accordance with the RCRA Subtitle C regulations. Although developed for different reasons, both EPA's hazardous waste and DEA's controlled substance regulatory programs are designed to track the regulated material from cradle to grave. DEA regulations have requirements similar to EPA's hazardous waste manifest. In particular, in order to ship a schedule II controlled substance, a DEA registrant must submit a DEA Form 222 to the supplier of the schedule II controlled substance. The DEA Form 222 is a numerically controlled form issued by the DEA to authorized registrants, containing certain pre-printed information. The supplier must indicate on the DEA Form 222, the quantity of packages shipped and the date the packages were shipped. Like a hazardous waste manifest, a copy of Form 222 must accompany the shipment and it must be kept by both the supplier and purchaser for at least two years (copies of manifests must be kept for three years). Suppliers and distributors may utilize the electronic version of the DEA Form 222, which requires the same information and retention period. Similarly, DEA Schedule III, IV and V controlled substances must be accompanied by an invoice, which also must include a detailed inventory of the contents shipped. A copy of the invoice must also be retained by the supplier and purchaser of the controlled substances for a period of two years. EPA believes that the DEA tracking and shipping requirements are sufficient to act in lieu of the RCRA hazardous waste manifest and hazardous waste transporter requirements. EPA requests comment on this assessment.

DEA has previously stated that controlled substance ''pharmaceutical wastage'' may be disposed of in accordance with applicable federal, state, and local laws, regulations, and healthcare facility policies, to include sewering or putting down the drain.[121] The term ''pharmaceutical wastage'' refers to leftover, unadministered pharmaceuticals (''*e.g.,* some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized'' [122]). EPA is proposing that the few hazardous waste pharmaceuticals that are also controlled substances would be exempt from RCRA, but only on the condition that they are incinerated at a permitted hazardous waste or municipal solid waste incinerator and managed in accordance with DEA regulations. As a result, if pharmaceutical wastage is both hazardous waste and controlled substance it would not be allowed to be sewered; it would have to be incinerated. Prior to incineration, the pharmaceutical wastage would be exempt from RCRA and could be collected in a container at the healthcare facility. As an alternative, we request comment on whether to allow the sewering of the pharmaceutical wastage for the five hazardous wastes that are also controlled substances. We are concerned, however, that this alternative approach will lead to the sewering of all pharmaceutical wastage as healthcare providers are unlikely to keep track of which hazardous waste pharmaceuticals are allowed to be sewered and which are not. We request comment on these approaches for pharmaceutical wastage and request data on the impact on healthcare facilities of not allowing pharmaceutical wastage to be sewered.

a. Long-term care facilities and the DEA final rule. As discussed previously, EPA is proposing that hazardous waste from long-term care facilities will no longer be considered exempt as household hazardous waste. Instead it will need to be managed as regulated hazardous waste. This interpretation will apply to all the hazardous waste generated by a long-term care facility, not just its hazardous waste pharmaceuticals, although the Agency expects that much of the hazardous waste generated by long-term care facilities consists of hazardous waste pharmaceuticals. However, there are

[120] See 40 CFR 403.5 for specific pretreatment prohibitions.

[121] See DEA letter to registrants re: clarifying disposal of pharmaceutical wastage dated Oct 17, 2014; *http://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf.*

[122] Ibid.

two exceptions. First, hazardous waste pharmaceuticals that are also controlled substances will not be subject to RCRA, provided they meet two conditions: (1) They are combusted at a permitted large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln), and (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances. Second, as discussed previously, EPA estimates that only 28% of long-term care facilities generate hazardous waste pharmaceuticals and of those, 85% generate small enough quantities of hazardous waste that they will qualify as CESQGs and will be subject to the reduced regulatory requirements of 40 CFR 261.5, and only the sewer ban provision of this new subpart.[123]

DEA's new regulations to implement the Secure and Responsible Drug Disposal Act of 2010 are expected to help alleviate the problem that long-term care facilities face when discarding controlled substances. DEA's new regulations allow retail pharmacies and hospital/clinics with an on-site pharmacy that are DEA registrants to modify their registrations and become ''collectors'' to place collection receptacles at long-term care facilities (or at the retail pharmacy or hospital/clinic with an on-site pharmacy) for the collection of controlled substances from ultimate users (*i.e.,* consumers).

Under the new DEA regulations, long-term care facilities have three options, two of which are new, for managing their patients' controlled substances. First, if a DEA registered retail pharmacy or hospital/clinic with an on-site pharmacy places a collection container at a long-term care facility, the staff from the long-term care facility may place the patients' controlled substances in the collection receptacles. Second, although long-term care facilities will not be able to conduct collection events for their patients' controlled substances for mail-back programs, they will be allowed to assist patients who choose to use a mail-back program for their own controlled substances, on an individual-by-individual basis. And third, law enforcement will continue to be allowed to pick up patients' controlled substances for disposal. With these changes to DEA's regulation, long-term care facilities can now dispose of patients' controlled substances in a more environmentally protective way. Because we are proposing that hazardous waste pharmaceuticals that are also controlled substances are conditionally exempt from RCRA, these wastestreams may also be managed in any of these three ways allowed by DEA, provided the waste is managed to meet the conditions of the RCRA conditional exemption.

The new DEA regulations do not mandate the placement of collection receptacles or patient participation in mail-back programs or take-back events. However, if long-term care facilities are prohibited from disposing of pharmaceuticals down the toilet or drain under RCRA (and as a method of destruction under DEA regulations), then the only way for patients at long-term care facilities to lawfully dispose of DEA controlled substances that are also RCRA hazardous wastes would be through participation in one of DEA's collection methods. Long-term care facilities are allowed to place patients' hazardous waste pharmaceuticals that are controlled substances in the DEA collection receptacles; the other hazardous waste pharmaceuticals generated by long-term care facilities must be managed under the proposed RCRA management standards for healthcare facilities. However, we note that if the long-term care facility is a CESQG, we are proposing as an acceptable method of disposal of the long-term care facility's hazardous waste pharmaceuticals would be to place them in a DEA collection receptacle, even if they are not controlled substances (see § 266.504(b)). DEA already allows controlled substances to be co-mingled with non-controlled substances. Therefore, EPA believes it is consistent to allow CESQG hazardous waste pharmaceuticals that are not controlled substances to be placed in DEA collection receptacles with controlled substances. EPA believes that management of CESQGs' hazardous wastes as DEA controlled substances is preferable to management as municipal solid waste because it provides greater protection to patients, visitors and workers at long-term care facilities to have the hazardous waste pharmaceuticals in DEA collection receptacles rather than in the regular trash. See Table 8 for a summary of the intersection of RCRA and DEA regulations for the disposal of hazardous waste pharmaceuticals at long-term care facilities:

TABLE 8—RCRA & DEA REGULATIONS AT LONG-TERM CARE FACILITIES

Types of pharmaceutical waste at long-term care facilities	Regulatory requirements	
	RCRA	DEA Authorized collection methods allowed for *patients'* pharmaceuticals
Hazardous Waste Pharmaceuticals that are also Controlled Substances.	Conditionally exempt from RCRA	Yes.
Hazardous Waste Pharmaceuticals that are not Controlled Substances.		
if LTCF is a CESQG	261.5 and sewer ban	Yes.
if LTCF is not a CESQG	Part 266, subpart P	No.

b. Household hazardous waste collected in DEA authorized collection receptacles. In response to questions that EPA has received since the DEA rule was published, we are taking this opportunity to clarify the current RCRA regulatory status of the pharmaceuticals collected in DEA authorized collection receptacles. DEA's regulations allow the co-mingling of controlled substances and non-controlled substances in its collection receptacles. In some instances, the pharmaceuticals that are collected by retail pharmacies and law enforcement in DEA authorized collection receptacles may contain pharmaceuticals that are RCRA hazardous waste. However, as household wastes, these hazardous waste pharmaceuticals would be excluded from regulation by

[123] See the docket for this rulemaking for data about long-term care facilities which was developed using data in the economic analysis: EPA–HQ–RCRA–2007–0932.

§ 261.4(b)(1) because the exclusion applies even when the household hazardous wastes are collected. It is important to note that in order to maintain the exclusion, a retail pharmacy (or other DEA authorized collector pharmacy) can use the DEA authorized collection receptacle to collect waste generated only at households and brought to the store for collection. The hazardous waste generated by the retail pharmacy and store, including hazardous waste pharmaceuticals, are not excluded household wastes under RCRA and may not be placed in the DEA authorized receptacle.[124] Furthermore, states generally regulate non-hazardous waste and they may have licensing or permitting requirements for the collection of solid waste. Because EPA would like to see the use of DEA authorized collection receptacles become widespread, we encourage states to streamline any requirements that may create a barrier to the use of the collection receptacles.

Under this proposal, pharmaceuticals collected in DEA authorized collection receptacles will continue to be excluded from regulation as household hazardous waste, with some conditions. The Agency has a long-standing recommendation that household hazardous waste collection programs manage the collected waste as hazardous waste. We strongly believe that if a program goes to the expense of collecting the waste, including waste pharmaceuticals, it should manage the waste as hazardous waste, rather than manage it as municipal solid waste, which the household could do absent the collection program. However, the current household waste exemption does not *require* an entity that hosts a household hazardous waste collection event to manage the collected waste as hazardous waste. Typically, the parties conducting household hazardous waste collection events have been government entities—municipalities and counties. It is relatively new that retail pharmacies and others are becoming interested in performing this function. To encourage this practice, while at the same time ensuring that collection programs are managing the collected waste properly, we are proposing that pharmaceuticals that are household hazardous waste (*i.e.,* ''household waste pharmaceuticals'') and are collected in DEA authorized collection receptacles where they may be co-mingled[125] with controlled substances continue to be excluded from RCRA regulation, provided they are:

(1) Combusted at a municipal solid waste or hazardous waste combustor, and

(2) managed in accordance with all applicable DEA regulations (see § 266.506(a)(2)).The Agency solicits comments on all these provisions.

On a separate, but related matter, EPA has received a number of inquiries about the exemption in the Clean Air Act regulations for Other Solid Waste Incinerator (OSWI) ''units that combust contraband or prohibited goods'' (see the exemption at 40 CFR 60.2887(p) for new OSWIs and 40 CFR 60.2993(p) for existing OSWIs). As indicated in a previous guidance memo, EPA does not consider pharmaceuticals, voluntarily collected from ultimate users in a take-back program, to be contraband or prohibited goods.[126] Likewise, EPA will not consider pharmaceuticals that are voluntarily dropped off at collection receptacles to be contraband or prohibited goods. Therefore, the OSWI exemption does not apply and law enforcement may not destroy voluntarily collected pharmaceuticals in the same way that it is allowed to destroy contraband or prohibited goods.

3. Management of Residues in Pharmaceutical Containers

a. Regulatory background. Over the years, EPA has received numerous inquiries regarding the regulatory status of various types of containers that once held pharmaceuticals that are considered hazardous waste when discarded because of the hazardous waste residue in the containers. Stakeholders have been particularly concerned about containers that once held pharmaceuticals that are on the ''P-list'' of acutely hazardous commercial chemical products in § 261.33(e) because a generator becomes an LQG if it generates more than 1 kg of acute hazardous waste per calendar month or accumulates more than 1 kg of acute hazardous waste at any time.[127] The current regulatory status of acute and non-acute commercial chemical product residues remaining in a container are specifically addressed in § 261.33:

The following materials or items are hazardous wastes if and when they are discarded or intended to be discarded . . .

(c) Any *residue* remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is *empty* as defined in § 261.7(b). [emphasis added]

According to § 261.7(b)(1), there are two ways a container that held a non-acute hazardous waste can be considered ''empty'':

A container or an inner liner removed from a container that has held any hazardous waste, except a waste that is a compressed gas or that is identified as an acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter is empty if:

(i) All wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, *e.g.,* pouring, pumping, aspirating, *and*

(ii) No more than 2.5 centimeters (one inch) of residue remain on the bottom of the container or inner liner, *or*

(iii)

(A) No more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size; or

(B) No more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size.

Therefore, if the container that held the non-acute hazardous waste pharmaceutical does not have its contents removed by a commonly employed practice *and* either has one inch or less of residue remaining or has 3 percent or less by weight of the total capacity of the container remaining,[128] then the container is *not* considered ''RCRA empty,'' even though the pharmaceutical may have been fully dispensed. If the container is not ''RCRA empty,'' then the residues are regulated as hazardous waste (since the residues are within the container, the container must be managed as hazardous waste, as well, even if it is not itself hazardous waste). On the other hand, if the contents of the container have been removed by a commonly employed

[124] DEA regulations also prohibits retail pharmacy stock/inventory from being placed in the collection receptacle or mail-back envelopes (see 21 CFR 1317.05(a)).

[125] DEA does not prohibit co-mingling of controlled substances with non-controlled substances provided they are all then managed as controlled substances.

[126] Rudzinski to RCRA Division Directors, September 26, 2012, RCRA Online #14833 *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/fcb11dd6f61d4b1685257afe005eb5ce!OpenDocument.*

[127] Additionally, acute hazardous wastes are included on the F-list of § 261.31; however none of those acute hazardous wastes are pharmaceuticals.

[128] We are assuming that containers that hold pharmaceuticals are in containers less than 119 gallons in size.

practice *and* either have one inch or less of residue remaining, or 3 percent or less of weight of the total capacity of the container remaining, then the container is considered ''RCRA empty,'' and may be managed as non-hazardous waste.

Likewise, according to § 261.7(b)(3), there are three ways that a container that held an acute hazardous waste can be considered ''empty'':

A container or an inner liner removed from a container that has held an acute hazardous waste listed in §§ 261.31 or 261.33(e) is ''empty'' if:

(i) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;

(ii) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or

(iii) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed.

Therefore, if the container that held the P-listed pharmaceutical is not triple rinsed, or cleaned by another method that has been demonstrated to achieve equivalent removal, or had the inner liner removed, the container is not considered ''RCRA empty,'' even though the pharmaceutical may have been fully dispensed. If the container is not ''RCRA empty,'' then the residues are regulated as acute hazardous waste.

In November 2011, EPA issued guidance about containers that once held P-listed pharmaceuticals [129] that provides three possible regulatory approaches for generators:

(1) Count only the weight of the residue toward generator category

(2) Demonstrate an equivalent removal method to render containers RCRA empty

(3) In the case of warfarin, show that the concentration in the residue is below the P-listed concentration.

This guidance was intended as a short-term solution that worked within the confines of the existing RCRA hazardous waste regulations and EPA indicated at the time that a more comprehensive solution would require notice and public comment that occurs during a rulemaking. We are proposing to amend the regulations that pertain to containers that once held pharmaceuticals that are RCRA hazardous wastes. We are proposing different regulatory solutions for different types of containers found in healthcare settings. Specifically, we address the following three types of containers: (1) Unit-dose containers (*e.g.,* packets, cups, wrappers, blister packs, and delivery devices) and dispensing bottles and vials; (2) dispensed syringes; and (3) other containers, including delivery devices. If finalized, these new regulations for pharmaceutical containers would replace the November 2011 guidance; however, in the meantime, the guidance remains in effect.

b. Unit-dose containers. First, with regard to unit-dose containers and dispensing bottles and vials up to 1 liter or 1000 pills, we are proposing a conditional exemption from the empty container regulations of § 261.7 for containers from which the pharmaceuticals have been fully dispensed. Specifically, we are proposing that the removal of the pharmaceuticals from the unit-dose containers, and dispensing bottles and vials (up to 1 liter or 1000 pills), is equivalent to rendering the container ''RCRA empty.'' Therefore, for containers that once held non-acute hazardous wastes, it will not be necessary to measure the remaining contents, and for containers that once held acute hazardous wastes, it will not be necessary to triple-rinse the containers or demonstrate an equivalent removal method. Rather, if the contents of the container have been fully dispensed by removing all pharmaceuticals that can be removed using the practices commonly employed to remove materials from that type of container, the residues (and therefore the container) may be disposed of as non-hazardous waste.

We are proposing this conditional exemption for two reasons. First, we want to eliminate the sewering of pharmaceuticals. We are particularly concerned that in a healthcare setting, when containers are triple rinsed, the rinsate will be poured down the drain which is not a good environmental practice. We think it is important that the residues be managed in a more controlled manner—such as municipal solid waste management—rather than poured down the drain. Second, although the ''empty container'' regulations of § 261.7 apply to all sizes of containers, they were developed with larger, industrial-sized containers in mind. For the most part, the containers that hold pharmaceuticals range in size from a few milliliters (*e.g.,* packaging for nicotine gum, paper cups used to dispense pharmaceuticals to in-patients) to a liter (*e.g.,* bottles that hold bulk quantities of pills). In rare circumstances, containers with pharmaceuticals are as large as two or three liters (*e.g.,* powders that are reconstituted with water). This differs significantly from the 55-gallon drums that are typically used in other sectors that generate hazardous waste. Consequently, the amount of residues in the containers was anticipated to be much more substantial than is the case for containers typically used for pharmaceuticals.

EPA has received data from three stakeholders demonstrating that there is very little residue remaining in fully dispensed containers of pharmaceuticals. In addition, EPA's ORD conducted similar research. The results from each of the four sources are summarized below; the full results are included in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).

i. *Consulting Firm.* One stakeholder, with a hazardous medical materials consulting firm, provided some laboratory testing. They had the residues from single-unit dose packaging of four different P-listed pharmaceuticals tested using gas chromatography/mass spectrometry (GC/MS) and high performance liquid chromatography/ultraviolet detector (HPLC/UV). The amount of active pharmaceutical ingredient in the residues remaining in containers was quantified and the results from containers that had been triple rinsed were compared with containers that had not been triple rinsed. For the containers that were triple rinsed, the active ingredient in the residues was non-detect in all cases. For the containers that were not triple rinsed, the highest level detected was 35.8 μg (or 0.0358 mg). The laboratory results submitted to EPA are summarized in Table 9; the full laboratory results are included in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932).

[129] Rudzinski to RCRA Division Directors, November 11, 2011, RCRA Online #14827 *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/57B21F2FE33735128525795F00610F0F/$file/14827.pdf.*

Table 9: Active Pharmaceutical Ingredient in Residues in Single-Unit Dose Packaging

Drug (packaging type)	HW Code	Active pharmaceutical ingredient in Triple-Rinsed Packaging (μg)	Active pharmaceutical ingredient in Non-Triple-Rinsed Packaging (μg)	Reporting Limit (μg)
Nicotine gum* (blister pack)	P075	ND	ND	0.00005
Nicotine patch* (single use packet)	P075	ND	35.8	0.00005
Warfarin** (blister pack)	P001	ND	6.4	5.0
Physostigmine** (ampoule)	P204	ND	ND	100

*Method EPA 8720B
**HPLC/UV
ND = non-detect

ii. *Large Retailer.* The second stakeholder that submitted data to EPA was a large retailer. Their data provide the weight of active pharmaceutical ingredient residues remaining in bulk containers (*i.e.,* 100-count) of various dosage strengths of warfarin. The residues were quantified using HPLC–UV/Vis (high performance liquid chromatography/ultraviolet/visible light detector). The data are summarized in Table 10; the full results submitted to EPA are included in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).

Table 10: Warfarin Residues in 100-Count Dispensing Bottles

Warfarin Dose	Number of Bottles Tested	Total Warfarin Residue in all Containers (mg)	Average Warfarin Residue/Bottle (mg)
Low (1 - 3 mg)	17	2.638	0.155
Medium (5 - 7.5 mg)	18	12.820	0.712
High (10 mg)	18	21.530	1.196

The results from each of the first two stakeholders reflect only the weight of the active pharmaceutical ingredient, not the full weight of the hazardous waste residues. Since it is the Agency's position that it is the full weight of the hazardous waste residues and not just the weight of the active pharmaceutical ingredients that must be counted in determining generator status, we have used the results to calculate the weight of the total residues. In the retailer's case, they have informed EPA that a typical pill with a 10 mg dose of Coumadin (brand name of warfarin) weighs 200 mg. The active ingredient represents 10 mg, or 5% of the weight of the pill, while 190 mg, or 95% of the weight of the pill, consists of ingredients other than the active ingredient. As indicated in Table 10, the average weight of warfarin residue remaining in a fully dispensed bottle of the high dose of warfarin (10 mg) is 1.196 mg. If we assume that the residue in the container has the same proportions of ingredients (*i.e.,* 5% of the residue is warfarin and 95% of the residue are other ingredients), then there would be an average of 23.92 mg of total hazardous waste residue remaining in a 100-count bottle of 10 mg pills of warfarin. The amount of hazardous waste residue remaining in a 100-count bottle of pills is very small compared with the residue that would remain in a 55-gallon drum, which is what the regulations for container residues envisaged.

iii. *Riverside County.* The third stakeholder that provided data to EPA was the Riverside County Department of Environmental Health, Hazardous Materials Management Branch. The county received a grant from the California Certified Unified Program Agency (CUPA) Forum Board to conduct a study of residues remaining in pharmaceutical containers. Researchers at the University of California, Riverside (UCR) conducted the study and provided their results in a report to Riverside County entitled, *Residue Analysis of P-Listed Pharmaceutical Containers for Warfarin and Nicotine.* The results are summarized below, but UCR's full results are in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).[130]

The intent of the study was to investigate the third regulatory approach suggested in the November 2011 memo discussed previously. That

[130] See Exhibit 2 of the CUPA Forum Board Trust Fund Grant Report submitted by the Riverside County Department of Environmental Health at the conclusion of the grant.

is, the study investigated whether the concentration of warfarin in the residues of warfarin pill bottles was greater than 0.3% and therefore met the listing criteria for P001 or whether the residues were at or below 0.3% and therefore met the listing criteria for U248. Although nicotine is not a concentration-based P-listing, packaging from nicotine-containing products were also investigated to determine total remaining residues.

The researchers collected a total of 59 samples containers, including 44 sample containers that had held warfarin pills but had been fully dispensed and another 15 sample containers from nicotine-containing products. The samples included warfarin and nicotine from several manufacturers, in a range of dose strengths and in various container types. The residues were solvent-extracted and then dried by rotary evaporation to determine the total weight of residues. Subsequently, the residues were re-dissolved in methanol and analyzed using HPLC to determine the concentration of the active pharmaceutical within the residues.

The majority of warfarin containers were plastic bottles, but some containers were blister packs and three samples were 30-pill blister packs, sometimes referred to as a ''bingo card.'' The results indicate that the concentration of the active pharmaceutical ingredient warfarin in the residues in plastic bottles was usually over the 0.3% concentration. However, the concentration of warfarin in the residues on blister packs, including the 30-pack blister pack, was consistently below 0.3%. Overall, in the majority of cases, the warfarin within the residues was present at a high enough concentration to be considered P001 (33 of 44 samples, 75 percent of the samples).

However, the results also confirm the results from the first two stakeholders. That is, the total weight of residues remaining in the containers after they were emptied of the warfarin pills is negligible. For the plastic bottles, the total weight of residue ranged from 4.3–82.3 mg. For the single-dose blister packs, the total weight of residue ranged from 3.5–7.6 mg. And for the 30-pack blister pack, the total weight ranged from 134.8–273 mg. Taking the smallest amount of residue of 3.5 mg, it would take close to 300,000 containers per month to exceed the 1 kg threshold to be an LQG. Even on the conservative side, taking the largest amount of residue of 273 mg, it would take close to 4000 containers per month to exceed the 1 kg threshold to be an LQG.

The results for nicotine residues were similar. For containers of gum and patches, the weight of total residues ranged from 9–111.2 mg, although the two containers of liquid nicotine solution contained more residues—1301 and 1616 mg. Although nicotine is not a concentration-based listing, it is worth noting that the active pharmaceutical ingredient of nicotine in the residues was below the quantifiable limit of 1.5 μg/ml in 8 of the 15 samples and for the other 7 samples, the concentration of nicotine ranged from 0.01–0.09%.

iv. *EPA's Office of Research and Development.* Finally, EPA's ORD conducted an analysis to evaluate whether simply removing a drug from the container is equivalent to triple rinsing the container. ORD's results are summarized in Table 11, but the Final Project Report containing the full results is in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932). ORD analyzed three different P-listed pharmaceuticals: Warfarin, nicotine and physostigmine salicylate. Table 11 lists the 18 different combinations of active pharmaceutical ingredients, form, dosage strengths and packaging combinations that ORD analyzed.

TABLE 11—PHARMACEUTICAL COMBINATIONS TESTED BY EPA'S ORD

Active pharmaceutical ingredient	Manufacturer/Brand name	Form	Dosage	Packaging type
Warfarin	Taro Pharmaceutical Industries, Ltd.	Tablet	1 mg	Plastic bottle.
		Tablet	5 mg	Plastic bottle.
		Tablet	10 mg	Plastic bottle.
		Tablet	2 mg	Single-dose blister pack.
	Upsher-Smith/Jantoven	Tablet	1 mg	Single-dose blister pack
		Tablet	10 mg	Single-dose blister pack.
Nicotine	GlaxoSmithKline/Nicorette	Gum	2 mg	Single-dose blister pack.
		Gum	4 mg	Single-dose blister pack.
	Rugby Laboratories	Gum	2 mg	Single-dose blister pack.
		Gum	4 mg	Single-dose blister pack.
	GlaxoSmithKline/Nicorette	Lozenge	2 mg	Plastic vial
		Lozenge	4 mg	Plastic vial.
	Rugby Laboratories	Patch	7 mg	Peel-off plastic.
	Habitrol	Patch	14 mg	Peel-off plastic.
	Rugby Laboratories	Patch	21 mg	Peel-off plastic.
	Pfizer/Nicotrol	Spray	10 mg/ml	Glass vial.
		Inhaler	10 mg	Plastic container.
Physostigmine Salicylate.	Akron Inc.	Liquid	1 mg/ml	Glass ampoule.

All combinations in Table 11 were analyzed in triplicate using the following three-step approach:

(1) After removing the tablets, gum, lozenges, etc from the containers, the amount of total residuals remaining in the container was determined using a sensitive balance to weigh the container before and after triple rinsing,

(2) The ''maximum possible weight of residual drug/total residual/container'' was calculated for each compound and packaging combination. This calculated result was used to infer a theoretical upper limit for the amount of active pharmaceutical compound in the total residue remaining in the container, and

(3) Thermal gravimetric analysis (TGA) was used to qualitatively evaluate the presence of active pharmaceutical ingredient in the residuals removed from the containers before and after triple-rinsing.

With respect to the weight of the remaining residuals in the containers, ORD's results are similar to the results

from the first three sources. That is, the weight of the total residuals remaining in the packaging of P-listed pharmaceuticals is minimal. For single-dose blister packs, lozenge vials and the peel-off plastic from nicotine patches the weight of the residuals was negligible and within the range of error of the balance, but all results were below 0.0002 grams. For plastic containers that held tablets, the weight of residuals were higher, but still very low, ranging from 0.0152–0.0157 grams. For containers that held liquids, the weight of residuals was the highest, but still very low, ranging from 0.0472 grams for glass vials of nicotine spray, to 0.0651 grams for glass ampoules that held liquid physostigmine salicylate. The residuals in the nicotine inhaler were not experimentally determined; rather, the manufacturer (Pfizer) states on the packaging that the 10 mg cartridge delivers a 4 mg dose, so the residuals are assumed to be 6 mg (or 0.006 grams).[131]

Unlike the quantitative results from the HPLC analyses from outside stakeholders, the results from the TGA are qualitative only. That is, the TGA was only intended to evaluate the presence of the API and compare the results from containers that had been triple rinsed with those that had not been triple rinsed. Using TGA, the API was not detected in the residuals, with one exception: The liquid nasal spray (note that TGA was not used on the nicotine inhaler residuals). In most cases, the TGA detected other, unspecified ingredients in the residuals, but not the active pharmaceutical ingredient on the P-list. The total weight of the residues was well under a gram and the active pharmaceutical ingredient is a small proportion of the total weight of the tablet, gum, etc. As a result, with the exception of the nicotine nasal spray, the TGA was not sensitive enough to detect the presence of the active pharmaceutical ingredient, regardless of whether the container had been triple rinsed or not.

EPA is aware that there are certain limitations with the data from the four sources. For instance, in the case of the consulting firm, no replicate samples were tested. In the case of the retailer, only warfarin residues were tested. However, given the size of the containers involved and the nominal quantities of residues involved, the Agency is proposing to allow the residues in single-unit dose containers/packaging and dispensing bottles, vials and ampules that once held pharmaceuticals to be managed as non-hazardous waste pharmaceuticals provided the pharmaceutical product has been fully dispensed (*e.g.,* all pills have been removed). EPA is soliciting comment on whether these studies are representative of the spectrum of formulations and containers that might be encountered.

Finally, we note that the Agency is concerned about the potential for diversion of the pharmaceutical containers that may occur when the pharmaceutical residues and containers are discarded in the municipal waste stream. In such instances, we are concerned that the containers could be diverted from the municipal waste stream and used for illicit purposes, such as packaging counterfeit pharmaceuticals. Therefore, EPA is proposing that ''RCRA empty'' pharmaceutical containers that are original pharmaceutical packages (and therefore are susceptible to diversion) should be destroyed prior to placing them in the trash. These types of containers would include dispensing bottles, vials or ampules typically used in pharmacies, but would not include paper or plastic cups, or blister packs used for dispensing singles doses to patients. The means of destruction could include crushing or shredding the container. We do not believe that simply defacing the label would be sufficient to avoid diversion, since labels could be replaced if the container is intact.

We request comment on these proposed provisions, including whether it is necessary to limit the size of the dispensing bottle to which this provision would apply. In our observation, EPA has rarely seen pharmaceutical dispensing bottles that are larger than 1000-count, which are approximately 1 liter in size. EPA requests comment on whether larger containers are used for dispensing pharmaceuticals and, if so, which pharmaceuticals they are used for and what RCRA hazardous waste codes apply. We also seek comment as to whether ''RCRA empty'' pharmaceutical containers that are the original pharmaceutical packages should be destroyed prior to placing them in the trash.

c. Dispensed syringes. With regard to dispensed syringes, EPA is proposing a conditional exemption for syringes that have been used to administer pharmaceuticals that are listed or characteristic hazardous waste when discarded. The residues remaining in a dispensed syringe would not be regulated as hazardous waste provided the syringe has been used to administer a pharmaceutical to a patient and the syringe is placed in a sharps container (if appropriate) and is managed in accordance with all applicable state and federal medical waste regulations. This would apply to syringes used to administer pharmaceuticals that are P- or U-listed, or exhibit a hazardous waste characteristic.

EPA issued guidance regarding the regulatory status of residues in syringes in December 1994 [132] and April 2008.[133] In the December 1994 RCRA/Superfund Hotline Q&A about whether epinephrine in a discarded syringe would be P042, EPA stated, ''Drug residues often remain in a dispensing instrument after the instrument is used to administer medication. EPA considers such residues remaining in a dispensing instrument to have been used for their intended purpose. The epinephrine remaining in the syringe, therefore, is not a commercial chemical product and not a P042 hazardous waste. The epinephrine could be a RCRA hazardous waste, however, if it exhibits a characteristic of hazardous waste.'' [134]

In the April 2008 memo, EPA clarified that the 1994 interpretation extends to other P- and U-listed pharmaceuticals that have been used to administer the pharmaceutical by syringe. This proposed conditional exemption for syringes, in large part, would maintain the existing interpretation. The primary difference is that under the proposed conditional exemption, healthcare facilities would not be required to determine if the residues in the syringes meet a listing description or exhibit a hazardous waste characteristic.

[131] Optimizing drug dose is a major factor in improving the sustainability of healthcare. The prescriber needs to be cognizant that prescribed treatments can have unanticipated, collateral impacts that reach far beyond the healthcare setting. See: Daughton and Ruhoy, *Lower-dose prescribing: Minimizing ''side effects'' of pharmaceuticals on society and the environment;* Sci Total Environ, 443(2013), pp. 324–336, which presents a critical examination of the multi-faceted potential role of drug dose in reducing the ambient levels of APIs in the environment and in reducing the incidence of drug wastage, which ultimately necessitates disposal of leftovers. (*http://sciencedirect.com/science/article/pii/S0048967120139 27#*)

[132] December 1994, RCRA Online #13718 *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/1C1DEB3648A62A868525670F006BCCD2/$file/13718.pdf.*

[133] Memo from Dellinger to Chilcott, April 14, 2008, RCRA Online #14788 *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/6A5DEDF2FBA24FE68525744B0045B4AF/$file/14788.pdf.*

[134] Note that since this Q&A was issued, EPA issued guidance indicating that epinephrine salts are not included in the scope of the P042 listing and therefore, most, if not all, medical applications of epinephrine are not P042 (October 15, 2007; RCRA Online #14778)

EPA believes this conditional exemption is important to minimize the potential for exposures to healthcare workers, which can happen if they are accidentally stuck with a needle. Typically, sharps containers are more readily available to a medical practitioner than a hazardous waste container. Therefore, the used syringe will be discarded more quickly into a sharps container and there will be less opportunity for accidental sticks to occur en route to disposing the sharp.

However, we also note that syringes in sharps containers are typically autoclaved prior to disposal. EPA is concerned that the residues remaining in the syringes could be aerosolized during autoclaving and inadvertently expose workers to the aerosolized hazardous waste residues, posing risks (via pulmonary exposure) to those present during venting of the autoclave. Research suggests that autoclaving may even increase the toxicity of certain drugs.[135] EPA seeks comment on the extent of risks associated with autoclaving hazardous waste residues leftover in syringes and whether it is necessary to place a limit on the volume of residue or the volume of the syringe to which this conditional exemption would apply or whether any other conditions would be appropriate. For instance, stakeholders have informed us that they will squirt the residues remaining in a syringe onto a gauze pad prior to placing the syringe in the sharps container. Then, if the residues on the gauze pad are hazardous waste, the gauze pad is managed as hazardous waste, while allowing the syringe to be fully dispensed before placing it in the sharps container. In EPA's view, this method of managing excess residues is preferred over another practice that is commonly used: The disposal of excess residues down the drain.

d. Other containers, including delivery devices. With regard to other containers, including delivery devices, EPA is proposing that the residues remaining in unused or used containers (such as IV bags and tubing, inhalers, aerosols, nebulizers, tubes of ointment, gels, or creams) would be regulated as hazardous waste if the residues are a P- or U-listed hazardous waste or exhibit a hazardous waste characteristic. In some cases, such as with IV bags, the volume of hazardous waste is much larger than with residues contained in syringes or unit-dose containers. Stakeholders have stated that it is common practice for the leftover contents of IV bags and tubing to be emptied into a sink, which is a practice we are striving to eliminate. It is extremely difficult to determine how much residue remains in tubes of ointment, gel or cream. In the case of aerosols, it would be inadvisable to remove the contents of the container. Since hazardous waste pharmaceuticals managed under this proposed rule would not be counted towards a facility's generator category, managing these residues and containers as hazardous waste under proposed 40 CFR part 266, subpart P should not pose the same burden that generators currently face with keeping track of the monthly amount of residues in containers that are not ''RCRA empty.'' Further, comments on the 2008 Pharmaceutical Universal Waste proposal indicated that stakeholders prefer clear distinctions in regulating the hazardous waste from healthcare facilities and this proposed standard for container residues responds to that comment. EPA seeks comment on whether these proposed provisions address stakeholder concerns, while protecting human health and the environment.

F. What are the proposed standards for shipping hazardous waste pharmaceuticals?

1. Shipping Standards for Non-Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals to Treatment, Storage, and Disposal Facilities

a. Shipping Standards for Non-Creditable Hazardous Waste Pharmaceuticals From Healthcare Facilities to TSDFs

Typically, hazardous waste pharmaceuticals generated in a healthcare facility fall into two categories: (1) Non-creditable (*e.g.,* patient care) hazardous waste pharmaceuticals and (2) potentially creditable hazardous waste pharmaceuticals. This section discusses the proposed requirements for shipping of non-creditable, patient care/floor hazardous waste pharmaceuticals. For information regarding the shipment of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and pharmaceutical reverse distributors, see Section V.F.2 of the preamble.

Generally, patient care/floor hazardous waste pharmaceuticals differ from potentially creditable hazardous waste pharmaceuticals in that they have been partially administered and often are not in their original packaging. In addition, patient care/floor hazardous waste pharmaceuticals cannot receive manufacturer's credit and therefore may not be shipped to a reverse distributor. EPA is proposing that patient care/floor hazardous waste pharmaceuticals generated at healthcare facilities, when shipped off-site, must be shipped to a designated facility (*i.e.,* an interim status or permitted hazardous waste TSDF), as currently required (unless the healthcare facility has interim status or a RCRA permit to store or treat hazardous waste). Specifically, EPA proposes that non-creditable hazardous waste pharmaceuticals must continue to comply with the existing pre-transport requirements for packaging, labeling and marking, and that the non-creditable hazardous waste pharmaceuticals must continue to be shipped using a hazardous waste transporter and tracked with a hazardous waste manifest. However, to avoid unnecessarily burdening the healthcare facility staff, who are unfamiliar with RCRA, EPA proposes that the hazardous waste numbers (often called hazardous waste codes) are not required to be entered into the hazardous waste manifest for non-creditable hazardous waste pharmaceuticals. In lieu of hazardous waste codes, EPA is proposing that the words, ''hazardous waste pharmaceuticals'' must be entered in the ''special handling and additional information'' box on the manifest (box # 14). All existing RCRA recordkeeping requirements regarding hazardous waste manifesting continue to apply, (see Section V.C.12), as well as all applicable DOT shipping requirements. EPA requests comment on this proposed approach for manifesting non-creditable hazardous waste pharmaceuticals from a healthcare facility.

b. Shipping Standards for Evaluated Hazardous Waste Pharmaceuticals From Pharmaceutical Reverse Distributors to TSDFs

For pharmaceutical reverse distributors, once potentially creditable hazardous waste pharmaceuticals have been deemed non-creditable or credit has been issued and they do not require any additional verification of credit, EPA is proposing that the hazardous waste pharmaceuticals be referred to as ''evaluated hazardous waste pharmaceuticals.'' As with shipping non-creditable hazardous waste pharmaceuticals, when evaluated hazardous waste pharmaceuticals are shipped off-site, EPA is proposing that they must be shipped in accordance

[135] Daughton CG, *Drugs and the Environment: Stewardship & Sustainability,* National Exposure Research Laboratory, Environmental Sciences Division, U.S. EPA, Las Vegas, NV; NERL–LV–ES 10/081, EPA/600/R–10/106; September 2010 (*http://www.epa.gov/nerlesd1/bios/daughton/APM200-2010.pdf.*)

with the existing pre-transport requirements for packaging, labeling and marking, and that evaluated hazardous waste pharmaceuticals must be shipped via a hazardous waste transporter using a hazardous waste manifest to a designated facility. This continues current practices under existing regulations for this type of hazardous waste pharmaceutical and does not represent an increase in burden. EPA believes that use of a hazardous waste manifest and a hazardous waste transporter are appropriate at this point for two reasons. First, once credit for the hazardous waste pharmaceuticals has been issued and verified, the potential for mismanagement is greater. This is because the pharmaceuticals have lost their value and will cost the reverse distributor money to dispose. Second, TSDFs are accustomed to receiving hazardous waste via a hazardous waste transporter with a hazardous waste manifest and it would place administrative and compliance burdens on the receiving TSDF to accept shipments of hazardous waste with alternative tracking.

EPA is proposing that the pharmaceutical reverse distributor list the appropriate hazardous waste codes on the manifest (even though the healthcare facility is not required to provide such information to the reverse distributor). Hazardous waste pharmaceuticals received by pharmaceutical reverse distributors are in their original packaging with their label, so the information to determine the appropriate hazardous waste codes should be readily available. Also, reverse distributors are currently required to include hazardous waste codes on the manifest and it is expected that they have the necessary expertise in the management of these hazardous wastes that healthcare workers lack. As described in Section V.G.3 (pharmaceutical reverse distributor management standards), reverse distributors must keep copies of hazardous waste manifests for three years from the date of shipment.

EPA requests comment regarding the proposed manifest and transportation requirements for non-creditable hazardous waste pharmaceuticals from healthcare facilities and evaluated hazardous waste pharmaceuticals from pharmaceutical reverse distributors.

c. Importing/Exporting Non-Creditable or Evaluated Hazardous Waste Pharmaceuticals

Under the existing regulations, a healthcare facility or pharmaceutical reverse distributor may not import hazardous waste pharmaceuticals unless it has a RCRA permit or interim status that allows it to accept hazardous waste from off-site and complies with the requirements for importing hazardous waste in 40 CFR part 262, subpart F. This proposal does not change the regulations as they apply to the import of non-creditable or evaluated hazardous waste pharmaceuticals. Likewise, under existing regulations, a healthcare facility or pharmaceutical reverse distributor may not export (non-creditable or evaluated) hazardous waste pharmaceuticals unless it complies with requirements for exporting hazardous waste in 40 CFR part 262, subpart E. This proposal also does not change the regulations as they apply to the export of (non-creditable or evaluated) hazardous waste pharmaceuticals.[136]

EPA requests comment on the likelihood that non-creditable hazardous waste pharmaceuticals that are shipped from a healthcare facility to a domestic TSDF, would then be exported to a TSDF in a foreign country. In addition, EPA does not anticipate that hazardous waste pharmaceuticals would be destined for transboundary shipments for purposes of recovery operations and therefore potentially subject to 40 CFR part 262, subpart H; however, we also request comment on whether this is the case.

2. Shipping Standards for Potentially Creditable Hazardous Waste Pharmaceuticals

This section discusses the proposed requirements for shipping potentially creditable hazardous waste pharmaceuticals from healthcare facilities to pharmaceutical reverse distributors and between pharmaceutical reverse distributors. The return of potentially creditable pharmaceuticals (hazardous and non-hazardous) to reverse distributors can involve multiple shipping steps before the pharmaceuticals are transported for ultimate treatment and disposal. In comments on the 2008 Pharmaceutical Universal Waste proposal and in response to EPA's request for information,[137] pharmaceutical reverse distributors explained various scenarios that require extra shipping steps. For example, a healthcare facility typically sends pharmaceuticals to the reverse distributor with which it has a contract. However, some manufacturers will only provide manufacturer's credit after the pharmaceuticals have been returned to the reverse distributor with which the manufacturer has a contract. Thus, if the reverse distributor with which the healthcare facility has a contract differs from the reverse distributor with which the manufacturer has a contract, then the healthcare facility's reverse distributor must send the pharmaceuticals on to the manufacturer's reverse distributor for the manufacturer's credit to be given to the healthcare facility. In some cases, a pharmaceutical manufacturer may require the reverse distributor to ship the returned pharmaceuticals to the manufacturer so that the manufacturer itself can verify pharmaceutical amounts and credits. The estimate of the amount of pharmaceuticals transported from reverse distributors to manufacturers for verification varies. Based on our request for information, reverse distributors have indicated that the percent of potentially creditable pharmaceuticals transported to manufacturers ranged from an estimated 25 percent to 93 percent, depending on the contractual agreement between the reverse distributor and the manufacturer. Both of the scenarios described previously happen routinely and are part of the business of returning pharmaceuticals to reverse distributors (including manufacturers) for manufacturer's credit.

As explained in Section V.D.1, EPA is proposing that pharmaceuticals transported to pharmaceutical reverse distributors for credit are solid wastes, some of which will also be considered hazardous wastes. Under the current RCRA Subtitle C regulations, hazardous waste, including hazardous waste pharmaceuticals must be manifested to a permitted or interim status TSDF and shipped using a hazardous waste transporter to ensure the cradle-to-grave system of RCRA is maintained. However, compared to other hazardous wastes, EPA believes that the risk of environmental release posed by most potentially creditable hazardous wastes pharmaceuticals during accumulation and transport are relatively low. The risk is low because of the form and packaging of most potentially creditable hazardous waste pharmaceuticals, which is typically in small, individually packaged doses (such as with many tablets and capsules) or small vials.

[136] The Controlled Substances Import and Export Act prohibits controlled substances from being imported or exported unless permitted by DEA, even when the controlled substances are wastes. See 21 U.S.C. 952 and 953.

[137] EPA sent nine pharmaceutical reverse distributors a letter asking for more information about their business practices in an effort to more fully understand reverse distribution of pharmaceuticals. The seven responses representing the views of eight reverse distributors can be found in the docket of this proposed rulemaking (EPA–HQ–RCRA–2007–0932).

These small volumes of individually wrapped or packaged pharmaceuticals, when aggregated in a larger container, are unlikely to spill or be released into the environment since they are essentially double-packed when transported to a reverse distributor.[138] Potentially creditable hazardous waste pharmaceuticals that are in liquid and aerosol forms may pose more of a risk during accumulation and transport due to possible spillage or leakage, but the small quantities in which they are generated, along with the DOT packaging requirements of 49 CFR parts 173, 178, and 180, would likely mitigate this risk (see EPA's recommendation regarding liquids and aerosols in Section V.D.2.). Further, the 2008 Pharmaceutical Universal Waste proposal specifically sought comment regarding the risks of transportation of hazardous waste pharmaceuticals and no commenters identified environmental risks.

Due to the low risk of release to the environment described previously, EPA is proposing to allow potentially creditable hazardous waste pharmaceuticals to be shipped *without* a hazardous waste manifest and *without* the use of hazardous waste transporters. However, this exemption from manifesting and use of hazardous wastes transporters only applies if the healthcare facility is sending potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor, or if a pharmaceutical reverse distributor is sending potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor. Further, DOT shipping requirements continue to apply to shipments of potentially creditable hazardous waste pharmaceuticals.

In lieu of requiring a hazardous waste manifest and the use of hazardous waste transporters, EPA is proposing an alternate type of tracking for potentially creditable hazardous waste pharmaceuticals—with two requirements. First, for each shipment, healthcare facilities and pharmaceutical reverse distributors must provide in writing (via letter or electronic communication), advance notice of the shipment to the pharmaceutical reverse distributor. Second, for each shipment, the receiving pharmaceutical reverse distributors must provide confirmation to the healthcare facility or pharmaceutical reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived. One way to comply with this requirement would be for the receiving reverse distributor to require the healthcare facility or pharmaceutical reverse distributor that initiates the shipment of potentially creditable hazardous waste pharmaceuticals to utilize some form of ''delivery confirmation'' mechanism that is provided by the shipper that confirms that a shipment to a reverse distributor has reached its destination and is under the custody and control of the recipient (*e.g.* delivery confirmation tracking with return receipt). This ''delivery confirmation'' notice can be paper-based or electronic. As part of the delivery confirmation system, a signature (paper or electronic) or other confirmation from a representative of the receiving pharmaceutical reverse distributor would be required. The signature by the pharmaceutical reverse distributor would provide assurance that the shipment was received by the reverse distributor. Without the signature or other confirmation of a representative of the pharmaceutical reverse distributor, it is possible for the shipper to state that delivery to the location has occurred, but it would not necessarily indicate that the recipient was there to receive the shipment. This proposed requirement is in direct response to concerns expressed by commenters over the lack of tracking of pharmaceuticals in the 2008 Pharmaceutical Universal Waste proposal.

Alternatively, EPA has learned that some stakeholders use bar-coding on the pharmaceuticals or on the boxes to track shipments. The barcodes contain detailed information, including the exact quantities and types of pharmaceuticals included in the shipment. Typically, when a reverse distributor receives a barcoded shipment, it will scan in the shipment and the sender will receive electronic notification that the shipment has arrived. This type of bar-code tracking would meet the delivery confirmation requirement of this proposed rule, but other mechanisms of ''delivery confirmation'' that are offered by common carriers, such as the U.S. Postal Service, FedEx or United Parcel Service (UPS), would also be acceptable.

Under this proposal, healthcare facilities and reverse distributors may use common carriers, such as the U.S. Postal Service, United Parcel Service, or FedEx [139] for shipments of potentially creditable hazardous waste pharmaceuticals to and between pharmaceutical reverse distributors. EPA believes that common carriers are able to provide safe shipment since these potentially creditable hazardous waste pharmaceuticals present low transportation risk. We note that healthcare facilities and pharmaceutical reverse distributors must meet the applicable Pipeline and Hazardous Materials Safety Administration (PHMSA) Hazardous Materials Regulation (HMR; 49 CFR parts 171–180) shipping requirements, including preparing proper shipping papers when shipping potentially creditable hazardous waste pharmaceuticals. A RCRA hazardous waste that does not meet DOT hazard classes 1–8 in the HMR, are only Class 9 hazardous materials when defined as a RCRA hazardous wastes that requires a manifest. As a result, the DOT shipping requirements will apply when potentially creditable hazardous waste pharmaceuticals are shipped to pharmaceutical reverse distributors only when the hazardous wastes are DOT class 1–8 hazardous materials.

EPA notes that a pharmaceutical reverse distributor is not required to sort the potentially creditable hazardous waste pharmaceuticals from the potentially creditable non-hazardous waste pharmaceuticals when they are destined for another reverse distributor. However, if the potentially creditable pharmaceuticals are not sorted, the pharmaceutical reverse distributor must follow the tracking procedures in this proposal for the entire shipment. On the other hand, if a pharmaceutical reverse distributor chooses to sort the potentially creditable hazardous waste pharmaceuticals from the creditable non-hazardous waste pharmaceuticals prior to shipping to another reverse distributor, only the potentially creditable hazardous waste pharmaceutical portion would have to be shipped according to these proposed standards. EPA asks for comment on whether the proposed tracking system and controls are sufficient to protect human health and the environment.

a. What Happens if a Healthcare Facility or Pharmaceutical Reverse Distributor Initiates a Shipment and Does Not Get Confirmation of Delivery?

If a healthcare facility or pharmaceutical reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation from the intended recipient within seven calendar days, EPA is proposing that the healthcare facility or pharmaceutical reverse

[138] Pharmaceutical Universal Waste proposal, 73 FR 73529; December 2, 2008.

[139] Note EPA is not endorsing the use of any of the shipping companies cited.

distributor that initiated the shipment must contact the shipper and the intended recipient promptly to (1) report that the confirmation was not received and (2) to determine the status and whereabouts of the potentially creditable hazardous waste pharmaceuticals that were shipped. The Agency requests comment on whether any additional requirements, such as reporting to the implementing agency, are necessary in such cases.

b. Importing/Exporting Potentially Creditable Hazardous Waste Pharmaceuticals

If a healthcare facility or pharmaceutical reverse distributor imports potentially creditable hazardous waste pharmaceuticals, then it must comply with the proposed requirements for the shipment of potentially creditable hazardous waste pharmaceuticals. The proposed requirements would be in lieu of those for manifested hazardous waste imports found at 40 CFR part 262, subpart F. EPA requests comment on whether potentially creditable hazardous waste pharmaceuticals are imported into the U.S. and, if so, how they are currently declared to customs when imported.

If a healthcare facility or pharmaceutical reverse distributor exports potentially creditable hazardous waste pharmaceuticals then it must generally comply with 40 CFR part 262, subpart E, except that it is not required to manifest the potentially creditable hazardous waste pharmaceuticals.[140]

c. Recordkeeping for Shipments of Potentially Creditable Hazardous Waste Pharmaceuticals

EPA is proposing to require healthcare facilities and reverse distributors to keep records of the shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Specifically, we are proposing that healthcare facilities and reverse distributors that initiate a shipment to another pharmaceutical reverse distributor keep (1) records of advance notification regarding shipments of potentially creditable hazardous waste pharmaceuticals, (2) shipping papers, and (3) confirmation of receipt of shipment for three years after the shipment was initiated. These records are necessary to ensure that potentially creditable hazardous waste pharmaceuticals are reaching their intended destination and not diverted. In most cases, retaining records for 3 years should be sufficient for inspection purposes; however, we are proposing that the periods of retention are automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator. The Agency seeks comment on whether additional recordkeeping is necessary to document the cases when the pharmaceutical reverse distributor does not receive a shipment of potentially creditable pharmaceuticals within 7 calendar days and the steps must be taken to locate the shipment.

G. What are the proposed standards for pharmaceutical reverse distributors?

1. Background on Pharmaceutical Reverse Distributor Operations

Pharmaceutical reverse distributors act as intermediaries between healthcare facilities and pharmaceutical manufacturers. They receive shipments of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and, on behalf of manufacturers, facilitate the process of crediting healthcare facilities for these pharmaceuticals. From stakeholder input and EPA site visits, EPA's understanding is that when a pharmaceutical reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its computer system. Based on manufacturers' return goods policies, the pharmaceutical reverse distributors determine which potentially creditable hazardous waste pharmaceuticals can be credited, as well as which must be sent on to another reverse distributor for completion of the crediting process.

In many cases, there is more than one reverse distributor involved in establishing and verifying manufacturer's credit for a particular potentially creditable hazardous waste pharmaceutical. For instance, reverse distributors may have contracts with specific pharmaceutical manufacturers such that only a specific pharmaceutical reverse distributor may facilitate credit for a particular manufacturer's pharmaceuticals. If the receiving reverse distributor has a contract with the healthcare facility, but not with the pharmaceutical manufacturer, then the receiving pharmaceutical reverse distributor sends the returned pharmaceutical on to the reverse distributor that has a contract with the pharmaceutical manufacturer in order to facilitate the credit process.

Because manufacturers' return goods policies change over time, sometimes a pharmaceutical reverse distributor receives a potentially creditable hazardous waste pharmaceutical that is not eligible for credit immediately, and the pharmaceutical reverse distributor retains the potentially creditable hazardous waste pharmaceutical on-site until it is credit eligible. EPA requests comment on how often this happens and how long the potentially creditable hazardous waste pharmaceuticals are kept on-site at reverse distributors to await changes in manufacturers' return goods policies.

In some cases, even after the pharmaceutical reverse distributor has awarded credit, a pharmaceutical manufacturer may request that the hazardous waste pharmaceuticals be transported back to the manufacturer to inventory and verify the amount of pharmaceuticals and credit. In developing this proposed rule, EPA considered all of the previous scenarios as part of the crediting process.

On the other hand, if the potentially creditable hazardous waste pharmaceuticals are not sent onward to another pharmaceutical reverse distributor, the pharmaceutical reverse distributor awards the manufacturer's credit to the healthcare facility and then manages the hazardous waste pharmaceuticals on-site until they are sent off-site for treatment and disposal. As discussed previously in this proposal, after a potentially creditable hazardous waste pharmaceutical has been evaluated and either credited or deemed non-creditable and no additional pharmaceutical reverse distributors will be involved in the crediting process, EPA proposes to use the term ''evaluated hazardous waste pharmaceutical.'' This is to distinguish between the potentially creditable hazardous waste pharmaceuticals awaiting determination within the reverse distribution system versus credited and non-creditable hazardous waste pharmaceuticals that have been through the reverse distributor process and are destined to be managed by a permitted or interim status TSDF. Both are considered hazardous waste pharmaceuticals, but they are managed differently under the proposed regulations.

EPA is not aware of any pharmaceutical reverse distributors that facilitate manufacturer's credit that also has interim status or a permit to treat or dispose of hazardous waste on-site. Therefore, EPA anticipates that pharmaceutical reverse distributors eventually send all evaluated hazardous waste pharmaceuticals off-site for

[140] The Controlled Substances Import and Export Act prohibits controlled substances from being imported or exported unless permitted by DEA, even when the controlled substances are wastes. See 21 U.S.C. 952 and 953.

treatment and disposal. EPA requests comment on whether the processes described previously are representative of the pharmaceutical reverse distribution process.

2. EPA's Rationale for Proposing New RCRA Management Standards for Pharmaceutical Reverse Distributors

This proposed rule is establishing standards for the management of both potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that pharmaceutical reverse distributors receive and manage. The Agency notes that the management standards discussed in this section apply only to reverse distributors of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals and do not apply to reverse distribution or reverse logistics systems that may exist for other consumer products.

The current federal RCRA hazardous waste regulations at 40 CFR part 262 provide that only RCRA- permitted and interim status TSDFs may receive hazardous waste from off-site for treatment, storage, or disposal. However, the Agency does not believe it is necessary for pharmaceutical reverse distributors to obtain permits or have interim status to store hazardous waste pharmaceuticals in order to protect human health and the environment. Thus, EPA proposes a new category under RCRA called a ''pharmaceutical reverse distributor,'' which we proposed to define as any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit. The definition specifies that any person, including forward distributors and pharmaceutical manufacturers, which processes pharmaceuticals for the facilitation or verification of manufacturer's credit is considered a pharmaceutical reverse distributor. EPA is proposing that pharmaceutical reverse distributors are not required to have interim status or a RCRA permit to accumulate hazardous waste pharmaceuticals and they may only accept potentially creditable hazardous waste pharmaceuticals from off-site provided they comply with the proposed standards in this rule. Pharmaceutical reverse distributors may not treat or dispose of hazardous waste on-site unless authorized to do so as a RCRA-permitted or interim status TSDF.

As discussed previously, EPA's existing interpretation allows pharmaceutical reverse distributors to be generators of hazardous waste pharmaceuticals after a decision is made about whether the pharmaceuticals will be repurposed. As a generator, a pharmaceutical reverse distributor currently must comply with the LQG, SQG, or CESQG generator requirements, depending on the total volume of hazardous waste generated in a calendar month. Some smaller pharmaceutical reverse distributors might stay under the hazardous waste quantity limits for CESQGs, which would mean that under the federal RCRA requirements, these CESQG pharmaceutical reverse distributors would not have to notify EPA as a generator and their hazardous waste pharmaceuticals could be disposed of with municipal and non-municipal solid waste (see § 261.5). However, the Agency has concerns with CESQG pharmaceutical reverse distributors not notifying EPA that they are managing hazardous waste. EPA is even more concerned about pharmaceutical reverse distributors that currently qualify as CESQGs placing the hazardous waste pharmaceuticals into the municipal and non-municipal solid waste stream and sending them to non-hazardous waste landfills. Some limited studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems.[141] [142] Landfill leachate is generally transported to a wastewater treatment plant to be treated before discharge; however, some pharmaceutical compounds pass through treatment and are discharged, becoming a potential contributor of the pharmaceutical compounds detected in our nation's waters.

EPA is proposing to revise its position regarding potentially creditable hazardous waste pharmaceuticals, such that they will be first considered discarded at the healthcare facilities, not at the reverse distributors. This revision is based on new information demonstrating to EPA that pharmaceuticals returned to a reverse distributor are rarely, if ever, recycled or reused, and therefore the decision to send a potentially creditable hazardous waste pharmaceutical to a pharmaceutical reverse distributor is a decision to discard the pharmaceutical (as discussed previously in Section V.D.1). Other comments on the December 2008 Pharmaceutical Universal Waste proposal indicated that notification to EPA by pharmaceutical reverse distributors and tracking of shipments of potentially creditable hazardous waste pharmaceuticals are critical and must be included in any regulatory scheme to ensure the safe management of potentially creditable hazardous waste pharmaceuticals.

As previously discussed, only between 2–6 percent of the potentially creditable hazardous wastes that are received by pharmaceutical reverse distributors are listed or characteristic hazardous wastes.[143] Therefore, the vast majority of the potentially creditable pharmaceutical waste that a pharmaceutical reverse distributor receives is not considered a characteristic or listed hazardous waste pharmaceutical under the existing definition of hazardous waste. This stands in contrast to a typical TSDF, which primarily manages hazardous waste. As a result, a pharmaceutical reverse distributor generally manages a smaller volume of hazardous waste than a typical permitted TSDF.

In addition, because the pharmaceuticals in the reverse distribution system are receiving credit, they are moved through the system efficiently. In fact, one national pharmacy retail chain informed EPA that the value of the credit they receive from manufacturers for returned pharmaceuticals is approximately $1 billion a year.[144] Healthcare facilities and reverse distributors have a vested interest in having potentially creditable hazardous waste pharmaceuticals processed and credited quickly and managed appropriately so money is not lost in the process.

Furthermore, potentially creditable hazardous waste pharmaceuticals generally present a low risk of release to the environment as they typically are still in the manufacturer's packaging. Since there is a low human health and environmental risk of release associated with the low volumes of potentially creditable hazardous waste pharmaceuticals shipped to reverse distributors for crediting purposes, and because EPA is not aware of any incidents of mismanagement resulting

[141] 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.

[142] Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (2009), Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002. Bulletin of Environmental Contamination and Toxicology, 82.6:635–659.

[143] See EPA's request of information from reverse distributors, as well as their responses to EPA in the docket for this rulemaking: EPA–HQ–RCRA–2007–0932.

[144] Meeting with representatives from CVS/Caremark (November 8, 2012); see the docket for meeting notes (EPA–HQ–RCRA–2007–0932).

in environmental harm or releases of hazardous waste pharmaceuticals by reverse distributors, EPA believes that is not necessary to require reverse distributors to obtain RCRA hazardous waste storage permits with respect to typical reverse distribution operations, such as receiving, sorting, consolidating, and reshipping potentially creditable hazardous waste pharmaceuticals.

Thus, EPA is proposing to take a ''middle-of-the-road'' approach to regulating pharmaceutical reverse distributors by regarding them as a new type of RCRA hazardous waste entity—a pharmaceutical reverse distributor. This proposed approach addresses comments that EPA received on the December 2008 Pharmaceutical Universal Waste proposal and reflects EPA's proposed revised interpretation that the point of generation for potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, not the reverse distributor.

EPA proposes to establish management standards for pharmaceutical reverse distributors in 40 CFR part 266, subpart P. These entities would not be subject to 40 CFR parts 262, 264, or 265. Generally, EPA is proposing that pharmaceutical reverse distributors comply with standards that are similar to the current federal LQG standards, in combination with certain requirements that permitted or interim status hazardous waste TSDFs must meet. We are establishing one set of requirements for all pharmaceutical reverse distributors, regardless of the amount of potentially creditable hazardous waste pharmaceuticals they receive. EPA believes this uniform set of standards will make it easier for pharmaceutical reverse distributors to comply with the new proposal, since the burden of having to count hazardous waste pharmaceuticals on a monthly basis, especially the 1 kg of acute hazardous waste pharmaceuticals, will be removed.

EPA proposes that a pharmaceutical reverse distributor will not be required to have a hazardous waste permit or interim status for on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals provided it follows the proposed pharmaceutical reverse distributor standards. However, for activities such as treatment or disposal of hazardous waste pharmaceuticals or other hazardous waste, a pharmaceutical reverse distributor must either obtain a RCRA permit or have interim status. This proposal requires pharmaceutical reverse distributors to comply with standards that are similar to LQG standards for on-site accumulation of hazardous waste that are found in § 262.34(a) and (b). We are proposing these requirements because, as discussed prevoiusly, the value of the potentially creditable pharmaceuticals creates an incentive for proper management and the risk of release is low. Furthermore, many pharmaceutical reverse distributors are already LQGs and therefore this proposed rule should not represent a large shift in current practices or increased burden. However, once credit is provided, the value of the pharmaceuticals is eliminated and therefore the evaluated hazardous waste pharmaceuticals have a greater potential for mismanagement. As a result, we are proposing that pharmaceutical reverse distributors have additional standards for the management of evaluated hazardous waste pharmaceuticals. Note that while the LQG accumulation standards are found in §§ 262.34(a) and (b), these generator regulations reference many interim status TSDF standards in part 265. However, in the regulatory text and preamble for this rule, we reference the standards in part 265 directly for the applicable accumulation standards for pharmaceutical reverse distributors (rather than § 262.34(a) which would then simply refer the reader to part 265). However, the Agency requests comment as to whether we should include the regulatory standard directly in 40 CFR part 266, subpart P, instead of providing a cross-reference to the standard in 40 CFR part 265 in an effort to make the rules easier to follow and comply with.

3. Detailed Discussion of Proposed Pharmaceutical Reverse Distributor Standards

The proposed standards for pharmaceutical reverse distributors are organized into three sections. The first section applies to the pharmaceutical reverse distributor for the management of all potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. The second section includes additional standards that would apply to the management of the potentially creditable hazardous waste pharmaceuticals that will be sent to another pharmaceutical reverse distributor for further evaluation or verification of credit and therefore continue to be regulated as potentially creditable hazardous waste pharmaceuticals. The third section includes additional standards that apply to the management of the evaluated hazardous waste pharmaceuticals that will not be sent to another pharmaceutical reverse distributor, but instead will be sent to a permitted or interim status TSDF.

a. Standards for Pharmaceutical Reverse Distributors

This portion of the preamble discusses the proposed standards that apply to pharmaceutical reverse distributors for the management of all hazardous waste pharmaceuticals on-site. Unlike the following two sections, the standards discussed in this section apply to all pharmaceutical reverse distributors, regardless of the subsequent destination of the hazardous waste pharmaceuticals. We note that a pharmaceutical reverse distributor must follow the proposed standards for the management of hazardous waste pharmaceuticals even if it generates other, non-pharmaceutical hazardous waste that is managed under 40 CFR part 262.

i. *Notification.* The first proposed requirement is that a pharmaceutical reverse distributor must notify EPA of its hazardous waste pharmaceutical activities via the Site ID form (EPA form 8700–12). Under the current RCRA Subtitle C program, both LQGs and TSDFs must submit a Site ID form to EPA. Thus, EPA believes it is appropriate, and in line with comments received on the 2008 Pharmaceutical Universal Waste proposal, to require pharmaceutical reverse distributors to notify EPA. A pharmaceutical reverse distributor that does not have an EPA ID number will be required to submit the Site ID form to obtain one. If this proposal is finalized, the Agency plans on revising the Site ID form to include a box to allow notifications by pharmaceutical reverse distributors. For those pharmaceutical reverse distributors that already have an EPA ID number, they will need to re-notify EPA as a pharmaceutical reverse distributor. Some pharmaceutical reverse distributors may also be generators of other types of hazardous waste (*e.g.,* from cleaning and maintenance operations). Therefore, it is possible that a pharmaceutical reverse distributor may notify on the same notification form as both a generator of hazardous waste and as a pharmaceutical reverse distributor.

ii. *Inventory.* EPA is proposing a new provision that is specific to pharmaceutical reverse distributors: the requirement is to keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on-site. The inventory must include the identity (*e.g.,* name or national drug code (NDC)) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceuticals. EPA

also recommends as a best management practice that pharmaceutical reverse distributors also keep an inventory of their non-hazardous waste pharmaceuticals as well. An inventory is a key requirement to protect public health by helping to prevent the diversion of hazardous waste pharmaceuticals. An inventory will allow the pharmaceutical reverse distributor to know which pharmaceuticals they have on-site at any time. The Agency believes that in many cases, pharmaceutical reverse distributors already maintain inventories and this proposed requirement is not expected to be burdensome for the pharmaceutical reverse distributors to implement. In fact, according to responses from pharmaceutical reverse distributors to a request for information, four out of eight of them indicated that they already keep inventories as best management practices or because it is required by the Board of Pharmacy in their state.[145] However, EPA requests comment on whether this practice is already commonly followed.

iii. *Security of the pharmaceutical reverse distributor.* EPA is proposing that pharmaceutical reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. Specifically, due to increased thefts of narcotics from pharmacies reported in recent years in major media outlets,[146] EPA is concerned that pharmaceutical reverse distributors could also face such thefts since they accumulate unused pharmaceuticals or those that have exceeded their expiration date. Further, commenters on the 2008 Pharmaceutical Universal Waste proposal suggested that pharmaceutical universal waste handlers should meet the TSDF facility security requirement. EPA agrees with the commenters that the requirements that appear in the interim status TSDF security regulations would be appropriate to adopt and apply to pharmaceutical reverse distributors to prevent the illicit use of these pharmaceuticals and safeguard human health and thus, has included this requirement for pharmaceutical reverse distributors. The security of the facility requirement of § 265.14(a) requires a facility to ''prevent the unknowing entry, and minimize the possibility for the unauthorized entry, of persons or livestock onto the active portion of his facility.'' EPA is proposing a similar requirement for pharmaceutical reverse distributors: they must prevent unknowing entry, and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (*e.g.,* a receiving area and accumulation area).

Based on site visits, EPA recognizes that many pharmaceutical reverse distributors may already meet the proposed security standard through the use of key cards that allow only authorized personnel into specific areas of the pharmaceutical reverse distributor, camera surveillance systems, and cages for storing pharmaceuticals. Some pharmaceutical reverse distributors may use fences and signs. EPA is including several examples of acceptable security measures in the regulatory text, but pharmaceutical reverse distributors are not limited to the examples provided. Further, if a pharmaceutical reverse distributor already meets the performance-based security standard by complying with other regulations, such as DEA's regulations, then the pharmaceutical reverse distributor would not need to install additional security.

iv. *Maximum 90 days for on-site accumulation and petition for an extension of accumulation time.*

EPA is proposing that, like LQGs, pharmaceutical reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for up to 90 calendar days without having interim status or a permit. However, because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, the Agency has decided not to propose specific container management standards.

The 90-day time limit begins when the potentially creditable hazardous waste pharmaceuticals initially arrive at the pharmaceutical reverse distributor. The 90-day time limit follows the potentially creditable pharmaceutical, even after it becomes an evaluated hazardous waste pharmaceutical. That is, there is a single 90-day accumulation limit for the hazardous waste pharmaceutical at each pharmaceutical reverse distributor. However, some potentially creditable hazardous waste pharmaceuticals travel through more than one pharmaceutical reverse distributor to receive manufacturer's credit. In such cases, each pharmaceutical reverse distributor that receives the potentially creditable hazardous waste pharmaceuticals has a new 90-day accumulation limit. EPA requests comment on the 90-day timeframe and whether this timeframe is sufficient, or whether an alternative timeframe should be allowed.

As discussed previously, EPA is proposing that a pharmaceutical reverse distributor must inventory potentially creditable hazardous waste pharmaceuticals upon arrival. Many pharmaceutical reverse distributors utilize barcoding and scanners to log potentially creditable pharmaceuticals into a database upon arrival or soon after a shipment arrives. Current inventory systems may be adapted to provide verification of the time limits. For example, if a pharmaceutical reverse distributor includes the date of arrival in the inventory, then the pharmaceutical reverse distributor will be able to use the inventory to verify that potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are not accumulated on-site for more than 90 calendar days. EPA is not proposing a specific method that pharmaceutical reverse distributors must use to document that accumulation does not exceed 90 calendar days. We anticipate that most pharmaceutical reverse distributors would use the inventory system to verify the 90-calendar day timeframe rather than using an additional requirement of labeling containers with dates for verification, but we request comment on this issue. We also request comment on whether EPA needs to specify a method of documenting that 90 calendar days is not exceeded.

Pharmaceutical reverse distributors have informed EPA that there are times when pharmaceutical returns may need to be consolidated for longer periods because they are subject to litigation and the pharmaceutical reverse distributor is not allowed to move them. Pharmaceutical reverse distributors may also need to handle large recalls of hazardous waste pharmaceuticals and might not be able to process all of the returned items within 90 calendar days. Therefore, EPA is proposing to allow a pharmaceutical reverse distributor to request from EPA an extension of the 90-day accumulation time limit for situations when the hazardous waste pharmaceuticals are involved in litigation, a recall, or in unforeseen circumstances beyond the control of the pharmaceutical reverse distributor. A pharmaceutical reverse distributor

[145] See all the responses EPA received from pharmaceutical reverse distributors in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).

[146] ''Pharmacies Besieged by Addicted Thieves'' by Abby Goodnough Published: February 6, 2011 *http://www.nytimes.com/2011/02/07/us/07pharmacies.html.*

seeking an extension must submit a written request to the EPA Regional Administrator (in writing or electronically), explaining the reason for the extension, the approximate volume or weight of the hazardous waste pharmaceuticals that will be stored for more than 90-days and the amount of additional time requested. Under the existing RCRA subtitle C regulations, the extension of time typically allowed is limited to an extra 30 days for LQGs. However, due to the complex nature of pharmaceutical litigation and recalls, EPA is proposing to allow the EPA Regional Administrator to grant a time extension at their discretion on a case-by-case basis. EPA requests comment on whether it is necessary to place a limit on the length of time for which an extension may be granted.

v. *Contingency plan and emergency procedures.* The Agency is proposing to require that pharmaceutical reverse distributors meet standards that are the same as those that appear in the federal LQG regulations for developing a contingency plan and emergency procedures at 40 CFR part 265, subpart D. EPA believes that a pharmaceutical reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Since many pharmaceutical reverse distributors are already LQGs, they should already have contingency plans to address the hazards on-site. It may be possible that the pharmaceutical reverse distributors will have to amend their contingency plans to include the potentially creditable hazardous waste pharmaceuticals, which have been considered products, not hazardous waste, but we believe that such modifications should not impose much burden.

vi. *Closure.* Due to the generally low risk of release of the hazardous waste pharmaceuticals that pharmaceutical reverse distributors will accumulate on-site, as well as the value of the hazardous waste pharmaceuticals, EPA is proposing to require a performance-based closure standard that is based on the federal LQG closure standard found at § 265.111. Specifically, when a pharmaceutical reverse distributor closes its operations related to hazardous waste pharmaceuticals, it must control or minimize post-closure releases of hazardous waste constituents into the environment. This will entail removing the containers of hazardous waste pharmaceuticals (both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste pharmaceuticals) from the facility before closure.

vii. *Reporting.* In some instances, a pharmaceutical reverse distributor may receive a shipment from a healthcare facility that includes items that are not potentially creditable pharmaceuticals. These shipments can include wastes that are clearly not eligible to receive credit, such as patient care waste (*e.g.,* IV tubing), contaminated personal protective equipment (PPE), medical waste, or other inappropriate wastes. Pharmaceutical reverse distributors are not the appropriate waste management facility for medical or infectious wastes and these wastes must be managed and transported from the healthcare facility directly to an appropriate waste disposal facility. In some cases, these non-creditable wastes may be hazardous waste. These non-creditable hazardous wastes are prohibited from being transported from a healthcare facility to a pharmaceutical reverse distributor; rather they should be manifested to a designated facility, such as a permitted or interim status TSDF. Nevertheless, a healthcare facility might incorrectly ship non-creditable hazardous wastes to a pharmaceutical reverse distributor.

EPA is proposing that if a pharmaceutical reverse distributor receives a shipment from a healthcare facility that includes hazardous waste that it is not authorized to receive, such as non-creditable hazardous waste or hazardous waste that is not a pharmaceutical, the pharmaceutical reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 15 days of receiving the hazardous waste. We have adapted the existing requirement for situations when permitted and interim status TSDFs receive unmanifested hazardous waste (§ 264.76 and § 265.76, respectively) to make it appropriate for pharmaceutical reverse distributors that receive unauthorized hazardous waste. However, we are also proposing two additional requirements for pharmaceutical reverse distributors that receive inappropriate hazardous waste. First, the pharmaceutical reverse distributor must send a copy of the unauthorized hazardous waste report to the healthcare facility that sent the unauthorized hazardous waste. This requirement is intended to alert the healthcare facility of its mistake in order to prevent further shipments of non-creditable hazardous waste or non-pharmaceutical hazardous waste. Second, the pharmaceutical reverse distributor must manage the unauthorized hazardous waste that it receives in accordance with all applicable regulations. The Agency expects that the pharmaceutical reverse distributor will likely pass these additional costs (*e.g.,* medical waste incineration) on to the healthcare facility for the management of the hazardous waste and this will act as an incentive for the healthcare facility to take measures to prevent further shipments of unauthorized hazardous waste. We request comment on whether EPA's understanding regarding this type of situation is representative.

In order to prevent exposing employees to unnecessary risk, EPA recommends as a best management practice that pharmaceutical reverse distributors avoid sorting through shipments that contain non-creditable waste since the shipment may include hazardous waste, including infectious or radioactive healthcare waste. As a result, it is possible that a pharmaceutical reverse distributor receiving a shipment that includes non-creditable waste may be unsure whether the shipment includes hazardous waste. In such cases, EPA recommends that the pharmaceutical reverse distributor assume the shipment includes hazardous waste and submit an unauthorized waste report. Further, we recommend that pharmaceutical reverse distributors work with their clients to reduce the occurrence of inappropriate shipments.

viii. *Recordkeeping.* EPA is proposing three recordkeeping requirements to provide transparency for the movement of potentially creditable hazardous waste pharmaceuticals and as a means of verification upon inspection. First, a pharmaceutical reverse distributor must keep a copy of its notification (EPA form 8700–12) to EPA to indicate that it is a pharmaceutical reverse distributor operating under 40 CFR part 266, subpart P. A pharmaceutical reverse distributor must keep the record of notification for as long as it is subject to these requirements. Second, a pharmaceutical reverse distributor must keep copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives. This includes a copy of the advance notification from the healthcare facility or other pharmaceutical reverse distributor, a copy of delivery confirmation, shipping papers and any unauthorized waste reports. We propose that these shipping records must be kept for three years from the date the pharmaceutical reverse distributor receives the shipment. We request comment on whether additional recordkeeping is necessary to document cases when shipments of potentially creditable hazardous waste pharmaceuticals do not reach their intended destination within 7 calendar

days. Third, a pharmaceutical reverse distributor must keep a copy of its current inventory at all times as long as the pharmaceutical reverse distributor remains in operation. The inventory is a living document that will constantly be updated and must be available for inspection. Finally, we propose that periods of record retention indicated previously for a pharmaceutical reverse distributor will be automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

Note that additional recordkeeping requirements may also pertain to pharmaceutical reverse distributors. For example, a pharmaceutical reverse distributor that manifests its non-pharmaceutical hazardous waste is subject to the manifest recordkeeping requirements of § 262.40. Further, as discussed in subsequent sections, there are additional recordkeeping requirements that apply to pharmaceutical reverse distributors for the management of potentially creditable hazardous waste pharmaceuticals destined for another pharmaceutical reverse distributor and others that apply to pharmaceutical reverse distributors for the management of evaluated hazardous waste pharmaceuticals.

ix. *Evaluating potentially creditable hazardous waste pharmaceuticals within 21 days.* Based on stakeholder input and site visits, EPA has learned that when a pharmaceutical reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its system. The pharmaceutical reverse distributor then determines which potentially creditable hazardous waste pharmaceuticals must be transported to another reverse distributor and which ones will be credited and then sent off-site for treatment and disposal. EPA is proposing that this evaluation process must be completed within 21 days of arriving at the pharmaceutical reverse distributor. Likewise, if the pharmaceutical reverse distributor is a manufacturer, EPA is proposing that the manufacturer must finish verifying the appropriate credit within 21 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals.

EPA has chosen to propose 21 calendar days to ensure that the pharmaceutical reverse distributor has a long enough of time to make the evaluation, yet a short enough time to ensure that potentially creditable hazardous waste pharmaceuticals do not linger awaiting evaluation. The Agency requests comment on this timeframe and whether it should be shortened or lengthened. We also want to emphasize that the 21 calendar days for evaluating the potentially creditable hazardous pharmaceuticals counts as part of the total 90 calendar days that the hazardous waste pharmaceuticals are allowed to accumulate on-site.

Once an evaluation is made on the incoming potentially creditable hazardous waste pharmaceuticals, if they are destined for another pharmaceutical reverse distributor, they are still considered potentially creditable hazardous waste pharmaceuticals. There are additional regulations in this proposal at § 266.510(b) that pertain to these potentially creditable hazardous waste pharmaceuticals (discussed in Section V.G.3.b.). If, however, they are destined for an interim status or permitted TSDF, they are considered ''evaluated hazardous waste pharmaceuticals.'' There are additional regulations in this proposal at § 266.510(c) that pertain to these evaluated hazardous waste pharmaceuticals (discussed in Section V.G.3.c.).

b. Additional Standards for Pharmaceutical Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceuticals Destined for Another Pharmaceutical Reverse Distributor

This section discusses the additional standards that apply to a pharmaceutical reverse distributor for the management of potentially creditable hazardous waste pharmaceuticals that require further evaluation or verification of manufacturer's credit at another pharmaceutical reverse distributor. These hazardous waste pharmaceuticals continue to be considered potentially creditable hazardous waste pharmaceuticals. Until manufacturer's credit is finalized, the potentially creditable hazardous waste pharmaceuticals retain their value and there is greater incentive to manage them carefully in order to receive full manufacturer's credit. Therefore, EPA is proposing few regulatory standards for the management of the potentially creditable hazardous waste pharmaceuticals that are destined for another pharmaceutical reverse distributor.

i. *Where potentially creditable hazardous waste pharmaceuticals can be sent.* The proposed regulations for pharmaceutical reverse distributors are structured so that there is a limit to the number of transfers of potentially creditable hazardous waste pharmaceuticals that may occur before they are ultimately transported to a TSDF for treatment and disposal. Stakeholders expressed concern that the 2008 Pharmaceutical Universal Waste proposal would have allowed hazardous waste pharmaceuticals to be shipped repeatedly and indefinitely from one universal waste handler to another. From discussions with pharmaceutical reverse distributors and reviewing information submitted via EPA's request for information, the Agency believes a reasonable limit is three transfers of potentially creditable hazardous waste pharmaceuticals before the pharmaceutical hazardous waste is ultimately transported to a TSDF. The three possible types of transfers are: [147]

(1) a healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor, which may or may not be a manufacturer;

(2) the first pharmaceutical reverse distributor may send the potentially creditable hazardous waste to another pharmaceutical reverse distributor, which may or may not be a manufacturer

(3) the second pharmaceutical reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals on to a pharmaceutical reverse distributor that is a manufacturer.

EPA anticipates that healthcare facilities that are CESQGs will send their potentially creditable hazardous waste pharmaceuticals directly to pharmaceutical reverse distributors, and that the accumulation mechanism that we are proposing will be used to send only non-creditable hazardous waste pharmaceuticals to off-site healthcare facilities (see Section V.C.15.). However, EPA requests comment on whether CESQG healthcare facilities would benefit from being able to consolidate potentially creditable hazardous waste pharmaceuticals off-site, as well. Depending on comments, EPA will consider allowing a fourth transfer (for this limited situation) when potentially creditable hazardous waste pharmaceuticals are sent from a CESQG healthcare facility to an off-site healthcare facility for accumulation, as would also be allowed by proposed § 266.504(a).

[147] A healthcare facility or pharmaceutical reverse distributor also has the option of sending its hazardous waste pharmaceuticals to a RCRA permitted or interim status TSDF.

This chain of transfers ensures that the potentially creditable hazardous waste pharmaceuticals will be accumulated for no more than 270 days in total after leaving a healthcare facility and before being transported to a RCRA-permitted or interim status TSDF for treatment and disposal (assuming no accumulation time extensions are granted). EPA requests comment as to whether the three-transfer and 90-day limits are appropriate and whether more or fewer transfers are necessary for verification of manufacturer's credit.

Put another way, if a pharmaceutical reverse distributor receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility, the pharmaceutical reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor (which may or may not be a manufacturer) or must manage them as evaluated hazardous waste pharmaceuticals under proposed § 266.510(c). However, a pharmaceutical reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another pharmaceutical reverse distributor is more limited in where it can send the potentially creditable hazardous waste pharmaceuticals. It can send potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor that is the manufacturer or else must manage them as evaluated hazardous waste pharmaceuticals under § 266.510(c).

Regardless of the destination, each pharmaceutical reverse distributor must make an evaluation of the hazardous waste pharmaceuticals within 21 calendar days and may only accumulate the hazardous waste pharmaceuticals on-site for a maximum of 90 calendar days, unless an extension is granted by the Regional Administrator before it ships them off-site to another pharmaceutical reverse distributor or a RCRA-permitted or interim status TSDF. In addition, all shipments of evaluated hazardous waste pharmaceuticals are subject to proposed § 266.508 and shipments of all potentially creditable hazardous waste pharmaceuticals are subject to proposed § 266.509.

ii. *Recordkeeping for pharmaceutical reverse distributors shipping of potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor.* Pharmaceutical reverse distributors must keep records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another pharmaceutical reverse distributor (whether it is a manufacturer or not). This includes a copy of the advance notification provided to the other pharmaceutical reverse distributor, a copy of delivery confirmation, as well as shipping papers or bill of lading. We propose that these shipping records must be kept for 3 years from the date it initiates the shipment.

c. Additional Standards for Pharmaceutical Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals

This section discusses the additional standards that apply to a pharmaceutical reverse distributor for the management of evaluated hazardous waste pharmaceuticals (*i.e.,* a hazardous waste pharmaceutical that was a potentially creditable hazardous waste pharmaceutical but has been evaluated by a pharmaceutical reverse distributor to establish whether it is eligible for manufacturer's credit and will not be sent to another pharmaceutical reverse distributor for further evaluation or verification). Evaluated hazardous waste pharmaceuticals have been through the entire crediting process. In order to minimize the potential for their mismanagement, EPA believes it is necessary to have additional standards for the evaluated hazardous waste pharmaceuticals.

i. *Accumulation area.* As discussed previously, EPA is proposing that a pharmaceutical reverse distributor must complete its evaluation of a potentially creditable hazardous waste pharmaceuticals within 21 calendar days of arriving at the pharmaceutical reverse distributor. Once the evaluation has been completed and the pharmaceutical reverse distributor knows that it is destined for treatment and disposal at a RCRA-permitted or interim status TSDF, rather than another pharmaceutical reverse distributor, the pharmaceutical is considered an evaluated hazardous waste pharmaceutical. Under the proposal, a pharmaceutical reverse distributor must establish an on-site accumulation area where it will accumulate these evaluated hazardous waste pharmaceuticals. An on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the potentially creditable hazardous waste pharmaceuticals.

ii. *Weekly inspections.* EPA is proposing that the accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at least weekly to ensure containers are not leaking and that diversion of the hazardous waste pharmaceuticals is not occurring. Under the recordkeeping requirements for pharmaceutical reverse distributors, we are proposing that a pharmaceutical reverse distributor must keep a log of the weekly inspections of the on-site accumulation area and that the log must be retained for at least three years from the date of inspection. The log is necessary to validate the weekly inspections.

iii. *Personnel training.* EPA is proposing to require that pharmaceutical reverse distributors meet the same federal classroom or on-the-job personnel training requirements that LQGs must meet (§ 265.16). However, we specify in this proposal that the personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals in the on-site accumulation area. EPA believes that these personnel are the individuals handling and managing the hazardous waste pharmaceuticals and must have appropriate hazardous waste training. The Agency requests comment on whether the training standards are appropriate for the specific reverse distributor personnel.

iv. *Labeling and management of containers in on-site accumulation area.* EPA is proposing container labeling similar to what was proposed under the 2008 pharmaceutical universal waste proposed rule. While containers of hazardous waste pharmaceuticals are in the accumulation area, they must be marked with the words, ''Hazardous Waste Pharmaceuticals.'' We are proposing this term in order to distinguish them from the non-hazardous waste pharmaceuticals and from the hazardous waste pharmaceuticals that are still considered potentially creditable. We are not proposing to require an accumulation start date on the label for the containers, because the reverse distributor's inventory will likely be used to verify the accumulation start date. However, a pharmaceutical reverse distributor may choose an alternate method, such as marking the date on each container as it arrives, to ensure that the hazardous waste pharmaceuticals are not accumulated at the pharmaceutical reverse distributor for more than 90 days, provided an extension is not granted. As explained previously, EPA prefers to allow a performance-based standard that allows flexibility to verify the 90-day accumulation time rather than require dating on the container labels, but we request comment regarding this requirement and whether

it is necessary to specify a method for how a pharmaceutical reverse distributor must verify that the 90-day maximum accumulation time is not exceeded.

In terms of container management standards, the Agency is proposing requirements that are similar to the container management standards for LQGs—that is, the standards in 40 CFR part 265, but the Agency is also proposing to include some additional management requirements specific to hazardous waste pharmaceuticals. Specifically, under 40 CFR 262.34(a)(1)(i), LQGs must comply with the container management standards in 40 CFR part 265, subpart I, which includes a requirement that containers of hazardous waste must be kept closed, except when adding or removing waste. In this document, EPA is proposing to require that only containers with hazardous waste pharmaceuticals that are liquids or gels be kept closed during accumulation due to the low potential for release for those hazardous waste pharmaceuticals that are in a solid form. However, because most potentially creditable hazardous waste pharmaceuticals are in their original packaging, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (*e.g.,* for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container standard. EPA requests comment on whether additional forms of hazardous waste pharmaceuticals (other than liquids and gels) need to be specified in the regulations and subject to the closed container requirement.

EPA is also proposing that containers of hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the hazardous waste pharmaceuticals placed in the container. In addition, we are proposing to require that a pharmaceutical reverse distributor that manages ignitable or reactive evaluated hazardous waste pharmaceuticals or that mixes or comingles incompatible evaluated hazardous waste pharmaceuticals must manage the container to prevent dangerous situations, such as fire, explosion, or release of toxic fumes.

Similar to healthcare facilities that accumulate non-creditable hazardous waste pharmaceuticals, pharmaceutical reverse distributors that accumulate evaluated hazardous waste pharmaceuticals must segregate the pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) and accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals.

There are also several existing LQG accumulation unit management standards in § 262.34(a) that EPA believes are not necessary to include for the management of evaluated hazardous waste pharmaceuticals. For instance, this proposal only sets standards for the accumulation of evaluated hazardous waste pharmaceuticals in containers. EPA does not think it is necessary to include accumulation units such as tanks, containment buildings, or drip pads because pharmaceutical reverse distributors do not currently use these types of accumulation units. However, if EPA is mistaken in this understanding and commenters indicate they would like to be able to use tanks, containment buildings, or drip pads, EPA would consider including in this proposal the LQG standards for accumulation in these units. The Agency solicits comment on this matter.

In addition, the Agency is not proposing to require pharmaceutical reverse distributors to meet the air emission standards found in 40 CFR part 265, subpart CC as required in § 262.34(a)(1)(i) because we anticipate that they will not be applicable. Specifically, § 265.1083(c) exempts tanks, surface impoundments, and containers from the organic air emission standards if the hazardous waste entering the accumulation unit has an average volatile organic concentration of less than 500 parts per million by weight, while § 265.1080(b)(2) exempts containers with a capacity of less than 0.1 m^3 (26 gallons) from the standards. EPA understands that the only evaluated hazardous waste pharmaceuticals that have the potential for air emissions are liquids and gels, but they generally do not contain volatile organics. Thus, they do not release organic air emissions, which is what the 40 CFR part 265, subpart CC, air emission standards for tanks, surface impoundments, and containers were promulgated to control. Moreover, because hazardous waste pharmaceuticals are often in their original packaging, and we are proposing to require that liquid and gel hazardous waste pharmaceuticals must be in intact, sealed packaging or otherwise in closed containers, EPA believes that the container air emission standards are unnecessary. In addition, the Agency anticipates that the packaging and containers for hazardous waste pharmaceuticals will often have a capacity less than 0.1 m^3 (26 gallons) further limiting the applicability of the container air emission standards.

Similarly, EPA does not anticipate that the 40 CFR part 265, subpart AA—air emissions standards for process vents—and subpart BB—air emission standards for equipment leaks—are applicable to the activities of a pharmaceutical reverse distributor and its management of hazardous waste pharmaceuticals. Therefore, like 40 CFR part 265, subpart CC discussed previously, EPA is not proposing to require that 40 CFR part 265, subparts AA and BB apply to pharmaceutical reverse distributors. EPA requests comments on whether its current understanding is correct and whether the 40 CFR part 265, subparts AA, BB, and CC RCRA air emission standards should be applied to pharmaceutical reverse distributors.

v. *Hazardous waste numbers (codes).* EPA is proposing to require that the containers of evaluated hazardous waste pharmaceuticals be labeled with the appropriate RCRA hazardous waste numbers. The hazardous waste numbers may be placed on the container label at any time during on-site accumulation, but they must be added prior to when the evaluated hazardous waste pharmaceuticals are transported off-site. The hazardous waste numbers must be marked on the container label in order to ensure that it is readily visible and cannot be separated from the hazardous waste. The hazardous waste numbers are necessary so that transporters, transfer facilities, and TSDFs to know how to properly transport, consolidate, treat, store and dispose of the hazardous waste in compliance with the applicable RCRA regulations. We are not requiring that the pharmaceutical reverse distributor be the party that adds the hazardous waste numbers to the containers. The proposed regulations allow a vendor to perform this duty on behalf of the pharmaceutical reverse distributor. In practice, however, if a vendor is responsible for assigning hazardous waste numbers, personnel from the pharmaceutical reverse distributor may need to assist in the process.

vi. *Shipping evaluated hazardous waste pharmaceuticals.* Although it is already stated in § 266.508(a) under the section of the regulations that pertains to shipping standards, for clarity, we propose to repeat in § 266.510 (the pharmaceutical reverse distributor section of the regulations) the requirement that pharmaceutical reverse distributors that ship evaluated hazardous waste pharmaceuticals off-site must do so in accordance with the proposed shipping requirements in

§ 266.508(a). This includes the applicable DOT packaging, marking and labeling requirements, as well as the requirement to utilize the hazardous waste manifest when shipping the evaluated hazardous waste to a designated facility.

vii. *Rejected shipments.* The Agency is proposing to require in § 266.510(c)(7) that pharmaceutical reverse distributors meet the same procedures as LQGs must meet for rejected shipments in § 262.42(c). If a designated permitted or interim status TSDF identified on the hazardous waste manifest cannot accept a shipment of evaluated hazardous waste pharmaceuticals from a pharmaceutical reverse distributor and the TSDF returns the shipment to the pharmaceutical reverse distributor, the pharmaceutical reverse distributor must sign the applicable item on the manifest. In addition, the pharmaceutical reverse distributor may consolidate the rejected hazardous waste pharmaceuticals on-site for up to 90 days provided they are managed in the on-site accumulation area and in accordance with this proposal's pharmaceutical reverse distributor standards for evaluated hazardous waste pharmaceuticals. The reporting requirements associated with rejected shipments are discussed separately under the reporting section.

viii. *Land disposal restrictions.* EPA is proposing in § 266.510(c)(8) that pharmaceutical reverse distributors are subject to the same land disposal restrictions (LDRs) that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals. In addition, EPA is proposing to amend the testing, tracking, and recordkeeping requirements for generators, treaters and disposal facilities at § 268.7 to add the words, ''pharmaceutical reverse distributors'' to the title of that section to make the applicability of the treatment standards clear.

ix. *Reporting by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals.*

(1) *Biennial report.* EPA is proposing that pharmaceutical reverse distributors submit a BR for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF in order for the Agency to have as complete a picture of the amount of hazardous waste generated, treated, stored, or disposed of annually. However, the BR should only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste pharmaceuticals that a pharmaceutical reverse distributor sends to another pharmaceutical reverse distributor. Specifically, we are proposing in § 266.510(c)(9)(i) that a pharmaceutical reverse distributor comply with the LQG BR requirements in § 262.41, except for § 262.41(a)(7), which includes the requirement to report changes in volume and toxicity of waste achieved during the year in comparison to previous years. The reason we are not requiring the pharmaceutical reverse distributor to provide such information is that they do not have control of the volume or toxicity of the hazardous waste pharmaceuticals it receives from the healthcare facility, and thus have no ability to reduce the volume or toxicity of the hazardous waste pharmaceuticals. Thus, EPA is not requiring the pharmaceutical reverse distributor to report this information in its BR.

(2) *Exception reporting.* For the reasons that EPA requires exception reporting generally—that is, to maintain the cradle to grave tracking system, EPA is proposing in § 266.510(c)(9)(ii)(A) that pharmaceutical reverse distributors provide an exception report when a TSDF does not return the hazardous waste manifest to the pharmaceutical reverse distributor for shipments of hazardous waste pharmaceuticals to a designated facility. Likewise, we are proposing in § 266.510(c)(9)(ii)(B) that pharmaceutical reverse distributors meet LQG exception reporting when a shipment from a pharmaceutical reverse distributor is rejected by the designated facility and forwarded onto an alternate facility.

x. *Recordkeeping by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals.* Many of the proposed recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals have been discussed in the sections previously, but for clarity, it is useful to restate them in this recordkeeping section, so that pharmaceutical reverse distributors can refer to one section to determine their recordkeeping requirements related to evaluated hazardous waste pharmaceuticals. In particular, we are proposing five recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors. First, EPA is proposing that a pharmaceutical reverse distributor keeps a log (written or electronic) of its weekly inspections of the on-site accumulation area. The other four recordkeeping requirements that we are proposing in § 266.510(c)(10) for pharmaceutical reverse distributors are the same as the LQG recordkeeping requirements that appear in §§ 262.40–42 and § 265.16; these include hazardous waste manifest records, records of biennial reports, exception reporting and training documentation. EPA believes that these recordkeeping requirements are appropriate for pharmaceutical reverse distributors, many of whom are currently LQGs, but requests comment on this requirement.

EPA asks commenters to review the standards EPA is proposing for pharmaceutical reverse distributors and provide specific comment on whether the standards are appropriate and sufficient to protect human health and the environment.

d. When a Pharmaceutical Reverse Distributor Must Have a RCRA Hazardous Waste Permit

EPA is proposing to not require that a pharmaceutical reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the pharmaceutical reverse distributor follows all the conditions of the permitting exemption in § 266.510. In other words, a pharmaceutical reverse distributor would be subject to regulation as a TSDF and require a RCRA permit (or interim status) if it does not meet the conditions of § 266.510. In addition, a pharmaceutical reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on-site or if it accepts manifested hazardous waste from off-site. A pharmaceutical reverse distributor is required to reject shipments of manifested hazardous waste that it may inadvertently receive from off-site because a pharmaceutical reverse distributor is not a designated facility and therefore is not eligible to receive hazardous waste via a manifest. EPA believes that this approach to regulation of pharmaceutical reverse distributors that accumulate hazardous waste pharmaceuticals strikes an appropriate balance because it recognizes that pharmaceutical reverse distributors are different from typical hazardous waste TSDFs for permitting purposes, while it still imposes certain conditions for exemption from permitting requirements that provide the necessary environmental protection.

VI. Implementation and Enforcement

A. Healthcare Facilities

1. Determining Whether a Healthcare Facility is Subject to Part 266, Subpart P

EPA is proposing that healthcare facilities that are currently considered LQGs or SQGs are subject to the new 40 CFR part 266, subpart P requirements for the management of hazardous waste pharmaceuticals. Thus, a healthcare facility that generates (or accumulates)

more than 100 kg hazardous waste per calendar month, or more than 1 kg of acute hazardous waste per calendar month, or more than 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31, or 261.33(e), must manage its hazardous waste pharmaceuticals in compliance with the 40 CFR part 266, subpart P requirements. In addition, healthcare facilities that are CESQGs are subject to the prohibition on sewering hazardous waste pharmaceuticals in § 266.5052.

To determine whether a healthcare facility is a subject to 40 CFR part 266, subpart P, or a CESQG regulated under § 261.5, a healthcare facility must count all the hazardous waste—pharmaceutical and non-pharmaceutical—it generates in a calendar month. In counting the amount of hazardous waste generated per calendar month, we note that EPA is proposing to change which pharmaceuticals will be considered hazardous wastes (*i.e.,* potentially creditable hazardous waste pharmaceuticals). Specifically, EPA is proposing that potentially creditable hazardous waste pharmaceuticals transported to a pharmaceutical reverse distributor will be considered solid waste from the point of generation at the healthcare facility and therefore must be counted when determining whether the healthcare facility is a CESQG regulated under § 261.5, or whether it is regulated under 40 CFR part 266, subpart P. This differs from current practice where, although a healthcare facility must count the non-creditable hazardous waste pharmaceuticals it generates each calendar month toward its hazardous waste generator category, it does not count the potentially creditable hazardous waste pharmaceuticals it sends to a pharmaceutical reverse distributor. Therefore, although a healthcare facility *currently* may be considered a CESQG, when it begins counting its potentially creditable hazardous waste pharmaceuticals, it may no longer be a CESQG. In that case, the healthcare facility would be subject to the 40 CFR part 266, subpart P requirements.

2. Healthcare Facilities Managing Hazardous Waste Pharmaceuticals Under Part 266, Subpart P

EPA is proposing that all healthcare facilities, with the exception of CESQGs, will be subject to the same regulations for the management of their hazardous waste pharmaceuticals, regardless of the quantity of hazardous waste pharmaceuticals generated. A healthcare facility that generates both pharmaceutical and non-pharmaceutical hazardous waste must manage the non-pharmaceutical hazardous waste pursuant to part 262, but need not count its hazardous waste pharmaceuticals toward the facility's monthly hazardous waste generator category. In addition, if a healthcare facility does not want to keep track of the amount of hazardous waste it generates to ensure it does not exceed the CESQG quantity limits, it could choose to operate under this proposed rule. If it chooses to operate under this proposed rule, however, a healthcare facility must comply with all the requirements of this subpart for the management of its hazardous waste pharmaceuticals.

B. Pharmaceutical Reverse Distributors

1. Pharmaceuticals Sent to Pharmaceutical Reverse Distributors Are Solid Wastes

One difference between this proposal and the 2008 Pharmaceutical Universal Waste proposal is how RCRA would apply to pharmaceuticals returned to pharmaceutical reverse distributors to obtain manufacturer's credit. EPA is proposing to change its existing position on this issue. If this rule is finalized, this change would mean that the decision by a healthcare facility to send a pharmaceutical to a pharmaceutical reverse distributor is the decision to discard the pharmaceutical. Therefore, under this proposed rule, once the healthcare facility makes the decision to send a pharmaceutical to a pharmaceutical reverse distributor for credit, it is a solid waste at the healthcare facility. It is likely that a portion of the potentially creditable solid waste pharmaceuticals at healthcare facilities that are destined for a pharmaceutical reverse distributor will also meet the definition of hazardous waste and as a result, these potentially creditable hazardous waste pharmaceuticals would need to be managed in accordance with the standards proposed in this document. However, until this rule is final and effective, EPA's current position will remain in effect.

In addition, the Agency notes that the proposed change in EPA's position concerning reverse distribution and the management standards discussed in this document pertain only to the reverse distribution of hazardous waste pharmaceuticals and does not apply to reverse distribution or reverse logistics systems that may exist for other consumer products. This limitation is because EPA has studied and collected data for reverse distribution systems for hazardous waste pharmaceuticals, and not all consumer products.[148]

2. Pharmaceutical Reverse Distributors Managing Hazardous Waste Pharmaceuticals Under Part 266, Subpart P

Under this proposal, all pharmaceutical reverse distributors are subject to 40 CFR part 266, subpart P and will be subject to the same standards with respect to their hazardous waste pharmaceuticals, regardless of the amount of hazardous waste pharmaceuticals they manage. Even pharmaceutical reverse distributors that are currently CESQGs will be regulated under 40 CFR part 266, subpart P for the management of their hazardous waste pharmaceuticals. Therefore, as with healthcare facilities, a pharmaceutical reverse distributor subject to 40 CFR part 266, subpart P will no longer have to keep track of the amount of hazardous waste pharmaceuticals that it generates on a monthly basis.

C. Healthcare Facilities and Pharmaceutical Reverse Distributors Managing Non-Pharmaceutical Hazardous Waste in Accordance With 40 CFR Part 262 or Part 273

Most, if not all, healthcare facilities and pharmaceutical reverse distributors generate hazardous wastes other than pharmaceuticals. These, non-pharmaceutical hazardous wastes will continue to be regulated under 40 CFR part 262 (and other applicable Subtitle C regulations). However, because a healthcare facility or pharmaceutical reverse distributor operating under 40 CFR part 266, subpart P no longer has to count its hazardous waste pharmaceuticals, including acute hazardous waste pharmaceuticals such as warfarin, it could result in a change in the facility's overall generator category and thus change how its non-pharmaceutical hazardous waste must be managed. For example, the generator category for a healthcare facility or pharmaceutical reverse distributor may be reduced from an LQG to an SQG or even a CESQG, when it stops counting its hazardous waste pharmaceuticals, especially acute hazardous waste pharmaceuticals, toward its generator category.

If finalized, the standards established by this rulemaking apply only to the management of hazardous waste

[148] EPA is examining the reverse logistics of non-pharmaceutical hazardous wastes as part of its analysis of comments received on the Retail Notice of Data Availability that was published on February 14, 2014 (79 FR 8926).

pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors. Healthcare facilities and pharmaceutical reverse distributors likely generate or manage other types of wastes. For example, hospitals may generate non-pharmaceutical hazardous wastes, such as solvents in their diagnostic laboratories; those hazardous wastes must still be managed in accordance with the RCRA Subtitle C requirements (such as the RCRA satellite accumulation regulations (§ 262.34(c)), or if it is a teaching hospital, the Academic Laboratories Rule (if it has opted into part 262, subpart K). Retail pharmacies in retail stores and grocery stores may have non-pharmaceutical hazardous wastes on-site as well, which must be managed in accordance with the 40 CFR part 262 requirements and all other applicable RCRA Subtitle C regulations. For example, fluorescent bulbs may be managed under the universal waste program (40 CFR part 273). For pharmaceutical reverse distributors, this proposed rule only applies to the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. Some pharmaceutical reverse distributors may generate other non-pharmaceutical hazardous wastes from activities, such as cleaning and maintenance; other RCRA requirements will apply to those non-pharmaceutical hazardous wastes.

D. State Enforcement Activities and Interpretations

States have taken a variety of approaches regarding pharmaceutical hazardous wastes. One major goal of this proposed rule is to provide clarity on this topic, and thereby promote national consistency, which, in turn, should promote better compliance among healthcare facilities, including pharmacies.

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) and Rite-Aid (2013). 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 nondispensable pharmaceuticals, including over-the-counter medications, through ''reverse distribution.'' [149] 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.

In 2012, Connecticut's Department of Energy and Environmental Protection (DEEP) took enforcement actions at seven CVS stores for violations of the RCRA hazardous waste regulations. Consent orders from Connecticut DEEP direct CVS stores in the state to follow a set of best management practices.[150] A number of the practices developed in these consent orders mirror some of the practices we are proposing in this rule, particularly with regard to pharmaceuticals destined for a pharmaceutical reverse distributor. Connecticut DEEP asserts RCRA jurisdiction over the pharmaceuticals destined for pharmaceutical reverse distributors by applying specific practices to their management. For example, CVS must maintain records of each shipment of non-dispensable pharmaceuticals to a pharmaceutical reverse distributor, including confirmation of receipt of the non-dispensable pharmaceuticals from the pharmaceutical reverse distributor receiving them. The best practices also include procedures for addressing situations when CVS does not receive delivery confirmation of shipment to a pharmaceutical reverse distributor. Further, the consent order sets out separate, more comprehensive practices for the non-dispensable pharmaceuticals that are not suitable for pharmaceutical reverse distribution.

Aside from best management practices developed by Connecticut as part of a consent order, at least two other states have developed guidance documents that apply conditions to the management of hazardous wastes pharmaceuticals in exchange for enforcement discretion. In particular, in 2008, the Washington State Department of Ecology issued guidance titled, Interim Enforcement Policy: Pharmaceutical Waste in Healthcare.[151] Like Connecticut's consent orders with CVS, this enforcement discretion policy has some elements in common with this proposed rule for hazardous waste pharmaceuticals. For instance, a healthcare facility must notify the Department of Ecology that it is operating under the policy and must train its staff involved in pharmaceutical waste management. Only a time limit, rather than a quantity limit, applies to the accumulation of the hazardous waste pharmaceuticals on-site. Of particular note is that Washington State prohibits disposing of most hazardous waste pharmaceuticals down the toilet or drain.

In 2011, Minnesota's Pollution Control Agency (MPCA) issued a fact sheet titled Reverse Distribution of Pharmaceuticals: Guidance for Minnesota Healthcare Providers.[152] In this guidance, Minnesota states, ''Whether a pharmaceutical is eligible for return credit does not affect its *product* or *waste* status. In Minnesota, if a pharmaceutical is not used or reused for its intended purpose, it is a *waste*. The MPCA considers health care practitioners and pharmacies to be *generators* of these pharmaceutical wastes. Nevertheless, the MPCA believes that the established reverse distribution system provides an environmentally protective method for handling waste pharmaceuticals. Therefore, it will allow Minnesota health care practitioners and pharmacies to manage certain pharmaceuticals through reverse distribution, subject to additional requirements discussed in this fact sheet.'' This is similar to the approach that EPA is proposing for potentially creditable hazardous waste pharmaceuticals. For example, like EPA's proposed rule, MPCA does not require hazardous waste pharmaceuticals destined for a pharmaceutical reverse distributor to be counted toward determining a healthcare facility's generator category, and MPCA does not require hazardous waste pharmaceuticals to be accompanied by a hazardous waste manifest when shipped to a pharmaceutical reverse distributor. By adopting a rule that is consistent with state approaches, EPA is bringing national consistency to the management

[149] *http://www.calepa.ca.gov/enforcement/orders/2012/CVSStipFinal.pdf* and *http://www.calepa.ca.gov/enforcement/orders/2012/CostcoFinal.pdf* or see the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

[150] *http://www.ct.gov/deep/lib/deep/enforcement/consentorder/COWSWDH13005.pdf.* or see the docket for this rulemaking EPA–HQ–RCRA–2007–0932.

[151] See the interim enforcement policy in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932) or see it online at *https://fortress.wa.gov/ecy/publications/documents/0704024.pdf.*

[152] See the guidance document in the docket for this rulemaking (EPA–HQ–RCRA–2007–0932) or see it online at *http://www.pca.state.mn.us/index.php/view-document.html?gid=4004.*

of hazardous waste pharmaceuticals, while avoiding disruption to practices already in place.

VII. Request for Comment on EPA's Efforts To Identify Additional Pharmaceutical Hazardous Wastes

Some of the comments EPA received in response to the 2008 Universal Waste proposal recommended that EPA add additional pharmaceutical wastes to the P and U hazardous waste lists (see § 261.33). Some commenters suggested that EPA assess the hazards from all discarded pharmaceuticals (especially chemotherapy drugs) that have come into the market since the promulgation of the original P and U hazardous waste lists [153] and that EPA update these lists to include discarded pharmaceuticals that are hazardous. In response to these comments, the Agency began gathering and reviewing information related to pharmaceuticals that may exhibit hazardous properties. EPA identified 204 drugs, which include 172 drugs that the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) identified as hazardous, and 32 drugs that NIOSH proposed for addition to its hazardous drug list.[154] EPA also collected toxicity data and other information for these 204 drugs. These findings, along with additional information regarding the management of pharmaceutical wastes, are presented in the final report entitled *Data Collection on the Toxicity, Use, and Disposal of Hazardous Drugs Report* (September 2011) placed in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).

Commenters specifically referred to EPA's P and U hazardous waste lists under the RCRA subtitle C regulations. Generally, in its hazardous waste determinations, EPA has evaluated both ''production wastes'' (from specific or non-specific sources; see §§ 261.31 and 261.32) and ''commercial chemical products'' that, when discarded, become wastes (§ 261.33). This latter category (commercial chemical products that are discarded) is the most relevant of the listed hazardous wastes to the pharmaceuticals wastes discussed elsewhere in this preamble, and to which commenters referred in the 2008 Universal Waste proposal. As discussed in Section IV.A.of this preamble, commercial chemical products listed in § 261.33 are (when discarded) defined as either P-listed ''acute'' hazardous wastes, or U-listed (non-acute) hazardous wastes. The criteria for listing a solid waste as hazardous under RCRA Subtitle C are described in § 261.11. A waste may be identified as a P-listed waste if it is shown to be fatal to humans or animals at low doses (see § 261.11(a)(2)). Thus, lethality data for any chemical is the principal factor for making a determination that a discarded commercial chemical product is a P-listed hazardous waste.[155]

In contrast, a waste may be identified as a U-listed waste if it contains any of the toxic constituents listed in Appendix VIII of 40 CFR part 261, and if, after examining each of 10 factors in § 261.11(a)(3), it is determined that the waste is capable of posing a ''substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.'' [156] Examples of these 10 factors include the toxicity and concentration of the hazardous constituent in the waste, the plausible types of improper management to which the waste could be subjected, the quantities of the waste generated at individual generation sites or on a regional or national basis, the nature and severity of the human health and environmental damage that has occurred as a result of the improper management of wastes, and action taken by other governmental agencies or regulatory programs based on the health or environmental hazard posed by the waste or waste constituent. EPA may only revise either of these lists of commercial chemical products through notice-and-comment rulemaking.

In its September 2011 report, EPA found that 11 drugs on the NIOSH or OSHA lists of hazardous drugs meet the specific criteria for acute toxicity in § 261.11(a)(2) (identified as ''Tier 1'' drugs in the report). An additional 114 drugs on the NIOSH or OSHA lists did *not* meet the specific criteria in § 261.11(a)(2) for acute toxicity, but did have lethal doses for other animals or humans (''Tier 2'' drugs). The remaining 79 drugs had limited human or animal toxicity data, and no lethality data, and were designated ''Tier 3'' in the report. Thus, the vast majority of the NIOSH/OSHA hazardous drugs evaluated in the EPA 2011 report do not meet the criteria for listing as acute hazardous waste under RCRA subtitle C.[157] As discussed previously, to include a drug on the U-list, the Agency must demonstrate that a discarded drug would be ''capable of posing a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.'' Therefore, for the NIOSH/OSHA drugs that do not meet the listing criteria for inclusion on the P-list, the Agency would have to examine the 10 factors in § 261.11(a)(3) to determine whether a drug meets the criteria to be included on the U-list. In addition to toxicity data (which is lacking in particular for the drugs identified as Tier 3), the types of information that would be relevant include waste volumes, plausible management scenarios, exposure potential, damage cases, and actions taken by other governmental agencies or regulatory programs. To obtain this information for this class of materials poses a challenge. While EPA has some information—the September 2011 report includes summaries of drug management practices and references to others—there remain significant gaps.

In addition, as discussed in Section IV.D. of this preamble, the EPA's OIG has recommended that EPA identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste, and establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste. While EPA has an existing process generally for defining whether or not a solid waste is a listed hazardous

[153] May 19, 1980 **Federal Register** (45 FR 33084) and November 25, 1980 **Federal Register** (45 FR 78525).

[154] See NIOSH's Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Healthcare Settings (*http://www.cdc.gov/niosh/docs/2004-165/*) and OSHA Technical Manual Section VI: Chapter 2—Controlling Occupational Exposure to Hazardous Drugs (*https://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html*). Note that the ''hazardous'' classification used by NIOSH and OSHA is not the same as the definition of hazardous under the RCRA subtitle C regulations.

[155] § 261.11(a)(2) states ''The Administrator shall list a solid waste as a hazardous waste only upon determining that 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 LD 50 toxicity (rat) of less than 50 milligrams per kilogram, an inhalation LC 50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD 50 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. (Waste listed in accordance with these criteria will be designated Acute Hazardous Waste.)''

[156] The Agency cannot list hazardous wastes under section § 261.11(a)(3) based on inherent toxicity alone without considering exposure factors, particularly the likelihood of mismanagement. That is, EPA needs to examine each of the 10 factors and, to the extent it does not use one or more of them, must explain why they are irrelevant or unimportant. See *Dithiocarbamate Task Force* v. *EPA* (No. 95–1249).

[157] EPA emphasizes that this finding reflects the manner in which EPA defines acute hazardous waste under the RCRA subtitle C program; the NIOSH/OSHA lists are based upon different criteria related to preventing occupational exposure to these drugs.

waste (*i.e.,* EPA has regulatory criteria for defining listed hazardous waste described previously; EPA has established policies for evaluating risk and other factors in making listing determinations; [158] and EPA must use the notice-and-comment rulemaking process when proposing listing determinations), the OIG observed that EPA's hazardous waste program has not kept pace with the large number of pharmaceuticals that have been developed since 1980. EPA plans to regularly review the NIOSH/OSHA lists of hazardous drugs, as they represent a source of valuable information on pharmaceuticals that have already been identified as having the possibility of posing risks that might warrant regulation as hazardous waste.

EPA is also exploring ways to identify new sources of information, along with alternative approaches that can most efficiently address these concerns. EPA is using the opportunity in this preamble to seek stakeholders' input on the best course of action concerning regulation of additional pharmaceuticals as hazardous wastes. It is also an opportunity for stakeholders to provide additional information that they may have about potentially hazardous pharmaceuticals. Thus, before deciding on a possible proposal to list additional pharmaceuticals as hazardous wastes, we request comment on the September 2011 final report, and solicit information regarding additional potentially hazardous pharmaceuticals. We request information on the sources and identity of additional potentially hazardous pharmaceuticals along with annual product generation data, annual waste generation data, use information, toxicity data, waste storage and handling information, and disposal information.

In addition, we request stakeholder input for alternative approaches to making hazardous waste listing determinations for pharmaceuticals that do not meet the acute hazardous criteria. Based on the existing listing determination process described previously for non-acute wastes, there is no single toxicity effect (*e.g.,* LD_{50}) to readily determine whether or not the waste is hazardous under RCRA subtitle C. As such, we are seeking ideas on alternative approaches to more efficiently evaluate potentially hazardous non-acute discarded pharmaceuticals. For example, should EPA develop and promulgate new criteria specific to discarded pharmaceuticals that would allow it to establish a single hazardous waste listing for all discarded pharmaceuticals that meet the new criteria? Such approaches could also include consideration of whether discarded pharmaceuticals are already managed under a regulatory scheme that prevents mismanagement that a hazardous waste designation would otherwise address (similar to the hazardous waste listing factor that takes into account ''actions taken by other governmental agencies or regulatory programs''). We also are seeking information on any innovative processes or programs that states may have for identifying, reviewing, and making a hazardous waste determination for discarded pharmaceuticals.

The Agency emphasizes that no regulatory action is being proposed with respect to expanding the number of pharmaceuticals that are considered hazardous waste. We will use the comments we receive to help inform how to proceed with evaluating discarded pharmaceuticals as listed or characteristic hazardous wastes. Any action taken would be part of a separate, proposed rulemaking in the future.

VIII. Request for Comment on EPA's Efforts To Amend the Acute Hazardous Waste Listing for Nicotine and Salts (Hazardous Waste No. P075)

A. Background

In 1980, as part of its final and interim final regulations implementing Section 3001 of RCRA, EPA promulgated the list of commercial chemical products or manufacturing chemical intermediates (40 CFR 261.33) that are hazardous wastes if they are discarded or intended to be discarded, which included nicotine and salts (45 FR 33124; May 19, 1980). 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)). A chemical substance is listed in 40 CFR 261.33(e) as an acutely hazardous waste if it meets any of the criteria in 40 CFR 261.11(a)(2), which states that the 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 LD 50 toxicity (rat) of less than 50 milligrams per kilogram, an inhalation LC 50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD 50 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.''

B. Basis for Original Listing

EPA listed nicotine and salts (referred to commonly as just nicotine) as acutely hazardous waste (P075) in § 261.33(e) based on an estimated oral LD50 toxicity to humans of 1 mg/kg and a dermal LD50 toxicity to rabbits of 50 mg/kg.[159] As discussed previously, for humans, the standard in the regulations for acute toxicity is ''fatal to humans in low doses'' (see § 261.11(a)(2)). EPA's Background Document for Section 261.33 from 1981 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''). The estimated oral LD50 to humans of 1 mg/kg falls within the criteria for ''fatal to humans in low doses.'' However, the background listing document and its references do not provide sufficient detail to determine the concentration of nicotine that was used to establish the estimated oral LD50 in humans.

C. Rationale for EPA's Efforts To Amend the P075 Listing

On February 14, 2014, EPA published a Notice of Data Availability (NODA) and Request for Comment (79 FR 8926) entitled ''Hazardous Waste Management and the Retail Sector: Providing and Seeking Information on Practices to Enhance Effectiveness to the RCRA Program.'' EPA received 44 comments in response to this NODA, many of which included comments related to pharmaceuticals, in particular comments concerning expired or returned low-concentration nicotine-containing smoking cessation products and e-cigarettes. The most detailed comments concerning the unsold low-concentration nicotine products were jointly submitted by the Retail Industry Leaders Association (RILA), the Food Marketing Institute (FMI), the National Association of Chain Drug Stores (NACDS), the National Retail Federation, and their members (referred to as the retail associations, retailers, or

[158] EPA's policy statement on hazardous waste listing determinations is contained in the **Federal Register** preamble to the first proposed Dyes and Pigments Listing Determination (59 FR 66072, December 22, 1994).

[159] See EPA's listing Background Document for Section 261.33, April 1981, in the docket for this proposed rule (EPA–HQ–RCRA–2007–0932).

commenters).[160] In their comments, 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 acute hazardous waste P075 classification under RCRA. The retailers believe these products do not meet RCRA's requirements for acute hazardous waste. Thus, according to the retailers, the acute hazardous classification is inappropriately making them subject to RCRA's LQG requirements, which become applicable when someone generates more than 1 kg/month of acute hazardous waste. The retailers also expressed concern that they are subject to increased economic burdens and reporting requirements because they are subject to RCRA's LQG requirements.

The commenters, to support their request to EPA, state that EPA's listing for nicotine and salts warrants a reevaluation, because in more recent literature concerning nicotine toxicity, doubts have been expressed about the estimated oral LD50 toxicity to humans of 1 mg/kg, used as a key basis for the listing. According to information provided by commenters, the estimated oral LD50 toxicity to humans of 1 mg/kg was based on extrapolations from toxicological effects observed as result of ''self-experiments'' performed with nonfatal doses of nicotine. However, according to the commenters, there are doubts about the 1 mg/kg estimate because people have survived after ingesting much larger amounts of nicotine.

The commenters also state that in 1980, when EPA listed nicotine and salts as acute hazardous wastes, the nicotine products in the market contained a high concentration of the chemical (*e.g.,* pesticides which contained 40 percent nicotine sulfate), but that these products are no longer on the market. The commenters stressed that the current nicotine products on the market are low-concentration nicotine products that do not meet the regulatory criteria for acutely hazardous wastes. The low-concentration nicotine-containing products that are currently on the market were identified by commenters as nicotine replacement therapy products (*e.g.,* gums, lozenges, patches, inhalers, and nasal sprays) and e-cigarettes. These products, according to the commenters, generally contain less than 3 percent nicotine.

While it may be reasonable for the commenters to conclude that toxicity is higher at higher concentrations of a chemical and lower at lower concentrations of a chemical, EPA currently lacks sufficient information to conclude that low-concentration nicotine-containing products are not acutely toxic as defined under 40 CFR 261.11(a)(2). In addition, except for warfarin and zinc phosphide, the listings for commercial chemical products under 40 CFR 261.33(e) are not concentration-based listings. The warfarin and zinc phosphide listings were changed to concentration-based listings because companies using products containing lower concentration formulations of warfarin and zinc phosphide petitioned EPA to amend the listings and provided LD50 data for animals for the lower concentration products to support their petition (see 49 FR 19922; May 10, 1984). The Agency does not think that linear extrapolations from toxicity levels determined using higher-concentration nicotine products can be used to characterize the acute toxicity of low-concentration nicotine-containing products. Furthermore, although nicotine pesticides are no longer available, high concentration nicotine products still exist. For example, manufacturers of nicotine-containing products, such as e-cigarettes, buy concentrated nicotine solutions and dilute them for consumer use.

In summary, nicotine and salts are P075 listed acute hazardous wastes if the waste arises from the discard of an unused commercial chemical product, manufacturing chemical intermediate, or off-specification material. Additionally, the P075 waste code applies only if the nicotine is present in pure or technical grade form, or is the sole active ingredient in the chemical formulation when discarded. As such, unused (unsold, expired, or returned) nicotine-containing products, including patches, gums, lozenges,[161] inhalers, nasal sprays and e-cigarettes,[162] are classified as P075 listed acute hazardous wastes when discarded. When discarded, these unsold products are causing many retailers to notify and operate as LQGs, which has resulted in increased economic burdens and reporting requirements for retailers. EPA is aware that this is an issue of great concern to the retail associations and their members and would like to address the issue, if possible, by amending the P075 listing to conditionally exempt certain low-concentration nicotine-containing products. The Agency is considering two possible approaches, described below, for amending the P075 listing.

D. Two Possible Approaches for Amending the P075 Listing

1. Exemption from P075 Listing for FDA-Approved Over-the-Counter Nicotine-Containing Smoking Cessation Products

The over-the-counter (OTC) nicotine-containing smoking cessation products, referred to also as nicotine replacement therapy (NRT) products (*i.e.,* nicotine patches, gums, and lozenges) are approved by the Food and Drug Administration (FDA), which ensures that the risk to the public using these products have been evaluated. EPA is currently trying to obtain the risk evaluation data for these products from FDA, which may provide data on the exact concentration of nicotine in the NRT products and any animal and/or human toxicity data associated with use of these products. The Agency is also trying to gather any publicly available animal and/or human toxicity data for these products, in particular toxicity data that could be compared to EPA's acute toxicity criteria under § 261.11(a)(2). If the Agency is successful in obtaining the toxicity data to support the conclusion that FDA-approved over-the-counter nicotine-containing smoking cessation products do not meet the criteria for listing as an acutely hazardous waste, then the Agency will propose to exempt these products from the P075 listing.

Since e-cigarettes have not been approved by the FDA as smoking cessation products, we do not anticipate being able to obtain animal or human toxicity data from the FDA on nicotine concentrations in e-cigarettes. To complicate matters, the concentration of nicotine in e-cigarettes is not limited by any regulation or approval process and is therefore unpredictable. As a result, this option would likely be limited to excluding FDA-approved over-the-counter nicotine-containing smoking cessation products from the P075 listing and would not include e-cigarettes.

2. Concentration-Based Exemption From P075 Listing for Low-Concentration Nicotine-Containing Products

The comments from the retail associations have stressed that the low

[160] See comments by the retail associations in response to EPA's Retail NODA in the docket for the Retail NODA (EPA–HQ–RCRA–2012–0426–0019).

[161] See memo from Dellinger to Smith, dated August 23, 2010, RCRA Online # 14817 regarding unused patches, gums and lozenges *http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/209444BADDA4ECDC852577ED00624E8F/$file/14817.pdf.*

[162] See memo from Johnson to DeWitt, May 8, 2015, regarding e-cigarettes, RCRA Online # 17850.

concentration nicotine products currently in the market (generally containing less than 3 percent nicotine) should not be classified as acutely hazardous wastes under RCRA. However, they did not submit any human toxicological data or animal LD50 data for these products to demonstrate that these products are not acutely toxic as defined under § 261.11(a)(2). Without these data, it is difficult for the Agency to justify exempting these products from the P075 listing. Furthermore, in order for the Agency to consider a concentration-based exemption for low-concentration nicotine-containing products from the P075 listing, the Agency needs human toxicological data and animal LD50 data for nicotine-containing products at maximum concentrations of nicotine in these products (*e.g.,* 3 percent nicotine). If the toxicological data for nicotine-containing products at maximum concentrations of nicotine in these products show that these products are not acutely toxic as defined under § 261.11(a)(2), then the Agency could propose a concentration-based exemption for these products (including e-cigarettes) from the P075 listing. However, depending on the toxicity data, the Agency may also propose to list the P075 exempt nicotine-containing products as non-acute hazardous wastes (U-listed wastes) under 40 CFR 261.33(f). In that case, the concentration-based exemption for nicotine-containing products from the P075 listing would be similar to what the Agency proposed for warfarin and zinc phosphide listings (see 48 FR 7714; February 23, 1983).

E. Request for Comments

EPA invites comments on all possible approaches to amend the acute hazardous waste listing for nicotine and salts, including the two approaches discussed above in Section VIII.D. We also request toxicity information for low-concentration nicotine-containing products that could help determine whether or not these products meet the criteria for acute hazardous wastes under § 261.11(a)(2). The Agency emphasizes that no regulatory language is currently being proposed with respect to amending the P075 listing to exempt the low-concentration nicotine-containing products. However, depending on the information received during the comment period, EPA could finalize one of the approaches discussed previously without a separate proposed rulemaking in the future.

In addition, we request comments on whether we should exempt other low-concentration nicotine-containing smoking cessation products, such as inhalers and nasal sprays, from the P075 listing under approach 1, described in the Section VIII.D, above. These products are also FDA-approved, but require a prescription to purchase. The nicotine-containing patches, gums, and lozenges are sold over-the-counter, so they do not require a prescription for purchase. We are interested in finding out what the differences are between nicotine-containing smoking cessation products requiring a prescription and those products that do not require a prescription (*e.g.,* in concentrations of nicotine, amount of nicotine delivered over time, health effects).

Finally, we request comment on whether we should include e-cigarettes and nicotine-containing e-liquids for the e-cigarettes within the scope of the definition of pharmaceutical. As described in this proposal, pharmaceutical hazardous wastes do not count toward generator category. Therefore, since e-cigarettes and nicotine-containing e-cigarette refill liquids (sometimes referred to as e-liquids or e-juice) are P075, if they are considered pharmaceuticals, they would not impact the hazardous waste generator category of the retailers. The retailers, however, would have to manage e-cigarettes and nicotine-containing liquids as hazardous waste pharmaceuticals under part 266, subpart P. We will use the comments we receive to help us decide whether and how to proceed with amending the scope of the definition of pharmaceutical to include e-cigarettes and nicotine-containing e-liquids.

IX. State Authorization

A. Applicability of Rules in Authorized States

Under Section 3006 of RCRA, EPA may authorize a qualified State to administer its own hazardous waste program within the State in lieu of the Federal program. Following authorization, EPA retains enforcement authority under Sections 3008, 3013, and 7003 of RCRA, although authorized States have primary enforcement responsibility. The standards and requirements for State authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that State. The federal requirements no longer applied in the authorized State, and EPA could not issue permits for any facilities in that State, since only the State was authorized to issue RCRA permits. When new, more stringent federal requirements were promulgated, the State was obligated to enact equivalent authorities within specified time frames. However, the new federal requirements did not take effect in an authorized State until the State adopted the federal requirement as State law.

In contrast, under RCRA Section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized States at the same time that they take effect in unauthorized States. The statute directs EPA to implement these requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While the State must still adopt HSWA related provisions as State law in order to retain final authorization, EPA implements the HSWA provisions in authorized States until the States do so.

Authorized States are required to modify their program only when EPA enacts federal requirements that are more stringent or broader in scope than the existing federal requirements. RCRA Section 3009 allows the States to impose standards more stringent than those in the federal program (see also § 271.1).[163] Therefore, authorized States may, but are not required to, adopt federal regulations, both HSWA and non-HSWA, that are considered less stringent than previous federal regulations.

B. Effect on State Authorization

This action proposes to add a new subpart P to 40 CFR part 266, and it is being proposed in part under the authority of HSWA and in part under non-HSWA authority. The bulk of 40 CFR part 266, subpart P is being proposed under non-HSWA authority. Thus, when finalized, the amendments promulgated under non-HSWA authority would be applicable on the effective date only in those states that do not have final authorization of their base RCRA programs. However, the prohibition of sewering pharmaceutical hazardous wastes (§ 266.504) is being proposed under HSWA authority in section 3018 of RCRA. Thus, when finalized, the amendments promulgated under the authority of HSWA would be applicable on the effective date of the final rule in all states. Moreover, authorized states are required to modify

[163] EPA notes that decisions regarding whether a state rule is more stringent or broader in scope than the federal program are made when the Agency authorizes state programs.

their programs only when EPA promulgates federal regulations that are more stringent or broader in scope than the authorized state regulations. This proposed rule is considered, on the whole, to be more stringent than the current federal standards. Therefore, authorized states will be required to modify their programs to adopt the amendments, when finalized. When a state adopts this new subpart, if elements of the state program are more stringent than this new subpart, the state has the option of retaining those more stringent elements. Likewise, when a state adopts this new subpart, the state has the option of adding elements that are more stringent or broader in scope than this new subpart.

C. Effect on State Authorization in States That Have Added Pharmaceuticals to the Universal Waste Program

The Universal Waste program allows states to add wastestreams to their own state program, even when the waste stream has not been added to the federal Universal Waste program, provided the state has adopted and been authorized for the petition process in §§ 260.20 and 260.23. Two states have added hazardous waste pharmaceuticals to their Universal Waste programs: Florida and Michigan. Because this proposed rule is considered more stringent than either the ''traditional RCRA'' standards or the Universal Waste program, both Florida and Michigan will be required to modify their programs to adopt an approach at least as stringent as the amendments, if this rule is finalized. Furthermore, because the Agency has determined that it is not appropriate to add hazardous waste pharmaceuticals to the Universal Waste program, both Florida and Michigan must remove hazardous waste pharmaceuticals from their Universal Waste program when they adopt this new subpart, although they may continue to regulate non-hazardous waste pharmaceuticals under the Universal Waste program, to the extent allowed under state law. In addition, states may not add hazardous waste pharmaceuticals to their Universal Waste program in the future.

X. Adding and Reserving Part 266, Subpart O

In addition to proposing new standards for the management of hazardous waste pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors, EPA is proposing to add and reserve 40 CFR part 266, subpart O. Specifically, on May 22, 2001, EPA finalized a Project XL rule in 40 CFR part 266, subpart O (66 FR 28066) for US Filter Recovery Services. However, on July 2, 2008, EPA published a rule that withdrew 40 CFR part 266, subpart O (73 FR 37858). Generally, in order to avoid the potential for confusion that might be caused by reusing a subpart, EPA reserves a subpart that has already been used and removed. In 2008, when we removed 40 CFR part 266, subpart O, we neglected to reserve it. Consequently, we are proposing to add and reserve 40 CFR part 266, subpart O.

XI. Summary of Regulatory Impact Analysis

In order to meet the Office of Management and Budget (OMB) Circular A–4 requirement that EPA analyze the costs and benefits of regulations, we conducted an economic analysis of the proposed rule. The economic analysis follows OMB guidelines and estimates the costs and benefits of the rule. The economic analysis is titled ''Regulatory Impact Analysis for EPA's Proposed Healthcare Facility-Specific Regulations for the Management of Hazardous Waste Pharmaceuticals'' and is hereafter referred to as the Regulatory Impact Analysis (RIA). The RIA is summarized here while the full RIA can be found at regulations.gov under docket number EPA–HQ–RCRA–2007–0932.

This proposed rule may affect several different types of healthcare facilities, including hospitals, physicians' offices, dentists' offices, outpatient care centers, pharmacies, veterinary clinics, nursing care facilities, coroners' offices, other health practitioners, other ambulatory care services, and pharmaceutical reverse distributors. Based on data from the 2007 Economic Census and a limited number of states, the RIA estimates that the rule will affect approximately 174,000 facilities. Table 12 lists the number of facilities (by NAICS code) expected to be affected by the proposed rule. The vast majority of these (83.6%) are CESQGs, followed by SQGs (13.4%), and LQGs (3.0%).

TABLE 12: PROPOSED PHARMECUTICALS RULE FACILITIES CLASSIFIED BY NAICS CODES AND TYPE OF FACILITY		
NAICS	FACILITY TYPE	NUMBER OF FACILITIES
HELTHCARE FACILITIES AS DEFINED BY THIS PROPOSED RULE		
44611	Pharmacies	11,617
54194	Veterinary Clinics	7,847
6211	Physicians' Offices	60,823
6212	Dentists' Offices	35,106
6213	Other Health Practitioners (e.g., chiropractors)	34,555
6214	Outpatient Care Centers	8,227
6219	Other Ambulatory Health Care Services	2,586
622	Hospitals	6,505
6231	Nursing Care Facilities	4,508
623311	Continuing Care Retirement Communities	1,641
Subset of 92219	Medical Examiners and Coroners' Offices	552
Reverse Distributors		
Various NAICS	Reverse Distributors	56
	TOTAL	**174,023**

We estimate that there is a total of approximately 139,000 tons of RCRA hazardous waste generated by healthcare facilities annually. Approximately 36,200 tons (26%) of this total are hazardous waste pharmaceuticals.

A. Costs of the Proposed Rule

The estimated costs of the proposed rule are the incremental costs over and above the ''baseline'' (*i.e.,* assumptions about the way in which healthcare facilities currently dispose of their hazardous waste pharmaceuticals). The base case set of baseline assumptions reflects ''full compliance'' with the current RCRA hazardous waste requirements for the management of hazardous waste pharmaceuticals. A sensitivity analysis of baseline assumptions was also conducted that reflects only ''partial compliance'' with current regulations. To see the results for the partial compliance baseline sensitivity analysis, please see the RIA.

The estimated cost of the proposed rule, including the proposed prohibition on sewering of hazardous waste pharmaceuticals is estimated at $37 million annually under the full compliance baseline. However, there are also significant cost savings under the proposed rule: $24.3 million annually under the full compliance baseline. Therefore the net cost of the rule is $13 million annually ($37million cost minus $24.3 million cost savings = $13 million net costs). Please see the RIA for more detailed analysis and results regarding the cost of the rule and the regulatory options analyzed.

B. Benefits of the Proposed Rule

The proposed rule for the management of hazardous waste pharmaceuticals is expected to yield a range of environmental benefits as hospitals, medical clinics, and other healthcare facilities divert hazardous waste pharmaceuticals currently disposed in sewers, municipal solid waste landfills (MSWLFs), municipal waste combustors (MWCs), and medical waste autoclaves and incinerators, to hazardous waste incinerators. The rule reduces the amount of hazardous waste pharmaceuticals sewered into waterways, provides regulatory clarity for industry and provides healthcare facilities and pharmaceutical reverse distributors with cost savings.

The largest quantified benefit is from avoided sewering of hazardous waste pharmaceuticals. Disposal of hazardous waste pharmaceuticals through sewering is believed to be a widespread practice of disposal. Sewering is believed to be one of the most deleterious disposal methods because active pharmaceutical ingredients (APIs) entering surface waters, often untreated by municipal wastewater treatment plants, pose the potential for adverse human health and environmental effects since they may be absorbed by humans and other organisms. Under the proposed rule, the Agency anticipates preventing approximately 6,400 tons of hazardous waste pharmaceuticals annually into waterways via a sewering ban. While the Agency was not able to quantify the human health and environmental benefits of reducing or eliminating the sewering of hazardous waste pharmaceuticals, EPA did estimate the cost savings of eliminating the wastewater treatment costs associated with sewering such pharmaceuticals. The estimated cost savings of eliminated wastewater treatment related to the prevented sewering of hazardous waste pharmaceuticals is estimated to be $4.3 million annually.

The proposed rule will yield other benefits beyond the reduction in sewering of hazardous waste pharmaceuticals. For example, under the proposed rule, healthcare facilities will no longer be required to count hazardous waste pharmaceuticals toward their RCRA generator category. This, in turn, will lead to changes in a healthcare facility's generator category,

enabling them to realize an additional cost savings. The extent to which such changes in generator category will occur under the proposed rule is uncertain, but these changes would be most likely for those healthcare facilities for which hazardous waste pharmaceuticals make up a large portion of their overall hazardous waste generation. Please see the RIA for a breakout of cost savings by regulatory requirement.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order 12866 (58 FR 51735; October 4, 1993), this action is a ''significant regulatory action'' because it is likely to raise novel legal or policy issues under section 3(f)(4). Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821; January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action (EPA–HQ–RCRA–2007–0932).

Findings for the RIA indicate that the rule, as proposed, is projected to result in an aggregate annual cost of approximately $37 million based on a discount rate of 7%. However, the proposed rule will also achieve an annual cost savings, which is estimated to be $24.3 million. Therefore, the net cost of the rule is estimated at $13 million annually. The costs, which represents annualized incremental costs relative to the full compliance baseline, is below the $100 million threshold established under part 3(f)(1) of the Order.

In addition to calling for an assessment of regulatory costs, Executive Order 12866 also requires Federal agencies to assess benefits and, ''recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.'' As discussed previously, the cost savings for the rule are estimated to be $24.3 million annually. These cost savings are considered benefits of the rule. Also, EPA estimates that the proposed rule will lead to the diversion of approximately 6,440 tons annually of hazardous waste pharmaceuticals from sewer disposal to alternate forms of disposal. This reduction in sewering will likely reduce the concentration of active pharmaceutical ingredients in the nation's waterways, potentially benefiting both ecosystems and human populations. Please see the RIA for more details on the benefits of the proposed rule.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2486.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

EPA is proposing in this rule, under a new subpart P to 40 CFR part 266, new and revised reporting and recordkeeping requirements for healthcare facilities and pharmaceutical reverse distributors managing hazardous waste pharmaceuticals. These proposed requirements, which are also identified in the ICR supporting this action, will enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals. The healthcare facilities must keep records of any test results, waste analyses or other determinations made on hazardous waste pharmaceuticals for three years from the date of analyses. In addition, the proposed requirements include provisions for improved tracking of hazardous waste pharmaceuticals that are routed through pharmaceutical reverse distributors.

EPA will use the collected information to ensure that hazardous waste pharmaceuticals are being managed in a protective manner. The tracking requirements ensure that these wastes arrive at their intended destinations rather than diverted for illicit purposes or managed at facilities not equipped to manage these wastes. These tracking requirements will also help facilities identify shipments that do not arrive at their destination as planned, allowing generators to take corrective action that will ensure that future shipments are transported to the appropriate location. In addition, during a facility inspection, information kept in facility records will help EPA and state environmental regulatory agencies determine whether or not regulatory requirements are being followed. Information marked on containers of hazardous waste pharmaceuticals will assist handlers and transporters in ensuring proper management during storage and shipment.

EPA has carefully considered the burden imposed upon the regulated community by the proposed regulations. EPA is confident that those activities required of respondents are necessary and, to the extent possible, has attempted to minimize the burden imposed. EPA believes strongly that if the minimum requirements specified under the proposed regulations are not met, neither the facilities nor EPA can ensure that hazardous waste pharmaceuticals are managed in a manner protective of human health and the environment.

EPA estimates that the total annual respondent burden for the new paperwork requirements in the proposed rule is approximately 54,857 hours, and the annual respondent cost for the new paperwork requirements in the rule is approximately $3,457,478. The estimated annual hourly burden ranges from 0.1 to 3.5 hours per response for the 28,637 respondents. However, in addition to estimating the annual respondent burden associated with new paperwork requirements in the proposed rule, the Agency also estimated the annual benefits (hours and cost savings) to respondents from the new paperwork requirements in comparison to complying with the existing RCRA hazardous waste information collection requirements for hazardous waste pharmaceuticals (*e.g.,* preparation of biennial reports, recordkeeping, etc.). Taking both the new proposed and existing RCRA requirements into account, EPA expects the proposed rule would result in a net annual paperwork burden to the 28,637 respondents of approximately 28,660 hours or $2,301,873. The net cost to EPA of administering the rule is expected to be negligible, since the Agency is not required to review and approve any information submitted by respondents. Burden is defined at 5 CFR 1320.3(b).

Respondents/affected entities: Private entities.

Respondent's obligation to respond: Mandatory per 40 CFR part 266, subpart P.

Estimated number of respondents: 28,637.

Frequency of response: Once.

Total estimated burden: 54,857 hours.

Total estimated cost: $3,457,478, includes $1,038,856 annualized capital or operation & maintenance costs.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9. Submit your comments on the Agency's need for this information, the accuracy of the

provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *oria_submissions@omb.eop.gov,* Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than October 26, 2015. The EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Small Business Analysis

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are indicated in Table 13. The Agency has determined that costs of the regulation for a facility are less than 1 percent of annual revenue.

To assess the number of small entities in the regulated universe, EPA consulted NAICS-level data from the 2007 Economic Census and tallied the number of facilities, by NAICS code, owned by entities with revenues below SBA's threshold for consideration as small. Entities in revenue categories above the SBA threshold are *not* considered small. See Table 12 for the SBA thresholds and revenues.

TABLE 13: SBA 2014 SMALL BUSINESS SIZE STANDARDS (USING 2007 NAICS CODES)

FACILITY TYPE	SBA SIZE STANDARD (FIRM-LEVEL, ANNUAL REVENUE)	PERCENTAGE OF GENERATORS CONSIDERED "SMALL" UNDER SBA STANDARD	NUMBER OF GENERATORS THAT ARE SMALL
Pharmacies	$27.5 million	46%	5,390
Veterinary Clinics	$7.5 million	95%	7,416
Physicians' Offices	$11.0 million	88%	53,577
Dentists' Offices	$7.5 million	97%	33,932
Other Health Practitioners (e.g., chiropractors)	$7.5 million	93%	32,036
Outpatient Care Centers (ex-kidney dialysis centers)	$15.0 million	68%	4,787
Outpatient Care Centers (kidney dialysis centers)	$38.5 million	14%	161
Other Ambulatory Health Care Services	$15.0 million	66%	1,707
Hospitals	$38.5 million	25%	1,634
Nursing Care Facilities (e.g., assisted living facilities, nursing homes, U.S. veterans domiciliary centers)	$15.0 million	44%	1,985
Continuing Care Retirement Communities	$27.5 million	62%	1,023
Medical Examiners and Coroners' Offices	Size standards not established	100%	552
Reverse Distributors	Various NAICS	50%	28
		Total Number of Small Facilities	**144,228**

Source:
U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes, effective July 14, 2014.

The percentage of facilities that qualify as small under SBA's thresholds were estimated for each industry affected by the proposed rule. These percentages were applied to the number of facilities in the regulatory universe, as presented in the RIA. After estimating the number of small entities by NAICS code, the average cost per small entity was estimated based on the model facility costs presented in the RIA. Next, the EPA determined whether the per

facility costs incurred by small entities represent more than 1% of annual revenues, which required estimating small entities' average annual revenues. For each NAICS code, the average per facility revenue of entities considered small under the SBA standard was estimated based on data from the 2007 Economic Census.

The proposed rule is expected to impact a total of 144,228 small entities (1,634 hospitals, 142,566 other healthcare facilities (*i.e.,* healthcare facilities that are not hospitals) and 28 pharmaceutical reverse distributors). The highest cost impact to small entities is estimated to be 0.013% of revenues at other healthcare facilities and 0.002% of revenues at hospitals. Because pharmaceutical reverse distributers are in various NAICS codes, the Agency was not able to obtain revenue data for pharmaceutical reverse distributors. However the estimated cost impact to small entity pharmaceutical reverse distributors is estimated at $5,300 annually, which the Agency does not anticipate will cause significant hardship on pharmaceutical reverse distributors that are small entities. However, the Agency requests comment on the cost impacts on small entity pharmaceutical reverse distributors that process creditable hazardous waste pharmaceuticals.

In the RIA, small entity impacts are presented incremental to the full compliance baseline. The annual per facility costs incremental to both baselines are estimated to be much less than 1% of average annual revenues. Since the incremental impact to the smallest healthcare facilities in terms of revenue is less than 1% of average annual revenues, the proposed rule is not expected to cause a significant impact to a substantial number of small businesses. Please see the RIA for a detailed analysis of cost impacts on small entities.

Although this proposed rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small entities. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act (UMRA)

This rule does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. As indicated previously, the annual net cost is estimated to be $13 million annually after cost savings ($37 million cost minus $24.3 million in cost savings). Thus, this proposed rule is not subject to the requirements of sections 202 or 205 of UMRA.

This proposed rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. While some hospitals and coroners' offices are publicly owned, the requirements affecting those facilities are not unique in that they are the same as those affecting all facilities in the proposed rule. Also, using data on revenues of hospitals owned by state and local governments, EPA estimated that the costs of the rule borne by state and local governments represent less than 0.001% of their revenues. Therefore, the costs incurred by small governments are not expected to be significant.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action may have tribal implications. However, it will neither impose substantial direct compliance costs on tribal governments, nor preempt tribal law.

To assess the potential tribal implications of the proposed rule, EPA compiled data on the number of tribally run healthcare facilities in the U.S. and estimated the costs of the proposed rule for these facilities. Estimates of tribally run healthcare facilities were obtained from the U.S. Department of Health and Human Services' Indian Health Service (IHS), as summarized in Table 14.[164] Data were not readily available on the size or hazardous waste generation amounts for the tribally run healthcare facilities identified by the IHS. To estimate the potential costs of each regulatory option, per facility costs derived in the RIA were applied to the IHS facility counts. Based on these values, Table 14 summarizes the costs that tribally run healthcare facilities are expected to incur under the proposed rule. OMB has not issued guidance on what constitutes a substantial burden on tribal governments under this executive order. The relatively low costs estimated for tribally run healthcare facilities in Table14, however, suggest that the proposed rule will not impose a substantial burden on tribal governments. EPA welcomes comments on the proposed rule's impact on tribal governments. EPA specifically solicits additional comment on this proposed action from tribal officials.

[164] Indian Health Service (IHS), U.S. Department of Health and Human Services, IHS Year 2013 Profile, available at *http://www.ihs.gov/PublicAffairs/IHSBrochure/Profile.asp,* accessed December 20, 2012.

TABLE 14: COST IMPACTS FOR HEALTHCARE FACILITIES OWNED AND OPERATED BY NATIVE AMERICAN TRIBES USING A 7 PERCENT DISCOUNT RATE (MILLIONS OF YEAR 2011$)

FACILITY TYPE	NUMBER OF FACILITIES[1]	PROPOSED RULE
Total Annual Costs Incremental to Full Compliance Baseline		
Hospitals	16	$0.019
Tribal Operated Facilities	16	$0.088
Health Centers	258	
Alaska Village Clinics	164	
Health Stations	75	
TOTAL	**529**	$0.107

Notes:

1. Indian Health Service (HIS), U.S. Department of Health and Human Services, IHS Year 2013 Profile, available at http://www.ihs.gov/PublicAffairs/IHSBrochure/Profile.asp, accessed December 20, 2012.
2. Estimate reflects annual cost impact for tribal operated facilities, health centers, Alaska village clinics, and health stations combined.

The EPA consulted with tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its development. A summary of that consultation is provided in the docket for this proposed rule (see EPA–HQ–RCRA–2007–0932).

As required by section 7(a), the EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this proposed rule (see EPA–HQ–RCRA–2007–0932).

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This proposed rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children.

To examine whether the proposed rule has a disproportionate impact on children, the RIA uses a geographic analysis of demographics near wastewater treatment plants and hazardous waste combustion facilities. Table 15 summarizes the results of this analysis. As indicated in the table, this analysis finds that children (*i.e.,* individuals under the age of 18) account for a slightly larger share of the population (28.5%) in the one-mile radius around wastewater treatment plants than they account for nationally (25.3%). Among the catchment zones of wastewater treatment plants, however, children make up a much smaller portion of the population (9.8%). Within both the one- and three-mile buffers around hazardous waste combustion facilities, children's share of the population slightly exceeds their share nationally.

These data suggest that the proposed rule will not result in a disproportionate adverse impact on children. Because the children's share of the population near hazardous waste combustion facilities is near the national average, any increase in the combustion of hazardous waste combustion that occurs as a result of the proposed rule is unlikely to have a significant disproportionate impact on children's health. The data in Table 15 also show that the number of children living in close proximity to wastewater treatment plants, in areas likely to benefit from the rule, far exceeds the number of children who live near hazardous waste combustion facilities. This suggests that the diversion of hazardous waste pharmaceuticals from wastewater treatment plants to combustion facilities will benefit a much greater number of children than it may put at greater risk of adverse health effects. See Table 15 for the demographics of children surrounding wastewater treatment plants and hazardous waste combustion facilities. Please see the RIA for a detailed methodology of the children's health analysis.

TABLE 15: SUMMARY OF CHILDREN'S HEALTH ASSESSMENT		
GEOGRAPHIC AREA	NUMBER OF CHILDREN IN AREA	NATIONAL % OF POPULATION UNDER THE AGE OF 18
Wastewater treatment plants, one-mile radius	7.8 million (28.5%)[1]	25.3%
Wastewater treatment plants, catchment areas	4.4 million (9.8%)[1]	
Hazardous waste combustion facilities, one-mile radius	5,012 (26.1%)[1]	
Hazardous waste combustion facilities, three-mile radius	64,710 (25.6%)[1]	
GEOGRAPHIC AREA	NUMBER OF FACILITIES WHERE CHILDREN'S SHARE OF THE LOCAL POPULATION EXCEEDS NATIONAL AVG. %	
Wastewater treatment plants, one-mile radius	8,908	
Wastewater treatment plants, catchment areas	5,171	
Hazardous waste combustion facilities, one-mile radius	13	
Hazardous waste combustion facilities, three-mile radius	11	
GEOGRAPHIC AREA	NUMBER OF FACILITIES WHERE CHILDREN'S SHARE OF THE LOCAL POPULATION EXCEEDS STATE AVG. %	
Wastewater treatment plants, one-mile radius	8,992	
Wastewater treatment plants, catchment areas	5,149	
Hazardous waste combustion facilities, one-mile radius	14	
Hazardous waste combustion facilities, three-mile radius	11	

Notes:
1. Values in parentheses represent children's proportion of the population.

Sources: RTI International, U.S. Synthesized Population 2005–2009 Version 2.0, August 2012; U.S. EPA Clean Watershed Needs Database; and U.S. EPA, Assessment of the Potential Costs, Benefits, & Other Impacts of the Hazardous Waste Combustion MACT Final Rule Standards, September 2005.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211, (66 FR 28355 (May 22, 2001)), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

The proposed rule does not directly regulate energy production or consumption. Changes in the management of hazardous waste pharmaceuticals stipulated in the proposed rule are not expected to impact energy production or distribution. Similarly, the management requirements outlined in the proposed rule will have minimal impact on energy consumption (*e.g.,* from transporting hazardous waste pharmaceuticals that otherwise would have been sewered). Because the changes in energy production and consumption under the proposed rule are likely to be minimal, the proposed rule is not expected to have a significant adverse effect on energy supply, distribution, or use. In addition, no measurable adverse impacts are expected on energy prices or foreign supplies.

I. National Technology Transfer and Advancement Act (NTTAA)

This proposed rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects

on minority, low-income or indigenous populations. The results of this evaluation are summarized in the following paragraphs. The evaluation is contained in the Regulatory Impact Analysis (RIA), which can be found at regulations.gov under docket number EPA–HQ–RCRA–2007–0932.

To meet the requirements of Executive Order 12898, EPA analyzed potential environmental justice impacts associated with the diversion of hazardous waste pharmaceuticals from sewer disposal to hazardous waste combustion facilities. Populations living near and downstream from wastewater treatment plants may also benefit from the elimination of sewering of hazardous waste pharmaceuticals. To the extent that minority and/or low-income populations near or downstream from wastewater treatment plants make up a disproportionately high portion of the overall population, the proposed rule may result in positive environmental justice impacts. See Table 16 for the results of the Environmental Justice analysis.

Overall, EPA expects that the proposed rule may positively affect U.S. environmental justice populations, although the size of the impact will vary by wastewater treatment plant. As suggested by Table 16, the reduction in sewering expected under the proposed rule may benefit relatively large minority and low-income populations in close proximity to or downstream from wastewater treatment plants. The diversion of hazardous waste pharmaceuticals to combustion facilities, however, may increase the environmental burden borne by environmental justice populations near these combustion facilities. Although these effects offset each other to a certain degree, the number of minority and low-income individuals near wastewater treatment facilities greatly exceeds the number near hazardous waste combustion facilities. This suggests that, on the whole, the proposed rule may benefit environmental justice populations.

TABLE 16: DEMOGRAPHICS FOR POPULATIONS NEAR WASTEWATER TREATMENT FACILITIES & COMMERCIAL HAZARDOUS WASTE COMBUSTION FACILITIES

GEOGRAPHIC AREA	MINORITY POPULATION	LOW-INCOME POPULATION	% OF NATIONAL POPULATION	
			RACIAL & ETHNIC MINORITIES	LOW-INCOME POPULATION
Wastewater treatment plants, one-mile radius	6.2 million (22.6%)[1]	3.8 million (14.0%)[1]	24.7%	11.4%
Wastewater treatment plants, catchment areas	3.8 million (8.6%)[1]	2.2 million (4.9%)[1]		
Hazardous waste combustion facilities, one-mile radius	3,578 (18.7%)[1]	3,130 (16.3%)[1]		
Hazardous waste combustion facilities, three-mile radius	67,329 (26.6%)[1]	42,782 (16.9%)[1]		

GEOGRAPHIC AREA	NO. OF FACILITIES EXCEEDING:	
	NATIONAL AVG. MINORITY %.	NATIONAL AVG. LOW-INCOME %.
Wastewater treatment plants, one-mile radius	3,233	7,886
Wastewater treatment plants catchment areas	3,151	7,358
Hazardous waste combustion facilities, one-mile radius	6	4
Hazardous waste combustion facilities, three-mile radius	7	4

GEOGRAPHIC AREA	NO. OF FACILITIES EXCEEDING:	
	STATE AVG. MINORITY %.	STATE AVG. LOW-INCOME%.
Wastewater treatment plants, one-mile radius	3,596	7,949
Wastewater treatment plants, catchment areas	3,562	7,391
Hazardous waste combustion facilities, one-mile radius	7	13
Hazardous waste combustion facilities, three-mile radius	8	16

Notes:

1. Values in parentheses represent the proportion of the population considered a racial or ethnic minority or below the Federal Poverty Level.

Sources: RTI International, U.S. Synthesized Population 2005–2009 Version 2.0, August 2012; U.S. EPA Clean Watershed Needs Database; and U.S. EPA, Assessment of the Potential Costs, Benefits, & Other Impacts of the Hazardous Waste Combustion MACT Final Rule Standards, September 2005.

List of Subjects

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

40 CFR Part 266

Environmental protection, Energy, Hazardous Waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 268

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 273

Environmental protection, Hazardous materials transportation, Hazardous waste.

Dated: August 31, 2015.

Gina McCarthy,

Administrator.

For the reasons stated in the preamble, Title 40, chapter I, of the Code of Federal Regulations is proposed to be amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

■ 2. Amend § 261.5 by adding paragraph (c)(8) to read as follows:

§ 261.5 Special requirements for hazardous waste generated by conditionally exempt small quantity generators.

* * * * *

(c) * * *

(8) Is a hazardous waste pharmaceutical managed under 40 CFR part 266, subpart P.

* * * * *

■ 3. Amend § 261.7 by adding paragraph (c) to read as follows:

§ 261.7 Residues of hazardous waste in empty containers.

* * * * *

(c) Healthcare facilities and pharmaceutical reverse distributors operating under 40 CFR part 266, subpart P are subject to § 266.507 for the management of hazardous waste pharmaceutical residues in containers, in lieu of this section.

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

■ 4. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C 6906, 6912, 6922–6925, 6937, and 6938.

■ 5. Amend § 262.10 by adding paragraphs (m) and (n) to read as follows:

§ 262.10 Purpose, scope and applicability.

* * * * *

(m) All pharmaceutical reverse distributors (as defined in § 266.500) are subject to 40 CFR part 266, subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

(n) Each healthcare facility (as defined in § 266.500) must determine whether it is subject to 40 CFR part 266, subpart P for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month (including pharmaceutical hazardous waste and non-pharmaceutical hazardous waste). Healthcare facilities that generate (or accumulate) more than 100 kg (220 pounds) of hazardous waste per calendar month, or more than 1 kg (2.2 pounds) of acute hazardous waste per calendar month, or more than 100 kg (220 pounds) per calendar month of any residue or contaminated soil, waste, or other debris, resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in § 261.31 or § 261.33(e), are subject to 40 CFR part 266, subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

■ 6. The authority citation for part 266 continues to read as follows:

Authority: 42 U.S.C. 1006, 2002(a), 3001–3009, 3014, 3017, 6905, 6906, 6912, 6921, 6922, 6924–6927, 6934, and 6937.

Subpart O—[Reserved]

■ 7. Add reserved subpart O:

■ 8. Add subpart P to read as follows:

Subpart P — Hazardous Waste Pharmaceuticals

Sec.

266.500 Definitions for this subpart.
266.501 Applicability.
266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.
266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.
266.504 Healthcare facilities that are conditionally exempt small quantity generators (CESQGs).
266.505 Prohibition of sewering hazardous waste pharmaceuticals.
266.506 Conditional exemption for hazardous waste pharmaceuticals that are also controlled substances.
266.507 Management of hazardous waste pharmaceutical residues in containers.
266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a pharmaceutical reverse distributor.
266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a pharmaceutical reverse distributor to a pharmaceutical reverse distributor.
266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors.

Subpart P—Hazardous Waste Pharmaceuticals

§ 266.500 Definitions for this subpart.

The following definitions apply to this subpart:

Evaluated hazardous waste pharmaceutical means a hazardous waste pharmaceutical that was a potentially creditable hazardous waste pharmaceutical but has been evaluated by a pharmaceutical reverse distributor to establish whether it is eligible for manufacturer's credit and will not be sent to another pharmaceutical reverse distributor for further evaluation or verification.

Hazardous waste pharmaceutical means 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.

Healthcare facility means:

(1) Any person that:

(i) 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

(ii) Sells or dispenses over-the-counter or prescription pharmaceuticals.

(2) This definition includes, but is not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of over-the-counter medications; and veterinary clinics and hospitals.

Household waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, but is exempt from being a hazardous waste under § 261.4(b)(1).

Long-term care facility means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, 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.

Non-creditable hazardous waste pharmaceutical means a hazardous waste pharmaceutical that is not expected to be eligible for manufacturer's credit.

Non-hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and is not listed in 40 CFR part 261, subpart D, and does not exhibit a characteristic identified in 40 CFR part 261, subpart C.

Non-pharmaceutical hazardous waste means a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261, subpart D, or exhibits one or more characteristics identified in 40 CFR part 261, subpart C, but is not a pharmaceutical, as defined in this section.

Pharmaceutical means any 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 includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and Cosmetic Act, prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with pharmaceuticals, and clean-up material from spills of pharmaceuticals.

Pharmaceutical reverse distributor means any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit. Any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer's credit is considered a pharmaceutical reverse distributor.

Potentially creditable hazardous waste pharmaceutical means:

(1) A hazardous waste pharmaceutical that has the potential to receive manufacturer's credit and is:

(i) Unused or un-administered; and

(ii) Unexpired or less than one year past expiration date.

(2) The term does 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.

§ 266.501 Applicability.

(a) A healthcare facility that is a conditionally exempt small quantity generator remains subject to § 261.5 and is *not* subject to this subpart, except for §§ 266.504, 266.505, and 266.507(a) and (b).

(b) A healthcare facility that is a conditionally exempt small quantity generator has the option of complying with this subpart for the management of its hazardous waste pharmaceuticals, as an alternative to complying with the conditional exemption of § 261.5.

(c) A healthcare facility or pharmaceutical reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste.

(d) With the exception of healthcare facilities identified in subsection (a), a healthcare facility is subject to:

(1) Sections 266.502 and 266.504 through 266.508 of this subpart with respect to the management of:

(i) Non-creditable hazardous waste pharmaceuticals, and

(ii) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a pharmaceutical reverse distributor.

(2) Sections 266.503 through 266.507 and 266.509 of this subpart with respect to the management of potentially creditable hazardous waste pharmaceuticals that are destined for a pharmaceutical reverse distributor.

(e) A pharmaceutical reverse distributor is subject to §§ 266.505 through 266.510 of this subpart with respect to the management of hazardous waste pharmaceuticals.

(f) This subpart does not apply to the management of hazardous waste pharmaceuticals that are generated or managed by entities other than healthcare facilities and pharmaceutical reverse distributors.

§ 266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

(a) *Notification and withdrawal from this subpart for healthcare facilities managing non-creditable hazardous waste pharmaceuticals*—(1) *Notification.* A healthcare facility must notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700–12), that it is a healthcare facility operating under this subpart. A healthcare facility is not required to fill out Box 11 (Description of Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each site or EPA Identification Number.

(i) A healthcare facility that already has an EPA identification number must re-notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A healthcare facility that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification form (EPA form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(iii) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to this subpart.

(2) *Withdrawal.* A healthcare facility that operated under this subpart but is no longer subject to this subpart, because it is a conditionally exempt small quantity generator under § 261.5, and elects to withdraw from this subpart, must notify the appropriate EPA Regional Administrator using the Site Identification Form (EPA form 8700–12) that it is no longer operating under this subpart. A healthcare facility is not required to fill out Box 11 (Description of Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each EPA Identification Number.

(i) A healthcare facility must submit the Site Identification Form notifying that it is withdrawing from this subpart before it begins operating under the conditional exemption of § 261.5(b).

(ii) A healthcare facility must keep a copy of its withdrawal on file for three years from the date of signature on the notification of its withdrawal.

(b) *Training of employees managing non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must ensure that all employees that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar

with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) *Hazardous waste determination for non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility that generates a solid waste that is a pharmaceutical must determine whether the solid waste pharmaceutical is a hazardous waste pharmaceutical (*i.e.,* it exhibits a characteristic identified in 40 CFR part 261, subpart C or is listed in 40 CFR part 261, subpart D) in order to determine whether the waste is subject to this subpart. A healthcare facility may choose to manage its solid waste pharmaceuticals as hazardous waste pharmaceuticals under this subpart even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261, subpart C and are not listed in 40 CFR part 261, subpart D.

(d) *Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(2) A healthcare facility that manages ignitable or reactive hazardous waste pharmaceuticals, or that mixes or commingles incompatible hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(i) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(iv) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(v) Through other like means threaten human health or the environment.

(3) A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(4) A healthcare facility may accumulate hazardous waste pharmaceuticals and non-hazardous pharmaceutical waste in the same container, except that hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of § 268.3(c) must be accumulated in separate containers.

(e) *Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must label or clearly mark each container of hazardous waste pharmaceuticals with the phrase ''Hazardous Waste Pharmaceuticals.''

(f) *Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on-site for one year or less without a permit or having interim status. A healthcare facility may accumulate for more than one year without a permit or having interim status, only if the requirements of paragraph (f)(3) of this section are met.

(2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(i) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that hazardous waste pharmaceuticals became a waste;

(ii) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceutical being accumulated first became a waste;

(iii) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste; or

(iv) 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.

(3) A healthcare facility may request from the EPA Regional Administrator an extension beyond the one year accumulation time limit for non-creditable hazardous waste pharmaceuticals involved in litigation, a recall, or unforeseen circumstances beyond the control of the healthcare facility.

(i) A request must be sent to the EPA Regional Administrator in writing (paper or electronic). The request for an extension must include an explanation of the reason an extension is requested, the approximate volume or weight of the hazardous waste pharmaceuticals that will be accumulated more than 90 days, and the amount of additional time requested.

(ii) The amount of time extension granted is at the discretion of the EPA Regional Administrator on a case-by-case basis.

(g) *Land disposal restrictions for non-creditable hazardous waste pharmaceuticals.* The hazardous waste pharmaceuticals generated by a healthcare facility are subject to the Land Disposal Restrictions of 40 CFR part 268. A healthcare facility that generates 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 (codes).

(h) *Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals.* A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter, may accumulate the returned hazardous waste pharmaceuticals on-site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with paragraphs (d) and (e) of this section. Upon receipt of the returned shipment, the healthcare facility must:

(1) Sign either:

(i) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(2) Provide the transporter a copy of the manifest;

(3) Within 30 days of delivery of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(4) Transport or offer for transport the returned shipment in accordance with the shipping standards of § 266.508(a).

(i) *Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals*—(1) *Biennial report by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41, with respect to non-creditable hazardous waste pharmaceuticals managed under this subpart.

(2) *Exception report by healthcare facilities for a missing copy of the manifest.* (i) For shipments from a

healthcare facility to a designated facility: If a healthcare facility does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(A) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located, and

(B) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(ii) For shipments rejected by the designated facility and shipped to an alternate facility: If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the handwritten signature of the owner or operator of the alternate facility within 60 days of the date the waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(A) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located, and

(B) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(3) *Additional reports.* The EPA Regional Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(j) *Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals.* (1) A healthcare facility must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

(2) A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

(3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) for at least three years from the date of the test, analysis, or other determination.

(4) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(k) *Response to releases of non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility must immediately contain all releases of non-creditable hazardous waste pharmaceuticals and other residues from non-creditable hazardous waste pharmaceuticals.

(2) A healthcare facility must determine whether any material resulting from the release is a non-creditable hazardous waste pharmaceutical, and if so, must manage the non-creditable hazardous waste pharmaceutical residues and spill clean-up materials in accordance with the requirements of this subpart.

(l) *Long-term care facilities that manage non-creditable hazardous waste pharmaceuticals.* A healthcare facility that is a long-term care facility and that has individuals that administer their own pharmaceuticals must collect any unused non-creditable hazardous waste pharmaceuticals from those self-administering individuals and manage them in accordance with this subpart.

(m) *Accepting creditable and non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a CESQG.* A healthcare facility may accept creditable and non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a conditionally exempt small quantity generator under § 261.5, 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 conditionally exempt small quantity generator healthcare facility that is sending the hazardous waste pharmaceuticals off-site or has a contractual relationship whereby the receiving healthcare facility supplies pharmaceuticals to the conditionally exempt small quantity generator healthcare facility,

(2) Is operating under this subpart for the management of its hazardous waste pharmaceuticals,

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off-site in compliance with this subpart, and

(4) Keeps records of the hazardous waste pharmaceuticals shipments it receives from off-site for 3 years from the date that the shipment is received.

§ 266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

(a) *Hazardous waste determination for creditable hazardous waste pharmaceuticals at the healthcare facility.* A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable solid waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical (*i.e.,* it listed in 40 CFR part 261, subpart D or exhibits a characteristic identified in 40 CFR part 261, subpart C). A healthcare facility may choose to manage its potentially creditable solid waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under § 266.509 even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261, subpart C and are not listed in 40 CFR part 261, subpart D.

(b) Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor.

(c) *Biennial Report by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41, with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

(d) *Recordkeeping.* (1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for 3 years from the date of shipment:

(i) A copy of the advance notification provided to the pharmaceutical reverse distributor;

(ii) The confirmation of delivery; and

(iii) The shipping papers or bill of lading.

(2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

§ 266.504 Healthcare facilities that are conditionally exempt small quantity generators (CESQGs).

(a) *Potentially creditable hazardous waste pharmaceuticals.* A healthcare facility that is a conditionally exempt small quantity generator may send its potentially creditable hazardous waste pharmaceuticals to a pharmaceuticals reverse distributor.

(b) *Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a CESQG.* A healthcare facility that is a conditionally exempt small quantity generator may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided the receiving healthcare facility meets the conditions in § 266.502(m) of this subpart.

(c) *Long-term care facilities that are CESQGs.* A long-term care facility that is a conditionally exempt small quantity generator may dispose of its hazardous waste pharmaceuticals in a collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

§ 266.505 Prohibition of sewering hazardous waste pharmaceuticals.

All healthcare facilities and pharmaceutical reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. The exclusion in § 261.4(a)(1)(ii) for mixtures of domestic sewage and other wastes that pass through a sewer system to a publicly-owned treatment works does not apply to a hazardous waste pharmaceutical.

§ 266.506 Conditional exemption for hazardous waste pharmaceuticals that are also controlled substances.

(a) The following are exempt from 40 CFR parts 260 through 273, provided the conditions of paragraph (b) of this section are met:

(1) A hazardous waste pharmaceutical that is also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308, and

(2) An authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that collects controlled substances collected from an ultimate user (as defined by the Drug Enforcement Administration) and co-mingles them with hazardous waste pharmaceuticals that are exempt as a household waste under § 261.4(b)(1).

(b) *Conditions for exemption.* The hazardous waste pharmaceuticals must be collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances, and combusted at one of the following:

(1) A permitted large municipal waste combustor (LMWC), subject to 40 CFR part 62, subpart FFF for existing LMWCs, or 40 CFR part 60, subparts Ea and Eb for new LMWCs, or

(2) A permitted small municipal waste combustor (SMWC), subject to 40 CFR part 62, subpart JJJ for existing SMWCs, or 40 CFR part 60, subparts AAAA and BBBB for new SMWCs, or

(3) A unit that has a permit or interim status to burn hazardous waste and is covered by 40 CFR part 63, subpart EEE. A unit that is exempt from 40 CFR part 63, subpart EEE as specified in § 63.1200(b) of this chapter is not covered by subpart EEE.

§ 266.507 Management of hazardous waste pharmaceutical residues in containers.

(a) *Dispensing and unit-dose containers.* A dispensing bottle, vial, or ampule (not to exceed 1 liter or 1000 pills); or a unit-dose container, (*e.g.,* a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided:

(1) All pharmaceuticals have been removed from the dispensing bottle, vial or ampule; or the unit-dose container, (*e.g.,* unit-dose packet, cup, wrapper, blister pack, or delivery device) using the practices commonly employed to remove materials from that type of container, and

(2) Any dispensing bottle or unit-dose container that is an original manufacturer's product package is destroyed prior to disposal in such a manner as would prevent further use of the container.

(b) *Dispensed syringes.* The residues remaining in a syringe are not regulated as hazardous waste provided:

(1) The syringe has been used to administer the pharmaceutical to a patient, and

(2) The syringe is placed in a sharps container that is managed in accordance with all applicable federal, state, and local medical waste requirements.

(c) *Other containers, including delivery devices.* The residues remaining in all other types of unused or used containers that once held pharmaceuticals must be managed as hazardous waste pharmaceuticals, if the residues are listed in 40 CFR part 261, subpart D or exhibit a characteristic identified in 40 CFR part 261, subpart C. This includes, but is not limited to, the residues in intravenous (IV) bags and tubing, inhalers, aerosols, nebulizers, tubes of ointment, gels or creams.

§ 266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a pharmaceutical reverse distributor.

(a) A healthcare facility or pharmaceutical reverse distributor that ships either non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, respectively, off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility), must comply with:

(1) The following pre-transport requirements, before transporting or offering for transport off-site:

(i) *Packaging.* Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR parts 173, 178, and 180.

(ii) *Labeling.* Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172, subpart E.

(iii) *Marking.* (A) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172, subpart D;

(B) Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety

authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Pharmaceutical Reverse Distributor's Name and Address__.

Healthcare Facility's or Pharmaceutical Reverse Distributor's EPA Identification Number__.

Manifest Tracking Number__.

(iv) *Placarding.* Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR part 172, subpart F.

(v) *Shipping papers.* Prepare shipping papers in accordance with 49 CFR part 172, subpart C.

(2) The manifest requirements of 40 CFR part 262, subpart B, except that:

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list hazardous waste codes in box 13 of EPA Form 8700–22.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the words ''hazardous waste pharmaceuticals'' in Box 14 (the special handling instructions and additional information) of EPA Form 8700–22.

(b) *Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* A healthcare facility or pharmaceutical reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262, subpart E.

(c) *Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262, subpart F. A healthcare facility or pharmaceutical reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, unless they have a permit or interim status that allows them to accept hazardous waste from off-site.

§ 266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a pharmaceutical reverse distributor to a pharmaceutical reverse distributor.

(a) A healthcare facility or a pharmaceutical reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a pharmaceutical reverse distributor must:

(1) Provide advance notice (paper or electronic) to the pharmaceutical reverse distributor of the intent to ship potentially creditable hazardous waste pharmaceuticals to the receiving pharmaceutical reverse distributor before each shipment of potentially creditable hazardous waste pharmaceuticals is sent, and

(2) Comply with the pre-transport requirements of § 266.508(a)(1)(i) through (v).

(b) Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving pharmaceutical reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or pharmaceutical reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived.

(c) If a healthcare facility or pharmaceutical reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor and does not receive delivery confirmation within seven calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or pharmaceutical reverse distributor that initiated the shipment must contact the shipper and the intended recipient (*i.e.,* the pharmaceutical reverse distributor) promptly to report that the confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) *Exporting potentially creditable hazardous waste pharmaceuticals.* (1) A healthcare facility or pharmaceutical reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the following requirements in addition to paragraphs (a) through (c) of this section:

(i) Comply with the requirements applicable to a primary exporter at 40 CFR 262.53, 262.56(a)(1) through (4), (a)(6), and (b) and 262.57;

(ii) Export such potentially creditable hazardous waste pharmaceuticals only upon consent of the receiving country and in conformance with the EPA Acknowledgement of Consent as defined in 40 CFR part 262, subpart E; and

(iii) Provide a copy of the EPA Acknowledgement of Consent for the shipment to the transporter transporting the shipment for export.

(2) A transporter of potentially creditable hazardous waste pharmaceuticals to a foreign destination other than those OECD countries specified 40 CFR 262.58(a)(1) (in which case the transporter is subject to the requirements of 40 CFR part 262, subpart H) may not accept a shipment if the transporter knows the shipment does not conform to the EPA Acknowledgment of Consent. In addition the transporter must ensure that:

(i) A copy of the EPA Acknowledgment of Consent accompanies the shipment; and

(ii) The shipment is delivered to the facility designated by the person initiating the shipment.

(e) *Importing potentially creditable hazardous waste pharmaceuticals.* Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to paragraphs (a) through (c) of this section in lieu of 40 CFR part 262, subpart F.

§ 266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors.

A pharmaceutical reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off-site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on-site without a permit or without having interim status, provided that it complies with the following conditions:

(a) *Standards for pharmaceutical reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.*

(1) *Notification.* A pharmaceutical reverse distributor must notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700–12), that it is a pharmaceutical reverse distributor operating under this subpart.

(i) A pharmaceutical reverse distributor that already has an EPA identification number must re-notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700–12), that it is a pharmaceutical reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A pharmaceutical reverse distributor that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA form 8700–12), that it is a pharmaceutical reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(2) *Inventory by the pharmaceutical reverse distributor.* A pharmaceutical reverse distributor must maintain an inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on-site.

(i) A pharmaceutical reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the pharmaceutical reverse distributor.

(ii) The inventory must include the identity (*e.g.,* name or national drug code (NDC)) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(3) *Security at the pharmaceutical reverse distributor facility.* A pharmaceutical reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(i) Examples of methods that may be used to prevent unknowing entry and minimize unauthorized entry include, but are not limited to:

(A) 24-hour continuous monitoring surveillance system;

(B) An artificial barrier such as a fence; or

(C) Means to control entry, such as keycard access.

(ii) If the pharmaceutical reverse distributor already meets the security requirements of this paragraph because of other regulatory requirements, such as Drug Enforcement Administration regulations, the facility is not required to provide separate security measures pursuant to this section.

(4) *Maximum accumulation time for hazardous waste pharmaceuticals at a pharmaceutical reverse distributor.* A pharmaceutical reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for 90 calendar days or less. The 90 days start when the potentially creditable hazardous waste pharmaceutical arrives at the pharmaceutical reverse distributor and applies to all hazardous waste pharmaceuticals accumulated on-site, regardless of whether they are destined for another pharmaceutical reverse distributor (*i.e.,* potentially creditable hazardous waste pharmaceuticals), or a permitted or interim status treatment, storage or disposal facility (*i.e.,* evaluated hazardous waste pharmaceuticals).

(5) *Extension of 90-day accumulation time limit at a pharmaceutical reverse distributor.* A pharmaceutical reverse distributor may request an extension of its 90-day accumulation time limit for hazardous waste pharmaceuticals from the EPA Regional Administrator due to unforeseen circumstances beyond the control of the pharmaceutical reverse distributor, or if the potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals are involved in litigation or a recall.

(i) A written request must be sent to the EPA Regional Administrator (paper or electronic). The request for an extension must include an explanation of the reason an extension is requested, the approximate volume or weight of the hazardous waste pharmaceuticals that will be accumulated more than 90 days, and the amount of additional time requested.

(ii) The amount of time granted for an extension is at the discretion of the EPA Regional Administrator on a case-by-case basis.

(6) *Contingency plan and emergency procedures at a pharmaceutical reverse distributor.* A pharmaceutical reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of 40 CFR part 265, subpart D.

(7) *Closure of a pharmaceutical reverse distributor.* When closing an area where a pharmaceutical reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the pharmaceutical reverse distributor must control, minimize, or eliminate to the extent necessary to protect human health and the environment, post-closure escape of hazardous waste, leachate, contaminated run-off, or hazardous waste decomposition products to the ground or surface waters or to the atmosphere.

(8) *Reporting by a pharmaceutical reverse distributor*—(i) *Unauthorized waste report.* A pharmaceutical reverse distributor must submit an unauthorized hazardous waste report if the pharmaceutical reverse distributor receives hazardous waste from off-site that it is not authorized to receive (*e.g.,* non-creditable hazardous waste pharmaceuticals, non-pharmaceutical hazardous waste). The pharmaceutical reverse distributor must prepare and submit an unauthorized waste report to the EPA Regional Administrator within 15 days after receiving the unauthorized hazardous waste and the pharmaceutical reverse distributor must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized hazardous waste. The pharmaceutical reverse distributor must manage the unauthorized hazardous waste in accordance with all applicable regulations for generators of non-pharmaceutical hazardous waste. The unauthorized waste report must be signed by the owner or operator of the pharmaceutical reverse distributor, or his authorized representative, and contain the following information:

(A) The EPA identification number, name and address of the pharmaceutical reverse distributor;

(B) The date the pharmaceutical reverse distributor received the hazardous waste;

(C) The EPA identification number, name and address of the healthcare facility that shipped the hazardous waste, if available;

(D) A description and the quantity of each unauthorized hazardous waste the pharmaceutical reverse distributor received;

(E) The method of treatment, storage, or disposal for each unauthorized hazardous waste; and

(F) A brief explanation of why the waste was unauthorized, if known.

(ii) *Additional reports.* The EPA Regional Administrator may require pharmaceutical reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(9) *Recordkeeping by pharmaceutical reverse distributors.* A pharmaceutical reverse distributor must keep the following records (paper or electronic):

(i) A copy of its notification on file for as long as the facility is subject to this subpart;

(ii) A copy of the advance notification, delivery confirmation, the shipping papers or bill of lading for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years from the date it receives the shipment;

(iii) A copy of its inventory for as long as the facility is subject to this subpart; and

(iv) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(10) A pharmaceutical reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 21 calendar days of arriving at the pharmaceutical reverse distributor to establish whether it is destined for another pharmaceutical reverse distributor for further evaluation or verification of manufacturer's credit or for a permitted or interim status treatment, storage or disposal facility. This 21 calendar days is part of the 90 calendar days allowed for on-site accumulation.

(i) A potentially creditable hazardous waste pharmaceutical that is destined for another pharmaceutical reverse distributor is still considered a ''potentially creditable hazardous waste pharmaceutical'' and must be managed in accordance with paragraph (b) of this section.

(ii) A potentially creditable hazardous waste pharmaceuticals that is destined for a permitted or interim status treatment, storage or disposal facility is considered an ''evaluated hazardous waste pharmaceutical'' and must be managed in accordance with paragraph (c) of this section.

(11) A pharmaceutical reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer's credit within 21 calendar days of arriving at the facility and must manage the evaluated hazardous waste pharmaceuticals in accordance with paragraph (c) of this section. This 21 calendar days is part of the 90 calendar days allowed for on-site accumulation.

(b) *Additional standards for pharmaceutical reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another pharmaceutical reverse distributor.* A pharmaceutical reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in paragraph (a) of this section, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another pharmaceutical reverse distributor for further evaluation or verification of manufacturer's credit:

(1) A pharmaceutical reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor within 90 days from when the potentially creditable hazardous waste pharmaceuticals arrived or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(2) A pharmaceutical reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another pharmaceutical reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor that is a pharmaceutical manufacturer within 90 days from when the potentially creditable hazardous waste pharmaceuticals arrived or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(3) A pharmaceutical reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another pharmaceutical reverse distributor in accordance with § 266.509.

(4) *Recordkeeping.* A pharmaceutical reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another pharmaceutical reverse distributor, for at least three years from the date of shipment:

(i) A copy of the advance notification provided to the pharmaceutical reverse distributor;

(ii) The confirmation of delivery; and

(iii) The shipping papers or bill of lading.

(c) *Additional standards for pharmaceutical reverse distributors managing evaluated hazardous waste pharmaceuticals.* A pharmaceutical reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of paragraph (a) of this section, for the management of evaluated hazardous waste pharmaceuticals:

(1) *Accumulation area at the pharmaceutical reverse distributor.* A pharmaceutical reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

(2) *Weekly inspections of on-site accumulation area.* A pharmaceutical reverse distributor must inspect its on-site accumulation area at least weekly, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

(3) *Personnel training at a pharmaceutical reverse distributor.* Personnel at a pharmaceutical reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of § 265.16.

(4) *Labeling and management of containers at on-site accumulation area.* A pharmaceutical reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must:

(i) Label the containers with the words, ''hazardous waste pharmaceuticals'';

(ii) Ensure the containers are in good condition and managed to prevent leaks;

(iii) Use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(iv) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(v) A pharmaceutical reverse distributor that manages ignitable or reactive evaluated hazardous waste pharmaceuticals, or that mixes or commingles incompatible evaluated hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(E) Through other like means threaten human health or the environment; and

(vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) (*e.g.,* arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the pharmaceutical reverse distributor.

(5) *Hazardous waste numbers.* Containers of evaluated hazardous waste pharmaceuticals must be marked with the applicable hazardous waste number(s) (*i.e.,* hazardous waste code(s)) prior to transport off-site.

(6) *Shipments.* A pharmaceutical reverse distributor must ship evaluated hazardous waste pharmaceuticals that

are destined for a permitted or interim status treatment, storage or disposal facility, in accordance with § 266.508(a).

(7) *Procedures for a pharmaceutical reverse distributor for managing rejected shipments.* A pharmaceutical reverse distributor who sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter, may accumulate the returned hazardous waste pharmaceuticals on-site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with paragraph (a) of this section. Upon receipt of the returned shipment, the pharmaceutical reverse distributor must:

(i) Sign either:

(A) Item 18c of the original manifest if the original manifest was used for the returned shipment; or

(B) Item 20 of the new manifest if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within 30 days of delivery of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the pharmaceutical reverse distributor; and

(iv) Transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the shipping standards of § 266.508(b).

(8) *Land disposal restrictions.* Evaluated hazardous waste pharmaceuticals are subject to the Land Disposal Restrictions of 40 CFR part 268. A pharmaceutical reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must comply with the land disposal restrictions in accordance with § 268.7(a) requirements.

(9) *Reporting by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals.* (i) *Biennial report by a pharmaceutical reverse distributor.* A pharmaceutical reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of a biennial report to the EPA Regional Administrator by March 1 of each even numbered year in accordance with § 262.41, except § 262.41(a)(7).

(ii) *Exception reporting by a pharmaceutical reverse distributor for a missing copy of the manifest.* (A) For shipments from a pharmaceutical reverse distributor to a designated facility:

(*1*) If a pharmaceutical reverse distributor does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the pharmaceutical reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(*2*) A pharmaceutical reverse distributor must submit an exception report to the EPA Regional Administrator for the Region in which the pharmaceutical reverse distributor is located if it has not received a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

(*i*) A legible copy of the manifest for which the pharmaceutical reverse distributor does not have confirmation of delivery; and

(*ii*) A cover letter signed by the pharmaceutical reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(B) For shipments rejected by the designated facility and shipped to an alternate facility:

(*1*) A pharmaceutical reverse distributor that does not receive a copy of the manifest with the handwritten signature of the owner or operator of the alternate facility within 35 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The 35 day timeframe begins the date the waste is accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

(*2*) A pharmaceutical reverse distributor must submit an Exception Report to the EPA Regional Administrator for the Region in which the pharmaceutical reverse distributor is located if it has not received a copy of the manifest with the handwritten signature of the owner or operator of the alternate facility within 45 days of the date the hazardous waste was accepted by the initial transporter. The 45-day timeframe begins the date the hazardous waste is accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility. The Exception Report must include:

(*i*) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(*ii*) A cover letter signed by the pharmaceutical reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(10) *Recordkeeping by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals.* (i) A pharmaceutical reverse distributor must keep a log (written or electronic) of the weekly inspections of the on-site accumulation area, required by paragraph (c)(2) of this section. This log must be retained as a record for at least three years from the date of the inspection.

(ii) A pharmaceutical reverse distributor must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility which received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(iii) A pharmaceutical reverse distributor must keep a copy of each biennial report for at least three years from the due date of the report.

(iv) A pharmaceutical reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(v) A pharmaceutical reverse distributor must keep records to document personnel training, in accordance with § 265.16.

(d) *When a pharmaceutical reverse distributor must have a permit.* A pharmaceutical reverse distributor is an operator of a hazardous waste treatment, storage or disposal facility and is subject to the requirements of 40 CFR parts 264, 265, and 267 and the permit requirements of 40 CFR part 270, if the pharmaceutical reverse distributor:

(1) Does not meet the conditions of this section;

(2) Accepts manifested hazardous waste from off-site; or

(3) Treats or disposes of hazardous waste on-site.

PART 268—LAND DISPOSAL RESTRICTIONS

■ 9. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

■ 10. Amend Section 268.7 by revising the section heading and the paragraph (a) subject heading to read as follows:

§ 268.7 Testing, tracking, and recordkeeping requirements for generators, pharmaceutical reverse distributors, treaters, and disposal facilities.

(a) *Requirements for generators and pharmaceutical reverse distributors:*

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* * * * *

■ 11. Amend § 268.50 by adding paragraphs (a)(4) and (5) to read as follows:

§ 268.50 Prohibitions on storage of restricted wastes.

(a) * * *

(4) A healthcare facility accumulates such wastes in containers on-site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the healthcare facility complies with the requirements in § 266.502 of this chapter.

(5) A pharmaceutical reverse distributor accumulates such wastes in containers on-site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the pharmaceutical reverse distributor complies with § 266.510 of this chapter.

* * * * *

PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT

■ 12. The authority citation for part 273 continues to read as follows:

Authority: 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

■ 13. Amend § 273.80 by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 273.80 General.

(a) Except as provided in paragraph (d), any person seeking to add a hazardous waste or category of hazardous waste to this part may petition for a regulatory amendment under this subpart and 40 CFR 260.20 and 260.23.

* * * * *

(d) Pharmaceutical hazardous waste is regulated by 40 CFR part 266, subpart P and may not be added as a category of hazardous waste for management under this part.

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