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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 260, 261, 264, 265, 268, 270 and 273

[EPA-HQ-RCRA-2007-0932; FRL [XXXX-X](#)]

RIN 2050-AG39

Amendment to the Universal Waste Rule: Addition of Pharmaceuticals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: EPA is proposing to add hazardous pharmaceutical wastes to the Universal Waste Rule. The Universal Waste Rule, originally promulgated on May 11, 1995, modified the Resource Conservation and Recovery Act’s hazardous waste regulations by establishing a set of streamlined requirements for the collection of certain widely-dispersed hazardous wastes, called “universal wastes.” This proposed rule would facilitate better management of pharmaceutical wastes by streamlining the generator requirements and encouraging generators of hazardous pharmaceutical wastes to manage them under the provisions of the Universal Waste Rule, which ensures that these hazardous pharmaceutical wastes are properly disposed of and treated as hazardous wastes. In addition, this proposed rule would facilitate the implementation of pharmaceutical take-back programs by removing RCRA barriers in the collection of pharmaceutical wastes from health care and other such regulated facilities, as well as facilitate the collection of pharmaceutical wastes from households, including non-hazardous pharmaceutical wastes.

DATES: Comments must be received on or before **[Insert date 60 days after**

publication in the Federal Register]. Under the Paperwork Reduction Act, since the Office of Management and Budget (OMB) is required to make a decision concerning the Information Collection Request (ICR) between 30 and 60 days after **[Insert date of publication in the Federal Register]**, a comment to OMB is best assured of having its full effect if OMB receives it by **[Insert date 30 days after date of publication in the Federal Register]**.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-RCRA-2007-0932, by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.
- Email: rcra-docket@epa.gov
- Fax: 202-566-9744
- Mail: **RCRA Docket**, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St. NW., Washington, DC 20503.
- Hand Delivery: EPA West Building, Room 3334, 1301 Constitution Avenue, NW., Washington, DC 20460. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-RCRA-2007-0932.

EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any

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Docket: All documents in the docket are listed in the www.regulations.gov index.

Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available

docket materials are available either electronically in www.regulations.gov or in hard copy at the RCRA Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the RCRA Docket is (202) 566-0270.

FOR FURTHER INFORMATION CONTACT: Lisa Lauer, Office of Solid Waste (5304P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: 703-308-7418; fax number: 703-605-0595; email address lauer.lisa@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This proposed rule could affect up to 634,552 entities in approximately 10 industries involved in health care and/or management of hazardous pharmaceutical wastes, as defined in this proposed rule. This includes pharmacies, hospitals, physicians' offices, dentists' offices, other health care practitioners, outpatient care centers, ambulatory health care services, residential care facilities, veterinary clinics and reverse distributors. Of these entities, EPA's Biennial Reporting System (BRS) indicates that approximately 181 are large quantity generators (LQGs) of hazardous waste. The remainder are likely to be either small quantity generators (SQGs) or conditionally-exempt small quantity generators (CESQGs). Under this proposal, hazardous

pharmaceutical waste generators may elect to have their hazardous pharmaceutical waste remain regulated under the current Resource Conservation and Recovery Act (RCRA) generator regulations as set forth in 40 CFR part 262, or may choose to manage their hazardous pharmaceutical wastes under the Universal Waste Rule (UWR). In RCRA-authorized states, the option of managing hazardous pharmaceutical waste under this proposal would be available once it has been adopted by the state.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through www.regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with the procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, Federal Register date and page number).
- Follow directions - The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible.
- Make sure to submit your comments by the comment period deadline identified.

3. *Docket Copying Costs.* Many documents are available only in the original and, therefore, must be photocopied. Patrons are allowed 100 free photocopies. Thereafter they are charged 15 cents per page. When necessary, an invoice stating how many copies were made, the cost of the order, and where to send a check will be issued to the patron.

Documents also are available on microfilm. The EPA/DC staff help patrons locate needed documents and operate the microfilm machines. The billing fee for printing microfilm documents is the same as for photocopying documents.

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I. Statutory Authority

These regulations are proposed under the authority of sections 2002(a), 3001, 3002, 3004, and 3006 of the Solid Waste Disposal Act of 1970, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), and as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6912(a), 6921, 6922, 6923, 6924, 6926, 6927, 6930 and 6937.

II. List of Abbreviations and Acronyms

| | |
|--------|---|
| AEA | Atomic Energy Act of 1954 |
| BRS | Biennial Reporting System |
| CERCLA | Comprehensive Environmental Response, Compensation, and Liability |

| | |
|-------|---|
| | Act |
| CESQG | Conditionally Exempt Small Quantity Generator |
| CFR | Code of Federal Regulations |
| CIV | Schedule IV Controlled Substance |
| CWA | Clean Water Act |
| DEA | Drug Enforcement Administration |
| DOE | Department of Energy |
| DOT | Department of Transportation |
| EPA | Environmental Protection Agency |
| FDA | Food and Drug Administration |
| HIPAA | Health Insurance Portability and Accountability Act |
| HSWA | Hazardous and Solid Waste Amendments of 1984 |
| IV | Intravenous |
| LD50 | Lethal Dose 50% |
| LDR | Land Disposal Restrictions |
| LQG | Large Quantity Generator |
| LQHUW | Large Quantity Handler of Universal Waste |
| NIOSH | National Institute for Occupational Safety and Health |
| NRC | Nuclear Regulatory Commission |
| OSHA | Occupational Safety and Health Administration |
| POTW | Publicly-Owned Treatment Works |
| RCRA | Resource Conservation and Recovery Act |
| RO | RCRA Online |

| | |
|--------|---|
| RQ | Reportable Quantity |
| SQG | Small Quantity Generator |
| SQHUUW | Small Quantity Handler of Universal Waste |
| TC | Toxicity Characteristic |
| TSDF | Treatment, Storage and Disposal Facility |
| UWR | Universal Waste Rule |

III. Introduction

This action proposes to add pharmaceutical wastes that are RCRA hazardous wastes to the universal waste system. Similar to other universal wastes, pharmaceutical wastes are produced by a large and diverse community of generators, often in small volumes. As discussed in the economic assessment prepared for this proposed rulemaking, over 600,000 individual facilities in the United States, including approximately 40,000 retail pharmacies, over 7,000 hospitals, and more than 300,000 physicians and dental offices, may be generators of hazardous pharmaceutical wastes. For example, it has been estimated that LQG hospitals in the United States generate a total of 10,600 tons of RCRA hazardous pharmaceuticals waste annually, while a single retail pharmacy may only generate 5 pounds of hazardous pharmaceutical wastes in a year (“Assessment of the Potential Costs, Benefits, and Other Impacts of Adding Pharmaceuticals to the Universal Waste Rule, as Proposed.” October 2008). Within these facilities, hazardous pharmaceutical waste may be generated in a single location (such as a pharmacy), or in multiple locations (such as hospital pharmacies, emergency rooms, operating rooms, and nursing stations) by many individuals. Pharmaceutical wastes may be RCRA hazardous because they contain any of 31 listed hazardous waste chemicals,

although many may be identified by a commercial name (rather than a chemical name), making it more difficult to readily identify them as potentially hazardous waste.

Some pharmaceutical wastes are hazardous wastes because they exhibit one or more of the four hazardous waste characteristics. This combination of a large number of individual generators, many with multiple generation points within their facilities, with a substantial number of chemicals potentially rendering pharmaceutical wastes RCRA hazardous, has made implementation of the RCRA hazardous waste regulations difficult for many of these facilities. The universal waste regulations help avoid such mismanagement by streamlining the collection requirements for certain hazardous wastes. The proposed rule may also reduce hazardous waste in the municipal solid waste stream by making it easier for universal waste handlers to collect these items and send them for proper disposal. Thus, expansion of the universal waste system to include hazardous pharmaceutical wastes may lead to better management of these wastes by providing a more streamlined, and effective waste management system. Due to the simplified requirements, this action, if finalized, would also provide regulatory relief to health care facilities, retail pharmacies, veterinary clinics and any other entities that generate hazardous pharmaceutical wastes. Moreover, this proposed rulemaking will alert generators of pharmaceutical wastes to the applicability of the RCRA hazardous waste regulations to their waste streams. Also, we anticipate that waste management systems established under this rule would facilitate the management of other pharmaceutical wastes, particularly those that may pose hazards if not properly managed, but are not regulated as hazardous under RCRA. Finally, the addition of hazardous pharmaceutical wastes to the Universal Waste program would facilitate the management

of pharmaceutical wastes via pharmaceutical take-back programs by removing RCRA barriers (e.g., hazardous waste determination, storage accumulation and time limits, etc.) for health care and other such regulated facilities that generate hazardous pharmaceutical wastes, as well as facilitate the collection of pharmaceutical wastes from households.¹

IV. Background

A. What Are the Current RCRA Generator Requirements Governing Hazardous Pharmaceutical Waste?

Any facility that generates RCRA hazardous pharmaceutical waste is subject to the RCRA generator regulations at 40 CFR part 262.² There are three categories of RCRA hazardous waste generators. A facility's generator status depends on the total amount of hazardous waste generated at the entire site in a calendar month, and that generator status determines the waste management requirements applicable to the facility under RCRA. Facilities that generate 1000 kg or more of hazardous waste per month, or greater than 1 kg of acute hazardous waste per month, are considered LQGs. Other facilities qualify as SQGs if they generate more than 100 kg per month, but less than 1000 kg per month of hazardous waste. SQGs are subject to fewer requirements than LQGs. For example, SQGs do not need to complete a biennial report, and have fewer personnel training and contingency planning requirements than LQGs (see 40 CFR 262.34(d)(5)). Additionally, facilities qualify as CESQGs if they generate less than or equal to 100 kg of hazardous waste per month, or less than or equal to 1 kg of acutely hazardous waste per month. CESQGs are not subject to the RCRA subtitle C hazardous

¹ The Agency notes that this rulemaking does not affect the Controlled Substance Act or regulations issued there under the Drug Enforcement Administration (DEA). Thus, organizers of collection events will still be required to contact DEA to ensure compliance with the federal laws and regulations concerning controlled substances.

² For more information on the current requirements for hazardous waste generators, please see the following EPA website: <http://www.epa.gov/osw/hazard/generation/index.htm>

waste regulations, provided that they comply with the requirements set forth in 40 CFR 261.5(f)(3) and (g)(3). Finally, under the household hazardous waste exclusion in 40 CFR 261.4(b)(1), hazardous wastes generated by households are not subject to the hazardous waste regulations.

Because RCRA generator status is determined on a monthly basis, it is possible that a generator's status can change from one month to the next, depending on the amount of hazardous waste generated in a particular month. This is commonly referred to as "episodic generation." If a generator's status does in fact change, the generator is required to comply with the respective regulatory requirements for that class of generators for any hazardous waste generated in that particular month (*i.e.*, LQG, SQG, CESQG).

B. How Are "Pharmaceutical" and "Pharmaceutical Universal Waste" Defined in This Proposal?

For the purposes of this proposed rule, "pharmaceutical" refers to "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 biohazardous waste, dental amalgams, medical devices not used for delivery or dispensing purposes, equipment, contaminated personal protective equipment or contaminated cleaning materials.”³ This proposed definition is meant to include, but is not limited to, pills or tablets, medicinal gums or lozenges, medicinal liquids, ointments and lotions, intravenous (IV) or other compounded solutions, chemotherapy drugs, vaccines, allergenic, medicinal shampoos, antiseptics and medicinal dermal patches, and any delivery devices with the primary purpose to deliver or dispense a chemical product, vaccine or allergenic.

In contrast, this definition does not include sharps (*e.g.*, needles from IV bags or syringes),⁴ infectious or biohazardous “red-bag” waste,⁵ waste chemicals from laboratories, medical devices (*e.g.*, blood pressure cuffs, mercury thermometers, x-ray films and fixers),⁶ dental amalgams, personal protective equipment contaminated with hazardous pharmaceuticals (*e.g.*, scrubs, gowns, gloves, *etc.*)⁷ or any materials used to clean up spills of hazardous pharmaceutical wastes. In addition, residues resulting from the manufacture, production, or distribution of such pharmaceuticals, including off-specification pharmaceutical products, are not considered pharmaceutical wastes for

³ Definition of “pharmaceutical” is adapted from the Federal Food, Drug and Cosmetic Act’s definition of “drug” (21 U.S.C. 321(g)(1)(B)).

⁴ Used sharps, such as needles or syringes with needles, are not included under this proposed rule as 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 to those sorting wastes and so have not be included in the proposed rule. See Technical Manual on Controlling Occupation Exposure to Hazardous Drugs found at http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html see (c)(1)(b) and Response Regarding Needlestick Injuries in the Sharps Recycling Industry (RO# 11778).

⁵ Infectious or biohazardous “red-bag” wastes are medical wastes, which are regulated at the state and local level.

⁶ Medical devices (with the exception of devices with a primary purpose of dispensing or delivering a chemical product, vaccine or allergenic) are not regulated under this proposal, since they do not fall within the definition of pharmaceutical. These wastes may be regulated when disposed based on whether or not they are listed or are characteristic hazardous wastes.

⁷ The Agency considers contaminated PPE to be comparable to clean-up materials as contaminated PPEs may be “different in form and composition from the universal waste they come from.” (60 FR 25528/3, May 11, 1995).

purposes of this proposal (see discussion of 40 CFR 273.81(b) at 60 FR 25514/1, May 11, 1995, which states that the Agency does not believe that wastes generated primarily in an industrial setting are appropriate for the universal waste system).

In addition, for the purposes of this rulemaking, the term “pharmaceutical universal waste” means a pharmaceutical that is a hazardous waste as defined in § 261.3, and containers (e.g., bottles, vials, IV bags, tubes of ointment/gels/creams, ampules, etc.) which have held any hazardous pharmaceutical waste and which would be classified as hazardous waste under § 261.7. The Agency decided to define “pharmaceutical universal waste” to ensure that any container which has held hazardous pharmaceutical wastes (and thus is also considered a hazardous pharmaceutical waste, unless that container is considered “RCRA-empty”^{8, 9}) could also be managed in the universal waste system. Please see section V.C. of this preamble for additional discussion on the inclusion of the definition of “pharmaceutical universal waste.”

The Agency is aware that the definitions in this proposed rule may overlap with similar definitions in other statutes implemented by other agencies. For example, the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Controlled Substances Act both

⁸ Under the current generator regulations, containers once holding listed wastes are themselves considered listed hazardous wastes due to the residues remaining in the containers (see 40 CFR 261.33(c)), unless the containers are “RCRA empty” in accordance with 40 CFR 261.7. A container holding a P-listed hazardous waste is considered “RCRA empty” if it has been triple-rinsed with an appropriate solvent or has been cleaned by a method that has been proven in scientific literature or by tests conducted by the generator to achieve the equivalent removal (see 40 CFR 261.7(b)(3)). A container holding a U-listed waste is considered “RCRA empty” if all wastes have been removed that can be removed using practices commonly employed to remove materials from the container and no more than one inch of residue or 3% by weight of the U-listed chemical remains if the container is less than or equal to 119 gallons in size (40 CFR 261.7(b)(1)).

⁹ EPA has interpreted 40 CFR 261.33 to mean that any syringe containing the residue of a P- or U-listed pharmaceutical is not considered a listed hazardous waste as the drug residue remaining in a syringe is considered to have been used for its intended purpose, and would be hazardous only if the residue exhibits a hazardous waste characteristic (see 54 FR 31335, 31336; July 28, 1989; “Epinephrine Residue in a Syringe is Not P042,” RCRA Online (RO) #13718; letter to Mr. Gary Chilcott (Sure-Way Systems Inc.) from Robert Dellinger RO # 14788).

define and regulate aspects of pharmaceuticals, and what the FFDCA considers a “device,” EPA may consider a “container.” Definitions from these other statutes should not be confused with those set out in this proposed rule. To avoid confusion, EPA has made an effort to use different terminology (such as “pharmaceutical” instead of the FFDCA term “drug”) and to provide definitions appropriate to waste management under the UWR framework in this proposed rule. Thus, in order to determine whether a particular waste may be managed as a pharmaceutical universal waste, the generator must look to the definitions in this proposed rule, and not rely on the definitions contained in other regulatory programs.

C. How Do the Current RCRA Hazardous Waste Regulations Apply to Generators of Pharmaceutical Waste?

1. Determining Whether Pharmaceutical Waste Is Subject to the Hazardous Waste Regulations

Any person who generates a “solid waste” is required by 40 CFR 262.11 to determine whether such waste meets the definition of RCRA hazardous waste. Proper hazardous waste determination is essential to the success, and is the foundation of, the “cradle to grave” RCRA hazardous waste program. The hazardous waste determination process can be simplified into several basic steps:

- 1) Is the material in question a solid waste (as defined in 40 CFR 261.2)?
- 2) Is the solid waste excluded from regulation as a hazardous waste under 40 CFR 261.4?
- 3) Is it or does it contain a hazardous waste listed in Subpart D of Part 261?
- 4) Does the waste exhibit any of the characteristics defined in Subpart C of Part

261 (ignitability, corrosivity, reactivity or toxicity)?

The RCRA hazardous waste generator regulations are applicable to all pharmaceutical wastes that meet the definition of “hazardous waste” set out in subtitle C of RCRA. Some pharmaceutical wastes are listed hazardous waste under 40 CFR 261.31-33, while some may exhibit one or more of the four chemical or physical characteristics of ignitability, corrosivity, reactivity or toxicity, as defined in 40 CFR 261.21-24. Others may qualify as “mixed waste” when they contain both hazardous waste subject to the requirements of RCRA and source, special nuclear, or byproduct material (*i.e.*, a radioactive component) subject to the requirements of the Atomic Energy Act of 1954 (AEA) (52 FR 15939, May 1, 1987).¹⁰ The following is a non-comprehensive list of chemicals that have pharmaceutical uses and which would, when discarded, be listed or characteristic hazardous wastes:

- P-listed pharmaceutical wastes¹¹ include arsenic trioxide (P012), phentermine (CIV) (P046, listed as alpha, alpha-dimethylbenzeneethanamine), epinephrine (P042),¹² physostigmine (P204), nicotine (P075), physostigmine salicylate (P188), nitroglycerin (P081), and warfarin (>0.3%) (P001).

¹⁰ As noted in the definition of pharmaceutical, pharmaceuticals that contain a radioactive component, such as mixed wastes, would not be eligible for management under the universal waste rule.

¹¹ The P- and U-lists list 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 (40 CFR 261.33(e)) and those on the U list are identified as toxic wastes (40 CFR 261.33(f)).

¹² The Agency clarified its regulation at 40 CFR 261.33, explaining that epinephrine salts are not included in the epinephrine P042 listing (since the listing only specifies epinephrine and not epinephrine salts); the salts, therefore, would be hazardous only if the waste epinephrine salt exhibited one or more of the hazardous waste characteristics (see “Scope of Hazardous Waste Listing P042 (Epinephrine),” October 15, 2007, RO# 14778).

- U-listed pharmaceutical wastes include chloral hydrate (CIV) (U034),¹³ paraldehyde (CIV) (U182), chlorambucil (U035), phenol (U188), cyclophosphamide (U058), reserpine (U200), daunomycin (U059), resorcinol (U201), dichlorodifluoromethane (U075), diethylstilbestrol (U089), selenium sulfide (U205), hexachlorophene (U132), streptozotocin (U206), lindane (U129), trichloromonofluoromethane (U121), melphalan (U150), uracil mustard (U237), mercury (U151), warfarin (<0.3%) (U248), and mitomycin C (U010).
- Characteristic¹⁴ pharmaceutical wastes include those that may exhibit the ignitability characteristic, such as solutions containing more than 24% alcohol. Others may exhibit the reactivity characteristic, such as nitroglycerine. Pharmaceuticals exhibiting the corrosivity characteristic are generally limited to compounding chemicals, including strong acids, such as glacial acetic acid, and strong bases, such as sodium hydroxide. Depending on the concentration in different pharmaceutical preparations, pharmaceuticals may also exhibit the toxicity characteristic (TC) because they contain arsenic (D004), barium (D005), cadmium (D006), chloroform (D022), chromium (D007), lindane (D013), m-cresol (D024), mercury (D009), selenium (D010), or silver (D011) at concentrations exceeding the regulatory criteria.

On the other hand, there are exceptions. Specifically, EPA has interpreted 40

¹³ EPA has interpreted the listing of chloral (U034) to include chloral hydrate (see letter to Elizabeth Knauss (Florida Department of Environmental Protection) from William Brandes; RO#14175).

¹⁴ Characteristic hazardous wastes are hazardous wastes that are not found on any of the lists, but are still hazardous waste because they exhibit one or more of the four characteristics defined in 40 CFR part 261, Subpart C.

CFR 261.33 to mean that any syringe containing the residue of a P- or U- listed drug is not considered a listed hazardous waste and would be hazardous only if the residue exhibits a hazardous waste characteristic (see “Epinephrine Residue in a Syringe is Not P042,” December 1994, RO# 13718). In addition, the P- and U-lists consist of commercial chemical products, which are defined as commercially pure grades and technical grades of the listed chemicals or chemical formulations in which the listed chemical is the sole active ingredient, which has not been used for its intended purpose (see 40 CFR 261.33(e) comment; 54 FR 31335, 31336; July 28, 1989). EPA considers such residues remaining in a syringe after administration to a patient to have been used for its intended purpose. Furthermore, the Agency clarified its regulation at 40 CFR 261.33, explaining that epinephrine salts are not included in the epinephrine P042 listing (since the listing only specifies epinephrine and not epinephrine salts); the salts, therefore, would be hazardous only if the waste epinephrine salt exhibited one or more of the hazardous waste characteristics (see “Scope of Hazardous Waste Listing P042 (Epinephrine),” October 15, 2007, RO# 14778). Finally, if a listed hazardous waste is listed solely because it exhibits the characteristics of ignitability, corrosivity and/or reactivity, and the waste does not exhibit the characteristic for which it was listed, then it is not a hazardous waste (66 FR 27286, May 16, 2001).¹⁵ As always, because local and state regulations can be broader (*i.e.*, more inclusive) or more stringent than the federal regulations, EPA recommends that the regulated community contact their local regulatory authorities to determine what exemptions and interpretations apply in their state.

2. Which Sources may Generate Hazardous Pharmaceutical Waste

¹⁵ Medicinal nitroglycerin may qualify for this exclusion as it typically does not exhibit the characteristic of reactivity (see explanation in RO #14654).

Subject to this Proposal?¹⁶

a. Health Care Facilities

Hazardous pharmaceutical wastes may be generated through a wide variety of activities in a number of different areas within a health care facility. For example, in the health care facility's pharmacy, waste may be generated by: IV preparation; general compounding¹⁷; spills from or breakage or damage to pharmaceutical containers; discontinued or unused preparations; unused unit dose repacks; and outdated pharmaceuticals. In the other areas of the health care facility, waste may be generated by partially used vials, syringes, and IVs containing pharmaceuticals, as well as patients' personal medications.¹⁸

At hospitals, pharmacies generally stock thousands of different items, each of which must be evaluated against state and federal hazardous waste regulations to determine whether any of the items would be considered a hazardous waste if discarded.¹⁹ In addition to the hospital pharmacy, pharmaceutical wastes are generated by health care workers at other locations across the hospital and are generally placed in waste bins in patient rooms, nursing stations, operating rooms and emergency rooms. At some hospitals, the wastes are then collected at a central location, such as the pharmacy

¹⁶ The Agency seeks comments on the following descriptions of current pharmaceutical waste handling practices. Specifically, how much pharmaceutical waste do health care facilities typically generate per month? Of that amount, what percentage is RCRA hazardous waste? What method of disposal are health care facilities utilizing for pharmaceutical wastes, including hazardous and non-hazardous? Additionally, the Agency seeks information regarding pharmaceutical waste management costs. In particular, what are the costs of collecting and treating hazardous pharmaceutical waste?

¹⁷ Compounding occurs when pharmacists formulate prescription medications specifically as prescribed by a physician for a patient. For more information, see http://www.iacprx.org/site/PageServer?pagename=What_is_Compounding

¹⁸ The Healthcare Environmental Resource Center and Practice Greenhealth. "Managing Pharmaceutical Waste: A 10-Step Blueprint for Health Care Facilities in the United States" (Revised August 2008). <http://www.hercenter.org/hazmat/tenstepblueprint.pdf>

¹⁹ Ibid.

or central accumulation area. At other hospitals, wastes may be picked up at the nursing stations by a contracted waste handling company. Hospitals, like other generators, are responsible for determining whether their wastes are RCRA solid wastes and, if so, whether they are hazardous wastes subject to regulation under RCRA subtitle C. The hospital must then manage the wastes accordingly.

Doctors' offices, veterinary clinics and other small health care facilities manage their pharmaceutical wastes in a similar manner as hospitals, although on a smaller scale. However, through communications with outside stakeholders, EPA understands that many health care facilities may be unaware of the applicability of the RCRA hazardous waste regulations to their hazardous pharmaceutical waste.

Many times, at health care facilities, pharmaceuticals are sent to a regulated medical waste incinerator (rather than a RCRA-permitted incinerator). Additionally, many health care facilities dispose of their pharmaceutical wastes down the drain.²⁰ EPA generally considers sewer disposal inadvisable for pharmaceuticals and discourages this practice, unless specifically required by the label. For these and other reasons, pharmaceutical waste management has become an increasingly critical issue in

²⁰ Under RCRA regulation 261.4(a)(1)(ii), EPA provides an exclusion from the definition of "solid waste" for "any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment." This RCRA domestic sewage exclusion can apply to industrial hazardous waste discharged to publicly owned treatment works (POTW) via a general use sewer system. EPA, acting under its authority under section 307(b) of the Clean Water Act (CWA), regulates in certain circumstances industrial discharges that are introduced to POTWs through a national pretreatment program. Section 307(b) and its implementing regulations at 40 CFR part 403 require that industrial facilities pretreat pollutants discharged to POTWs to the extent that these pollutants interfere with, pass through, or are otherwise incompatible with the operations of the POTW. Pretreatment requirements apply to pollutants introduced to a POTW by a user of the POTW whether introduced indirectly through sewers or directly (for example, by truck or rail). The RCRA domestic sewage exclusion however, does not apply if the industrial hazardous waste never mixes with sanitary waste in the pipe prior to treatment or storage at the POTW (*e.g.*, the hazardous waste arrives at the POTW via a dedicated pipeline or by truck or rail). In addition, if the mixture of hazardous waste and sanitary waste leaks from the sewer line prior to arriving at the POTW, this mixture does not qualify for the domestic sewage exclusion (see explanation in the March 10, 1997, letter to Mr. William Warren from David Bussard; RO#14068). Finally, please note that states may issue regulations that are more stringent or broader in scope than the federal hazardous waste regulations and, therefore, not all local environmental regulations include the domestic sewage exclusion.

environmental management for health care facilities.

b. Pharmacies

Pharmacies, such as those found in retail drug stores and health care facilities, including long-term care facilities, may be subject to the RCRA hazardous waste generator regulations. Pharmacies may generate hazardous pharmaceutical wastes via compounding or preparation, or if any portion of their pharmaceutical stock expires, is damaged, or is returned by the consumer. Pharmacies can stock thousands of different items, each of which must be evaluated against state and federal hazardous waste regulations to determine whether the item would be considered a hazardous waste when discarded.²¹ If the pharmacy's pharmaceutical wastes meet the RCRA definition of hazardous waste, the pharmacy would be considered a hazardous waste generator, subject to the requirements of its particular generator status.

c. Long-Term Care Facilities

Nursing homes, assisted living centers, and other long-term care facilities also may be subject to the RCRA hazardous waste generator regulations. However, many long-term care facilities may be unaware of the applicability of the RCRA hazardous waste regulations to their hazardous pharmaceutical waste.

Most long-term care facilities generate two types of hazardous pharmaceutical waste. First, the 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

²¹ The Healthcare Environmental Resource Center and Practice Greenhealth. "Managing Pharmaceutical Waste: A 10-Step Blueprint for Health Care Facilities in the United States" (Revised August 2008). <http://www.hercenter.org/hazmat/tenstepblueprint.pdf>

resulting wastes are generated by that facility (see 40 CFR part 262). The long-term care facilities, like other generators, are responsible for determining whether the wastes it generates are hazardous wastes subject to regulation under RCRA subtitle C. If so, the facility must then manage the wastes accordingly. Long-term care facilities face many of the same issues that health care facilities and pharmacies do in managing hazardous pharmaceutical waste, as discussed above.

Secondly, 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 (40 CFR 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.

d. Reverse Distributors of Pharmaceuticals

Based on information provided by reverse distribution companies, the Agency understands that pharmaceutical manufacturers often offer credit on the return of their unused or expired pharmaceuticals as a financial incentive to pharmacies, hospitals and other health care facilities to stock their products, (since many drugs are expensive and may have short shelf lives). Reverse distributors of pharmaceuticals provide a service to the health care industry by keeping track of the manufacturer return policies and facilitating the return of these unused or expired drugs for potential credit from the manufacturer. In addition, this reverse distribution system for pharmaceuticals helps ensure that unused and expired pharmaceuticals do not get diverted to inappropriate uses, and that the returned pharmaceuticals, are managed appropriately.

Because unused or expired pharmaceuticals are being returned (via the reverse distributor) for possible manufacturer credit, they still have potential value to the pharmacy or hospital and are thus not considered wastes. Therefore, when a health care facility hires a reverse distributor to manage its unused/expired pharmaceuticals, the health care facility can ship the unused or expired pharmaceuticals by using commercial carriers or mail-in services. Once the unused or expired pharmaceuticals reach the reverse distributor, the reverse distributor determines which drugs are eligible for credit from the manufacturer or distributor, and ensures that the health care facility receives the proper credit. Once credit is recorded (for eligible drugs), the manufacturer will instruct the reverse distributor to either dispose of the drug or to ship it back (to the manufacturer's facility). Thus, for those credited pharmaceuticals that the manufacturer has instructed the reverse distributor to dispose of, and for those pharmaceuticals not eligible for credit, reverse distributors must determine which are RCRA solid and hazardous wastes. Then, they must manage all such wastes in accordance with federal, state, and/or local environmental regulations.

The Agency notes that this discussion pertains only to reverse distributors of pharmaceuticals and does not attempt to describe reverse distribution systems that may exist for any other consumer product. EPA requests comment on the accuracy of this description of the functions and operations of reverse distributors of pharmaceuticals, and solicits any additional information and data regarding the operations, material and waste handling procedures (including the handling of hazardous wastes) of reverse distributors of pharmaceuticals. EPA also solicits comment on its understanding of when it is determined that unused and/or expired pharmaceuticals managed in pharmaceutical

reverse distribution systems become waste, and hence potentially subject to the universal waste regulations proposed in this rule.

e. Pharmaceutical Take-Back Programs

Pharmaceutical take-back or collection programs are periodic or on-going events intended to allow patients and consumers to bring their unused drugs to a central location, such as a local pharmacy or police station for proper management and disposal. Some communities have begun to arrange these programs for their citizens, but they are not widely available. Take-back programs generally facilitate the proper handling and disposal of drugs that may be hazardous wastes under RCRA.²² Household hazardous wastes are not required to be managed under the federal RCRA hazardous waste management scheme. However, once such household hazardous pharmaceutical wastes are consolidated at the collection point, most communities manage the waste in compliance with the full hazardous waste management regulations, even though such wastes retain their household hazardous waste exemption.²³

The Agency supports the establishment of these take-back programs as they redirect hazardous and non-hazardous pharmaceutical wastes generated by households, from municipal trash handling systems and sewer systems to hazardous waste management facilities. It should be noted that in establishing and operating pharmaceutical take-back programs, community organizers should seek input from their state and/or local environmental agencies. Additionally, they must seek assistance from the U.S. DEA to ensure the programs comply with federal laws and regulations

²² Links for finding pharmaceutical take-back programs are listed at:
<http://www.epa.gov/ppcp/links.html#state>.

²³ Please check with state and local environmental regulations as some may be more stringent than the federal regulation and may require that collected household hazardous wastes be managed as hazardous wastes.

concerning the handling and management of controlled substances.²⁴ This proposed action does not alter any federal statutory or regulatory requirements relating to controlled substances; thus all take-back programs must maintain compliance with the Controlled Substances Act and DEA regulations.

While EPA believes that this rulemaking, if finalized, will simplify pharmaceutical take-back programs by streamlining the requirements for handling hazardous pharmaceutical wastes received as part of a take-back program,²⁵ the Agency seeks comment on how this proposed action may affect community take-back programs. Beyond the take-back programs themselves, EPA seeks comments on whether this rulemaking could have unforeseen consequences in the generation, characterization, and management of hazardous pharmaceutical wastes that would potentially increase risks to human health or the environment.

D. Why is Management of Pharmaceutical Waste Difficult under the RCRA Subtitle C Hazardous Waste Regulations?

In its proposal for the Universal Waste management system, EPA discussed the differences between large industrial or manufacturing facilities' generation of hazardous waste and hazardous waste generation by commercial, non-manufacturing entities (58 FR 8102, February 11, 1993). In that discussion, the Agency expressed concern about the difficulties of implementing the RCRA hazardous waste regulatory program for commercial products that are hazardous when discarded at the end of their useful life, which are widely dispersed in commerce, and which may be generated as waste in

²⁴ Without law enforcement involvement, these programs are not able to accept narcotics or other drugs that are controlled substances under DEA regulations, which preclude transfer of a controlled substance originally prescribed to a patient to any other entity, with the exception of law enforcement officers.

²⁵We believe this proposal would remove RCRA barriers for health care and other such regulated facilities that generate hazardous pharmaceutical wastes, as well as facilitate the collection of pharmaceutical wastes from households.

relatively small volumes by large numbers of generators nationwide. Pharmaceuticals, when discarded, are such wastes. Specifically, pharmaceutical waste is generated at a large number of facilities nationwide, potentially at several locations within a facility, such as at hospital nursing stations, pharmacies, and patient, emergency and operating rooms, and typically in relatively small quantities. Furthermore, thousands of pharmaceuticals are approved for use, so individual generators of hazardous pharmaceutical wastes may generate hundreds of different types of pharmaceutical waste, some of which may be regulated as RCRA hazardous, and some of which are not.²⁶ Sorting out the RCRA regulated pharmaceutical wastes from the non-hazardous pharmaceutical wastes at a hospital nursing station or emergency room can be difficult, and establishing separate collection of these small volumes of hazardous waste from multiple points within a facility, such as a hospital, in particular, can be complicated and burdensome for these generators. In contrast, industrial generators tend to generate only a few predictable waste streams in large quantities at relatively few generation points in the facility.

The Agency's information about pharmaceutical waste management is limited. However, we do know that there are over 7,000 hospitals, and approximately 72,000 long-term-care facilities, 27,000 veterinary care facilities, 40,000 retail pharmacies, and several hundred thousand office's of doctors, dentists and other health care service providers in the United States, all of which are likely to generate some volume of pharmaceutical wastes and many of which will generate some that are RCRA hazardous.

²⁶ See discussion in Section IV.C.1 above. There are approximately 31 chemical ingredients used in drugs that are P or U listed, and which may make the waste drugs RCRA hazardous. This may translate into a hundred or more different commercial products. For example, warfarin and salts (P001) is used in at least 6 commercial pharmaceutical products, and Memphian (U150) is used in 5 products. Further, pharmaceuticals may also contain chemicals from the TC regulatory list, such as arsenic or chromium (please see 40 CFR 261.24 for a complete list of TC chemicals and their regulatory thresholds).

Yet, based on the 2005 Biennial Report, only 94 hospitals and 19 pharmacies, for example, reported themselves to be LQGs of hazardous waste, and no long-term care or veterinary care facilities did so. While the vast majority of pharmaceutical waste generators are undoubtedly SQGs or CESQGs, information provided by generators themselves show a low level of knowledge about RCRA and its regulatory requirements, even on the part of some large facilities.

The following sections provide an overview of some of the difficulties that generators of hazardous pharmaceutical waste have expressed concerning the current hazardous waste generator regulations.

1. Waste Determination

As a result of communications with pharmaceutical waste generators, the Agency understands that numerous health care facilities are either unaware of how the hazardous waste regulations apply to pharmaceutical wastes or, even if there is knowledge of RCRA, they have problems with training the workers that are generating these wastes on how to manage hazardous wastes properly.

Other issues compound these difficulties in making hazardous waste determinations for pharmaceutical wastes. Pharmacists, nurses, and other health care workers generally do not receive training on hazardous waste management during their academic studies, while safety and environmental service managers may not be familiar with the active ingredients and formulations of the hundreds of available pharmaceutical products that may be used at a health care facility to enable them to make hazardous waste determinations.²⁷ Yet these health care workers are often the generators of

²⁷ The Healthcare Environmental Resource Center and Practice Greenhealth. "Managing Pharmaceutical Waste: A 10-Step Blueprint for Health Care Facilities in the United States" (Revised August 2008).

pharmaceutical wastes. Environmental service managers cannot be present as pharmaceutical wastes are being generated to make a hazardous waste determination and implement proper waste management. Making a hazardous waste determination is a multi-step process. First, generators must determine if the pharmaceutical waste in question is a solid waste (as defined in 40 CFR 261.2). If the pharmaceutical is a solid waste, then the generator must determine if it is a solid waste excluded from regulation. If the waste is not excluded, the generator must determine whether the pharmaceutical waste is a listed hazardous waste in subpart D of Part 261. If the solid waste is not or does not contain a listed hazardous waste, the worker must then determine whether the solid waste exhibits any of the hazardous characteristics defined in subpart C of Part 261. While the hazardous waste determination could be made for pharmaceuticals that may become waste before they leave the pharmacy (by the pharmacists and the environmental manager together), implementing a separate collection system for these small volumes of hazardous pharmaceutical wastes could be burdensome, particularly in facilities with multiple points of generation.

Failure to comply with the hazardous waste regulations by improperly managing and disposing of such waste can and has resulted in violations of the RCRA hazardous waste regulations, leading to large penalties for all types of health care facilities, from doctors' and veterinarians' offices and clinics, to pharmacies, long-term care facilities, and hospitals (see Profile of the Health Care Industry, EPA Office of Compliance Sector Notebook Project, EPA Publication # EPA/310-R-05-002, also found at <http://www.epa.gov/compliance/resources/publications/assistance/sectors/notebooks/health>

<http://www.hercenter.org/hazmat/tenstepblueprint.pdf>

h.pdf).

In addition to the hazardous waste regulations, pharmaceuticals are subject to a number of other statutes administered by other federal agencies and their regulatory regimes, and health care facilities have expressed confusion regarding the overlap between these other regulations and the hazardous waste requirements. Examples include pharmaceuticals that are controlled substances and subject to the Controlled Substances Act and DEA regulations; pharmaceuticals that have been prescribed to a patient and are subject to the Health Insurance Portability and Accountability Act (HIPAA) patient privacy requirements; pharmaceuticals with a radioactive component and are subject to the Atomic Energy Act (AEA); and infectious pharmaceutical wastes that are subject to state and local medical waste regulations.²⁸ These potentially overlapping requirements (both with RCRA and with each other) make the appropriate management of pharmaceutical wastes a complex matter.

2. Change in Generator Status From Conditionally Exempt Small Quantity Generators to Large Quantity Generators Due to Generation of Acutely Hazardous Wastes

Hospitals and other health care facilities have also reported that their RCRA hazardous waste generator status periodically shifts from CESQG to LQG status due to the acutely hazardous (P-listed) pharmaceutical wastes they generate, since P-listed wastes have a low threshold for triggering a change in generator status (as CESQGs cannot generate or accumulate more than one kilogram per month), and CESQGs could find themselves easily exceeding this threshold to become a LQG. In addition, the

²⁸ Some state and local regulations may be more stringent than others regarding the regulation of infectious wastes. Some states require that wastes that are both infectious and hazardous be treated for both properties, whereas other states require that these “dual” wastes be treated as hazardous.

requirements that containers once holding P-listed hazardous wastes are themselves considered P-listed hazardous wastes (see 40 CFR 261.33(c)), unless considered “RCRA empty” either by triple-rinsing with an appropriate solvent²⁹ or cleaning by a method that has been proven in scientific literature or by tests conducted by the generator to achieve the equivalent removal (see 40 CFR 261.7(b)(3)) can also contribute to a change in generator status. Therefore, in the event that such containers have not been properly cleaned, the weight of these containers that hold, or that have held, P-listed wastes quickly add up to exceed one kilogram, pushing facilities into LQG status and, thus, subjecting them to more stringent requirements than facilities with SQG or CESQG status. These requirements clearly add to the complexity and burden of managing pharmaceutical waste appropriately under the RCRA hazardous waste regulations and, given the number of different pharmaceuticals generated as waste and their small volumes, the benefit of the additional P-list requirements may not always be commensurate with the burden they impose.

3. Accumulation Time Limits

Health care facilities and other pharmaceutical waste generators also express concern that the accumulation time limits for hazardous waste generators are not cost-effective with regard to hazardous pharmaceutical wastes. Pharmaceutical wastes are typically packaged and accumulated in relatively small volumes, so it can take a significant amount of time for a health care facility to accumulate enough waste to make offsite shipment using a hazardous waste transporter cost-efficient. Thus, health care facilities have advocated longer accumulation times for hazardous pharmaceutical wastes.

²⁹ The rinsates from the triple-rinsing of containers which have held commercial chemical products listed in 40 CFR 261.33(e) are also RCRA hazardous wastes because of the “mixture and derived-from rule” (see 40 CFR 261.3(a)(2)(iv)).

E. What is the Universal Waste Rule?

This proposed rule would incorporate hazardous pharmaceutical wastes into 40 CFR part 273, the UWR. The UWR was promulgated on May 11, 1995 (60 FR 25491), modifying the hazardous waste regulations by establishing a set of streamlined requirements for the collection of certain widely-dispersed hazardous wastes, which are called “universal wastes.” The UWR is designed to accomplish three general goals (see 58 FR 8105-8106, February 11, 1993; and 60 FR 25501-25502, May 11, 1995):

- To encourage resource conservation.
- To improve implementation of the current RCRA subtitle C hazardous waste regulatory program.
- To separate universal waste from the municipal waste stream.

The current federal universal wastes system includes hazardous waste batteries, certain hazardous waste pesticides, mercury-containing equipment, and hazardous waste lamps. These wastes share several characteristics (see 60 FR 25493, May 11, 1995): they are frequently generated in a wide variety of settings, often in settings other than the industrial settings usually associated with hazardous wastes; they are generated by a large community, the size of which poses implementation difficulties for both those facilities that are regulated and the regulatory agencies charged with implementing the hazardous waste program; and they may be present in significant volumes in non-hazardous waste management systems.

Under the UWR, handlers and transporters who generate or manage items designated as a universal waste are subject to the management standards under 40 CFR 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 wastes” (LQHUU; those who handle more than 5,000 kilograms of total universal waste at one time) and “small quantity handlers of universal waste” (SQHUU; those who handle 5,000 kilograms or less of universal waste at one time). The 5,000 kilogram accumulation criterion applies to the quantity of all universal wastes accumulated. The streamlined standards include modified requirements for storage, labeling and marking, preparing the waste for shipment off site, employee training, responses 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. The primary difference between the universal waste transporter requirements and the subtitle C transportation requirements is that no manifest is required for the transport of universal waste. The details of the universal waste management standards for both handlers and transporters will be addressed later in this preamble.

Under the UWR, destination facilities are those facilities that treat, store, dispose, 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. Hazardous waste recycling facilities that do not store hazardous wastes prior to recycling may be exempt from permitting under the federal regulations (40 CFR 261.6(c)(2)).

Finally, states that are authorized to implement the UWR may add wastes that are not federal universal wastes to their lists of universal wastes. Therefore, in some states, hazardous pharmaceutical wastes may already be regulated as universal wastes.

F. Why is Pharmaceutical Waste Appropriate for Inclusion in the Universal Waste Framework?

The Agency expects that the addition of hazardous pharmaceutical wastes to the UWR will improve the management of such pharmaceutical wastes by providing a more streamlined waste management system, while ensuring that they are sent to hazardous waste management facilities for final disposal. In addition, this proposed rulemaking would increase the accumulation and storage time limits in comparison to the full RCRA subtitle C hazardous waste regulations for hazardous pharmaceutical wastes, which would allow facilities to accumulate enough waste to make shipment through a hazardous waste hauler more cost-effective. Finally, while not required, this proposed rulemaking could facilitate the management of non-RCRA pharmaceutical wastes as universal wastes. If facilities choose to manage these non-RCRA pharmaceutical wastes as universal wastes, then: 1) health care and other regulated facilities would no longer need to identify and separate hazardous pharmaceutical wastes from non-hazardous pharmaceutical wastes; and 2) the regulated community could decide to develop drug take-back programs, resulting in a decrease in the disposal of pharmaceutical wastes in municipal solid waste disposal facilities.

EPA considers eight factors when evaluating whether or not it is appropriate to include a particular waste or wastes in the universal waste system. The factors were designed to determine whether regulating a particular hazardous waste under the streamlined standards of the UWR would improve overall management of the waste. These factors, which are codified at 40 CFR 273.81, are: (1) the waste, or category of waste, as generated by a wide variety of generators, should be a listed or characteristic hazardous waste; (2) the waste, or category of waste, should not be exclusive to a

particular industry or group of industries, but generated by a wide variety of establishments; (3) the waste, or category of waste, should be generated by a large number of generators and generated frequently, but in relatively small quantities; (4) the systems to be used for collecting the waste, or category of waste (including packaging, marking and labeling practices), should ensure close stewardship of the waste; (5) the risks posed by the waste, or category of waste, during accumulation and transport should be relatively low compared to the risks posed by other hazardous waste, and specific management standards would be protective of human health and the environment during accumulation and transport; (6) the regulation of the waste, or category of waste, under 40 CFR part 273 will increase the likelihood that the waste will be diverted from non-hazardous waste management systems (*e.g.*, the municipal solid waste stream) to recycling, treatment or disposal in compliance with subtitle C of RCRA; (7) the regulation of the waste, or category of waste, under 40 CFR part 273 will improve the implementation and compliance with the hazardous waste regulatory program; and (8) such factors as may be appropriate.

The Agency weighed these factors collectively, rather than individually, when deciding to propose to add hazardous pharmaceutical waste to the universal waste system; however, as discussed in the final preamble of the UWR (60 FR 25492, May 11, 1995), it is not necessary for a particular waste or wastes to meet every factor to be classified as a universal waste (see 60 FR 25513). The following section discusses how pharmaceutical wastes meet these factors, and EPA solicits comment on the applicability of these factors to hazardous pharmaceutical wastes.

1. *The Waste, or Category of Waste, as Generated by a Wide Variety of*

Generators, Should Be a Listed or Characteristic Hazardous Waste: Several prescribed and over-the-counter pharmaceuticals, when discarded, are either listed hazardous wastes themselves or may contain a listed hazardous chemical as the sole active ingredient.³⁰ For example, coumadin (listed as warfarin as P001 and as U248),³¹ and products containing nicotine (listed as P075), as the sole active ingredient, are listed hazardous wastes.³² Other pharmaceuticals exhibit one or more characteristics of hazardous waste--ignitability, corrosivity, reactivity and/or toxicity. For example, certain topical preparations, including Cleocin T, Erythromycin topical solution and Retin A gel may exhibit the ignitability characteristic. Acetic acid and sodium hydroxide are corrosive and certain nitroglycerin formulations may be reactive. Finally, mercury, arsenic, barium and other pharmaceuticals containing these metals may exhibit the TC.

2. The Waste, or Category of Waste, Should Not Be Exclusive to a Particular Industry or Group of Industries, But Generated by a Wide Variety of Establishments:

Pharmaceutical wastes are generated by a variety of generators including, but not limited to: doctors' offices; veterinary clinics and hospitals; morgues; retail pharmacies; long-term care facilities; hospitals; reverse distributors; and households. These entities engage in diverse activities and, as a result, generate varying amounts of hazardous pharmaceutical waste. Therefore, these generators come from a variety of sectors and range in generator status (LQG, SQG, or CESQG) to being exempt from the RCRA

³⁰ If a chemical is listed on the P-list, then its container must also be managed as a hazardous waste, unless it has been declared "RCRA empty" via triple-rinsing see (40 CFR 261.7(b)(3) and 261.33(c)). Rinsates must also be managed as a hazardous waste because of the "mixture and derived-from rule" (see 40 CFR 261.3(a)(2)(iv)). A container of U-listed waste must be managed as hazardous waste unless the waste is removed using practices commonly employed to remove material and no more than one inch of residue or 3% by weight of the U-listed chemical remains if the container is less than or equal to 119 gallons in size (40 CFR 261.7(b)(1)).

³¹ The P001 listing applies to warfarin and its salts when present at concentrations greater than 0.3 percent, and the U248 listing applies to warfarin and its salts when present at concentrations of 0.3 percent or less.

³² Please refer to 40 CFR 261.33 for the complete lists of P- and U-listed hazardous wastes.

hazardous waste regulations under the household hazardous waste exclusion (40 CFR 261.4(b)(1)) to LQGs.

3. *The Waste, or Category of Waste, Should Be Generated by a Large Number of Generators and Generated Frequently, But in Relatively Small Quantities:* As described above, EPA believes that hazardous pharmaceutical wastes are generated by a wide range of generators from different sectors across the country. EPA believes that hazardous pharmaceutical wastes are also generated by a large number of generators as pharmaceuticals are commonly used for diagnosing, treating, or preventing an extremely broad range of medical problems and for cosmetic and lifestyle purposes. Health care facilities use pharmaceuticals on a daily basis and, thus, many also generate hazardous and non-hazardous pharmaceutical waste on a daily basis. Data from EPA's primary repository for information reported by LQGs, the 2005 BRS, indicate that there is a limited number of health care-related LQGs of hazardous pharmaceutical waste. The 2005 BRS lists approximately 94 hospitals, 13 reverse distributors, 22 physician's offices, 19 pharmacies, 19 outpatient care centers, and 6 ambulatory care centers in the United States that are LQGs generating hazardous pharmaceutical wastes. However, these BRS data do not represent households, CESQGs, or SQGs. In addition, these data do not represent any facilities that fail to report their RCRA-regulated hazardous waste generation activities, although, as discussed above, EPA believes that many health care-related facilities are unaware of their RCRA obligations. Therefore, the BRS data likely under-represents the total number of hazardous pharmaceutical waste generators in the U.S. Conversely, the BRS data may actually indicate that in the majority of healthcare-related facilities, small amounts of hazardous pharmaceutical wastes are generated, but

not enough to categorize them as LQGs; or that many healthcare-related facilities are unaware of the RCRA hazardous waste requirements governing hazardous pharmaceutical wastes. Thus, the Agency believes that the generation of hazardous pharmaceutical waste is frequent and widespread, and it is generated in small amounts. However, the Agency solicits comment on this factor and specifically, any data that may be available regarding the number of generators that generate hazardous pharmaceutical waste, the frequency of generation, and the quantities that are generated.

4. *Systems To Be Used for Collecting the Waste, or Category of Waste (Including Packaging, Marking and Labeling Practices), Should Ensure Close Stewardship of the Waste:* As discussed in the preamble of the 1995 UWR (60 FR 25514, May 11, 1995), the goal of this factor is to add those wastes to the universal waste system that are most likely to be collected in a manner that ensures good management. EPA believes that adding hazardous pharmaceutical wastes to the UWR will, by streamlining some waste handling requirements, ensure the close stewardship of these wastes as it will: 1) help ensure the safe management of hazardous pharmaceutical wastes; 2) encourage the management of non-RCRA pharmaceutical wastes as universal wastes; and 3) facilitate pharmaceutical collection (take-back) programs. In addition, the packaging and labeling practices required for universal wastes will further: 1) ensure that any hazardous pharmaceutical wastes being managed as universal wastes must be packed in containers that are structurally sound and compatible with the waste (see section V.D.1 for further discussion), and the container must be labeled appropriately with the words “Universal Waste – Pharmaceuticals” or “Waste Pharmaceuticals” (see section V.E for further discussion); and 2) provide a framework for the management of any

pharmaceutical waste that is not a RCRA listed or characteristic hazardous waste, but nevertheless may be hazardous to human health and the environment, and which the generator decides to manage as a universal waste, to be packed in appropriate containers and labeled as a universal waste as opposed to being disposed of in trash cans, containers containing sharps, or in sewers.

5. Risks Posed by the Waste, or Category of Waste, During Accumulation and Transport Should Be Relatively Low Compared to the Risks Posed by Other Hazardous Waste, and Specific Management Standards Would Be Protective of Human Health and the Environment During Accumulation and Transport: Compared to other hazardous wastes, the environmental risks posed by most hazardous pharmaceutical wastes during accumulation and transport are relatively low. Most hazardous pharmaceutical wastes present a relatively low risk during accumulation and transport due to their form and packaging, which is typically in small, individually packaged doses, such as pills, capsules, or small vials. These small volumes of individually wrapped or packaged pharmaceuticals, when aggregated in a larger container, are unlikely to spill or be released into the environment since they are essentially double-packed when accumulated for disposal. Other pharmaceuticals, such as liquids and aerosols, 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 UWR container requirements would likely obviate this risk.

6. Regulation of the Waste, or Category of Waste, Under 40 CFR Part 273 Will Increase the Likelihood that the Waste Will Be Diverted From Non-Hazardous Waste Management Systems (e.g., the Municipal Solid Waste Stream) to Recycling,

Treatment or Disposal in Compliance with Subtitle C of RCRA: EPA expects the addition of pharmaceutical wastes to the universal waste system will increase the diversion of hazardous pharmaceutical wastes from non-hazardous waste management systems, as the streamlined UWR requirements will facilitate collection and disposal in accordance with the RCRA hazardous waste requirements of hazardous pharmaceutical wastes generated by households. In addition, identifying pharmaceuticals under the universal waste system also will likely divert non-hazardous pharmaceutical wastes from non-hazardous waste management systems.

Additionally, regulation of hazardous pharmaceutical wastes under the UWR will facilitate the collection of commingled hazardous and non-hazardous pharmaceutical wastes at healthcare-related and other such facilities.

7. *Regulation of the Waste, or Category of Waste, Under 40 CFR Part 273 Will Improve the Implementation and Compliance with the Hazardous Waste Regulatory Program:* Participation in the universal waste program by handlers of hazardous pharmaceutical wastes will improve implementation of and compliance with the hazardous waste regulations. Because hazardous pharmaceutical waste is often generated in small quantities by a diverse array of generators, such as hospitals, pharmacies, physicians' offices and veterinary clinics, among others, that are unfamiliar with or confused by the full RCRA hazardous waste rules, compliance with the full subtitle C hazardous waste requirements is difficult to achieve. Rather, we believe that these generators will find the UWR regime simpler and easier to follow and are thus more likely to comply with its requirements.

For the above reasons, the Agency is proposing to add pharmaceutical wastes to

the Universal Waste framework.

G. How Will Adding Hazardous Pharmaceutical Wastes to the Universal Waste Rule Help Address Pharmaceutical Waste Management Issues?

1. Application of the Universal Waste Rule to Pharmaceutical Wastes

EPA believes that hazardous pharmaceutical wastes share the characteristics of other universal wastes discussed above. Specifically, most hazardous pharmaceutical wastes present a relatively low risk during accumulation and transport due to their form and packaging, which is typically in small, individually packaged dosages, such as pills or capsules. Hazardous pharmaceutical wastes are frequently generated in a wide variety of settings, including hospitals, pharmacies, long-term care facilities, veterinary offices and by reverse distributors, among others. They also are generated by several different types of personnel at these facilities, including pharmacists, doctors, nurses, and individual consumers. In addition, the RCRA hazardous waste management requirements often are unfamiliar to health care workers, retail pharmacy employees and other generators, prompting them to improperly dispose of hazardous pharmaceutical wastes as municipal or bulk wastes. This proposed action would streamline the current regulations governing these wastes, ensuring that larger quantities of hazardous pharmaceutical wastes are managed properly. Furthermore, this proposed rulemaking will bring to the generators' attention that hazardous pharmaceutical wastes are subject to the RCRA hazardous waste regulations.

The UWR is specifically designed to reduce the complexity of the RCRA hazardous waste generator regulations for universal wastes. It streamlines the collection and handling requirements for widely-dispersed hazardous wastes and facilitates their

inclusion in the hazardous waste management system. By proposing to incorporate hazardous pharmaceutical waste in the universal waste regulations, EPA expects the management of hazardous pharmaceutical wastes to improve, while decreasing the regulatory burden for many hazardous pharmaceutical waste generators, large and small.

The UWR also allows handlers to transport such materials with a common carrier that abides by the regulations set forth in Subpart D of the UWR, rather than a hazardous waste transporter, and generally would no longer require a handler to manifest waste to destination facilities.³³ Furthermore, while the UWR regulates only RCRA hazardous wastes, the Agency anticipates that including pharmaceutical wastes in the UWR will encourage persons to manage other pharmaceutical wastes in the same manner, particularly those wastes that are not hazardous under RCRA, but which may nonetheless pose risks. Moreover, EPA expects that including hazardous pharmaceutical wastes in the UWR will facilitate the implementation of pharmaceutical take-back programs for retailers and commercial generators of such wastes preventing mismanagement. Thus, the Agency expects that increased quantities of pharmaceutical wastes will be managed in destination facilities that are subject to the full RCRA subtitle C regulatory controls, as opposed to non-hazardous waste landfills and combustors. The Agency requests comment on the likelihood that the addition of pharmaceutical wastes to the universal waste system will increase the quantities of pharmaceutical wastes sent to hazardous waste management facilities.

a. Waste Determination

This proposal would streamline the hazardous waste identification process for

³³ If the universal waste will be transported through a state that does not recognize the waste as a universal waste, then a manifest must accompany the shipment for that portion of the trip.

pharmaceutical waste generators in a number of ways. Specifically, the universal waste rule does not distinguish between acutely hazardous P-listed wastes and other hazardous wastes. As a result, handlers³⁴ of pharmaceutical universal wastes would not be required to separate P-listed wastes from other hazardous wastes for purposes of tracking the volumes generated or accumulation volume limits. Additionally, while the proposal would cover only those wastes that are hazardous under the RCRA hazardous waste regulations, the streamlined management requirements may encourage facilities to manage the non-hazardous portion of the waste stream in a similar manner as the hazardous portion. That is, it could simplify the waste determination process by providing, but not requiring, the opportunity for all pharmaceutical wastes, hazardous or not, to be managed as a single waste stream.

b. Accumulation Time and Generation Volume Limits

As discussed above, handlers of universal waste are eligible for longer on-site accumulation time limits when compared to generators of hazardous waste (non-universal wastes). Also, while SQGs are subject to the hazardous waste generation volume limits of 1,000 kilograms per month, small quantity handlers of pharmaceutical universal waste would be subject to a higher threshold of 5,000 kilograms of all universal waste at any one time.

EPA expects these increased generation volumes and accumulation time limits for pharmaceutical universal waste to address the episodic generator status due to the generation of P-listed hazardous pharmaceutical wastes, which is currently affecting

³⁴ A handler of universal waste can be a person who generates, or creates, universal waste. A handler can also be a person who receives universal waste from generators or other handlers, consolidates the waste, and then sends it on to other handlers or treatment or disposal facilities. Universal waste handlers accumulate universal waste, but do not treat, recycle or dispose of them. See Section V.B.3. for further discussion.

some hazardous pharmaceutical waste generators. EPA believes that the provisions proposed in this rulemaking would not increase the risk posed by the management of P-listed hazardous pharmaceutical wastes for several reasons. First, only eight chemicals on the P-list are used as pharmaceuticals, and of those eight, two are infrequently found to be hazardous waste in their pharmaceutical forms (see previous discussion of epinephrine, P042, and nitroglycerine, P081 in section IV.C.1 of this preamble). Thus, it is unlikely that the P-listed pharmaceutical wastes would be accumulated in large quantities. Furthermore, as stated earlier in this proposed rulemaking, the form and packaging in which pharmaceuticals are typically found (small, individually packaged doses, such as pills, capsules, or small vials) reduce the potential for release or exposure while they are being accumulated by handlers, shipped by transporters, and/or managed for disposal at destination facilities that are fully subject to RCRA subtitle C.

EPA also expects that the longer accumulation times will allow pharmaceutical universal waste handlers to accumulate their waste in volumes large enough to make management of the pharmaceutical universal wastes more cost-effective by allowing handlers more control and flexibility in scheduling the removal of waste from their facility and by reducing the number of shipments. To the extent that this proposed rule results in the co-management of RCRA hazardous and non-hazardous pharmaceuticals with federally controlled substances, compliance with the Controlled Substances Act and DEA regulations might impact accumulation times for those wastes that are controlled substances.

V. Detailed Discussion of this Proposed Rule

A. Intent and Purpose of This Proposed Rule

The Agency believes that pharmaceutical wastes meet the criteria for being identified as a universal waste and, thus, inclusion in the universal waste system is appropriate. Similarly, some states have already added hazardous pharmaceutical wastes to their universal waste programs³⁵ in order to streamline their management and to facilitate their collection, and a number of other states have also considered doing so.³⁶

It should be noted, however, that the inclusion of hazardous pharmaceutical wastes in the universal waste system will not supersede or otherwise amend other laws or regulations and would only become effective if adopted and implemented by individual authorized states. Therefore, any entity involved in the handling or transport of pharmaceutical wastes as universal wastes must continue to comply with all requirements of the Controlled Substances Act and DEA regulations (21 CFR parts 1300-1316) for the handling of Schedule II through V drugs. Furthermore, any entity involved in the handling or transport of pharmaceutical wastes as universal wastes must comply with the U.S. Department of Health and Human Services' HIPAA standards in 45 CFR Parts 160, 162, and 164.

With this proposal, EPA intends to stay within the existing UWR's framework. Therefore, the management requirements for pharmaceutical universal waste in this proposed rule do not significantly differ from the existing requirements for other universal wastes in 40 CFR part 273. By proposing to add hazardous pharmaceutical wastes to the UWR, EPA is not reopening, and does not seek new comment upon, any

³⁵ Florida (62-730.186, F.A.C.) and Michigan (MICH. ADMIN. CODE R 299.9228 (2007)) have added pharmaceutical wastes to their UWRs. The Agency requests comment on how this proposed rule, if finalized, would affect Michigan's and Florida's authorization to run their pharmaceutical universal waste programs.

³⁶ EPA has explained that authorized states may expand their universal waste programs to include a waste that is not considered a universal waste under the federal regulations, as long as the waste meets the established universal waste criteria and the waste is a recognized hazardous waste in that particular state (60 FR 25537, May 11, 1995; also see "Universal Waste Question and Answer Document," RO# 14088).

provisions of the UWR not specifically addressed in this notice.

B. Applicability

1. RCRA Hazardous Pharmaceutical Wastes

If finalized, the UWR will regulate only those pharmaceuticals that are RCRA hazardous waste. Under the current federal hazardous waste regulations, until a pharmaceutical is actually discarded, or the decision is made to discard the material, the pharmaceutical is not subject to the RCRA hazardous waste regulations since a material must first be a solid waste before it can be considered a hazardous waste (see 40 CFR 261.2 for the regulatory definition of solid waste). Once a generator establishes that a pharmaceutical is a solid waste under RCRA, the generator must then determine if the pharmaceutical waste is excluded from regulation and if not, whether it is a RCRA hazardous waste by verifying whether the waste appears on any of the hazardous wastes lists (F-list, K-list, P-list, or U-list),³⁷ and/or exhibits at least one of four characteristics—ignitability, corrosivity, reactivity, or toxicity.³⁸ An unused or expired drug that is being returned for potential credit to a reverse distributor is still considered to potentially have value for the pharmacy or hospital and so is not considered a solid waste. See Section IV.C.2.d for further discussion. On the other hand, pharmaceuticals that have no reasonable expectation of generating a manufacturer credit, and are not useable, must be managed as a waste. For example, opened or partially used containers of pharmaceuticals would not be considered to have value because they cannot be returned

³⁷ It is unlikely that pharmaceutical wastes would appear on the F- and K-lists as these lists represent wastes generated during common manufacturing and industrial processes (non-specific source wastes) and wastes generated by specific industries (source specific wastes), respectively. For more information, see 40 CFR 261.31 for the F-list, and 40 CFR 261.32 for the K-list.

³⁸ For additional information on hazardous waste identification, please see <http://www.epa.gov/osw/hazard/wastetypes/wasteid/index.htm>.

to a reverse distributor for possible credit, and so would be considered waste. When a pharmaceutical is no longer useable or the decision is made by the generator to discard the material, the RCRA regulations apply, and the generator must determine whether the waste is RCRA hazardous, and thus, manage it under the RCRA Subtitle C hazardous waste regulations.

EPA is proposing to include within the universal waste system all pharmaceuticals that are hazardous wastes. Under this proposal, entities generating hazardous pharmaceutical wastes would have two options for managing them. Facilities may choose to continue managing these hazardous wastes under the full subtitle C hazardous waste regulations at 40 CFR parts 260 to 268 and 270, or they may choose to manage their hazardous pharmaceutical wastes as universal wastes using the requirements laid out in 40 CFR part 273. It is important to note that only pharmaceutical wastes that are listed or characteristic hazardous wastes (40 CFR 261.21 - .33) are required to be managed under either the subtitle C hazardous waste regulations or, where allowed, under the UWR. However, as noted previously, EPA intends the UWR to encourage generators of hazardous wastes to manage the non-hazardous portions of the waste stream in a similar manner as the hazardous portion. Therefore, EPA supports a generator's decision to use the universal waste management framework to manage any pharmaceutical waste even if it is not regulated as hazardous waste, but which nonetheless may pose a risk to human health or the environment when not properly managed. For example, a health care facility may decide to take advantage of the streamlined requirements and manage pharmaceutical wastes containing the drugs listed in Appendix A of the National Institute for Occupational Safety and Health (NIOSH)

Alert, “Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings³⁹” as universal wastes, in addition to the facility’s RCRA hazardous waste drugs as a way of ensuring the safe disposal of these drugs. Other pharmaceutical wastes containing categories of non-regulated drugs that may be managed as universal wastes are outlined in the Hospitals for a Healthy Environment’s “Managing Pharmaceutical Waste: A 10-Step Blueprint for Health Care Facilities in the United States” (August 2008).⁴⁰ For instance, a health care facility may choose to co-manage the following with pharmaceutical universal wastes as best management practices, although they are not RCRA hazardous wastes:

- Any drug that contains a P- or U-listed chemical, regardless of whether or not that P- or U-listed chemical is the sole active ingredient⁴¹;
- Chemotherapy drugs; and
- Drugs meeting OSHA and NIOSH hazardous drug criteria.

It is important to note that this rulemaking would not apply to any hazardous pharmaceutical waste that also contains a radioactive material component (*i.e.*, mixed wastes). Mixed wastes are regulated by multiple agencies: the hazardous portion of the waste is regulated by EPA or the authorized state, while the radioactive component of the waste is regulated under the AEA by either the Nuclear Regulatory Commission (NRC)

³⁹ <http://cdc.gov/niosh/docs/2004-165/2004-165c.html>

⁴⁰ <http://www.hercenter.org/hazmat/tenstepblueprint.pdf>

⁴¹ Under the federal RCRA hazardous waste regulations, in order to be a P- or U-listed waste, the chemical in question must, among other things, contain the P- or U-listed chemical as the sole active ingredient. (Comment after 40 CFR 261.33(d); 45 FR 78541, Nov. 25, 1980.) Therefore, if a pharmaceutical has more than one active ingredient, and one or more of those active ingredients are P-and/or U-listed chemicals, then that pharmaceutical is not a listed hazardous waste. Additionally, if a P- or U-listed chemical is an inactive ingredient in a pharmaceutical, then that pharmaceutical is also not a listed hazardous waste (see comment to Section 261.33 (d); RO #s 11350 and 13530). However, while the pharmaceuticals in these examples are not considered listed hazardous wastes, they may still be RCRA hazardous wastes if they exhibit at least one of the four RCRA characteristics of hazardous waste.

or the Department of Energy (DOE).⁴² Section 1006 of RCRA states that if RCRA regulations are inconsistent with the AEA requirements, then the RCRA requirements do not apply. Therefore, if generators managing a mixed hazardous pharmaceutical waste under RCRA subtitle C encounter RCRA requirements that are inconsistent with the AEA requirements, the AEA requirements apply. However, as 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 and relief from an inconsistency would be limited to that specific RCRA requirement, and that the determination of an inconsistency would not relieve the generator from all other RCRA requirements.

The Agency would like this opportunity to reiterate that RCRA, as well as this proposed rulemaking, does not supersede the requirements of the Controlled Substances Act and DEA regulations for the disposal of controlled substances. Thus, any entity generating, collecting, handling or managing a RCRA hazardous pharmaceutical waste that is also a controlled substance in Schedule II-V⁴³ must abide by RCRA as well as the requirements of the Controlled Substances Act and DEA regulations. Three examples of listed hazardous wastes that are also controlled substances are phentermine (alpha, alpha-dimethyl-benzenethanamine, P046), chloral hydrate (U034), and paraldehyde (U182). Not being an exhaustive list, there are possibly other controlled substances that exhibit characteristics of hazardous waste. EPA is requesting comment regarding how hazardous wastes that are controlled substances are currently being managed; if the inclusion of

⁴² The NRC regulates radioactive wastes generated by commercial or non-DOE facilities, whereas DOE regulates radioactive wastes generated by DOE facilities.

⁴³ See 21 CFR 1308 for a complete list of controlled substances.

federally controlled substances in the federal universal waste program will change how these co-regulated wastes are being managed; and, if there are any negative effects on properly managing these wastes under both set of regulations. Finally, EPA seeks information on the volumes of controlled substances that are hazardous wastes disposed of annually.

Due to the stringent management of pharmaceutical wastes that are both controlled substances and RCRA hazardous wastes and their expected low volumes of generation due to the limited numbers of listed control substances, EPA also is seeking comment on whether or not hazardous pharmaceutical wastes that are also Schedule II-V controlled substances should be included in the federal universal waste program.

The Agency requests information on whether health care facilities, reverse distributors and other hazardous pharmaceutical waste generators will choose to manage their pharmaceutical wastes as universal wastes if this proposed rule is finalized. Specifically, the Agency is requesting information on the likelihood of the following scenarios: (1) facilities choosing to manage their hazardous and non-hazardous pharmaceutical wastes as universal wastes; (2) facilities choosing to manage their hazardous pharmaceutical wastes and only certain categories (such as certain chemotherapy drugs) of pharmaceutical wastes not currently regulated as hazardous waste as universal wastes; (3) facilities choosing to manage only their hazardous pharmaceutical wastes as universal wastes; and (4) facilities choosing to manage their hazardous pharmaceutical wastes as hazardous wastes, not universal wastes. Furthermore, the Agency requests an explanation of why generators would choose one approach over another. Additionally, the Agency solicits information on the amount of

pharmaceutical wastes generated at various health care facilities, as well as these facilities' pharmaceutical waste management practices. Finally, the Agency is seeking any cost information for the aforementioned scenarios.

2. Households and Conditionally Exempt Small Quantity Generators

Currently, under the household hazardous waste exclusion in 40 CFR 261.4(b)(1) of the federal hazardous waste program, hazardous wastes from households are not subject to the hazardous waste regulations, including the UWR provisions. However, EPA encourages "households" to dispose of any pharmaceutical wastes generated in their homes through local household hazardous waste management programs or community take-back programs. Links for finding pharmaceutical take-back programs and donation programs are listed at: <http://www.epa.gov/ppcp/links.html#state>.

CESQGs are subject to limited waste management requirements under 40 CFR 261.5. Specifically, CESQGs are not required to obtain an EPA ID number or to comply with the same accumulation and storage, manifesting, or recordkeeping and reporting requirements as SQGs or LQGs. However, CESQGs are required to identify which wastes are hazardous wastes, comply with some accumulation requirements and ensure that their hazardous wastes are properly treated or disposed. Under the existing UWR provisions, CESQGs may choose to manage certain hazardous wastes in accordance with either the CESQG regulations under 40 CFR 261.5 or under the UWR at 40 CFR part 273. In addition, the provision under 40 CFR 273.8(b), which requires any universal waste that is mixed with a household or CESQG waste to be handled as a universal waste in accordance with 40 CFR part 273, will remain unchanged by this proposal, if finalized.

The Agency requests information on whether persons exempted from subtitle C

regulation would choose to manage their pharmaceutical wastes under the UWR.

3. Handlers of Universal Waste

A handler of universal waste can be a person who generates universal waste. A handler can also be a person who receives universal waste from generators or other handlers, consolidates the waste, and then sends it on to other handlers or treatment or disposal facilities. Universal waste handlers accumulate universal waste, but do not treat, recycle or dispose of them. In addition, each location that is generating or collecting universal waste is considered a separate universal waste handler. Therefore, if a company has several locations at which universal waste is generated or collected, each location is a separate handler. Finally, the accumulation threshold that distinguishes between small and large handlers does not refer to *any one category* of universal waste, but refers to the *total* quantity of all universal waste accumulated on-site (UW pesticides, mercury-containing equipment, *etc.*).

As an example of who may be treated as a universal waste handler, if hazardous pharmaceutical wastes are added to the UWR, a hospital that is currently a LQG under the subtitle C regulations can decide to manage its hazardous pharmaceutical waste as a universal waste, as a universal waste handler.⁴⁴ Additionally, reverse distributors may choose to become universal waste handlers under the UWR and may choose to accept universal waste from other universal waste handlers for purposes of consolidation.⁴⁵

Under this scenario, reverse distributors may accept both pharmaceutical universal waste and unused and “creditable” pharmaceutical products from health care facilities, but, due

⁴⁴ Wastes that are managed as universal wastes do not count toward the facility’s hazardous waste generator status. See 40 CFR 261.5; 262.10. However, while the facility may be recognized as a handler for the purposes of universal waste, it is still considered a generator if any other listed or characteristic hazardous wastes are generated in addition to the universal wastes. See 40 CFR 261.5(c).

⁴⁵ Currently under RCRA, reverse distributors can only accept pharmaceuticals that are product and not waste. Please see discussion in section IV.C.2.d of this preamble.

to requirements under current DEA regulations, reverse distributors may not accept controlled substances from consumers or other persons who are not registered with DEA.⁴⁶

Under this proposal, most of the existing universal waste requirements currently applicable to SQHUWs and LQHUWs would also apply to handlers of hazardous pharmaceutical wastes. For both SQHUWs and LQHUWs, these requirements include labeling and marking, accumulation time limits, employee training, response to releases, requirements related to off-site shipments, and export requirements. Sections V.B.3.a and V.B.3.b discuss the specific differences between the small quantity handler and large quantity handler requirements for universal wastes.

a. Small Quantity Handler of Universal Waste

As defined in 40 CFR 273.9, a SQHUW is a universal waste handler who accumulates less than 5,000 kilograms total of universal waste at any time (*e.g.*, batteries, pesticides, mercury-containing equipment (MCE), lamps and pharmaceuticals (as proposed), calculated collectively). SQHUWs do not need to notify EPA of their universal waste activities (as noted under 40 CFR 273.12) and are not required to obtain an EPA identification number prior to managing universal wastes. In addition, SQHUWs have less stringent requirements for the training of employees (discussed in section V.G.) and for the tracking of universal wastes (discussed in section V.J.) compared to the requirements for LQHUWs. However, if a SQHUW accumulates 5,000 kg or more of universal waste at any one time, that handler must then comply with all LQHUW requirements and must continue to do so for the remainder of the calendar year.

EPA is proposing to maintain and is soliciting comment on maintaining the

⁴⁶ See http://www.deadiversion.usdoj.gov/faq/general.htm#pre_med for more information.

current SQHUW threshold and notification requirements for those small quantity handlers that would be managing hazardous pharmaceutical wastes as universal wastes. EPA is not soliciting comment on or considering changes to these requirements for SQHUWs of other universal wastes.

b. Large Quantity Handlers of Universal Waste

A LQHUW is defined in 40 CFR 273.9 as a universal waste handler who accumulates 5,000 kilograms or more of universal waste at any time (*e.g.*, the total amount of batteries, pesticides, MCE, lamps and pharmaceuticals (as proposed), calculated collectively). As is discussed in subpart C of 40 CFR part 273 of the existing regulations, LQHUWs must send written notification of their universal waste management to the Regional Administrator, and receive an EPA identification number before meeting or exceeding the 5,000 kg storage limit. However, a LQHUW is not required to notify/re-notify that he is handling universal waste if he has already notified EPA and obtained an identification number for other hazardous waste management activities. Once the 5,000 kg threshold is met, the designation of LQHUW is retained by the handler for the remainder of the calendar year; however, the handler may reevaluate his status as a LQHUW in the following calendar year. In addition to the notification requirements, LQHUWs have more stringent training and waste tracking requirements than SQHUWs. These requirements are discussed further in sections V.G. and V.J. of this preamble, respectively.

EPA is proposing to maintain the existing LQHUW threshold and notification requirements for those large quantity handlers that would be managing hazardous pharmaceutical wastes as universal wastes and solicits comments on this proposal. EPA

is not soliciting comment on or considering changes to these requirements for LQHUWs of other universal wastes.

C. Definitions

As used in this proposed rule,⁴⁷ the term “pharmaceutical” refers to “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 biohazardous waste, dental amalgams, medical devices not used for delivery or dispensing purposes, equipment, contaminated personal protective equipment or contaminated cleaning materials.” The definition of pharmaceutical is adapted from the Federal Food, Drug and Cosmetic Act’s definition for “drug.” 21 U.S.C. 321(g)(1)(B) and (C). As discussed above, this definition is meant to include, but is not limited to, such things as pills or tablets, medicinal gums or lozenges, medicinal liquids, ointments and lotions, IV or other compounded solutions, chemotherapy drugs, vaccines, allergenics, medicinal shampoos, antiseptics and medicinal dermal patches, and any delivery devices with the primary purpose to dispense or deliver a chemical product,

⁴⁷ Please see discussion in section IV.B of this preamble for more information regarding the definitions proposed for this rulemaking.

vaccine or allergenic.

In contrast, the definition of pharmaceutical is not intended to include sharps (*e.g.*, needles from IV bags or syringes),⁴⁸ waste chemicals from laboratories, medical devices (*e.g.*, blood pressure cuffs, mercury thermometers, x-ray films and fixers),⁴⁹ dental amalgams, infectious or biohazardous “red-bag” waste,⁵⁰ personal protective equipment contaminated with hazardous pharmaceuticals (*e.g.*, scrubs, gowns, gloves), any materials used to clean up spills of hazardous pharmaceutical wastes, or wastes resulting from pharmaceuticals manufacturing or distribution.

In addition, for the purposes of this rulemaking, the term “pharmaceutical universal waste” means a pharmaceutical that is a hazardous waste as defined in § 261.3, and containers (*e.g.*, pill bottles, vials, IV bags, and tubes of ointment/gel/cream, etc.) which have held any hazardous pharmaceutical waste and which would be classified as hazardous waste under § 261.7. The Agency decided to define “pharmaceutical universal waste” to ensure that any container which has held hazardous pharmaceutical wastes (and thus is also considered a hazardous pharmaceutical waste, unless that container is considered “RCRA-empty”^{51, 52}) could also be managed in the universal waste system.

⁴⁸ Used sharps, such as needles or syringes with needles, are not included under this proposed rule as 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 to those sorting wastes and so have not be included in the proposed rule. See Technical Manual on Controlling Occupation Exposure to Hazardous Drugs found at http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html see (c)(1)(b). and Response Regarding Needlestick Injuries in the Sharps Recycling Industry (RO# 11778).

⁴⁹ Medical devices (with the exception of devices with a primary purpose of dispensing or delivering a chemical product, vaccine or allergenic of delivery devices) are not regulated under this proposal, since they do not fall within the definition of pharmaceutical. These wastes may be regulated when disposed based on whether or not they are listed or are characteristic hazardous wastes.

⁵⁰ Infectious or biohazardous “red-bag” wastes are medical wastes, which are regulated at the state and local level.

⁵¹ Under the current generator regulations, containers once holding listed wastes are themselves considered listed hazardous wastes due to the residues remaining in the containers (see 40 CFR 261.33(c)). Please see footnote #6 for more details.

⁵² Any syringe containing the residue of a P- or U-listed drug is not considered a listed hazardous waste,

As a result of defining “pharmaceutical universal waste” for the reason described above, the “Applicability” section in § 273.6 of the proposed regulatory text will not be parallel to the “Applicability” sections for the other universal waste regulations included in the federal RCRA subtitle C hazardous waste regulations.⁵³ Specifically, the Agency has proposed to omit the regulatory language describing what pharmaceuticals would not be covered under 40 CFR part 273 of the proposed pharmaceutical universal waste rule. The reason for proposing this omission is that discussing what is not covered would be redundant as the proposed definition of “pharmaceutical universal waste” clearly addresses that 40 CFR part 273 would apply to pharmaceuticals and “non-empty” containers of pharmaceutical waste that are hazardous wastes. The Agency notes that these proposed modifications were only made in order to avoid redundancy with the definitions proposed in 40 CFR 260.10 and 273.9.

The Agency is requesting comment on the proposed definition of “pharmaceutical.” Specifically, EPA is seeking comment on whether the definition of “pharmaceutical” is clear and appropriate, and whether it encompasses the full range of pharmaceuticals available. In addition, EPA is seeking comment on whether this definition inadvertently includes items not intended to be incorporated into the universal waste system, such as dental or medical devices. The Agency is also requesting comment on, in order to add hazardous pharmaceutical wastes to the UWR, whether additional elements not included in this proposal need to be added to this proposed definition.

Finally, the Agency requests comment on whether the proposed definition of

and would be hazardous only if the residue exhibits a hazardous waste characteristic (“Epinephrine Residue in a Syringe is Not P042,” RO #13718; letter to Mr. Gary Chilcott (Sure-Way Systems Inc.) from Robert Dellinger RO # 14788).

⁵³ The “Applicability” sections for each universal waste are found in subpart A of part 273. Each “Applicability” section describes the following: 1) what wastes are included under 40 CFR 273; 2) what wastes are not covered under 40 CFR 273; and 3) when the material becomes a “waste.”

“pharmaceutical universal waste” is clear and appropriate.

D. Waste Management

As it is stated in 40 CFR 273.11 and 273.31, all universal waste handlers are prohibited from disposing of universal wastes, or diluting or treating universal waste, except for responding to releases (as provided in 40 CFR 273.17 and 273.37), or managing specific wastes (as provided in 40 CFR 273.13 and 273.33). Handlers of pharmaceutical universal wastes must manage these wastes in a manner that prevents releases of universal wastes or components thereof into the environment (as is required for other universal wastes; see 40 CFR 273.13 and 273.33). These existing provisions are mostly maintained in this proposed rulemaking -- that is, paragraphs 273.13(e) and 273.33(e) of these proposed regulations address the specific waste management requirements proposed for pharmaceutical wastes by small and large quantity handlers, respectively. Some other aspects of universal waste handling would be revised only for pharmaceutical wastes by this proposal as described immediately below.

1. Containers

To prevent their release into the environment, the Agency is proposing to require that pharmaceutical universal wastes must be packed into containers that are structurally sound and compatible with the pharmaceutical wastes that will be contained within them. That is, the containers must not have any evidence of leakage, spillage or damage that could result in the release of waste under reasonably foreseeable circumstances. EPA intends this requirement to mean that containers used for holding pharmaceutical universal wastes must be in good condition, with no severe rusting, apparent structural defects, or deterioration. Furthermore, the Agency is proposing to require that

incompatible wastes not be placed in the same container, unless in compliance with 40 CFR 265.17(b).

Unlike the container requirements for other universal wastes, the proposed container requirements for pharmaceutical universal wastes do not include the requirement that containers be “closed.” EPA believes that requiring closed containers for pharmaceutical wastes would provide a burden that is unwarranted in these situations as most pharmaceutical universal wastes would be unused and in their original packaging when disposed, and so accumulating these wastes in a larger container would pose little, if any, risk of release through spillage, leakage or emission to the air. Thus, as proposed, accumulation containers for pharmaceutical universal wastes may be open, covered, or sealed, as long as the performance standard to prevent releases is met.⁵⁴ However, the Agency also understands that there are likely to be pharmaceutical universal wastes that have been removed from their original packaging, or that will be in liquid or semi-solid form when discarded into the universal waste container. Therefore, handlers must take any appropriate measures necessary to prevent releases of these wastes. Such measures may mean covering the container to prevent emissions or placing the collection container in an inconspicuous space or securing the container to a building support, cart or other equipment to prevent releases due to the container being tipped or knocked over.

EPA seeks comment on whether the proposed container management standards are appropriate for pharmaceutical universal wastes. Additionally, EPA seeks comment on whether the containers should be required to be “closed” or “covered,” except when waste is being added to or removed from the containers, in order to prevent releases

⁵⁴ Please note that persons managing controlled substances must comply with all requirements of the Controlled Substances Act and DEA regulations for the handling and disposal of controlled substances.

during accumulation. Specifically, EPA is requesting information on scenarios in which a “closed” or “covered” requirement would be appropriate. EPA is not seeking, nor will we respond to, comments on whether to remove the term “closed” from the container requirements of the other types of universal wastes, since that is not the subject being addressed in this proposed rule. Finally, EPA also requests comment on whether handlers of pharmaceutical universal wastes should be required to maintain the pharmaceutical wastes in their original packaging if received as such.

2. Sorting

The Agency is proposing specifically to allow, but not require, sorting of pharmaceutical universal wastes. Sorting is currently allowed for handlers of universal waste batteries (see 40 CFR 273.13(a)(2) for SQHUW and 40 CFR 273.33(a)(2) for LQHUW). For pharmaceutical universal wastes, the proposed rule allows sorting provided the handler ensures compliance with all applicable OSHA regulations⁵⁵ and ensures that employees tasked with sorting the pharmaceutical wastes are thoroughly familiar with the pharmaceutical universal waste handling and emergency procedures. Handlers also should not commingle sharps, such as needles, scalpel blades or scissors, medical devices⁵⁶ or infectious wastes, with the pharmaceutical wastes being managed. If a handler sorts pharmaceutical universal wastes to separate those that are incompatible or to segregate out non-universal wastes from the pharmaceutical universal wastes, EPA

⁵⁵ For more information on applicable OSHA standards, see OSHA’s Bloodborne Pathogens Standard at 29 CFR 1910.1030, Technical Manual on Controlling Occupation Exposure to Hazardous Drugs, found at http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html and Compliance Assistance document for the Health Care Industry, found at

http://www.osha.gov/dcsp/compliance_assistance/quickstarts/health_care/health_care.html#Step%201

⁵⁶ Some medical devices, such as mercury thermometers, may meet the definition of “mercury-containing equipment” in 40 CFR 273.9 and thus may be eligible for management under the UWR as “Universal waste – Mercury Containing Equipment.” (Please see subpart B and C of the UWR for the small quantity and large quantity handler standards, respectively, for mercury-containing equipment.)

recommends that handlers keep pharmaceutical universal wastes in their original packaging, to decrease chemical exposure for employees handling the wastes, as well as the risk of reactions between any possible incompatible materials. Alternatively, the Agency encourages, but is not requiring, handlers generating pharmaceutical universal waste to place any pharmaceutical that is not in its original packaging⁵⁷ or is contained in packing that could be compromised⁵⁸ (especially liquids, IV bags, IV bag tubing, *etc.*) into a separate individual container, such as a sealed zipper storage bag, prior to placing the pharmaceutical universal waste into the universal waste accumulation container. Adhering to these precautions would further protect the personnel sorting the wastes and would prevent contamination of the commingled waste should any bags, tubing, or vials leak or break. Furthermore, the individual containers would prevent entanglement of tubing, thereby reducing sorting time.

EPA seeks comment on the proposed pharmaceutical universal waste sorting provisions. Specifically, the Agency requests comments on whether sorting of pharmaceutical universal wastes should be required, or whether requiring sorting is unnecessary due to the forms in which pharmaceuticals are typically found. Finally, the Agency requests examples of accidents that have occurred, or may occur, at health care facilities or reverse distributors due to incidents of incompatible hazardous pharmaceutical wastes being stored together.

3. Generation of Solid Wastes

As a result of sorting activities, solid wastes (both pharmaceutical and non-pharmaceutical) may be generated. It is the responsibility of the handler to determine if

⁵⁷ That is, any pharmaceutical that is not already contained in a blister pack, bottle, box, *etc.*, but is loose.

⁵⁸ Any pharmaceutical contained in packaging that can be punctured (*e.g.*, IV bags) or broken (*e.g.*, glass vials), *etc.*

the generated solid waste is a listed hazardous waste or exhibits a hazardous waste characteristic (see subparts C and D in 40 CFR part 261). If it is determined that the waste is hazardous, but it does not meet the definition of “pharmaceutical,” then it must be managed in compliance with all applicable requirements of 40 CFR parts 260 through 268 and 270. The handler would also be considered a generator of hazardous waste and would therefore be subject to the generator requirements at 40 CFR part 262. However, if it is determined that the generated solid waste is not hazardous, then it can be managed as a solid waste, and must be managed in accordance with all applicable federal, state or local solid waste regulations.

E. Labeling/Marking

The Agency is proposing that universal waste handlers managing pharmaceutical universal waste label each individual pharmaceutical universal waste item or accumulating container holding the pharmaceutical universal waste with the words “Universal Waste— Pharmaceuticals,” or “Waste Pharmaceuticals.” These requirements can be found in 40 CFR 273.14(f) and 273.34(f) of the proposed rule. The Agency is requesting comments on the appropriateness of the proposed general labeling requirements for pharmaceutical universal wastes. Specifically, the Agency requests comment on whether, in order for the destination facility to have sufficient information on the pharmaceutical universal wastes they receive, universal waste handlers should be required to include on the label the relevant chemical information or the hazardous waste code.

F. Accumulation Time Limits

The existing UWR contains a one year accumulation limit for both SQHUWs and LQHUWs, as well as requirements for demonstrating the accumulation time (*e.g.*, dating the label when the item first becomes a waste, or maintaining an inventory system identifying the date when the item became a waste). The UWR allows accumulation for more than one year if it is solely for accumulating such quantities of universal waste as are necessary to facilitate proper recovery, treatment, or disposal. See 40 CFR 273.15(a) – (c) and 273.35(a) – (c). Thus, we assume that any accumulation up to one year is for this purpose but, for any accumulation beyond one year, the handler bears the burden of demonstrating that accumulation is solely to facilitate proper recovery, treatment or disposal.

The Agency is proposing to continue to use these accumulation time limits for pharmaceutical universal wastes. The Agency is requesting comments, however, on whether a different time limit is appropriate for handlers of pharmaceutical universal wastes and whether small and large pharmaceutical universal waste handlers should be subject to different accumulation time limits. In addition, the Agency is seeking comment and data on whether any pharmaceutical wastes or mixtures of pharmaceutical wastes tend to become more dangerous with age. EPA is not seeking, nor will it respond to, comments on whether to change the accumulation time limits for handlers of other types of universal wastes, which are not covered in this proposal.

G. Employee Training

The employee training requirements for small and large quantity handlers of universal waste can be found in 40 CFR 273.16 and 273.36, respectively. The Agency is proposing that the employee training requirements for pharmaceutical universal wastes be

the same as the training requirements for other universal wastes.⁵⁹ Briefly, the existing universal waste training requirements require that LQHUU ensure that all employees are thoroughly familiar with the proper waste handling and emergency procedures related to their responsibilities during normal facility operations and emergencies.⁶⁰ SQHUW must inform all employees that handle or have responsibilities for managing universal waste of the proper handling and emergency procedures appropriate to the type(s) of universal wastes managed at the facility.⁶¹ A basic employee training requirement is necessary to ensure that employees are specifically familiar with the waste handling procedures under the UWR. The Agency believes that training provided under other programs that would meet any or all of the 40 CFR part 273 training requirements may be used to fulfill these requirements. As long as the substantive standards of the training provisions are met, the handler has fulfilled the training requirement. There is no requirement that the training provided to meet these requirements must be separate from other training given to employees. In addition, the Agency strongly urges handlers to familiarize their employees with the regulations of the U.S. Department of Health and Human Services (regarding HIPAA), DEA, OSHA and DOT as these agencies' regulations may impose additional training requirements beyond those of the UWR.

The Agency is requesting comments on whether this rule should require specialized training for some or all handlers for sorting pharmaceutical universal wastes. EPA is not seeking, nor will the Agency respond to, comments on whether to change the

⁵⁹ For further discussion of the UWR employee training requirements, see 60 FR 25527-25528; May 11, 1995.

⁶⁰ LQHUU are not required to keep employee training records (see 60 FR 25528; May 11, 1995).

⁶¹ SQHUW may inform their employees of proper handling and emergency procedures via verbal communication or through the distribution of pamphlets or other documentation (see 60 FR 25528; May 11, 1995).

training requirements for handlers of other types of universal wastes which are not covered in this proposal.

H. Responses to Releases

The response to releases requirements for small and large quantity handlers of universal waste are found in 40 CFR 273.17 and 273.37. These regulations include basic release responses, including the requirement that handlers immediately contain all releases of, and other residues from, universal wastes. Then the handlers must determine whether any material resulting from the release is hazardous waste and, if so, must manage it under the full RCRA subtitle C hazardous waste regulations. Handlers, however, are not subject to facility-wide corrective action when there is a release of universal waste.

Any releases of universal waste not cleaned up constitutes illegal disposal allowing further action by EPA under RCRA. In addition, any releases of hazardous substances above the reportable quantity (RQ) thresholds must be reported under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (see CERCLA section 103 (42 U.S.C 9603(a))). Since universal wastes are hazardous wastes and, thus, hazardous substances under CERCLA, reporting for universal waste releases is required if RQs are exceeded (see 40 CFR 302.4 for RQs for hazardous substances). Such reports provide notification to the Agency concerning releases and would thus allow the Agency to take action, if necessary, under either RCRA or CERCLA.

This notice does not propose to change any of the existing requirements for responding to releases of hazardous pharmaceutical wastes.

I. Off-Site Shipments

The requirements for off-site shipments under the UWR are included in 40 CFR 273.18 and 273.38. To summarize the off-site shipment requirements of the UWR, handlers of both small and large quantities of universal waste are prohibited from sending or taking universal waste to a place other than another universal waste handler, a destination facility, or a foreign destination. Universal waste handlers can either contract with someone else to transport their universal waste or transport it themselves.⁶² If a universal waste being offered for off-site transportation meets the definition of hazardous materials under DOT 49 CFR 171–180, the handler of the universal waste must package, label, mark, and placard the shipment in accordance with the DOT regulations under 49 CFR parts 172–180 and must prepare the proper shipping papers.

Under the UWR, both the shipper (a small or large quantity handler of universal waste who is shipping the universal waste to another handler or destination facility) and the receiving facility (a small or large quantity handler of universal waste, or destination facility receiving a shipment of universal waste from another universal waste handler) share certain responsibilities for the proper handling of the universal wastes being shipped. For instance, in order to prevent or limit rejected shipments, 40 CFR 273.18(d) and 273.38(d) of the UWR specify that the shipper of the universal waste must ensure that a receiving universal waste handler agrees to receive the shipment prior to the waste being sent. In addition, 40 CFR 273.18(e) and 273.38(e) of the rule specify that if the shipper sends universal waste to another handler or destination facility and the shipment is rejected, the shipping handler must receive the waste back or agree with the receiving

⁶² If a handler chooses to self-transport universal wastes off-site, that handler must comply with the universal waste transporter requirements found in subpart D of the universal waste regulations.

facility on a destination facility to which the shipment will be sent. Sections 273.18(f), 273.38(f) and 273.61(b) provide that if an unsuitable shipment containing universal waste is received, the receiving facility, in turn, may reject the full shipment or a portion of the shipment. At that time, the receiving facility must notify the shipper of the rejection and discuss reshipment of the load.⁶³ In addition, 40 CFR 273.18(g), 273.38(g), and 273.61(c) of the UWR address the procedures to be followed if a handler receives a shipment of hazardous waste that is not a universal waste. Specifically, these subsections state that should such a shipment be received, the receiving facility must immediately notify the appropriate regional EPA office (or the authorized state, when appropriate) of the illegal shipment and provide the name, address, and phone number of the shipper. The EPA regional office (or state) would provide instructions to the receiving facility for managing the hazardous waste. Finally, when a handler of universal waste receives a shipment of non-hazardous, non-universal waste, the handler must manage the waste in compliance with applicable federal or state solid waste regulations.

This notice does not propose to change any of the existing requirements applicable to the off-site shipping of universal waste, including pharmaceutical waste managed as universal waste.

J. Tracking Universal Waste Shipments

Manifests are not required for any shipments of universal waste by small and large quantity handlers of universal waste. Small quantity handlers are not required to track shipments,⁶⁴ including shipments to destination facilities. However, the UWR does

⁶³ The receiving facility may send the rejected shipment back to the original shipper or to a mutually agreed upon destination facility.

⁶⁴ If the universal waste will be transported through a state that does not recognize the waste as a universal waste, then a manifest is required.

include a basic recordkeeping requirement to track waste shipments arriving at and leaving from handlers of LQHUWs. These basic tracking requirements are found in 40 CFR 273.19 and 273.39.

For each shipment of universal waste received at or sent by a large quantity handler, the record⁶⁵ must include the name and address of the universal waste handler or foreign shipper to or from whom the universal waste was sent; the quantity of each type of universal waste sent or received (*e.g.*, batteries, pesticides, thermostats, MCEs, lamps, and pharmaceuticals, if this rule is finalized as proposed); and the date of receipt of the shipment of universal waste.

This notice does not propose to change any of the existing requirements applicable to the tracking of universal waste shipments, including pharmaceutical waste managed as universal waste.

K. Exports

The export requirements for small and large handlers of universal waste are found in 40 CFR 273.20 and 273.40, respectively. A handler sending universal waste to a foreign destination, without first sending the waste to a consolidation point or destination facility, would be subject to the requirements equivalent to the existing hazardous waste export requirements found at subpart E of 40 CFR part 262, even though a manifest would not be required. Thus, all universal waste shipments would follow procedures for notification and consent which are independent of the manifest procedures. Also, as discussed in the previous section, LQHUW are required to keep records of where they

⁶⁵ The required records may take the form of a log, invoice, manifest, bill of lading or other shipping document.

send universal waste, and from where they receive universal waste, including foreign destinations or shippers.

This notice does not propose to change any of the existing requirements applicable to the export of universal wastes, including pharmaceutical waste managed as universal waste.

L. Standards for Universal Waste Transporters

The requirements for universal waste transporters are found under 40 CFR 273.50 through 273.56. Briefly, universal waste transporters are prohibited from disposing and diluting or treating universal wastes; must handle universal wastes in compliance with all applicable DOT regulations; and must only transport universal wastes to handlers, destination facilities, or to foreign destinations. In addition, transporters may only store universal wastes for ten days or less⁶⁶; must respond to releases; and must follow certain export requirements, if shipping to a foreign destination.⁶⁷

This notice does not propose to change any of the existing requirements applicable to transporters of universal wastes, including pharmaceutical wastes managed as universal wastes.

M. Standards for Destination Facilities

As described in 40 CFR 273.9 of the existing UWR, a destination facility is “a facility that treats, disposes of, or recycles a particular category of universal waste, except those management activities described in paragraphs (a) and (c) of 40 CFR 273.13 and

⁶⁶ A transporter storing a universal waste for more than ten days will be considered a handler and must comply with the standards for either a small or large quantity handler, whichever is appropriate.

⁶⁷ For a more detailed discussion regarding the universal waste transporter requirements, please see 60 FR 25532 – 25533 of the May 11, 1995, final UWR.

273.33. A facility at which a particular category of universal waste is only accumulated is not a destination facility for purposes of managing that category of universal waste.”

The standards for destination facilities can be found under 40 CFR part 273, subpart E of the existing UWR, and they are briefly summarized below.

The standards state that destination facilities are subject to all applicable requirements of 40 CFR parts 264, 265, 266, 268, 270 and 124 of Title 40 and, if the destination facility recycles universal wastes without storing them before they are recycled, to 40 CFR 261.6(c)(2). In addition, the notification requirement under § 3010 of RCRA still applies to destination facilities accepting universal wastes.

Destination facilities also have requirements for off-site shipments of universal wastes. Similar to the off-site shipment standards for universal waste handlers (previously discussed in section V.I of this preamble), destination facilities can only send or take universal wastes to handlers, other destination facilities or foreign destination facilities. Destination facilities can also reject shipments or portions of shipments containing universal wastes, but the destination facility owner or operator must notify the shipper of the rejection and arrange for re-shipment. Analogous to the handler requirements with which small and large quantity handlers of universal waste must comply, if a destination facility receives a shipment of hazardous waste that is not a universal waste, the facility must notify its regional EPA office (or authorized state). Finally, if the facility receives non-hazardous, non-universal waste in the shipment, the destination facility may manage the waste in any manner that is in compliance with applicable federal or state and local solid waste regulations.

Tracking of universal waste shipments also applies to destination facilities. The UWR requires that the owner or operator of a destination facility keep the same records for receipt of universal waste shipments as those kept by handlers of large quantities of universal wastes (discussed in section of V.J. of this preamble). A record must be kept for each shipment of universal waste received at the facility. The record may be in the form of a log, invoice, manifest, bill of lading or other shipping document, and must include the following information: (1) the name and address of the universal waste handler or foreign shipper from whom the universal waste was sent; (2) the quantity of each type of universal waste received; and (3) the date of receipt of the shipment of universal waste. In addition, destination facilities are required to maintain these records for three years.

This notice does not propose to change any of the existing requirements applicable to destination facilities that manage universal wastes, including pharmaceutical wastes managed as universal wastes.

N. Import Requirements

Pharmaceutical universal wastes entering the country would be subject to the same UWR provisions as any other universal waste. The import requirements for universal wastes are found in 40 CFR 273.70. This section clarifies that universal wastes that are imported from another country must be managed, upon entry into the United States, in compliance with the appropriate universal waste requirements for transporters, handlers, or destination facilities, depending on the universal waste management activities conducted within the United States.

This notice does not propose to change any of the existing universal waste

requirements applicable to the import of universal wastes, including pharmaceutical wastes managed as universal wastes.

O. Land Disposal Restrictions

Pursuant to the Land Disposal Restrictions (LDR) provisions of the Hazardous and Solid Waste Amendments of 1984 (HSWA), all hazardous wastes listed or identified in accordance with RCRA section 3001 are prohibited, on specified timetables, from land disposal unless they are appropriately treated or otherwise meet the specified treatment standard. The regulations for the LDR program in 40 CFR part 268 apply to persons who generate or transport hazardous waste and owners and operators of hazardous waste treatment, storage, and disposal facilities, unless they are specifically excluded from regulation in 40 CFR parts 261 or 268.

As discussed in the preambles for the proposed and final UWR (58 FR 8123 – 8124, February 11, 1993; 60 FR 25534 – 25535, May 11, 1995, respectively), handlers and transporters of universal wastes must comply with all of the substantive LDR requirements, but not the administrative requirements. These substantive requirements include: (1) a prohibition on accumulating prohibited hazardous wastes directly on the land (land disposal); (2) a requirement to treat wastes to meet the treatment standards prior to land disposal; (3) a prohibition on dilution; and (4) a prohibition on waste accumulation, except for purposes of accumulating quantities sufficient for proper recovery, treatment or disposal. Destination facilities are required to comply with all of the 40 CFR part 268 LDR requirements for universal waste, which include both the substantive and administrative requirements.

This notice does not propose to change any of the existing requirements with

respect to the land disposal restrictions for universal wastes, including pharmaceutical wastes managed as universal wastes.

VI. State Authority

A. Applicability of Rule in Authorized States

Under section 3006 of RCRA, EPA may authorize qualified states to administer and enforce the RCRA hazardous waste program within the state. 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 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 requirements 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. EPA is directed by the statute to implement these requirements and prohibitions in authorized states, including the issuance of permits, until the state is granted authorization to administer the HSWA requirements and prohibitions. States must adopt and be

authorized for more stringent HSWA-related provisions to retain final authorization.

Authorized states are required to modify their programs 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 40 CFR 271.1). Therefore, authorized states may, but are not required to, adopt federal regulations, both HSWA and non-HSWA, that are determined to be less stringent than previous federal regulations.

B. Effect on State Authorization

This notice proposes regulations that would not be promulgated under the authority of HSWA. Thus, the standards proposed would be applicable on the effective date only in those states that do not have final authorization. This proposed rule is less stringent than the current hazardous waste standards. Therefore, authorized states would not be required to modify their programs to adopt regulations consistent with and equivalent to these proposed standards. Nevertheless, because EPA believes that this proposed rule would encourage better overall management of hazardous pharmaceutical wastes, EPA strongly encourages states to adopt this rule once it is promulgated.

VII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is a "significant regulatory action."

Pursuant to the terms of Executive Order 12866, the Agency has determined that this proposed rule is a significant regulatory action because it contains novel policy issues. Accordingly, EPA submitted this action to the Office of Management and Budget

(OMB) for review under EO 12866 and any changes made in response to OMB recommendations have been documented in the docket for this action.

In addition, EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis is contained in the document entitled, *Assessment of the Potential Costs, Benefits, and Other Impacts of Adding Pharmaceuticals to the Universal Waste Rule, As Proposed (referred to as the Assessment document)*. Findings from this document are summarized below. This document, and any changes made in response to OMB review, is maintained in the RCRA docket established for this action. Interested persons are encouraged to read and comment on all aspects of this document.

The following section summarizes the findings from our *Assessment* document, as identified above. A detailed review of our analytical methodology, data sources, findings, and limitations are presented in the full *Assessment* document.

The Agency has identified the following facilities potentially affected by the proposed rule: pharmacies, hospitals, physicians' offices, dentists' offices, other health practitioners, outpatient care centers, other ambulatory health care services, residential care facilities, reverse distributors, and veterinary clinics. While the BRS has only limited data for the types of facilities likely to be affected by the proposed rule, it includes sufficient data to develop an approximation of the total tonnage of hazardous pharmaceutical waste generated by hospitals and reverse distributors. In total, the affected hospitals and reverse distributors generated a total of 14,200 tons of hazardous pharmaceutical waste during 2005, based on BRS data. Therefore, it is expected that on the order of 14,000 tons of hazardous pharmaceutical waste could be managed as

universal waste each year.

The proposed rule is optional, which means that individual facilities may choose to be regulated under the UWR, or continue to operate under the existing RCRA subtitle C hazardous waste regulations. The assessment assumes that facilities will only choose to be subject to the rule if it is deemed to be in their interest. For purposes of the economic assessment, it is assumed that only facilities that would experience a reduction in hazardous waste management costs would choose to be subject to the proposed rule. The aggregate annualized cost savings associated with the proposed rule are estimated to range from \$33.9 to \$35.2 million for hospitals and reverse distributors combined. For other types of facilities, the data necessary to support a nationwide estimate of the cost impacts are not readily available. However, based on a 2003 survey by King County, Washington, cost savings associated with ambulatory care facilities, retail pharmacies, and veterinary clinics are estimated to range from \$0 to \$162.3 thousand for King County. The Agency also evaluated an alternative scenario under which facilities possibly in non-compliance with the RCRA hazardous waste regulations decide to opt into the universal waste system. For more information regarding this alternative baseline, please see the *Assessment* document in the docket.

EPA anticipates that the proposed addition of hazardous pharmaceutical waste to the UWR will facilitate the environmentally-sound collection and disposal of this waste. Although EPA has not quantified the environmental impacts of the proposed rule, the Agency expects that the rule will reduce the release of pharmaceutically active compounds to the environment and also reduce the incidence of any adverse effects associated with human and ecosystem exposure to these substances.

B. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR number 2324.01.

The information requirements established for this proposed rulemaking, and identified in the ICR supporting this action are largely self-implementing. This process would ensure that (1) regulated entities managing hazardous pharmaceutical wastes are held accountable to the applicable requirements; and (2) state inspectors can verify compliance when needed. For example, the universal waste proposal requires LQHUWs and SQHUWs to demonstrate the length of time that hazardous pharmaceutical wastes have been accumulated from the date they were received or became a waste. The proposal also requires LQHUWs and destination sites to keep records of all shipments sent and received. Further, the proposal requires waste handlers and destination facilities to notify EPA under certain circumstances (*e.g.*, when large amounts of hazardous pharmaceutical waste are accumulated or when illegal shipments are received).

EPA will use the collected information in the event of an inspection to ensure that hazardous pharmaceutical waste is being managed in a protective manner. The information aids the Agency in tracking waste shipments and identifying improper management practices. In addition, information kept in facility records helps handlers, processors and destination facilities to ensure that all facilities are managing these wastes properly.

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 pharmaceutical wastes are being 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 960 hours per year, and the annual respondent cost for the new paperwork requirements in the rule is approximately \$54,000. The estimated annual hourly burden ranges from 0.8 to 2.5 hours per respondent for the 1,119 respondents who will likely choose to manage their hazardous pharmaceutical wastes under the UWR.⁶⁸ However, in addition to the new paperwork requirements in the rule, the Agency also estimated the burden and cost that generators are currently subject to in complying with the existing RCRA hazardous waste information collection requirements for hazardous pharmaceutical wastes (e.g., preparation of hazardous waste manifests, biennial reporting, etc.). Taking both the new proposed and existing RCRA requirements into account, EPA expects the proposed rule would result in a net reduction in national annual paperwork burden to the 1,119 respondents of approximately 935 hours or \$39,000. As summarized in the Economics Background Document and in the prior sub-section of this notice, EPA expects this net cost savings to be further supplemented by annual cost savings to these same facilities

⁶⁸ Many generators of hazardous pharmaceutical wastes are CESQGs, and thus are not subject to the RCRA subtitle C hazardous waste regulations, provided that they comply with the requirements set forth in 40 CFR 261.5(f)(3) and (g)(3). It is likely that many CESQGs may decide not to manage their hazardous pharmaceutical wastes under the UWR.

from reduced disposal costs. The net cost to EPA of administering the rule is expected to be negligible, since facilities are not required under this proposed rule to submit any information to the Agency for review and approval. Burden is defined at 5 CFR 1320.3(b).

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 EPA's regulations in 40 CFR are listed in 40 CFR part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, EPA has established a public docket for this rule, which includes this ICR, under Docket ID number EPA-HQ-RCRA-2007-0932. Submit any comments related to the ICR to EPA and OMB. See **ADDRESSES** section at the beginning of this notice for where to submit comments to EPA. Send comments to OMB at the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after **[Insert date of publication in the Federal Register]**, a comment to OMB is best assured of having its full effect if OMB receives it by **[Insert date 30 days after publication in the Federal Register]**. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking

requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) a small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this proposed rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, since the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives "which minimize any significant economic impact of the rule on small entities." 5 USC 603 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule.

The small entity analysis conducted for this proposed rule indicates that streamlining the requirements for hazardous pharmaceutical wastes would generally result in savings to affected entities compared to the baseline requirements. Under a

scenario assuming full compliance, the proposed rule is not expected to result in a net cost to any affected entity. Thus, adverse impacts are not anticipated. Costs could increase for entities that are not complying with the current requirements, but even these costs, which are not properly attributable to the current proposed rulemaking, would not be expected to result in significant impacts on a substantial number of small entities. We have therefore concluded that this proposed rule will relieve regulatory burden for all affected 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

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531-1538 for State, local, or tribal governments or the private sector. UMRA generally excludes from the definition of "Federal governmental mandate" (in sections 202, 203, and 205) and from the definition of "federal private sector mandate" duties that arise from participation in a voluntary federal program. If finalized, this rule will be voluntary because it will be less stringent than the current regulations. As a result, state governments will not be required to adopt the change, and the private sector will not be required to participate. In any event, EPA has determined that this proposed rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and tribal governments, in the aggregate, or the private sector in any one year. The total cost impact of the proposed action results in cost savings estimated to be between at least \$33.9 million to \$35.2 million per year. Therefore this action is not subject to the requirements of sections 202 and 205 of UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure “meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.”

This proposed rule does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. This proposed rulemaking directly affects primarily generators of hazardous pharmaceutical wastes as defined in this proposal. There are no state and local government bodies that incur direct compliance costs by this rulemaking.

Thus, Executive Order 13132 does not apply to this proposed rule. In the spirit of Executive Order 13132 and consistent with EPA policy to promote communications between EPA and state and local governments, EPA specifically solicits comment on this proposed rule from state and local officials.

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

Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), requires EPA to develop an

accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” EPA has concluded that this proposed rule may have tribal implications to the extent that entities generating hazardous pharmaceutical wastes on tribal lands could be affected. However, this proposed rule will neither impose substantial direct compliance costs on tribal governments nor preempt tribal law.

EPA did not consult directly with representatives of Tribal governments early in the process of developing this proposal. However, EPA did conduct outreach with the affected industry. Thus, EPA believes it has captured the concerns that also would have been expressed by representatives of Tribal governmental. EPA solicits additional comments on this proposed rule from Tribal officials.

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

This action is not subject to EO 13045 (62 F.R. 19885, April 23, 1997) because it is not economically significant as defined in EO 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this proposed action will present a disproportionate risk to children.

H. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution or Usage

This proposed rule is not a “significant energy action” as defined in Executive Order 13211, “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (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. Further, we have

concluded that the proposed rule is not likely to have any adverse energy effects.

I. National Technology Transfer Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (“NTTAA”), Public Law No. 104-113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

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

Executive Order (EO) 12898 (59 FR 7629, Feb. 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or

the environment. While the Agency is proposing to streamline the management requirements governing hazardous pharmaceutical wastes, EPA expects that such an action will actually increase compliance with the hazardous waste regulations and reduce exposures to both hazardous and non-hazardous pharmaceutical wastes by the public, including minority populations and low-income populations.

List of Subjects

40 CFR Part 260

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 261

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

40 CFR Part 264

Environmental protection, Hazardous waste, Packaging and containers, Security measures, Surety bonds.

40 CFR Part 265

Environmental protection, Air pollution control, Hazardous waste insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Water supply.

40 CFR Part 268

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 270

Environmental protection, Hazardous materials transportation, Reporting and recordkeeping requirements.

40 CFR Part 273

Environmental protection, Hazardous materials transportation, Hazardous waste.

Dated:

Stephen L. Johnson,

Administrator.

For the reasons set out in the preamble, title 40, Chapter I of the Code of Federal Regulations, is proposed to be amended as follows:

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

1. The authority citation for part 260 continues to read as follows:

Authority: 42 U.S.C 6905, 6912(a), 6921-6927, 6930, 6934, 6935, 6937, 6938, 6939, and 6974.

2. Section 260.10 is amended as follows:

- a. By adding the definition of “pharmaceutical” in alphabetical order.
- b. By adding the definition of “pharmaceutical universal waste” in alphabetical order.
- c. By republishing the introductory text of and revising paragraphs (3) and (4) and adding paragraph (5) to the definition of “Universal Waste” to read as follows:

§ 260.10 Definitions.

* * * * *

Pharmaceutical means 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 biohazardous waste, dental amalgams, medical

devices not used for delivery or dispensing purposes, equipment, contaminated personal protective equipment or contaminated cleaning materials.

* * * * *

Pharmaceutical Universal Waste means a pharmaceutical that is a hazardous waste as defined in § 261.3, and containers which have held any hazardous pharmaceutical waste and which would be classified as hazardous waste under § 261.7.

* * * * *

Universal Waste means any of the following hazardous wastes that are managed under the universal waste requirements of part 273 of this chapter:

* * * * *

- (3) Mercury-containing equipment as described in § 273.4 of this chapter;
- (4) Lamps as described in § 273.5 of this chapter; and
- (5) Pharmaceutical Universal Wastes as described in § 273.6 of this chapter.

* * * * *

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

3. 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.

4. Section 261.9 is amended as follows:

- a. By revising paragraphs (c) and (d).
- b. By adding paragraph (e) to read as follows:

§ 261.9 Requirements for universal waste.

* * * * *

- (c) Mercury-containing equipment as described in § 273.4 of this chapter;
- (d) Lamps as described in § 273.5 of this chapter; and
- (e) Pharmaceutical Universal Wastes as described in § 273.6 of this chapter.

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE AND DIPOSAL FACILITIES

5. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, and 6925.

6. Section 264.1 is amended as follows:

- a. By revising paragraphs (g)(11)(iii) and (iv).
- b. By adding paragraph (g)(11)(v) to read as follows:

§ 264.1 Purpose, scope, and applicability.

* * * * *

(g) * * *

(11) * * *

- (iii) Mercury-containing equipment as described in § 273.4 of this chapter;
- (iv) Lamps as described in § 273.5 of this chapter; and
- (v) Pharmaceutical Universal Wastes as described in § 273.6 of this chapter.

* * * * *

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE AND DISPOSAL FACILITIES

7. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, and 6937.

8. Section 265.1 is amended as follows:

a. By revising paragraphs (c)(14)(iii) and (iv).

b. By adding paragraph (c)(14)(v) to read as follows:

§ 265.1 Purpose, scope and applicability.

* * * * *

(c) * * *

(14) * * *

(iii) Mercury-containing equipment as described in § 273.4 of this chapter;

(iv) Lamps as described in § 273.5 of this chapter; and

(v) Pharmaceutical Universal Wastes as described in § 273.6 of this chapter.

* * * * *

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. Section 268.1 is amended as follows:

a. By revising paragraphs (f)(3) and (4).

b. By adding paragraph (f)(5) to read as follows:

§ 268.1 Purpose, scope and applicability.

* * * * *

(f) * * *

(3) Mercury-containing equipment as described in § 273.4 of this chapter;

(4) Lamps as described in § 273.5 of this chapter; and

(5) Pharmaceutical Universal Wastes as described in § 273.6 of this chapter.

PART 270—EPA ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM

11. The authority citation for part 270 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974.

12. Section 270.1 is amended as follows:

a. By revising paragraphs (c)(2)(viii)(C) and (D).

b. By adding paragraph (c)(2)(viii)(E) to read as follows:

§ 270.1 Purpose and scope of these regulations.

* * * * *

(c) * * *

(2) * * *

(viii) * * *

(C) Mercury-containing equipment as described in § 273.4 of this chapter;

(D) Lamps as described in § 273.5 of this chapter; and

(E) Pharmaceutical Universal Wastes as described in § 273.6 of this chapter.

* * * * *

PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT

13. The authority citation for part 273 continues to read as follows:

Authority: 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

14. Section 273.1 is amended as follows:

a. By revising paragraphs (a)(3) and (4).

b. By adding paragraph (a)(5) to read as follows:

§ 273.1 Scope.

(a) * * *

(3) Mercury-containing equipment as described in § 273.4 of this chapter;

(4) Lamps as described in § 273.5 of this chapter; and

(5) Pharmaceutical Universal Wastes as described in § 273.6 of this chapter.

* * * * *

15. Add § 273.6 to read as follows:

§ 273.6 Applicability—Pharmaceutical Universal Wastes.

(a) *Pharmaceutical Universal Wastes covered under this part 273.* The requirements of this part apply to persons managing pharmaceutical universal wastes, as described in § 273.9.

(b) *Generation of pharmaceutical universal wastes.*

(1) A partially-used pharmaceutical becomes a pharmaceutical universal waste on the date it is discarded.

(2) An unused pharmaceutical becomes a pharmaceutical universal waste on the date the handler decides to discard it.

16. Section 273.9 is amended by adding the definitions of “Pharmaceutical” and “Pharmaceutical Universal Waste” in alphabetical order and by revising the definitions of “Large quantity handler of universal waste,” “Small quantity handler of universal waste,” and by republishing the introductory text and revising paragraphs (3) and (4), and adding paragraph (5), to the definition “Universal waste” to read as follows:

§ 273.9 Definitions.

* * * * *

Large Quantity Handler of Universal Waste means a universal waste handler (as defined in this section) who accumulates 5,000 kilograms or more total of universal waste (batteries, pesticides, mercury-containing equipment, lamps, or pharmaceutical universal wastes, calculated collectively) at any time. This designation as a large quantity handler of universal waste is retained through the end of the calendar year in which the 5,000 kilogram limit is met or exceeded.

* * * * *

Pharmaceutical means 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 biohazardous waste, dental amalgams, medical devices not used for delivery or dispensing purposes, equipment, contaminated personal protective equipment or contaminated cleaning materials.

* * * * *

Pharmaceutical Universal Waste means a pharmaceutical that is a hazardous waste as defined in § 261.3 of this chapter, and containers which have held any hazardous

pharmaceutical waste and which would be classified as hazardous waste under § 261.7 of this chapter.

* * * * *

Small Quantity Handler of Universal Waste means a universal waste handler (as defined in this section) who does not accumulate 5,000 kilograms or more of universal waste (batteries, pesticides, mercury-containing equipment, lamps, or pharmaceutical universal wastes, calculated collectively) at any time.

* * * * *

Universal Waste means any of the following hazardous wastes that are subject to the universal waste requirements of this part 273:

* * * * *

- (3) Mercury-containing equipment as described in § 273.4 of this chapter;
- (4) Lamps as described in § 273.5 of this chapter; and
- (5) Pharmaceutical Universal Wastes as described in § 273.6 of this chapter.

* * * * *

17. Section 273.13 is amended by adding paragraph (e) to read as follows:

§ 273.13 Waste Management.

* * * * *

(e) *Pharmaceutical Universal Wastes.* A small quantity handler of universal waste must manage pharmaceutical universal wastes in a way that prevents releases of any universal waste or component of a universal waste to the environment, as follows:

(1) A small quantity handler of universal waste must contain pharmaceutical universal wastes in a container that is structurally sound, compatible with the pharmaceutical universal wastes, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(i) Incompatible wastes must not be placed in the same container, unless in compliance with § 265.17(b) of this chapter.

(2) A small quantity handler of universal waste may sort pharmaceutical universal wastes provided the handler:

(i) Ensures compliance with applicable OSHA regulations; and

(ii) Ensures that employees sorting pharmaceutical universal wastes are thoroughly familiar with proper pharmaceutical universal waste handling and emergency procedures;

(3) A small quantity handler of universal waste who generates a solid waste as a result of the sorting activities under paragraph (e)(2) of this section must determine whether the solid waste exhibits a characteristic of hazardous waste or is a listed hazardous waste identified in 40 CFR part 261, subparts C and D.

(i) If the solid waste is a listed hazardous waste or exhibits a characteristic of hazardous waste, it must be managed in compliance with all applicable requirements of 40 CFR parts 260 through 272. The handler is considered the generator of hazardous waste and is subject to 40 CFR part 262.

(ii) If the solid waste is not hazardous, the handler may manage the waste in a manner that is in compliance with applicable federal, state or local solid waste regulations.

18. Section 273.14 is amended by adding paragraph (f) to read as follows:

§ 273.14 Labeling/markings.

* * * * *

(f) Pharmaceutical universal waste, or a container in which the pharmaceutical universal waste is contained, must be labeled or marked clearly with either of the following phrases: “Universal Waste—Pharmaceuticals” or “Waste Pharmaceuticals.”

19. Section 273.32 is amended by revising paragraph (b)(4) to read as follows:

§ 273.32 Notification.

* * * * *

(b) * * *

(4) A list of all the types of universal waste managed by the handler (*e.g.*, batteries, pesticides, mercury-containing equipment, lamps, and pharmaceutical universal wastes); and

20. Section 273.33 is amended by adding paragraph (e) to read as follows:

§ 273.33 Waste management.

* * * * *

(e) *Pharmaceutical Universal Wastes.* A large quantity handler of universal waste must manage pharmaceutical universal waste in a way that prevents releases of any

universal waste or component of a universal waste to the environment, as follows:

(1) A large quantity handler of universal waste must contain pharmaceutical universal wastes in a container that is structurally sound, compatible with the pharmaceutical universal wastes, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(i) Incompatible wastes must not be placed in the same container, unless in compliance with § 265.17(b) of this chapter.

(2) A large quantity handler of universal waste may sort pharmaceutical universal wastes provided the handler:

(i) Ensures compliance with applicable OSHA regulations; and

(ii) Ensures that employees sorting pharmaceutical universal wastes are thoroughly familiar with proper pharmaceutical universal waste handling and emergency procedures;

(3) A large quantity handler of universal waste who generates a solid waste as a result of the sorting activities under paragraph (e)(2) of this section must determine whether the solid waste exhibits a characteristic of hazardous waste or is a listed hazardous waste identified in 40 CFR part 261, subparts C and D.

(i) If the solid waste is a listed hazardous waste or exhibits a characteristic of hazardous waste, it must be managed in compliance with all applicable requirements of 40 CFR parts 260 through 272. The handler is considered the generator of hazardous waste and is subject to 40 CFR part 262.

(ii) If the solid waste is not hazardous, the handler may manage the waste in a manner that is in compliance with applicable federal, state or local solid waste regulations.

21. Section 273.34 is amended by adding paragraph (f) to read as follows:

§ 273.34 Labeling/marketing.

* * * * *

(f) Pharmaceutical universal waste, or a container in which the pharmaceutical waste is contained, must be labeled or marked clearly with either of the following phrases:

“Universal Waste—Pharmaceuticals” or “Waste Pharmaceuticals.”