# SUPPORTING STATEMENT FOR
# EPA INFORMATION COLLECTION REQUEST NUMBER 2486.02
# REPORTING AND RECORDKEEPING REQUIREMENTS FOR THE FINAL RULE ON MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS

June 2018

# Table of Contents

## EXHIBITS

# 1. IDENTIFICATION OF THE INFORMATION COLLECTION

## 1(a) Title and Number of the Information Collection

This information Collection Request (ICR) is entitled "Management Standards for Hazardous Waste Pharmaceuticals," EPA ICR Number 2486.02.

## 1(b) Short Characterization

Section 3001 of the Resource Conservation and Recovery Act (RCRA) of 1976, as amended, requires the Environmental Protection Agency (EPA) to identify which solid wastes are hazardous wastes and therefore must be managed as hazardous waste during treatment, storage, or disposal. Under this authority, EPA established four hazardous waste characteristics (toxicity, reactivity, ignitability, and corrosivity), and listed specific wastes that must be managed as hazardous wastes. A small portion of pharmaceuticals are regulated as hazardous waste under Subtitle C of RCRA when discarded. However, healthcare (and associated) facilities that generate hazardous waste pharmaceuticals have reported having difficulties complying with the manufacturing-oriented framework of the Subtitle C hazardous waste regulations for several reasons, including the following:

- Healthcare workers are typically unfamiliar with the hazardous waste regulations, as their primary focus is to provide healthcare to their patients.

- Healthcare facilities stock thousands of items in their drug formularies and may find it difficult to ascertain which items are hazardous wastes when disposed.

- Some pharmaceuticals are listed as acute hazardous wastes under RCRA, which are stringently regulated even in small amounts.

To facilitate compliance and to respond to the above concerns, EPA is revising the regulations to improve management and disposal of hazardous waste pharmaceuticals and tailor them to address the specific issues that hospitals, pharmacies and other healthcare-related facilities face. The revisions are also intended to clarify regulation of the reverse distribution mechanism used by healthcare facilities for management of unused and/or expired pharmaceuticals. In 2008, the Agency proposed to address pharmaceutical hazardous waste management issues by adding them to the Universal Waste program (73 FR 73520; December 2, 2008). In order to address the adverse comments received on the 2008 proposal, EPA then re-proposed sector specific regulations for the management of hazardous waste pharmaceuticals (80 FR 58014; September 25, 2015). EPA is now finalizing the sector specific regulations for the management of hazardous waste pharmaceuticals.

EPA is adding a new subpart P under part 266. This new subpart is a tailored, sector-specific regulatory framework for managing hazardous waste pharmaceuticals at healthcare

facilities and reverse distributors. Healthcare facilities that are currently small quantity generators (SQGs) or large quantity generators (LQGs) and all reverse distributors, regardless of RCRA generator category, will be required to manage hazardous waste pharmaceuticals under this new subpart P of part 266, in lieu of part 262. That is, the final standards are not an optional alternative to managing hazardous waste pharmaceuticals under part 262, they are mandatory standards.

Healthcare facilities will have different management standards for their non-creditable and potentially creditable hazardous waste pharmaceuticals. Non-creditable hazardous waste pharmaceuticals will be managed on-site similar to how they would have been under the 2008 Universal Waste proposal for pharmaceutical waste. When they are shipped off-site, they must be transported as hazardous wastes and sent to a RCRA interim status or permitted hazardous waste facility. On the other hand, healthcare facilities will continue to be allowed to send potentially creditable hazardous waste pharmaceuticals to reverse distributors for verification of manufacturer credit. EPA is finalizing standards to ensure the safe and secure delivery of the potentially creditable hazardous waste pharmaceuticals to reverse distributors.

EPA is also finalizing standards for the accumulation of the hazardous waste pharmaceuticals at reverse distributors. The standards regard reverse distributors as a new type of hazardous waste entity called reverse distributors. The standards for reverse distributors are, in many respects, similar to the LQGs standards, with some supplementary standards that were added to respond to commenters' concerns.

The key provisions of EPA's final rule are:

- Hazardous waste pharmaceuticals managed under the new rule are not counted toward a facility's RCRA generator status.

- Reverse distributors must comply with LQG-like standards regardless of the quantity of hazardous waste pharmaceuticals that they manage.

- FDA approved over-the-counter nicotine replacement therapies, such as patches, gums, and lozenges, will no longer by managed as hazardous waste.

- Sewer disposal of hazardous waste pharmaceuticals is prohibited.

The requirements covered in this ICR are for the requirements that healthcare facilities (including retail facilities) and reverse distributors managing hazardous waste pharmaceuticals have under 40 CFR part 266 subpart P. The final rule is expected to result in a reduction in paperwork burden for a subset of facilities. For example, EPA expects that many facilities will be able to operate as very small quantity generators (VSQGs) rather than large quantity generators (LQGs) as a result of the exemption for FDA approved over-the-counter nicotine replacement therapies. However, rather than estimating the burden reduction for the affected facilities under this ICR, EPA estimates the total burden to reverse distributors and healthcare

facilities for the paperwork requirements under subpart P. In a separate action, EPA will amend the base Hazardous Waste Generator Standards ICR to reflect the burden reduction that results from this final rule.[1] The burden reduction from the final rule is due to the fact that many facilities will experience a change in generator category from LQG to VSQG, and therefore EPA will amend the base Hazardous Waste Generator ICR to remove the facilities from the universe that are no longer expected to comply with the standards for LQGs.

## 2. NEED FOR AND USE OF THE COLLECTION

### 2(a) Need and Authority for the Collection

The requirements covered in this ICR are necessary for EPA to identify the universe of healthcare facilities (including retail facilities) and reverse distributors managing hazardous waste pharmaceuticals under 40 CFR part 266 subpart P. The notification requirements are needed to assist the Agency and regulated facilities in tracking hazardous waste pharmaceuticals. In addition, the tracking requirements will help EPA and facilities ensure that hazardous waste pharmaceuticals arrive at their intended destination rather than at facilities not equipped to manage these wastes.

### 2(b) Practical Utility and Users of the Data

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

## 3. NONDUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

### 3(a) Nonduplication

None of the information required by the final rule would duplicate information required by existing RCRA regulations.

### 3(b) Public Notice

1 EPA will amend EPA ICR Number 0820.13 “Hazardous Waste Generator Standards” to reflect the burden reduction under this final rule. The ICR was last renewed in September 2014.

In compliance with the Paperwork Reduction Act of 1995, EPA opened a 90-day public comment period on September 25, 2015 when the proposed rule was published in the *Federal Register*. To assist the public in commenting on the proposal, EPA raised a number of issues in the preamble to the proposed rule and asked for the public to comment on them. At the end of the comment period, EPA reviewed public comments received in response to the notice and addressed comments received, as appropriate.

### 3(c) Consultations

EPA consulted and collected information from interested parties over several years to support the proposed amendment to the Universal Waste Rule (the 2008 proposal). EPA staff made site visits to hospitals, reverse distributors, and other pharmaceutical waste generators, met with retailers, and communicated with states and other interested parties. The summaries of the site visits, meetings, and telephone conversations with interested parties are available in the docket for the rule (Docket ID No. EPA-HQ-RCRA-2007-0932). Additional site visits and consultations have been made to support the 2015 proposal and this final rule.

### 3(d) Effects of Less Frequent Collection

EPA has carefully considered the burden imposed upon the regulated community by the final rule. EPA is confident that those activities required of respondents are necessary, and to the extent possible, the Agency has attempted to minimize the burden imposed. EPA believes strongly that, if the minimum information collection requirements of the final rule are not met, neither the industry nor EPA will be able to ensure that pharmaceutical wastes are being managed in a manner protective of human health and the environment.

### 3(e) General Guidelines

This ICR adheres to the guidelines stated in the Paperwork Reduction Act of 1995, OMB's implementing regulations, EPA's ICR Handbook, and other applicable OMB guidance.

### 3(f) Confidentiality

Section 3007(b) of RCRA and 40 *CFR* Part 2, Subpart B, which defines EPA's general policy on public disclosure of information, contain provisions for confidentiality. However, the Agency does not anticipate that businesses will assert a claim of confidentiality covering all or part of the final rule. If such a claim were asserted, EPA must and will treat the information in accordance with the regulations cited above. EPA also will assure that this information collection complies with the Privacy Act of 1974 and OMB Circular 108.

### 3(g) Sensitive Questions

No questions of a sensitive nature are included in the information collection requirements associated with the final rule.

## 4. THE RESPONDENTS AND THE INFORMATION REQUESTED

### 4(a) Respondents and NAICS Codes

The following is a list of North American Industrial Classification System (NAICS) codes associated with the facilities most likely to be affected by the information collection requirements covered in this ICR.

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

### 4(b) Information Requested

This section describes reporting and recordkeeping requirements for facilities managing hazardous waste pharmaceuticals under the final rule.

**(1) Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals Under 40 CFR § 266.502.**

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

(i) A healthcare facility that already has an EPA identification number must notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700-12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if it is not

required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to his subpart.

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

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

(B) ***Notification of Withdrawal.*** A healthcare facility that operated under this subpart but is no longer subject to this subpart, because it is a very small quantity generator under 40 CFR § 262.14, and elects to withdraw from this subpart, must notify the appropriate EPA Regional Administrator using the Site Identification Form (EPA form 8700-12) that it is no longer operating under this subpart. A healthcare facility is not required to fill out Box 11 (Description of Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each EPA Identification Number.

(i) A healthcare facility must submit the Site Identification Form notifying that it is withdrawing from this subpart before it begins operating under the conditional exemption of § 262.14.

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

(C) ***Labeling.*** A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase “Hazardous Waste Pharmaceuticals.”

(D) ***Maximum Accumulation Time.*** A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(i) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that hazardous waste pharmaceuticals became a waste;

(ii) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceutical being accumulated first became a waste;

(iii) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

(E) ***Tracking Rejected Shipments.*** Upon receipt of the returned shipment, the healthcare facility must:

(i) sign either

(a) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(b) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within 30 days of receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(iv) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of § 266.508(a).

(F) ***Exception report for a missing copy of the manifest.*** For shipments from a healthcare facility to a designated facility: If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(i) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located, and

(ii) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

For shipments rejected by the designated facility and shipped to an alternate facility: If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility within 60 days of the date the waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(iii) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located, and

(iv) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(G**)** ***Additional reports.*** The EPA Regional Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(H) ***Recordkeeping.***

(i) A healthcare facility must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

(ii) A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

(iii) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) for at least three years from the date the waste was last sent to on-site or off-site treatment, storage, or disposal. A healthcare facility that manages all of its non-creditable non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals is not required to keep documentation of hazardous waste determinations.

(iv) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(v) A healthcare facility that accepts hazardous waste pharmaceuticals from off site VSQG healthcare facilities must keep records of the shipments it receives from off site for three years from the date the shipment is received.

**(2) Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals Under 40 CFR § 266.503.**

(A) ***Recordkeeping.*** A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor, for 3 years from the date of shipment:

(i) the confirmation of delivery and

(ii) the shipping paperspreparedin accordance with 49 CFR part 172 subpart C, if applicable..

The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

**(3) Shipping Non-Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or Evaluated Hazardous Waste Pharmaceuticals from a Reverse Distributor Under 40 CFR § 266.508.**

(A) ***Labeling.*** A healthcare facility or reverse distributor must label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172 subpart E.

(B) ***Marking.*** Mark each package of hazardous waste pharmaceuticals in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172 Subpart D; Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.
Healthcare Facility's or Reverse Distributor's Name and Address _____.
Healthcare Facility's or Reverse Distributor's EPA Identification Number_____.
Manifest Tracking Number _____.

(C) ***Placarding.*** Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR part 172, subpart F.

(D) ***Manifesting.*** The requirements of part 262 subpart B, except that:

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable hazardous waste numbers (i.e., hazardous waste codes) in Item 13 of EPA Form 8700-22.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the words "PHARMS" in Item 13 of EPA Form 8700-22.

(E*) **Exporting Requirements.*** A healthcare facility or reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to part 262 subpart H.

(F) ***Importing Requirements.*** Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to part 262 subpart H. A healthcare facility or reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, unless they have a permit or interim status that allows them to accept hazardous waste from off-site.

**(4) Shipping Potentially Creditable Hazardous Waste Pharmaceuticals from a Healthcare Facility or a Reverse Distributor to a Reverse Distributor Under 40 CFR § 266.509.**

(A) ***Delivery Confirmation.*** Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived at its destination and is under the custody and control of the reverse distributor. If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within 35 calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or reverse distributor that initiated the shipment must contact the carrier and the intended recipient (i.e., the reverse distributor) promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(B) ***Exporting Requirements.*** A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the applicable sections of 40 CFR part 262 subpart H, except the manifesting requirements of § 262.83(c), in addition to paragraph (A) of this section.

(C) ***Importing Requirements.*** Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to paragraphs (A) of this section in lieu of 40 CFR part 262 subpart H.

**(5) Reverse Distributors Managing Potentially Creditable and Evaluated Hazardous Waste Pharmaceuticals Under 40 CFR § 266.510.**

(A) ***Notification.*** A reverse distributor must notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700-12), that it is a reverse distributor operating under this subpart.

(i) A reverse distributor that already has an EPA identification number must notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700-12), that it is a reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A reverse distributor that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA form 8700-12), that it is a pharmaceutical reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(B) ***Inventory.*** A reverse distributor must maintain an inventory of all the potentially creditable and evaluated hazardous waste pharmaceuticals that are accumulated on-site.

(i) A reverse distributor must maintain a current inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of arriving at the reverse distributor.

(ii) The inventory must include the identity (e.g., name or national drug code (NDC)) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(C) ***Maximum Accumulation Time.*** A reverse distributor that accumulates potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site may choose to demonstrate the length of time that the hazardous waste pharmaceuticals have been accumulating. EPA assumes they will use their inventory to keep track of how long have been accumulating.

(D) ***Contingency Planning.*** A reverse distributor must prepare a contingency plan and comply with the other requirements of 40 CFR 262 subpart M.

(E) ***Reporting.*** A reverse distributor must submit an unauthorized hazardous waste report if the reverse distributor receives waste from off-site that it is not authorized to receive (e.g., non-pharmaceutical hazardous waste, regulated medical waste). The reverse distributor must prepare and submit an unauthorized waste report to the EPA Regional Administrator within 45 calendar days after the unauthorized waste arrives at the reverse distributor and the reverse distributor must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The pharmaceutical reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor, or its authorized representative, and contain the following information:

(i) The EPA identification number, name and address of the reverse distributor;

(ii) The date the reverse distributor received the unauthorized waste;

(iii) The EPA identification number, name and address of the healthcare facility that shipped the unauthorized waste, if available;

(iv) A description and the quantity of each unauthorized waste the reverse distributor received;

(v) The method of treatment, storage, or disposal for each unauthorized waste; and

(vi) A brief explanation of why the waste was unauthorized, if known.

(F) ***Additional Reports.*** The EPA Regional Administrator may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(G) ***Recordkeeping.*** A reverse distributor must keep the following records (paper or electronic):

(i) A copy of its notification on file for as long as the facility is subject to this subpart

(ii) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives for at least three years from the date the shipment arrives at the reverse distributor.

(iii) A copy of its current inventory for as long as the facility is subject to this subpart.

(H) ***Additional Records.*** A reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three years from the date of shipment:

(i) the confirmation of delivery, and

(iii) the shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

(H) ***Labeling.*** A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must label the containers with the words, "hazardous waste pharmaceuticals";

(I) ***Marking.*** Prior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable hazardous waste numbers (i.e., hazardous waste codes).

(J) **M*anaging Rejected Shipments.*** Upon receipt of the returned shipment, the reverse distributor must:

(i) Sign either item 18c of the original manifest if the original manifest was used for the returned shipment; or item 20 of the new manifest if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within 30 days of delivery of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; and

(iv) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the shipping standards of § 266.508(a) or (b).

(K) ***Biennial Reporting for Evaluated Hazardous Waste Pharmaceuticals.*** A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of a biennial report to the EPA Regional Administrator by March 1 of each even numbered year in accordance with § 262.41.

(L) ***Exception reporting for a missing copy of the manifest.*** For shipments from a reverse distributor to a designated facility:

(i) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(ii) A reverse distributor must submit an exception report to the EPA Regional Administrator for the Region in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include: (a) A legible copy of the manifest for which the reverse distributor does not have confirmation of delivery; and (b) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(M) ***Rejected Shipments.*** For shipments rejected by the designated facility and shipped to an alternate facility:

(i) A reverse distributor that does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The 35-day timeframe begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

(ii) A reverse distributor must submit an Exception Report to the EPA Regional Administrator for the Region in which the reverse distributor is located if it has not received a copy of the manifest with the signature of the owner or operator of the alternate facility

within 45 days of the date the hazardous waste was accepted by the initial transporter. The 45-day timeframe begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility. The Exception Report must include: (a) A legible copy of the manifest for which the generator does not have confirmation of delivery; (b) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(N) ***Recordkeeping for evaluated hazardous waste pharmaceuticals.***

(i) A reverse distributor must keep a log (written or electronic) of the inspections of the on-site accumulation area, required by paragraph (c)(2) of this section. This log must be retained as a record for at least three years from the date of the inspection.

(ii) A reverse distributor must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility which received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(iii) A reverse distributor must keep a copy of each biennial report for at least three years from the due date of the report.

(iv) A reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(v) A reverse distributor must keep records to document personnel training, in accordance with § 262.17(a)(7)(iv).

## 5. THE INFORMATION COLLECTED --AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

### 5(a) Agency Activities

Most of the information that is required of facilities managing hazardous waste pharmaceuticals would be kept on site and not be submitted to EPA for review. The Agency will collect a limited amount of information from healthcare facilities and reverse distributors in states that are not authorized to operate their RCRA Subtitle C hazardous waste program. In general, however, most authorized state programs will collect information in lieu of EPA. In states that are not authorized to operate their RCRA Subtitle C hazardous waste program, EPA will collect information related to notification, Biennial Reporting, and exception reporting. EPA will receive notifications from healthcare facilities and reverse distributors when they begin operating under subpart P. However, as stated earlier, it is assumed that LQGs and SQGs have previously notified EPA of their hazardous waste management activities under RCRA and have received an EPA Identification number. Nevertheless, they will be required to notify the Agency

under the final rule to indicate that they are operating under this new part 266 subpart P. This should not cause a significant increase in burden to the Agency compared to existing burden. EPA will also receive exception reports from healthcare facilities and reverse distributors when they do not receive a copy of the manifest with the signature of the owner or operating of the designated facility. EPA will also receive biennial reports from healthcare facilities and reverse distributors. However, these facilities are already estimated to be preparing biennial reports in the baseline, and thus it should not cause an increase in burden to the Agency.

### 5(b) Collection Methodology and Management

The information collected will be managed in a similar manner to previous notifications and exception reporting received by EPA. EPA will use equipment such as personal computers and applicable database software.

### 5(c) Small Entity Flexibility

The final rule is not expected to cause a significant impact on small entities. Under the final rule, healthcare facilities, including healthcare facilities currently operating as large quantity generators (LQGs) and small quantity generators (SQGs) will benefit due to greater flexibility in how they manage their hazardous waste. Hazardous waste pharmaceuticals will no longer be counted against a facility's hazardous waste generator status. In addition, EPA allows very small quantity generators (VSQGs) to manage their hazardous waste pharmaceuticals either under the specific provisions of the final rule or under the existing VSQG exemption in 40 CFR 261.5.

### 5(d) Collection Schedule

As stated in 5(a) above, most of the information that is required of facilities managing hazardous waste pharmaceuticals would be kept on site and not be submitted to EPA for review. Facilities will be required to submit a notification to EPA in order to indicate that they are operating under the new part 266 subpart P. A notification must be submitted within 60 days of when a facility becomes subject to the rule.

## 6. ESTIMATING THE HOUR AND COST BURDEN OF THE COLLECTION

### 6(a) Estimating Respondent Burden

In Exhibit 1, EPA presents the estimates of the annual respondent burden associated with the new information collection requirements in the final rule. As shown in the exhibit, EPA estimates that the total annual respondent burden for the paperwork requirements in the rule is 39,255 – 43,350 hours when averaged over three years.

### 6(b) Estimating Respondent Costs

In Exhibits 1, EPA also presents estimates of the total annual respondent costs for the changes in paperwork requirements in the final rule. EPA expects the final rule will result in a total annual respondent cost of $2,290,488-$2,531,327 (averaged over three years). This change in costs includes annual labor, capital, and operation and maintenance (O&M) costs to be incurred or saved by respondents affected by the information collection requirements covered in this ICR. Specific data and/or assumptions used in developing these costs are described below.

**Labor Costs**

For purposes of this analysis, EPA estimates an average hourly respondent labor cost of $128 for legal staff, $108 for managerial staff, $53 for technical staff, and $30 for clerical staff. These hourly labor costs were obtained from the economics background document developed for the final rule (see "Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals," which is available in the public docket identified under Section 6(g)).

**Annual Capital and Operation & Maintenance Costs**

Capital costs usually include any produced physical good needed to provide the needed information, such as machinery, computers, and other equipment. EPA does not anticipate that respondents will incur capital costs in carrying out the information collection requirements of the final rule.

O&M costs are those costs associated with paperwork requirements incurred continually over the life of the ICR. They are defined by the EPA as "the recurring dollar amount of costs associated with O&M or purchasing services." For this ICR, O&M costs would be for mailing and photocopying.

**6(c) Estimating Agency Burden and Costs**

The annual burden and costs to the Agency for collecting information under the rule is negligible. Generally, respondents would keep all records required under the final rule on-site. There are minimal provisions that require respondents to submit any information for its review and approval under the final rule.

ICR uses the 2017 Federal Pay Schedule salary figures to estimate hourly compensation of EPA legal, managerial, technical, and clerical staff.[2] For purposes of this ICR, the following government services levels were assigned:

- Legal Staff: GS-15, Step 5 ($115.31/hr)
- Managerial Staff: GS-13, Step 5 ($82.95/hr)
- Technical Staff: GS-11, Step 5 ($58.21/hr)

2 U.S. Office of Personnel Management, Salary Table 2017-GS, Incorporating the 1% General Schedule Increase, Effective January 2017, Hourly Basic Rates by Grade and Step, accessed at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/ September 26, 2017.

- Clerical Staff: GS-06, Step 5 ($35.39/hr)

The hourly rates above reflect base salary plus the fringe benefit and overhead factors cited above.

EPA estimates that the Agency will face a one-time burden for reviewing notifications submitted by healthcare facilities that were previously operating as SQGs in unauthorized states (Iowa and Alaska). EPA estimates that between 73 and 106 healthcare facilities will submit notifications to EPA for review. LQGs in these states can submit notifications during their next biennial report. EPA relies on the ICR for the proposed rule to add aerosol cans to universal waste to estimate the amount of time it takes the Agency to review notifications for completeness.[3] EPA estimates that it will take 0.08 hours of manager time, 0.93 hours of technician time, and 0.08 hours of clerical time for the one-time burden of reviewing notification submitted by healthcare facilities. This results in a total estimated burden of 73 – 106 hours at a total cost of $4,920 – $7,145 for the Agency, or an average annual cost of $1,640 to $2,382 over the first three years of the rule.

Although the Agency will review biennial reports from reverse distributors for their hazardous waste pharmaceuticals in these states, EPA expects that the Agency will already review biennial reports from reverse distributors due to their non-pharmaceutical hazardous waste, and thus will not face an increase in burden under this rule.

### 6(d) Estimating the Respondent Universe and Total Burden and Costs

#### Respondent Universe

In Exhibit 1, EPA provides estimates of the annual number of respondents that will be required to comply with the new paperwork requirements in the final rule. The number of respondents varies based on type of paperwork requirement. This is because the paperwork requirements are not the same for all respondents (i.e., reverse distributors, healthcare facilities, and VSQGs). Table 1 presents the number of respondents that could potentially be affected by the final rule.[4] It shows that EPA estimates 11,916-13,373 facilities handle hazardous waste pharmaceuticals each year that will have paperwork burdens. There are no paperwork requirements in the final rule for VSQGs (except for VSQG reverse distributors, although EPA estimates all reverse distributors are LQGs).

**TABLE 1**

**NUMBER OF FACILITIES POTENTIALLY AFFECTED BY THE FINAL RULE**

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3 See "Supporting Statement for EPA Information Collection Request Number 1597.12, "Reporting and Recordkeeping Requirements for the Proposed Aerosol Can Universal Waste Rule."

4These universe assumptions are based on the economics background document developed for the final rule: "Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals."

| Type of Respondent | Number of Facilities |
|---|---|
| Reverse Distributors | 27 |
| Healthcare Facilities[1] | 11,889-13,346 |
| **Total** | 11,916-13,373 |

1.) Includes healthcare facilities that are estimated to remain LQGs and SQGs under 40 CFR part 262 and healthcare facilities that are estimated to drop down to VSQGs for their non-pharmaceutical hazardous waste but must still comply with the subpart P recordkeeping requirements. See "Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals" for more detail on the universe of impacted facilities. EPA estimates that of these healthcare facilities, 6,337 were operating as LQGs prior to subpart P and will either drop down a generator category or will continue operating as LQGs in addition to operating as healthcare facilities under subpart P. EPA estimates that 5,552-7,009 were operating as SQGs and will either drop down a generator category or will continue operating as SQGs in addition to operating as healthcare facilities under subpart P.
2.) This assumes VSQGs, except for VSQG reverse distributors, are unlikely to read the rule because there are no new information collection requirements for VSQGs in the final rule.

**Respondent Burden and Cost**

Based on the universe data presented in Table 1 and information contained in the economics background document developed for the final rule, EPA estimated the changes in respondent burden and cost associated with the changes in information collection requirements covered in this ICR. A discussion of the assumptions used in developing these burden and cost estimates follows.

**Reading the Regulations**

As shown in Exhibit 1, EPA estimates that 11,889 - 13,346 facilities will need to read the rule in order to understand and comply with the new information collection requirements. For purpose of this analysis, we assumed that the hours required for reading/reviewing this new rule would be similar to the hours used in EPA's assessment of the impacts associated with reading/reviewing the 2009 Final Rule governing the Exporting of Spent Lead-Acid Batteries (SLAB). EPA estimated 3.5 hours per respondent for reading the rule for the 11,889 - 13,346 respondents. This resulted in total burden of 41,706 – 46,806 hours, at total cost of $2,878,012 - $3,229,914, for all of the respondents reading the rule.

**Notifications to EPA**

Under current RCRA Subtitle C regulations, LQGs and SQGs are required to notify EPA and obtain an EPA ID number prior to managing hazardous wastes. LQGs and some SQGs are also subject to biennial reporting. Therefore, there are no additional notification costs to generators that are already submitting a biennial report, since they can notify when they submit their biennial report. The initial notification costs are estimated only for SQGs that will also be

healthcare facilities operating under subpart P located in states that do not require SQGs to submit biennial reports. EPA estimated that there are 4,586 – 5,750 facilities in such states. EPA also estimated a one-time cost of approximately $64.42 for initial notification. Based on this information, the total respondent burden for notifications is estimated to be 4,999 – 6,268 hours, at a cost of $295,410 – $370,389 (see Exhibit 1).

**Labeling**

Under the final rule, healthcare facilities and reverse distributors are required to label containers holding non-creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals with the words "Hazardous Waste Pharmaceuticals," but are not required to mark an indication of the hazards of the contents of the container or the accumulation start date on the container (which is required under RCRA Subtitle C regulations for LQGs and SQGs). To ensure compliance with accumulation time limits, however, it is likely most facilities will label the accumulation start date on the container. EPA estimates that of these healthcare facilities, 6,337 were operating as LQGs prior to subpart P and will either drop down a generator category or will continue operating as LQGs in addition to operating as healthcare facilities under subpart P. EPA estimates that 5,552-7,009 were operating as SQGs and will either drop down a generator category or will continue operating as SQGs in addition to operating as healthcare facilities under subpart P. EPA estimates that reverse distributors and healthcare facilities that were operating as LQGs prior to subpart P and will either drop down a generator category or will continue operating as LQGs in addition to operating as healthcare facilities under subpart will spend 1 hour labeling containers in their primary storage area and .5 hours labeling containers in satellite storage areas.[5] EPA estimate that healthcare facilities that were operating as SQGs and will either drop down a generator category or will continue operating as SQGs in addition to operating as healthcare facilities under subpart P will spend .25 hours labeling containers in their primary storage area and .25 hours labeling containers in their satellite storage area. Based on this information, the total respondent burden is estimated to be 12,282-13,010 hours at a cost of $653,990 - $692,783 (see Exhibit 1).

**Rejected Shipments and Exception Reporting**

Under the final rule, healthcare facilities and reverse distributors must track or manage rejected shipments by signing an item on the manifest, providing the transporter with a copy of the manifest, and sending a copy of the manifest to the designated facility that returned or rejected the shipment. Additionally, healthcare facilities and reverse distributors must submit exception reports for a missing copy of a manifest. EPA assessment of the impacts for exception reporting is similar to the hours used in EPA's assessment of the impacts associated with the Requirements for Generators, Transporters, and Waste Management Facilities under the RCRA Hazardous Waste Manifest System – Final Fee Rule.[6] EPA estimates it will take a healthcare

5 The assumptions for the labeling estimates are based on the economics background document developed for the final rule: "Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals."

6 See Supporting Statement for Information Collection Request (ICR) Number 0801.22 "Requirements for Generators, Transporters, and Waste Management Facilities under the RCRA Hazardous Waste Manifest System – Final Fee Rule (Final Rule)"

facility and reverse distributor 1.10 hours to prepare and submit an exception report and 0.1 hours to keep a copy of the exception report. EPA assumes it will take a similar amount of time for a healthcare facility or reverse distributor to track or manage rejected shipments by signing an item on the manifest, providing the transporter with a copy of the manifest, and sending a copy of the manifest to the designated facility that returned or rejected the shipment. In line with the Final Fee Rule ICR, EPA estimates that 1% of the manifests sent offsite will require an exception report. EPA assumes a similar number of rejected shipments will need to be tracked or managed by healthcare facilities and reverse distributors. EPA assumes that healthcare facilities will send one shipment of non-creditable hazardous waste pharmaceuticals to a designated facility annually that requires a manifest and a revere distributor will send 4 shipments of evaluated hazardous waste pharmaceuticals to a designated facility annually that require a manifest (assuming that facilities will accumulate hazardous waste pharmaceuticals on site for the maximum allowed time under subpart P). Thus, EPA estimates that there are 11,997 to 13,454 shipments annually that will require a manifest. EPA estimates that 120 to 135 shipments annually will require an exception report, and that 120 to 135 shipments annually will be rejected and requiring managing or tracking. Based on this information, the total respondent burden is estimated to be 276-311 hours at a cost of $20,490 to $23,051 (see Exhibit 1).

**Recordkeeping**

Under the final rule, reverse distributors and healthcare facilities must keep a signed copy of each manifest for three years and a copy of their notification on file as long as they are subject to this subpart. Healthcare facilities must keep records of any test results, waste analyses, or other determinations in support of hazardous waste determinations. Reverse distributors must keep records of inspections of on-site accumulation areas for three years, a copy of each biennial report for three years from the submission of the report, and records documenting personnel training. A healthcare facility that accepts hazardous waste pharmaceuticals from off site VSQG healthcare facilities must keep records of the shipments it receives from off site. EPA relies on the Final Hazardous Waste Generator Improvements Rule ICR to estimate the percentage of healthcare facilities that accept hazardous waste from off site and assumes it is the same as the percentage of LQGs receiving intra-organization transfers (17 percent).[7] EPA estimates the time required for each recordkeeping to be 0.1 hours annually per respondent per record, at cost of $5.32. The total annual respondent burden for recordkeeping is estimated to be 3,782-4,244 hours at a cost of $201,407 to $226,004. (see Exhibit 1).

Healthcare facilities and reverse distributors that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep records of the delivery confirmation and the shipping papers under the final rule. As described in the preamble to the final rule, current carrier services generally used by healthcare facilities and reverse distributors meet the delivery confirmation requirements. Thus, EPA assumes there will be no additional paperwork burden for healthcare facilities and reverse distributors as a result of this provision, as they are assumed to be keeping electronic copies in the baseline. Under the final

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7 See supporting statement for EPA Information Collection Request number 2513.02, “Reporting and Recordkeeping Requirements for the Final Hazardous Waste Generator Improvements Rule.”

rule, reverse distributors are also required to keep records of their current inventory as long as the facility is subject to subpart P. As discussed in the preamble to the final rule, reverse distributors is aware that revere distributors generally inventory and evaluate potentially creditable hazardous waste pharmaceuticals at the same time using an electric system. Thus, EPA assumes there will be no additional paperwork burden for reverse distributors relative to the baseline as a result of the inventory requirements and the associated inventory recordkeeping requirement.

**Manifests and Shipping**

Under the final rule, healthcare facilities must complete manifests for non-creditable pharmaceuticals shipped to a TSDF, but need not include RCRA waste codes on these manifests. This represents a burden of approximately 0.31 hours per shipment for a technician to complete a manifest and 0.21 hours of administrative time.[8] For reverse distributors, the final rule requires a full manifest (including waste codes) for evaluated hazardous waste pharmaceuticals shipped to a TSDF. This represents a burden of approximately 0.41 hours per shipment for a technician to complete a manifest and 0.21 hours of administrative time. As discussed previously, EPA assumes that healthcare facilities will sent one shipment of non-creditable hazardous waste pharmaceuticals to a designated facility annually that requires a manifest and a reverse distributor will send 4 shipments of evaluated hazardous waste pharmaceuticals to a designated facility annually that require a manifest. Thus, because reverse distributors complete 4 manifests annually, this represents a burden of 1.64 hours of technician time and 0.84 hours of administrative time.

In order to estimate the number of healthcare facilities and reverse distributors that export evaluated, or potentially creditable hazardous waste pharmaceuticals, EPA relies on the supporting statement for the 2014 ICR renewal for the Hazardous Waste Generator Standards.[9] In the 2014 ICR, EPA estimated there are 67,288 generators total, and of them there are 702 that export hazardous waste. Thus, EPA estimated that approximately 1% of hazardous waste generators export hazardous waste. EPA applies this percentage to the estimated universe of healthcare facilities and reverse distributors to estimate the number that export non-creditable, evaluated, or potentially creditable hazardous waste pharmaceuticals. EPA estimates that one reverse distributor will export hazardous waste pharmaceuticals and 119 to 133 healthcare facilities will export hazardous waste pharmaceuticals. This ICR accounts for the burden associated with completing a movement document for each export of non-creditable or evaluated hazardous waste pharmaceuticals. EPA uses the estimate from the 2016 ICR for the final Hazardous Waste Export-Import Revisions Rule.[10] EPA estimates it will take 0.5 hours of technical time and 0.5 hours of administrative time to complete a movement document. As result

8 The assumptions for the manifest estimates are based on the economics background document developed for the final rule: "Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals."

9 See Supporting Statement for EPA Information Collection Request Number 0820.13, "Hazardous Waste Generator Standards," September 2014.

10 See Supporting Statement for EPA Information Collection Request Number 2519.01 "Hazardous Waste Export-Import Revisions Rule."

of the manifest and shipping requirements in the final rule, EPA estimates that the burden will be 6,369-7,141 hours, resulting in a cost of $280,017 to $2,600,329 (see Exhibit 1).

**Contingency Planning**

Under the final rule, a reverse distributor must comply will the contingency plan requirements of 40 CFR 262 subpart M. This ICR assumes that reverse distributors have already prepared contingency plans. Therefore, only reverse distributors that need to amend their contingency plans annually will have a paperwork burden under this provision of the final rule. In the 2014 ICR renewal for the Hazardous Waste Generator Standards, EPA estimated that 10 percent of their universe of LQGs will amend their contingency plan annually.[11] EPA uses the same percentage for this ICR, and estimates that 3 reverse distributors will amend their contingency plan annually. EPA also relies on the 2014 ICR renewal for the Hazardous Waste Generator Standards for the estimated burden, and estimates that it takes 1.5 hours of technician time and 1.5 hours of administrative time to amend a contingency plan. As result of the contingency planning requirements in the final rule, EPA estimates that the burden will be 9 hours, resulting in a cost of $376 (see Exhibit 1).

**Unauthorized Waste Reporting**

Under the final rule, a reverse distributor must submit an unauthorized hazardous waste report if it receives waste it is not authorized to receive. EPA estimates that 1% of the shipments that go from a healthcare facility to a reverse distributor will be waste that the reverse distributor is not authorized to receive. Using the assumptions from the RIA for the final rule, EPA estimates healthcare facilities send 4 shipments of hazardous waste pharmaceuticals to reverse distributors annually.[12] Thus, EPA estimates in total that healthcare facilities will send between 47,556-52,384 shipments to the 27 reverse distributors annually, resulting in an estimated 476-534 shipments that healthcare facilities send to the 27 reverse distributors annually that they are not authorized to receive. EPA estimates that each reverse distributor will therefore submit 18-20 unauthorized waste reports per year. EPA assumes it will a similar amount of time to submit an unauthorized waste report as it does to submit an exception report. Thus, EPA estimates it will take 0.5 hours of management time, 0.5 hours of technician time, and 0.1 hours of administrative time to submit an unauthorized waste report. On average, each reverse distributor will therefore spend 9.5 hours of management time, 9.5 hours of technician time, and 1.9 hours of administrative time submitting unauthorized waste reports. As a result of the final rule, EPA estimates the burden associated with submitting unauthorized waste reports will result in a total burden of 564 hours annually at a cost of $42,019 (see Exhibit 1).

**Biennial Reports**

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11 See Supporting Statement for EPA Information Collection Request Number 0820.13, "Hazardous Waste Generator Standards," September 2014.

12 The assumptions for the manifest estimates are based on the economics background document developed for the final rule: "Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals."

Under the final rule, hazardous waste pharmaceuticals will no longer count toward a healthcare facility's generator status and need not be included in facilities' Biennial Report submissions. Reverse distributors will still be required to submit a biennial report if they ship evaluated hazardous waste pharmaceuticals off site. The fixed costs of preparing a biennial report include the time to read the instructions, complete the site ID form, and submit the report to state authorities or EPA. However, EPA expects that reverse distributors will remain LQGs for their non-pharmaceutical hazardous waste generation and will continue to submit a biennial report as a result. Thus, they will incur the fixed costs of preparing a biennial report under part 262. The only costs they will incur for operating under subpart P will be the variable costs include completing the Waste Generation and Management Form (GM form) for each waste stream of evaluated hazardous waste pharmaceuticals. Based on the 2018 ICR for the proposed rule to designate aerosol cans as universal waste, this is estimated to take 0.13 hours of management time, 0.15 hours of technician time, and 0.04 hours of administrative time per GM form on an annual basis.[13] Following the methodology used to estimate the number of GM forms submitted per facility in the RIA for the final rule, EPA estimates that reverse distributors will submit an average of 70 GM forms per biennial report.[14] EPA estimates that it will take 9.1 hours of management time, 10.5 hours of technician time, and 2.8 hours of administrative time to prepare the GM forms. EPA estimates this will result in a total burden of 605 hours at a cost of $44,022 (see Exhibit 1).

**Containers**

Under the final rule, reverse distributors must mark containers of evaluated hazardous waste pharmaceuticals with the applicable hazardous waste codes prior to being shipped off site. EPA estimates it takes a similar amount of time to mark the containers with the hazardous waste code as it does to mark the containers with an indication of the hazards of the contents. Based on the RIA for the final rule, EPA estimates it takes 0.08 hours (5 minutes) of a technician's time to make the labels. EPA estimates this will result in a total burden of 2 hours at a cost of $115 (see Exhibit 1).

**6(e) Bottom Line Burden Hours and Costs**

**Respondent Tally**

In Exhibit 1, EPA presents the annual respondent burden hours and costs associated with the new information collection requirements in the final rule. As described specifically in Section 6(d) above, the information collection requirements apply to 11,916-13,373 affected facilities (respondents). As shown in Exhibit 1, the total annual respondent burden for these paperwork requirements is approximately 39,458-43,577 hours averaged over the first three years of the rule, at an annual cost of approximately $2,301,250-$2,543,409.

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13 See "Supporting Statement for EPA Information Collection Request Number 2513.03, "Reporting and Recordkeeping Requirements for the final Hazardous Waste Generator Improvements Rule." This ICR proposed to amend the base Generator ICR with the aerosol can rule.

14 The assumptions are based on the manifest and tracking section of the RIA developed for the final rule. See page 74 in "Regulatory Impact Analysis for EPA's Final Regulations for the Management of Hazardous Waste Pharmaceuticals."

### 6(f) Reasons for Change in Burden

EPA is finalizing a new set of sector-specific regulations for healthcare facilities and reverse distributors in 40 CFR part 266 subpart P in lieu of the standard RCRA generator regulations of 40 CFR part 262. Specifically, the final rule includes several requirements to ensure the responsible management of hazardous waste pharmaceuticals. The key provisions of the final rule have been described earlier in Section 1(b).

### 6(g) Burden Statement

The estimated average annual burden over three years for this collection of information ranges from 39,458 to 43,577 hours. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. 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 are listed in 40 CFR part 9 and 48 CFR chapter 15.

| Information Activity | Exhibit 1. Estimated Annual Respondent Burden and Costs | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Hours and Cost per Respondent | | | | | | | | Total Hours and Costs | | | | | |
| | Leg. $128.48/Hr | Mgr. $108.40/Hr | Tech. $53.25/Hr | Cler. $30.32/Hr | Resp. Hours/Yr | Labor Cost/Yr | Capital/Startup Cost | O&M Cost | **Number of Resp. (Low)** | **Number of Resp. (High)** | **Total Hours/Yr (Low)** | **Total Hours/Yr (High)** | **Total Cost/Yr (Low)** | **Total Cost/Yr (High)** |
| Reading the Rule | | | | | | | | | | | | | | |
| Reading the Rule | 0 | 1.00 | 2.50 | 0 | 3.50 | $242 | $0 | 0 | 11,916 | 13,373 | 41,706 | 46,806 | $2,878,012 | $3,229,913.83 |
| Notification | | | | | | | | | | | | | | |
| Initial Notification - Complete and submit EPA Form 8700-12 | 0 | 0.08 | 0.93 | 0.08 | 1.09 | $60.62 | $0 | $3.80 | 4,586 | 5,750 | 4,999 | 6,268 | $295,431 | $370,415.58 |
| Subsequent Notification - Complete and submit EPA Form 8700-12 | 0 | 0 | 0 | 0 | 0 | 0 | $0 | $0.00 | 7,330 | 7,623 | 0 | 0 | $0 | $0.00 |
| Labeling | | | | | | | | | | | | | | |
| Label containers in primary storage area (LQG) | 0 | 0 | 1 | 0 | 1.00 | $53 | $0 | $0 | 6,337 | 6,337 | 6,337 | 6,337 | $337,445 | $337,445 |
| Label containers in primary storage area (SQG) | 0 | 0 | 0.25 | 0 | 0.25 | $13 | $0 | $0 | 5,552 | 7,009 | 1,388 | 1,752 | $73,911 | $93,307 |
| Label containers in satellite storage area (LQG) | 0 | 0 | 0.5 | 0 | 0.50 | $27 | $0 | $0 | 6,337 | 6,337 | 3,169 | 3,169 | $168,723 | $168,723 |
| Label containers in satellite storage area (SQG) | 0 | 0 | 0.25 | 0 | 0.25 | $13 | $0 | $0 | 5,552 | 7,009 | 1,388 | 1,752 | $73,911 | $93,307 |
| Exception Reporting and Rejected Shipment | | | | | | | | | | | | | | |
| Submit exception report | 0 | 0.5 | 0.5 | 0.1 | 1.10 | $84 | $0 | $0 | 120 | 135 | 132 | 149 | $10,063 | $11,321 |
| Keep copy of exception report | 0 | 0 | 0 | 0.1 | 0.10 | $3 | $0 | $0 | 120 | 135 | 12 | 14 | $364 | $409 |
| Track or manage rejected shipment | 0 | 0.5 | 0.5 | 0.1 | 1.10 | $84 | $0 | $0 | 120 | 135 | 132 | 149 | $10,063 | $11,321 |
| Recordkeeping | | | | | | | | | | | | | | |
| Signed copy of manifest | 0 | 0 | 0.1 | 0 | 0.10 | $5 | 0 | $0 | 11916 | 13373 | 1,192 | 1,337 | $63,453 | $71,211 |
| Copy of notification | 0 | 0 | 0.1 | 0 | 0.10 | $5 | $0 | $0 | 11916 | 13373 | 1,192 | 1,337 | $63,453 | $71,211 |

| | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Paperwork in support of hazardous waste determinations | 0 | 0 | 0.1 | 0 | 0.10 | $5 | $0 | $0 | 11889 | 13346 | 1,189 | 1,335 | $63,309 | $71,067 |
| Records of inspections | 0 | 0 | 0.1 | 0 | 0.10 | $5 | $0 | $0 | 27 | 27 | 3 | 3 | $144 | $144 |
| Copy of biennial report | 0 | 0 | 0.1 | 0 | 0.10 | $5 | $0 | $0 | 27 | 27 | 3 | 3 | $144 | $144 |
| Records documenting personnel training | 0 | 0 | 0.1 | 0 | 0.10 | $5 | $0 | $0 | 27 | 27 | 3 | 3 | $144 | $144 |
| Records of offsite shipments | 0 | 0 | 0.1 | 0 | 0.10 | $5 | $0 | $0 | 2,021 | 2,269 | 202 | 227 | $10,762 | $12,082 |
| Manifests and Shipping | | | | | | | | | | | | | | |
| Complete manifest with no waste codes | 0 | 0 | 0.31 | 0.21 | 0.52 | $23 | $0 | $0 | 11889 | 13346 | 6,182 | 6,940 | $271,957 | $305,286 |
| Complete manifest with waste codes | 0 | 0 | 1.64 | 0.84 | 2.48 | $113 | $0 | $0 | 27 | 27 | 67 | 67 | $3,046 | $3,046 |
| Complete a movement document | 0 | 0 | 0.5 | 0.5 | 1.00 | $42 | $0 | $0 | 120 | 134 | 120 | 134 | $5,014 | $5,599 |
| Contingency Planning | | | | | | | | | | | | | | |
| Amend contingency plan | 0 | 0 | 1.5 | 1.5 | 3.00 | $125 | $0 | $0 | 3 | 3 | 9 | 9 | $376 | $376 |
| Unauthorized Waste | | | | | | | | | | | | | | |
| Submit unauthorized waste report | 0 | 9.5 | 9.5 | 1.9 | 20.90 | $1,593 | $0 | $0 | 27 | 27 | 564 | 564 | $43,019 | $43,019 |
| Biennial Reporting | | | | | | | | | | | | | | |
| Gather info and prepare GM Forms (total) | 0 | 9.1 | 10.5 | 2.8 | 22.40 | $1,630 | $0 | $0 | 27 | 27 | 605 | 605 | $44,022 | $44,022 |
| Containers | | | | | | | | | | | | | | |
| Mark containers with waste codes | 0 | 0 | 0.08 | 0 | 0.08 | $4 | $0 | $0 | 27 | 27 | 2 | 2 | $115 | $115 |
| **TOTAL ONE-TIME COSTS** | | | | | | | | | | | **46,705** | **53,073** | **$3,173,442** | **$3,600,329** |
| **TOTAL RECURRING COSTS** | | | | | | | | | | | **23,889** | **25,886** | **$ 1,243,436** | **$1,343,300** |
| **TOTAL AVERAGE ANNUAL COSTS FOR THE FIRST THREE YEARS** | | | | | | | | | | | **39,458** | **43,577** | **$2,301,250** | **$2,543,409** |