SUPPORTING STATEMENT FOR
EPA INFORMATION COLLECTION REQUEST NUMBER 2486.01
REPORTING AND RECORDKEEPING REQUIREMENTS FOR THE PROPOSED RULE ON MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS

June 2015

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EXHIBITS

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title and Number of the Information Collection

This information Collection Request (ICR) is entitled "Reporting and Recordkeeping Requirements for the Proposed Rule on Management Standards for Hazardous Waste Pharmaceuticals (Proposed Rule)," EPA ICR Number 2486.01, OMB Number 2050-NEW.

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 proposing to revise 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). However, in order to address the adverse comments received on the 2008 proposal, EPA is now re-proposing sector specific regulations for the management of hazardous waste pharmaceuticals.

In the current proposal, 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 pharmaceutical reverse distributors. If finalized, healthcare facilities that are currently small quantity generators (SQGs) or large quantity generators (LQGs) and all pharmaceutical reverse distributors, regardless of 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 proposed standards are not an optional alternative to managing hazardous waste pharmaceuticals under part 262, they are mandatory standards.

Briefly, healthcare facilities will have different management standards for their non-creditable and creditable hazardous waste pharmaceuticals. Non-creditable hazardous waste pharmaceuticals 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 creditable hazardous waste pharmaceuticals to reverse distributors for processing manufacturers' credit. In response to comments received on the Universal Waste proposal, EPA is proposing standards to ensure the safe and secure delivery of the creditable hazardous waste pharmaceuticals to reverse distributors.

EPA is also proposing standards for the accumulation of the creditable hazardous waste pharmaceuticals at reverse distributors. Similar to healthcare facilities, reverse distributors will not be regulated under part 262 as generators, nor will they be regulated under parts 264, 265 and 270 as TSDFs. The proposal regards reverse distributors as a new type of hazardous waste entity called pharmaceutical reverse distributors. The proposed 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 proposal are:

- Sewer disposal of hazardous waste pharmaceuticals is prohibited.

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

- Long-term care facilities currently exempt from RCRA under the household hazardous waste exclusion must comply with the rule requirements.

- Potentially creditable hazardous waste pharmaceuticals sent to a reverse distributor must ship with a return receipt notification.

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

- **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 and pharmaceutical 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, EPA is proposing to require that healthcare facilities and pharmaceutical reverse distributors must keep records of any test results, waste analyses or other determinations made on hazardous waste pharmaceuticals for three years from the date that the hazardous waste pharmaceuticals were sent for treatment, storage and disposal.

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 pharmaceutical waste 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 proposed rule would duplicate information required by existing RCRA regulations.

3(b) Public Notice

In compliance with the Paperwork Reduction Act of 1995, EPA will open a 90-day public comment period at the time that this proposed rule is 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 will review public comments received in response to the notice and will address 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 and other pharmaceutical waste generators, met with reverse distributors, 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 proposed rule (Docket ID No. EPA-HQ-RCRA-2007-0932). Additional site visits and consultations have been made to support this new proposal.

3(d) Effects of Less Frequent Collection

EPA has carefully considered the burden imposed upon the regulated community by the proposed 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 proposed 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 proposed 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 proposed 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
44611	Pharmacies
54194	Veterinary Clinics
6211	Physicians' Offices
6212	Dentists' Offices
6213	Other Health Practitioners (e.g. chiropractors)
6214	Outpatient Care Centers
6219	Other Ambulatory Health Care Services
622	Hospitals
6231	Nursing Care Facilities (e.g., assisted living facilities, nursing homes, veterans domiciliary centers)
623311	Continuing Care Retirement Communities (e.g., assisted living facilities with on-site nursing facilities)
Subset of 92219	Medical Examiners and Coroners' Offices
Various NAICS	Reverse Distributors (RDs)

4(b) Information Requested

This section describes reporting and recordkeeping requirements for facilities managing hazardous waste pharmaceuticals under the proposed 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 re-notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700-12), that it is a healthcare facility, within 60 days of the effective date of this subpart.

(ii) A healthcare facility that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification form (EPA form 8700-12), that it is a healthcare facility, within 60 days of the effective date of 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 conditionally exempt small quantity generator under 40 CFR § 261.5, and elects to withdraw from this subpart, must notify the appropriate EPA Regional Administrator using the Site Identification Form (EPA form 8700-12) that it is no longer operating under this subpart. A healthcare facility is not required to fill out Box 11 (Description of Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each EPA Identification Number.

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

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

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

(D) ***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; or

(iv) Any other method which clearly demonstrates the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating from the date it first became a waste.

(E) ***Tracking Rejected/Returned Shipment.*** 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 delivery of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(iv) 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 handwritten signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(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 handwritten signature of the owner or operator of the alternate facility within 60 days of the date the waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(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 of the test, analysis, or other determination.

(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.

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

(A) ***Hazardous Waste Determination***. A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable solid waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical (i.e., it's listed in part 261 subpart D or exhibits a characteristic identified in part 261 subpart C). A healthcare facility may choose to manage its potentially creditable solid waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under § 266.509 even if the solid waste

pharmaceuticals do not exhibit a characteristic identified in part 261 subpart C and are not listed in part 261 subpart D.

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

(i) a copy of the advance notification provided to the pharmaceutical reverse distributor

(ii) the confirmation of delivery and

(iii) the shipping papers or bill of lading.

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 Pharmaceutical Reverse Distributor Under 40 CFR § 266.508.

(A) ***Packaging.*** A healthcare facility or pharmaceutical reverse distributor must package the waste in accordance with the applicable Department of Transportation regulations on packaging under 49 CFR parts 173, 178, and 179.

(B***) Labeling.*** Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172.

(C) ***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; Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

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

(D) ***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.

(E) ***Shipping Papers.*** Prepare shipping papers in accordance with 40 CFR 172 Subpart C.

(F) ***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 hazardous waste codes in box 13 of EPA Form 8700-22.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the words "hazardous waste pharmaceuticals" in Box 14 (the special handling instructions and additional information) of EPA Form 8700-22.

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

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

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

(A) ***Advance Notice.*** A healthcare facility or a pharmaceutical reverse distributor who transports or offers to transport potentially creditable hazardous waste pharmaceuticals off-site to a pharmaceutical reverse distributor must provide advance notice (paper or electronic) to the pharmaceutical reverse distributor of the intent to ship potentially creditable hazardous waste pharmaceuticals to the receiving pharmaceutical reverse distributor before each shipment of potentially creditable hazardous waste pharmaceuticals is sent to a pharmaceutical reverse distributor, and comply with the pre-transport requirements of 266.508(a)(1)(i) – (v).

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

(C) ***Exporting Requirements.*** A healthcare facility or pharmaceutical reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the following requirements in addition to paragraphs (a) – (c) of this section:

(i) Comply with the requirements applicable to a primary exporter at 40 CFR 262.53, 262.56(a)(1) through (4), (6) and (b) and 262.57;

(ii) Export such potentially creditable hazardous waste pharmaceuticals only upon consent of the receiving country and in conformance with the EPA Acknowledgement of Consent as defined in part 262 subpart E; and

(iii) Provide a copy of the EPA Acknowledgement of Consent for the shipment to the transporter transporting the shipment for export.

(D) ***Transporting Requirements to a Foreign Destination.*** A transporter of potentially creditable hazardous waste pharmaceuticals to a foreign destination other than those OECD countries specified 40 CFR 262.58(a)(1) (in which case the transporter is subject to the requirements of 40 CFR part 262 subpart H) may not accept a shipment if the transporter knows the shipment does not conform to the EPA Acknowledgment of Consent. In addition the transporter must ensure that:

(i) A copy of the EPA Acknowledgment of Consent accompanies the shipment; and

(ii) The shipment is delivered to the facility designated by the person initiating the shipment.

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

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

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

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

(ii) A pharmaceutical reverse distributor that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form

(EPA form 8700-12), that it is a pharmaceutical reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

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

(i) A pharmaceutical reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the pharmaceutical reverse distributor.

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

(C) **A*ccumulation Time*.** A pharmaceutical reverse distributor may accumulate potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceuticals on-site for 90 calendar days or less. The 90-days start when the potentially creditable hazardous waste pharmaceutical arrives at the pharmaceutical reverse distributor and applies to all hazardous waste pharmaceuticals accumulated on-site, regardless of whether they are destined for another pharmaceutical reverse distributor (i.e., potentially creditable hazardous waste pharmaceuticals), or a permitted or interim status treatment, storage or disposal facility (i.e., evaluated hazardous waste pharmaceuticals).

(i) A pharmaceutical reverse distributor may request an extension of its 90-day accumulation time limit for hazardous waste pharmaceuticals from the EPA Regional Administrator due to unforeseen circumstances beyond the control of the pharmaceutical reverse distributor, or if the potentially creditable hazardous waste pharmaceutical or evaluated hazardous waste pharmaceuticals are involved in litigation or a recall.

(ii) A written request must be sent to the EPA Regional Administrator (paper or electronic). The request for an extension must include an explanation of the reason an extension is requested, the approximate volume or weight of the hazardous waste pharmaceuticals that will be accumulated for more than 90 days, and the amount of additional time requested. The amount of time granted for an extension is at the discretion of the EPA Regional Administrator on a case-by-case basis.

(D) ***Contingency Plan.*** A pharmaceutical reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of 40 CFR part 265 subpart D.

(E) ***Reporting.*** A pharmaceutical reverse distributor must submit an unauthorized hazardous waste report if the pharmaceutical reverse distributor receives hazardous waste from off-site that it is not authorized to receive (e.g., non-creditable hazardous waste pharmaceuticals, non-pharmaceutical hazardous waste). The pharmaceutical reverse distributor must prepare and

submit an unauthorized waste report to the EPA Regional Administrator within 15 days after receiving the unauthorized hazardous waste and the pharmaceutical reverse distributor must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized hazardous waste. The pharmaceutical reverse distributor must manage the unauthorized hazardous waste in accordance with all applicable regulations for generators of non-pharmaceutical hazardous waste. The unauthorized waste report must be signed by the owner or operator of the pharmaceutical reverse distributor, or his authorized representative, and contain the following information:

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

(ii) The date the pharmaceutical reverse distributor received the hazardous waste;

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

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

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

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

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

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

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

(ii) A copy of the advance notification, delivery confirmation and the shipping papers or bill of lading for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives for at least three years from the date it receives the shipment.

(iii) A copy of its inventory; and

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

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

(i) a copy of the advance notification provided to the pharmaceutical reverse distributor

(ii) the confirmation of delivery, and

(iii) the shipping papers or bill of lading.

(I) ***Labeling.*** A pharmaceutical 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";

(J) ***Marking.*** Containers of evaluated hazardous waste pharmaceuticals must be marked with the applicable hazardous waste number(s) (i.e., hazardous waste code(s)) prior to being transported off-site.

(K) **M*anaging Rejected Shipments.*** A pharmaceutical reverse distributor who sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter, may accumulate the returned waste pharmaceuticals on-site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with paragraph (a) of this section. Upon receipt of the returned shipment, the pharmaceutical reverse distributor must:

(i) Sign either 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 pharmaceutical reverse distributor; and

(L) ***Reporting for Evaluated Hazardous Waste Pharmaceuticals.*** A pharmaceutical reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of a biennial report to the EPA Regional Administrator by March 1 of each even numbered year in accordance with § 262.41, except § 262.41(a)(7).

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

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

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

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

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

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

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

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

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

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

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

(v) A pharmaceutical reverse distributor must keep records to document personnel training, in accordance with § 265.16.

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 exception is re-notifications by facilities that have previously notified as SQGs or LQGs and notifications by facilities that did not have to notify previously. However, as stated earlier, it is being 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 would be required to re-notify the Agency under the proposed 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.

5(b) Collection Methodology and Management

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

5(c) Small Entity Flexibility

The proposed rule is not expected to cause a significant impact on small quantity generators (SQGs) of hazardous waste pharmaceuticals. Under the proposed rule, SQGs will benefit due to greater flexibility in how they train staff and manage their hazardous waste. Hazardous waste pharmaceuticals will no longer be counted against a facility's hazardous waste generator category. In addition, EPA allows conditionally exempt small quantity generators (CESQGs) to manage their hazardous waste pharmaceuticals either under the specific provisions of the proposed rule or under the existing CESQG 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 re-notification or a new notification to EPA in order to indicate that they are operating under the new part 266 subpart P. A new notification must be submitted within 60 days of when a facility becomes subject to the rule and a re-notification on existing schedule (i.e., as part of biennial reporting).

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 proposed rule. As shown in the exhibit, EPA estimates that the total annual respondent burden for the new paperwork requirements in the rule is 53,602 hours.

6(b) Estimating Respondent Costs

EPA also presents in Exhibit 1 estimates of the total annual respondent cost for the new paperwork requirements in the proposed rule. The total annual respondent cost is $3,388,492. This cost includes annual labor, capital, and operation and maintenance (O&M) costs to be incurred 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 $108 for legal staff, $79 for managerial staff, $49 for technical staff, and $29 for clerical staff. These hourly labor costs were obtained from the economics background document developed for the proposed rule (see "Regulatory Impact Analysis for EPA's Proposed Healthcare Facility-Specific 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 proposed 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.

The total O&M cost is $1,038,856.

Category	Cost per respondent	# of Respondents	Total Cost
Notifications	$3.31	19,695	$65,190
Recordkeeping	$0.40	21	$8.40
Manifests	$34	28,637	$973,658
Total			**$1,038,856**

6(c) Estimating Agency Burden and Costs

The annual burden and costs to the Agency for collecting information under the rule would be negligible. This is because the Agency is not requiring respondents to submit any information for its review and approval under the proposed rule. Also, respondents would keep all records required under the proposed rule on-site.

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 proposed 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., LQGs, SQGs, and CESQGs). Table 1 presents the number of respondents that could potentially be affected by the proposed rule.[1] It shows that EPA estimates 174,023 LQG, SQG, and CESQG facilities handle hazardous waste pharmaceuticals each year. However, there are no paperwork requirements in the proposed rule for CESQGs (except for CESQG reverse distributors).

1These universe assumptions are based on the economics background document developed for the proposed rule: "Regulatory Impact analysis for EPA's Proposed Healthcare Facility-Specific Regulations for the Management of Hazardous Waste Pharmaceuticals."

TABLE 1

NUMBER OF FACILITIES POTENTIALLY AFFECTED BY THE PROPOSED RULE

Type of Respondent	Number of Facilities
Large Quantity Generators (LQG)	5,302
Small Quantity Generators (SQG)	23,314
Conditionally Exempt Small Quantity Generators (CESQG)	145,407
Total	174,023

Respondent Burden and Cost

Based on the universe data presented in Table 1 and information contained in the economics background document developed for the proposed rule, EPA estimated the respondent burden and cost associated with all of the new information collection requirements covered in this ICR in Exhibit 1. 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 28,637 facilities will need to read the rule in order to understand and comply with the new information collection requirements. (This assumes CESQGs, except for CESQG reverse distributors, are unlikely to read the rule because there are no new information collection requirements for CESQGs in the proposed rule). 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 28,637 respondents. This resulted in total burden of 100,230 hours, at total cost of $5,759,784, for all of the respondents reading the rule. In estimating the annual respondent burden and cost over the three year period covered by this ICR, EPA annualized the burden and cost of this one-time activity by dividing the number of hours and cost for this activity by three. This resulted in total annual burden of 33,410 hours, at a total cost of $1,919,928 (see Exhibit 1).

Notifications and Re-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 and re-notification costs are estimated only for CESQGs operating as reverse distributors (this is because all reverse distributors (RDs), including CESQG RDs, are proposed to be regulated as LQGs and required to notify), SQGs and LQGs that previously had a household waste exemption, and SQGs in states without biennial reporting requirements. EPA estimated that there are 21 CESQG RDs, 834 SQGs with household waste exemption, and 137 LQGs with household waste exemption that will be required to notify and 18,703 SQGs in states without biennial reporting requirements that must re-notify. EPA also estimated a one-time cost of approximately $53 for initial notification and a one-time cost of approximately $37 for re-notification. Based on these data, the total additional annual respondent burden for notifications is estimated to be 1,276 hours, at cost of $70,100 (see Exhibit 1).

Labeling

Under current RCRA Subtitle C regulations, LQGs and SQGs are required to label all containers holding hazardous waste. Thus, there would be no change in burden and costs associated with labeling for LQG and SQG healthcare facilities that use containers. The additional burden and costs for labeling are result of LQG and SQG healthcare facilities that previously used sewer and also because some facilities were exempt as household hazardous waste generators and are now regulated. EPA estimated approximately 1.5 hours annually for labeling at each LQG healthcare facility and approximately 0.5 hour annually at each SQG healthcare facility. The estimated annual labor cost for labeling was $73.45 at each LQG healthcare facility and $24.48 at each SQG healthcare facility. Based on these data, the total additional annual respondent burden for labeling is estimated to be 9,918 hours, at cost of $485,672 (see Exhibit 1).

Recordkeeping

Under current RCRA Subtitle C regulations, LQGs and SQGs are required to keep records of waste characterization for three years from the date the last waste, including hazardous waste pharmaceuticals, was sent off site. The proposed rule does not include waste characterization recordkeeping requirements for hazardous waste pharmaceuticals generated by healthcare facilities. Reverse distributors, however, are required to keep these records. Reverse distributors, however, are required to keep records of waste characterization for three years under the proposed rule. This represents additional burden and costs for CESQG reverse distributors. LQG and SQG reverse distributors incur these costs already under the current regulations. EPA estimated that there are 21 CESQG RDs that will be required to keep records. EPA also estimated the time required for recordkeeping to be 0.1 hour annually per respondent, at cost of $4.90. There is an additional annual O&M cost of $0.40 per respondent. Based on these data,

the total additional annual respondent burden for recordkeeping is estimated to be 2 hours, at cost of $111 (see Exhibit 1).

Manifests

Under current RCRA Subtitle C regulations, LQGs and SQGs are required to prepare a manifest that, among other information, includes the RCRA waste codes for each hazardous waste shipment. There are no manifest requirements for CESQGs. However, under the proposed rule, LQG and SQG healthcare facilities must complete manifests for non-creditable pharmaceuticals shipped to a TSDF, but need not include RCRA waste codes on these manifests. Also, under the proposed rule, healthcare facilities are not required to prepare manifests for potentially creditable hazardous waste pharmaceuticals shipped to a reverse distributor. Instead, shipping documents with return receipt notifications are required. EPA assumes that each health care facility sends four shipments of pharmaceuticals to a reverse distributor each year at an estimated cost of $8.49 per shipment. This represents an additional cost for LQG and SQG healthcare facilities. For reverse distributors, the proposed rule would require a full manifest (including waste codes) for hazardous waste pharmaceuticals shipped to a TSDF, as is currently required. No manifest, however, is required for shipments of hazardous waste pharmaceuticals between reverse distributors, though shipping documents with return receipts are required. As result of these changes in manifest requirements, EPA estimated that the total annual burden on the 28,637 affected facilities for preparing manifests would be 10,251 hours, at cost of $981,667 (see Exhibit 1).

Total Respondent Burden and Costs

In Exhibit 2, EPA presents a summary of the total estimated annual respondent burden and costs savings and net annual respondent burden and costs associated with this ICR. The specific information collection activities of the new paperwork requirements are described throughout this ICR, and the total annual burden and cost estimates associated with them are presented in Exhibit 1. The cost savings come from additional flexibility provided to healthcare facilities and reverse distributors under the proposed rule.

6(e) Bottom Line Burden Hours and Costs

Respondent Tally

In Exhibit 2, EPA presents the net annual respondent burden hours and costs associated with the new information collection requirements in the proposed rule. As described specifically in Section 6(d) above, the new information collection requirements apply to as many as 28,637 affected facilities (respondents). As shown in Exhibit 2, the total annual respondent burden for these new paperwork requirements is approximately 54,857 hours, at an annual cost of approximately $3,457,478.

As also shown in Exhibit 2, the total annual respondent burden savings from these new paperwork requirements, compared to the existing paperwork requirements, is approximately 26,197 hours, at an annual cost savings of approximately $1,155,605. In the same Exhibit 2,

EPA then combines the burden and cost impacts under both new and existing paperwork requirements and estimates the net annual respondent burden and costs for all information collection activities at approximately 28,660 hours, at an annual cost of approximately $2,301,873.

6(f) Reasons for Change in Burden

EPA is proposing 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 proposed rule includes several requirements to ensure the responsible management of hazardous waste pharmaceuticals. The key provisions of the proposed rule have been described earlier in Section 1(b).

6(g) Burden Statement

The estimated annual burden for this collection of information ranges from 0.1 to 3.5 hours per response for the 28,637 respondents. The annual public reporting and recordkeeping burden for this collection of information is estimated to average about 2 hours per response. 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.

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, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID Number EPA-HQ-RCRA-2007-0932, which is available for online viewing at www.regulations.gov, or in person viewing at the RCRA Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW, Washington, D.C. The EPA Docket Center 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 Reading Room is (202) 566-1744, and the telephone number for the RCRA Docket is (202) 566-0270. An electronic version of the public docket is available at www.regulations.gov. This site can be used to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. When in the system, select “search,” then key in the Docket ID Number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, D.C. 20503, Attention: Desk Officer for EPA. Please

include the EPA Docket ID Number EPA-HQ-RCRA-2007-0932 and OMB Control Number 2050-NEW in any correspondence.

Exhibit 1 - Estimated Annual Respondent Burden and Costs											
	Hours and Costs per Respondent								Total Hours and Costs		
INFORMATION ACTIVITY	Leg. $108/Hr	Mgr. $79/Hr	Tech. $49/Hr	Cler. $29/Hr	Resp. Hours/Yr	Labor Cost/Yr	Capital/ Startup Cost	O & M Cost	Number of Resp.	Total Hours/Yr	Total Cost/Yr
RESPONDENTS (LQGs, SQGs, and CESQG RDs)											
Reading the Rule	0.0	0.33	0.83	0.0	3.5	$201	0.0	0.0	28,637	33,410	$1,919,928
LQGs, SQGs, and CESQG RDs											
Notification	0.0	0.08	varies	0.08	varies	varies	0.0	$3.31	19,695	1,276	$70,100
LQGs, SQGs, and CESQG RDs											
Labeling	0.0	0.0	varies	0.0	varies	varies	0.0	0.0	21,068	9,918	$485,672
CESQG RDs											
Recordkeeping	0.0	0.0	0.1	0.0	0.1	$4.90	0.0	$0.40	21	2	$111
LQGs, SQGs, and CESQG RDs											
Manifests	0.0	varies	varies	varies	varies	varies	0.0	$34	28,637	10,251	$981,667
Total		varies	varies	varies	varies	varies	0.0	$37.71	varies	**54,857**	**3,457,478**

Agency Data Sources:

Wage Rate Data: Exhibit 3-2 in the "Regulatory Impact analysis for EPA's Proposed Healthcare Facility-Specific Regulations for the Management of Hazardous Waste Pharmaceuticals."

Labor Hours: Supporting Statement for EPA Information Collection Number 2308.02: Revisions to the Requirements for Export Shipments of Spent Lead Acid Batteries (December 2009) and "Regulatory Impact analysis for EPA's Proposed Healthcare Facility-Specific Regulations for the Management of Hazardous Waste Pharmaceuticals."

O&M Cost: "Regulatory Impact analysis for EPA's Proposed Healthcare Facility-Specific Regulations for the Management of Hazardous Waste Pharmaceuticals."

Exhibit 2 – Estimated Annual Respondent Burden and Cost Savings and Net Annual Respondent Burden and Costs						
Activity	Affected Facilities	Number of Respondents	Total Labor Hours	Total Labor Cost	Total Capital/Startup and O&M Cost	Total Annual Cost
Labeling	LQGs & SQGs	varies	(1,118)	($54,743)	$0	($ 54,743)
Biennial Reports	LQGs & SQGs	varies	(5,333)	($311,206)	($665)	($311,871)
Recordkeeping	LQGs & SQGs	varies	(2,761)	($135,198)	($11,044)	($146,242)
Manifests	LQGs & SQGs	varies	(16,985)	($638,063)	($4,686)	($642,749)
Total Annual Respondent Burden and Cost savings			(26,197)	($1,139,210)	($16,395)	($1,155,605)
Pharmaceutical ICR	2486.01	Varies	54,857	N/A	N/A	$3,457,478
Net Annual Respondent Burden and Costs of Pharmaceutical ICR			**28,660**			**$2,301,873**

Agency Data Sources: "Regulatory Impact analysis for EPA's Proposed Healthcare Facility-Specific Regulations for the Management of Hazardous Waste Pharmaceuticals."