SUPPORTING STATEMENT

STUDY OF UNUSED PHARMACEUTICALS FROM MEDICAL AND VETERINARY FACILITIES

INFORMATION COLLECTION REQUEST SUPPORTING THE U.S. EPA CLEAN WATER ACT SECTION 304(b) EFFLUENT GUIDELINES ANNUAL REVIEWS

U.S. ENVIRONMENTAL PROTECTION AGENCY

July 2008

TABLE OF CONTENTS

Page

PART A OF THE SUPPORTING STATEMENT

TABLE OF CONTENTS (Continued)

Page

PART A OF THE SUPPORTING STATEMENT

1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title of the Information Collection

Study of Unused Pharmaceuticals from Medical and Veterinary Facilities

1(b) Short Characterization/Abstract

This Information Collection Request (ICR) package requests the Office of Management and Budget (OMB) review and approval of the U.S. Environmental Protection Agency's (EPA's), Office of Water project titled: "Study of Unused Pharmaceuticals from Medical and Veterinary Facilities." The project includes two questionnaire instruments, one for medical facilities and one for veterinary facilities. EPA identified the health services industry as a candidate for a study in the 2006 Clean Water Act (CWA) Section 304(b) Effluent Guidelines Review (71 FR 76656; December 21, 2006). EPA is collecting information about disposal of unused pharmaceuticals to better understand the current management practices and the magnitude of discharges to waters of the United States.

The discharge of pharmaceuticals to publicly owned treatment works (POTWs), with few exceptions, is not currently regulated or monitored and thus, wastewater data are generally not available. Facilities within the health services industry (e.g., hospitals, hospices, long-term care facilities (LTCFs), and veterinary facilities) may dispose of excess, expired, and unwanted medications (referred to collectively as "unused pharmaceuticals") down the drain or toilet, after which drugs may pass through POTWs and into surface waters.

EPA believes that the health services industry accounts for the majority of institutional (non residential) discharges of unused pharmaceuticals to wastewater. Areas for investigation include:

- What are the current industry practices for disposing of unused pharmaceuticals?
- Which pharmaceuticals are being disposed of and at what quantities?
- What are the options for disposing of unused pharmaceuticals other than down the drain or toilet?
- What factors influence disposal decisions?
- Do disposal practices differ within industry sectors?
- What Best Management Practices (BMPs) could facilities implement to reduce the generation of unused pharmaceuticals?
- What reductions in the quantities of pharmaceuticals discharged to POTWs would be achieved by implementing BMPs or alternative disposal methods?
- What are the costs of current disposal practices compared to the costs of implementing BMPs or alternative disposal methods?

To collect this information, EPA will distribute a questionnaire to a sample of medical and veterinary facilities. There are two versions of the questionnaire, one tailored to facilities that treat people (i.e., hospitals, hospices, and LTCFs) and one tailored to facilities that treat animals (i.e., veterinary facilities).

Copies of both questionnaires are included in Attachment 1.

To complete the questionnaire, respondents will be required to report 30 days worth of pharmaceutical disposal data, which may require development of a tracking system for unused pharmaceuticals and time to train staff on proper tracking protocols. EPA estimates the total respondent burden and costs associated with completing the questionnaires are approximately 145,000 hours and $5,200,000. There are no capital costs associated with responding to these questionnaires. Operation and maintenance (O&M) costs include only photocopying and postage or express delivery.

Additional details on burden can be found in Section 6. An overview of the questionnaire burden is provided below:

- Estimated total number of potential respondents: 3,544;
- Frequency of response: 1 time;
- Estimated total average number of responses for each respondent: 1;
- Estimated total annual burden hours: 145,304;
- Average burden hours per respondent: 41; and
- Average cost per respondent: $1,463.

2. NEED FOR AND USE OF THE INFORMATION COLLECTION

2(a) Need/Authority for the Information Collection

The 1972 Clean Water Act (CWA) directs EPA to develop and annually review national technology-based regulations, placing limits on the pollutants that are discharged by categories of industry to surface waters (termed "effluent guidelines") or to sewage treatment plants[1] (termed "pretreatment standards").

Under Section 308 of the CWA, 33 U.S.C. Section 1318, EPA has the authority to collect information relevant to its CWA responsibilities. Currently, national data on disposal practices and water discharges related to unused pharmaceuticals do not exist.

2(b) Practical Utility/Users of the Data

EPA will use the data collected to gain a thorough understanding of unused pharmaceuticals disposal practices at health services facilities including:

[1] Also referred to as publicly owned treatment works or POTWs.

- The factors driving current disposal practices;
- Information on the amount of unused pharmaceuticals currently disposed of via the drain or flushing; and
- The alternatives to drain disposal and flushing.

The goal of EPA's unused pharmaceuticals disposal analysis is to determine the current disposal methods for unused pharmaceuticals at medical and veterinary facilities; identify and evaluate potential BMPs or alternative disposal methods. EPA will also compare disposal practices across the United States and estimate the amount and types of drugs discharged to surface water.

Table 2-1 summarizes the information requested in the questionnaires and how the data will be used.

Table 2-1. Potential Use of Information from the Medical and Veterinary Facility Questionnaires

Analysis Component	Question/Information Requested	Utility for Analysis
Current Discharge Practices	EPA requests 30 days of records of the number or amount of pharmaceuticals disposed (e.g., tablets, pharmaceuticals leftover in partially used IV bags or syringes), the dose of the medication, and the method of disposal.	Using this information, EPA can calculate the quantity disposed to wastewater (e.g., 200 pills/month × 25 mg/pill = 5,000 mg/month)
BMPs and Alternate Disposal Methods	EPA requests facilities to provide information on practices used to reduce *generation* of unused pharmaceuticals.	EPA will use this information to identify BMPs used at medical and veterinary facilities.
	EPA requests facilities to discuss alternate *disposal* methods to flushing down the drain or toilet.	EPA will use this information to highlight alternate disposal methods for medical and veterinary facilities.
Evaluation of Effectiveness of BMPs and Barriers to Implementation	EPA requests facilities to explain why unused pharmaceuticals are generated each month ("sources of unused pharmaceuticals") and indicate the percentage that each source contributes to the total amount of unused pharmaceuticals generated.	EPA will use this information to estimate waste generation reductions that use of BMPs can achieve.
	EPA requests facilities report how they dispose of unused controlled substances and other unused pharmaceuticals and indicate the percentage that each method is used.	EPA will use this information to estimate the reductions that alternate disposal methods can achieve.
	EPA requests information on the transfer of pharmaceuticals from the pharmacy to the facility and to the patient (e.g., on-site pharmacy, contract pharmacy).	The presence or absence of an on-site pharmacy may impact the options available to the facility for redistribution of unused pharmaceuticals. In addition, EPA expects that LTCFs will have more restrictions on feasible disposal alternatives than hospitals because LTCFs handle prescribed medications that are owned by the resident and typically contract off-site LTC pharmacies.

Table 2-1. Potential Use of Information from the Medical and Veterinary Facility Questionnaires

Analysis Component	Question/Information Requested	Utility for Analysis
Facility Economic Data	EPA requests hospital facilities identify the subtype to which it belongs (e.g., general medical and surgical, psychiatric and substance abuse, or other specialty).	Types and amounts of pharmaceuticals may vary by hospital type.
	EPA requests information on the labor descriptions of the people involved in managing unused pharmaceuticals.	EPA will use this information to estimate the current labor burden for managing unused pharmaceuticals.
	EPA asks for the number of employees, revenue, and operating costs.	EPA will develop an industry profile for each of the subsectors of the health services industry. EPA asks for three years of revenue and operating costs in order to evaluate recent trends for each subsector. EPA will use the information on operating costs to evaluate the percentage of those costs associated with managing unused pharmaceuticals.
	EPA asks the respondent to identify whether its ownership is government, not-for-profit, or for-profit. If the ownership is a community, the respondent is asked to identify whether it services a population of ≤50,000 or >50,000.	EPA will develop industry profile information including the number of small entities.
	If the respondent is owned by a not-for-profit or for-profit entity, EPA asks for the name of the owning organization, whether it is public or private, number of facilities owned, number of employees, and three years of operating cost and revenue data.	EPA will develop industry profile information on ownership patterns, small/large businesses and organizations, and recent trends in the health services industry. EPA plans to use secondary data to capture revenue/budget information for government facilities.
Evaluation of Costs	EPA requests information on costs of current disposal practices.	EPA will use this information to determine the costs of current disposal practices and to estimate costs for implementing alternative disposal methods (including no disposal to wastewater).

EPA will use information obtained from the questionnaire to identify small entities. For example, the Regulatory Flexibility Act defines a small governmental entity as one that serves a population of 50,000 or fewer; a small not-for-profit organization as one that is independently owned and not dominant in its field; and uses the size standards developed by the Small Business Administration to classify small businesses. The questions in the two questionnaires are tailored to develop profile information for the three types of entities—governmental, not-for-profit, and for-profit. EPA will use the information to evaluate the percentage of operating costs and labor burden formed by the current methods of managing unused pharmaceuticals.

3. NONDUPLICATION, CONSULTATIONS, AND OTHER COLLECTION EFFORTS

3(a) Nonduplication

The Office of Science and Technology of the Agency's Office of Water has made every reasonable attempt to ensure that the questionnaires do not request data and information currently available through less burdensome mechanisms. EPA is working with a range of stakeholders (e.g., industry representatives; government agencies; and public interest groups) to identify information on the industry and its practices already available.

To conduct initial research and involve stakeholders, EPA conducted a combination of seven meetings and teleconferences between May 2007 and July 2008. Through these meetings, EPA identified interested parties and provided an overview of the study and data collection needs. These are discussed in section 3(c).

EPA has determined that existing public data are insufficient to meet its needs and that more comprehensive information on medical and veterinary facilities, as described in Section 4 of this supporting statement, is needed to determine whether to initiate an effluent guidelines rulemaking relating to unused pharmaceuticals.

3(b) Public Notice Required Prior to ICR Submission to OMB

(i) Publication of the Federal Register Notice

EPA published a Federal Register Notice (FRN) announcing EPA's intention to develop an industry questionnaire to support this study and to seek OMB approval for the questionnaire under the Paperwork Reduction Act.

(ii) Public Response to the Federal Register Notice

[EPA will also add a summary here of the comments received after publication of the **Federal Register** notice.]

(iii) EPA Action Resulting from Public Comment

[EPA will add a summary here of EPA's response to the public comments received after publication of the **Federal Register** notice.]

3(c) Consultations

The Agency organized and conducted numerous meetings and teleconferences with industry trade groups, Federal agencies such as the U.S. Food and Drug Administration (FDA), the U.S. Department of Health and Human Services (HHS), and the U.S. Drug Enforcement Administration (DEA), and other stakeholders to better understand the industry and its practices. Table 3-1 lists the dates for all formal meetings with Federal agencies and other stakeholder meetings.

Table 3-1. List of EPA Outreach Activities and Coordination Efforts

No.	Meeting/Teleconference	Location	Date	DCN[a]
1	Meeting with the Pharmaceutical Research and Manufacturers of America (PhRMA)	Washington, DC	1-May-07	05964
2	Outreach Meeting with the Center of Excellence in Assisted Living (CEAL) Advisory Council	Washington, DC	18-October-07	05961
3	Teleconference with Hospitals for a Healthy Environment (H2E) Members	Washington, DC	19-October-07	05962
4	Stakeholder Meeting	Washington, DC	26-October-07	05963
5	Meeting with the Food and Drug Administration (FDA)	Washington, DC	4-March-08	05959
6	Meeting with the Members of the Department of Health and Human Services	Washington, DC	1-April-08	05960
7	Meeting with Members of the Drug Enforcement Administration	Washington, DC	1-July-08	05998

[a] Docket ID No. EPA-HQ-OW-2007-0517

While developing the questionnaires, EPA distributed draft versions to several stakeholder groups, including healthcare organizations and regulatory authorities. Some of these stakeholders distributed the draft questionnaire to facilities, nine of which submitted completed draft questionnaires to EPA. EPA contacted three of these facilities to learn how long it took to complete the questionnaire and what person(s) within the organization completed the form. EPA used this information to adjust its burden estimate. These contacts included Kevin Taylor at Heritage Place (Senior Housing and Assisted Living in Bountiful, Utah), Mike Shurtz at Lakeview Hospital (Bountiful, Utah), and Fran Frankie at Golden Living Center Black Hills (LTCF in Rapid City, South Dakota).

3(d) Effects of Less Frequent Collection

This effort is a *mandatory, one time only* data collection activity for the respondents.

3(e) General Guidelines

EPA will conduct data collection activities in accordance with the Paperwork Reduction Act guidelines in 5 CFR 1320.6 and EPA's Quality Assurance Guidance. Information to be disseminated will comply with EPA's Information Quality Guidelines, which were developed for implementing OMB's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of the Information Disseminated by Federal Agencies.

3(f) Confidentiality

The questionnaires inform respondents of their right to claim information as business confidential in accordance with 40 CFR Part 2, Subpart B, Section 2.203. The questionnaires provide instructions for claiming confidentiality, and informs respondents of the terms and rules governing the protection of Confidential Business Information (CBI) under the Clean Water Act and 40 CFR 2.203(B). Each question which requests potentially confidential information is

accompanied by a CBI checkbox. Questionnaire respondents are requested to check the CBI checkboxes which accompany responses they claim as confidential.

EPA and its contractors will follow existing written procedures to protect data labeled as CBI. These procedures include the following:

- Ensure secure handling of completed questionnaires to preclude access by unauthorized personnel;
- Store completed questionnaires and databases in secured areas of offices, and restrict access to authorized EPA and contractor personnel only; and
- Restrict any publication or dissemination of confidential study results or findings to aggregate statistics and coded listings. Individual respondents will not be identified in summary reports and EPA contractors will not release respondents' names to unauthorized individuals.

A copy of the written procedures for gathering, safeguarding, and securing CBI is located in the Office of Water, Office of Science and Technology's "Confidential Business Information Application Security Plan," which EPA included in the record supporting this ICR (see DCN 05359).

Information covered by a claim of confidentiality will be disclosed by EPA only to the extent of, and by means of, the procedures set forth in 40 CFR Part 2, Subpart B. In general, submitted information protected by a business confidentiality claim may be disclosed to other employees, officers, or authorized representatives of the United States concerned with implementing the Clean Water Act. Exemption 4 of the Freedom of Information Act (FOIA) protects from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." See 5 U.S.C. 552(b)(4).

Information covered by a claim of confidentiality will be made available to EPA's contractor under EPA Contract Number 68-C02-095 to enable the contractor to perform the work required by their contracts with EPA. The contractor that collects, possesses, or stores CBI is responsible for the proper handling of that data. The contractor will safeguard information as described in Section 2.211(d) of Subpart B and is obligated to use or disclose information only as permitted by the contract under which the information is furnished.

3(g) Sensitive Questions

No sensitive questions pertaining to private or personal information, such as sexual behavior or religious beliefs, will be asked in the questionnaire.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents/NAICS Codes

The respondent universe for these questionnaires is made up of facilities from the following NAICS codes:

- 622110 (General Medical and Surgical);
- 622210 (Psychiatric and Substance Abuse);
- 622310 (Specialty except Psychiatric and Substance Abuse Hospitals);
- 623110 (Nursing Care Facilities);
- 623311 (Continuing Care Retirement Facilities); and
- 541940 (Veterinary Services).

EPA estimates that there are approximately 21,446 medical and 2,830 veterinary facilities in the United States.[2] EPA describes several potential sampling methodologies that it intends to investigate in DCN 05999 (Docket ID No. EPA-HQ-OW-2008-0517).

4(b) Information Requested

(i) Data items, including recordkeeping requirements

Data items requested include the following:

General Facility Information:

- Facility name and address;
- Facility type (e.g.; nursing home; hospice; hospital);
- Services offered; and
- Number of patient visits/occupancy.

Economic Information:

- Number of employees;
- Facility ownership (e.g.; government; for profit; non profit); and
- Annual operating costs and revenues.

Information on Management of Unused Pharmaceuticals:

- Type of on-site pharmacy, if any;
- Facility policy/staff responsible for dispensing medicines;
- Quantity/amount of medicines dispensed;
- Quantity/amount unused medicines;
- Reasons for unused medications (e.g., patient death; expiration; spill/accident);
- Method of disposal (e.g., sewer, trash, hazardous waste, incineration);
- Staff responsible for medicine disposal (e.g., pharmacist, nurses, aides);
- Identification and classification of pharmaceutical waste;
- Communication of disposal procedures to staff;

[2] Data Sources include: 2008 Directory of U.S. Hospitals, Institute for Healthcare Information; 2008 Directory of Nursing Homes, Institute for Healthcare Information; list of accredited continuing care retirement communities, Commission on Accreditation of Rehabilitation Facilities; March 2008 HOSPICE data set, Health and Human Services, Centers for Medicare and Medicaid Services; and May 2008 database, American Animal Hospital Association.

- Costs to dispose of unused medications (labor and fees);
- State/federal regulatory influences on disposal practices; and
- Best management practices employed at facility.

Recordkeeping: EPA requests that 30 days of pharmaceutical disposal data be collected and submitted. The respondents should retain the completed questionnaire for up to one year in the event that EPA has to contact the facility for clarification of any response.

(ii) Respondents Activities

Along with the questionnaire itself, each respondent will receive a transmittal letter with attachments citing EPA's authority under Section 308 of the Clean Water Act to collect this information, the ability of the respondent to make a claim of business confidentiality, and EPA's process for gathering, safeguarding, and securing CBI. Respondents must read the Instructions section at the beginning of the questionnaire, which describe the purpose and use of the questionnaire, helpline information, how to return the questionnaire, and provisions regarding data confidentiality.

To complete the questionnaire, respondents will be required to report 30 days worth of pharmaceutical disposal data, which may require development of a tracking system and time to train staff on proper tracking and reporting protocols. After receiving the questionnaire, respondents must read and understand the questionnaire, gather information, compile and review information, and complete and return the questionnaire form. There will be no need for ongoing recordkeeping because this is a one-time information collection effort.

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

5(a) Agency Activities

The Agency has conducted, is conducting, or will conduct the following activities associated with this data collection effort:

- Develop the questionnaires;
- Meet with stakeholders;
- Publish notice of anticipated ICR;
- Respond to all comments received;
- Revise questionnaires based on comments;
- Design questionnaire distribution method, including associated database development to track all responses;
- Design and develop a mailing list database; develop system to track mailing and receipt activities; distribute questionnaires;
- Set up and maintain a helpline for respondents who require assistance in completing their questionnaires;
- Receive and review questionnaire responses;

- Summarize and analyze questionnaire responses; and
- Conduct technical and economic analyses to identify available and affordable BMPs for hospitals, hospices, LTCFs, and veterinary facilities.

The Agency will transfer data received from the questionnaire forms to a master database for future use if the Agency decides to initiate an effluent guidelines rulemaking.

5(b) Collection Methodology and Management

The questionnaires will be sent via Federal Express or comparable carrier to ensure that a point of contact (the facility contact person) receives and signs for the questionnaire package. Each respondent can complete the questionnaire by legibly handwriting or typing the responses in the spaces provided, or they may use the electronic version. Each facility will be allowed 60 calendar days to return the completed questionnaire. The questionnaire requests submittal of 30 days of data reflecting drug disposal practices. If a facility has not maintained such records, EPA requests that 30 days of disposal data be collected and submitted. Depending on the respondent's existing data collection and tracking procedures, development of a tracking system and employee training on that system may be required.

EPA will include an e-mail address and phone number in the instructions that respondents can use to request assistance in completing the questionnaire. Respondents will be contacted by EPA's contractor, who will provide assistance in completing the questionnaire. Respondents can request communication via e-mail or telephone. Using these assistance methods enables the respondents to receive a timely response to any inquiries that they may have. E-mail and telephone communication will also reduce any misinterpretations of the questionnaire and thus decrease the burden of follow-up phone calls and letters to the respondents.

Each page of the questionnaire will include space to indicate the facility name for ease of tracking. EPA will also use facility identification numbers to assist in tracking responses. The Agency will make follow-up calls as needed to clarify inconsistencies in responses, and to remind non-respondents of their requirement to complete and return the questionnaire.

Upon receipt of completed questionnaires, EPA will review the questionnaires for completeness and internal consistency and enter the responses into a database. Data entry will be checked for accuracy, and this database will then be used to perform data analysis.

5(c) Small Entity Flexibility

Data from the 2002 Economic Census indicate that approximately 40 to 70 percent of hospitals and 80 percent of LTCFs meet the SBA's definition of a small business or cannot be identified as large because their employment or revenue figures are not known. EPA has taken several steps to minimize the burden of responding to the questionnaire for all respondents, including small businesses. The questions are phrased with commonly used terminology. Questions requesting similar types of information are arranged together to facilitate review of pertinent records and completion of the questionnaire. EPA will be providing a helpline to answer questions respondents might have when completing the questionnaire.

5(d) Collection Schedule

Based on a maximum of 30 days for OMB review, the schedule for the questionnaire distribution, response receipt, and data collection activities following OMB approval is as follows:

Action	Approximate Number of Calendar Days After OMB Approval
Draw industry sample and conduct meetings and teleconferences for respondents	15
Mail questionnaire	30
Receive questionnaire responses	90
Complete questionnaire review follow-up	180
Complete data entry of response data in database and data verification	210
Analyze questionnaire responses	211-365

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a) Estimating Respondent Burden

The EPA burden estimate is based on the number of entities receiving the questionnaire. To reduce the survey burden, EPA intends to select a sample of entities within the health services industry. The resulting sample will minimize the burden to the industry in completing the questionnaire and to the Agency in managing and effectively utilizing the data and information supplied by respondents.

EPA's burden estimate assumes that the sample of health services facilities will consist of approximately 14 percent of facilities in this sector, or 3,248 medical facilities and 296 veterinary facilities.

For the purpose of estimating the burden of completing the questionnaire, EPA divided the respondents into groups—medical and veterinary facilities. This section provides details about EPA's burden calculation.

(i) Respondent Burden

EPA assigned burden estimates for all sections of the questionnaire, as shown in Table 6-1. EPA identified labor categories associated with all respondent activities necessary to complete the questionnaire: manager (pharmacist, health services manager), clerical (pharmacist assistant, nursing aide, veterinary assistant), and veterinarian. The Agency estimated the required response time for each labor category per section.

Table 6-1. Respondent Hours for Questionnaire

Respondent Activity	Hours by Job Category			
	Manager (Pharmacist, Health Services Manager)	Clerical (Pharmacist Assistant, Nursing Aide, Veterinary Assistant)	Veterinarian	Response Hours
Medical Questionnaire				
Read instructions	0.5	1		1.5
Collect data for 30 days	12	25		37
Fill out form	1	0		1
Call with questions	0.5	0		0.5
Transmit	0	1		1
TOTAL	14	27		41
Veterinarian Questionnaire				
Read instructions		1	0.5	1.5
Collect data for 30 days		25	12	37
Fill out form		0	1	1
Call with questions		0	0.5	0.5
Transmit		1	0	1
TOTAL		27	14	41

(ii) Total Estimated Respondent Burden

EPA calculated the total estimated respondent burden using the estimated response time (41 hours) in Table 6-1 and multiplying it by the total number of respondents—3,544 facilities. This results in a total respondent burden of 145,304 hours.

6(b) Estimating Respondent Costs

(i) Estimating Labor Costs

The direct labor cost to respondents to complete the questionnaire equals the time required to read and understand the questionnaire, gather the information, compile and review the information, and complete the questionnaire form. Labor costs will comprise the majority of the financial burden imposed on the industry.

Table 6-2 presents earnings data from the Bureau of Labor Statistics, National Occupational Employment and Wage Estimates for the related labor categories for 2007[3] (latest year for which data are available) multiplied by 1.6 to account for overhead.

[3] BLS. 2007d. Bureau of Labor Statistics. Employer Costs for Employee Compensation—May 2007. Released May 9, 2008. http://www.bls.gov/oes/current/oes_nat.htm, Accessed June 11, 2008.

Table 6-2. 2007 Labor Rate Data

Job Category	Manager (Pharmacist, Health Services Manager)	Clerical (Pharmacist Assistant, Nursing Aide, Veterinary Assistant)	Veterinarian
Median Hourly Earnings (base year 2007)	$71.20	$16.80	$64.69

EPA calculated the estimated respondent burden using the estimated response time per section shown in Table 6-1 and the labor rates shown in Table 6-2 to calculate a total labor cost of $5,113,240.

(ii) Estimating Capital and Operation and Maintenance (O&M) Costs

Because EPA will not require questionnaire respondents to purchase any goods, including equipment or machinery, to respond to the questionnaire, the Agency does not expect capital costs to result from the administration of this data collection questionnaire. O&M costs include only photocopying and postage and/or express delivery for the completed questionnaires.

(iii) Capital/Start-up Operation and Maintenance Costs

EPA estimates there will be no capital or start up costs associated with responding to the questionnaire. O&M costs include only photocopying and postage or express delivery. EPA assumes that the costs incurred by the respondents will be approximately $20 per respondent assuming that they will copy the form and return the completed questionnaire via Federal Express or a comparable delivery carrier that requires signature to acknowledge receipt.

(i) Annualizing Capital Costs

EPA estimates that there will be no capital costs associated with responding to the questionnaire.

6(c) Estimating Agency Burden and Costs

Table 6-3 presents an estimate of the burden and labor costs that EPA will incur to administer the questionnaire. The table identifies the collection administration tasks to be performed by Agency employees and contractors, with the associated hours required for each grouping of related tasks. EPA determined Agency labor costs by multiplying Agency burden figures by the hourly Agency labor rate of $80. EPA determined contractor labor costs by multiplying contractor burden figures by an average contract labor rate of $80 per hour. This rate is consistent with current Agency contracts.

Table 6-3. Estimated Agency Burden and Labor Costs

Information Collection Activity	Hours			Labor Cost		
	Agency	Contractor	Total Hours	Agency	Contractor	Total Cost
Develop the questionnaire instruments; meet with stakeholders; publish notice of anticipated ICR in Federal Register.	200	500	700	$16,000	$40,000	$56,000
Respond to all comments received.	100	0	100	$8,000	$0	$8,000
Revise questionnaire instruments based on comments.	25	100	125	$2,000	$8,000	$10,000
Design electronic distribution method, including associated database development.	100	400	500	$8,000	$32,000	$40,000
Design and develop a mailing list database; develop a system to track mailing and receipt activities; mail questionnaire instruments.	50	100	150	$4,000	$8,000	$12,000
Develop and maintain helpline.	50	200	250	$4,000	$16,000	$20,000
Data Entry and QA	200	500	700	$16,000	$40,000	$56,000
Data analysis	500	600	1,100	$40,000	$48,000	$88,000
Totals	**1,225**	**2,400**	**3,625**	**$98,000**	**$192,000**	**$290,000**

6(d) Estimating the Respondents Universe and Total Burden and Costs

EPA expects to receive 3,544 completed questionnaires. EPA estimates a total burden of 145,304 hours and a total labor and O&M cost of $5,184,120 for all respondents.

6(e) Bottom Line Burden Hours and Cost Tables

Tables 6-4 and 6-5 summarize the total costs that the health services industry and the Agency will incur as a result of the information collection.

Table 6-4. Total Estimated Respondent Burden and Cost

Number of Respondents	Total Burden (Hours)	Total Labor Cost	Total O&M Cost	Total Cost
3,544	145,304	$5,113,240	$70,880	$5,184,120

Table 6-5. Total Estimated Agency Burden and Cost Summary

Total Burden (Hours)	Total Labor Cost	Total Cost
3,625	$290,000	$290,000

6(f) Burden Statement

EPA estimates that the total burden to the 3,544 health services facilities responding to the questionnaire will be approximately 145,305 hours, or $5,200,000 (including labor and O&M costs). EPA estimates that there will be no start-up or capital costs associated with completing and returning the questionnaire.

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 to collect, validate, and verify information, process and maintain information, and disclose and provide information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel 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 No. EPA-HQ-OW-2008-0517, which is available for public viewing at the Water Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426. An electronic version of the public docket is available through the Federal Data Management System (FDMS) at www.regulations.gov. Use FDMS to view and submit 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. Once in the system, select “Advanced 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 No. (EPA-HQ-OW-2008-0517) and OMB control number (2040-NEW) in any correspondence.