SUPPORTING STATEMENT FOR PHARMACY BILLING REQUIREMENTS

OMB CONTROL NO. 1240-0050

This ICR seeks a three year extension of expiration date.

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

The Office of Workers' Compensation Programs (OWCP) is the agency responsible for administration of the Federal Employees' Compensation Act (FECA), 5 U.S.C. 8101 et seq., the Black Lung Benefits Act (BLBA), 30 U.S.C. 901 et seq., and the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA), 42 U.S.C. 7384 et seq. All three of these statutes require that OWCP pay for covered medical treatment provided to beneficiaries; this medical treatment can include medicinal drugs dispensed by pharmacies. In order to determine whether amounts billed for drugs are appropriate, OWCP must receive the required data elements, including the name of the patient/beneficiary, the National Drug Code (NDC) number of the drugs prescribed, the quantity provided, the prescription number and the date the prescription was filled. The regulations implementing these statutes require the collection of information needed to enable OWCP to determine if bills for drugs submitted directly by pharmacies, or as reimbursement requests submitted by claimants, should be paid. (20 CFR 10.801, 30.701, 725.701 and 725.705).

There is no standardized paper form for submission of the billing information collected in this Information Collection Request (ICR). Over the past several years, the majority of pharmacy bills submitted to OWCP have been submitted electronically using one of the industry-wide standard formats for the electronic transmission of billing data through nationwide data clearinghouses devised by the National Council for Prescription Drug Programs (NCPDP). However, since some pharmacy bills are still submitted using a paper-based bill format, OWCP will continue to accept any of the many paper-based bill formats still used by some providers so long as they contain the data elements needed for processing the bill. None of the paper-based or electronic billing formats have been designed by or provided by OWCP; they are billing formats commonly accepted by other Federal programs and in the private health insurance industry for drugs. Nonetheless, the three programs (FECA, BLBA and EEOICPA) provide instructions for the submission of necessary pharmacy bill data elements in provider manuals distributed or made available to all pharmacies enrolled in the programs.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

The required data elements are used by OWCP and contractor bill processing staff to process paper and electronic bills for drugs dispensed by pharmacies. To enable OWCP and its contractor staff to consider the appropriateness of the requested payment in a timely fashion, it is essential that bill submissions include the data elements needed to evaluate the bill, such as the NDC number and the pharmacy's provider identification number. To do this, OWCP evaluates the same data elements that are commonly evaluated by other Federal agencies and private health insurance carriers. If all the billing data elements required by OWCP are not collected, the contractor staff cannot process the bill.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (e.g., permitting electronic submission of responses) and the basis for the decision to adopt this means of collection. Also, describe any consideration of using information technology to reduce burden.

Pharmacies either submit their bills electronically through one of several nationwide billing clearinghouses (e.g., National Data Corporation) or mail their paper bills for drugs directly to OWCP's contractor responsible for the automated processing of all medical bills. The NCPDP has devised standardized specifications for the electronic transmission of these billing data elements that are used by the great majority of pharmacies for billing government programs such as Medicare and many private third-party payers. OWCP's acceptance of these standardized formats keeps the burden to the public at a minimum because they are widely available in various automated billing programs, they provide the information needed to process the bill, and they are acceptable to both government and private sector payers. Electronically transmitted pharmacy bills covered under the FECA, BLBA, and EEOICPA are currently accepted using one of the NCPDP standardized data formats.

As an additional service to encourage electronic submission of pharmacy bills, OWCP offers "real-time" adjudication of bills to our pharmacy providers that indicate whether or not a prescribed drug will be paid for by OWCP, and "real-time" authorization of certain prescriptions over the telephone. These services increase the number of bills submitted electronically to the three programs since uncertainty regarding payment responsibility is eliminated. Electronic submission also eliminates the need for pharmacies to print hard copies of the NCPDP (or other) paper billing form and eliminates keying time for OWCP's contractor, thus reducing total burden hours.

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Item A.2 above.

The pharmacy billing requirements are used by FECA, BLBA and EEOICPA to obtain information necessary to appropriately process pharmacy bills for drugs provided under each program. Duplicate information is not obtained since the programs service different populations. Other Federal agencies such as Civilian Health and Medical Program for Uniform Services (CHAMPUS) and Centers for Medicare and Medicaid Services (CMS) need similar information but the claimant populations serviced are not the same; therefore, no duplication of information is expected.

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

Collection of this information does not have a significant economic impact on a substantial number of small businesses. Freestanding pharmacies, hospital pharmacies, and other providers of prescription drugs such as pharmacies associated with clinics classified as small businesses are required to submit the needed billing data elements in accordance with program specifications for payment requests for pharmaceuticals covered under the Acts.

Efforts to minimize burden on providers include acceptance of the NCPDP standardized electronic billing data formats, which are in wide use by pharmacies and facilitate automated bill processing through standard coding language for the data elements provided. Additionally, the FECA, BLBA and EEOICPA programs have compiled instructions for the submission of the required billing data and the use of electronic transmission standards in program manuals that are distributed to all pharmacies enrolled in the programs, and provide opportunities for those enrolled pharmacies to attend workshops conducted by OWCP's servicing contractor. The NCPDP data formats are reviewed periodically by user work groups who are members of the NCPDP and changes in the formats are initiated as appropriate.

6. Describe the consequence to federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

All information collected is bill-specific and necessary to properly adjudicate and process each bill for payment. The data is not available from another source. Billing data is compiled and submitted by the pharmacy after each prescription (or set of prescriptions) is filled, and decisions about which billing cycle to use are made by each pharmacy. OWCP does not require that a pharmacy submit its billings at set intervals, since requiring the submission of pharmacy bills less frequently would result in delayed payment for medicinal drugs, and might cause problems with prescription refill requests that could adversely affect a claimant's medical treatment. Thus, requiring that billing information be collected less frequently would not be appropriate and may not meet accounting requirements of the programs.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner:

There are no special circumstances for the collection of this information.

- **requiring respondents to report information to the agency more often than quarterly;**

- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

- **requiring respondents to submit more than an original and two copies of any document;**

- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**

- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**

- **requiring the use of statistical data classification that has not been reviewed and approved by OMB;**

- **that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**

- **requiring respondents to submit proprietary, trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

8. If applicable, provide a copy and identify the date and page number of publication in the *Federal Register* of the agency's notice, required by 5 CFR 1320.8(d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

Describe efforts to consult with persons outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported.

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years -- even if the collection-of-information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

The NCPDP is the private sector industry group that sets the standards for pharmacy billing, and they regularly solicit views from both member pharmacies and payers for consideration by their various work groups. The current NCPDP standards were developed by them for use by pharmacies and payers, and are reviewed and revised as necessary to meet the needs of billing pharmacies and those entities responsible for paying bills. The NCPDP standard electronic billing data formats are widely used.

A Federal Register Notification inviting public comment was published at 87 FR 22951 on June 17, 2022. Comments were not received.

9. Explain any decision to provide any payments or gifts to respondents, other than remuneration of contractors or grantees.

The only payment made to respondents is for medicinal drugs and similar products provided under the three programs. No gifts or other forms of remuneration are made.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

All drug bill payment requests that are submitted are fully protected by the Privacy Act in the following systems of records: DOL/GOVT-1 (FECA); DOL/OWCP-2 (BLBA); DOL/OWCP-11 (EEOICPA).

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no questions of a sensitive nature in the pharmacy billing requirements.

12. Provide estimates of the hour burden of the collection of information. The statement should:

- **Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the**

variance. Generally, estimates should not include burden hours for customary and usual business practices.[1]

- **If this request for approval covers more than one form, provide separate hour burden estimates for each form.**

- **Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here. Instead, this cost should be included in Item 13.**

Estimated Annualized Respondent Cost and Hour Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Responses	Average Burden (Hours)	Total Burden (Hours)	Hourly Wage Rate	Monetized Value of Respondent Time
Electronic Bills	864,558	1	864,558	0.0167 (1 minute)	14,438 hours	$8.97	$129,508.86
Manual Bills	514	1	514	0.00833 (5 minutes)	42.82 hours)	$8.97	$384.10
TOTAL	874,414		874,414		14,481		$129,892.96

About 874,414 medicinal drug bills are processed for OWCP annually; of these, approximately 864,558 drug bills are submitted electronically and 514 drug bills are submitted manually. It is estimated that each bill takes one minute to prepare electronically and five minutes to complete manually.

13. Provide an estimate of the total annual cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden shown in Items 12 and 14).

[1] Indicate the retention period for any recordkeeping requirements that pertain to the ICR.

- **The cost estimate should be split into two components: (a) a total capital and start up cost component (annualized over its expected useful life); and (b) a total operation, maintenance and purchase of service component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information. Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**

- **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**

- **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government or (4) as part of customary and usual business or private practices.**

The cost of submitting the pharmacy billing requirements is included in the amount billed by respondents for the medicinal drugs provided. Therefore, no operation or maintenance costs are experienced by respondents.

14. Provide estimates of the annualized cost to the Federal Government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information. Agencies also may aggregate cost estimates from Items 12, 13, and 14 into a single table.

There are no developmental, printing or mailing costs that are associated with this collection of information. The small numbers of paper bills submitted for payment are either purchased from non-government printers or computer-generated; the remainders of bills are submitted electronically. The instructions for the required billing data elements are in the provider manuals that are available and/or disseminated by the servicing contractor to all pharmacies enrolled in the programs. When necessary, updates are issued to the provider community. Printing and mailing costs for provider manuals and updates are built into the contract that OWCP has with

the contractor providing program ADP support services. The cost to the pharmacy for the electronic submission of bills using the NCPDP standardized data formats is minimal and comparable to other payment request submission costs.

Processing/Reviewing Costs:

Under OWCP's contractor medical bill processing system, the average contractor cost to process one pharmacy billing submission is $8.97. Therefore, the contractor cost to process 874,414 bills for OWCP will be $7,843.493.58 (874,414 bills x $8.97/bill = $7,843,494 rounded).

15. Explain the reasons for any program changes or adjustments.

There has been a decrease in the number of bill submissions. As a result there is a decrease in burden hours from 24,203 to 14,481 which is an adjustment decrease of 9,722 burden hours.

16. For collections of information whose results will be published, outline plans for tabulations, and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

There are no plans to publish data collected.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

Since there is no standard paper form for these collections, they cannot display the OMB number and expiration date. Instead, OWCP will publish a notice in the Federal Register containing the OMB number and expiration date for this collection.

18. Explain each exception to the certification statement.

There are no exceptions to the certification statement.

B. COLLECTIONS OF INFORMATON EMPLOYING STATISTICAL METHODS.

Statistical methods are not used in these collections of information.