SUPPORTING STATEMENT

PHARMACY BILLING REQUIREMENTS
1240-0050

This ICR would revise the information collection to incorporate proposed regulatory updates to the existing approved Health Insurance information collection requirements. Proposed regulations at 20 CFR 30.701 include information collections covered by this ICR.

A. Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collections. Attach a copy of the appropriate section of each statute and of each 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 for adopting 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 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 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 of 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 circumstance required in the conduct of this information collection.

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

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.

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.

Concurrent with submission of this ICR submission, OWCP issued a Notice of Proposed Rulemaking that provides a 60-day period for the public to comment on the proposed change to the collection of information. In addition, the NPRM instructed that comments on the information collections in the proposed rule could be sent directly to OMB during a 30-day period.

9. Explain any decision to provide any payment or gift 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, regulations, 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/ESA-6 (BLBA); DOL/ESA-49 (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 make special surveys to obtain information on which to base burden estimates. Consultation with a sample of potential respondents is desirable. If the burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated burden and explain the reason for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**

The following burden estimates for the three programs have been derived from data compiled during the latest complete calendar year CY 2014. In general, pharmacies have weekly billing cycles, so approximately 4,344 respondents submit this information every year:

FECA: About 1,221,256 medicinal drug bills are processed by the FECA program annually; of these, approximately 1,218,887 drug bills are submitted electronically. It is estimated that each bill takes one minute to prepare electronically and five minutes to complete manually.

Total annual hour burden of 20,543 hours (20,346 + 197 = 20,543)
Electronic (1,218,328 x .0167 = 20,346 hours)
Manual (2,369 x 0.0833 = 197 hours)

BLBA: About 65,758 medicinal drug bills are processed for the BLBA program annually; of these, approximately 65,752 drug bills are submitted electronically. It is estimated that each bill takes one minute to prepare electronically and five minutes to complete manually.

Total annual hour burden of 1,099 hours (1,098 + 1 = 1,099)
Electronic (65,752 x 0.0167 = 1,098 hours)
Manual (6 x 0.0833 = 1 hour)

EEOICPA: About 166,286 medicinal drug bills are processed for the EEOICPA program annually; of these, approximately 166,255 drug bills are submitted electronically. It is estimated that each bill takes one minute to prepare electronically and five minutes to complete manually.

Total annual hour burden of 2,779 hours (2,776 + 3 = 2,779)
Electronic (166,255 x 0.0167 = 2,776 hours)
Manual (31 x 0.0833 = 3 hours)

Combining the burden hours for all three programs, the pharmacy billing requirements have a total respondent burden hour estimate of 24,421 hours (20,543 + 1,099 + 2,779 = 24,421). The mean wage rate for billing clerks (based on Bureau of Labor Statistics data, http://www.bls.gov/oes/current/naics4_622100.htm) is estimated to be $17.05 per hour. Thus, the respondent cost estimate for this collection is $416,378 (24,421 hours x $17.05 = $416,378).

13. Annual Costs to Respondents (capital/start-up & operation and maintenance).

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 annualized cost to the Federal government

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:

FECA: Under OWCP's contractor medical bill processing system, the average contractor cost to process one pharmacy billing submission is $1.44. Therefore, the contractor cost to process 1,221,256 bills for the FECA program will be $1,758,609 (1,221,256 bills x $1.44/bill = $1,758,609).

Bills that suspend out of the contractor medical bill processing system and require review are examined by 60 data entry operators, whose services are contracted from private concerns, key data on paper pharmacy bills. About 95% percent of their time is spent keying data, and about 16% of their time keying data is devoted to keying data on paper pharmacy bills. Pharmacy bills (paper and electronic) that suspend out of the bill processing system and require manual review are examined by 80 bill resolution clerks and coding specialists employed by the government at the GS-5 level, and 12 at the GS-9 level; approximately 8% of their time is required for this function.

Data entry operators: The cost to provide this review function is $274,786 [60 x $30,130/year using Bureau of Labor Statistics data (http://www.bls.gov/news.release/ocwage.htm) = $1,807,800 x 95% (general time keying bills) = $1,717,410 x 16% (specific paper pharmacy bill keying time) = $274,786].

Government bill resolution clerks/coding specialists: The cost to provide this processing function is $272,911 [80 at $35,140 (GS 5, step 4 using Salary Table 2015-RUS) per year x 8% = $224,896, plus 12 at $50,016 (GS 9, step 2 using Salary Table 2015-RUS) per year x 8% = $48,015 for a total of $272,911].

Total FECA Processing/Reviewing costs: $2,306,306 ($1,758,609 + $274,786 + $272,911).

BLBA: Under OWCP's contractor medical bill processing system, the average contractor cost to process one pharmacy billing submission is $1.44. Therefore, the contractor cost to process 65,758 bills for the BLBA program will be $94,652 (52,082 bills x $1.44/bill = $94,652).

EEOICPA: Under OWCP's contractor medical bill processing system, the average contractor cost to process pharmacy billing submission is $1.44. Therefore, the contractor cost to process 166,286 bills for the EEOICPA program will be $239,452 (166,286 x $1.44/bill = $239,452).

Two Federal employees in Washington, DC review all bills processed for EEOICPA under this contract: a payment systems manager (GS-14, step 3 using Salary Table 2015-DCB https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/15Tables/html/DCB.aspx) at $114,480 yearly and an assistant payment systems manager (GS-13, step 7 using Salary Table 2015-DCB https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/15Tables/html/DCB.aspx) at $108,987 yearly. About 8% of both their time is attributable to managing the processing and reviewing of paper pharmacy bills by OWCP's contractor staff. $114,480 + $108,987 = $223,467 x 8% = $17,877.

Total EEOICPA Processing/Reviewing costs: $257,329 ($239,452 + $17,877).

Total Federal Costs: $2,658,287 [$2,306,306 (FECA costs) + $94,652 (BLBA costs) + $257,329 (EEOICPA costs)].

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

There has been an increase in the number of electronic submission. As a result there is a decrease in burden hours from 26,917 to 24,421 which is an adjustment decrease of 2,496 burden hours.

16. For collections of information whose results will be published, outline plans for tabulation 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 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. Collections of Information Employing Statistical Methods: Explain each exception to the certification statement identified in ROCIS.

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods:

Statistical methods are not used in these collections of information.