

SUPPORTING STATEMENT

PHARMACY BILLING REQUIREMENTS OMB NO. 1215-0194

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

1. 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 19 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.

2. 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.

3. 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 indicates 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.

4. 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 (Item 5 of 014B Form 83-1), describe any methods used to minimize burden.

5. 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.

6. 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 that would cause an information collection to be conducted in a manner.

7. 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.

8. 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 Notice inviting public comment was published on *****, 2009. No comments were received.

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

9. 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.

10. 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). The form/template provides a Privacy Act Statement.

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.

11. 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. If the request for approval is for more than one form, provide separate burden estimates for each form and aggregate the hour burdens in Item 13 of OMB Form 83-1.

- 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 14.

12. The following burden estimates for the three programs have been derived from data compiled during the latest complete fiscal year—FY 2009. In general, pharmacies have weekly billing cycles, so approximately 28,150 respondents submit this information every year (1,463,800 responses divided by 52 weeks = 28,150):

FECA: About 1,260,654 medicinal drug bills are processed by the FECA program annually; of these, approximately 1,256,493 drug bills are submitted electronically. The FECA program requires 19 data elements to process drug bills; additional fields in the paper and electronic formats are optional. It is estimated that each bill takes five minutes to prepare, for an annual hour burden of 104,634 hours (1,260,654 x 0.083 = 104,634.28 hours).

BLBA: About 148,403 medicinal drug bills are processed for the BLBA program annually; of these, approximately 147,669 drug bills are submitted electronically. The BLBA program requires 19 data elements to process drug bills; additional fields in the paper and electronic formats are optional. It is estimated that each bill takes five minutes to prepare, for an annual hour burden of 12,317 hours (148,403 x 0.083 = 12,317.449 hours).

EEOICPA: About 54,735 medicinal drug bills are processed for the EE0ICPA program annually; of these, approximately 53,668 drug bills are submitted electronically. The EE0ICPA program requires 19 data elements to process drug bill; additional fields in the various paper formats are optional. It is estimated that each bill takes five minutes to prepare, for an annual hour burden of 4,543 hours (54,735 x 0.083 = 4,543.005 hours).

Combining the burden hours for all three programs, the pharmacy billing requirements have a total respondent burden hour estimate of 121,494 hours (104,634 + 12,317 + 4,543 = 121,494). The mean wage rate for billing clerks (based on Bureau of Labor Statistics data) is estimated to be \$15.44 per hour. Thus, the respondent cost estimate for this collection is \$1,875,867 (121,494 hours x \$15.44 = \$1,875,867.).

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

13. 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

14. There are no developmental, printing or mailing costs that are associated with this collection of information. The small number of paper bills submitted for payment are either purchased from non-government printers or computer-generated; the remainder 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 \$1.26. Therefore, the contractor cost to process 1,260,654 bills for the FECA program will be \$1,588,424 (1,260,654 bills x \$1.26/bill = \$1,588,424).

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 \$247,243 (60 x \$27,110/year using Bureau of Labor Statistics data = \$1,626,600 x 95% general time keying bills) = \$1,545,270 x 16% (specific paper pharmacy bill keying time) = \$247,243.

Government bill resolution clerks/coding specialists: The cost to provide this processing function is \$262,886 (80 at \$33,849 (GS 5, step 4 using Salary Table 2009-RUS) per year x 8% = \$216,634, plus 12 at \$48,179 (GS 9, step 2 using Salary Table 2009-RUS) per year x 8% = \$46,252 for a total of \$262,886.

Total FECA Processing/Reviewing costs: \$2,098,553.

BLBA: Under OWCP's contractor medical bill processing system, the average contractor cost to process one pharmacy billing submission is \$1.26. Therefore, the contractor cost to process 148,403 bills for the BLBA program will be \$186,988 (148,403 bills x \$1.26/bill = \$186,988).

EEOICPA: Under OWCP's contractor medical bill processing system, the average contractor cost to process pharmacy billing submission is \$1.26. Therefore, the contractor cost to process 54,735 bills for the EEOICPA program will be \$68,966.1 (54,735 x \$1.26/bill = \$68,966).

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 2009-DCB) at \$109,570 yearly and an assistant payment systems manager (GS-13, step 7

using Salary Table 2009-DCB) at \$104,314 yearly. About 8% of both their time is attributable to managing the processing and reviewing of paper pharmacy bills by OWCP's contractor staff. $\$109,570 + \$104,314 = \$213,884 \times 8\% = \$17,111$.

Total EEOICPA Processing/Reviewing costs: \$86,077.

$\$2,098,553$ (FECA costs) + $\$186,988$ (BLBA costs) + $\$86,077$ (EEOICPA costs) = Total Federal Cost of $\$2,371,618$.

15. Explain the reasons for any program changes or adjustments reported in Items 13 or 14 of the OMB Form 83-I.

15. There has been is a decrease of one hour in the number of pharmacy bills submitted to the FECA program in recent years. Therefore, OMB Form 83-I shows a net adjustment decrease of -1 hour.

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.

16. 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.

17. 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 Item "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.

18. There are no exceptions to the certification statement.