SUPPORTING STATEMENT FOR CERTIFICATION OF MEDICAL NECESSITY

OMB CONTROL NO. 1240-0024

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 Black Lung Benefits Act (30 U.S.C. 901) and its implementing regulations necessitate this information collection. The regulations at 20 CFR 725.701 set out a miner's eligibility for medical services and supplies for the length of time required by the miner's pneumoconiosis and related disability. 20 CFR 725.705 requires prior approval before ordering medical equipment where the purchase price exceeds $300.00. 20 CFR 725.706 provides for the ongoing supervision of the miner's medical care, including the necessity, character and sufficiency of care to be furnished; gives the authority to request medical reports; and indicates the right to refuse payment for failing to submit any report required. To implement the statute and these regulations, it was necessary to devise a form to collect the required information. The form is the CM-893, Certification of Medical Necessity (CMN).

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 claims staff uses the information on the CMN to determine if the patient has had a recent hospitalization that needs to be taken into account, if the medical condition is covered by the program, the length of time the item will be needed, and what durable medical equipment (DME) or outpatient service the doctor is prescribing. The CMN requires submission of objective test results to support the request and permits the physician to enter certain required information on the form if the information is not contained in the test report itself. The claims staff uses each of these items to determine if the CMN request can be approved. The Department of Labor (DOL) reimbursement standards appear on the second page of the form. The second page is also used for the doctor's signature indicating the doctor's approval and certification of the information on the CMN and shows the doctor's clinical relationship to the patient. Also, there is an area for additional medical information the doctor may wish to present in order for the CMN to be approved. The CMN is considered a medical prescription, which requires pre-authorization.

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.

The CMN data is part of the program's benefit information system. By entering this data into the computer system, it allows DOL to quickly identify duplicate requests and allows the provider's bill to be processed in a consistent and timely manner. This system prevents reimbursement of unauthorized services.

The CM-893 is available for on-screen filling and/or downloading on the Division of Coal Mine Workers' Compensation (DCMWC) web site, as mandated by the Government Paperwork Elimination Act (GPEA). The form is available at http://www.dol.gov/owcp/dcmwc/regs/compliance/blforms.htm.

The CM-893 may be submitted online through the COAL Mine Portal at https://eclaimant.dol-esa.gov/bl.

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.

There is no similar information available.

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

Small businesses are involved because a physician is responsible for submitting the information on the CMN.

Burden on physicians and medical suppliers is reduced by requiring the CMN only once at the beginning of each prescription for oxygen instead of annually, and by no longer requiring a CMN for certain durable medical equipment. Recertification of the same oxygen prescription requires only a letter from the physician, not a new form and test results. The number of forms required over the patient's lifetime of care has been substantially reduced.

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.

If the information on the CMN were not gathered, DCMWC would not be able to determine if the prescribed item or service would be appropriate to treat the miner's pulmonary condition. Without this information and pre-authorization, the program would be subject to abuse.

For durable medical equipment and home nursing care, the information is collected at the time a new prescription is written. We have determined that our policy of requiring less burdensome reporting for recertification of previously-approved equipment (by physician's letter instead of

the form) has not affected the patient's receipt of necessary medical treatment or the over prescribing of unnecessary services.

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

- **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 confidentially 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 confidentially to the extent permitted by law.**

There are no special circumstances for this information collection.

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.

A Federal Register Notice inviting public comment was published on December 9, 2020 (89 FR 79223). No public comments were received.

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

No payments or gifts are made to respondents to furnish the information.

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

Since the completed form is maintained in the miner's case file, this information is covered by the Privacy Act System of Records, DOL/OWCP-2 and DOL/OWCP-9, published at 81 Federal Register 25765, 25858, and 25865 (April 29, 2016), or as updated and republished.

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.

This collection contains no questions of a sensitive nature.

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. General, estimates should not include burden hours for customary and usual business practices.**

- **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 14.

The estimated burden of this information collection is approximately 488 hours. This burden is based on the average number of 1,300 submissions. Approximately 130 (10%) responses involve a pulmonary function study, which requires about 30 minutes to administer and calculate the results. Reading, completing and submitting the form takes another ten minutes for a total of 40 minutes (40/60 hours).

40/60 hrs. x 130 = 87 hours (86.66 rounded up).

Approximately 1,105 (85%) responses involve an arterial blood gas study, which takes about 10 minutes to administer and calculate the results. Reading, completing and submitting the form takes another 10 minutes for a total of 20 minutes (20/60 hours.)

20/60 hrs. x 1,105 = 368 hours.

The remainder of the responses, 65 (5%), involve submission of existing treatment records, requiring 20 minutes to copy and collate. Reading, completing and submitting the form takes another 10 minutes for a total of 30 minutes (30/60 hour.)

30/60 hrs. x 65 = 33 hours.

Thus, the total burden is 488 hours.

Any estimated annualized cost to respondents for providing the requested information is offset by direct payment by the Program to the respondent for the usual and customary cost for the medical tests and reports. This includes any mail and handling charges.

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	Total Burden Cost
PFT	130	1	130	40/60	87	$152.43	$13,261
ABG	1,105	1	1,105	20/60	368	$118.26	$43,520

Records	65	1	65	30/60	33	$175.00	$5,775
Total	1,300		1,300		488		$62,556

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

- **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 and 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.**

Operational and maintenance costs associated with the collection of this information are reimbursed.

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), 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.

The estimated total cost to the Federal Government for mailing and processing 1,300 forms and for reimbursement to the respondents for providing the information is approximately $190,964.15. The costs are computed as follows:

- Mailing (1,300 X .58) (.55 stamp and .03 envelope)	$ 754.00
- Processing	$29,095.95
Total (mail & processing)	$29,849.95

A GS-12/6 ($42.89/ hour) spends an average of 30 minutes evaluating and processing each form, and contract staff are reimbursed at $18.73/hour spends an average of 3 minutes on clerical duties associated with each form. (The Salary Table for 2020-RUS was used to calculate the GS-12/6 salary https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2020/general-schedule/ and salary from Bureau of Labor Statistics https://www.bls.gov/OES/Current/naics4_813900.htm#43-0000) was used to calculate the contract staff salary.

1,300 X .50 = 650 hours x $42.89 = $27,878.50
1,300 X 3 = 3,900/60 = 65 hours x $18.73 = $1,217.45
Processing $29,095.95

Respondent Reimbursement: $161,868.20. The estimated cost to the government for reimbursement to physicians is calculated by the following (costs are derived from the maximum fee payable by DCMWC for each service):

ABG(rest)	$118.26 x 1,105 =	$130,677.30
PFS(pre)	$152.43 x 130 =	$19,815.90
Records	$175.00 x 65 =	$11,375.00
Total reimbursement =		$161,868.20

Total cost to government: $190,964.15
($29,095.95 + $161,868.20 = $190,964.15)

The estimated annualized cost to the respondents for the burden hours for the collection of information, including postage and envelopes at $0.58 (.55 postage .03 envelope), is reimbursed to the parties by the Program. We did not include the physician's cost with the estimate of the annualized cost to respondents for the burden hours, because any burden-hour cost to CM-893 respondents (physicians) is offset by direct payment by DCMWC to the physicians for the usual and customary cost for the necessary testing, medical records, and completing and returning the form. Physician's office staff costs are overhead costs and are reimbursed as part of the physician's fee.

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

The decrease in burden hours and number of responses are due to fewer CMNs submitted.

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 this collection of information.

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.

This ICR does not seek a waiver from the requirement to display the expiration date.

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.