SUPPORTING STATEMENT
CERTIFICATE OF MEDICAL NECESSITY
1240-0024

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 Black Lung Benefits Act (30 U.S.C. 901, et. seq.) and its implementing regulations necessitate this information collection. The regulations at 20 CFR 725.701 et. seq., establish miner eligibility for medical services and supplies for the length of time required by the miner's pneumoconiosis and related disability. 20 CFR 725.706 requires prior approval before ordering an apparatus where the purchase price exceeds $300.00. 20 CFR 725.707 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. Because of the above legislation and regulations, it was necessary to devise a form to collect the required information. The form is the CM-893, Certificate 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. The CMN screen shows what action was taken on a requested item. 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 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 was 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. Recertifications of the same oxygen prescription require 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 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.

If the information on the CMN were not gathered, there would be no way of determining if the prescribed item or service would be appropriate in the care of 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 circumstance required in the conduct of this information collection.

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.

A Federal Register Notice inviting public comment was published on October 18, 2017 (82 FR 48532). No public comments were received.

9. Explain any decision to provide any payment 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, regulations, or agency policy.

Since the completed form is maintained in the beneficiary's case file, information collection involving a beneficiary's record is covered by the Privacy Act System of Records, DOL/OWCP-2, published at 81 Federal Register 25765, 25858 (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 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 estimated burden of this information collection is

approximately 563 hours. This burden is based on the average number of 1,500 submissions. Approximately 150 (10%) responses involve a pulmonary function study which requires about 30 minutes to administer and calculate the results. Reading, completing and mailing the form takes another ten minutes for a total of 40 minutes (40/60 hours)

40/60 hrs. x 150 = 100 hours.

Approximately 1,275 (85%) responses involve an arterial blood gas study which takes about 10 minutes to administer and calculate the results. Reading, completing and mailing the form takes another 10 minutes for a total of 20 minutes (20/60 hours.)

20/60 hrs. x 1,275 = 425 hours.

The remainder of the responses, 75 (5%), involve submission of existing treatment records, requiring 20 minutes to copy and collate. Reading, completing and mailing the form takes another 10 minutes for a total of 30 minutes (30/60 hour.)

30/60 hrs. x 75 = 38 hours.

Thus, the total burden is 563 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 mail and handling charges.

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

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

14. Provide estimates of annualized cost to the Federal government.

The estimated total cost to the Federal Government for mailing and processing 1,500 forms and for reimbursement to the respondents for providing the information is approximately $184,391.25. The cost is computed as follows:

-	Mailing (1,500 X .52)	$ 780
-	Processing	$ 31,567.50
	Total	$ 32,347.50

A GS-12/6 spends an average of 30 minutes evaluating and processing each form, and contract staff reimbursed at $17.50/hour spends an average of 3 minutes on clerical duties associated with each form. (The Salary Table for 2017-RUS was used to calculate the GS-12/6 salary https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2017/RUS_h.pdf.

1,500 X .50 = 750 hours x $ 40.34 =	$ 30,255.00
1,500 X 3 = 4,500/60 = 75 hours x $ 17.50 =	$ 1,312.50
Total Processing	$ 31,567.50

Respondent Reimbursement: $152,043.75

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) $94.61 x 1,275 =	$120,627.75
PFS(pre) $121.94 x 150 =	$ 18,291.00
Records $175.00 x 75 =	$ 13,125.00
Total reimbursement =	$152,043.75

Grand total cost to government: $ 184,391.25
($32,347.50 + $152,043.75 = $184,391.25)

The estimated annualized cost to the respondents for the burden hours for the collection of information including postage and envelopes at $0.52 (.49 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 overall request is a revision because the forms were revised. The decrease (adjustment) in the burden hours, number of responses, cost burden is due to fewer CMNs being submitted for processing.

Changes have been made to CM-893 to include:

“DOL’s Case ID Number” to Item 3
Item 5 is now blank
Removed “Original or Certified Copies” from Item 10.
Added “(Explain Under Item 12” under Items 10c and 10h
Added “If the patient is homebound or non-ambulatory, or if other circumstances related to his/her condition prevent the sample from being analyzed within 30 minutes, the prescribing physician may submit a narrative rationale explaining the circumstances and substantiate the medical necessity for the item or service prescribed.” to Item 11a
Added “PFT – Test results with tracings and flow volume loop must be attached. ABG – Test strip must be attached. ” To Item 11b
Added “PFT – Test results with tracings and flow volume loop must be attached. ABG – Test strip must be attached. ” To Item 11e
Removed “Faxes CANNOT be accepted” from Item 11f.
Added “Prescribing” to Item 13.a.
Item 13.e. added “I certify that all data accompany the submission is an accurate representation of the test results.”
Removed “original” and “(Do not use stamp) (See 11.f)” from Item 13.e.
Under physician signature block, added information on two options to file the completed form.
Under Item 13.f. changed the word Provider to “Provide” and added “who is supplying the equipment or service”
Updated Privacy Act
Under “Notice” changed “examiner” to “staff”.

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 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 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.