

**NG STATEMENT  
Disclosure of Medical Evidence  
1240-0054**

This Information Collection Request (ICR) is being submitted in association with a Final Rule. The Department of Labor asks that the Office of Management and Budget conclude its review by approving the information collections in this ICR in accordance with 5 C.F.R. § 1320.11(h).

**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 Department's Final Rule will revise the regulations implementing the Black Lung Benefits Act (BLBA), 30 U.S.C. 901 *et seq.*, addressing several issues that have arisen in claims processing and adjudications. Among these revisions, the Department's Final Rule (to be codified at 20 C.F.R. § 725.413) will require parties to exchange all medical information about the miner they develop in connection with a claim for benefits, including information the parties do not intend to submit as evidence in the claim. The Final Rule will help protect a miner's health, assist unrepresented parties, and promote accurate benefit determinations.

The potential parties to a BLBA claim include the benefits claimant, the responsible coal mine operator and its insurance carrier, and the Director, Office of Workers' Compensation Programs (OWCP). Under this Final Rule, a party or a party's agent who receives medical information about the miner must send a copy to all other parties within 30 days after receipt or, if a hearing before an administrative law judge has already been scheduled, at least 20 days before the hearing. The exchanged information will be entered into the record of the claim only if a party submits it into evidence.

The Department's authority to engage in information collection is specified in BLBA sections 413(b), 422(a), and 426(a). See 30 U.S.C. § 923(b), 932(a), and 936(a).

**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.**

Parties to a black lung benefits claim will be required to exchange certain medical information about the miner that the party or the party's agent received by sending a complete copy of the medical information to all other parties in the claim. The purpose of this exchange is to help protect a miner's health, assist unrepresented parties, and promote accurate benefit determinations.

**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.**

This Final Rule will not preclude electronic responses. However, these exchanges will be made in the context of a claim's litigation, and the allowable transmission methods will be dictated by the procedures established by the particular forum adjudicating the claim (either an OWCP district director or an administrative law judge in the Department's Office of Administrative Law Judges). In some circumstances, the forum may allow exchange by electronic methods, such as facsimile or e-mail. But the Department anticipates that parties will usually exchange these documents by U.S. postal mail or a commercial delivery service (e.g., Federal Express, UPS), and has calculated the associated burdens accordingly.

**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 information collected will not be duplicative of any information available elsewhere.

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

The Department does not believe this Final Rule will have a significant economic impact on a substantial number of small entities because in many (and perhaps the majority) of cases, the parties already exchange all of the medical information in their possession as part of their evidentiary submissions.

**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.**

This information collection will be required by regulations codified at 20 C.F.R. § 725.413. If the collection were not conducted or conducted less frequently, there would be a direct negative impact on the parties to BLBA claims because the miner may not have full access to information about his or her health and benefit determinations may be less accurate.

**7. Explain any special circumstances 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.**

On April 29, 2015, the Department proposed revising the BLBA's implementing regulations to resolve several procedural issues that had arisen in claims administration and adjudication, and make other technical changes. 80 FR 23743 (NPRM). On one of these issues, the Department proposed a new rule, to be codified at 20 C.F.R. 725.413, requiring the parties to exchange any medical information about the miner that they developed in connection with the claim. The Department also estimated the associated time and cost burdens with this exchange and specifically asked for comments on the collection. 80 FR 23749.

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The Department received comments on the substance of the proposed rule. A summary of these comments and the Department's response is set forth below. References to "the Act" in this discussion refer to the Black Lung Benefits Act, 30 U.S.C. 901 *et seq.* The Department received no comments relevant to the time and cost burdens associated with the collection.

Some commenters ask the Department to withdraw the rule, arguing that the Department lacks statutory authority to promulgate it. The Department disagrees with this comment. Congress granted the Secretary broad rulemaking authority generally, and in governing evidentiary matters specifically. See 30 U.S.C. 923(b) (incorporating 42 U.S.C. 405(a)) and 936(a). The statute also plainly authorizes the Department to depart from traditional procedural and evidentiary rules (such as those governing discovery) in order to best ascertain the rights of the parties in claims adjudications. 33 U.S.C. 923(a), as incorporated by 30 U.S.C. 932(a).

The objecting commenters dispute the Department's reliance on these statutory authorities. Without acknowledging the Secretary's general rulemaking authority under 30 U.S.C. 936(a), they contend that neither the incorporated Longshore Act nor the incorporated Social Security Act provisions support promulgation of § 725.413. First, these commenters assert that the Department's reliance on Longshore Act section 23(a) is hypocritical because proposed § 725.413 is itself a technical rule of procedure. While § 725.413 is undoubtedly procedural, it will relieve the parties from the burden of complex discovery rules and will simplify claim proceedings and make them fairer, especially for those parties not represented by counsel. The rule is thus fully consistent with section 23(a)'s overarching command to "best ascertain the rights of the parties."

Next, the same commenters state that the Department cannot rely on Social Security Act section 205(a), which they claim has no applicability to Part C BLBA claim proceedings (*i.e.*, claims filed after 1973 and administered by the Department) because it is located in Part B of the Act, and provides no authority for importing Social Security Administration procedures into Part C claim adjudications. The commenters misapprehend the Department's authority and actions in this regard. The fact that the Social Security Act incorporation appears in Part B of the Act does not preclude the Secretary from basing regulations for Part C claims on that authority. See 30 U.S.C. 940 (providing that "amendments made by the Black Lung Benefits Act

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of 1972," which included the incorporation of Social Security Act section 205(a), "shall, to the extent appropriate, also apply to this part [C]."). Indeed, both the District of Columbia and Fourth Circuit Courts of Appeals have upheld the Department's procedural regulations governing Part C claims by relying at least in part on this statutory authority. See *Nat'l Min. Ass'n. v. Dep't. of Labor*, 292 F.3d 849, 874 (D.C. Cir. 2002) (holding that section 205(a) and 5 U.S.C. 556(d)—which allows agencies to exclude "unduly repetitious evidence" as "a matter of policy"—constituted sufficient authority for the regulatory evidence limitations at 20 CFR 725.414, which are applicable to Part C claims); *Elm Grove Coal v. Director, OWCP*, 480 F.3d 278, 293 (4th Cir. 2007) (holding in Part C claim that incorporation of section 205(a), Administrative Procedure Act section 556(d), and grant of general rulemaking authority in 30 U.S.C. 936 "authorize the Secretary to adopt reasonable regulations on the nature and extent of the proofs and evidence in order to establish rights to benefits under the Act"). Moreover, § 725.413 does not import Social Security Administration procedures but instead provides a new rule applicable to Part C claims.

Three commenters claim that requiring parties to exchange medical information is an overreaction to an isolated case, claiming that only one attorney engaged in the conduct addressed by proposed § 725.413. These commenters state that the Department cited only one case involving undisclosed medical information in the NPRM, and failed to fully assess the need for the rulemaking.

Although the Department illustrated the need for the rule with a detailed summary of miner Gary Fox's claims, it also cited two additional cases (involving different attorneys) in the NPRM. 80 FR 23746. More importantly, the issue of withholding medical information generated by non-testifying experts has persistently recurred in black lung claims and has been litigated by some members of the associations making this comment. Several other commenters listed and described additional claims in which medical evidence was withheld. These cases, along with others the Department has identified, generally fall into three categories. In the first, the adjudication officer denies the party's (either the claimant's or the operator's) motion to compel discovery of the medical information because the party did not meet the standard for gaining discovery of a non-testifying expert's opinion imposed under the Office of Administrative Law Judges Rules of Practice and Procedure (OALJ

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Rules). See, e.g., *Keener v. Peerless Eagle Coal Co.*, ALJ Ruling and Order on Claimant's Motion to Compel and Employer's Motion for Protective Order, 2004-BLA-06265 (Apr. 12, 2005), *aff'd* BRB Decision and Order, BRB No. 05-1008 (Jan. 26, 2007); *Lester v. Royalty Smokeless Coal Co.*, ALJ Decision and Order on Remand Granting Benefits, 2004-BLA-05700 (Mar. 4, 2008). In the second, the claimant's motion to compel is granted, but the employer still avoids disclosure by accepting liability for benefits and paying the claim. See, e.g., *Daugherty v. Westmoreland Coal Co.*, ALJ Order Remanding Case to District Director, 2001-BLA-00594 (Mar. 21, 2005); *Renick v. Consolidation Coal Co.*, ALJ Order of Remand for Payment, 2002-BLA-00083 (Sept. 9, 2002); and *Harris v. Westmorland Coal Co.*, Order Denying Claimant's Request for Reconsideration, 1998-BLA-0188 (Aug. 7, 1998). And in the third, the motion to compel is granted and the medical information is disclosed. See, e.g., *Wood v. Elkay Mining Co.*, ALJ Decision and Order - Awarding Benefits, 2001-BLA-00701 (May 23, 2007); *Huggins v. Windsor Coal Co.*, BRB Decision and Order, BRB No. 06-0710 (Aug. 15, 2007). It is the first two categories of cases in which § 725.413 will change the result by requiring the exchange of previously undisclosed medical information.

These commenters also assert that the Department failed to quantify the general impact of non-disclosure on miners' health. Doing so with any certainty is impractical for several reasons. By their nature, these cases come to light only when a party takes affirmative action to discover medical information; the Department cannot quantify the volume of undisclosed medical information in cases where parties do not pursue discovery of that information and, in fact, might not even know of its existence. The same is true in those instances where the employer has chosen to accept liability for the claim rather than disclosing the non-testifying expert's opinion. The Department also cannot assess whether any particular piece of medical information would have an impact on any one miner's course of treatment or disease. But common sense dictates that better-informed miners and medical providers are able to make better decisions regarding a miner's care.

And, to the extent these commenters are correct in stating that, with very few exceptions, parties already exchange all medical information developed, they should not be affected by the final rule. Apart from a slightly earlier deadline for exchanging medical information, § 725.413 will not change those parties' current practice.

The Department received several comments suggesting various clarifications and other changes to the proposed definition of "medical information" at § 725.413(a). As proposed, "medical information" includes medical data about a miner that was developed in connection with a claim for benefits (§ 725.413(a)) *and* that is: (1) an examining physician's assessment of the miner, including findings, test results, diagnoses, and conclusions (§ 725.413(a)(1)); or (2) any other physician's or medical professional's opinion or interpretation of tests, procedures and related documentation, but only to the extent they address the miner's respiratory or pulmonary condition (§ 725.413(a)(2)-(4)). 80 FR 23747, 23752. Thus, the medical data subject to disclosure is generally limited to data generated in the claim's litigation and relevant to the primary question in the claim—the miner's respiratory or pulmonary condition. Two commenters express concern that proposed § 725.413(a) does not specifically exclude a miner's medical treatment records from the definition of "medical information" subject to mandatory exchange between parties. As the Department explained in the NPRM, 80 FR 23747, treatment records are not medical data a party "develops in connection with a claim" and thus do not meet the definition of "medical information." Instead, these records are generated in the routine course of a miner's treatment and, if pertinent to the miner's respiratory or pulmonary condition, are admissible without limitation. 20 CFR 725.414(a)(4). But to allay any concern, the Department has revised § 725.413 to explicitly exclude treatment records from the "medical information" subject to exchange between the parties under this regulation. The new language is in paragraph (b)(1) of the final regulation.

Several commenters assert that § 725.413 should exclude from "medical information" all draft medical reports. These same commenters also urge the Department to exclude all communications between a party's attorney and its medical experts. For the reasons that follow, the Department disagrees that draft medical reports should be excluded from "medical information" but has adopted the commenters' suggestion to exclude attorney communications with experts from § 725.413's disclosure requirements.

To support their request for these exclusions, the commenters point variously to Federal Rule of Civil Procedure 26(b)(4)(B) and (C) and the OALJ Rules, 80 FR 28793 (May 19, 2015) (to be codified at 29 CFR 18.51(d)), which incorporate the concepts

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embodied in the Federal Rule. When an expert is required to submit written reports or other disclosures, those rules protect his or her draft reports from discovery. Fed. R. Civ. P. 26(b)(4)(B); 80 FR 28793 (to be codified at 29 CFR 18.51(d)(2)). Similarly, the rules generally protect from disclosure communications between the party's attorney and the expert witness except when those communications pertain to the expert's compensation, facts or data the attorney provided to the expert, or assumptions provided by the attorney to the expert that the expert relied on in forming his or her opinion. Fed. R. Civ. P. 26(b)(4)(C); 80 FR 28793 (to be codified at 29 CFR 18.51(d)(3)). These rules are designed to allow discovery of the facts and data on which the expert bases his or her opinion without unnecessarily interfering with effective communication between the attorney and the expert or disclosing the attorney's mental impressions and theories about the case. See *generally* FRCP 26, Advisory Committee comment to 2010 amendments.

Formal rules of procedure do not strictly apply in black lung claims adjudications. And a program-specific regulation applies over either the Federal Rules or the OALJ Rules. 80 FR 28785, to be codified at 29 CFR 18.10 (OALJ rules do not apply "[i]f a specific Department of Labor regulation governs[,] and the Federal Rules of Civil Procedure apply only in situations not provided for in the OALJ rules or other governing regulation). See also 80 FR 28773 (discussing 29 CFR 18.10 and stating that "[n]othing in [the OALJ] rules would prevent the Department from adopting a procedural rule that applies only in BLBA claim adjudications or other program-specific contexts.").

In this instance, the Department believes a rule governing draft reports designed specifically for the Black Lung program will serve the program's purposes better than the general rule. Exempting all draft medical reports from § 725.413's disclosure requirements could easily eviscerate the rule: the disclosure requirement could be avoided simply by labeling any medical report a "draft." Any party could solicit additional medical opinions on the miner's condition and simply not share them with the opposing party, or perhaps even their remaining expert witnesses. If an employer engaged in that conduct, a primary purpose of the rule—protecting the health and safety of the miner by ensuring access to all information about his or her health—would be thwarted. And if a claimant did the same, another primary purpose of the rule—accurate claims adjudication—could be in jeopardy.

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On the other hand, the Department does not see a similarly compelling need to routinely require disclosure of communications from an attorney (or lay representative) to a medical expert. When prepared by an attorney, these communications are generally protected from disclosure, except in the circumstances noted above, and are more likely to include the attorney's impressions and legal analysis of the case. And they generally do not have a direct bearing on protecting the miner's health. Accordingly, the Department believes these communications should not be considered "medical information" subject to mandatory exchange with the other parties. The Department has added new language to paragraph (b)(2) in the final rule to exclude attorney (and lay representative) communications from the rule's disclosure requirements. The Department notes, however, that the exclusion would not protect disclosure of these communications when otherwise ordered. See, e.g., *Elm Grove Coal*, 480 F.3d at 299-303. The rule simply does not require their exchange.

Two commenters ask the Department to revise § 725.413(a) to include "an exhaustive list" of "medical information" that must be exchanged. They claim that the proposed rule does not adequately describe the scope of covered information. To illustrate, the commenters point to several examples, such as data the Social Security Administration considers "health information" (e.g., a patient's method of bill payment) and suggest that "medical information" could be construed to include such data.

The Department has not added a complete list of "medical information" to the final rule. As explained, the rule expressly limits disclosure to medical information developed in connection with a claim for benefits and, with the exception of an examining physician's report, further limits required disclosure to data addressing the miner's respiratory or pulmonary condition. These two limitations serve to substantially narrow and define the scope of information that must be exchanged with opposing parties (e.g., data about a billing method would not meet the criteria). Moreover, developing an exhaustive list would not be practical because it could easily omit relevant medical data. Another black lung program regulation (20 CFR 718.107(a) (2014)) correctly countenances the possibility that medical testing methods other than those explicitly addressed in the regulations may be used to evaluate a miner's respiratory or pulmonary condition. See *id.* (allowing for admission of "any medically

acceptable test or procedure reported by a physician and not addressed in this subpart, which tends to demonstrate the presence or absence of pneumoconiosis, the sequelae of pneumoconiosis or a respiratory or pulmonary impairment"). Adopting a finite list in § 725.413 could inadvertently exclude otherwise important data, especially as testing methods evolve in the future.

Two commenters ask the Department to clarify whether the form in which the party receives the medical information (*i.e.*, written, electronic, or orally) affects the duty under § 725.413 to exchange that information. As proposed, § 725.413(a)(1) and (2) require the parties to exchange physicians' "written or testimonial assessment of the miner." The remainder of the rule is silent regarding the form of the communication. The Department agrees that the rule should be clarified on this point and has revised paragraph (a) in the final rule. With this change, the Department intends to make all written medical information, whether received in electronic (*e.g.*, e-mail, facsimile, Web portal or other electronic media) or hard-copy format, subject to § 725.413's requirements. This would also include testimonial medical information resulting from depositions (*e.g.*, transcripts of depositions). But the rule is not intended to cover oral communications. The Department has no mechanism to monitor oral communications, and compliance with such a rule would be impossible to enforce.

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

There would be no payments or gifts made to respondents.

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

Claimants who file an application for BLBA benefits are provided a Privacy Act notice that explains how the Department will use the information (*i.e.*, to adjudicate claims) and with whom the information may be shared (*i.e.*, potentially liable coal mine operators and insurance carriers; individuals or entities adjudicating the claim; medical providers for use in treatment or claims evaluations; and governmental entities for law enforcement or proper payment purposes). These records are governed by Systems of Records Notices DOL/ESA-6 (Office of Workers' Compensation, Black Lung Benefits Claim File) and

DOL/ESA-30 (Office of Workers' Compensation Programs, Black Lung Automated Support Package). See 67 FR 16816.

**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.**

Providing medical information may be considered sensitive; however, the exchange is necessary in the context of ensuring all parties have the necessary information to protect their interests.

**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. Provide estimates of the hour burden of the collection of information.**

As noted above (see response to no. 5), the Department does not believe this information collection will have a large impact on the parties to black lung benefits claims. But because this information collection has not been conducted in the past, the Department has chosen to develop upper-bound burden estimates. These estimates likely overstate the actual burdens that would be imposed with the Final Rule.

The Department based this upper-bound estimate on the following factors: (1) the number of black lung cases adjudicated by OWCP and the Office of Administrative Law Judges in Fiscal Year 2015, which totaled 6,472 claims; and (2) the assumption that in each

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claim, one party had to disclose three pages of medical information to two other parties (i.e. the claimant, the coal mine operator/insurance carrier, or the Director, OWCP). The Department chose the three-page measure because many supplemental medical opinions or interpretations of test results (such as an X-ray reading) fall within this limit. The hour burden estimate of this information collection is approximately 1,079 hours. This burden is based on 6,472 claims, where each claim requires the respondent to photocopy and mail 3-pages of medical evidence to two other parties. Respondent will spend an estimate of 10 minutes to identify the medical evidence, photocopy the documents, address envelopes, affix postage, and mail the documents to two other parties.

$6,472 \text{ responses} \times 10 \text{ minutes} = 64,720 \text{ minutes}$  or 1,079 (1,078.67 rounded up to 1,079) hours.

The estimated annualized value of the burden hours to respondents to take this action is \$23,263 (1,079 hours  $\times$  \$21.56 per hour). This hourly wage is the median identified in the Occupational Earnings Tables: United States, May 2014, <http://www.bls.gov/oes/current/oes436012.htm>, published by the Bureau of Labor Statistics, under the heading of Occupational Employment and Wages, Legal Secretaries.

$1,079 \text{ hours} \times \$21.56 \text{ per hour} = \$23,263.24$

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

This information collection would not require the use of systems or technology for exchanging data beyond those respondents already use in customary business practice. Thus, operational costs are limited to photocopying and mailing. The estimated annual operational cost to respondents is approximately \$10,614.08, which is based on 6,472 claims, where each claim requires the respondent to photocopy and mail 3-pages of medical evidence.

The cost to respondents to photocopy the medical documents is estimated at \$3,883.20, which is based on 3 documents photocopied for two parties of the claim.

$6 \text{ pages} \times \$0.10 \text{ a page} = \$0.60$

$\$0.60 \times 6,472 = \$3,883.20$

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The cost to respondents to mail the medical documents is estimated at \$1.04 per mailing (49¢ stamp plus 3¢ for the envelope) to two parties of the claim, for a total respondent cost of \$6,730.88 (\$1.04 x 6,472).

$$6,472 \times \$1.04 = \$6,730.88$$

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

There are no annualized costs to the Federal government. The Department usually submits any medical information it develops about a miner as evidence in the claim record. Thus, the Department generally has no additional medical information that it would be required to exchange under the Final Rule.

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

This is a new information collection.

**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 as a result of this information collection.

**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.**

The Department associates no forms with this information collection.

**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.