(b) Affected ADs

This AD replaces AD 2009–17–01, Amendment 39 15991 (74 FR 40061, August 11, 2009) (''AD 2009–17–01'').

(c) Applicability

This AD applies to the Gulfstream Aerospace Corporation airplanes, certificated in any category, identified in paragraphs (c)(1) through (c)(5) of this AD.

(1) Model G–IV airplanes, having serial numbers (S/Ns) 1000 and subsequent.

(2) Model GIV–X airplanes, having S/Ns 4001 and subsequent.

(3) Model GV airplanes, having S/Ns 501 and subsequent.

(4) Model GV–SP airplanes, having S/Ns 5001 and subsequent.

(5) Model GVI airplanes, having S/Ns 6001 and subsequent.

(d) Subject

Air Transport Association (ATA) of America Code 49, Airborne Auxiliary Power; and 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by a report indicating that the type design sealant is flammable and failed a certification test and a company test. We are issuing this AD to provide the flight crew with operating procedures for airplanes that have flammable sealant compound applied to the auxiliary power unit (APU) enclosure (firewall). Under certain anomalous conditions such as an APU failure/APU compartment fire, flammable sealant could ignite the exterior surfaces of the APU enclosure and result in propagation of an uncontained fire to other critical areas of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Airplane Flight Manual (AFM) Revision

Within 30 days after the effective date of this AD, revise the Limitations Section of the applicable Gulfstream AFM specified in paragraphs (h)(1) through (h)(6) of this AD to include the information in the applicable Gulfstream AFM supplement (AFMS) specified in paragraphs (h)(1) through (h)(6) of this AD. These AFM supplements (AFMSs) introduce operating limitations on the use of the APU during certain ground and flight operations.

Note 1 to paragraph (g) of this AD: This AFM revision may be done by inserting a copy of the applicable AFMS into the applicable AFM specified in paragraphs (h)(1) through (h)(6) of this AD. When the AFMS has been included in the general revision of the AFM, the general revision may be inserted into the AFM, provided the relevant information in the general revision is identical to that in the applicable AFMS specified in paragraphs (h)(1) through (h)(6) of this AD.

(h) AFMSs

For the AFM revision required by paragraph (g) of this AD, insert the applicable AFMS into the applicable Gulfstream AFM identified in paragraphs (h)(1) through (h)(6) of this AD.

(1) Gulfstream GIV/G300/G400 AFM Supplement GIV–2016–01, dated July 27, 2016, to the GIV AFM, dated April 22, 1987; the G300 AFM, dated January 15, 2003; and the G400 AFM, dated November 18, 2002.

(2) Gulfstream G450/G350 AFM Supplement G450–2016–01, dated July 27, 2016, to the G450 AFM, dated August 12, 2004; and the G350 AFM, dated October 28, 2004.

(3) Gulfstream GV AFM Supplement GV–2016–01, dated July 27, 2016, to the GV AFM, dated April 11, 1997.

(4) Gulfstream G550/G500 AFM Supplement G550–2016–01, dated July 27, 2016, to the G550 AFM, dated August 14, 2003; and the G500 AFM, dated December 5, 2003.

(5) Gulfstream GVI (G650) AFM Supplement G650–2016–01, dated July 27, 2016, to the GVI (G650) AFM dated, September 7, 2012.

(6) Gulfstream GVI (G650ER) AFM Supplement G650ER–2016–03, dated July 27, 2016, to the GVI (G650ER) AFM, dated October 2, 2014.

(i) Credit for Previous Actions

This paragraph provides credit for the action required by paragraph (g) of this AD, if that action was performed before the effective date of this AD using the applicable service information specified in paragraphs (i)(1) through (i)(4) of this AD. This service information was incorporated by reference in AD 2009–17–01.

(1) Gulfstream G–IV/G300/G400 AFM Supplement G–IV–2009–02, Revision 1, dated June 25, 2009.

(2) Gulfstream G450/G350 AFM Supplement G450–2009–03, Revision 1, dated June 25, 2009.

(3) Gulfstream GV AFM Supplement GV–2009–03, Revision 1, dated June 25, 2009.

(4) Gulfstream G550/G500 AFM Supplement G550–2009–03, Revision 1, dated June 25, 2009.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (k)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) AMOCs approved previously for paragraph (h) of AD 2009–17–01 are approved as AMOCs for the corresponding provisions of paragraph (g) of this AD.

(k) Related Information

(1) For more information about this AD, contact Ky Phan, Aerospace Engineer, Propulsion and Services Branch, ACE–118A, FAA, Atlanta ACO 1701 Columbia Avenue, College Park, GA 30337; phone: 404–474–5536; fax: 404–474–5606; email: *ky.phan@faa.gov.*

(2) For service information identified in this AD, contact Gulfstream Aerospace Corporation, Technical Publications Dept., P.O. Box 2206, Savannah, GA 31402–2206; telephone 800–810–4853; fax 912–965–3520; email *pubs@gulfstream.com;* Internet *http://www.gulfstream.com/product_support/technical_pubs/pubs/index.htm.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on December 16, 2016.

Ross Landes,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–31362 Filed 1–3–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

20 CFR Part 725

RIN 1240–AA11

Black Lung Benefits Act: Medical Benefit Payments

AGENCY: Office of Workers' Compensation Programs, Labor.

ACTION: Notice of proposed rulemaking; request for comments.

SUMMARY: The Department is proposing revisions to regulations under the Black Lung Benefits Act (BLBA or Act) governing the payment of medical benefits. The Department is basing these rules on payment formulas that the Centers for Medicare & Medicaid Services (CMS) uses to determine payments under the Medicare program. The Department also intends to make the rules similar to those utilized in the other programs that the Office of Workers' Compensation Programs (OWCP) administers. These rules will determine the amounts payable for covered medical services and treatments provided to entitled miners, when those services or treatments are paid by the Black Lung Disability Trust Fund. In addition, the proposed rule would eliminate two obsolete provisions.

DATES: The Department invites written comments on the proposed regulations from interested parties. Written comments must be received by March 6, 2017.

ADDRESSES: You may submit written comments, identified by RIN number

1240–AA11, by any of the following methods. To facilitate receipt and processing of comments, OWCP encourages interested parties to submit their comments electronically.

• *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions on the Web site for submitting comments.

• *Facsimile:* (202) 693–1395 (this is not a toll-free number). Only comments of ten or fewer pages, including a FAX cover sheet and attachments, if any, will be accepted by FAX.

• *Regular Mail or Hand Delivery/Courier:* Submit comments on paper to the Division of Coal Mine Workers' Compensation, Office of Workers' Compensation Programs, U.S. Department of Labor, Suite C–3520, 200 Constitution Avenue NW., Washington, DC 20210. The Department's receipt of U.S. mail may be significantly delayed due to security procedures. You must take this into consideration when preparing to meet the deadline for submitting comments.

Instructions: All submissions received must include the agency name and the Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Michael Chance, Director, Division of Coal Mine Workers' Compensation, Office of Workers' Compensation Programs, U.S. Department of Labor, Suite C–3520, 200 Constitution Avenue NW., Washington, DC 20210. Telephone: 1–800–347–2502. This is a toll-free number. TTY/TDD callers may dial toll-free 1–877–889–5627 for further information.

SUPPLEMENTARY INFORMATION:

I. Background of This Rulemaking

The BLBA, 30 U.S.C. 901–944, provides for the payment of benefits to coal miners and certain of their dependent survivors on account of total disability or death due to coal workers' pneumoconiosis. 30 U.S.C. 901(a); *Usery* v. *Turner Elkhorn Min. Co.,* 428 U.S. 1, 5 (1976). Benefits are paid by either an individual coal mine operator that employed the coal miner (or its insurance carrier), or the Black Lung Disability Trust Fund. *Director, OWCP* v. *Bivens,* 757 F.2d 781, 783 (6th Cir. 1985).

A miner who is entitled to disability benefits under the BLBA is also entitled to medical benefits. 33 U.S.C. 907, as incorporated by 30 U.S.C. 932(a); 20 CFR 725.701. The current rules governing the payment of medical benefits are contained in 20 CFR part 725, subpart J. Under these rules, a miner is entitled to ''such medical, surgical, and other attendance and treatment, nursing and hospital services, medicine and apparatus, and any other medical service or supply, for such periods as the nature of miner's pneumoconiosis and disability requires.'' 20 CFR 725.701(b).

In most cases, a responsible operator is liable for the payment of medical benefits. But OWCP pays medical benefits from the Trust Fund in three instances: (1) If no responsible operator can be identified as the party liable for a claim, and the Trust Fund is liable as a result (*id.*); (2) when the identified responsible operator declines to pay benefits pending final adjudication of a claim (*see* 20 CFR 725.522, 725.708(b)); and (3) when the responsible operator fails to meet its payment obligations on a final award (*see* 20 CFR 725.502). For interim payments made pending final adjudication, OWCP seeks reimbursement from the operator after the claim is finally awarded. 20 CFR 725.602(a). Likewise, OWCP seeks reimbursement for payments made when an operator fails to meet its obligations on a final award. 20 CFR 725.601.

Current § 725.706(c) provides that payment for medical benefits ''shall be made at no more than the rate prevailing in the community in which the providing physician, medical facility or supplier is located.'' 20 CFR 725.706(c). The current regulations, however, do not address how the prevailing community rate for a particular medical service or treatment is determined. For medical benefits paid by the Trust Fund, the Division of Coal Mine Workers' Compensation (DCMWC) currently bases payment for professional medical services, medical equipment, and inpatient and outpatient medical services and treatments, on internally-derived payment formulas. DCMWC currently pays for prescription medications utilizing a payment formula similar to that employed by the three other workers' compensation programs that OWCP administers.

The Department now proposes to revise Subpart J. Specifically, the Department proposes to base Trust Fund payments for all medical services and treatments rendered on or after the effective date of this rule on payment formulas derived from those used by CMS under the Medicare program. The proposed payment formulas are similar to those used by the other OWCP programs, but are tailored to the specific geography, medical conditions, and needs of black lung program stakeholders. *See* proposed § 725.707. The proposal also gives OWCP the flexibility to depart from the payment formulas if they cannot be used to determine the prevailing community rate, and requires OWCP to review (and, if necessary, update, revise or replace) the payment formulas at least annually. *See* proposed § 725.707(e). This flexibility will allow OWCP to timely address any issues that may result from the implementation and application of the payment formulas, including any impact on miners' access to health care.

The Department believes that the proposed payment formulas more accurately reflect prevailing community rates for authorized treatments and services than do the internally-derived formulas that OWCP currently uses for the black lung program. Moreover, because the Department believes that responsible operators and their insurance carriers utilize payment formulas or fee schedules that are substantially similar to the proposed payment formulas, the Trust Fund is more likely to be fully reimbursed for the payments it makes on an interim basis. Thus, this change will serve to control the health care costs associated with the BLBA, conserve the Trust Fund's limited resources, and provide greater clarity and certainty with respect both to fees paid to providers and reimbursements sought from operators and carriers. Likewise, it will ensure more consistent payment policies across all of the compensation programs administered by OWCP. The Department invites comments on the proposed rule from all interested parties. The Department is particularly interested in comments addressing the impact of the proposed payment formulas on health care services providers and any resulting impact on miners' access to health care.

II. Summary of the Proposed Rule

A. General Provisions

The Department is proposing several general revisions to advance the goals set forth in Executive Order 13563 (2012). That Order states that regulations must be ''accessible, consistent, written in plain language, and easy to understand.'' 76 FR 3821. *See also* E.O. 12866, 58 FR 51735 (Sept. 30, 1993) (agencies must draft ''regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such

uncertainty''). Accordingly, the Department proposes numerous technical and stylistic changes to Subpart J to improve clarity, consistency, and readability.

The Department proposes to remove the imprecise term ''shall'' throughout the sections that it is amending or republishing, and to substitute ''must,'' ''must not,'' ''will,'' or other situation-appropriate terms. No alteration in meaning either results from or is intended by these changes, which are made in the following proposed regulations: § 725.701, § 725.703, § 725.704, § 725.705, § 725.706, § 725.718, and § 725.720.

Consistent with the goal of making this regulation easier to understand, the Department proposes several additional technical changes. First, the Department proposes to replace references to ''the Office'' with ''OWCP'' because that acronym is more commonly used by stakeholders. As explained in current § 725.101(a)(21), ''Office'' and ''OWCP'' both mean ''the Office of Workers' Compensation Programs, United States Department of Labor.'' Thus, no alteration in meaning either results from or is intended by this change, which is made in the following regulations: § 725.703, § 725.704, § 725.705, and § 725.706.

Second, where appropriate, the Department proposes to replace references to a coal-mine ''operator'' with ''operator or carrier'' because § 725.360(a)(4) makes any coal-mine operator's insurance carrier a party to the operator's claims. Because either an operator or a carrier may defend or pay claims for medical benefits, no alteration in meaning either results from or is intended by this change, which is made in the following regulations: § 725.704, § 725.706, and § 725.718. Additionally, the Department proposes to replace a reference to ''insurer'' with the word ''carrier'' because, under § 725.101(a)(18), both mean an entity ''authorized under the laws of a State to insure employers' liability under workers' compensation laws.'' Thus, no alteration in meaning either results from or is intended by this change, which appears in § 725.704.

Third, where appropriate, for purposes of consistency with the rest of the Subpart, the Department proposes to substitute the broader term ''provider'' for the term ''physician'' and/or ''facility'' as well as to substitute the term ''medical equipment'' for the term ''apparatus.'' No alteration in meaning either results from or is intended by these changes, which are made in the following regulations: § 725.701, § 725.704, § 725.705, and § 725.706.

Finally, to make the regulations clearer and more user-friendly, the Department proposes new titles, phrased in question form, for all of the regulations appearing in Subpart J.

Executive Order 13563 also instructs agencies to review ''rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them.'' The Department proposes to cease publication of two obsolete rules (20 CFR 725.308(b) and 725.702). Because of the deletion of current § 725.702 and the addition of new rules adopting the payment formulas noted above, other current regulations (20 CFR 725.703–725.708 and 725.710–725.711) will be renumbered.

All technical and stylistic changes designated here are not included in the section-by-section explanation. All proposed substantive revisions to existing rules and all proposed new rules are discussed below.

B. Section-by-Section Explanation

§ 725.308 Time Limits for Filing Claims

The Department proposes to discontinue publication of § 725.308(b) because it is obsolete. Current § 725.308(b) establishes a time limit applicable to miners' claims for medical benefits filed under Section 11 of the Black Lung Benefits Reform Act, 30 U.S.C. 924a, *repealed,* Public Law 107–275, 2(c)(2), 116 Stat. 1926 (2002). For the reasons explained in the discussion under 20 CFR subpart J below, continued publication of regulations related to Section 11 is unnecessary. To implement this change, the Department also proposes conforming technical amendments to current § 725.308(c), including renumbering current paragraph (c) as paragraph (b).

Subpart J—Medical Benefits and Vocational Rehabilitation

The Department proposes multiple revisions and additions to the provisions governing medical benefits in Subpart J. Because the proposed changes are substantial, the Department has republished Subpart J in its entirety below.

In the existing regulations and in compliance with Executive Order 13563, the Department proposes to discontinue publication of § 725.702 because it is obsolete. 20 CFR 725.702. Section 725.702 implements Section 11 of the Black Lung Benefits Reform Act passed in 1977. 30 U.S.C. 924a, *repealed,* Public Law 107–275, 2(c)(2), 116 Stat. 1926 (2002). Section 11 required the Secretary of Health, Education and Welfare to notify miners receiving benefits under Part B of the Act that they could file a claim for medical benefits under Part C of the Act. Current §§ 725.308 and 725.702 required miners to file these claims on or before December 31, 1980, unless the period was extended for good cause shown. Few, if any, Section 11 claims for medical benefits only remain in litigation. In fact, Congress repealed Section 11 as obsolete in 2002. Thus, continued publication of this regulation is unnecessary. If any Section 11 claim results in litigation after the effective date of these regulations, the claim will continue to be governed by the criteria in the 2015 edition of the Code of Federal Regulations. As a consequence of the deletion of current § 725.702, and the addition of new provisions regarding payments for medical services and treatments, other current regulations (20 CFR 725.703–725.708, 725.710–725.711) will be renumbered.

The Department also proposes a new set of regulations that adopt payment formulas and related procedures for determining the prevailing community rate for medical benefits paid by the Trust Fund. The subheadings and other regulatory references in this discussion generally refer to the location of the proposed rule if promulgated as a final rule.

Specifically, the Department proposes to replace current § 725.706(c) with proposed §§ 725.707–725.717, which adopt payment formulas and procedures to determine the rates at which various medical services and treatments will be paid by the Trust Fund, as well as the rates at which OWCP will seek reimbursement from operators for medical benefits paid on an interim basis. Similar payment formulas are used by the other three workers' compensation programs that OWCP administers. Such payment formulas were first developed and adopted for use in claims under the Federal Employees' Compensation Act, 5 U.S.C. 8101 *et seq.,* in 1986. *See* 51 FR 8276–82 (Mar. 10, 1986). Subsequently, similar formulas were adopted for claims under the Longshore Act in 1995 and for claims under the Energy Employees Occupational Illness Compensation Program Act, 42 U.S.C. 7384 *et seq.,* in 2001. *See* 60 FR 51347–48 (Oct. 2, 1995); 66 FR 28957–59, 79–80 (May 25, 2001).

The payment formulas the Department proposes to adopt for claims under the BLBA (and those it already utilizes under the other OWCP programs) are derived from the payment formulas that CMS uses to determine payments for medical services and

treatments under the Medicare program. The proposed formulas encompass locality-based payment rates for physician services and medical equipment (*see* proposed § 725.708), as well as for outpatient and inpatient medical services (*see* proposed §§ 725.710 and 725.711, respectively). The Department also proposes, consistent with existing practice and similar to the other OWCP programs, to adopt a single national formula for the payment of prescription-drug costs. *See* proposed § 725.709.

Finally, the Department proposes to adopt specific procedures for providers to enroll with OWCP for authorization to submit medical bills for payment, and for miners to request reimbursement for covered medical expenses and transportation costs. *See* proposed §§ 725.714–725.717. Most of these provisions simply implement current procedures and, to the extent any differences are proposed, the procedures are consistent with current industry standards. Specific provisions proposed for addition to the regulations in Subpart J are discussed in detail below.

§ 725.701 What medical benefits are available?

Proposed § 725.701 is a revision of current § 725.701. The Department proposes to combine current paragraphs (e) and (f), and add subdivisions to paragraph (e) for greater clarity and ease of comprehension. Likewise, the Department proposes to delete the confusing reference to ''other employer'' in paragraph (b). Proposed paragraph (b) also enumerates more clearly the medical services and treatments to which a miner is entitled. The terms ''service'' and ''treatment'' are used interchangeably throughout Subpart J to indicate those benefits for which the responsible operator or Trust Fund may be liable. The Department proposes to revise paragraphs (d) and (e)(3) for greater clarity and readability. For the same reason, in paragraph (e), the Department proposes replacing the word ''supply'' with ''treatment.'' Finally, the Department also proposes to replace the reference to ''district director'' in paragraph (d) with ''OWCP,'' as communication may be made with either the OWCP national or district offices.

§ 725.702 Who is considered a physician?

Proposed § 725.702 is substantively identical to current § 725.703. For consistency, however, osteopathic physicians (DO) are now identified in the same manner as other doctors of medicine (MD). The reference to ''district director'' in the final sentence is changed to ''OWCP,'' as the supervision of care may be provided by either the OWCP national office or district offices, depending upon factors such as the geographic location of the miner or provider, the particular services or treatments required by the miner, and the relative resource levels in the OWCP national and district offices.

§ 725.703 How is treatment authorized?

Proposed § 725.703 is a revision of current § 725.704 and contains only technical changes described in Section II–A above.

§ 725.704 How are arrangements for medical care made?

Proposed § 725.704 is a revision of current § 725.705. References to ''such operator'' have been changed to ''the operator,'' ''decisionmaking'' has been changed to ''decision-making,'' and ''such designation'' has been changed to ''this designation.'' The Department does not intend any substantive alteration to the current provision.

§ 725.705 Is prior authorization for medical services required?

Proposed § 725.705 is a revision of paragraphs (a) and (b) of current § 725.706. The Department proposes to replace the reference to ''Chief, Branch of Medical Analysis and Services, DCMWC'' with ''Chief, Medical Audit and Operations Section, DCMWC'' to reflect the correct title of the employee authorized to approve requests for hospitalization or surgery by telephone. Paragraph (c) of current § 725.706 is deleted and replaced by proposed §§ 725.707–725.711 (*see* below).

§ 725.706 What reports must a medical provider give to OWCP?

Proposed § 725.706 is a revision of current § 725.707. The Department proposes to replace the reference to ''district director'' in paragraph (b) with ''OWCP,'' as payment determinations may be made by either the OWCP national or district offices.

§ 725.707 At what rate will fees for medical services and treatments be paid?

Proposed § 725.707 is a new provision that sets out general rules governing the payment of compensable medical bills by the Trust Fund. Paragraph (a) provides that the Trust Fund will pay no more than the prevailing community rate for medical services, treatments, drugs or equipment. Paragraph (b) provides that the prevailing community rate for various types of treatments and services will be determined under the provisions of §§ 725.708–725.711. Paragraph (c), however, precludes the application of §§ 725.708–725.711 to charges for services or treatments furnished by the U.S. Public Health Services or the Departments of the Army, Navy, Air Force or Veterans Affairs. Payment for services or treatments furnished by these providers is made under the provisions of proposed § 725.707(d). Because the Department recognizes that there may be circumstances where the provisions of §§ 725.708–725.711 cannot be used to determine the prevailing community rate, paragraph (d) permits OWCP to determine the prevailing community rate based on other payment formulas or evidence. Paragraph (e) requires OWCP to review the payment formulas in §§ 725.708–725.711 annually, and permits OWCP to adjust, revise or replace any formula (or its components) when needed. This provision allows OWCP to change the payment formulas in §§ 725.707–725.711 (or replace them entirely) if, at any given time, OWCP finds that those formulas cannot be used to determine prevailing community rates, are adversely impacting miners' access to care, or are otherwise not appropriate. Finally, paragraph (f) makes §§ 725.707–725.711 applicable to all services and treatments provided on or after the rule's effective date.

§ 725.708 How are payments for professional medical services and medical equipment determined?

Proposed § 725.708 is a new provision to govern payments for compensable professional medical services and medical equipment. Paragraph (a) provides that OWCP will pay for professional medical services based on a fee schedule derived from the CMS Medicare program fee schedule. OWCP's fee schedule will be used to determine the prevailing rate paid for a given medical service in the community in which the provider is located. To calculate the maximum allowable payment, each professional service is identified by a Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) code,[1] which is assigned a relative value for work, practice expense, and malpractice expense. OWCP proposes to utilize relative values established by CMS for the Medicare program. Where CMS does not have a relative value for

[1] CPT codes are established and updated by the American Medical Association. HCPCS codes were developed by CMS to complement the CPT. The use of these codes is standard practice in the coding and processing of medical bills.

a service, OWCP may develop and assign one. The relative value is multiplied by a relevant geographic adjustment factor as defined by CMS. The resulting value is then multiplied by a monetary conversion factor (which is defined by OWCP) to determine the prevailing community rate for each coded service. Some professional services are not covered by the fee schedule described in paragraph (a). Thus, paragraph (b) provides that payment for services not covered by the paragraph (a) fee schedule is derived from other fee schedules or pricing formulas utilized by OWCP for professional services. Finally, paragraph (c) provides that payment for medical equipment identified by a HCPCS/CPT code is based on fee schedules or pricing formulas utilized by OWCP for medical equipment.

§ 725.709 How are payments for prescription drugs determined?

Proposed § 725.709 is a new provision to govern payment for compensable prescription drugs. It merely codifies existing policy and does not change current payment practice. Paragraph (a) provides for payment for prescribed medication at a percentage of the national average wholesale price (or another baseline price designated by OWCP). In addition, the provider of the drug will receive a flat-rate dispensing fee, to be set by OWCP. Paragraph (b) provides that where the pricing formula in paragraph (a) cannot be used, OWCP may make payment based on other pricing formulas. Lastly, paragraph (c) provides that OWCP may require the use of specific providers for certain medications and may require the use of generic versions of medications where available.

§ 725.710 How are payments for outpatient medical services determined?

Proposed § 725.710 is a new provision to govern payment for compensable outpatient medical services. Paragraph (a) provides that, where appropriate, OWCP will utilize the Outpatient Prospective Payment System (OPPS) devised by CMS for the Medicare program. Under OPPS, outpatient services are generally assigned to Ambulatory Payment Classifications based on their clinical and resource cost similarities. Payment rates are based on those classifications, adjusted by other factors, including the hospital wage index for the locality where the service is provided. The OPPS was first implemented by CMS in 2000, and the industry is familiar with this payment system for hospital outpatient services. Where outpatient services cannot be assigned or priced appropriately under the OPPS system, paragraph (b) provides that payment for the services will be based on fee schedules and other pricing formulas utilized by OWCP. Finally, paragraph (c) specifies that services provided at an ambulatory surgery center are not paid for under OPPS. Rather, such services are paid under § 725.707(d).

§ 725.711 How are payments for inpatient medical services determined?

Proposed § 725.711 is a new provision to govern payment for compensable hospital inpatient services. Under paragraph (a), OWCP will pay for inpatient services utilizing a Diagnosis-Related Group (DRG) system derived from the Medicare Severity DRG (MS–DRG) methodology used by Medicare in the Inpatient Prospective Payment System (IPPS). DRG-based pricing is the industry standard for determining the payment rates for inpatient hospital treatment and services. In addition to Medicare, it is used by the Department of Veterans' Affairs, and TRICARE (formerly known as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)), as well as by numerous state workers' compensation programs and private insurance plans. Paragraph (a) specifies that hospital discharge diagnoses are classified into groups (DRGs) based on the patient's diagnosis and the procedures furnished. Each DRG is assigned a base payment rate, which is then adjusted for both geographic and provider-specific factors to determine the payment rate for each admission. Under paragraph (b), where a compensable inpatient service cannot be paid under the DRG system, payment for the service will be based on fee schedules or other pricing formulas utilized by OWCP.

§ 725.712 When and how are fees reduced?

Proposed § 725.712(a) is a new provision addressing reductions in requested fees. The Department proposes that, where a provider submits a properly coded bill, OWCP will pay no more than the maximum amount allowable under §§ 725.707–725.711. Where a bill is improperly coded, OWCP will either return it to the provider for correction, or deny it outright. Under proposed paragraph (b), if a bill exceeds the maximum amount allowed under the regulations, OWCP will pay only the allowed amount and advise the provider of any reduction in the requested fee. Finally, consistent with current practice, proposed paragraph (c) provides that disputes over fee payments may be referred to the Department's Office of Administrative Law Judges. *See* 20 CFR 725.708, to be re-codified at 20 CFR 725.718.

§ 725.713 If a fee is reduced, may a provider bill the claimant for the balance?

Proposed § 725.713 is a new provision addressing reductions in requested fees. It codifies current OWCP policy. The proposed provision provides that if a fee has been reduced in accordance with this subpart, providers may not recover any additional amount from the miner. This provision thus would prohibit the practice of ''balance billing,'' which occurs when providers receive only a portion of their submitted charges from third-party payers and seek to recover the ''balance'' from the patient.

§ 725.714 How do providers enroll with OWCP for authorizations and billing?

Proposed § 725.714 is a new provision, but it simply codifies OWCP's existing practice of requiring all non-pharmacy providers seeking payments from the Trust Fund to enroll in the OWCP bill payment processing system. Paragraph (a) requires non-pharmacy providers to enroll in the system and paragraph (b) specifies the manner of enrollment. Paragraph (c) requires non-pharmacy providers to maintain proof of their eligibility for enrollment in the system. Paragraph (d) requires non-pharmacy providers to notify OWCP of any change in the provider's enrollment information. Paragraph (e) explains that pharmacy providers are required to obtain a National Council for Prescription Drug Programs number, and that upon obtaining such number, they will be automatically enrolled in OWCP's pharmacy billing system. Finally, paragraph (f) requires providers to submit bills via a specified bill-processing portal or to the requisite OWCP mailing address and to include any identifying numbers OWCP may require.

§ 725.715 How do providers submit medical bills?

Proposed § 725.715 is a new provision that prescribes the forms and documents providers must submit to be paid for rendering covered medical services or treatments to miners. Paragraph (a) lists the forms that a provider must submit for each type of service or treatment. Paragraph (b) sets out the coding or other information that must be included on the forms for each type of service or treatment. Finally, under paragraph (c), a provider, by submitting a bill or accepting payment, signifies that the

service or treatment was necessary and appropriate and was billed in accordance with standard industry practices. In addition, paragraph (c) requires providers to comply with the regulations in Subpart J with respect to the provision of, and billing for, services and treatments.

§ 725.716 How should a miner prepare and submit requests for reimbursement for covered medical expenses and transportation costs?

In some instances, a miner will pay for covered medical services out of his or her own pocket. Proposed § 725.716 is a new provision that reflects existing procedures allowing the miner to be reimbursed for these payments. Proposed paragraph (a) requires the miner to submit the appropriate form along with an itemized bill and proof of payment for the services. Proposed paragraph (b) allows OWCP to waive these requirements if the delay between the time of the service and approval of the miner's claim makes it difficult to obtain this information. Proposed paragraph (c) provides for reimbursement at the rate allowed under proposed §§ 725.707–725.711. If that reimbursement is less than the full amount the miner paid, proposed paragraph (d) places responsibility on the miner to seek a refund or a credit from the provider. But if those efforts fail, proposed paragraph (e) protects the miner by allowing OWCP to make a reasonable reimbursement based on the facts and circumstances in the particular case. Finally, proposed paragraph (f) specifies the form and documentation that a miner must submit to be reimbursed for travel costs and other incidental expenses related to obtaining covered medical services.

§ 725.717 What are the time limitations for requesting payment or reimbursement for medical services and treatments?

Proposed § 725.717 would impose a new time limitation on requests for payment or reimbursement for medical services and treatments. The proposed provision would require providers to request payment no later than one year after the end of the calendar year during which either the service or treatment was rendered or in which the miner received a final award of benefits, whichever is later. Miners seeking reimbursement for covered medical services are also governed by this provision. Time limitations on requests for payment will encourage providers and miners to act promptly and will help prevent delays in the submission of bills and reimbursement requests to the Trust Fund. OWCP may waive the time limitation if the provider or miner demonstrates good cause for the late submission of a payment or reimbursement request.

§ 725.718 How are disputes concerning medical benefits resolved?

Proposed § 725.718 is a revision of current § 725.708. The Department proposes to revise paragraph (a) to clarify that the dispute-resolution procedures apply to disputes over the payment or cost of a particular medical service or treatment as well as to the miner's entitlement to such service or treatment. The current regulation requires that hearing requests on whether a miner is entitled to a service or treatment must be given priority over other hearing requests. The proposed provision does not change this requirement, but adds language to paragraph (b) clarifying that disputes over only the payment or cost of a service or treatment are not prioritized over other hearing requests. In paragraph (a) and (b), the Department also proposes to change the references to ''the district director'' to ''OWCP,'' as informal resolution efforts and referrals for hearing may be made by either the OWCP national or district offices. In addition, the Department proposes to replace the reference to ''the Director'' in the last sentence of paragraph (b) with ''OWCP,'' and to edit the introductory clause in the first sentence of paragraph (b) for clarity and consistency. Finally, the Department proposes to replace the phrase ''over medical benefits'' in paragraph (d) with ''under this subpart,'' for clarity and to avoid redundancy.

§ 725.719 What is the objective of vocational rehabilitation?

Proposed § 725.719 is a revision of current § 725.710. For conciseness and clarity, the Department proposes to replace the phrase ''for work in or around a coal mine and who is unable to utilize those skills which were employed in the miner's coal mine employment'' in the first sentence with ''by pneumoconiosis.'' *See* 20 CFR 718.204(b)(1)(ii) (defining total disability as inability to ''engag[e] in gainful employment in the immediate area of his or her residence requiring the skills or abilities comparable to those of any employment in a mine or mines in which he or she previously engaged with some regularity over a substantial period of time''). No change in the meaning of the current provision is intended.

§ 725.720 How does a miner request vocational rehabilitation assistance?

Proposed § 725.720 is a revision of current § 725.711 and contains only technical changes described in Section II–A above.

III. Statutory Authority

Section 426(a) of the BLBA, 30 U.S.C. 936(a), authorizes the Secretary of Labor to prescribe rules and regulations necessary for the administration and enforcement of the Act.

IV. Information Collection Requirements (Subject to the Paperwork Reduction Act) Imposed Under the Proposed Rule

The Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* and its implementing regulations, 5 CFR part 1320, require that the Department consider the impact of paperwork and other information collection burdens imposed on the public. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the Office of Management and Budget (OMB) under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person may generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Although the proposed medical benefit payment rules in Subpart J contain collections of information within the meaning of the PRA (*see* proposed §§ 725.715–725.716), these collections are not new. They are currently approved for use in the black lung program and other OWCP-administered compensation programs by OMB under Control Numbers 1240–0007 (OWCP–915 Claim for Medical Reimbursement); 1240–0019 (OWCP–04 Uniform Billing Form); 1240–0021 (OWCP–1168 Provider Enrollment Form); 1240–0037 (OWCP–957 Medical Travel Refund Request); 1240–0044 (OWCP–1500 Health Insurance Claim Form). The requirements for completion of the forms and the information collected on the forms will not change if this rule is adopted in final. Since no changes are being made to the collections, the overall burdens imposed by the information collections will not change.

While the Department has determined that the rule does not affect the general terms of the information collections or their associated burdens, consistent

with requirements codified at 44 U.S.C. 3506(a)(1)(B), (c)(2)(B) and 3507(a)(1)(D); 5 CFR 1320.11, the Department has submitted a series of Information Collection Requests to OMB for approval under the Paperwork Reduction Act of 1995 (PRA) in order to update the information collection approvals to reflect this rulemaking and provide interested parties a specific opportunity to comment under the PRA. Allowing an opportunity for comment helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

In addition to having an opportunity to file comments with the Department, the PRA provides that an interested party may file comments on the information collection requirements in a proposed rule directly with OMB, at the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments to the Department by one of the methods set forth above. OMB will consider all written comments that the agency receives within 30 days of publication of this Notice of Proposed Rulemaking (NPRM) in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention at least one of the OMB control numbers cited in this preamble.

OMB and the Department are particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

The information collections in this rule may be summarized as follows. The number of responses and burden estimates listed are not specific to the black lung program; instead, the estimates are cumulative for all OWCP-administered compensation programs that collect this information.

1. *Title of Collection:* Claim for Medical Reimbursement Form.
OMB Control Number: 1240–0007.
Total Estimated Number of Responses: 31,824.
Total Estimated Annual Time Burden: 5,283 hours.
Total Estimated Annual Other Costs Burden: $54,737.

2. *Title of Collection:* Uniform Billing Form (OWCP–04).
OMB Control Number: 1240–0019.
Total Estimated Number of Responses: 190,970.
Total Estimated Annual Time Burden: 21,811 hours.
Total Estimated Annual Other Costs Burden: $0.

3. *Title of Collection:* Provider Enrollment Form.
OMB Control Number: 1240–0021.
Total Estimated Number of Responses: 37,257.
Total Estimated Annual Time Burden: 4,955 hours.
Total Estimated Annual Other Costs Burden: $18,629.

4. *Title of Collection:* Medical Travel Refund Request.
OMB Control Number: 1240–0NEW.
Total Estimated Number of Responses: 342,462.
Total Estimated Annual Time Burden: 56,849 hours.
Total Estimated Annual Other Costs Burden: $171,231.

5. *Title of Collection:* Health Insurance Claim Form.
OMB Control Number: 1240–0044.
Total Estimated Number of Responses: 2,646,438.
Total Estimated Annual Time Burden: 254,875 hours.
Total Estimated Annual Other Costs Burden: $0.

V. Executive Orders 12866 and 13563 (Regulatory Planning and Review)

Executive Orders 12866 and 13563 direct agencies to assess all the costs and benefits of the available alternatives to regulation and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, harmonizing rules, and promoting flexibility. It also instructs agencies to review ''rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them.''

The Department has considered the proposed rule with these principles in mind and has determined that the affected community will benefit from this regulation. The discussion below sets out the rule's anticipated economic impact and discusses non-economic factors favoring adoption of the proposal. The Office of Information and Regulatory Affairs of OMB has determined that the Department's rule represents a ''significant regulatory action'' under Section 3(f)(4) of Executive Order 12866 and has reviewed the rule.

A. Economic Considerations

The proposed rule could have an economic impact on parties to black lung claims and others, including health care services providers that furnish covered medical services to entitled miners. The rule is nevertheless necessary to define the prevailing community rate used to pay for particular medical services and treatments for the affected community. As explained in Section I of this preamble, miners found entitled to monthly disability benefits under the BLBA are also entitled to medical benefits, *i.e.,* those medical services and treatments as the miner's pneumoconiosis and resulting disability require. The Trust Fund pays for medical benefits both when the Trust Fund is primarily liable for a claim and on behalf of non-paying responsible operators. When the Trust Fund pays medical benefits on behalf of a non-paying operator, it later seeks reimbursement from the operator responsible for the miner's benefits.

As detailed in Section II.B. of this preamble, the proposed regulations would change the formulas OWCP currently utilizes to calculate the amount paid for non-hospital health care services, outpatient hospital services, and inpatient hospital services.[2] The Trust Fund currently pays for non-hospital and hospital services based on internally-derived payment formulas. The payment formulas in the proposed rule, however, are based on those utilized by CMS for

[2] Proposed § 725.709 is a codification of the current payment formula for prescription drugs. Since adoption of this proposed rule would not change current practices or policies, it would have no economic impact on providers. As a result, proposed § 725.709 is not included in this analysis.

the payment of services under the Medicare program, and are similar to the payment formulas utilized by OWCP in the other programs it administers. Thus, the proposed rule would more closely conform Trust Fund medical payments to industry-wide standards for medical bill payment and more accurately reflect prevailing community rates for authorized treatments and services.

This analysis provides the Department's estimate of the economic impact of the proposed rule, both on the economy as a whole and at the firm level. The Department invites comments on this analysis from all interested parties. The Department is particularly interested in comments addressing the Department's evaluation of the impact of the proposed rule on health care services providers and on miners' access to providers and services.

1. Data Considered

To determine the proposed rule's general economic impact, the Department calculated the amount that the Trust Fund actually paid to health care services providers for medical services performed in Fiscal Year (FY) 2014 (current practice), and the amount the Trust Fund would have paid for the same services using the proposed payment formulas. The Department then compared the amounts to measure potential impact. Overall, the proposed rule would have saved the Trust Fund $3,154,267 for services rendered in FY 2014.[3] Because payments are calculated differently depending upon the type of health care services provider being reimbursed, the analysis below consists of three sections: (1) Non-hospital health care services (primarily physician services, but also services of other health care professionals including providers of durable medical equipment and ambulance suppliers); (2) hospital outpatient services; and (3) hospital inpatient services. The providers included in the dataset are those that were actually paid for covered services in FY 2014, including 1,210 non-hospital providers, 184 hospitals providing outpatient services, and 156 hospitals providing inpatient services.

a. Non-Hospital Health Care Services

Under proposed § 725.708, the Department would pay for non-hospital health care services with fee schedules derived from those utilized by CMS for payment under the Medicare program. *See* 42 CFR part 414. The Department estimates that under the proposed payment formulas, non-hospital health care services providers would receive, in aggregate, slightly less in payments from the Trust Fund than under current practice. The Trust Fund paid $2,672,782 for the non-hospital health care services provided in FY 2014. *See* Table 1. The Department estimates that under proposed § 725.708, the Trust Fund would have paid $2,664,290 for non-hospital health care services, a total decrease of only $8,492 (0.3%), far less than a 1% reduction. *See* Table 1.

The Department estimates that non-hospital health care services providers in twelve states would experience a net aggregate reduction in payments from the Trust Fund, totaling $89,139. The largest decreases in dollar amount would occur in Kentucky ($39,338, a 4.5% decrease), Missouri ($17,056, a 40.9% decrease), and Virginia ($12,870, a 2.3% decrease). *See* Table 1. Nearly offsetting these reductions, however, providers in sixteen states would experience a net aggregate increase in payments from the Trust Fund, totaling $80,647. The largest increases by dollar amount would occur in Pennsylvania ($53,507, a 12.3% increase), Tennessee ($10,095, a 5.4% increase) and Illinois ($7,444, a 23.3% increase). *See* Table 1.

The aggregate payment decrease, $8,492, would represent a reduction in transfer payments from the Trust Fund to non-hospital health care services providers. This small aggregate reduction, however, represents the combination of reductions and increases spread over 1,210 non-hospital health care services providers.[4] The Department therefore believes that proposed § 725.708 will not significantly affect non-hospital providers, or create issues for miners seeking access to these health care services providers.

[3] The Trust Fund paid a total of $17,480,555 in FY 2014 for non-hospital health care services, outpatient hospital services, and inpatient hospital services. Of that total, it paid $2,672,782 for non-hospital services, $2,383,641 for outpatient hospital services, and $12,424,132 for inpatient hospital services. To provide context, in FY 2014, the Trust Fund also paid $152,397,971 in disability and survivor benefits under Part C of the BLBA.

[4] In Sections V and VI of this preamble, the Department uses the terms ''provider,'' ''entity,'' and ''firm'' interchangeably. The OWCP data used as part of the analyses in Sections V and VI is based on provider-level data as identified by provider number in its billing system. The U.S. Census Bureau and the U.S. Small Business Administration, by contrast, publish data (used to assess the impact of the proposed rule in Sections V and VI) on a firm-level basis. A firm may consist of multiple establishments or providers, and the Department is unable to identify firms in its data. The Department believes, however, that there is not a meaningful difference between ''providers'' and ''firms'' in this context because the great majority of non-hospital and hospital small firms that provide medical services to miners consist of single providers or establishments. As a result, the Department believes that the use of firm-level data instead of provider-level data does not materially impact its analysis and, if it has any effect, results in an overstatement of the proposed rule's economic impact.

Table 1: Comparison of Trust Fund Payments to Non-Hospital Health Care Services Providers for Services Performed 10/1/2013-9/30/2014 (Current Practice v. Estimated Payments Under the Proposed Rule).

State	Amount Billed By Providers[1]	Amount Paid Under Current Practice	Amount That Would Be Paid Under The Proposed Rule	Difference	Number of Providers
Alabama	$21,257	$13,740	$15,437	$1,697	22
Arkansas	$685	$482	$270	-$212	2
California	$96	$88	$37	-$51	1
Colorado	$15,484	$7,192	$7,604	$412	13
Florida	$18,123	$9,509	$11,037	$1,528	22
Georgia	$6,083	$3,292	$3,230	-$62	6
Illinois	$52,042	$31,961	$39,405	$7,444	41
Indiana	$209,099	$89,139	$78,556	-$10,582	43
Iowa	$1,176	$517	$710	$193	1
Kansas	$1,881	$605	$833	$228	2
Kentucky	$1,721,762	$871,962	$832,624	-$39,338	270
Maryland	$18,917	$10,535	$10,387	-$148	12
Michigan	$27,314	$11,636	$12,786	$1,151	19
Minnesota	$1,722	$910	$1,020	$110	1
Missouri	$80,132	$41,655	$24,599	-$17,056	11
Nevada	$1,669	$236	$352	$116	2
New Jersey	$4,906	$3,390	$4,136	$745	4
New Mexico	$1,572	$841	$1,037	$197	2
North Carolina	$27,476	$13,148	$12,703	-$445	12
Ohio	$41,692	$22,731	$24,968	$2,237	53
Pennsylvania	$782,783	$433,306	$486,813	$53,507	244
South Carolina	$3,964	$1,486	$728	-$757	3
Tennessee	$500,266	$188,604	$198,700	$10,095	118
Texas	$6,827	$3,107	$3,276	$168	2
Utah	$23,264	$9,761	$9,524	-$237	7
Virginia	$1,090,098	$550,299	$537,429	-$12,870	115
West Virginia	$622,121	$346,678	$339,297	-$7,381	178
Wyoming	$14,263	$5,973	$6,792	$819	4
Total	**$5,296,676**	**$2,672,782**	**$2,664,290**	**-$8,492**	**1,210**

Notes:
[1] These amounts reflect actual amounts billed, including bills presented for non-covered medical services.

b. Hospital Outpatient Services

Under proposed § 725.710, the Department would pay for outpatient services with an outpatient prospective payment system (OPPS) derived from the OPPS utilized by CMS for payment under the Medicare program. The Department estimates that under proposed § 725.710, there would be a reduction in payments from the Trust Fund to hospitals for outpatient services. Under current practice, the Trust Fund paid $2,383,641 for outpatient services rendered in FY 2014. The Department estimates that, under proposed § 725.710, the Trust Fund would have paid $664,098, a decrease of $1,719,543 (or 72%). *See* Table 2. The Department estimates that hospitals in twenty states would receive reduced payments. The largest decreases by dollar amount would occur in Kentucky ($902,425, a decrease of 74%), Virginia ($327,304, a decrease of 77%), West Virginia ($148,104, a decrease of 60%); and Pennsylvania ($85,169, a decrease of 71%). *See* Table 2. Colorado is the only state that would see an increase in payments.

The total estimated reduction in hospital outpatient payments is sizeable, but necessary to bring payments for black lung outpatient hospital care in line with industry standards. Under current practice, hospitals were paid, in aggregate, 431% of their costs for outpatient services performed in FY 2014, with payments to individual hospitals made at rates as

high as 1,559% of costs.[5] This divergence explains the need for a new payment formula.

While proposed § 725.710 would result in an aggregate decrease in the transfer payments from the Trust Fund to hospitals for outpatient services, hospitals would continue to be paid at rates they are currently accepting from other small third-party payers, including the other OWCP programs, and at rates above those paid by Medicare. In aggregate, hospitals would be paid approximately 120% of costs for outpatient services under the proposed rule.[6] The Department therefore believes that proposed § 725.710 will not affect miners' access to care. Moreover, providers being paid significantly above costs under the current practice are likely to be most impacted by proposed § 725.710. The Department, however, invites comments on these determinations. In particular, the Department seeks comments on whether any projected impact of the proposal on miners' access to outpatient services would be short-term or long-term.

Table 2: Comparison of Trust Fund Payments to Hospital Outpatient Services Providers for Services Performed 10/1/2013-9/30/2014 (Current Practice v. Estimated Payments Under the Proposed Rule).

State	Amount Billed By Providers[1]	Amount Paid Under Current Practice	Amount That Would Be Paid Under the Proposed Rule	Difference	Number of Providers
Alabama	$16,684	$6,368	$1,913	-$4,456	5
Colorado	$5,720	$1,239	$1,303	$65	3
Florida	$16,678	$9,609	$1,485	-$8,124	3
Georgia	$1,969	$1,002	$195	-$807	1
Illinois	$143,267	$109,908	$39,010	-$70,898	14
Indiana	$74,182	$62,530	$13,532	-$48,997	10
Kentucky	$1,663,284	$1,224,699	$322,274	-$902,425	35
Maryland	$2,027	$2,027	$1,044	-$982	1
Michigan	$1,515	$1,263	$601	-$663	1
Missouri	$6,096	$1,554	$434	-$1,120	2
New Jersey	$1,427	$354	$243	-$111	1
New Mexico	$1,209	$341	$311	-$30	1
North Carolina	$22,119	$7,272	$2,759	-$4,513	4
Ohio	$45,738	$41,173	$8,267	-$32,906	13
Oklahoma	$825	$460	$356	-$104	1
Pennsylvania	$192,582	$119,714	$34,545	-$85,169	27
Tennesee	$179,825	$125,028	$42,433	-$82,595	21
Utah	$632	$358	$93	-$265	2
Virginia	$524,313	$423,055	$95,751	-$327,304	11
West Virginia	$291,941	$245,465	$97,361	-$148,104	26
Wyoming	$344	$223	$188	-$35	2
Total	**$3,192,377**	**$2,383,641**	**$664,098**	**-$1,719,543**	**184**

Notes:
[1] These amounts reflect actual amounts billed, including bills presented for non-covered medical services.

c. Hospital Inpatient Services

Under proposed § 725.711, the Department would pay for hospital inpatient services under an inpatient prospective payment system (IPPS) derived from the IPPS utilized by CMS for payment under the Medicare program. The Department estimates that under proposed § 725.711, there would be a small reduction in payments from the Trust Fund to hospitals for inpatient services. Under current practice, the Trust Fund paid $12,424,132 for inpatient services rendered in FY 2014. *See* Table 3. The Department estimates that, under proposed § 725.711, the Trust Fund would have paid $10,997,900, a decrease of $1,426,232 (or 11.5%). *See* Table 3.

The Department estimates that hospitals in eight states would

[5] Total costs for hospital outpatient services performed in FY 2014 and paid for by the black lung program are estimated at $552,549 by multiplying actual billed reimbursable charges by hospital and state outpatient cost-to-charge ratios maintained by CMS in their most recent publically available Impact File.

[6] Total costs for hospital outpatient services performed in FY 2014 that would be paid for by the black lung program under the proposed rule are estimated at $552,549 by multiplying projected reimbursable charges by hospital and state outpatient cost-to-charge ratios maintained by CMS in their most recent publically available Impact File.

experience a net aggregate reduction of $2,301,580 in payments for inpatient services under proposed § 725.711. The largest decreases in dollar amount would occur in Kentucky ($1,291,411, a decrease of 26.2%), Virginia ($629,932, a decrease of 25.3%), and Florida ($205,315, a decrease of 71.9%). *See* Table 3. Hospitals in nine states would experience a net aggregate increase of $875,348 in payment for inpatient services under proposed § 725.711. The largest increases in dollar amount would occur in Alabama ($623,383, an increase of 152%), West Virginia ($86,455, an increase of 6.2%), and Pennsylvania ($79,664, an increase of 5.5%).

Several factors contribute to these projected changes in payments among the states. First, analysis reveals that although the average payment per covered inpatient stay would decrease under proposed § 725.711, the Trust Fund would also pay for almost twice as many inpatient stays as under the current system. This change is because the DRG methodology focuses on the primary purpose for a hospital stay, which would result in more hospital stays being classified as black-lung-related. By way of illustration, of the 996 inpatient stays that hospitals billed the black lung program for in FY 2014, the Trust Fund paid the full allowed amount for 427 stays and a portion of the full amount for an additional 199 stays. In contrast, under proposed § 725.711, the Trust Fund would pay for 825 inpatient stays, all paid at the full allowed amount.[7] Relatedly, because the cost of an individual inpatient stay may be quite high depending on the treatment provided, coverage of any given stay can greatly shift aggregate payments. For example, each lung transplant-related hospitalization occurring in FY 2014 for which the Trust Fund paid cost hundreds of thousands of dollars. Thus, covering or not covering even a single inpatient hospitalization can significantly increase or decrease aggregate Trust Fund payments. Finally, just as in the outpatient context, there is a wide disparity in pay-to-cost ratios among individual hospitals, with hospitals being paid up to 971% or more of costs under the current system.[8] The states with the largest payment decreases under proposed § 725.711 include hospitals that are currently being paid at rates significantly above cost. While proposed § 725.711 would result in an aggregate decrease in the transfer payments from the Trust Fund to hospitals for inpatient services, hospitals would continue to be paid at rates they are accepting from other small third-party payers, including the other OWCP programs, and at rates above those paid by Medicare. These rates would result in hospitals being paid, in aggregate, approximately 155% of costs for inpatient services.[9] The Department therefore believes that proposed § 725.711 will not significantly affect hospitals or affect miners' access to inpatient hospital care. The Department, however, invites comments on these determinations. In particular, the Department seeks comments on whether any projected impact of the proposal on miners' access to outpatient services would be short-term or long-term.

[7] The remaining 171 hospital stays billed to the Trust Fund were not covered stays (*i.e.,* they are not for the treatment of totally disabling pneumoconiosis) and therefore would not be paid for by the Trust Fund. In most circumstances, hospitals stays billed to, but not paid by, the Trust Fund are paid for by Medicare or another insurer.

[8] Total costs for hospital inpatient services performed in FY 2014 and paid for by the black lung program are estimated by multiplying actual billed reimbursable charges by hospital and state inpatient cost-to-charge ratios maintained by CMS in their most recent publically available Impact File.

[9] Total costs for hospital inpatient services performed in FY 2014 that would be paid for by the black lung program under the proposed rule are estimated at $7,095,760 by multiplying projected reimbursable charges by hospital and state inpatient cost-to-charge ratios maintained by CMS in their most recent publically available Impact File.

Table 3: Comparison of Trust Fund Payments to Hospital Inpatient Services Providers for Services Performed 10/1/2013-9/30/2014 (Current Practice v. Estimated Payments Under the Proposed Rule).

State	Amount Billed By Providers[1]	Amount Paid Under Current Practice	Amount That Would Be Paid Under the Proposed Rule	Difference	Number of Providers
Alabama	$3,545,778	$409,999	$1,033,382	$623,383	5
Colorado	$120,458	$4,238	$36,622	$32,384	3
Florida	$447,694	$285,364	$80,049	-$205,315	4
Illinois	$530,523	$141,665	$117,093	-$24,572	6
Indiana	$508,630	$189,608	$182,645	-$6,963	5
Iowa	$15,498	$1,118	$7,908	$6,790	1
Kentucky	$13,699,340	$4,924,531	$3,633,120	-$1,291,411	30
Missouri	$71,345	$65,811	$29,665	-$36,146	1
Michigan	$29,959	$2,804	$16,069	$13,264	2
Nevada	$3,870	$0	$1,443	$1,443	1
North Carolina	$302,626	$62,667	$73,675	$11,007	3
Ohio	$430,704	$152,408	$173,364	$20,956	8
Pennsylvania	$7,493,897	$1,440,520	$1,520,184	$79,664	30
Tennessee	$2,458,263	$851,512	$746,186	-$105,326	19
Utah	$21,462	$1,916	$0	-$1,916	1
Virginia	$5,033,404	$2,485,686	$1,855,754	-$629,932	11
West Virginia	$4,335,581	$1,404,286	$1,490,742	$86,455	26
Total	**$39,049,031**	**$12,424,132**	**$10,997,900**	**-$1,426,232**	**156**

Notes:
[1] These amounts reflect actual amounts billed, including bills presented for non-covered medical services.

2. Economic Impact Summary

The Department believes that the proposed rule will not have a significant impact on the economy as a whole, and will have only a de minimis impact on firms that provide black lung-related health care to entitled miners. The Department has used a $100 million dollar annual threshold for determining the proposed rule's significance. *See, e.g.,* E.O. 12866 (defining regulation that has annual effect on the economy of $100 million or more as ''significant''). As shown in Section V.A.1. of this preamble, the Department estimates the proposed rule would result in an aggregate annual reduction in payments from the Trust Fund of $3,154,297 ($8,492 in reduced payments to non-hospital providers, $1,719,543 in reduced payments for outpatient hospital services, and $1,426,232 in reduced payments for inpatient hospital services). Because this aggregate annual reduction in payments is far less than $100 million, the Department has determined that the proposed rule will not have a significant impact on the economy as a whole.

Likewise, the Department has determined that the proposed rule will have only a de minimis impact at the firm level. *See* Table 4. To determine the firm-level impact of the proposed rule, the Department first considered total industry revenues for both non-hospital health care services providers and hospitals. Non-hospital providers generated $827.9 billion in revenues, according to the U.S. Census Bureau's Statistics of U.S. Businesses (SUSB) most recent data for 2012.[10] Dividing annual revenues by the number of firms in the sector in the entire U.S. (485,235),[11] non-hospital providers generated average annual revenues of $1.7 million per firm. *See* Table 4. A total of 1,210 non-hospital providers rendered services to entitled miners in FY 2014. *See* Table 1. Based on an analysis of the Trust Fund payment data, the Department estimates that 420 firms (out of 1,210) would receive net reductions in payments from the Trust Fund under the proposed rule.[12] The

[10] *See https://www.census.gov//econ/susb/data/susb2012.html.* There is no exact proxy for the non-hospital health care services provider category. The Department has used North American Industry Classification System (NAICS) code 621(Ambulatory Health Care Services) as the proxy for such providers. This category is over inclusive because it includes types of providers not used by entitled miners. It is, however, the most reasonable proxy because 91% of non-hospital health care services providers used by such miners are part of this category. The Department has performed the same analysis shown here at the 4-digit NAICS level and found that the conclusion of no significant impact did not change.

[11] *See https://www.census.gov//econ/susb/data/susb2012.html.*

[12] As discussed in Section V.A.1. of the preamble, the Department estimated the number of providers that could be negatively affected by the proposed rule based on the number of providers receiving reimbursements from the Trust Fund that would see a decrease in the amount of reimbursement using

Department estimates that the aggregate reduction in payments for these 420 negatively affected firms would be $373,156. *See* Table 4. Thus, the average reduction in payments to each negatively affected firm would be $888 (373,156 divided by 420), or 0.05% (888 divided by 1,700,000) of average firm revenue. *See* Table 4. The Department believes that this average reduction is de minimis and would not significantly affect non-hospital providers.

Hospitals generated $883.1 billion in revenues during 2012.[13] Dividing annual revenues by the number of firms in the sector (3,497),[14] hospital firms generated average annual revenues of $252.5 million. Based on Trust Fund payment data, OWCP found that a total of 184 hospital firms provided outpatient services to entitled miners in FY 2014. *See* Table 2. The Department estimates that 177 firms (out of 184) would receive net reductions in payments from the Trust Fund under the proposed rule.[15] The Department estimates that the aggregate reduction in payments for these 177 negatively affected firms would be $1,720,182. *See* Table 4. Thus, the average reduction in payments to each negatively affected hospital providing outpatient services would be $9,719 (1,720,182 divided by 177), or 0.004% (9,719 divided by 252.5 million) of average annual revenue for the negatively affected firms. *See* Table 4. The Department believes that this average reduction is de minimis and would not significantly affect hospital outpatient services providers.

With respect to inpatient hospital services, Trust Fund payment data showed that 156 hospitals provided such services to entitled miners in FY 2014. *See* Table 3. The Department estimates that 80 firms (out of 156) would receive net reductions in payments from the Trust Fund under the proposed rule.[16] The Department estimates that the aggregate reduction in payments for these 80 negatively affected firms would be $3,338,650. *See* Table 4. Thus, the average reduction in payments to each negatively affected hospital providing inpatient services would be $41,733 (3,338,650 divided by 80), or 0.016% (41,733 divided by 252.5 million) of average annual revenue. *See* Table 4. The Department believes that this average annual reduction in revenue is de minimis and would not significantly affect hospital inpatient services providers.

Finally, the Department does not believe that any reduction in payments from the Trust Fund to firms that provide both outpatient and inpatient hospital services would be significant. For example, if payments to a particular firm for outpatient services were reduced by $9,719 (the average reduction for all providers of outpatient services) and payments to the same firm for inpatient services were reduced by $41,733 (the average reduction for all providers of inpatient services), the combined reduction of $51,452 would represent only 0.2% (51,452 divided by 252.5 million) of average firm revenue. Notably, some firms that provide both types of services (outpatient and inpatient) may experience a reduction in payments for only one type of service, while simultaneously experiencing an offsetting increase in payments for the other type of service.

Neither does the Department believe that the rule's impact will increase over time. While the total amount of payments by the Trust Fund to providers for medical services and treatments may decrease over time as the number of entitled miners receiving benefits declines, the decrease in payments would result from the decline in the number of beneficiaries, not the proposed rule.[17]

In sum, the Department believes that the estimated aggregate annual reduction in Trust Fund payments of $3,154,297 will not have a significant impact on the economy. Similarly, the Department believes that the reduction in annual revenue for negatively affected firms (0.05% of average annual revenue for non-hospital health care services providers, 0.004% of average annual revenue for hospitals providing outpatient services, and 0.016% of average annual revenue for hospitals providing inpatient services) will not have a significant impact on those individual firms.

the proposed formulas versus current practice. *See* Table 5 *infra* for the geographic distribution of negatively affected non-hospital providers.

[13] The Department has used NAICS code 622 (Hospitals) as the proxy for providers of both outpatient and inpatient services.

[14] *See https://www.census.gov//econ/susb/data/susb2012.html.*

[15] *See* Section V.A.1. of the preamble and n.11. *See* Table 6 *infra* for the geographic distribution of negatively affected outpatient hospital providers.

[16] *See* Section V.A.1. of the preamble and nn.11 & 14. *See* Table 7 *infra* for the geographic distribution of negatively affected inpatient hospital providers.

[17] For example, in FY 2005, the Trust Fund paid approximately $51.2 million to providers for medical services and treatments for 16,794 entitled miners. By FY 2014, Trust Fund payments had dropped to $17.5 million (not adjusted for inflation) for 6,189 entitled miners.

Table 4. Summary of Economic Impact

	Non-Hospital Health Care Services Providers	Hospitals Providing Outpatient Services	Hospitals Providing Inpatient Services
Industry Revenue	$827.9 billion	$881.3 billion	$881.3 billion
Number of Firms	485,235	3,497	3,497
Revenue per Firm	$1,700,000	$252.5 million	$252.5 million
Cumulative Cost of Rule for All Negatively Affected Firms	$373,156	$1,720,182	$3,338,650
Number of Negatively Affected Firms	420	177	80
Cost per Negatively Affected Firm	$888	$9,719	$41,733
Cost of Rule as % of Revenue per Negatively Affected Firm	0.050%	0.004%	0.016%

Source: U.S. Department of Labor, Office of Workers' Compensation Programs

B. Other Considerations

The Department considered numerous options and methods before proposing these payment formulas for the black lung program. The Department believes that the proposed formulas and methods best serve the interests of all stakeholders. The proposed rule would bring medical payments under the black lung program in line with today's industry-wide practice, protect the Trust Fund from excessive payments, and compensate health care services providers sufficiently to ensure that entitled miners have continued access to medical care. Thus, the adoption of the payment formulas, as set forth in proposed §§ 725.707–725.711, has multiple advantages.

In addition, the Department will realize some economies of scale by using payment formulas that are similar to those in OWCP's other compensation programs. Maintaining a wholly separate system for black lung medical bill payments has required increased administration and therefore increased costs. It has also led to disparities in provider reimbursements. The proposed payment formulas, like other modern medical payment methodologies, have built-in cost control mechanisms that help prevent inaccurate payments and would therefore preserve Trust Fund assets. Also, because the amounts paid under these formulas reflect industry standards, recouping medical benefits paid by the Trust Fund on an interim basis from liable operators and their insurance carriers should be routine. And by migrating to the new system, the Department hopes to shorten the time period for reimbursements, thus benefitting providers with prompt payment. Finally, the proposed rule will benefit claimants, liable operators, insurance carriers, medical service providers, and secondary medical payers simply by improving the clarity of the black lung medical bill payment process.

VI. Regulatory Flexibility Act and Executive Order 13272 (Proper Consideration of Small Entities in Agency Rulemaking)

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601 *et seq.,* establishes ''as a principle of regulatory issuance that agencies shall endeavor, consistent with the objectives of the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the business, organizations, and governmental jurisdictions subject to regulation.'' Public Law 96–354. As a result, agencies must determine whether a proposed rule may have a ''significant'' economic impact on a ''substantial'' number of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions. *See* 5 U.S.C. 603. If the agency estimates that a proposed rule would have a significant impact on a substantial number of small entities, then it must prepare a regulatory flexibility analysis as described in the RFA. *Id.* However, if a proposed rule is not expected to have a significant impact on a substantial number of small entities, the agency may so certify and a regulatory flexibility analysis is not required. *See* 5 U.S.C. 605(b). The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

The RFA does not define ''significant'' or ''substantial.'' 5 U.S.C. 601. It is widely accepted, however, that ''[t]he agency is in the best position to gauge the small entity impacts of its regulations.'' SBA Office of Advocacy, ''A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act,'' at 18 (May 2012) (''SBA Guide for Government Agencies'').[18] One measure for determining whether an economic impact is ''significant'' is the percentage of revenue affected. For this rule, the Department used as a standard of significant economic impact whether the costs for a small entity equal or exceed 3% of the entity's annual revenue. Similarly, one measure for determining whether a ''substantial'' number of small entities are affected is the percentage of small entities affected on an industry-wide basis. For this rule, the Department has used as a standard

[18] Accessed at *http://www.sba.gov/sites/default/files/rfaguide_0512_0.pdf.*

to measure a ''substantial number of small entities'' whether 15% or more of the small entities in a given industry are significantly affected. The regulatory flexibility analysis for this NPRM is based on these two measures.[19]

Although the proposed rule is not expected to have a significant economic impact on a substantial number of small entities, the Department has conducted this initial regulatory flexibility analysis to aid stakeholders in understanding the impact of the proposed rule on small entities and to obtain additional information on such impacts. The Department invites interested parties to submit comments on the analysis, including the number of small entities affected by the proposed rule, the cost estimates, and whether alternatives exist that would reduce the burden on small entities. In particular, because the Department does not have access to revenue data for affected providers (and, thus, based this analysis on nationwide revenue averages), the Department is particularly interested in receiving comments regarding the proposed rule's potential revenue impact on affected firms.

A. Description of the Reasons That Action by the Agency Is Being Considered

The Department's current regulations specify that payments for medical services and treatments must be paid at ''no more than the rate prevailing in the community [where the provider is located].'' 20 CFR 725.706(c). But the rules do not address how that rate should be determined. Currently, OWCP applies internally-derived formulas to determine payments for services and treatments under the BLBA. The current system, however, is difficult to administer and, in some instances, may not accurately reflect prevailing community rates. In addition, because the current payment formulas do not always reflect standard industry practice, the Department has encountered resistance from operators and insurance carriers when seeking reimbursement for medical benefits initially paid by the Trust Fund on an interim basis or when the Department seeks to enforce a final benefit award.

B. Objectives of, and Legal Basis for, the Proposed Rule

Section 426(a) of the BLBA authorizes the Secretary to ''issue such regulations as he deems appropriate to carry out the provisions of this title.'' 30 U.S.C. 936(a). The proposed rule adopts formulas for the payment of medical services and treatments under the black lung program that are derived from those used in the Medicare program and are similar to the payment formulas utilized in the other compensation programs that OWCP administers. The proposed payment formulas conform to current industry practice, and more accurately reflect prevailing community rates. The proposed rule, therefore, will help prevent inaccurate payments, control health care costs, streamline the processing of bills, and provide for similar payment policies and practices throughout all OWCP programs.

C. Number of Small Entities Affected

1. Introduction

The Regulatory Flexibility Act requires an agency to describe and, where feasible, estimate the number of small entities to which a proposed rule will apply. 5 U.S.C. 603(b)(3). Small entities include small businesses, small organizations, and small governmental jurisdictions. 5 U.S.C. 601(6). Under the RFA, small organizations are defined as not-for-profit, independently owned and operated enterprises, that are not dominant in their field. 5 U.S.C. 601(4); *see also* SBA Guide for Government Agencies at 14. To ensure it adequately addresses potential impact on small entities, the Department's analysis assumes that all not-for-profit entities that provide medical services to miners under the BLBA are independently owned and operated, not dominant in their field, and thus are small organizations regardless of their revenue size.

The data sources used in the Department's analysis are the Small Business Administration (SBA) Table of Small Business Size Standards,[20] the U.S. Census Bureau's Statistics of U.S. Businesses (SUSB),[21] and the U.S. Census Bureau's Economic Census,[22] which provide annual data on the number of firms, employment, and annual revenue by industry. The industrial classifications most directly affected by this rule are: (1) Ambulatory Health Care Services (North American Industry Classification System (NAICS) code 621), which includes offices of physicians, outpatient care centers,[23] medical and diagnostic laboratories, and home health care services (collectively referred to as ''non-hospital health care services providers'' or ''non-hospital providers''); and (2) Hospitals (NAICS code 622).

2. The Department's Analysis

The Department estimated the number of small businesses of each provider type that could be negatively affected by the rule by multiplying (a) the percentage of small entities of that provider type in the industry as a whole by (b) the estimated number of black lung service providers of that type (both small and large entities) that could be negatively affected by the rule. The Department estimated the number of non-hospital and hospital providers that could be negatively affected by the proposed rule by comparing: (a) The amount that the Trust Fund actually paid to providers for medical services performed in Fiscal Year 2014 (current practice); and (b) the amount the Trust Fund would have paid to providers for the same services using the payment formulas in the proposed rule. *See* Section V.A.1. The next two subsections provide additional details on how the Department estimated the number of small, negatively impacted, non-hospital and hospital providers.

a. Non-Hospital Health Care Service Providers

According to SUSB data, there are 485,235 non-hospital health care services providers in the United States. Of that total, 482,584, or 99.5%, are classified as small businesses by the SBA (this includes both for-profit and not-for-profit businesses).[24] Of the remaining 2,651 non-hospital providers that are not classified as small under the SBA definition, 1.7%—or 45 (2,651 × 0.17)—are classified as not-for-profit by the Economic Census, and thus considered small organizations (*i.e.,* any not-for-profit entity that is independently owned and operated and

[19] The Department has used the threshold of 3% of revenues for the definition of significant economic impact and the threshold of 15% for the definition of substantial number of small entities affected in a number of recent rulemakings. *See, e.g.,* Wage and Hour Division, Establishing a Minimum Wage for Contractors, Notice of Proposed Rulemaking, 79 FR 34568, 34603 (June 17, 2014); Office of Federal Contract Compliance Programs, Government Contractors, Requirement To Report Summary Data on Employee Compensation, Notice of Proposed Rulemaking, 79 FR 46562, 46591 (Aug. 8, 2014). The 3% and 15% standards are also consistent with the standards utilized by various other Federal agencies in conducting their regulatory flexibility analyses. *See, e.g.,* Department of Health and Human Services Centers for Medicare & Medicaid Services, ''Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II; Final Rule,'' 79 FR 27106, 27151 (May 12, 2014).

[20] *See http://www.sba.gov/content/small-business-size-standards.*

[21] *See https://www.census.gov/econ/susb/.*

[22] *See http://factfinder.census.gov/.*

[23] Outpatient care centers are distinct from hospitals that provide outpatient services.

[24] The SBA's small business size standards for subsectors within the ambulatory health care services industry range from $7.5 million to $38.5 million.

not dominant in its field). In total, the Department estimates that 482,629 non-hospital providers (482,584 classified as small under SBA revenue criteria, plus 45 additional not-for-profit providers) are small entities for purposes of the RFA. Thus, 99.5%, (482,629 divided by 485,235) of all non-hospital providers in the United States are classified as small entities within the meaning of the RFA.

To determine the number of small non-hospital providers that could be negatively impacted by the proposed rule, the Department multiplied the overall, industry-wide percentage of small, non-hospital providers (99.5%) by the number of non-hospital providers (both small and large) that the Department estimates could be negatively affected by the rule (420). *See* Table 5. That multiplication yielded an estimate that 418 small, non-hospital providers could be negatively affected by the rule. Table 5 provides information on all negatively impacted non-hospital providers, small and large, on a state-by-state basis.

Table 5: Comparison of Trust Fund Payments to Negatively Affected Non-Hospital Health Care Services Providers for Services Performed 10/1/2013-9/30/2014 (Current Practice v. Estimated Payments Under the Proposed Rule).

State	Amount Billed By Negatively Affected Providers[1]	Amount Paid to Negatively Affected Providers Under Current Practice	Amount That Would Be Paid to Negatively Affected Providers Under The Proposed Rule	Difference	Number of Negatively Affected Small Providers[2,3]	Number of Negatively Affected Providers	Number of Providers
Alabama	$2,231	$1,873	$1,042	-$831	8	8	22
Arkansas	$380	$380	$146	-$235	1	1	2
California	$96	$88	$37	-$51	1	1	1
Colorado	$9,594	$4,609	$3,689	-$920	5	5	13
Florida	$9,565	$5,646	$4,703	-$943	7	7	22
Georgia	$4,428	$2,109	$1,820	-$289	4	4	6
Illinois	$16,751	$11,521	$10,096	-$1,425	15	15	41
Indiana	$120,201	$52,751	$31,180	-$21,571	13	13	43
Iowa	N/A	N/A	N/A	N/A	0	0	1
Kansas	N/A	N/A	N/A	N/A	0	0	2
Kentucky	$741,034	$415,171	$274,020	-$141,152	96	96	270
Maryland	$8,861	$5,935	$3,626	-$2,309	4	4	12
Michigan	$6,236	$3,242	$2,575	-$667	9	9	19
Minnesota	N/A	N/A	N/A	N/A	0	0	1
Missouri	$58,511	$35,142	$16,356	-$18,786	6	6	11
Nevada	N/A	N/A	N/A	N/A	0	0	2
New Jersey	$130	$101	$39	-$62	2	2	4
New Mexico	N/A	N/A	N/A	N/A	0	0	2
North Carolina	$14,153	$8,087	$5,697	-$2,390	7	7	12
Ohio	$18,561	$11,811	$9,174	-$2,638	22	22	53
Pennsylvania	$216,092	$162,407	$138,619	-$23,788	79	79	244
South Carolina	$3,964	$1,486	$728	-$757	3	3	3
Tennessee	$97,484	$61,893	$44,958	-$16,935	46	46	118
Texas	$5,715	$2,532	$2,392	-$140	1	1	2
Utah	$20,678	$8,652	$7,774	-$879	4	4	7
Virginia	$527,257	$291,673	$201,962	-$89,711	35	35	115
West Virginia	$287,472	$166,771	$120,124	-$46,646	51	51	178
Wyoming	$71	$43	$12	-$31	1	1	4
Total	**$2,169,465**	**$1,253,923**	**$880,769**	**-$373,156**	**418**	**420**	**1,210**

Notes:

[1] These amounts reflect actual amounts billed, including bills presented for non-covered medical services.

[2] The estimated number of negatively affected small providers was derived by multiplying the number of negatively affected providers in each state by the percentage (99.5%) of non-hospital health care services providers categorized as small under RFA guidelines (i.e., including non-profit providers with revenues above the SBA threshold for small non-hospital entities).

[3] The estimated numbers of negatively affected small providers were rounded for clarity, so will not total 418 exactly.

b. Hospitals

According to SUSB data, there are 3,497 hospitals in the United States. Of that total, 1,547, or 44.2%, are classified as small businesses by the SBA (this includes both for-profit and not-for-profit businesses).[25] Of the remaining 1,950 hospitals that are not classified as small under the SBA definition, 87.9%—or 1,714 (1,950 × 0.879)—are classified as not-for-profit by the Economic Census, and thus considered small organizations (*i.e.* any not-for-profit entity that is independently owned and operated and not dominant in its field). In total, the Department estimates that 3,261 hospitals (1,547 classified as small under SBA revenue criteria, plus 1,714 additional not-for-profit hospitals) are small entities for purposes of the RFA. Thus, 93.3%, (3,261 divided by 3,497) of all hospitals in the United States are classified as small entities within the meaning of the RFA.

To determine the number of small hospitals that could be negatively impacted by the proposed rule, the Department multiplied the overall, industry-wide percentage of small hospitals (93.3%) by the number of hospitals (both small and large) that the Department estimates could be negatively affected by the rule.

The Department performed the above-described analysis separately for: (a) Hospitals providing outpatient services to entitled black lung patients; and (b) hospitals providing inpatient services to entitled black lung patients. Specifically, for outpatient providers, the Department estimated that a total of 177 hospitals could be negatively affected by the proposed rule and that, of that total, 165 (or 93.3%) are small hospitals. *See* Table 2, Table 6. Similarly, for inpatient providers, the Department estimated that a total of 80 hospitals could be negatively affected by the proposed rule and that, of that total, 75 (or 93.3%) are small hospitals.

Tables 6 and 7 provide information on all negatively impacted hospitals, small and large, on a state-by-state basis, addressing, respectively, hospitals providing outpatient services to black lung patients and hospitals providing inpatient services to black lung patients.

[25] SBA defines a hospital provider as small if it has $38.5 million or less in annual revenue.

Table 6: Comparison of Trust Fund Payments to Negatively Affected Hospital Outpatient Services Providers for Services Performed 10/1/2013-9/30/2014 (Current Practice v. Estimated Payments Under the Proposed Rule).

State	Amount Billed By Negatively Affected Providers[1]	Amount Paid to Negatively Affected Providers Under Current Practice	Amount That Would Be Paid to Negatively Affected Providers Under The Proposed Rule	Difference	Number of Negatively Affected Small Providers[2, 3]	Number of Negatively Affected Providers	Number of Providers
Alabama	$16,684	$6,368	$1,913	-$4,456	5	5	5
Colorado	$1,192	$556	$320	-$236	1	1	3
Florida	$16,678	$9,609	$1,485	-$8,124	3	3	3
Georgia	$1,969	$1,002	$195	-$807	1	1	1
Illinois	$139,426	$109,545	$38,410	-$71,136	11	12	14
Indiana	$74,182	$62,530	$13,532	-$48,997	9	10	10
Kentucky	$1,663,284	$1,224,699	$322,274	-$902,425	33	35	35
Maryland	$2,027	$2,027	$1,044	-$982	1	1	1
Michigan	$1,515	$1,263	$601	-$663	1	1	1
Missouri	$6,096	$1,554	$434	-$1,120	2	2	2
New Jersey	$1,427	$354	$243	-$111	1	1	1
New Mexico	$1,209	$341	$311	-$30	1	1	1
North Carolina	$22,119	$7,272	$2,759	-$4,513	4	4	4
Ohio	$45,738	$41,173	$8,267	-$32,906	12	13	13
Oklahoma	$825	$460	$356	-$104	1	1	1
Pennsylvania	$192,163	$119,569	$34,394	-$85,174	24	26	27
Tennesee	$179,825	$125,028	$42,433	-$82,595	20	21	21
Utah	$632	$358	$93	-$265	2	2	2
Virginia	$524,313	$423,055	$95,751	-$327,304	10	11	11
West Virginia	$290,722	$245,093	$96,894	-$148,199	23	25	26
Wyoming	$188	$67	$32	-$35	1	1	2
Total	**$3,182,215**	**$2,381,923**	**$661,741**	**-$1,720,182**	**165**	**177**	**184**

Notes:

[1] These amounts reflect actual amounts billed, including bills presented for non-covered medical services.

[2] The estimated number of negatively affected small providers was derived by multiplying the number of negatively affected providers in each state by the percentage (93.3%) of hospital services providers categorized as small under RFA guidelines (i.e., including non-profit hospitals with revenues above the SBA threshold for small hospital entities).

[3] The estimated numbers of negatively affected small providers were rounded for clarity, so will not total 165 exactly.

Table 7: Comparison of Trust Fund Payments to Negatively Affected Hospital Inpatient Services Providers for Services Performed 10/1/2013-9/30/2014 (Current Practice v. Estimated Payments Under the Proposed Rule).

State	Amount Billed By Negatively Affected Providers[1]	Amount Paid to Negatively Affected Providers Under Current Practice	Amount That Would Be Paid to Negatively Affected Providers Under The Proposed Rule	Difference	Number of Negatively Affected Small Providers[2, 3]	Number of Negatively Affected Providers	Number of Providers
Alabama	$59,871	$44,963	$40,453	-$4,510	1	1	5
Colorado	n/a	n/a	n/a	n/a	0	0	3
Florida	$363,422	$277,218	$70,951	-$206,267	3	3	4
Illinois	$501,048	$138,504	$101,524	-$36,980	4	4	6
Indiana	$237,730	$163,254	$89,806	-$73,448	2	2	5
Iowa	n/a	n/a	n/a	n/a	0	0	1
Kentucky	$12,158,023	$4,507,961	$2,960,490	-$1,547,471	17	18	30
Michigan	n/a	n/a	n/a	n/a	0	0	2
Missouri	$71,345	$65,811	$29,665	-$36,146	1	1	1
Nevada	n/a	n/a	n/a	n/a	0	0	1
North Carolina	$116,562	$31,238	$11,460	-$19,778	2	2	3
Ohio	$280,703	$134,545	$103,752	-$30,793	3	3	8
Pennsylvania	$5,566,429	$978,185	$640,613	-$337,572	13	14	30
Tennessee	$1,824,847	$638,819	$461,001	-$177,818	13	14	19
Utah	$21,462	$1,916	$0	-$1,916	1	1	1
Virginia	$4,793,968	$2,401,580	$1,725,549	-$676,031	8	9	11
West Virginia	$1,286,638	$613,262	$423,343	-$189,919	7	8	26
Total	**$27,282,049**	**$9,997,257**	**$6,658,607**	**-$3,338,650**	**75**	**80**	**156**

Notes:
[1] These amounts reflect actual amounts billed, including bills presented for non-covered medical services.
[2] The estimated number of negatively affected small providers was derived by multiplying the number of negatively affected providers in each state by the percentage (93.3%) of hospital services providers categorized as small under RFA guidelines (i.e., including non-profit hospitals with revenues above the SBA threshold for small hospital entities).
[3] The estimated numbers of negatively affected small providers were rounded for clarity, so may not total 75 exactly.

D. Costs to Small Entities Affected

The Department estimates that the proposed rule will not result in a significant impact (defined as 3% or more of annual revenue) on a substantial number of small entities (defined as 15% or more of all negatively affected small entities in the relevant industry). The relevant industries are defined as non-hospital health care services providers and hospitals. The Department has determined that the proposed rule will not impose any additional reporting, recordkeeping, or other compliance costs on affected entities. With respect to the reduction in payments from the Trust Fund, the Department estimates that no small entities providing non-hospital health care services will experience a significant impact (a loss of 3% or more of annual revenues). As for hospitals, the Department estimates that hospitals with revenues/receipts between $100,000 and $499,900 providing outpatient services and hospitals with revenues/receipts between $100,000 and $999,999 providing inpatient services would experience a significant impact. Assuming that the affected hospitals exhibit the same revenue distribution as firms nationally, the Department estimates that only one small firm providing outpatient services and two small firms providing inpatient services will be significantly impacted. These entities do not constitute a substantial number (15% or more) of the total number of negatively affected small hospitals providing either outpatient or inpatient services.

1. Estimated Reporting, Recordkeeping, and Other Compliance Costs to Small Entities

Based on its analysis of available data, the Department has determined that the proposed rule will not impose any additional reporting, recordkeeping, or

other compliance costs on providers. The proposed procedures for the submission and payment of medical bills conform to current industry standards for the processing of such bills. Providers are familiar with the proposed procedures and already have adequate billing systems in place for use in connection with other programs such as Medicare. Moreover, a number of provisions in the proposed rule simply codify current practice. Thus, the Department has determined that the proposed rule would not impose any additional reporting, recordkeeping, or compliance costs on providers, regardless of firm size.

2. Estimated Costs to Small Entities From Changes in Payments by the Trust Fund

In order to determine whether the proposed rule would result in a significant impact on any small businesses, the Department first estimated the revenues for negatively affected small entities of each provider type (non-hospital and hospital service providers) and then determined whether the estimated impact on those firms was significant. *See* Section V.A.2. The Department does not have individual revenue data for black lung service providers, but does have SBA data on the distribution of firms across the industry by revenue size. The Department therefore estimated the number of small negatively affected firms of each provider type in different revenue/receipts bands, by multiplying the industry-distribution percentage of firms in those revenue/receipts bands by the number of negatively affected black lung providers of that type, accounting for the fact that all not-for-profit providers are classified as small entities. *See* Tables 8–10. The Department then determined whether the estimated cost to each firm, as calculated in Section V.A.2. of this preamble, was significant (a reduction in average annual revenue of 3% or more) to a firm in that revenue band. The Department determined that only 3 of the 658 negatively affected black lung providers in all provider categories were significantly impacted. *See* Tables 8–10, Table 11. The Department finally calculated whether the number of small providers of each type that would experience a significant impact as a result of the proposed rule represented a substantial percentage (15% or more) of all negatively affected small entities of that type, and determined that they did not. *See* Tables 8–10, Table 11.

a. Non-Hospital Health Care Services Providers

As discussed earlier, the Department estimates that 420 non-hospital health care services providers would experience a reduction in payments from the Trust Fund as a result of the proposed rule, and that 418 of these are estimated to be small entities. *See* VI.C.2.a., Table 4, Table 8, Table 11. Also, the Department estimates the annual cost of the proposed rule will be $888 for each negatively affected non-hospital health care services provider. *See* Section V.A.2., Table 4, Table 8, Table 11. The Department divided the estimated annual cost of the proposed rule to non-hospital health care services providers by the average revenue in each revenue band to estimate the average percentage of revenue lost by these providers. *See* Table 8. The Department acknowledges that uniformly applying the annual cost of the proposed rule across all negatively affected entities is an analytical assumption that likely does not reflect the true distribution of the costs of this proposed rule. However, OWCP does not have the data to develop a more accurate distribution of costs and believes that this proportional distribution likely overestimates the costs to the smallest providers. The costs of this proposed rule are small relative to the revenue and receipts of most providers and the impact of these costs might be hidden were OWCP to more heavily weight the distribution of costs towards larger firms. The Department believes this proportional distribution allows OWCP to focus this analysis on the impact on the smallest providers even though these impacts may be overstated. Based on these calculations, the Department does not believe that any of the negatively affected small entities providing non-hospital health care services will experience a significant impact (*i.e.,* a loss of 3% or more of annual revenue) from the proposed rule. *See* Table 8, Table 11. For example, even in the lowest revenue band (less than $100,000 in annual revenue), the average annual revenue reduction resulting from the proposed rule would be only 1.77% ($888 divided by $50,173). *See* Table 8. The number of small non-hospital health care services providers that would experience a significant impact (zero) is plainly not a significant percentage (15% or more) of all such negatively affected small entities.

Table 8: Costs to Negatively Affected Small Firms – Non-Hospital Health Care Services Providers

Firm Size[1, 2]	Number of All Industry Firms	Number of Negatively Affected Small Firms (418 Total)[3]	Annual Cost per Firm[4]	Annual Revenue for All Industry Firms	Average Revenue per Firm[5]	Annual Cost per Negatively Affected Firm as Percent of Revenue[6]
Firms with sales/receipts/revenue below $100,000	67,309	58	$888	$3,377,069,000	$50,173	1.77%
Firms with sales/receipts/revenue of $100,000 to $499,999	193,782	168	$888	$53,752,291,000	$277,385	0.32%
Firms with sales/receipts/revenue of $500,000 to $999,999	109,226	95	$888	$77,311,310,000	$707,811	0.13%
Firms with sales/receipts/revenue of $1,000,000 to $2,499,999	74,584	65	$888	$112,002,453,000	$1,501,695	0.06%
Firms with sales/receipts/revenue of $2,500,000 to $4,999,999	20,837	18	$888	$71,115,977,000	$3,412,966	0.03%
Firms with sales/receipts/revenue of $5,000,000 to $7,499,999	6,554	6	$888	$38,847,269,000	$5,927,261	0.01%
Firms with sales/receipts/revenue of $7,500,000 to $9,999,999	3,173	3	$888	$26,328,703,000	$8,297,732	0.01%
Firms with sales/receipts/revenue of $10,000,000 to $14,999,999	3,222	3	$888	$36,800,355,000	$11,421,588	0.01%
Firms with sales/receipts/revenue of $15,000,000 to $19,999,999	1,604	1	$888	$24,776,590,000	$15,446,752	0.01%
Firms with sales/receipts/revenue of $20,000,000 to $24,999,999	897	1	$888	$17,319,311,000	$19,308,039	0.00%
Firms with sales/receipts/revenue of $25,000,000 to $29,999,999	641	1	$888	$14,927,993,000	$23,288,601	0.00%
Firms with sales/receipts/revenue of $30,000,000 to $34,999,999	429	<1	$888	$11,900,102,000	$27,739,166	0.00%
Firms with sales/receipts/revenue of $35,000,000 to $39,999,999	326	<1	$888	$9,749,213,000	$29,905,561	0.00%
Firms with sales/receipts/revenue of $40,000,000 or greater	45	<1	$888	$5,604,847	$124,367	0.71%

Notes:

[1] The U.S. Small Business Administration's small business size standards for subsectors within the ambulatory health care services industry range from $7.5 to $38.5 million. The Department used these thresholds to define small businesses in the analysis of the health care industry.

[2] Per the RFA definitions, not-for-profit, independently owned and operated firms of any size, that are not dominant in their field, are considered small. The revenue band of $40,000,000 or more includes only not-for-profits firms. The total number of firms (45) included in this revenue band was calculated by multiplying the percentage (1.7%) of not-for-profit firms in the non-hospital health care services industry by the total number of large firms (2,651) identified in the SBA data.

[3] The estimated numbers of negatively affected small firms were rounded for clarity, so will not total 418 exactly. Any fraction under one was denoted <1.

[4] The annual cost per firm ($888) was derived by calculating the total cost of the proposed rule (i.e., the total net decrease in payments summed over all negatively affected firms, $373,156) and dividing by the total number of negatively affected firms (420).

[5] The average revenue per firm was derived by dividing the total annual revenue for all industry firms by the number of industry firms.

[6] The annual cost per negatively affected firm as a percent of revenue was derived by dividing the annual cost per firm by the average revenue per firm.

b. Hospital Outpatient Service Providers

The Department estimates that 177 hospitals that provide outpatient services to entitled miners would experience a reduction in payments from the Trust Fund as a result of the proposed rule, and that 168 of these hospitals are small. *See* VI.C.2.b., Table 4, Table 9, Table 11. Also, the Department estimates the annual cost of the proposed rule will be $9,719 for each negatively affected hospital outpatient services provider.[26] *See* V.A.2., Table 4, Table 11. The Department divided the estimated annual cost of the proposed rule for negatively affected hospital outpatient services providers by the average revenue in each revenue band to estimate the average percentage of revenue lost by these providers. *See* Table 9. Based on these calculations, the Department estimates that only one provider (in the $100,000–$499,000 revenue band) will experience a significant impact from the proposed rule. *See* Table 9. The Department estimates that this firm would experience a reduction in revenue of 3.73% ($9,719 divided by $260,292). *See* Table 9. Because this single entity represents only 0.6% (1 divided by 165) of all negatively affected small outpatient service entities, however, the proposed rule will not have a significant effect on a substantial number (15% or more) of all negatively affected small hospital outpatient service providers. *See* Table 11.

Because revenue data for entities in the $0–100,000 revenue band is not available, *see* Table 9, the Department was unable to calculate whether the impact of the proposed rule on providers in that revenue band would be significant. Nonetheless, even assuming that the only negatively impacted entity in the $0–$100,000 revenue band also experienced a significant impact, only 1.2% (2 divided by 165) of negatively affected small entities would experience a significant impact. This impact is still less than the 15% threshold for determining whether a substantial number of all negatively affected small entities would experience a significant impact.

[26] As previously noted, the Department acknowledges that uniformly applying the annual cost of the proposed rule across all negatively affected entities likely overstates the impact on smaller providers. *See* Section VI.D.2.a. of the preamble.

Table 9: Costs to Negatively Affected Small Firms – Hospital Outpatient Services Providers

Firm Size[1,2]	Number of All Industry Firms	Number of Negatively Affected Small Firms (165 Total)[3]	Annual Cost per Industry Firm[4]	Annual Revenue for All Industry Firms[5]	Average Revenue per Firm[6]	Annual Cost per Negatively Affected Firm as Percent of Revenue[7]
Firms with sales/receipts/revenue below $100,000	15	1	$9,719	N/A	N/A	N/A
Firms with sales/receipts/revenue of $100,000 to $499,999	24	1	$9,719	$6,247,000	$260,292	3.73%
Firms with sales/receipts/revenue of $500,000 to $999,999	9	< 1	$9,719	$5,933,000	$659,222	1.47%
Firms with sales/receipts/revenue of $1,000,000 to $2,499,999	13	1	$9,719	$24,443,000	$1,880,231	0.52%
Firms with sales/receipts/revenue of $2,500,000 to $4,999,999	83	4	$9,719	$337,257,000	$4,063,337	0.24%
Firms with sales/receipts/revenue of $5,000,000 to $7,499,999	137	7	$9,719	$847,157,000	$6,183,628	0.16%
Firms with sales/receipts/revenue of $7,500,000 to $9,999,999	153	8	$9,719	$1,311,989,000	$8,575,092	0.11%
Firms with sales/receipts/revenue of $10,000,000 to $14,999,999	293	15	$9,719	$3,603,160,000	$12,297,474	0.08%
Firms with sales/receipts/revenue of $15,000,000 to $19,999,999	243	12	$9,719	$4,175,289,000	$17,182,259	0.06%
Firms with sales/receipts/revenue of $20,000,000 to $24,999,999	200	10	$9,719	$4,297,241,000	$21,486,205	0.05%
Firms with sales/receipts/revenue of $25,000,000 to $29,999,999	154	8	$9,719	$3,992,287,000	$25,923,942	0.04%
Firms with sales/receipts/revenue of $30,000,000 to $34,999,999	113	6	$9,719	$3,474,943,000	$30,751,708	0.03%
Firms with sales/receipts/revenue of $35,000,000 to $39,999,999	110	6	$9,719	$3,979,151,000	$36,174,100	0.03%
Firms with sales/receipts/revenue of $40,000,000 or greater	1,714	87	$9,719	$753,319,701,000	$439,509,744	0.00%

Notes:

[1] The U.S. Small Business Administration's small business size standard for subsectors within the hospital industry is $38.5 million. The Department used this threshold to define small businesses in the analysis of the hospital industry.

[2] Per the RFA definitions, not-for-profit, independently owned and operated firms of any size, that are not dominant in their field, are considered small. The revenue band of $40,000,000 or more includes only not-for-profits firms. The total number of firms (1,714) included in this revenue band was calculated by multiplying the percentage (87.9%) of not-for-profit firms in the hospital industry by the total number of large firms (1,950) identified in the SBA data.

[3] The estimated numbers of negatively affected small firms were rounded for clarity, so will not total 165 exactly. Any fraction under one was denoted <1.

[4] The annual cost per firm ($9,719) was derived by calculating the total cost of the proposed rule (i.e., the total net decrease in payments summed over all negatively affected firms, $1,720,182) and dividing by the total number of negatively affected firms (177).

[5] The annual and average revenue per firm for firms with sales/receipts/revenue below $100,000 are not available on the Census website. Data for that revenue band were withheld to avoid disclosing information of individual businesses.

[6] The average revenue per firm was derived by dividing the total annual revenue for all industry firms by the number of industry firms.

[7] The annual cost per negatively affected firm as a percent of revenue was derived by dividing the annual cost per firm by the average revenue per firm.

c. Hospital Inpatient Services Providers

Finally, the Department estimates that 80 hospitals that provide inpatient services to entitled miners would experience an annual reduction in payments from the Trust Fund as a result of the proposed rule, and that 35 of these are small entities. *See* VI.C.2.b., Table 4, Table 10, Table 11. Also, the Department estimates the annual cost of the proposed rule will be $41,733 for each negatively affected hospital inpatient services provider. [27] *See* V.A.2., Tables 4, Table 11. The Department divided the estimated annual cost of the proposed rule on each negatively affected hospital inpatient services provider by the average revenue in each revenue band to estimate the average percentage of revenue lost by these providers. *See* Table 10. Based on these calculations, the Department estimates that only two entities (one in the $100,000–$499,999 revenue band and one in the $500,000–$999,999 revenue band) will experience a significant impact (greater than 3% of annual revenue) from the proposed rule. *See* Table 10. Because these two entities represent only 2.6% (2 divided by 75) of all negatively affected entities, however, the proposed rule will not a have significant effect on a substantial number (15% or more) of all negatively affected hospital inpatient services providers. *See* Table 11.

Because revenue data for entities in the $0–100,000 revenue band are not available, *see* Table 10, the Department was unable to calculate whether the impact of the proposed rule on providers in that revenue band would be significant. Assuming that the only negatively impacted entity in the $0–$100,000 revenue band also experienced a significant impact, only 4.0% (3 divided by 75) of all negatively affected small entities would experience a significant impact. This impact is still less than the 15% threshold for determining whether a substantial number of negatively affected small entities would experience a significant impact.

[27] As previously noted, the Department acknowledges that uniformly applying the annual cost of the proposed rule across all negatively affected entities likely overstates the impact on smaller providers. *See* Section VI.D.2.a. of the preamble; n.34.

Table 10: Costs to Negatively Affected Small Firms – Hospital Inpatient Services Providers

Firm Size[1,2]	Number of All Industry Firms	Number of Negatively Affected Small Firms (75 total)[3]	Annual Cost per Firm[4]	Annual Revenue for All Industry Firms [5]	Average Revenue per Firm[6]	Annual Cost per Negatively Affected Firms as Percent of Revenue[7]
Firms with sales/receipts/revenue below $100,000	15	< 1	$41,733	N/A	N/A	N/A
Firms with sales/receipts/revenue of $100,000 to $499,999	24	1	$41,733	$6,247,000	$260,292	16.03%
Firms with sales/receipts/revenue of $500,000 to $999,999	9	< 1	$41,733	$5,933,000	$659,222	6.33%
Firms with sales/receipts/revenue of $1,000,000 to $2,499,999	13	< 1	$41,733	$24,443,000	$1,880,231	2.22%
Firms with sales/receipts/revenue of $2,500,000 to $4,999,999	83	2	$41,733	$337,257,000	$4,063,337	1.03%
Firms with sales/receipts/revenue of $5,000,000 to $7,499,999	137	3	$41,733	$847,157,000	$6,183,628	0.67%
Firms with sales/receipts/revenue of $7,500,000 to $9,999,999	153	4	$41,733	$1,311,989,000	$8,575,092	0.49%
Firms with sales/receipts/revenue of $10,000,000 to $14,999,999	293	7	$41,733	$3,603,160,000	$12,297,474	0.34%
Firms with sales/receipts/revenue of $15,000,000 to $19,999,999	243	6	$41,733	$4,175,289,000	$17,182,259	0.24%
Firms with sales/receipts/revenue of $20,000,000 to $24,999,999	200	5	$41,733	$4,297,241,000	$21,486,205	0.19%
Firms with sales/receipts/revenue of $25,000,000 to $29,999,999	154	4	$41,733	$3,992,287,000	$25,923,942	0.16%
Firms with sales/receipts/revenue of $30,000,000 to $34,999,999	113	3	$41,733	$3,474,943,000	$30,751,708	0.14%
Firms with sales/receipts/revenue of $35,000,000 to $39,999,999	110	3	$41,733	$3,979,151,000	$36,174,100	0.12%
Firms with sales/receipts/revenue of $40,000,000 or greater	1,714	39	$41,733	$753,319,701,000	$439,509,744	0.01%

Notes:

[1] The U.S. Small Business Administration's small business size standard for subsectors within the hospital industry is $38.5 million. The Department used this threshold to define small businesses in the analysis of the hospital industry.

[2] Per the RFA definitions, not-for-profit, independently owned and operated firms of any size, that are not dominant in their field, are considered small. The revenue band of $40,000,000 or more includes only not-for-profits firms. The total number of firms (1,714) included in this revenue band was calculated by multiplying the percentage (87.9%) of not-for-profit firms in the hospital industry by the total number of large firms (1,950) identified in the SBA data.

[3] The estimated numbers of negatively affected small firms were rounded for clarity, so will not total 75 exactly. Any fraction under one was denoted <1.

[4] The annual cost per firm ($41,733) was derived by calculating the total cost of the proposed rule (i.e., the total net decrease in payments summed over all negatively affected firms, $3,338,650) and dividing by the total number of negatively affected firms (80).

[5] The annual and average revenue per firm for firms with sales/receipts/revenue below $100,000 are not available on the Census website. Data for that revenue band were withheld to avoid disclosing information of individual businesses.

[6] The average revenue per firm was derived by dividing the total annual revenue for all industry firms by the number of industry firms.

[7] The annual cost per negatively affected firm as a percent of revenue was derived by dividing the annual cost per firm by the average revenue per firm.

E. Summary

In summary, the Department estimates that the proposed rule will not have a significant impact on any small entity providing non-hospital health care services. In addition, it will have a significant impact on only one small hospital entity providing outpatient services and two providing inpatient services. For each category of provider, the percentage of small entities experiencing a significant impact (loss of 3% or more of annual revenue) from the proposed rule (0% for professional medical services, 0.6% for outpatient hospital services, and 2.6% for inpatient hospital services) does not represent a substantial number (15% or more) of all negatively affected small entities in that category.

Moreover, the Department's calculations likely overestimate the impact of the proposed rule on negatively affected small entities. The per-provider loss calculations are based on an average of all entities in each category, regardless of size. The Department presumes that larger entities—*i.e.,* those with revenue exceeding the SBA's thresholds—treat more entitled miners, and thus receive larger total payments from the Trust Fund than smaller entities. Thus, the actual per-provider cost for small entities in each provider category likely will be smaller than the estimates used by the Department in this analysis. To ensure adequate consideration of the impact on small entities, however, the Department used these unlikely, category-wide average cost estimates to determine whether the rule would have a significant economic impact on a substantial number of small entities.

Table 11: RFA Summary

	Non-Hospital Health Care Services Providers	Hospitals Providing Outpatient Services	Hospitals Providing Inpatient Services
Number of Small Firms	482,629	3,261	3,261
Number of Negatively Affected Small Firms	418	165	75
Cost Per Small Firm	$888	$9,719	$41,733
Number of Small Firms for Whom the Cost Is Significant (≥ 3% of Annual Revenue)	0	1	2
Percent of Negatively Affected Small Firms for Whom the Cost Is Significant	0.0%	0.6%	2.7%
Significant Impact on a Substantial Number of Small Firms (≥15% of Small Firms)?	No	No	No

Source: U.S. Department of Labor, Office of Workers' Compensation Programs

F. Identification of Relevant Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rule

The Department is unaware of any rules that may duplicate, overlap, or conflict with the proposed rule.

G. Description of Any Significant Alternatives to the Proposed Rule That Accomplish the Stated Objectives of Applicable Statutes and That Minimize Any Significant Impact of the Proposed Rule on Small Entities

The RFA requires the Department to consider alternatives to the proposed rule that would minimize any significant economic impact on small entities without sacrificing the stated objectives of the applicable statute. There is no basis in the statute for exempting small firms from payment rules or for providing different payment rules for small versus large firms. Moreover, providing different rules would defeat the proposed rule's stated objective: To employ modern payment methods and streamline the payment process, while protecting the limited resources of the Trust Fund.

H. Comments To Assist the Regulatory Flexibility Analysis

Although the Department estimates that the proposed rule would not have a significant economic impact (more than 3% of revenue) on a substantial number of small entities (more than 15% in the industry), the Department would appreciate feedback on the data, factors, and assumptions used in its analysis. Accordingly, the Department invites all interested parties to submit comments regarding the costs and benefits of the proposed rule, with particular attention to the effects of the rule on small entities.

VII. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531 *et seq.,* directs agencies to assess the effects of Federal Regulatory Actions on State, local, and tribal governments, and the private sector, ''other than to the extent that such regulations incorporate requirements specifically set forth in law.'' 2 U.S.C. 1531. For purposes of the Unfunded Mandates Reform Act, this rule does not include any Federal mandate that may result in increased expenditures by State, local, tribal governments, or increased expenditures

by the private sector of more than $100,000,000.

VIII. Executive Order 13132 (Federalism)

The Department has reviewed this proposed rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have ''federalism implications.'' E.O. 13132, 64 FR 43255 (Aug. 4, 1999). The proposed rule will not ''have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government'' if promulgated as a final rule. *Id.*

IX. Executive Order 12988 (Civil Justice Reform)

The proposed rule meets the applicable standards in Sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

X. Congressional Review Act

The proposed rule is not a ''major rule'' as defined in the Congressional Review Act, 5 U.S.C. 801 *et seq.* If promulgated as a final rule, this rule will not result in: An annual effect on the economy of $100,000,000 or more; a major increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

List of Subjects in 20 CFR Part 725

Administrative practice and procedure, Black lung benefits, Claims, Coal miners' entitlement to benefits, Health care, Reporting and recordkeeping requirements, Survivors' entitlement to benefits, Total disability due to pneumoconiosis, Vocational rehabilitation, Workers' compensation.

For the reasons set forth in the preamble, the Department of Labor proposes to amend 20 CFR part 725 as follows:

PART 725—CLAIMS FOR BENEFITS UNDER PART C OF TITLE IV OF THE FEDERAL MINE SAFETY AND HEALTH ACT, AS AMENDED

■ 1. The authority citation for part 725 continues to read as follows:

Authority: 5 U.S.C. 301; 28 U.S.C. 2461 note (Federal Civil Penalties Inflation Adjustment Act of 1990); Pub. L. 114–74 at sec. 701; Reorganization Plan No. 6 of 1950, 15 FR 3174; 30 U.S.C. 901 *et seq.,* 902(f), 921, 932, 936; 33 U.S.C. 901 *et seq.;* 42 U.S.C. 405; Secretary's Order 10–2009, 74 FR 58834.

■ 2. Amend § 725.308 as follows:
■ a. Remove paragraph (b);
■ b. Redesignate paragraph (c) as paragraph (b);
■ c. Remove from the second sentence in paragraph (c) ''However, except as provided in paragraph (b) of this section,''.
■ 3. In part 725, revise subpart J as follows:

Subpart J—Medical Benefits and Vocational Rehabilitation

Sec.
725.701 What medical benefits are available?
725.702 Who is considered a physician?
725.703 How is treatment authorized?
725.704 How are arrangements for medical care made?
725.705 Is prior authorization for medical services required?
725.706 What reports must a medical provider give to OWCP?
725.707 At what rate will fees for medical services and treatments be paid?
725.708 How are payments for professional medical services and medical equipment determined?
725.709 How are payments for prescription drugs determined?
725.710 How are payments for outpatient medical services determined?
725.711 How are payments for inpatient medical services determined?
725.712 When and how are fees reduced?
725.713 If a fee is reduced, may a provider bill the claimant for the balance?
725.714 How do providers enroll with OWCP for authorizations and billing?
725.715 How do providers submit medical bills?
725.716 How should a miner prepare and submit requests for reimbursement for covered medical expenses and transportation costs?
725.717 What are the time limitations for requesting payment or reimbursement for medical services or treatments?
725.718 How are disputes concerning medical benefits resolved?
725.719 What is the objective of vocational rehabilitation?
725.720 How does a miner request vocational rehabilitation assistance?

Subpart J—Medical Benefits and Vocational Rehabilitation

§ 725.701 What medical benefits are available?

(a) A miner who is determined to be eligible for benefits under this part or part 727 of this subchapter (*see* § 725.4(d)) is entitled to medical benefits as set forth in this subpart as of the date of his or her claim, but in no event before January 1, 1974. Medical benefits may not be provided to the survivor or dependent of a miner under this part.

(b) A responsible operator, or where there is none, the fund, must furnish a miner entitled to benefits under this part with such medical services and treatments (including professional medical services and medical equipment, prescription drugs, outpatient medical services, inpatient medical services, and any other medical service, treatment or supply) for such periods as the nature of the miner's pneumoconiosis and disability requires.

(c) The medical benefits referred to in paragraphs (a) and (b) of this section include palliative measures useful only to prevent pain or discomfort associated with the miner's pneumoconiosis or attendant disability.

(d) An operator or the fund must also pay the miner's reasonable cost of travel necessary for medical treatment (to be determined in accordance with prevailing United States government mileage rates) and the reasonable documented cost to the miner or medical provider incurred in communicating with the operator, carrier, or OWCP on matters connected with medical benefits.

(e)(1) If a miner receives a medical service or treatment, as described in this section, for any pulmonary disorder, there will be a rebuttable presumption that the disorder is caused or aggravated by the miner's pneumoconiosis.

(2) The party liable for the payment of benefits may rebut the presumption by producing credible evidence that the medical service or treatment provided was for a pulmonary disorder apart from those previously associated with the miner's disability, or was beyond that necessary to effectively treat a covered disorder, or was not for a pulmonary disorder at all.

(3) An operator or the fund, however, cannot rely on evidence that the miner does not have pneumoconiosis or is not totally disabled by pneumoconiosis arising out of coal mine employment to defeat a request for coverage of any medical service or treatment under this subpart.

(4) In determining whether the treatment is compensable, the opinion of the miner's treating physician may be entitled to controlling weight pursuant to § 718.104(d).

(5) A finding that a medical service or treatment is not covered under this subpart will not otherwise affect the miner's entitlement to benefits.

§ 725.702 Who is considered a physician?

The term ''physician'' includes only doctors of medicine (MD) and doctors of osteopathy (DO) within the scope of their practices as defined by State law. No treatment or medical services performed by any other practitioner of the healing arts is authorized by this part, unless such treatment or service is authorized and supervised both by a physician as defined in this section and by OWCP.

§ 725.703 How is treatment authorized?

(a) Upon notification to a miner of such miner's entitlement to benefits, OWCP must provide the miner with a list of authorized treating physicians and medical facilities in the area of the miner's residence. The miner may select a physician from this list or may select another physician with approval of OWCP. Where emergency services are necessary and appropriate, authorization by OWCP is not required.

(b) OWCP may, on its own initiative, or at the request of a responsible operator, order a change of physicians or facilities, but only where it has been determined that the change is desirable or necessary in the best interest of the miner. The miner may change physicians or facilities subject to the approval of OWCP.

(c) If adequate treatment cannot be obtained in the area of the claimant's residence, OWCP may authorize the use of physicians or medical facilities outside such area as well as reimbursement for travel expenses and overnight accommodations.

§ 725.704 How are arrangements for medical care made?

(a) *Operator liability.* If an operator has been determined liable for the payment of benefits to a miner, OWCP will notify the operator or its insurance carrier of the names, addresses, and telephone numbers of the authorized providers of medical benefits chosen by an entitled miner, and require the operator or carrier to:

(1) Notify the miner and the providers chosen that the operator or carrier will be responsible for the cost of medical services provided to the miner on account of the miner's total disability due to pneumoconiosis;

(2) Designate a person or persons with decision-making authority with whom OWCP, the miner and authorized providers may communicate on matters involving medical benefits provided under this subpart and notify OWCP, the miner and providers of this designation;

(3) Make arrangements for the direct reimbursement of providers for their services.

(b) *Fund liability.* If there is no operator found liable for the payment of benefits, OWCP will make necessary arrangements to provide medical care to the miner, notify the miner and providers selected of the liability of the fund, designate a person or persons with whom the miner or provider may communicate on matters relating to medical care, and make arrangements for the direct reimbursement of the medical provider.

§ 725.705 Is prior authorization for medical services required?

(a) Except as provided in paragraph (b) of this section, medical services from an authorized provider which are payable under § 725.701 do not require prior approval of OWCP or the responsible operator.

(b) Except where emergency treatment is required, prior approval of OWCP or the responsible operator must be obtained before any hospitalization or surgery, or before ordering medical equipment where the purchase price exceeds $300. A request for approval of non-emergency hospitalization or surgery must be acted upon expeditiously, and approval or disapproval will be given by telephone if a written response cannot be given within 7 days following the request. No employee of the Department of Labor, other than a district director or the Chief, Medical Audit and Operations Section, DCMWC, is authorized to approve a request for hospitalization or surgery by telephone.

§ 725.706 What reports must a medical provider give to OWCP?

(a) Within 30 days following the first medical or surgical treatment provided under § 725.701, the provider must furnish to OWCP and the responsible operator or its insurance carrier, if any, a report of such treatment.

(b) In order to permit continuing supervision of the medical care provided to the miner with respect to the necessity, character and sufficiency of any medical care furnished or to be furnished, the provider, operator or carrier must submit such reports in addition to those required by paragraph (a) of this section as OWCP may from time to time require. Within the discretion of OWCP, payment may be refused to any medical provider who fails to submit any report required by this section.

§ 725.707 At what rate will fees for medical services and treatments be paid?

(a) All fees charged by providers for any medical service, treatment, drug or equipment authorized under this subpart will be paid at no more than the rate prevailing for the service, treatment, drug or equipment in the community in which the provider is located.

(b) When medical benefits are paid by the fund at OWCP's direction, either on an interim basis or because there is no liable operator, the prevailing community rate for various types of service will be determined as provided in §§ 725.708–725.711.

(c) The provisions of §§ 725.708–725.711 do not apply to charges for medical services or treatments furnished by medical facilities of the U.S. Public Health Service or the Departments of the Army, Navy, Air Force and Veterans Affairs.

(d) If the provisions of §§ 725.708–725.711 cannot be used to determine the prevailing community rate for a particular service or treatment or for a particular provider, OWCP may determine the prevailing community rate by reliance on other federal or state payment formulas or on other evidence, as appropriate.

(e) OWCP must review the payment formulas described in §§ 725.708–725.711 at least once a year, and may adjust, revise or replace any payment formula or its components when necessary or appropriate.

(f) The provisions of §§ 725.707–725.711 apply to all medical services or treatments rendered on or after the effective date of this rule.

§ 725.708 How are payments for professional medical services and medical equipment determined?

(a)(1) OWCP pays for professional medical services based on a fee schedule derived from the schedule maintained by the Centers for Medicare & Medicaid Services (CMS) for the payment of such services under the Medicare program (42 CFR part 414). The schedule OWCP utilizes consists of: An assignment of Relative Value Units (RVU) to procedures identified by Healthcare Common Procedure Coding System/Current Procedural Terminology (HCPCS/CPT) code, which represents the work (relative time and intensity of the service), the practice expense and the malpractice expense, as compared to other procedures of the same general class; an assignment of Geographic Practice Cost Index (GPCI) values, which represent the relative work, practice expense and malpractice expense relative to other localities throughout the country; and a monetary

value assignment (conversion factor) for one unit of value for each coded service.

(2) The maximum payment for professional medical services identified by a HCPCS/CPT code is calculated by multiplying the RVU values for the service by the GPCI values for such service in that area and multiplying the sum of these values by the conversion factor to arrive at a dollar amount assigned to one unit in that category of service.

(3) OWCP utilizes the RVUs published, and updated or revised from time to time, by CMS for all services for which CMS has made assignments. Where there are no RVUs assigned, OWCP may develop and assign any RVUs that OWCP considers appropriate. OWCP utilizes the GPCI for the locality as defined by CMS and as updated or revised by CMS from time to time. OWCP will devise conversion factors for professional medical services using OWCP's processing experience and internal data.

(b) Where a professional medical service is not covered by the fee schedule described in paragraph (a) of this section, OWCP may pay for the service based on other fee schedules or pricing formulas utilized by OWCP for professional medical services.

(c) OWCP pays for medical equipment identified by a HCPCS/CPT code based on fee schedules or other pricing formulas utilized by OWCP for such equipment.

§ 725.709 How are payments for prescription drugs determined?

(a)(1) OWCP pays for drugs prescribed by physicians by multiplying a percentage of the average wholesale price, or other baseline price as specified by OWCP, of the medication by the quantity or amount provided, plus a dispensing fee.

(2) All prescription medications identified by National Drug Code are assigned an average wholesale price representing the product's nationally recognized wholesale price as determined by surveys of manufacturers and wholesalers, or another baseline price designated by OWCP.

(3) OWCP may establish the dispensing fee.

(b) If the pricing formula described in paragraph (a) of this section is inapplicable, OWCP may make payment based on other pricing formulas utilized by OWCP for prescription medications.

(c) OWCP may, in its discretion, contract for or require the use of specific providers for certain medications. OWCP also may require the use of generic equivalents of prescribed medications where they are available.

§ 725.710 How are payments for outpatient medical services determined?

(a)(1) Except as provided in paragraphs (b) and (c) of this section, OWCP pays for outpatient medical services according to Ambulatory Payment Classifications (APCs) derived from the Outpatient Prospective Payment System (OPPS) devised by the Centers for Medicare & Medicaid Services (CMS) for the Medicare program (42 CFR part 419).

(2) For outpatient medical services paid under the OPPS, such services are assigned according to the APC prescribed by CMS for that service. Each payment is derived by multiplying the prospectively established scaled relative weight for the service's clinical APC by a conversion factor to arrive at a national unadjusted payment rate for the APC. The labor portion of the national unadjusted payment rate is further adjusted by the hospital wage index for the area where payment is being made. Additional adjustments are also made as required or needed.

(b) If a compensable service cannot be assigned or paid at the prevailing community rate under the OPPS, OWCP may pay for the service based on fee schedules or other pricing formulas utilized by OWCP for outpatient services.

(c) This section does not apply to services provided by ambulatory surgical centers.

§ 725.711 How are payments for inpatient medical services determined?

(a)(1) OWCP pays for inpatient medical services according to pre-determined rates derived from the Medicare Inpatient Prospective Payment System (IPPS) used by the Centers for Medicare & Medicaid Services (CMS) for the Medicare program (42 CFR part 412).

(2) Inpatient hospital discharges are classified into diagnosis-related groups (DRGs). Each DRG groups together clinically similar conditions that require comparable amounts of inpatient resources. For each DRG, an appropriate weighting factor is assigned that reflects the estimated relative cost of hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups.

(3) For each hospital discharge classified within a DRG, a payment amount for that discharge is determined by using the national weighting factor determined for that DRG, national standardized adjustments, and other factors which may vary by hospital, such as an adjustment for area wage levels. OWCP may also use other price adjustment factors as appropriate based on its processing experience and internal data.

(b) If an inpatient service cannot be classified by DRG, occurs at a facility excluded from the Medicare IPPS, or otherwise cannot be paid at the prevailing community rate under the pricing formula described in paragraph (a) of this section, OWCP may pay for the service based on fee schedules or other pricing formulas utilized by OWCP for inpatient services.

§ 725.712 When and how are fees reduced?

(a) A provider's designation of the code used to identify a billed service or treatment will be accepted if the code is consistent with the medical and other evidence, and the provider will be paid no more than the maximum allowable fee for that service or treatment. If the code is not consistent with the medical evidence or where no code is supplied, the bill will be returned to the provider for correction and resubmission or denied.

(b) If the charge submitted for a service or treatment supplied to a miner exceeds the maximum amount determined to be reasonable under this subpart, OWCP must pay the amount allowed by §§ 725.707–725.711 for that service and notify the provider in writing that payment was reduced for that service in accordance with those provisions.

(c) A provider or other party who disagrees with a fee determination may seek review of that determination as provided in this subpart (*see* § 725.718).

§ 725.713 If a fee is reduced, may a provider bill the claimant for the balance?

A provider whose fee for service is partially paid by OWCP as a result of the application of the provisions of §§ 725.707–725.711 or otherwise in accordance with this subpart may not request reimbursement from the miner for additional amounts.

§ 725.714 How do providers enroll with OWCP for authorizations and billing?

(a) All non-pharmacy providers seeking payment from the fund must enroll with OWCP or its designated bill processing agent to have access to the automated authorization system and to submit medical bills to OWCP.

(b) To enroll, the non-pharmacy provider must complete and submit a Form OWCP–1168 to the appropriate location noted on that form. By completing and submitting this form, providers certify that they satisfy all applicable Federal and State licensure and regulatory requirements that apply

to their specific provider or supplier type.

(c) The non-pharmacy provider must maintain documentary evidence indicating that it satisfies those requirements.

(d) The non-pharmacy provider must also notify OWCP immediately if any information provided to OWCP in the enrollment process changes.

(e) All pharmacy providers must obtain a National Council for Prescription Drug Programs number. Upon obtaining such number, they are automatically enrolled in OWCP's pharmacy billing system.

(f) After enrollment, a provider must submit all medical bills to OWCP through its bill processing portal or to the OWCP address specified for such purpose and must include the Provider Number/ID obtained through enrollment, or its National Provider Number (NPI) or any other identifying numbers required by OWCP.

§ 725.715 How do providers submit medical bills?

(a) A provider must itemize charges on Form OWCP–1500 or CMS–1500 (for professional services, equipment or drugs dispensed in the office), Form OWCP–04 or UB–04 (for hospitals), an electronic or paper-based bill that includes required data elements (for pharmacies) or other form as designated by OWCP, and submit the form promptly to OWCP.

(b) The provider must identify each medical service performed using the Current Procedural Terminology (CPT) code, the Healthcare Common Procedure Coding System (HCPCS) code, the National Drug Code (NDC) number, or the Revenue Center Code (RCC), as appropriate to the type of service. OWCP has discretion to determine which of these codes may be utilized in the billing process. OWCP also has the authority to create and supply codes for specific services or treatments. These OWCP-created codes will be issued to providers by OWCP as appropriate and may only be used as authorized by OWCP. A provider may not use an OWCP-created code for other types of medical examinations, services or treatments. (1) For professional medical services, the provider must list each diagnosed condition in order of priority and furnish the corresponding diagnostic code using the ''International Classification of Disease, 10th Edition, Clinical Modification'' (ICD–10–CM), or as revised.

(2) For prescription drugs or supplies, the provider must include the NDC assigned to the product, and such other information as OWCP may require.

(3) For outpatient medical services, the provider must use HCPCS codes and other coding schemes in accordance with the Outpatient Prospective Payment System.

(4) For inpatient medical services, the provider must include admission and discharge summaries and an itemized statement of the charges.

(c)(1) By submitting a bill or accepting payment, the provider signifies that the service for which reimbursement is sought was performed as described, necessary, appropriate, and properly billed in accordance with accepted industry standards. For example, accepted industry standards preclude upcoding billed services for extended medical appointments when the miner actually had a brief routine appointment, or charging for the services of a professional when a paraprofessional or aide performed the service; industry standards prohibit unbundling services to charge separately for services that should be billed as a single charge.

(2) The provider agrees to comply with all regulations set forth in this subpart concerning the provision of medical services or treatments and/or the process for seeking reimbursement for medical services and treatments, including the limitation imposed on the amount to be paid.

§ 725.716 How should a miner prepare and submit requests for reimbursement for covered medical expenses and transportation costs?

(a) If a miner has paid bills for a medical service or treatment covered under § 725.701 and seeks reimbursement for those expenses, he or she may submit a request for reimbursement on Form OWCP–915, together with an itemized bill. The reimbursement request must be accompanied by evidence that the provider received payment for the service from the miner and a statement of the amount paid. Acceptable evidence that payment was received includes, but is not limited to, a copy of the miner's canceled check (both front and back) or a copy of the miner's credit card receipt.

(b) OWCP may waive the requirements of paragraph (a) of this section if extensive delays in the filing or the adjudication of a claim make it unusually difficult for the miner to obtain the required information.

(c) Reimbursements for covered medical services paid by a miner generally will be no greater than the maximum allowable charge for such service as determined under §§ 725.707–725.711.

(d) A miner will be only partially reimbursed for a covered medical service if the amount he or she paid to a provider for the service exceeds the maximum charge allowable. If this happens, OWCP will advise the miner of the maximum allowable charge for the service in question and of his or her responsibility to ask the provider to refund to the miner, or credit to the miner's account, the amount he or she paid which exceeds the maximum allowable charge.

(e) If the provider does not refund to the miner or credit to his or her account the amount of money paid in excess of the charge allowed by OWCP, the miner should submit documentation to OWCP of the attempt to obtain such refund or credit. OWCP may make reasonable reimbursement to the miner after reviewing the facts and circumstances of the case.

(f) If a miner has paid transportation costs or other incidental expenses related to covered medical services under this part, the miner may submit a request for reimbursement on Form OWCP–957 or OWCP–915, together with proof of payment.

§ 725.717 What are the time limitations for requesting payment or reimbursement for medical services or treatments?

OWCP will pay providers and reimburse miners promptly for all bills received on an approved form and in a timely manner. However, absent good cause, no bill will be paid for expenses incurred if the bill is submitted more than one year beyond the end of the calendar year in which the expense was incurred or the service or supply was provided, or more than one year beyond the end of the calendar year in which the miner's eligibility for benefits is finally adjudicated, whichever is later.

§ 725.718 How are disputes concerning medical benefits resolved?

(a) If a dispute develops concerning medical services or treatments or their payment under this part, OWCP must attempt to informally resolve the dispute. OWCP may, on its own initiative or at the request of the responsible operator or its insurance carrier, order the claimant to submit to an examination by a physician selected by OWCP.

(b) If a dispute cannot be resolved informally, OWCP will refer the case to the Office of Administrative Law Judges for a hearing in accordance with this part. Any such hearing concerning authorization of medical services or treatments must be scheduled at the earliest possible time and must take precedence over all other hearing

requests except for other requests under this section and as provided by § 727.405 of this subchapter (*see* § 725.4(d)). During the pendency of such adjudication, OWCP may order the payment of medical benefits prior to final adjudication under the same conditions applicable to benefits awarded under § 725.522.

(c) In the development or adjudication of a dispute over medical benefits, the adjudication officer is authorized to take whatever action may be necessary to protect the health of a totally disabled miner.

(d) Any interested medical provider may, if appropriate, be made a party to a dispute under this subpart.

§ 725.719 What is the objective of vocational rehabilitation?

The objective of vocational rehabilitation is the return of a miner who is totally disabled by pneumoconiosis to gainful employment commensurate with such miner's physical impairment. This objective may be achieved through a program of re-evaluation and redirection of the miner's abilities, or retraining in another occupation, and selective job placement assistance.

§ 725.720 How does a miner request vocational rehabilitation assistance?

Each miner who has been determined entitled to receive benefits under part C of title IV of the Act must be informed by OWCP of the availability and advisability of vocational rehabilitation services. If such miner chooses to avail himself or herself of vocational rehabilitation, his or her request will be processed and referred by OWCP vocational rehabilitation advisors pursuant to the provisions of §§ 702.501 through 702.508 of this chapter as is appropriate.

Dated: December 21, 2016.

Leonard J. Howie III,

Director, Office of Workers' Compensation Programs.

[FR Doc. 2016–31382 Filed 1–3–17; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 655

[FHWA Docket No. FHWA–2009–0139]

RIN 2125–AF34

National Standards for Traffic Control Devices; the Manual on Uniform Traffic Control Devices for Streets and Highways; Maintaining Pavement Marking Retroreflectivity

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Supplemental notice of proposed amendments (SNPA); request for comments.

SUMMARY: The Manual on Uniform Traffic Control Devices (MUTCD) is incorporated in FHWA regulations and recognized as the national standard for traffic control devices used on all streets, highways, bikeways, and private roads open to public travel. The FHWA proposed in an earlier notice of proposed amendment (NPA) to amend the MUTCD to include standards, guidance, options, and supporting information related to maintaining minimum levels of retroreflectivity for pavement markings. Based on the review and analysis of the numerous comments received in response to the NPA, FHWA has substantially revised the proposed amendments to the MUTCD and, as a result, is issuing this SNPA.

DATES: Comments must be received on or before May 4, 2017. Late-filed comments will be considered to the extent practicable.

ADDRESSES: Mail or hand deliver comments to the U.S. Department of Transportation, Dockets Management Facility, 1200 New Jersey Avenue SE., Washington, DC 20590, or submit electronically at *http://www.regulations.gov.* All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or may print the acknowledgment page that appears after submitting comments electronically. In accordance with the Administrative Procedure Act, DOT solicits comments from the public to better inform its rulemaking process. The DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* In order to facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

FOR FURTHER INFORMATION CONTACT: Ms. Cathy Satterfield, Office of Safety, *cathy.satterfield@dot.gov,* (708) 283–3552; or Mr. William Winne, Office of the Chief Counsel, *william.winne@dot.gov,* (202) 366–1397, Federal Highway Administration, 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

You may submit or access all comments received by the DOT online through *http://www.regulations.gov.* Electronic submission and retrieval help and guidelines are available on the Web site. It is available 24 hours each day, 365 days this year. Please follow the instructions. An electronic copy of this document may also be downloaded from the Office of the Federal Register's home page at: *http://www.ofr.gov* and the Government Publishing Office's Web page at: *http://www.gpo.gov* and is available for inspection and copying, as prescribed in 49 CFR part 7, at the FHWA Office of Transportation Operations (HOTO–1), 1200 New Jersey Avenue SE., Washington, DC 20590. Furthermore, the text of the proposed revision is available on the MUTCD Internet Web site at *http://mutcd.fhwa.dot.gov.* The proposed additions are shown in blue text and proposed deletions are shown as red strikeout text. The complete current 2009 edition of the MUTCD is also available on the same Internet Web site. A copy of the proposed revision is included at the conclusion of the preamble in this document and is also available as a separate document under the docket number noted above at *http://www.regulations.gov.*