

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
19-Jul-18	NE	Norfolk	Norfolk Rgnl/Karl Stefan Memorial Fld.	8/8711	5/21/18	VOR Rwy 19, Amdt 8
19-Jul-18	MO	St Louis	Creve Coeur	8/9092	5/21/18	Takeoff Minimums and Obstacle DP, Amdt 2
19-Jul-18	MA	Beverly	Beverly Rgnl	8/9547	5/21/18	RNAV (GPS) Rwy 27, Amdt 1A
19-Jul-18	SC	Aiken	Aiken Muni	8/9658	5/21/18	ILS OR LOC/DME Rwy 7, Orig-C
19-Jul-18	SC	Aiken	Aiken Muni	8/9659	5/21/18	NDB Rwy 25, Amdt 10C
19-Jul-18	SC	Aiken	Aiken Muni	8/9660	5/21/18	RNAV (GPS) Rwy 25, Amdt 1C
19-Jul-18	SC	Aiken	Aiken Muni	8/9661	5/21/18	RNAV (GPS) Rwy 7, Amdt 1C
19-Jul-18	SC	Aiken	Aiken Muni	8/9662	5/21/18	VOR/DME-A, Amdt 1A

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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: Final rule.

SUMMARY: This final rule revises the regulations under the Black Lung Benefits Act (BLBA or Act) governing the payment of medical benefits and maintains the level of care available to miners. The final rule establishes methods for determining the amounts that the Black Lung Disability Trust Fund (Trust Fund) will pay for covered medical services and treatments provided to entitled miners. The Department based the rule on payment formulas that the Centers for Medicare & Medicaid Services (CMS) uses to determine payments under the Medicare program, which are similar to the formulas used by other programs that the Office of Workers' Compensation Programs (OWCP) administers. The Department is adopting these payment formulas for the black lung program because they more accurately reflect prevailing community rates for authorized treatments and services than do the internally-derived payment formulas that OWCP currently uses. In addition, the final rule eliminates two obsolete provisions.

DATES:

Effective Date: This rule is effective August 31, 2018.

Applicability Dates: Sections 725.708(d), 725.709, and 725.711 apply to medical equipment, prescription drugs, and inpatient medical services provided or rendered after August 31,

2018. Sections 725.708(a) and (b) and 725.710 apply to professional medical services and outpatient medical services rendered after November 30, 2019.

FOR FURTHER INFORMATION CONTACT: Michael A. Chance, Director, Division of Coal Mine Workers' Compensation, Office of Workers' Compensation Programs, U.S. Department of Labor, 200 Constitution Avenue NW, Suite N-3520, Washington, DC 20210. Telephone: 1-800-347-2502. This is a toll-free number. TTY/TDD callers may dial toll-free 1-800-877-8339 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). 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. Those medical benefits entitle a miner to medical, surgical, and other treatment—including hospital services, medicine, equipment, and supplies—for his or her pneumoconiosis and related disability. 20 CFR 725.701(b). The rules governing the payment of medical benefits are contained in 20 CFR part 725, subpart J.

Benefits are paid by either a "responsible" coal mine operator (or its insurance carrier), or the Trust Fund. *Director, OWCP v. Bivens*, 757 F.2d 781, 783 (6th Cir. 1985); *see* 20 CFR 725.495 (criteria for determining a responsible operator). 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 (*see* 20 CFR 725.701(b)); (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 an effective 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 an effective award. 20 CFR 725.601.

Although the current regulations provide that medical services and supplies be paid at the rate prevailing in the community where the physician, medical facility or supplier is located, they do not address how the prevailing community rate should be determined. *See* 20 CFR 725.706(c). OWCP currently bases Trust Fund payments for professional medical services, medical equipment, and inpatient and outpatient medical services and treatments on internally-derived payment formulas. For prescription medications, OWCP uses a payment formula similar to that employed by the three other workers' compensation programs that it administers.

On January 4, 2017, the Department issued a Notice of Proposed Rulemaking (NPRM), proposing a revised Subpart J. 82 FR 739-770 (Jan. 4, 2017). Specifically, the Department proposed to base Trust Fund payments for all medical services and treatments rendered on or after the effective date of the rule on payment formulas derived from those used by CMS under the Medicare program. *Id.* at 740. The proposed payment formulas were similar to those used by other OWCP programs, but were tailored to the specific geography, medical conditions, and needs of black lung program stakeholders. *See id.* at 767 (proposed § 725.707).

The Department chose these payment formulas for several reasons. The proposed formulas more accurately reflected prevailing community rates for authorized treatments and services than did OWCP's internally-derived formulas. *Id.* at 740. In addition,

because responsible operators and their insurance carriers utilize payment formulas or fee schedules that are substantially similar to the proposed payment formulas, use of such formulas would more likely lead operators to reimburse fully the Trust Fund for the payments the Trust Fund makes on an interim basis. *Id.* Thus, the proposed rule would 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. The rule would also ensure more consistent payment policies across all of the programs administered by OWCP. *Id.*

The public comment period closed on March 6, 2017. The Department has fully evaluated these comments and has determined that proceeding with a final rule is in the best interests of the stakeholders and the program's administration.

II. 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 BLBA. The Secretary is also explicitly empowered to promulgate regulations addressing medical fees and charges, including determining the prevailing community rate. 33 U.S.C. 907(g), as incorporated by 30 U.S.C. 932(a).

III. Discussion of Significant Comments

The Department received eleven comments on the proposed regulations. Most of these comments focus on a few substantive issues. Some commenters generally supported OWCP's efforts to modernize the medical payment formulas and no commenters expressed overall objections to the promulgation of these rules. Several commenters applauded the technical changes made to several rules to simplify and clarify the language, such as replacing the term "Office" with "OWCP." No negative comments were received on the following revised or new regulations: §§ 725.308, 725.701, 725.702, 725.703, 725.704, 725.706, 725.708, 725.711, 725.712, and 725.714–725.720. Thus, the Department is promulgating these regulations as proposed. The Department received one negative comment on the substantive provisions of § 725.705 (titled "Is prior authorization for medical services required?"), but the Department proposed only technical changes to this rule and did not open it for substantive

comment. Thus, the Department is promulgating § 725.705 as proposed.

In addition to comments received on specific sections of the proposed rules (discussed below in the Section-by-Section Explanation), a few commenters offered more general comments. One suggested that the medical bill payment rules should contain provisions allowing the Director to sue operators who fail to properly reimburse the Trust Fund for medical benefit payments made on their behalf. The BLBA incorporates various provisions of the and Harbor Workers' Compensation Act, 33 U.S.C. 918(a), 921(d), as incorporated by 30 U.S.C. 932(a), that already provide the Department with authority to undertake such suits. *See generally* 20 CFR 725.601–725.605 (regulations implementing enforcement of liability against operators). The implementing regulations clarify that these enforcement tools may be used when an operator fails to reimburse the Trust Fund for medical benefits. 20 CFR 725.602(a). Thus, the Department does not believe that any additional authority is necessary.

Another commenter requested that the Department specify when OWCP will exercise its discretion to modify or change payment formulas or parts thereof as provided in several proposed regulations. *See proposed* §§ 725.707, 725.708, 725.709, 725.710, 725.711. The vast majority of payments for medical services and treatments will be determined under the payment formulas set out in these regulations. The provisions giving OWCP discretion to modify or change payment formulas are intended to allow OWCP to respond quickly to unique or novel medical, technological, or financial circumstances that arise in implementing the payment formulas both initially and over time. The Department cannot predict when that might occur, and thus cannot specify when OWCP would take such discretionary actions.

Finally, the Department has determined that a two-phase implementation of this rule will be more efficient and cost-effective, allow sufficient time to update and improve its computer processes, and result in less disruption, than implementing the entire rule at once. Except for §§ 725.708(a) and (b) and 725.710, all provisions of this rule (including the payment formulas for medical equipment, prescription drugs and inpatient medical services) will apply to services and treatments rendered after the effective date of the rule, August 31, 2018. The Department can apply these regulations immediately because they

either codify existing practices or require easily implemented modifications to current payment processes. The provisions of §§ 725.708(a) and (b) and 725.710 (governing the payment of professional medical services and outpatient medical services) will apply to services and treatments rendered after November 30, 2019. Both regulations would require extensive modifications to the existing computer processes for full implementation. The Department is currently transitioning to a new computer system and will realize cost-savings by building the new payment methodologies into that system rather than modifying the existing one. The Department has revised three provisions (§§ 725.707, 725.708 and 725.710) to reflect the two-phase implementation. The changes to each provision are discussed in the Section-by-Section Explanation.

Section-by-Section Explanation

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

(a) Section 725.707 is a new provision that sets out general rules governing the payment of compensable medical bills by the Trust Fund. It provides that the Trust Fund will pay no more than the prevailing community rate for medical services, treatments, drugs or equipment, and that the prevailing community rate for various types of treatments and services will generally be determined under the provisions of §§ 725.708–725.711. Where the provisions of §§ 725.708–725.711 cannot be used to determine the prevailing community rate, the rule permits OWCP to determine the prevailing community rate based on other payment formulas or evidence. This section also 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.

(b) Four commenters express concern that the proposed payment formulas may have a negative impact on miners' access to care. This concern stems from the fact that reduced payments will result in some circumstances under the proposed rules. One commenter believes that rural Appalachia would feel the greatest impact.

The Department agrees that maintaining miners' access to care is of paramount importance in implementing the payment formulas for various services and treatments. In fact, OWCP made access to care a primary

consideration during the development of the proposed rules. Although the text of proposed § 725.707 does not directly address impact on access to care, the NPRM's preamble makes repeated reference to this concern and expresses OWCP's intent to continually review the payment formulas to ensure that they do not adversely impact access to care. In particular, the rule requires OWCP to review the payment formulas at least annually and revise them if needed, § 725.707(e), and the preamble to this provision makes clear that it is intended to allow OWCP to quickly make changes to the formulas if they "are adversely impacting miners' access to care, or are otherwise not appropriate." 82 FR 742; *see also id.* at 740, 746, 748, 749, 752. These changes could include adjustments for particular geographic areas.

Nonetheless, the commenters' general concern is important and the Department agrees that maintaining access to care should be codified in the regulation. Thus, the Department has revised § 725.707(e) in the final rule to specifically require that OWCP consider and ensure miners' access to care in its annual review of the payment formulas in §§ 725.708–725.711. The Department believes that this clarification of its intent will prevent miners' access to care from being negatively affected by the new payment formulas.

(c) Finally, the Department has revised § 725.707(f) to reflect the phased implementation of this rule. This paragraph now provides that the provisions of the rule apply to all medical services or treatments rendered after the effective date of the rule (August 31, 2018), except as otherwise noted in the rule. A different application date for the payment formulas for professional medical services and outpatient medical services is now provided in §§ 725.708 and 725.710. These regulations apply to services and treatments rendered after November 30, 2019.

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

Section 725.708 is a new provision governing payment for professional medical services and medical equipment. No comments were received on this provision. The Department, however, has revised the provision to reflect the phased implementation of this rule. The Department has added a new paragraph (c), which states that the provisions of paragraphs (a) and (b) apply to professional medical services rendered after November 30, 2019. This later applicability date does not apply to

payments for medical equipment, which are instead governed by the general applicability date in § 725.707(f). The Department has also renumbered paragraph (c) of the proposed rule (dealing with payment for medical equipment) as paragraph (d).

20 CFR 725.709 How are payments for prescription drugs determined?

(a) Section 725.709 is a new provision governing payment for compensable prescription drugs. The regulation codifies existing policy and does not change current payment practice. It is also consistent with the payment practices of the other programs that OWCP administers. Section 725.709 generally provides for payment for prescribed medication at a percentage of the national average wholesale price (or another baseline price designated by OWCP) for a particular medication, plus a flat-rate dispensing fee. It also provides that OWCP may, in its discretion, require the use of specific providers for certain medications.

(b) One commenter asks OWCP to specify when miners will be required to use specific providers for certain medications. The comment also requests clarification of whether OWCP will directly negotiate with drug manufacturers, presumably with respect to the cost of medications.

The Department declines to revise the regulation in response to this comment. OWCP does not currently require the use of specific providers for any medication under the BLBA. The provision in § 725.709 gives OWCP the option of doing so in the future if it would be in the best interests of both the agency and the program's stakeholders. It is not possible to predict or specify when OWCP might use this option. OWCP, however, would advise miners and providers before any such requirement were implemented. With respect to negotiating drug prices with drug manufacturers, OWCP is a third-party payer and does not directly purchase medications or distribute them to miners.

20 CFR 725.710 How are payments for outpatient medical services determined?

(a) Section 725.710 is a new provision governing payment for compensable outpatient medical services. As proposed, it provides that, where appropriate, OWCP will utilize the Outpatient Prospective Payment System (OPPS) devised by CMS for the Medicare program. The proposed rule also states that where outpatient services cannot be assigned or priced appropriately under the OPPS system, payment will be based on fee schedules

and other pricing formulas utilized by OWCP.

(b) One commenter requested clarification of the proposed rules with respect to payments that would be made to Critical Access Hospitals (CAHs) for outpatient hospital services. CAHs are small hospitals (generally 25 beds or less) in isolated rural areas (35 miles or more from another hospital, 15 or more miles in mountainous areas) that provide emergency services and offer short-term (generally less than 96 hours) inpatient services. *See* 42 U.S.C. 1395i–4, 1395x; 42 CFR 485.601–485.647. Medicare uses different payment formulas for services and treatments at CAHs than those used to pay other hospitals. In particular, Medicare excludes CAHs from both its inpatient and outpatient prospective payment systems. The commenter notes that under proposed § 725.711 (inpatient hospital services), services at facilities (such as CAHs) that are excluded from Medicare's Inpatient Prospective Payment System will be paid under fee schedules or other pricing formulas. The commenter requests clarification of whether a similar policy will be applied for outpatient services, given that CAHs are excluded from Medicare's OPSS. The commenter also requests that the Department consider undertaking additional economic analysis of applying the OPSS to CAHs.

During the development of the proposed rules, OWCP determined that CAHs would be exempt from the new outpatient and inpatient prospective payment systems generally applicable to other hospitals, as CAHs are excluded from Medicare's prospective payment systems. While this determination was codified in the inpatient regulation (§ 725.711), it was omitted from the outpatient regulation (§ 725.710). The Department agrees with the commenter that § 725.710 should be revised to clarify that the outpatient payment formula described in paragraph (a) of the provision does not apply to services at facilities (such as CAHs) that are excluded from Medicare's OPSS. Thus, the Department has revised § 725.710(b) in the final rule to provide that services at such facilities will be paid "based on fee schedules or other pricing formulas utilized by OWCP for outpatient services." This revision mirrors the inpatient rule and is consistent with Medicare's exclusion of CAHs from its OPSS. Since the Department has revised § 725.710 to exclude CAHs from the general payment formula, there is no need to analyze the economic impact of that formula on CAHs.

(c) Finally, the Department has revised § 725.710 to reflect the phased

implementation of this rule. The Department has added a new paragraph (d), which states that the provisions of this section apply to outpatient medical services rendered after November 30, 2019.

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

(a) Section 725.713 is a new provision addressing reductions in requested fees. The proposed regulation provides that if a billed fee has been reduced (*i.e.*, only paid in part) in accordance with the provisions of Subpart J, providers may not recover any additional amount from the miner. It, thus, prohibits 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.

(b) Three commenters request that the proposed rule be extended to prohibit balance billing where OWCP makes *no* payment for a treatment or service, as well as where the agency makes partial payment. The commenters also request that the principle that disabled miners and their families should never have to make any payments for covered treatments and services under the BLBA be explicitly stated in the rule.

It is OWCP’s longstanding position and practice that miners should not be subject to balance billing for treatments and services that are covered under these regulations. To make this clear, the Department has revised § 725.713 in the final rule to explicitly state that providers cannot bill miners for, and that miners are not required to pay, any remaining balance for any treatments or services provided pursuant to this subpart (*i.e.*, that are for a miner’s disabling pneumoconiosis) after OWCP makes partial payment for such treatments and services. *See also* discussion at § 725.717 (noting similar revision). OWCP, however, has no legal authority to pay bills for services or treatments not covered under the BLBA (*i.e.*, that are unrelated to a miner’s disabling pneumoconiosis), or to regulate the payment and collection of such bills. Thus, the Department declines to extend § 725.713 to situations where OWCP denies payment entirely for noncovered services or treatments.

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

(a) Section 725.717 is a new provision setting time limits on the submission of bills by providers and reimbursement

requests by miners. Bills and reimbursement requests must be submitted within one year of either (1) the end of the calendar year in which the service or treatment was provided or (2) the end of the calendar year in which the miner’s entitlement to benefits was finally adjudicated, whichever is later. OWCP may waive these time limits for good cause shown.

(b) As discussed under § 725.713, several commenters asked the Department to clarify in the regulations that miners are not required to pay for covered treatments and services. The Department agrees with the commenters’ point. Thus, in addition to revising § 725.713, the Department has revised the title and text of § 725.717 to clarify that a provider may not seek reimbursement from a miner when OWCP denies an otherwise-compensable bill due to late submission.

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 current, valid OMB Control Number. In addition, no person may generally be subject to penalty for failing to comply with an information collection that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Although the medical benefit payment rules in Subpart J contain collections of information within the meaning of the PRA (*see* §§ 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); and 1240–0044 (OWCP–1500 Health Insurance Claim Form). The requirements for completion of the forms and the information collected on the forms do not change under this rule.

Since no changes are being made to the collections, the overall burdens imposed by them also 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 submitted a series of Information Collection Requests (ICRs) to OMB for approval concurrent with the NPRM to update the information collections to reflect this rulemaking and provide interested parties a specific opportunity to comment under the PRA. The NPRM specifically invited comments regarding the information collection and notified the public of their opportunity to file such comments with both OMB and the Department. 82 FR 742. On March 6, 2017, OMB concluded its review of the ICRs by asking the Department to submit updated ICRs at the final rule stage after considering any public comments regarding the information collection requirements in the rule. While the Department received comments on the substance of the proposed rule, which are addressed in the Section-by-Section Explanation above, it received no comments about the information collection burdens.

The Department submitted updated ICRs to OMB for the information collections in this final rule. *See* ICR Reference Numbers 1240–0007: 201805–1240–0006; 1240–0019: 201805–1240–0005; 1240–0021: 201805–1240–0004; 1240–0037: 201805–1240–0003; and 1240–0044: 201805–1240–0002. A copy of these requests (including supporting documentation) may be obtained free of charge from the *Reginfo.gov* website at www.Reginfo.gov or by contacting Michael A. Chance, Director, Division of Coal Mine Workers’ Compensation, Office of Workers’ Compensation Programs, U.S. Department of Labor, 200 Constitution Avenue NW, Suite N–3464, Washington, DC 20210. Telephone: (202) 693–0978 (this is not a toll-free number). TTY/TDD callers may dial toll-free 1–800–877–8339. Concurrent with its approval of this rule, OMB also approved the updated ICRs.

The information collections in this rule are 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 (OWCP–915).

OMB Control Number: 1240–0007.

Total Estimated Number of

Responses: 34,564.

Total Estimated Annual Time Burden: 5,738 hours.

Total Estimated Annual Other Costs Burden: \$59,450.

2. *Title of Collection:* Uniform Billing Form (OWCP–04).

OMB Control Number: 1240–0019.

Total Estimated Number of

Responses: 259,865.
Total Estimated Annual Time Burden: 29,466 hours.

Total Estimated Annual Other Costs Burden: \$0.

3. *Title of Collection:* Provider Enrollment Form (OWCP–1168).

OMB Control Number: 1240–0021.

Total Estimated Number of

Responses: 64,325.
Total Estimated Annual Time Burden: 8,555 hours.

Total Estimated Annual Other Costs Burden: \$33,449.

4. *Title of Collection:* Medical Travel Refund Request (OWCP–957).

OMB Control Number: 1240–0037.

Total Estimated Number of

Responses: 333,528.
Total Estimated Annual Time Burden: 55,366 hours.

Total Estimated Annual Other Costs Burden: \$173,435.

5. *Title of Collection:* Health Insurance Claim Form (OWCP–1500).

OMB Control Number: 1240–0044.

Total Estimated Number of

Responses: 3,381,232.
Total Estimated Annual Time Burden: 321,455 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 costs and benefits of available regulatory alternatives 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, of harmonizing rules, and of 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 final rule with these

principles in mind and has determined that the regulated community will benefit from this regulation.

The Department addressed these issues in the NPRM. 82 FR 745–752. The Department comprehensively analyzed the potential economic impact of the new payment formulas and determined that they would not have a significant impact on either the economy as a whole or on firms that provide black lung-related health care to entitled miners. 82 FR 745–751. Comparing Trust Fund medical benefit payments for Fiscal Year 2014 with payment amounts that would be made under the proposed regulations for the same services, the Department estimated an aggregate \$3,154,297 annual reduction in Trust Fund payments under the proposed payment formulas. 82 FR 751. Further analysis revealed that even for negatively affected providers, the proposed rule would not have significant impact on individual firms. *Id.*

The Department also noted the rule’s multiple advantages that serve the interests of stakeholders. 82 FR 752. The proposed formulas would bring Trust Fund payments in line with industry standards, help protect the Trust Fund from inaccurate and excessive payments, ease recouping of medical benefits paid by the Trust Fund on a liable operator’s behalf, and conserve the Trust Fund’s limited resources. *Id.* Additionally, the new formulas would decrease administrative costs, reduce disparities in provider reimbursements, shorten the time period providers must wait for reimbursement, and provide all stakeholders with greater clarity and certainty regarding the black lung medical benefit payment process. *Id.*

The Department received one comment suggesting that the economic analysis in the NPRM improperly focused solely on the nation-wide impacts of the proposed rules. This is incorrect. In addition to considering the overall impact of the proposed rules, the analysis addressed the impact of the proposed payment formulas on a state-by-state basis. *See* 82 FR 746–751.

The same commenter takes issue with a statement in the NPRM’s economic analysis that any decline in the number of entitled claimants may result in a decline in payments by the Trust Fund, even apart from any change in payments resulting from the new payment formulas. *See* 82 FR 751. The commenter suggests that claims filed by miners with complicated pneumoconiosis, a more serious form of the disease, are in fact increasing in certain areas. The Department did not mean to suggest that miners would be

less likely to contract pneumoconiosis in the future or that the number of claims filed could not fluctuate from year to year. Rather, the Department was simply noting that there had been a long-term decline in both the number of beneficiaries covered, and medical benefit payments made, by the Trust Fund. *See id.*, n.17.

The Department received no other comments calling its cost-benefit analysis into question. Thus, the Department continues to believe that the cost savings and other benefits of this rule support its promulgation.

The Office of Information and Regulatory Affairs of the Office of Management and Budget has determined that this rule is a “significant regulatory action” under section 3(f)(4) of Executive Order 12866 and has reviewed it.

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.*, and Executive Order 13272 require agencies to review proposed and final rules to assess their impact on small entities. The agency 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 an initial regulatory flexibility analysis as described in the RFA. *Id.* The RFA also requires agencies to prepare a final regulatory flexibility analysis when promulgating a final rule. 5 U.S.C. 604. However, the RFA does not require a regulatory flexibility analysis if the agency certifies that the proposed or final rule will not have a significant economic impact on a substantial number of small entities and provides the factual basis for the certification. 5 U.S.C. 605. The Department has determined that a final regulatory flexibility analysis is not required for this rulemaking.

The Department conducted an initial regulatory flexibility analysis to aid understanding of the impact of the proposed rule and invited comments on all aspects of the costs and benefits of the proposed rule, with particular attention to the effects of the rule on small entities. *See* 82 FR 752–765. To determine whether the rule would have a significant impact on a small entity,

the Department used as its standard whether the rule would impose costs that equal or exceed 3% or more of the entity's annual revenue. 82 FR 752. Applying this standard, the Department considered whether the rule would significantly impact 15% or more of the small entities in the relevant industry. 82 FR 752–53. The Department separately examined the rule's impact on small entities of each provider type (non-hospital health care services providers, hospitals providing outpatient services, and hospitals providing inpatient services) affected by the rule. 82 FR 753–764. The Department estimated that the rule will not have a significant impact on any small entity providing non-hospital health care services. 82 FR 759. The Department estimated that one small hospital entity providing outpatient services and two providing inpatient services will be significantly impacted, but these entities do not constitute a substantial number of the total number of negatively affected small hospitals providing either outpatient or inpatient services. 82 FR 761, 763. The Department noted that its analysis likely overstated the impact of the rule on negatively affected small entities. 82 FR 765. The Department therefore concluded that the rule, if adopted, would not have a significant impact on a substantial number of small entities. *Id.*

No comments were received that raise a significant issue regarding the initial regulatory flexibility analysis or that provide a basis for departing from the conclusion reached in the analysis. Significantly, with the exception of CAHs, no commenter or interested small business brought forth any information that contradicts the Department's assumptions or conclusions in the initial regulatory flexibility analysis, despite the Department's specific request for comments about adverse effects on small businesses. And the Department's determination, as explained in the Section-by-Section Explanation above, to exclude CAHs from the new payment formulas renders the request to analyze the impact of those formulas on CAHs moot.

Based on these facts, the Department certifies for the purposes of 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. Accordingly, it has not prepared a final regulatory impact analysis. The Department will provide the Chief Counsel for Advocacy of the Small Business Administration with a copy of this certification. See 5 U.S.C. 605.

VII. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

This final rule is not subject to the requirements of Executive Order 13771 because this final rule addresses transfer costs and does not impose any new requirements apart from the transfers. OMB's interim guidance on E.O. 13771 (Para II, Q2) (February 2, 2017) and OMB additional guidance on E.O. 13771 (Para III, Q13) (April 5, 2017); *see also* 82 FR 746, 748–49 (recognizing rules as implicating transfer costs).

VIII. 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.

IX. Executive Order 13132 (Federalism)

The Department has reviewed this rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have “federalism implications.” The 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.” *Id.*

X. Executive Order 12988 (Civil Justice Reform)

This 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.

XI. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a report, which includes a copy of the rule, to each House of Congress and to the Comptroller General of the United States. OWCP will report this rule's promulgation to each House of Congress and the Comptroller General

simultaneously with publication of the rule in the **Federal Register**. The report will state that the rule is not a “major rule” as defined by 5 U.S.C. 804(2).

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 amends 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 redesignated paragraph (b) “However, except as provided in paragraph (b) of this section, the” and add in its place “The”.

■ 3. In part 725, revise subpart J to read 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 covered 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) of this subchapter.

(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 to ensure miners' access to care or for other reasons.

(f) Except as otherwise provided in this subpart, the provisions of §§ 725.707–725.711 apply to all medical services and treatments rendered after August 31, 2018.

§ 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) Paragraphs (a) and (b) of this section apply to professional medical services rendered after November 30, 2019.

(d) 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 or occurs at a facility excluded from the Medicare 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.

(d) This section applies to outpatient medical services rendered after November 30, 2019.

§ 725.711 How are payments for inpatient medical services determined?

(a)(1) OWCP pays for inpatient medical services according to predetermined 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?

Where a provider submits a bill to OWCP and OWCP has reduced the provider's fee, the miner is not responsible for any additional payment for services or treatments covered under this subpart. Thus, 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 covered 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. A provider may not request reimbursement from a miner for a bill denied by OWCP due to late submission of the bill by the provider.

§ 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: June 5, 2018.

Julia K. Hearthway,

Director, Office of Workers' Compensation Programs.

[FR Doc. 2018-12418 Filed 6-13-18; 8:45 am]

BILLING CODE 4510-CR-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA-2018-N-1928]

Medical Devices; Immunology and Microbiology Devices; Classification of the Brain Trauma Assessment Test

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the brain trauma assessment test into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the brain trauma assessment test's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective June 14, 2018. The classification was applicable on February 14, 2018.

FOR FURTHER INFORMATION CONTACT: Erin Cutts, Center for Devices and Radiological Health, Food and Drug