U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

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May 29, 2018

The Honorable Orrin G. Hatch
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Greg Walden
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Kevin Brady
Chairman
The Honorable Richard Neal
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare and Medicaid Services: Medicare Program; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) entitled "Medicare Program; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas" (RIN: 0938-AT21). We received the rule on May 10, 2018. It was published in the *Federal Register* as an interim final rule with comment period on May 11, 2018. 83 Fed. Reg. 21,912. The effective date is June 1, 2018.

The interim final rule with comment period makes technical amendments to the regulation to reflect the extension of the transition period from June 30, 2016, to December 31, 2016, that was mandated by the 21st Century Cures Act for phasing in fee schedule adjustments for certain durable medical equipment (DME) and enteral nutrition paid in areas not subject to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). In addition, this interim final rule with comment period amends the regulation to resume the transition period's blended fee schedule rates for items furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and United States territories) not subject

to the CBP from June 1, 2018, through December 31, 2018. This interim final rule with comment period also makes technical amendments to existing regulations for DMEPOS items and services to reflect the exclusion of infusion drugs used with DME from the DMEPOS CBP.

The Congressional Review Act (CRA) requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). This interim final rule has a stated effective date of June 1, 2018. We received the interim final rule on May 10, 2018, and it was published in the *Federal Register* on May 11, 2017. 83 Fed. Reg. 21,912. Therefore, this interim final rule does not have a 60-day delay in effective date.

However, any rule which an agency for good cause finds "that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, may take effect at such time as the agency determines." 5 U.S.C. § 808(2). As set forth in the enclosed report, CMS found good cause to waive publication of a proposed rule and solicitation of public comment and thus the 60-day delay requirement does not apply.

Enclosed is our assessment of CMS's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review of the agency's submissions to us indicates that CMS complied with the applicable requirements.

If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Agnes Thomas
Regulations Coordinator
Department of Health and Human Services

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE AND MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM; DURABLE MEDICAL EQUIPMENT FEE SCHEDULE ADJUSTMENTS TO RESUME THE TRANSITIONAL 50/50 BLENDED RATES TO PROVIDE RELIEF IN RURAL AREAS AND NON-CONTIGUOUS AREAS"
(RIN: 0938-AT21)

(i) Cost-benefit analysis

The Centers for Medicare and Medicaid Services (CMS) prepared a cost benefit analysis of the interim final rule with comment period and resumes the blended adjusted Medicare fee schedule amounts during the transition period for certain items and services that are furnished in rural and non-contiguous areas not subject to the competitive bidding program (CBP) beginning June 1, 2018. It is estimated that these adjustments will cost $290 million in Medicare benefit payments and $70 million in Medicare beneficiary cost sharing for the period beginning June 1, 2018, and ending December 31, 2018. CMS states that it is unable to quantify the benefits of this interim final rule with comment period at this time; however, it further states that the goal of this interim final rule is to preserve beneficiary access to durable medical equipment (DME) items and services in rural and non-contiguous areas not subject to the CBP during a transition period in which CMS will continue to study the impact of the change in payment rates on access to items and services in these areas. According to CMS, the alternative to the interim final rule with comment period would have been to allow the full phase in of fee schedule adjustments based on competitive bidding prices to continue in all non-competitive bidding areas (non-CBAs). CMS states that it believes that resuming the fee schedule adjustment transition period in rural and non-contiguous areas promotes stability in the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) market in these areas and enables CMS to work with stakeholders to preserve beneficiary access to DMEPOS.

(ii) Agency actions relevant to the Regulatory Flexibility Act (RFA), 5 U.S.C. §§ 603-605, 607, and 609

The Regulatory Flexibility Act (September 19, 1980, Pub. L. No. 96-354) (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 85 percent of the DME industry is considered small businesses according to the Small Business Administration's size standards with total revenues of $6.5 million or less in any 1 year and a small percentage are nonprofit organizations. Individuals and states are not included in the definition of a small entity. CMS states that it expects the interim final rule with comment period DME provisions will have a significant impact on small suppliers. A substantial number of small suppliers will benefit from the increased fee schedule amounts. Although not legally required, this interim final rule with comment period will increase payments to small suppliers such that the beneficiaries should have improved access to items.

In addition, section 1102(b) of the Act requires the preparation of a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of RFA. For purposes of section 1102(b) of the Act, a small rural hospital is defined as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. CMS data indicates that only around 6.9 percent of small rural hospitals are organizationally linked to a DME supplier with paid claims in 2017. Thus, CMS does not believe this interim final rule with comment period will have a significant impact on operations of a substantial number of small rural hospitals.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million. CMS determined that UMRA does not apply to this rule because it does not contain mandates that impose spending costs on state, local, or tribal governments in the aggregate.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq*.

CMS stated that it ordinarily publishes a notice of proposed rulemaking in the *Federal Register* and invites public comment on the proposed rule before the provisions of the rule take effect in accordance with 5 U.S.C. 553(b) of the Administrative Procedure Act (APA) and section 1871 of the Act. Similarly, section 1871(b)(1) of the Social Security Act (the Act) requires the Secretary of Health and Human Services to provide for notice of the proposed rule in the *Federal Register* and provide a period of not less than 60 days for public comment. Section 553(b)(3)(B) of APA and section 1871(b)(2)(C) of the Act authorize an agency to waive these procedures, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. Section 553(d) of APA ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the *Federal Register*. This 30-day delay in effective date can be waived, however, if an agency finds good cause to support an earlier effective date. Section 1871(e)(1)(B)(i) of the Act also prohibits a rule from taking effect before the end of the 30-day period that begins the date that the rule is issued or published. However, section 1871(e)(1)(B)(ii) of the Act permits a substantive rule to take effect before 30 days if the Secretary finds that a waiver of the 30-day period is necessary to comply with statutory requirements or that the 30-day delay would be contrary to the public interest. In addition, the Congressional Review Act (5 U.S.C. 801(a)(3)) requires a 60-day delayed effective date for major rules. However, agencies can waive the delay in effective date of the rule if there is good cause, that notice and public procedure is impracticable, unnecessary, or contrary to the public interest, and incorporates a statement of the finding and the reasons in the rule issued (5 U.S.C. 808(2)). CMS found good cause to waive the notice of proposed rulemaking to address fee schedule adjustments in rural and non-contiguous areas based on information from the CBP and to make technical changes to the regulations so they conform to the statutory requirement under section 5004(b) of the Cures Act that infusion drugs used with DME be excluded from the DMEPOS CBP. CMS also found good cause to waive the delay in effective date and issue this interim final rule with comment period with an effective date of June 1, 2018. It is providing a 60-day public comment period. CMS states that it solicited stakeholder input

regarding the impact of the fee schedule adjustments as required by section 16008 of the Cures Act, through a national provider call on March 23, 2017, as well as through an accompanying written comment period, and that it received numerous comments from stakeholders. CMS provided a detailed explanation of the reasons that it found good cause to waive the delay in effective date and summarized some of the comments in the interim rule with comment period.

Paperwork Reduction Act (PRA), 44 U.S.C. §§ 3501-3520

CMS states that the interim final rule with comment period does not impose information collection requirements. Consequently, they state that there is no need for review by the Office of Management and Budget (OMB) under the authority of PRA.

Statutory authorization for the rule

CMS promulgated the rule under sections 5004(b) and 16007(a) of the 21st Century Cures Act (the Cures Act) (Pub. L. 114-255), sections 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. §§ 1302, 1395hh, and 1395rr(b)(l)), and sections 1834(a), 1842, and 1847 of the Social Security Act (42 U.S.C. 1395m, 1395u, and 1395w–3).

Executive Order No. 12,866 (Regulatory Planning and Review)

According to CMS, it estimated that the interim final rule with comment period is "economically significant" as measured by the $100 million threshold under Regulatory Planning and Review, and hence is also a major rule under the Congressional Review Act. In addition, OMB has determined that the actions are significant within the meaning of section 3(f)(4) of Regulatory Planning and Review. Accordingly, it prepared a Regulatory Impact Analysis (RIA) that presents the costs and benefits of the rulemaking. OMB has reviewed this interim final rule with comment period and CMS is soliciting comments on its RIA.

Executive Order No. 13,132 (Federalism)

CMS states that it has determined that this interim final rule with comment period does not impose substantial direct requirement costs on state or local governments, preempt states, or otherwise have a federalism implication.