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B-333874

January 7, 2022

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
House of Representatives

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

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in the CARES Act; 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 & Medicaid Services (CMS) entitled "Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in the CARES Act; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas" (RINs: 0938-AU17, 0938-AT21, and 0938-AU32). We received the rule on December 27, 2021. It was published in the *Federal Register* as a final rule on December 28, 2021. 86 Fed. Reg. 73860. The effective date is February 28, 2022.

According to CMS, the final rule establishes methodologies for adjusting the Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) fee schedule amounts using information from the Medicare DMEPOS competitive bidding program. CMS stated the final rule also establishes procedures for making benefit category and payment determinations for new

items and services that are durable medical equipment (DME), prosthetic devices, orthotics and prosthetics, therapeutic shoes and inserts, surgical dressings, or splints, casts, and other devices used for reductions of fractures and dislocations under Medicare Part B. In addition, CMS stated the final rule classifies continuous glucose monitors as DME under Medicare Part B. Lastly, CMS stated the final rule finalizes certain DME fee schedule-related provisions that were included in two previous interim final rules with comment period that CMS issued on May 11, 2018, and May 8, 2020.

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. 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 Shari Brewster, Assistant General Counsel, at (202) 512-6398.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
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 & MEDICAID SERVICES
ENTITLED
"MEDICARE PROGRAM; DURABLE MEDICAL EQUIPMENT,
PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) POLICY ISSUES,
AND LEVEL II OF THE HEALTHCARE COMMON PROCEDURE
CODING SYSTEM (HCPCS); DME INTERIM PRICING IN THE CARES ACT;
DURABLE MEDICAL EQUIPMENT FEE SCHEDULE ADJUSTMENTS
TO RESUME THE TRANSITIONAL 50/50 BLENDED RATES
TO PROVIDE RELIEF IN RURAL AREAS AND NON-CONTIGUOUS AREAS"
(RINS: 0938-AU17, 0938-AT21, AND 0938-AU32)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated the final rule would cost $0.2 million a year for the period from 2022–2026 at both the three and seven percent discount rates. CMS further estimated the final rule would result in additional transfers in the same period. CMS estimated transfers from the federal government to durable medical equipment providers in the amount of $912 million a year at the seven percent discount rate or $933 million a year at the three percent discount rate. Additionally, CMS estimated transfers from Medicare beneficiaries to durable medical equipment providers in the amount of $219 million a year at the seven percent discount rate or $224 million a year at the three percent discount rate. Finally, CMS estimated transfers from the state governments to beneficiaries in the amount of $28 million a year at both the three and seven percent discount rates.

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

CMS certified the final rule would not have a significant economic impact on a substantial number of small entities. CMS further determined the final rule would not have a significant economic impact on a substantial number of rural hospitals.

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

CMS determined the final rule imposes mandates that will result in anticipated costs to state, local, and tribal governments, or the private sector, but the transfer costs will be less than the statutory threshold. As a result, CMS determined the final rule would not impose a mandate that will result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of more than $158 million in any one year.

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

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

On May 11, 2018, CMS published the interim final rule 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". 83 Fed. Reg. 21912. Additionally, on May 8, 2020, CMS published an interim final rule entitled "Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program". 85 Fed. Reg. 27550. Finally, on November 4, 2020, CMS published a proposed rule entitled "Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Policy Issues and Level II of the Healthcare Common Procedure Coding System". 85 Fed. Reg. 70358. CMS received 331 pieces of timely correspondence containing multiple comments from durable medical equipment, prosthetics, and orthotics suppliers, manufacturers, trade associations, beneficiaries, the Medicare Payment Advisory Commission, law firms, and healthcare providers. CMS responded to the comments and finalized provisions from the interim final rules and proposed rule in the final rule.

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

CMS determined the final rule does not contain information collection requirements subject to the PRA.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 1302, 1395hh, and 1395rr of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated the Office of Management and Budget reviewed the final rule and determined it was economically significant.

Executive Order No. 13132 (Federalism)

CMS estimated the state governments' Medicaid payments in aggregate for dual eligible beneficiaries will increase by an estimated $150 million from 2022 to 2026. CMS stated that because the final rule imposes costs on state or local governments, the requirements of the Order are applicable.