U.S. GOVERNMENT ACCOUNTABILITY OFFICE

**441 G St. N.W.**
**Washington, DC 20548**

B-335753

November 27, 2023

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

The Honorable Cathy McMorris Rodgers
Chair
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Jason Smith
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 & Medicaid Services: Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements*

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) titled "Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements" (RIN: 0938-AV03). We received the rule on November 1, 2023. It was published in the *Federal Register* as a final rule on November 13, 2023. 88 Fed. Reg. 77676. The stated effective date is January 1, 2024.

According to CMS, this final rule sets forth routine updates to the Medicare home health payment rates for calendar year 2024 in accordance with existing statutory and regulatory requirements. CMS stated that this rule discusses comments received regarding access to home health aide services; implements home health payment-related changes; rebases and revises the home health market basket and revises the labor-related share; codifies statutory requirements for disposable negative pressure wound therapy; and implements the new items and services payment for the home intravenous immune globulin benefit. CMS also stated that the final rule finalized changes to the Home Health Quality Reporting Program requirements and the expanded Home Health Value-Based Purchasing Model; implements the new Part B benefit for lymphedema compression treatment items, codifies the Medicare definition of brace, and makes other codification changes based on recent legislation; adds an informal dispute resolution and special focus program for hospice programs; codifies the durable medical equipment, prosthetics, orthotics, and supplies refill policy; and finalizes proposed revisions for Medicare provider and supplier enrollment requirements.

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). The House of Representatives and the Senate both received this final rule on November 1, 2023. 169 Cong. Rec. H5403 (daily ed. Nov. 3, 2023); 169 Cong. Rec. S5426 (daily ed. Nov. 8, 2023). The final rule was published in the *Federal Register* on November 13, 2023. The stated effective date of the rule is January 1, 2024. Thus, based on the date of publication in the *Federal Register*, the final rule does not have the required 60-day delay in its effective date.

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
Centers for Medicare & Medicaid Services
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
TITLED
"MEDICARE PROGRAM; CALENDAR YEAR (CY) 2024
HOME HEALTH (HH) PROSPECTIVE PAYMENT SYSTEM RATE UPDATE;
HH QUALITY REPORTING PROGRAM REQUIREMENTS; HH VALUE-BASED
PURCHASING EXPANDED MODEL REQUIREMENTS; HOME INTRAVENOUS
IMMUNE GLOBULIN ITEMS AND SERVICES; HOSPICE INFORMAL DISPUTE RESOLUTION
AND SPECIAL FOCUS PROGRAM REQUIREMENTS, CERTAIN REQUIREMENTS
FOR DURABLE MEDICAL EQUIPMENT PROSTHETICS AND ORTHOTICS SUPPLIES;
AND PROVIDER AND SUPPLIER ENROLLMENT REQUIREMENTS"
(RIN: 0938-AV03)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS) conducted an economic analysis of this final rule. According to CMS, the calendar year (CY) 2024 Home Health Prospective Payment System provisions will result in $140 million in transfers from the federal government to home health agencies (HHAs). CMS stated that the Home Health Quality Reporting Program would result in $5,123,430 in cost. CMS also stated that the changes to the expanded Home Health Value-Based Purchasing Model will result in a $662.4 million decrease at a 7 percent discount rate and $669.7 million decrease at a 3 percent discount rate in annualized monetized transfers from the federal government to hospitals and skilled nursing facilities for a period covering CYs 2023–2027. CMS stated further that the Medicare Home Intravenous Immune Globulin Items and Services provisions will result in $8.7 million in annualized monetized transfers from the federal government to durable medical equipment, prosthetics, and orthotics supplies (DMEPOS) suppliers. Lastly, CMS prepared an accounting statement showing the classification of the several expenditures associated with the provisions of the rule concerning DMEPOS.

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

CMS stated that the Secretary of HHS has determined that this final rule would have significant economic impact on a substantial number of small entities. CMS estimated that the net impact of the policies in the rule is approximately $140 million in increased payments to HHAs in CY 2024.

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

CMS stated that this final rule would not impose a mandate that would result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of more than $177 million ($100 million, adjusted for inflation) in any one year.

(iv) Agency actions relevant to the Administrative Pay-As-You-Go-Act of 2023, Pub. L. No. 118-5, div. B, title III, 137 Stat 31 (June 3, 2023)

Section 270 of the Administrative Pay-As-You-Go-Act of 2023 amended 5 U.S.C. § 801(a)(2)(A) to require GAO to assess agency compliance with the Act, which establishes requirements for administrative actions that affect direct spending, in GAO's major rule reports. In guidance to Executive Branch agencies, issued on September 1, 2023, the Office of Management and Budget (OMB) instructed that agencies should include a statement explaining that either: "the Act does not apply to this rule because it does not increase direct spending; the Act does not apply to this rule because it meets one of the Act's exemptions (and specifying the relevant exemption); the OMB Director granted a waiver of the Act's requirements pursuant to section 265(a)(1) or (2) of the Act; or the agency has submitted a notice or written opinion to the OMB Director as required by section 263(a) or (b) of the Act" in their submissions of rules to GAO under the Congressional Review Act. OMB, *Memorandum for the Heads of Executive Departments and Agencies,* Subject: Guidance for Implementation of the Administrative Pay-As-You-Go Act of 2023, M-23-21 (Sept. 1, 2023), at 11–12. OMB also states that directives in the memorandum that supplement the requirements in the Act do not apply to proposed rules that have already been submitted to the Office of Information and Regulatory Affairs, however agencies must comply with any applicable requirements of the Act before finalizing such rules.

CMS stated that the Director of OMB has waived the requirements of section 263 of the Act pursuant to sections 265(a)(1) and (a)(2) of the Act.

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

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

On July 10, 2023, CMS published a proposed rule. 88 Fed. Reg. 43654. CMS stated that it summarized and responded to the public comments in the preamble of the final rule.

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

CMS determined that this final rule contains information collection requirements (ICRs) under the Act and submitted them to OMB for review. CMS estimates that the ICRs for the Home Health Quality Reporting Program (OMB Control Number 0938-1279) will result in a net reduction of 58,540.1 hours of clinician burden across all HHAs or 5 hours for each of the 11,700 active HHAs and a reduction in costs of $5,123,430 related to the implementation of the proposals outlined in the final rule across all HHAs or a $438 reduction for each of the 11,700 active HHAs. CMS also stated that the ICRs for the Home Health Value-Based Purchasing Model and the Hospice Information Dispute Resolution and Hospice Special Focus Program are exempt from PRA. CMS did not provide burden or cost estimates for the ICRs under the DMEPOS Refills provisions of the final rule. Also, according to CMS, most of the Provider Enrollment Provisions of the final rule do not impose an ICR burden. However, CMS stated that the ICRs under the High-Risk Screening and Fingerprinting provision are approved under OMB Control Number 1110-0046, but it did not score the burden since the fingerprint card is not owned by CMS. CMS also stated that there are ICRs imposed by the 36-month rule provision, Form CMS-855A (OMB Control Number 0938-0685), which will result in an additional burden of 150 hours and an annual cost burden of $6,225. CMS's analysis included several additional costs associated with its 36-month rule.

Statutory authorization for the rule

CMS promulgated this final rule pursuant to sections 1302, 1395i-3, 1395m, 1395x, 1395aa, 1395cc, 1395ff, 1395hh, 1395rr, and 1395ddd, of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that OMB's Office of Information and Regulatory Affairs has determined this rulemaking significant under the Order.

Executive Order No. 13132 (Federalism)

CMS determined that this final rule would not impose substantial direct costs on state or local governments.