



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

B-336842

November 22, 2024

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) 2025 Home Health Prospective Payment System (HH PPS) Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin (IVIG) Items and Services Rate Update; and Other Medicare Policies*

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; Calendar Year (CY) 2025 Home Health Prospective Payment System (HH PPS) Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin (IVIG) Items and Services Rate Update; and Other Medicare Policies” (RIN: 0938-AV28). We received the rule on November 6, 2024. It was published in the *Federal Register* on November 7, 2024. 89 Fed. Reg. 88354. The rule has a stated effective date of January 1, 2025.

This rule sets forth routine updates to the Medicare home health payment rates; the payment rate for the disposable negative pressure wound therapy devices; and the intravenous immune globulin items and services payment rate for calendar year 2025 in accordance with existing statutory and regulatory requirements. In addition, it finalizes changes to the Home Health

Quality Reporting Program requirements and provides an update on potential approaches for integrating health equity in the Expanded Health Value Based Purchasing Model. It also finalizes a new standard for an acceptance-to-service policy in the home health conditions of participation. Finally, it updates the provider and supplier enrollment requirements and changes to the long-term care reporting requirements for acute respiratory illness.

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 rule was received by the House and the Senate on November 6, 2024, and was published in the *Federal Register* on November 7, 2024. Email from Regulations Coordinator, HHS, to CRA Rules, GAO, *Subject: Official Submission - RIN 0938-AV28* (Nov. 6, 2024); 89 Fed. Reg. 88354. The rule has a stated effective date of January 1, 2025. Therefore, the stated effective date is less than 60 days from November 7, 2024.

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 Charlie McKiver, Assistant General Counsel, at (202) 512-5992.



Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Christina Kang
Regulations Coordinator
Centers for Medicare & Medicaid Services

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; CALENDAR YEAR (CY) 2025 HOME HEALTH
PROSPECTIVE PAYMENT SYSTEM (HH PPS) RATE UPDATE;
HH QUALITY REPORTING PROGRAM REQUIREMENTS;
HH VALUE-BASED PURCHASING EXPANDED MODEL REQUIREMENTS;
HOME INTRAVENOUS IMMUNE GLOBULIN (IVIG) ITEMS AND SERVICES RATE UPDATE;
AND OTHER MEDICARE POLICIES”
(RIN: 0938-AV28)

(i) Cost-benefit analysis

The Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS) prepared an analysis of the costs and benefits for this rule. See 89 Fed. Reg. 88476–88483 (Nov. 7, 2024). According to CMS, the net transfer impact related to the changes in Medicare payments under the Home Health Prospective Payment System for calendar year 2025 is estimated to be \$85 million, or 0.5 percent. *Id.* at 88476.

(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 certified that this rule will not have a significant impact on a substantial number of small entities. See 89 Fed. Reg. 88484. Additionally, CMS stated that the Secretary has certified that the rule will not have a significant impact on the operations of a substantial number of small rural hospitals. *Id.*

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

CMS determined that this rule will not have an effect on state, local, or tribal governments, in the aggregate, or on the private sector, of \$100 million in 1995 dollars, updated annually for inflation, in any one year. See 89 Fed. Reg. 88484.

(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 waived the requirements of the Act. 89 Fed. Reg. 88485.

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

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

On July 3, 2024, CMS published a proposed rule. 89 Fed. Reg. 55312. CMS stated that they received comments from various interested parties. See 89 Fed. Reg. 88357. CMS responded to comments in the rule. *Id.*

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

CMS determined that this rule contains information collection requirements under the Act. 89 Fed. Reg. 88468.

Statutory authorization for the rule

CMS promulgated this rule pursuant to 42 U.S.C. §§ 1302, 1395hh.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that this rule is significant under the Order. See 89 Fed. Reg. 88476. CMS stated that the rule was submitted to OMB for review. *Id.*

Executive Order No. 13132 (Federalism)

CMS determined that this rule does not have federalism implications. See 89 Fed. Reg. 88484.