U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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Washington, DC 20548

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November 18, 2020

The Honorable Chuck Grassley
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Greg Walden
Ranking Member
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 and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update, Home Health Quality Reporting Program Requirements, and Home Infusion Therapy Services and Supplier Enrollment Requirements; and Home Health Value-Based Purchasing Model Data Submission 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) entitled "Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update, Home Health Quality Reporting Program Requirements, and Home Infusion Therapy Services and Supplier Enrollment Requirements; and Home Health Value-Based Purchasing Model Data Submission Requirements" (RINs: 0938-AU06, 0938-AU31, 0938-AU32). We received the rule on November 4, 2020. It was published in the *Federal Register* as a final rule on November 4, 2020. 85 Fed. Reg. 70298. The stated effective date of the final rule is January 1, 2021.

According to CMS this final rule updates the home health prospective payment system (HH PPS) payment rates and wage index for calendar year (CY) 2021. CMS noted that this final rule also implements the changes to the home health regulations regarding the use of telecommunications technology in providing services under the Medicare home health benefit as described in the "Medicare and Medicaid Programs, Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" interim final rule with comment period. *See* 85 Fed. Reg. 19230 (Apr. 6, 2020). In addition, CMS stated, this rule implements the permanent home infusion therapy services benefit and supplier enrollment requirements for CY 2021 and finalizes conforming regulations text changes excluding home infusion therapy services from coverage under the Medicare home health benefit. CMS stated further that this rule also finalizes a policy to align the Home Health Value-Based Purchasing (HHVBP) Model data submission requirements with any exceptions or extensions granted for purposes of the Home Health Quality Reporting Program (HH QRP) during the COVID-19 public health emergency and also finalizes a policy for granting exceptions to the New Measures data reporting requirements during the COVID-19 public health emergency, as described in the "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" interim final rule with comment period. *See* 85 Fed. Reg. 27550 (May 8, 2020) (May 2020 IFR).

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 *Congressional Record* reflects that the Senate received the final rule on November 3, 2020. 166 Cong. Rec. S6652 (daily ed. November 10, 2020). The *Congressional Record* reflects that the House received the final rule on November 5, 2020. 166 Cong. Rec. H5794 (daily ed. November 16, 2020). The final rule was published in the *Federal Register* as a final rule on November 4, 2020. The stated effective date of the final rule is January 1, 2020. Therefore the final rule does not have the required 60-day delay in its effective date.

The 60-day delay in effective date can be waived if the agency finds for good cause that delay is impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. Here, although CMS did not specifically mention the CRA's 60-day delay in effective date requirement, with regard to the portion of this final rule related to regulation text changes made to 42 C.F.R. §§ 409.64(a)(2)(ii), 410.170(b), and 484.110, which according to CMS were inadvertently left out of the May 2020 IFR, CMS waived notice and comment procedures under the Administrative Procedure Act, 5 U.S.C. § 553(b). CMS stated that notice and comment procedures with regard to these text changes would be unnecessary and contrary to the public interest as the May 2020 IFR was already subject to notice and comment procedures, and, according to CMS, these regulation text changes do not reflect any substantive changes in policy and are

required by section 3708 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Pub. L. No. 116-136, § 3780, 134 Stat. 281, 418 (Mar. 27, 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: Vanessa Jones
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 AND MEDICAID PROGRAMS; CY 2021 HOME HEALTH PROSPECTIVE PAYMENT SYSTEM RATE UPDATE, HOME HEALTH QUALITY REPORTING PROGRAM REQUIREMENTS, AND HOME INFUSION THERAPY SERVICES AND SUPPLIER ENROLLMENT REQUIREMENTS; AND HOME HEALTH VALUE-BASED PURCHASING MODEL DATA SUBMISSION REQUIREMENTS"
(RINs: 0938-AU06, 0938-AU31, 0938-AU32)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) conducted an economic analysis of this final rule. CMS stated it estimates that the provisions in this final rule would result in an estimated net increase in home health payments of 1.9 percent for calendar year (CY) 2021 ($390 million). The $390 million increase in estimated payments for CY 2021 reflects the effects of the CY 2021 home health payment update percentage of 2.0 percent ($410 million increase) and an estimated −0.1 percent decrease in payments due to the rural add-on percentages mandated by the Bipartisan Budget Act of 2018 for CY 2021 ($20 million decrease). *See* Pub. L. No. 115-123, 132 Stat. 64 (Feb. 9, 2018).

CMS stated that the changes in this final rule will: ensure home health payments are consistent with statutory payment authority for CY 2021; simplify the submission of data process; provide home health agencies with more flexibility to respond to the COVID-19 public health emergency; ensure that payment from home infusion therapy services are consistent with statutory authority for CY 2021; and ensure the home infusion therapy suppliers meet all the applicable requirements.

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

The Secretary of the Department of Health and Human Services has determined that this final rule would not have a significant economic impact on a substantial number of small entities, nor on the operations 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

According to CMS, this rule is not anticipated to have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of $156 million ($100 million, adjusted for inflation) or more.

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

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

On June 30, 2020, CMS published a proposed rule. *Medicare and Medicaid Programs; CY 2021 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Requirements; and Home Infusion Therapy Services Requirements*, 85 Fed. Reg. 39408 (Proposed Rule). CMS stated that it received approximately 162 timely pieces of correspondence from the public, including from home health agencies, national and state provider associations, patient and other advocacy organizations, nurses, and other healthcare professionals. CMS stated further that it summarized the proposed provisions and the public comments, and provided the responses to comments in various sections throughout the final rule.

CMS also stated that it is finalizing regulatory and policy changes published in two separate interim final rules with request for comments. *See Medicare and Medicaid Programs, Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency*, 85 Fed. Reg. 19230 (Apr. 6, 2020); *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 (May 8, 2020) (May 2020 IFR).

CMS noted that this final rule amends 42 C.F.R. §§ 409.64(a)(2)(ii), 410.170(b), and 484.110, and that the amendments are simply additional regulation text changes that were inadvertently left out of the text changes in the May 2020 IFR and do not reflect any substantive changes in policy. CMS stated that policy to be instituted by this regulatory change was subject to notice and comment rulemaking in the May 2020 IFR. CMS stated further that undertaking further notice and comment procedures to incorporate these corrections into this final rule is unnecessary and contrary to the public interest, as these regulation text changes are required by section 3708 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Pub. L. No. 116-136, § 3780, 134 Stat. 281, 418 (Mar. 27, 2020).

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

CMS determined that this final rule contains information collection requirements (ICRs) under the Act. CMS stated it submitted a copy of this final rule to the Office of Management and Budget (OMB) for review of the rule's information collection requirements. According to CMS, the ICR submission “Medicare and Medicaid Programs: Conditions of Participation for Home Health Agencies” (OMB Control No. 0938-1299), would not create any additional burden on participating Home Health Agencies. CMS stated form CMS-855B “Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers” (OMB Control Number: 0938-0685), is estimated to impose a burden of 1,750 hours at a cost of $85,750. CMS stated further that, when averaged over the typical 3-year OMB approval period, it estimates an annual burden of 583 hours at a cost of $28,583. Lastly, CMS noted there are ICRs associated with the appeals process for applications that are denied or revoked. CMS asserted that the ICRs are exempt from PRA because, in accordance with the implementing regulations of PRA at 5 C.F.R. § 1320.4(a)(2), the ICRs associated with the appeals process are subsequent to an administrative action.

Statutory authorization for the rule

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

Executive Order No. 12866 (Regulatory Planning and Review)

CMS determined that this final rule is economically significant under the Order.

Executive Order No. 13132 (Federalism)

CMS has determined that the final rule will not impose substantial direct costs on state or local governments