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November 19, 2021

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 and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID-19 Reporting Requirements for Long-Term Care Facilities*

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 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Model Expansion; Home Health and Other Quality Reporting Program Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; and COVID-19 Reporting Requirements for Long-Term Care Facilities" (RIN: 0938-AU37 and 0938-AU32). We received the rule on November 8, 2021. It was published in the *Federal Register* as a final rule on November 9, 2021. 86 Fed. Reg. 62240. The effective date is January 1, 2022.

According to CMS, the final rule updates the home health and home infusion therapy services payment rates for calendar year (CY) 2022 in accordance with existing statutory and regulatory

requirements. CMS also stated the final rule finalizes recalibration of the case-mix weights and updates the functional impairment levels and comorbidity adjustment subgroups while maintaining the current low utilization payment adjustment (LUPA) thresholds for CY 2022. Additionally, CMS stated the final rule finalizes a policy to utilize the physical therapy LUPA add-on factor to establish the occupational therapy add-on factor for the LUPA add-on payment amounts and makes conforming regulations text changes to reflect that allowed practitioners are able to establish and review the plan of care. CMS also stated the final rule finalizes proposed changes to the Home Health Quality Reporting Program (QRP) including finalizing proposed measure removals and adoptions, public reporting, and modification of effective dates. According to CMS, the final rule also finalizes proposed modifications to the effective date for the reporting of measures and certain standardized patient assessment data in the Inpatient Rehabilitation Facility QRP and Long-Term Care Hospital QRP.

In addition, CMS stated the final rule codifies certain Medicare provider and supplier enrollment policies; it also makes permanent selected regulatory blanket waivers related to home health aide supervision that were issued to Medicare participating home health agencies during the COVID-19 public health emergency (PHE), and updates the home health conditions of participation regarding occupational therapist assessment completion to implement provisions of the Consolidated Appropriations Act, 2021, Pub. L. No. 116-260, 134 Stat. 1182 (Dec. 27, 2020) (CAA 2021). CMS additionally stated the final rule finalizes proposals to expand the Home Health Value-Based Purchasing (HHVBP) Model and to end the original HHVBP Model one year early. Lastly, CMS stated the final rule establishes survey and enforcement requirements for hospice programs as set forth in the CAA 2021 and finalizes revisions to the infection control requirements for long-term care facilities that will extend the mandatory COVID-19 reporting requirements beyond the current COVID-19 PHE until December 31, 2024.

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 final rule was published on November 9, 2021. 86 Fed. Reg. 62240. The *Congressional Record* does not indicate when Congress received the rule. The final rule has a stated effective date of January 1, 2022. Therefore, based on the date of publication in the Federal Register, the final rule does not have the required 60-day delay in effective date, with the exception of changes made by the final rule to 42 C.F.R. § 484.50(d)(5) where, as explained below, CMS waived notice and comment procedures for good cause.

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. 5 U.S.C. §§ 553(b)(3)(B), 808(2). Here, CMS waived notice and comment procedures for good cause for changes made by the final rule to 42 C.F.R. § 484.50(d)(5). CMS determined it had good cause because, according to CMS, notice-and-comment rulemaking procedure is unnecessary for the technical change that added “or allowed practitioner” at § 484.50(d)(5) because CMS inadvertently omitted the reference at this location during prior rulemaking (85 FR 27550). CMS stated this change is technical in nature and ensures that all providers, physicians and allowed practitioners issuing orders for the patient are informed of a discharge of the patient, and aligns with changes made throughout the Home Health Agency Conditions of Participation.

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

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 2022 HOME HEALTH PROSPECTIVE
PAYMENT SYSTEM RATE UPDATE;
HOME HEALTH VALUE-BASED PURCHASING MODEL
REQUIREMENTS AND MODEL EXPANSION;
HOME HEALTH AND OTHER QUALITY
REPORTING PROGRAM REQUIREMENTS;
HOME INFUSION THERAPY SERVICES REQUIREMENTS;
SURVEY AND ENFORCEMENT REQUIREMENTS FOR HOSPICE PROGRAMS;
MEDICARE PROVIDER ENROLLMENT REQUIREMENTS;
AND COVID-19 REPORTING REQUIREMENTS
FOR LONG-TERM CARE FACILITIES"
(RIN: 0938-AU37 AND 0938-AU32)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated the 2022 Home Health Agency Prospective Payment System would result in a transfer from the federal government to home health agencies in the amount of $570 million, and ensure home health payments are consistent with statutory payment authority for 2022. CMS further estimated the Home Health Value-Based Purchasing Model would lead to a decrease of Medicare payments from the federal government to hospitals and skilled nursing facilities in the amount of $669.7 million at the three percent discount rate and $662.4 million at the seven percent discount rate. Finally, CMS estimated the annualized net monetary burden for home health agencies' submission of the Outcome and Assessment Information Set would be reduced in the amount $2,762,277.

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

CMS conducted a Final Regulatory Flexibility Analysis and determined the final rule would not have a substantial economic impact on a significant number of small entities. CMS further certified the final rule would not have a significant economic impact 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

CMS determined the final rule is not anticipated to have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of $158 million or more.

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

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

On July 7, 2021, CMS published a proposed rule. 86 Fed. Reg. 35874. CMS received comments and addressed them in the final rule. For changes made by the final rule to 42 C.F.R. § 484.50(d)(5), CMS waived notice and comment procedures for good cause. CMS determined it had good cause because, according to CMS, notice-and-comment rulemaking procedure is unnecessary for the technical change that added "or allowed practitioner" at § 484.50(d)(5) because CMS inadvertently omitted the reference at this location during a prior rulemaking (85 FR 27550). CMS stated this change is technical in nature and ensures that all providers, physicians and allowed practitioners issuing orders for the patient are informed of a discharge of the patient, and aligns with changes made throughout the Home Health Agency Conditions of Participation.

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

CMS determined the final rule contained Information Collection Requirements (ICRs) subject to the PRA. The ICRs are associated with Office of Management and Budget (OMB) Control Numbers 0938-0391, 0938-0842, 0938-1163, 0938-1279, and 0938-1299. CMS estimated the burden hours for the ICR in the final rule.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 1302, 1320a-7, 1320a-7j, 1395i, 1395i-3, 1395x, 1395aa, 1395cc, 1395ff, 1395hh, and 1396r of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS stated that OMB determined the final rule is economically significant.

Executive Order No. 13132 (Federalism)

CMS reviewed the final rule under the criteria of the Order and determined that it will not impose substantial direct costs on state or local governments.