U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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January 8, 2021

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 Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-Owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) to Report COVID-19 Therapeutic Inventory and Usage and to Report Acute Respiratory Illness During the Public Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19)*

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: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; Physician-Owned Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity To Apply for Available Slots, Radiation Oncology Model; and Reporting Requirements for Hospitals and Critical Access Hospitals (CAHs) to Report COVID-19 Therapeutic Inventory and Usage and to Report Acute Respiratory Illness During the Public

Health Emergency (PHE) for Coronavirus Disease 2019 (COVID-19)" (RIN: 0938-AU12). We received the rule on December 8, 2020. It was published in the *Federal Register* as a final rule with comment period and interim final rule with comment period on December 29, 2020. 85 Fed. Reg. 85866. The comment period closed on January 4, 2021. The stated effective date of the rule is January 1, 2021, with the exception of certain amendatory instructions, which are effective on December 4, 2021.

According to CMS, the final rule revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for Calendar Year (CY) 2021. CMS stated the final rule describes the changes to the amounts and factors used to determine the payment rates for Medicare services paid under OPPS and those paid under the ASC payment system. CMS also stated the final rule updates and refines the requirements for the Hospital Outpatient Quality Reporting Program and the ASC Quality Reporting Program. CMS further stated the final rule establishes and updates the Overall Hospital Quality Star Rating beginning with CY 2021; removes certain restrictions on the expansion of physician-owned hospitals that qualify as "high Medicaid facilities," and clarifies that certain beds are counted toward a hospital's baseline number of operating rooms, procedure rooms, and beds; adds two new service categories to the Hospital Outpatient Department Prior Authorization Process; provides notice of the closure of two teaching hospitals and the opportunity to apply for available slots for purposes of indirect medical education (IME) and direct graduate medical education payments; and revises the Clinical Laboratory Date of Service policy. Also, according to CMS, the interim final rule modifies the Radiation Oncology Model performance period for CY 2021, and establishes new requirements in the hospital and critical access hospital Conditions of Participation for tracking of COVID-19 therapeutic inventory and usage and for tracking of the incidence and impact of Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection) during the ongoing COVID-19 public health emergency.

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 60-day in effective date can be waived, however, 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. § 808(2). CMS determined it had good cause to waive the delay for the final rule because the United States is responding to the COVID-19 pandemic. CMS stated the agency had to divert energy and personnel resources that would otherwise have been used to complete this OPPS/ASC payment system final rule with comment period to other priority matters, including four interim final rules necessary because of the pandemic. Although, according to CMS, the agency devoted significant resources to completing the OPPS/ASC payment system final rule, CMS determined it was impracticable for it to complete the work needed on the rule in accordance with its usual schedule for this rulemaking or in sufficient time to ensure a full 60-day period of public notice prior to the next calendar year that begins on January 1, 2021. CMS further stated the OPPS/ASC payment system final rule is necessary to annually review and update the payment systems, and it is critical to ensure that the payment policies for these systems are effective on the first day of the calendar year to which they are intended to apply.

As for the interim final rule, CMS determined it had good cause to waive the delayed effective date, also, because of the COVID-19 pandemic. CMS stated the interim final rule is needed to ensure timely distribution of COVID-19 therapeutics to areas based on need as it provides CMS the necessary information to ensure effective and timely distribution. CMS stated effective

distribution methods use a variety of indicators, tailored to the specific therapeutic, to estimate the geographic and regional distribution that is recommended for that particular therapeutic, and analyzing and understanding the usage patterns specific to each new therapeutic requires real-world information in real time. CMS further stated lacking accurate information on the usage rates and current inventory on hand for a particular therapeutic, can possibly result in scarce therapeutic supplies being sent to areas that already have adequate inventories on hand. CMS determined such an inefficient and ill-informed distribution strategy for these therapeutics could very quickly lead to a situation that could negatively impact areas of the nation that already have inadequate supplies and resources.

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: HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT AND AMBULATORY SURGICAL CENTER PAYMENT SYSTEMS AND QUALITY REPORTING PROGRAMS; NEW CATEGORIES FOR HOSPITAL OUTPATIENT DEPARTMENT PRIOR AUTHORIZATION PROCESS; CLINICAL LABORATORY FEE SCHEDULE: LABORATORY DATE OF SERVICE POLICY; OVERALL HOSPITAL QUALITY STAR RATING METHODOLOGY; PHYSICIAN-OWNED HOSPITALS; NOTICE OF CLOSURE OF TWO TEACHING HOSPITALS AND OPPORTUNITY TO APPLY FOR AVAILABLE SLOTS, RADIATION ONCOLOGY MODEL; AND REPORTING REQUIREMENTS FOR HOSPITALS AND CRITICAL ACCESS HOSPITALS (CAHS) TO REPORT COVID-19 THERAPEUTIC INVENTORY AND USAGE AND TO REPORT ACUTE RESPIRATORY ILLNESS DURING THE PUBLIC HEALTH EMERGENCY (PHE) FOR CORONAVIRUS DISEASE 2019 (COVID-19)"
(RIN: 0938-AU12)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated the final rule and interim final rule would result in several costs to the federal government and various elements of the health care sector. CMS estimated a $1,490,000,000 payment from the federal government to hospital outpatient prospective payment system hospitals and providers for Calendar Year (CY) 2021. CMS also estimated a $100,000,000 payment from the federal government to Medicare providers and suppliers in CY 2021. CMS further estimated an annual payment of $38,000,000 from the federal government to health care providers for the radiology oncology model at a 7 percent discount rate or a $40,000,000 payment at a 3 percent discount rate. CMS further estimated costs to providers of $139,000,000 for information collection requirements (ICRs) and $1,195,000 for regulatory familiarization. CMS finally estimated an overall economic impact on the health care sector of $2,888,040 in the first year.

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

CMS determined the final rule would not have a significant economic impact on a substantial number of small entities. It further determined the final rule would not have a significant impact on approximately 586 small rural hospitals. CMS indicated the preamble to the rule should be considered a Regulatory Flexibility Analysis.

(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 does not mandate any requirements for state, local, or tribal governments, or for the private sector.

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

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

CMS published a proposed rule on August 12, 2020. 85 Fed. Reg. 48772. CMS stated it received approximately 1,350 pieces of correspondence on the proposed rule and addressed those comments that were in scope in the final rule.

CMS waived the delay in effective date for the final rule for good cause because the United States is responding to the COVID-19 pandemic. CMS stated the agency had to divert energy and personnel resources that would otherwise have been used to complete this OPPS/ASC payment system final rule with comment period to other priority matters, including four interim final rules necessary because of the pandemic. Although, according to CMS, the agency devoted significant resources to completing the OPPS/ASC payment system final rule, CMS determined it was impracticable for it to complete the work needed on the rule in accordance with its usual schedule for this rulemaking or in sufficient time to ensure a full 30-day period of public notice prior to the next calendar year that begins on January 1, 2021. CMS further stated the OPPS/ASC payment system final rule is necessary to annually review and update the payment systems, and it is critical to ensure that the payment policies for these systems are effective on the first day of the calendar year to which they are intended to apply.

CMS also waived notice and comment procedures and the delayed effective date for the interim final rule because of the COVID-19 pandemic. CMS stated the interim final rule is needed to ensure timely distribution of COVID-19 therapeutics to areas based on need, as it provides CMS the necessary information to ensure effective and timely distribution. CMS stated effective distribution methods use a variety of indicators, tailored to the specific therapeutic, to estimate the geographic and regional distribution that is recommended for that particular therapeutic, and analyzing and understanding the usage patterns specific to each new therapeutic requires real-world information in real time. CMS further stated lacking accurate information on the usage rates and current inventory on hand for a particular therapeutic, can possibly result in scarce therapeutic supplies being sent to areas that already have adequate inventories on hand. CMS determined such an inefficient and ill-informed distribution strategy for these therapeutics could very quickly lead to a situation that could negatively impact areas of the nation that already have inadequate supplies and resources.

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

CMS determined the final rule contained ICRs subject to the Act. The ICRs are associated with Office of Management and Budget (OMB) Control Numbers 0938-1109, 0938-1270, 0938-1368, and 0938-NEW. CMS estimated the total aggregate burden for all ICRs in the final rule to be $139 million.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 1302, 1315a, 1395*l*, 1395m, 1395w-101 *et seq.*, 1395hh, 1395nn, 1395rr, and 1395ddd.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS determined the final rule was economically significant and stated OMB had reviewed the final rule.

Executive Order No. 13132 (Federalism)

CMS determined that the final rule will not have a substantial direct effect on state, local or tribal governments, preempt state law, or otherwise have a federalism implication.