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January 11, 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; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID-19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for 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; CY 2021 Payment Policies Under the

Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID-19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID-19” (RINs: 0938-AU10, 0938-AU31, 0938-AU32, 0938-AU33). We received the rule on December 3, 2020. It was published in the *Federal Register* as final rule and interim final rule on December 28, 2020. 85 Fed. Reg. 84472. The regulations in the final rule are effective on January 1, 2021.

According to CMS, this final rule and interim final rules with comment period addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program requirements; Medicaid Promoting Interoperability Program requirements for Eligible Professionals; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; Medicare enrollment of Opioid Treatment Programs; payment for office/outpatient evaluation and management services; requirement for Electronic Prescribing for Controlled Substances for a Covered Part D drug under a prescription drug plan or an MA-PD plan and Medicare Diabetes Prevention Program expanded model Emergency Policy. CMS stated this final rule also finalizes certain provisions of the interim final rules with comment period that CMS issued on March 31, 2020, May 8, 2020, and September 2, 2020, in response to the Public Health Emergency (PHE) for the Coronavirus Disease 2019 (COVID-19). CMS stated further that this rule also establishes coding and payment for virtual check-in services and for personal protective equipment (PPE) on an interim final basis.

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 delay 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. §§ 553(b)(3)(B), 808(2). CMS stated, in light of the PHE for COVID-19, and the resulting strain on its resources to that end, it was impracticable for CMS to publish this final rule 60 days prior to the beginning of the upcoming year, and CMS has determined that, for good cause, it would be contrary to the public interest to delay the effective date. CMS stated further that it is providing a 30-day delay in the effective date of the final rule. Notwithstanding, this final rule was published in the *Federal Register* on December 28, 2020, and the effective date of the rule is January 1, 2021.

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.

A handwritten signature in black ink that reads "Shirley A. Jones". The signature is written in a cursive style with a large initial 'S' and 'J'.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
Regulations Coordinator
Department of Health and Human Services

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THEDEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE & MEDICAID SERVICES

ENTITLED

“MEDICARE PROGRAM; CY 2021 PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND OTHER CHANGES TO PART B PAYMENT POLICIES; MEDICARE SHARED SAVINGS PROGRAM REQUIREMENTS; MEDICAID PROMOTING INTEROPERABILITY PROGRAM REQUIREMENTS FOR ELIGIBLE PROFESSIONALS; QUALITY PAYMENT PROGRAM; COVERAGE OF OPIOID USE DISORDER SERVICES FURNISHED BY OPIOID TREATMENT PROGRAMS; MEDICARE ENROLLMENT OF OPIOID TREATMENT PROGRAMS; ELECTRONIC PRESCRIBING FOR CONTROLLED SUBSTANCES FOR A COVERED PART D DRUG; PAYMENT FOR OFFICE/OUTPATIENT EVALUATION AND MANAGEMENT SERVICES; HOSPITAL IQR PROGRAM; ESTABLISH NEW CODE CATEGORIES; MEDICARE DIABETES PREVENTION PROGRAM (MDPP) EXPANDED MODEL EMERGENCY POLICY; CODING AND PAYMENT FOR VIRTUAL CHECK-IN SERVICES INTERIM FINAL RULE POLICY; CODING AND PAYMENT FOR PERSONAL PROTECTIVE EQUIPMENT (PPE) INTERIM FINAL RULE POLICY; REGULATORY REVISIONS IN RESPONSE TO THE PUBLIC HEALTH EMERGENCY (PHE) FOR COVID-19; AND FINALIZATION OF CERTAIN PROVISIONS FROM THE MARCH 31ST, MAY 8TH AND SEPTEMBER 2ND INTERIM FINAL RULES IN RESPONSE TO THE PHE FOR COVID-19”

(RINs: 0938-AU10, 0938-AU31, 0938-AU32, 0938-AU33)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) prepared accounting statements for this final rule. According to CMS, the estimates in the accounting statements include growth in incurred benefits from calendar year (CY) 2020 to CY 2021 based on the fiscal year (FY) 2021 President's Budget baseline. CMS stated that it estimates \$0.0 billion in increased expenditures for annualized and monetized transfers from the federal government to physicians, other practitioners, providers, and suppliers who receive payment under Medicare in CY 2021 based on the physician fee schedule (PFS) conversion factor update. CMS also stated that it estimates \$0.0 billion for CY 2021 in annualized monetized transfers of beneficiary cost coinsurance from beneficiaries to the federal government. CMS stated further that it prepared a regulatory impact analysis (RIA) that presents the costs and benefits of this final rule. The RIA includes: (1) a statement of need; (2) overall impact; (3) changes in relative value unit impacts; (4) effect of changes related to telehealth services; (5) effect of changes related to scopes of practice; (6) effect of changes to bundled payments under PFS for substance use disorders; (7) effect of modifications to Medicare coverage for opioid use disorder treatment services furnished by opioid treatment programs; (8) other provisions of the regulation; (9) alternatives considered for changes related to scopes of practice; (10) impact on beneficiaries; (11) estimating regulatory familiarization cost; (12) accounting statement; and (13) conclusion.

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

CMS prepared a final regulatory flexibility analysis (FRFA). According to CMS this final rule will have a significant impact on a substantial number of small entities. CMS stated that approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities and many of the entities affected by this final rule are small entities. CMS stated further that the FRFA must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities. CMS explained that the RIA and other areas of the final rule provide the information needed to comply with the stated RFA requirements. Finally, CMS certified that this final rule will not have a significant impact on the operations of a substantial number 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 that this final rule imposes no mandates that require spending in any one year of \$156 million (\$100 million in 1995 dollars, adjusted for inflation) on state, local, or tribal governments or on the private sector.

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

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

On October 5, 2020, CMS published a proposed rule. 85 Fed. Reg. 50074 (CY 2021 PFS proposed rule). CMS received 44,163 comments. CMS addressed comments throughout the preamble of this final rule. CMS also stated that it indicated in the CY 2021 PFS proposed rule its intent that for certain provisions of the March 31st, May 8th, and September 2nd COVID-19 interim final rules with comment period,¹ it would respond to comments received in this final rule. CMS stated further that it responded to public comments and finalized certain provisions of the March 31st, May 8th, and September 2nd COVID-19 interim final rules with comment period (IFC) in this final rule.

CMS asserts that it would be impracticable and contrary to the public interest to undergo notice and comment procedures before finalizing the interim final rules. CMS stated that delaying implementation of these policies in this interim final rule is unnecessary because the impact on other PFS services for 2021 is negligible and the practical alternative for this treatment is no payment under Medicare Part B. CMS noted that, in either case, payments for 2022 and

¹ *Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency*, 85 Fed. Reg. 19230 (Apr. 6, 2020) (March 31st COVID-19 IFC); *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 8th COVID-19 IFC); and *Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency*, 85 Fed. Reg. 54820 (Sept. 2, 2020) (September 2nd COVID-19 IFC).

beyond would be informed by public comments. Thus, CMS stated that it found good cause to waive the notice of proposed rulemaking and to issue this interim final rule with an opportunity for public comment. Finally, CMS stated that it is providing a 60-day public comment period for the provisions in this interim final rule related to Coding and Payment of Virtual Check-in Services and Coding and Payment for Personal Protective Equipment.

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 that it published a notice in the *Federal Register* and solicited public comment about the ICRs, which it plans to submit to the Office of Management and Budget (OMB) for review and approval. The ICRs include: Conditions for Payment, Form CMS-855A (OMB Control Number 0938-0685); Conditions for Payment, Form CMS-855B (OMB Control Number 0938-1377); Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan (OMB Control Number 0938-TBD); Quality Payment Program (OMB Control Number 0938-1314); Quality Payment Program (OMB Control Number 0938-1222). CMS estimates the total cost of these ICRs to be \$170,342,155.

Statutory authorization for the rule

CMS promulgated this final rule pursuant to sections 1302, 1306, 1395m, 1395w-101 through 1395w-152, 1395hh, 1395rr, 1395ddd, and 1395jjj of title 42; and chapter 35 of title 44, 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 determined that this final rule does not impose any costs on state or local governments. Thus, according to CMS, the requirements of the Order are not applicable.