

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

B-333779

November 30, 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 Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review 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 Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements” (RIN: 0938-AU42). We received the rule on November 8, 2021. It was published in the *Federal Register* as a final rule on November 19, 2021. 86 Fed. Reg. 64996. The effective date is January 1, 2022.

According to CMS, the final rule addresses: changes to the physician fee schedule; 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; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; updates to certain Medicare provider enrollment policies; requirements for prepayment and post payment medical review activities; requirements for electronic prescribing for controlled

substances for a covered Part D drug under a prescription drug plan, or a Medicare Advantage Prescription Drug plan; updates to the Medicare Ground Ambulance Data Collection System; changes to the Medicare Diabetes Prevention Program expanded model; and amendments to the physician self-referral law regulations.

The Congressional Review Act (CRA) requires a 60-day delay in 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 19, 2021. 86 Fed. Reg. 64996. The *Congressional Record* does not indicate when the final rule was received by Congress. 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.

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, flowing style.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
Regulations Coordinator

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; CY 2022 PAYMENT POLICIES
UNDER THE PHYSICIAN FEE SCHEDULE AND
OTHER CHANGES TO PART B PAYMENT POLICIES;
MEDICARE SHARED SAVINGS PROGRAM REQUIREMENTS;
PROVIDER ENROLLMENT REGULATION UPDATES;
AND PROVIDER AND SUPPLIER PREPAYMENT
AND POST-PAYMENT MEDICAL REVIEW REQUIREMENTS”
(RIN: 0938-AU42)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated the final rule would increase expenditures from the federal government to providers in the amount of \$2.7 billion due to changes in the physician fee schedule conversion factor. CMS further estimated there would be reduction in transfers from beneficiaries to the federal government in the amount of \$0.7 billion.

(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. The analysis included: (1) a statement of need for the final rule; (2) a description of its overall impact; (3) an explanation of changes in relative value unit impacts; (4) a description of the effect of changes related to telehealth services; (5) a description of the effect of changes related to services furnished in whole or in part by physical therapist assistants and occupational therapy assistants; (6) a discussion of other provisions of the final rule; (7) a description of an impact on beneficiaries; (8) an estimate of the regulatory familiarization costs; and (9) an accounting statement.

CMS also certified the final rule would 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 the final rule will impose no mandates 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 July 23, 2021, CMS published a proposed rule. 86 Fed. Reg. 39104. CMS received comments on the proposed rule and addressed them in the final rule.

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

CMS determined the final rule contained Information Collection Requirements (ICRs) subject to PRA. CMS discussed the burdens and the Office of Management and Budget (OMB) control numbers associated with each ICR in the final rule.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 263a, 405, 1302, 1306, 1320b-12, 1395m, 1395w-101 through 1395w-152, 1395x, 1395y, 1395ff, 1395hh, 1395n, 1395kk, 1395rr, 1395ww, 1395ddd, and 1395jjj of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

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

Executive Order No. 13132 (Federalism)

CMS determined that since the final rule does not impose any costs on state or local governments, the requirements of the Order are not applicable.