U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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November 23, 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

The Honorable Robert C. "Bobby" Scott
Chairman
The Honorable Virginia Foxx
Ranking Member
Committee on Education and Labor
House of Representatives

Subject: *Department of the Treasury, Internal Revenue Service, Office of the Secretary; Department of Labor, Employee Benefits Security Administration; Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of the Secretary: Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency*

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 the Treasury, Internal Revenue Service, Office of the Secretary; Department of Labor, Employee Benefits Security Administration; Department of Health and Human Services, Centers for Medicare & Medicaid Services, Office of the Secretary (the agencies) entitled "Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" (RINs: 1545-BP97; 1210-AB98; 0938-AU35). We received the rule on November 4, 2020. It was published in the *Federal Register* as an interim final rule with request for comments on November 6, 2020. 85 Fed. Reg. 71142. The effective date of the rule is November 2, 2020, except for certain amendatory instructions, which are effective on January 1, 2021.

The interim final rule implements section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Pub. L. No. 116-136, 134 Stat. 281 (Mar. 27, 2020), which, according to the agencies, established Medicare Part B coverage and payment for Coronavirus Disease 2019 (COVID-19) vaccine and its administration. According to the agencies, the rule implements requirements in the CARES Act that providers of COVID-19 diagnostic tests make public their cash prices for those tests and establishes an enforcement scheme to enforce those requirements. The agencies stated that the rule also establishes an add-on payment for cases involving the use of new COVID-19 treatments under the

Medicare Inpatient Prospective Payment System. The rule, according to the agencies, provides for separate payment for new COVID-19 treatments under the Outpatient Prospective Payment System for the remainder of the public health emergency for COVID-19 when these treatments are provided at the same time as a Comprehensive Ambulatory Payment Classification service. The agencies further stated that the rule interprets and implements the requirement to maintain Medicaid beneficiary enrollment in order to receive the temporary increase in federal funding in the Families First Coronavirus Response Act, Pub. L. No. 116-127, 134 Stat. 178 (Mar. 18, 2020). Additionally, the agencies stated that the rule modifies policies of the Comprehensive Care for Joint Replacement model and adds technical changes to accommodate these policy changes.

Also, the agencies state that the rule amends regulations regarding coverage of preventive health services to implement section 3203 of the CARES Act, which shortens the timeframe within which non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage must begin to cover without cost sharing qualifying coronavirus preventive services, including recommended COVID-19 immunizations, according to the agencies. Lastly, the rule revises regulations to set forth flexibilities in the public notice requirements and post award public participation requirements for State Innovation Waivers under section 1332 of the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (Mar. 23, 2010), during the public health emergency for COVID-19, according to the agencies.

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). Here, the agencies stated that it is critically important that the agencies implement the policies in this interim final rule as quickly as possible, as the United States is in the midst of the public health emergency for COVID-19. The agencies stated that it is impracticable and contrary to the public interest not to waive the delay in effective date of the rule under CRA. Therefore, the agencies stated that there is good cause to waive CRA's delay in effective date.

Enclosed is our assessment of the agencies' 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
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Enclosure

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Department of the Treasury

Jeanne Klinefelter Wilson
Acting Secretary, Employee Benefits
Security Administration
Department of Labor

ENCLOSURE

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF THE TREASURY,
INTERNAL REVENUE SERVICE,
OFFICE OF THE SECRETARY;
DEPARTMENT OF LABOR,
EMPLOYEE BENEFITS SECURITY ADMINISTRATION;
DEPARTMENT OF HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE & MEDICAID SERVICE,;
OFFICE OF THE SECRETARY
ENTITLED
"ADDITIONAL POLICY AND REGULATORY REVISIONS IN
RESPONSE TO THE COVID-19 PUBLIC HEALTH EMERGENCY"
(RINs: 1545-BP97; 1210-AB98; 0938-AU35)

(i) Cost-benefit analysis

The Department of the Treasury, Internal Revenue Service, Office of the Secretary; Department of Labor, Employee Benefits Security Administration; Department of Health and Human Services, Centers for Medicare & Medicaid Services; Office of the Secretary (the agencies) conducted an economic analysis of this interim final rule. This analysis discussed the (1) effect of price transparency for Coronavirus Disease 2019 (COVID-19) diagnostic tests during the public health emergency; (2) effects of Medicare inpatient prospective payment system new COVID-19 treatments add-on payment for the remainder of the public health emergency; (3) effects of the Medicare outpatient prospective payment system separate payment for new COVID-19 treatments policy for the remainder of the public health emergency; (4) effects of temporary increase in federal Medicaid funding; (5) effects of updates to the comprehensive care for joint replacement model, performance year 5, during the public health emergency; (6) effects of rapid coverage of preventative services for coronavirus; (7) effects of changes to state innovation waivers policy and regulatory revisions in response to the COVID-19 public health emergency; (8) effects of Medicare coding and payment for COVID-19 vaccine, and (9) effects of application fee as part of Form CMS-855B enrollment as mass immunization roster biller.

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

The agencies stated that because this interim final rule was not preceded by a general notice of proposed rulemaking, the requirements of RFA do not apply.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

The agencies stated that because this interim final rule was not preceded by a general notice of proposed rulemaking, the requirements of the Act do not apply.

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

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

The agencies stated that it is critically important that the policies in this interim final rule be implemented as quickly as possible, as the United States is in the midst of the public health emergency for COVID-19. Therefore, the agencies stated that they found good cause to waive notice of proposed rulemaking under the Act. 5 U.S.C. § 553(b).

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

The agencies determined that this interim final rule contains information collection requirements (ICRs) under PRA. The agencies stated that ICRs and burden will be submitted to the Office of Management and Budget (OMB) under Control Number 0938-NEW. Regarding ICRs for price transparency for COVID-19 diagnostic tests, the agencies estimated 83,309 burden hours, a one-time cost per provider of $72.62, and a total estimated cost of $6,049,900. Regarding ICRs for state innovation waivers policy and regulatory revision in response to COVID-19 public health emergency, the agencies estimated the total burden hours, assuming approximately 15 states apply for and receive approval of the modification request, of 18.75 with an equivalent cost of approximately $2,094. With respect to ICRs regarding the comprehensive joint replacement model, the agencies stated that PRA does not apply. With respect to ICRs regarding enrollment as mass immunization roster biller, cost of completing Form CMS-855B, the agencies projected a total burden of 150,000 hours at a cost of $7,350,000. The agencies additionally provided that when averaged over the typical 3-year OMB approval period, they estimate an annual burden of 50,000 hours at a cost of $2,450,000.

Statutory authorization for the rule

The agencies promulgate this interim final rule pursuant to various sections of titles 31, 42, 26, and 29, United States Code; section 101(g) of Public Law 104-191; section 401(b) of Public Law 105-200; section 512(d) of Public Law 110-343; various sections of Public Law 111-148, as amended by Public Law 111-152; division M of Public Law 113-235; and various sections of Public Law 116-136.

Executive Order No. 12866 (Regulatory Planning and Review)

The agencies determined that this interim final rule is likely to have economic impacts of $100 million or more in at least one year and, thus, meets the definition of “economically significant” under the Order. Therefore, according to the agencies, the rule was reviewed by OMB.

Executive Order No. 13132 (Federalism)

The agencies stated that they engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners (NAIC), and consulting with state insurance officials on an individual basis. Also, the agencies stated that, while developing this interim final rule, they attempted to balance the states’ interests in regulating health insurance issuers with the need to ensure market stability.