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November 24, 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

Subject: *Department of the Treasury, Internal Revenue Service; Department of Labor, Employee Benefits Security Administration; Department of Health and Human Services: Transparency in Coverage*

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; Department of Labor, Employee Benefits Security Administration; Department of Health and Human Services (the Departments) entitled "Transparency in Coverage" (RINs: 1545-BP47; 1210-AB93; 0938-AU04). We received the rule on November 4, 2020. It was published in the *Federal Register* as a final rule on November 12, 2020. 85 Fed. Reg. 72158. The effective date of the final rule is January 11, 2021.

According to the Departments, the final rule sets forth requirements for group health plans and health insurance issuers in the individual and group markets to disclose cost-sharing information upon request to a participant, beneficiary, or enrollee (or his or her authorized representative), including an estimate of the individual's cost-sharing liability for covered items or services furnished by a particular provider. The Departments stated, under the final rule, plans and issuers are required to make this information available on an internet website and, if requested, in paper form, thereby allowing a participant, beneficiary, or enrollee (or his or her authorized representative) to obtain an estimate and understanding of the individual's out-of-pocket expenses and effectively shop for items and services. The Departments stated further, the final

rule also requires plans and issuers to disclose in-network provider negotiated rates, historical out-of-network allowed amounts, and drug pricing information through three machine-readable files posted on an internet website, thereby allowing the public to have access to health coverage information that can be used to understand health care pricing and potentially dampen the rise in health care spending. The Departments noted, the Department of Health and Human Services is also finalizing amendments to its medical loss ratio (MLR) program rules to allow issuers offering group or individual health insurance coverage to receive credit in their MLR calculations for savings they share with enrollees that result from the enrollees shopping for, and receiving care from, lower-cost, higher-value providers.

Enclosed is our assessment of the Departments' 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 fluid and cursive, with the first letters of each name being capitalized and prominent.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Vanessa Jones
Regulations Coordinator
Department of Health and Human Services

Carrie E. Mudd
Director, Legal Processing Division

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

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF THE TREASURY,
INTERNAL REVENUE SERVICE;
DEPARTMENT OF LABOR,
EMPLOYEE BENEFITS SECURITY ADMINISTRATION;
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ENTITLED
(RIN: 1545-BP47; 1210-AB93; 0938-AU04)

(i) Cost-benefit analysis

The Department of the Treasury, Internal Revenue Service; Department of Labor, Employee Benefits Security Administration; Department of Health and Human Services (the Departments) conducted an economic impact analysis. This analysis included a statement of need; overall impact; regulatory review costs; and regulatory alternatives considered. The Departments stated that the benefits of the final rule include potential societal resource savings (non-quantified efficiency portion of any overall reduction in consumer health care expenditures) and potential to reduce the cost of surprise billing to consumers. The Departments stated further that they estimate the annualized monetary cost to be \$4,047.7 million to \$5,472.4 million from 2021 through 2025.

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

The Departments stated that the final rule will not have a significant impact on any entity subject to the final rules including small entities. The Departments stated further that the 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

The Departments stated the final rule includes instructions for disclosures that would affect private sector firms, but that they expect the combined impact on state, local, and tribal governments to be below the threshold of \$156 million (\$100 million, adjusted for inflation), or more. The Departments also stated they recognize that due to the size and complexity of the machine-readable files required by the final rule, some states will incur increased burdens and costs to review and ensure compliance with the requirements in the final rule. The Departments stated further that, at this time, they do not have available funding to provide grants to assist states in their efforts. The Departments noted that they will consider and evaluate the potential necessity to provide grants to assist states in their efforts should a significant need arise. The Departments stated they expect that a number of states with the requisite authority to enforce the provisions of the final rule may defer enforcement to federal regulators because of a lack of funds.

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

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

On November 27, 2019, the Departments published a proposed rule entitled *Transparency in Coverage*, 84 Fed. Reg. 65464 (Proposed Rules). The Departments stated that they received over 25,000 comments in response to the Proposed Rules from a range of stakeholders, including plans and issuers, health care providers, prescription drug companies, employers, state regulators, health IT companies, health care policy organizations and think tanks, and individuals. The Departments noted that it received a number of comments and suggestions that were outside the scope of the proposed rules that are not addressed in the final rule (for example, regarding hospital prices, other methods for reducing health care and prescription drug costs, consumer education and provider directories). The Departments asserted that they carefully considered the comments and they are finalizing the Proposed Rules with certain modifications made in response to comments. The comments and modifications are discussed in the preamble of the final rule.

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

The Departments determined that the final rule contains information collection requirements (ICRs) under the Act. Some ICRs in the final rule are currently approved by the Office of Management and Budget (OMB). The ICRs submitted for approval to OMB are associated with CMS-10715—Transparency in Coverage (OMB Control Number 0938-1372). The Departments note that high-end 3-year estimated values were used to determine the overall estimated 3-year average of annual burden estimates. The Departments estimate the total annual burden hours for the ICRs to be 57,210,971 hours and the total cost to be \$7,981,977,844.10.

Statutory authorization for the rule

The Departments promulgated the final rule pursuant to sections 7805 and 9833 of title 26, United States Code; sections 1135, 1185d, and 1191c of title 29, United States Code; and sections 300gg to 300gg-63, 300gg-91, 300gg-92, and 300gg-94 of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

The Departments determined that the final rule is economically significant under the Order and stated the rule was reviewed by OMB.

Executive Order No. 13132 (Federalism)

The Departments stated that the final rule may have federalism implications. The Departments stated further that they have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences for the National Association of Insurance Commissioners, and consulting with state insurance officials on an individual basis. The Departments noted they attempted to balance the states' interests in regulating issuers with Congress's intent to provide an improved level of price transparency to the public in every state.