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Washington, DC 20548

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December 16, 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 Health and Human Services, Centers for Medicare and Medicaid Services: Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations*

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 and Medicaid Services (CMS) entitled “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations” (RIN: 0938-AU02). We received the rule on November 25, 2020. It was published in the *Federal Register* as a final rule on December 2, 2020. 85 Fed. Reg. 77898. The effective date of this final rule is February 1, 2021.

According to CMS this final rule revises the Organ Procurement Organizations Conditions for Coverage to increase donation rates and organ transplantation rates by

replacing the current outcome measures with new transparent, reliable, and objective outcome measures and increasing competition for open donation service areas.

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 cursive script that reads "Shirley A. Jones". The signature is written in black ink and is positioned above the typed name and title.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

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

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 AND MEDICAID SERVICES
ENTITLED
“MEDICARE AND MEDICAID PROGRAMS; ORGAN PROCUREMENT
ORGANIZATIONS CONDITIONS FOR COVERAGE: REVISIONS TO THE
OUTCOME MEASURE REQUIREMENTS FOR
ORGAN PROCUREMENT ORGANIZATIONS”
(RIN: 0938-AU02)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) conducted an analysis of the costs and benefits of the final rule and prepared an accounting statement and table. According to CMS the accounting table estimates do not include substantial out-year benefits to patients, additional savings to the end-stage renal disease program, and substantial costs to public and private insurance programs that will occur outside the 5-year estimating window. CMS annualized and monetized its estimates for years 2022 through 2026. The accounting table presents values in 2017 dollars at discount rates of 3 and 7 percent. CMS estimated the annual health benefits to be \$1,370 million at the 7 percent discount rate, and \$1,430 million at the 3 percent discount rate. CMS stated that it estimated the annual medical expenditure savings to be \$1,450 million at 3 and 7 percent discount rates. CMS noted, because increased transplant activity imposes costs upfront but yields savings over time, a longer time horizon would show medical expenditure impacts falling in magnitude, potentially to the point of being exceeded by longevity benefits. CMS estimated the annualized cost to be \$10 million. CMS also noted administrative costs in the event of Organ Procurement Organization (OPO) decertification and for regulatory compliance are believed to be relatively minor compared to the high costs and benefits of increasing donors and transplants.

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

According to CMS the great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the U.S. Small Business Administration definition of a small business. CMS asserts that there would be no significant economic effect on a substantial number of hospitals and that increases in transplant volume will be neutral or positive. CMS also discussed the potential economic effects on OPOs and provided a range of possible outcomes. CMS stated that the RFA, Regulatory Impact Analysis, and preamble taken as a whole contain a number of requirements for the content of a Final Regulatory Flexibility Analysis, including a description of the reasons why action is being considered, a statement of the objectives and legal basis for the rule, a description of any reporting or record-keeping requirements of the rule, and a description of any other federal rules that duplicate, overlap, or conflict with the proposed or final rule (CMS states there are none in this case), among others. Lastly, CMS determined that this 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 rule contains no mandates that directly impose spending costs of \$156 million (\$100 million, adjusted for inflation), or more on state, local, or tribal governments, or by 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 in the *Federal Register* on December 23, 2019, entitled, “Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations. 84 Fed. Reg. 70628. CMS stated that it received approximately 834 total comments. According to CMS, commenters included individual OPOs, transplant hospitals, national associations and coalitions, academic researchers, advocacy organizations, health care professionals and corporations, donor families, and numerous individuals from the general public. CMS also stated that most commenters supported the proposed rule's goals to improve organ donation and transplantation in the U.S. and to update the current OPO outcome measures. CMS stated further that it provided a summary of each proposed provision, a summary of the public comments received and its responses to them, and an explanation for changes in the policies that it is finalizing.

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

CMS determined that this final rule contains information collection requirements (ICRs) under PRA. CMS noted that it plans to submit the ICRs in this final rule to the Office of Management and Budget (OMB) for review and approval. CMS will submit a revised information collection request for the OPO Conditions for Coverage (CfC) (OMB Control Number 0938-0688, expiring February 28, 2021) information to reflect the opportunity it is providing for OPOs to request an extraordinary circumstances exception. CMS estimated that this ICR would result in an annual cost of \$284. CMS stated that there is another ICR associated with OMB Control Number 0938-0688. This final rule provides an opportunity of OPOs to apply for open donation service areas. CMS estimated that this application process could result in a total annual burden of 1,898 hours at a cost of \$161,038. CMS stated further that it is eliminating an ICR associated with OMB Control Number 0938-0688, but it is not attributing any quantifiable burden reduction to eliminating this requirement in the final rule because the type of data and how it is reported is already covered by the ICRs associated with OMB control number 0915-0157 (expiring August 31, 2023). Lastly, CMS asserted that an ICR associated with the information collection request for OPO requirements, OMB Control Number 0938-0688, is exempt, as defined in 5 C.F.R. § 1320.3(b)(2), because the time, effort, and financial resources necessary to comply with this collection of information would be incurred by persons in the normal course of their activities. Accordingly, CMS, believes this change would not impose any additional ongoing quantifiable burden.

Statutory authorization for the rule

CMS promulgated this final rule pursuant to sections 273, 1302, 1320b-8, and 1395hh of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS estimated and OMB has determined that this rule is economically significant under the Order.

Executive Order No. 13132 (Federalism)

CMS determined that this final rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Order.