



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

B-332770

December 14, 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 Program; Modernizing and Clarifying the Physician Self-Referral Regulations*

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 Program; Modernizing and Clarifying the Physician Self-Referral Regulations” (RIN: 0938-AT64). 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. 77492. The final rule has an effective date of January 19, 2021.

According to CMS, the final rule addresses any undue regulatory impact and burden of the physician self-referral law, 42 U.S.C. § 1395. This final rule is being issued in conjunction with CMS’s Patients over Paperwork initiative and the Department of Health and Human Services’ Regulatory Sprint to Coordinated Care. CMS stated the final rule establishes exceptions to the physician self-referral law for certain value-based compensation arrangements between or among physicians, providers, and suppliers. CMS further stated it also establishes a new exception for certain arrangements under which a physician receives limited remuneration for items or services actually provided by the physician; establishes a new exception for donations of cybersecurity technology and related services; and amends the existing exception for electronic health records (EHR) items and services. CMS also stated this final rule provides

critically necessary guidance for physicians and health care providers and suppliers whose financial relationships are governed by the physician self-referral statute and regulations.

The Congressional Review Act (CRA) requires a 60-day 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 House of Representatives received the final rule on December 2, 2020. 166 Cong. Rec. H6857 (daily ed. Dec. 4, 2020). The Senate also received the final rule on December 2, 2020. 166 Cong. Rec. S7211 (daily ed. Dec. 3, 2020). The final rule was published on December 2, 2020. 85 Fed. Reg. 77492. The final rule has an effective date of January 19, 2021. Therefore 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 style with a large, looped initial 'S'.

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 PROGRAM; MODERNIZING AND CLARIFYING  
THE PHYSICIAN SELF-REFERRAL REGULATIONS”  
(RIN: 0938-AT64)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) estimated the final rule would create a cost of \$4.3 million a year from 2020 to 2029 at a 7 percent discount rate, or a cost of \$3.6 million a year at a 3 percent discount rate for the same period.

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

CMS determined the final rule will not have a significant impact on small businesses because, according to CMS, it will likely reduce, not increase, regulatory burden. CMS also determined, and the Secretary of the Department of Health and Human Service certified, the final rule will not have a significant impact on 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 imposes no mandates on state, local, or tribal governments, or on the private sector, and reduces regulatory burden on health care providers and suppliers.

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

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

On October 17, 2019, CMS published a proposed rule. 84 Fed. Reg. 55766. On the same day, the Office of Inspector General for the Department of Health and Human Services published a proposed rule under the anti-kickback statute. 84 Fed. Reg. 55694. CMS received comments and addressed them in the final rule.

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

CMS determined the writing, signature, and record retention requirements imposed by this final rule should be considered usual and customary business practice and exempt from the Act.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 1302, 1395w-101 *et seq.*, 1395hh, and 1395nn of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

CMS determined the final rule was economically significant and stated the rule was reviewed by the Office of Management and Budget.

Executive Order No. 13132 (Federalism)

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