



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

B-331769

February 3, 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 & Medicaid Services: Medicare, Medicaid, and Children’s Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process*

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, Medicaid, and Children’s Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process” (RIN: 0938-AS84). We received the rule on January 17, 2020. It was published in the *Federal Register* as a final rule with comment period on September 10, 2019. 84 Fed. Reg. 47794. The effective date of the rule is November 4, 2019.

According to CMS, the final rule implements statutory provisions that require Medicare, Medicaid, and Children’s Health Insurance Program (CHIP) providers and suppliers to disclose certain current and previous affiliations with other providers and suppliers. CMS states that the rule also provides the agency with additional authority to deny or revoke a provider’s or supplier’s Medicare enrollment in certain specified circumstances. According to CMS, the provisions in this rule are necessary to address various program integrity issues and vulnerabilities by enabling CMS to take action against unqualified and potentially fraudulent entities and individuals, which in turn could deter other parties from engaging in improper behavior.

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 final rule was received by both Houses of Congress on January 17, 2020. 166 Cong. Rec. H334 (daily ed. Jan. 21, 2020), 166 Cong. Rec. S635 (daily ed. Jan. 28, 2020). The final rule was published in the *Federal Register* on September 10, 2019. 84 Fed. Reg. 47794. The final rule has an effective date of November 4, 2019. Therefore, the final rule does not have the required 60-day delay in its 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 Janet Temko-Blinder, Assistant General Counsel, at (202) 512-7104.

signed

Shirley A. Jones  
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II  
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 & MEDICAID SERVICES  
ENTITLED  
“MEDICARE, MEDICAID, AND CHILDREN’S HEALTH INSURANCE PROGRAMS;  
PROGRAM INTEGRITY ENHANCEMENTS TO THE  
PROVIDER ENROLLMENT PROCESS”  
(RIN: 0938-AS84)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimates that the final rule will cost providers and suppliers \$937,500 in each of the first 3 years of this rule. According to CMS, this cost involves the information collection burden associated with the requirement that Medicare, Medicaid, and Children’s Health Insurance Programs (CHIP) disclose certain current and prior associations.

CMS also projected the following savings: (1) the new revocation authority will lead to approximately 2,600 new revocations per year, resulting in a 10-year savings of \$4.16 billion (based on a projected per-revoked provider amount of \$160,000); (2) the new reenrollment and reapplication bar provisions will apply to approximately 400 of CMS’s revocations per year, resulting in an estimated 10-year actual savings of \$1.79 billion (based on a projected per-revoked provider amount of \$160,000) and a caused savings of \$4.48 billion; and (3) a range of savings related to the final rule’s affiliations provisions, which ranged from estimates of annual savings of \$2.06 billion to \$6.22 billion.

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

CMS determined that the rule will not have a significant economic impact on a substantial number of small businesses. CMS also determined that this 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

CMS determined that the rule does not mandate any requirements for state, local, or tribal governments or for 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 March 1, 2016, CMS published a proposed rule. 81 Fed. Reg. 10720. CMS received 87 timely pieces of correspondence in response to the rule. CMS responded to comments in the final rule.

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

CMS determined that this final rule contains information collection requirements (ICR) under the Act. CMS estimated the burden of each ICR. CMS estimated the annual ICR burden over each of the first 3 years of the rule to be 25,000 hours at a cost of \$937,500.

Statutory authorization for the rule

CMS promulgated this final rule pursuant to sections 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k) of title 42, United States Code.

Executive Order No. 12,866 (Regulatory Planning and Review)

CMS determined that the rule is economically significant under the Order.

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule does not impose any costs on state or local governments.