



441 G St. N.W.
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December 22, 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, Office of Inspector General: Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

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, Office of Inspector General (HHS) entitled “Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements” (RIN: 0936–AA10). We received the rule on December 8, 2020. It was published in the *Federal Register* as a final rule on December 2, 2020. 85 Fed. Reg. 77684. The final rule has an effective date of January 19, 2021.

According to HHS, the final rule amends the safe harbors to the federal anti-kickback statute, 42 U.S.C. § 1395, by adding new safe harbors and modifying existing safe harbors that protect certain payment practices and business arrangements from sanctions under the anti-kickback statute. HHS also stated the final rule amends the civil monetary penalty rules by codifying a revision to the definition of “remuneration” added by the Bipartisan Budget Act of 2018, Pub. L. No. 115-123, 132 Stat. 64 (Feb. 9, 2018).

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 House of Representatives received the final rule on December 16, 2020. 166 Cong. Rec. H7276 (daily ed. Dec. 18, 2020). The Senate received the final rule on December 11, 2020. 166 Cong. Rec. S7541 (daily ed. Dec. 16, 2020). The final rule was published on December 2, 2020. 85 Fed. Reg. 77684. The final rule has an effective date of January 19, 2021. Therefore the final rule does not have the required 60-day delay.

Enclosed is our assessment of HHS'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, flowing style.

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,
OFFICE OF INSPECTOR GENERAL
ENTITLED
“MEDICARE AND STATE HEALTH CARE PROGRAMS:
FRAUD AND ABUSE; REVISIONS TO SAFE HARBORS UNDER THE
ANTI-KICKBACK STATUTE, AND CIVIL MONETARY PENALTY RULES
REGARDING BENEFICIARY INDUCEMENTS”
(RIN: 0936-AA10)

(i) Cost-benefit analysis

The Department of Health and Human Services, Office of Inspector General (HHS) stated the final rule may: (1) remove barriers to robust participation in beneficial value-based health care delivery and payment systems, including those administered by the Centers for Medicare & Medicaid Services (CMS) and non-federal payers; (2) facilitate arrangements for beneficial patient care coordination among affiliated and unaffiliated health care providers, practitioners, suppliers, and others; (3) remove barriers to providing tools and supports to patients to better engage them in their care and improve health outcomes; (4) provide certainty for participants in the Medicare Shared Savings Program and Innovation Center models; (5) facilitate the continued adoption and use of electronic health records by making permanent the safe harbor for the donation of such items and services; and (6) promote more robust cybersecurity throughout the health care system.

HHS also stated the final rule may lead to: (1) improved care coordination for patients, including federal health care program beneficiaries; (2) improved quality of care and outcomes for patients, including health care program beneficiaries; (3) potential reduction in compliance costs to individuals and entities to which the federal anti-kickback statute's and beneficiary inducements civil monetary penalty's prohibitions apply; (4) reduction in administrative complexity and related waste from continued progress toward interoperability of data and electronic health records; (5) protection against the corruption of or access to health records and other information essential to the safe and effective delivery of health care; and (6) reduction in impacts of cybersecurity attacks, including the improper disclosure of protected health information (PHI), and reduction in costs associated with cybersecurity attacks, including ransom payments, costs to patients whose PHI is improperly disclosed, and costs to providers, suppliers, and others to reestablish cybersecurity.

HHS further stated with respect to the final rule's impact on parties currently participating in the Medicare Shared Savings Program and Innovation Center models, the final rule would not significantly alter the conditions upon which such providers and suppliers operate.

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

HHS determined the final rule would not have a significant impact on a substantial number of small entities. HHS also determined the final rule would not have a significant impact on a substantial number of rural hospitals.

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

HHS stated that no significant costs will be associated with the final rule that would impose any mandates on state governments, tribal governments, local governments, or the private sector that would result in an expenditure of \$154 million (\$100 million, adjusted for inflation) in any given year.

(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, HHS published a proposed rule. 84 Fed. Reg. 55694. HHS received comments on the proposed rule and addressed them in the final rule.

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

HHS determined the final rule does not contain information collection requirements subject to the Act.

Statutory authorization for the rule

HHS promulgated the final rule pursuant to section 6101 note of title 31 and sections 262a, 1302, 1320-7, 1320a-7, 1320a-7a, 1320a-7b, 1320a-7d, 1320b-10, 1395u, 1395w-104, 1395w-141, 1395y, 1395cc, 1395dd, 1395hh, 1395mm, 1395nn, 1395ss, 1396b, 11131, and 11137 of title 42, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

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

Executive Order No. 13132 (Federalism)

HHS determined that the final rule will not significantly affect the rights, roles, and responsibilities of state or local governments.