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June 12, 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, Office of the Secretary: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers*

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), Office of the Secretary entitled “Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers” (RIN: 0938-AT79). We received the rule on May 8, 2020. It was published in the *Federal Register* as a final rule on May 1, 2020. 85 Fed. Reg. 25510. The effective date of the rule is June 30, 2020.

According to CMS, the final rule is intended to move the health care ecosystem in the direction of interoperability and to signal the department’s commitment to the vision set out in the 21st Century Cures Act and by Executive Order No. 13813, October 12, 2017. This vision, according to CMS, is to improve the quality and accessibility of information, including data about health

care prices and outcomes that Americans need to make informed health care decisions, while minimizing reporting burdens on affected health care providers and payers. See Pub. L. No. 114-255, 130 Stat. 1034 (Dec. 13, 2016); Exec. Order No. 13813, *Promoting Healthcare Choice and Competition Across the United States*, 82 Fed. Reg. 48385 (Oct. 17, 2017). Additionally, CMS states that the rule creates and implements new mechanisms to enable patients to access their own health care information through third-party software applications, requiring the payers subject to this final rule to make data available through an application programming interface.

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). It was published in the *Federal Register* as a final rule on May 1, 2020. The House of Representatives received the rule on May 28, 2020, and is reflected in the *Congressional Record* published on June 8, 2020. 116 Cong. Rec. H2375 (daily ed. June 8, 2020) (Executive Communications, Etc.). According to HHS officials, it continues to experience difficulties delivering the rule to the Senate. See E-mail from Regulations Coordinator, Immediate Office of the Secretary, HHS, to CRA Rules, GAO (May 28, 2020 5:47 PM EST). The rule has a stated effective date of June 30, 2020. 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 Shari Brewster, Assistant General Counsel, at (202) 512-6398.



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 HEALTH AND HUMAN SERVICES,
CENTERS FOR MEDICARE & MEDICAID SERVICES,
OFFICE OF THE SECRETARY
ENTITLED
“MEDICARE AND MEDICAID PROGRAMS; PATIENT PROTECTION AND
AFFORDABLE CARE ACT; INTEROPERABILITY AND PATIENT ACCESS
FOR MEDICARE ADVANTAGE ORGANIZATION AND MEDICAID MANAGED CARE PLANS,
STATE MEDICAID AGENCIES, CHIP AGENCIES AND CHIP MANAGED CARE ENTITIES,
ISSUERS OF QUALIFIED HEALTH PLANS ON THE FEDERALLY-FACILITATED
EXCHANGES, AND HEALTH CARE PROVIDERS”
(RIN: 0938-AT79)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS), Office of the Secretary analyzed the benefits and costs of this final rule. Regarding benefits, according to CMS, the application programming interface (API) requirements will alleviate the burden for patients to go through separate processes to obtain access to each system and the need to manually aggregate information that is delivered in various, often non-standardized, formats. CMS states that the API requirement allows for the administration of a more efficient and effective Medicaid program by taking advantage of commonly used methods of information sharing and data standardization. CMS also states that the API requirements would help to create a health care information ecosystem that allows and encourages the health care market to tailor products and services to compete for patients, thereby increasing quality, decreasing costs, providing potential benefits, and helping them live better, healthier lives. According to CMS, privacy and security policies are being implemented that permit payers to request third-party apps to attest to privacy and security provisions prior to providing the app access to the payer's API. Regarding costs, CMS provides estimates of annualized costs each year from 2020 through 2029, in 2019 dollars. In its primary estimate, CMS estimates costs ranging from \$122 million per year at the 7 percent discount rate, to \$112.4 million per year at the 3 percent discount rate. CMS notes that non-quantified costs include non-hospital provider costs associated with development of a broad health care information ecosystem, acknowledging that regulatory benefits and fraud reduction are largely contingent upon these non-mandatory costs being incurred. CMS also provides estimates of transfers from the federal government to enrollees of commercial plans each year from 2020 through 2029. CMS estimates that these transfers will range from \$5.4 million per year in 2019 dollars at the 7 percent discount rate, to \$5.5 million per year in 2018 dollars at the 3 percent discount rate. CMS notes that non-quantified transfers include reduced fraudulent payments to providers from the federal government and other payers.

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

The Secretary of HHS determined that this final rule will not have a significant economic impact on a substantial number of small entities. Furthermore, CMS determined, and the Secretary

certifies, that this final rule would 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 final rule will not have an effect on state, local, or tribal governments, in the aggregate, or on the private sector, of \$156 million (\$100 million, adjusted for inflation) or more.

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

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

On March 4, 2019, CMS published a proposed rule. 84 Fed. Reg. 7610 (Mar. 4, 2019). CMS responded to comments and outlines its final policies in this final rule.

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

CMS determined that this final rule contains information collection requirements (ICRs) under the Act. CMS determined this final rule creates new ICRs for API and “Electronic Notifications” associated with Office of Management and Budget (OMB) Control Number 0938-New and affects an existing ICR for “MMA File” (OMB Control Number 0938-0958). For the new ICR associated with API, CMS estimated that 345 entities would incur an estimated aggregate burden of 5,796,000 hours of work at a cost of \$544,005,936 during the first year and 589,950 hours at a cost of \$54,391,527 during subsequent years. For the new ICRs associated with “Electronic Notifications,” CMS estimated that 2,400 hospitals and psychiatric hospitals would incur an estimated aggregate burden of 84,000 hours at a cost of \$4,037,568 during the first year and an aggregate burden of 19,200 at a cost of \$812,544 in subsequent years, and 679 critical access hospitals would incur the estimated aggregate burden of 23,765 hours at a cost of \$1,142,295.28 during the first year and 5,432 hours at a cost of \$229,882.24 in subsequent years. For the ICR associated with “MMA File,” CMS estimated a one-time aggregate burden 34,560 hours at a cost of \$3,111,091.

Statutory authorization for the rule

CMS promulgated this final rule pursuant to section 36B of title 26, United States Code, section 9701 of title 31, United States Code, and sections 1302, 1306, 1395w–101 through 1395w–152, 1395hh, 1395rr, 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, and 18082 of title 42, United States Code.

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

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

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a federalism implication.