



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

B-329999

April 30, 2018

The Honorable Orrin G. Hatch
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Greg Walden
Chairman
The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Kevin Brady
Chairman
The Honorable Richard Neal
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; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program*

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; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program” (RIN: 0938-AT08). We received the rule on April 12, 2018. It was published in the *Federal Register* as a final rule on April 16, 2018. 83 Fed. Reg. 16,440. The rule is effective June 15, 2018.

The final rule revises the Medicare Advantage (MA) program (Part C) regulations and Prescription Drug Benefit program (Part D) regulations to implement certain provisions of the Comprehensive Addiction and Recovery Act to further reduce the number of beneficiaries who may potentially misuse or overdose on opioids while still having access to important treatment options; implement certain provisions of the 21st Century Cures Act; support innovative approaches to improve program quality, accessibility, and affordability; offer beneficiaries more choices and better care; improve the CMS customer experience and maintain high beneficiary satisfaction; address program integrity policy related to payments based on prescriber, provider

and supplier status in MA, Medicare cost plan, Medicare Part D and the PACE programs; provide an update to the official Medicare Part D electronic prescribing standards; and clarify program requirements and certain technical changes regarding treatment of Medicare Part A and Part B appeal rights related to premiums adjustments.

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. Our review of the agency's submission to us indicates that CMS complied with the applicable requirements.

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 Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Agnes Thomas
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; CONTRACT YEAR 2019 POLICY AND
TECHNICAL CHANGES TO THE MEDICARE ADVANTAGE, MEDICARE
COST PLAN, MEDICARE FEE-FOR-SERVICE, THE MEDICARE
PRESCRIPTION DRUG BENEFIT PROGRAMS, AND THE PACE PROGRAM”
(RIN: 0938-AT08)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) states the final rule has a net savings of between \$280 to \$335 million for each of the next 5 years. CMS further states the savings are equivalent of about \$295 million per year for both 7 percent and 3 percent interest rates.

CMS estimates that creation of a lock-in status and implementation of other provisions of the Comprehensive Addiction and Recovery Act will lead to a \$19 million reduction in Trust Fund expenditures in 2019, and this reduction will increase in 2023. CMS also estimates that industry will experience a savings of \$54.7 million per year due to changes in timing and method of disclosure requirements. Also, CMS estimates that providers will save \$34.4 million in 2019 from changes to preclusion list requirements. Finally, CMS estimates a reduction in reinsurance resources of \$204.6 million in 2019 due to updates of the stop-loss protection requirements in physician incentive plans, and this reduction will increase in following years.

CMS estimates industry will experience costs of \$2.8 million per year implementing the Comprehensive Addiction Recovery Act. Further, CMS estimates providers will experience a cost of \$9.3 million in 2019 and continuing costs in later years of below \$50,000 to implement the preclusion list requirements.

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

CMS states the Secretary of Health and Human Services has determined that the final rule will not have a significant economic impact on a substantial number of small entities and the requirements of RFA have been met. The agency also states the Secretary certifies that the 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 states the final rule is not anticipated to have an effect on state, local, or tribal governments, in the aggregate, or on the private sector of \$148 million or more.

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

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

CMS published a notice of proposed rulemaking on November 28, 2017. 82 Fed. Reg. 56,336. CMS states that it received 1,669 timely pieces of correspondence containing multiple comments on the proposed rule. CMS also states while the final rule finalizes several provisions of the proposed rule, there are a number of provisions from the proposed rule that the agency will finalize later and some they do not intend to finalize at all. The agency states comments to the provisions contained in the final rule are addressed in the final rule, but comments on provisions to be finalized later will be addressed at that time. The agency further states comments on provisions that will not be finalized or considered out of scope will not be addressed. CMS published the final rule on April 16, 2018. 83 Fed. Reg. 16,440.

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

CMS stated it solicited comment on a new information collection request (ICR) as required under PRA in the proposed rule. CMS addressed the comments received in the final rule and states that final rule should reduce the burden on the private sector and beneficiaries in responding to the ICR. CMS estimates that total annual hours in response would decrease by 128,171 and that total cost would decrease by \$69,107,926. CMS has sent the ICR to the Office of Management and Budget (OMB) for approval.

Statutory authorization for the rule

CMS promulgated the rule under 31 U.S.C. § 9701, 42 U.S.C. §§ 263(a), 300e, 300e-5, 300e-9, 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

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

CMS states the final rule was reviewed by OMB in accordance with the provisions of the Order.

Executive Order No. 13,132 (Federalism)

CMS states the requirements of the Order are not applicable because the final rule does not impose any substantial costs on state or local governments.