



441 G St. N.W.
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February 1, 2017

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 & Medicaid Services: Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies*

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 and Medicaid Program: Conditions of Participation for Home Health Agencies" (RIN: 0938-AG81). We received the rule on January 18, 2017. It was published in the *Federal Register* as a final rule on January 13, 2017, with a stated effective date of July 13, 2017. 82 Fed. Reg. 4504.

The final rule revises the conditions of participation (CoPs) that home health agencies (HHAs) must meet in order to participate in the Medicare and Medicaid programs. According to CMS, these requirements focus on the care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements. These changes are a part of CMS's overall effort to achieve broad-based, measurable improvements in the quality of care furnished through the Medicare and Medicaid programs, while at the same time eliminating unnecessary procedural burdens on providers.

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 procedural steps taken 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 & MEDICAID SERVICES
ENTITLED
"MEDICARE AND MEDICAID PROGRAM: CONDITIONS OF
PARTICIPATION FOR HOME HEALTH AGENCIES"
(RIN: 0938-AG81)

(i) Cost-benefit analysis

The Centers for Medicare and Medicaid Services (CMS) estimated that annualized net costs for this final rule from calendar years 2017 to 2021 will be \$291 million in 2015 dollars at both 3 percent and 7 percent discount rates. CMS identified burdens associated with (1) information collection requirements, (2) patient rights, (3) quality assessment and performance improvement, and (4) infection prevention and control. CMS also identified decreased burdens associated with removal of (1) the 60-day summary requirement, (2) the group of professional personnel requirement, and (3) the evaluation of the agency's program.

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

CMS certified that this final rule would not have a significant economic impact on a substantial number of small entities. 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 this final rule includes no mandates on state, local, or tribal governments. However, CMS also determined that its estimates of the costs and benefits of this rule exceed the Act's \$146 million threshold (\$100 million, adjusted for inflation), and CMS states that it provided an assessment of the anticipated costs and benefits in the rule.

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

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

On October 9, 2014, CMS published a proposed rule for home health agencies (HHAs) that choose to participate in Medicare and Medicaid. 79 Fed. Reg. 61,164. CMS received 199 letters of public comment from HHA industry associations, patient advocacy organizations, HHAs, and individuals. CMS summarized major issues and its responses in the final rule. For certain provisions of the final rule, CMS found good cause to waive the publication of a notice of proposed rulemaking. CMS found good cause because a change was operational, non-controversial and has already been implemented at the sub-regulatory level; because not doing so would create a direct conflict between state and federal requirements which would impede the ability of home health aides to do their jobs efficiently and effectively and would negatively impact patient care and outcomes; or because the only significant difference between certain

terms is the geographical locations in which these terms are used and continuing the use of both terms, as has been required in the HHA conditions of participation for more than a decade, will have no impact on patient care or HHA operations.

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

CMS determined that this final rule contains information collection requirements under the Act. Specifically, CMS identified 19 provisions of the rule which, in total, impose an annual burden of 4,462,805 hours for a cost of \$182,350,264.

Statutory authorization for the rule

CMS promulgated this final rule under the authority of sections 1102, 1834, 1871, 1881, and 1893 of the Social Security Act. 42 U.S.C. §§ 1302, 1395m, 1395hh, 1395ddd.

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

CMS stated that it examined the impacts of this rule as required by the Order.

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule has no federalism implications under the Order.