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October 18, 2016

The Honorable Lamar Alexander
Chairman
The Honorable Patty Murray
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

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

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services: Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities*

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 Programs; Reform of Requirements for Long-Term Care Facilities" (RIN: 0938-AR61). We received the rule on September 30, 2016. It was published in the *Federal Register* as a final rule on October 4, 2016, with an effective date of November 28, 2016. 81 Fed. Reg. 68,688.

The final rule revises Medicare and Medicaid participation requirements for long-term care (LTC) facilities. As stated by CMS, the rule reflects an effort to improve the quality of life, care, and services in LTC facilities, optimize resident safety, reflect current professional standards, and improve the logical flow of the regulations.

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 PROGRAMS; REFORM OF
REQUIREMENTS FOR LONG-TERM CARE FACILITIES"
(RIN: 0938-AR61)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) summarized the costs and benefits resulting from this final rule. CMS estimated that the total projected cost of this final rule will be about \$831 million in the first year and \$736 million per year for subsequent years. CMS acknowledged that this is a large amount in total, but mentioned that the average cost per facility is estimated to be approximately \$62,900 in the first year and \$55,000 in subsequent years. CMS also anticipated that the cost to the federal government will be \$15 to \$20 million in start-up costs, which CMS expects will be incurred between FY17 and FY18. These start-up costs will go towards updating the interpretive guidance, updating the survey process, and make IT systems changes. Additionally, CMS estimated that the annual costs to the federal government will be between \$15 and \$20 million.

CMS found that the overall benefits will include creating new efficiencies and flexibilities for facilities, which, it states, will support improved resident quality of life and quality of care. CMS acknowledged that improvements to quality of life can be difficult to translate into dollars saved, but cited evidence suggesting that the factors that improve quality of life may also increase the rate of improvement in quality and can have positive business benefits for facilities. Additionally, CMS found that this rule can result in improvements in the caregiver's quality of work life and in savings to the facility. Savings can be accrued through reduced turnover, decreased use of agency labor, and decreased worker compensation costs.

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

CMS determined that this final rule will not have a significant economic impact on a substantial number of small entities. Additionally, CMS 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 assessed the various costs and benefits of this final rule. This final rule will not mandate any new requirements for state, local, or tribal governments. For the private sector facilities, CMS states that the regulatory impact section together with the remainder of the preamble constitutes its analysis required under the Unfunded Mandates Reform Act of 1995.

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

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

On July 16, 2015, CMS published a proposed rule. 80 Fed. Reg. 42,168. CMS received over 9,800 public comments from long-term care consumers, advocacy groups for long-term care consumers, organizations representing providers of long-term care and senior service, long-term care ombudsman, state survey agencies, various health care associations, legal organizations, and many individual health care professionals. CMS responded to comments in the final rule.

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

CMS determined that sections 4204(b) and 4214(d) of the Omnibus Budget Reconciliation Act of 1987 waives PRA requirements for these regulations. However, CMS provides burden estimates for the new information collection requirements finalized in the rule, and particularly for the requirements specifically implemented as a result of the Affordable Care Act.

CMS estimates that the one-time costs for the quality assurance and performance improvement (QAPI) program will be 56 burden hours at a cost of \$4,812 per long-term care (LTC) facility and 876,568 burden hours at a cost of \$75,322,236 for all LTC facilities. These one-time costs are for developing and documenting a comprehensive, data-driven QAPI program. CMS estimates that the annual costs for collecting and analyzing data for QAPI activities will be 40 burden hours at a cost of \$3,204 per LTC facility and 626,120 burden hours at a cost of \$50,152,212 for all LTC facilities.

Information collection requirements regarding compliance and ethics programs are estimated to cost 42 burden hours at a cost of \$3,562 per operating organization and 307,188 burden hours at a cost of \$26,052,468 for all operating organizations in the first year. For all subsequent years, CMS estimates that compliance will cost 10 burden hours at a cost of \$850 per operating organization and 73,140 burden hours at a cost of \$6,216,900 for all operating organizations. ICRs regarding training requirements are estimated to cost 4 burden hours at a cost of \$244 per LTC facility and 62,612 burden hours at a cost of \$3,819,332 for all LTC facilities.

Statutory authorization for the rule

CMS promulgated this rule under section 353 of the Public Health Service Act, sections 205(a), 1102, 1128I, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1888(k) of the Social Security Act. 42 U.S.C. §§ 263a, 405(a), 1032, 1302, 1320a-7j, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, 1395ww(k).

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

CMS determined that this final rule is economically significant. This rule was reviewed by the Office of Management and Budget.

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule does not contain policies that have substantial direct effects on the states, on the relationship between the U.S. government and the states, or the distribution of power and responsibilities among the various levels of government.