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May 27, 2014

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

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
House of Representatives

The Honorable Dave Camp
Chairman
The Honorable Sander Levin
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 Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II*

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; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II" (RIN: 0938-AR49). We received the rule on May 8, 2014. It was published in the *Federal Register* as a final rule on May 12, 2014. 79 Fed. Reg. 27,106.

This final rule amends Medicare regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, as well as certain regulations under the Clinical Laboratory Improvement Amendments of 1988. This final rule also increases the ability of health care professionals to devote resources to improving patient care by eliminating or reducing requirements that impede quality patient care or that divert resources away from providing high-quality patient care. This is the latest in a series of rules developed by CMS over the last 5 years to reform existing rules to reduce unnecessary costs and increase flexibility for health care providers.

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 final rule has a stated effective date of July 11, 2014, with the exception of amendments to part 483 of title 42, Code of Federal Regulations (Part 483), which have a stated effective date of May 12, 2014. The rule was received on May 8, 2014, and published in the *Federal Register* on May 12, 2014. 159 Cong. Rec. S2953 (May 13, 2014); 79 Fed. Reg. 27,106. Therefore, the amendments to part 483 in the final rule do not have the required 60-day delay in effective date. The 60-day delay in effective date can be waived, however, if the agency finds for good cause that notice and public procedures thereon are impracticable, unnecessary, or contrary to the public interest, and the agency incorporates a statement of the findings and its reasons in the rule issued. 5 U.S.C. § 808(2). CMS found good cause exists to make the changes to part 483 effective immediately upon publication. Therefore, the 60-day delay is not required.

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: Ann Stallion
Deputy Director
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; REGULATORY PROVISIONS
TO PROMOTE PROGRAM EFFICIENCY, TRANSPARENCY,
AND BURDEN REDUCTION; PART II"
(RIN: 0938-AR49)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) estimated the costs and savings of this final rule. CMS estimates that this final rule will save between \$230 million and \$830 million per year, annualized over the next 5 years. CMS's primary estimate is that the annualized savings will be about \$640 million and the total cost savings over the next 5 years will be approximately \$3.2 billion.

(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 effect on a substantial number of small entities. CMS has also determined that this final rule will not have a significant negative 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 does not contain any mandates under the Act.

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

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

On February 7, 2013, CMS published a proposed rule. 78 Fed. Reg. 9216. CMS received comments on the proposed rule, to which it responded in the final rule. CMS waived the 30-day delay in effective date under the Administrative Procedure Act, in addition to the 60-day delay under the Congressional Review Act for a portion of the rule. CMS found good cause to make part 483 of title 42, Code of Federal Regulations, effective immediately upon publication. CMS determined that absent such timely action, a number of nursing homes will be unable to apply for, and obtain, an extension of the due date to achieve full sprinkler status before mandatory sanctions take effect, despite their taking action to build a replacement facility or undertake major modifications that may qualify the facility for an extension of time under this final rule.

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

CMS determined that this final rule imposes no new information collection requirements under the Act.

Statutory authorization for the rule

CMS promulgated this final rule under the authority of sections 1102, 1812(d), 1814(b), 1815, 1833(a), (i), and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act, section 124 of Public Law 106–113, section 3201 of Public Law 112–96, and section 632 of Public Law 112–240. 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww; 113 Stat. 1501A–332; 126 Stat. 156; 126 Stat. 2354.

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

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

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 states, or otherwise have a federalism implication.