



441 G St. N.W.
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December 28, 2016

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

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

The Honorable Kevin Brady
Chairman
The Honorable Sander M. Levin
Ranking Member
Committee on Ways and Means
House of Representatives

Subject: *Department of Health and Human Services, Centers for Medicare & Medicaid Services:
Medicare Program; Conditions for Coverage for End-Stage Renal Disease Facilities—
Third Party Payment*

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 Program; Conditions for Coverage for End-Stage Renal Disease Facilities—Third Party Payment” (RIN: 0938-AT11). We received the rule on December 15, 2016. It was published in the *Federal Register* as an interim final rule with comment period on December 14, 2016, with an effective date of January 13, 2017. 81 Fed. Reg. 90,211.

The interim final rule implements new requirements for Medicare-certified dialysis facilities that make payments of premiums for individual market health plans. This interim final rule applies to dialysis facilities that make such payments directly, through a parent organization, or through a third party.

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). This interim final rule was published in the *Federal Register* on December 14, 2016. 81 Fed. Reg. 90,211. It was received on December 15, 2016,

and has a stated effective date of January 13, 2017. 81 Fed. Reg. 90,212. Therefore, the final rule does not have the required 60-day delay in its effective date.

The 60-day delay in effective date can be waived, however, if the agencies find for good cause that delay is impracticable, unnecessary, or contrary to the public interest, and the agencies incorporate a statement of the findings and their reasons in the rule issued. 5 U.S.C. § 553(d)(3), 808(2). CMS found good cause that notice and public procedure is contrary to the public interest. CMS believes patients are currently at risk of harm because health-related and financial risks are not fully disclosed to them, and they may have their transplant readiness delayed or face additional financial consequences. Further, CMS found that consumers are at risk of mid-year coverage disruptions. Therefore, CMS determined that the rule will become effective on January 13, 2017, to best protect consumers.

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 PROGRAM; CONDITIONS FOR COVERAGE
FOR END-STAGE RENAL DISEASE FACILITIES—
THIRD PARTY PAYMENT"
(RIN: 0938-AT11)

(i) Cost-benefit analysis

The Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS) summarized the costs and benefits of this interim final rule. CMS stated that dialysis facilities and issuers will incur administrative costs to comply with the requirements of this interim final rule. Additionally, CMS stated that if patients covered through individual market plans opt to move to (or return to) Medicare and Medicaid, then there will be a transfer of patient care costs to the Medicare and Medicaid programs. In the accounting table CMS provided in the interim final rule, CMS stated that the estimated annual administrative costs will be \$29.1 million. CMS estimated that the annual transfer costs will be \$688.4 million.

CMS stated that the benefits of this interim final rule include reducing the likelihood of disruption of care, gaps in coverage, limited access to necessary treatment, denial of access to kidney transplants or delay in transplant readiness, and denial of post-surgical care. Additionally, CMS stated that many individuals can avoid potential financial loss due to Medicare late enrollment penalties; higher cost-sharing, especially for out-of-network services; higher deductibles; and coverage limits in individual market plans.

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

CMS determined that this interim final rule will not affect a substantial number of small entities, and therefore a regulatory flexibility analysis is not required. Additionally, CMS determined that this interim final rule will not affect 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 stated that this interim final rule does not impose an unfunded mandate on state, local, or tribal governments.

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

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

CMS determined that issuing the interim final rule as a proposed rulemaking such that it would not become effective until after public comments are submitted, considered, and responded to in a final rule, would be contrary to the public interest and would cause harm to patients. CMS

determined that the widespread practice of third parties making payments of premiums for individual market coverage places dialysis patients at significant risk of three kinds of harms: (1) having their ability to be determined ready for a kidney transplant negatively affected, (2) being exposed to additional costs for health care services, and (3) being exposed to a significant risk of a mid-year disruption in health care coverage. Therefore, CMS found good cause to waive notice and comment rulemaking and to issue this interim final rule with comment. CMS is providing a 30-day public comment period.

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

CMS found that this interim final rule contains information collection requirements that are subject to review by the Office of Management and Budget. For information collection requests regarding patient rights, the total estimated annual burden for each facility will be 54.75 burden hours with an equivalent cost of approximately \$2,844 and approximately \$4 in printing and materials costs. The total estimated annual burden for all 6,064 facilities will be 332,004 burden hours with an equivalent cost of approximately \$17,244,288 and approximately \$22,134 in printing and materials costs. For information collection requests regarding disclosure of third party premium payments, or contributions to such payments, to issuers, the total annual burden for all facilities for sending the notifications will be 3,500 burden hours with an equivalent cost of \$132,510. There are an estimated 468 issuers in the individual market. CMS assumed that the approximately 7,000 patients are uniformly distributed between these issuers. Therefore, CMS found the total estimated annual burden for all issuers to respond to 7,000 notifications will be 10,500 hours with an equivalent cost of \$910,280.

Statutory authorization for the rule

CMS stated that it promulgated this final rule under 42 U.S.C. § 1302 and 42 U.S.C. § 1395hh.

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

CMS estimates that this interim final rule is economically significant as measured by the \$100 million threshold. CMS prepared a Regulatory Impact Analysis that presents the costs and benefits of the interim final rule.

Executive Order No. 13,132 (Federalism)

CMS found this interim final rule does not have direct effects on the states, the relationship between the federal government and states, or on the distribution of power and responsibilities among various levels of government.