



441 G St. N.W.
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October 10, 2019

The Honorable Chuck Grassley
Chairman
The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

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

The Honorable Richard Neal
Chairman
The Honorable Kevin Brady
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; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care*

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; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care” (RIN: 0938-AT23). We received the rule on October 1, 2019. It was published in the *Federal Register* as a final rule on September 30, 2019. 84 Fed. Reg. 51732. The effective date of the rule is November 29, 2019.

The final rule reforms Medicare regulations that are identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers. The 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 furnishing high quality patient care. Additionally, this rule updates fire safety

standards for Medicare and Medicaid participating End-Stage Renal Disease facilities by adopting the 2012 editions of the Life Safety Code and the 2012 edition of the Health Care Facilities Code. Finally, this final rule updates the requirements that hospitals and Critical Access Hospitals must meet to participate in the Medicare and Medicaid programs. These requirements are intended to conform to current standards of practice and support improvements in quality of care, reduce barriers to care, and reduce some issues that may exacerbate workforce shortage concerns.

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 House received the rule on October 2, 2019. 165 Cong Rec. H8094 (daily ed. Oct. 4, 2019). The *Congressional Record* does not reflect the date of receipt by the Senate. It was published in the *Federal Register* on September 30, 2019, and has a stated effective date of November 29, 2019. 84 Fed. Reg. 51732. Therefore, the final rule does not have the required 60-day delay in effective date.

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. 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 Janet Temko-Blinder, Assistant General Counsel, at (202) 512-7104.

signed

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Calvin E. Dukes II
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; REGULATORY PROVISIONS
TO PROMOTE PROGRAM EFFICIENCY, TRANSPARENCY, AND
BURDEN REDUCTION; FIRE SAFETY REQUIREMENTS FOR CERTAIN DIALYSIS
FACILITIES; HOSPITAL AND CRITICAL ACCESS HOSPITAL (CAH) CHANGES TO
PROMOTE INNOVATION, FLEXIBILITY, AND IMPROVEMENT IN PATIENT CARE”
(RIN: 0938-AT23)

(i) Cost-benefit analysis

The Department for Health and Human Services, Centers for Medicare & Medicaid Services (CMS) estimated the final rule would have life extending and medical cost reduction benefits that have not been quantified. CMS also states the final has qualitative benefits in potential reduction in morbidity and mortality for hospital and critical access hospital patients.

CMS further estimated the final rule would lead to an annualized cost savings of \$801 million at a discount rate of 7 percent for years 2019-2028 and an annualized cost savings of \$803 million at a discount rate of 3 percent for the same period.

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

CMS certified the final rule would not have a significant economic impact on a substantial number of small entities or 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 some of the provisions of the final rule do contain private sector mandates but their costs are generally anticipated to be mostly offset by savings. The Regulatory Impact Analysis for those provisions serves as the analysis under the Act. For all other provisions in the final rule, CMS determined they do not impose mandates on state, local, or tribal government or on the private sector.

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

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

On September 20, 2018, CMS published a proposed rule. 83 Fed. Reg. 47686. CMS responded to comments in the final rule.

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

CMS determined that the final rule contains information collection requirements (ICR) under the Act and these ICRs were submitted to the Office of Management and Budget (OMB). The final rule will impact OMB Control Numbers 0938–0328, 0938–0334, 0938–0338, 0938–1043, 0938–1067, 0938–1069, 0938–1071, 0938–1091, 0938–1245, and 0938–1325. CMS estimated the burden for each ICR.

Statutory authorization for the rule

CMS promulgated the final rule pursuant to sections 263a, 273, 1302, 1302a–7, 1320b–8, 1395, 1395i, 1395hh, 1395rr, 1395eee, 1396r, and 1396u–4 of title 42, United States Code.

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

CMS determined the final rule was economically significant and stated the rule had been reviewed by OMB. CMS prepared a Regulatory Impact Analysis.

Executive Order No. 13,132 (Federalism)

CMS determined the provision does not impose substantial direct requirement costs on state and local governments, preempt state law, or otherwise have federalism implications.