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Washington, DC 20548

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October 3, 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 and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers*

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; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers" (RIN: 0938-AO91). We received the rule on September 13, 2016. It was published in the *Federal Register* as a final rule on September 16, 2016. 81 Fed. Reg. 63,860.

The final rule establishes national emergency preparedness requirements for Medicare- and Medicaid-participating providers and suppliers to plan for both natural and man-made disasters and coordinate with federal, state, tribal, regional, and local emergency preparedness systems. CMS expects the rule will also assist providers and suppliers in adequately preparing to meet the needs of patients, residents, clients, and participants during disasters and emergency situations. CMS believes this rule will provide consistent emergency preparedness requirements, enhance patient safety during emergencies for persons served by Medicare- and Medicaid-participating facilities, and establish a more coordinated and defined response to natural and man-made disasters.

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;
EMERGENCY PREPAREDNESS REQUIREMENTS
FOR MEDICARE AND MEDICAID PARTICIPATING
PROVIDERS AND SUPPLIERS"
(RIN: 0938-AO91)

(i) Cost-benefit analysis

The Centers for Medicare & Medicaid Services (CMS) analyzed the costs and benefits of this final rule. CMS stated that the qualitative benefits of this rule will be to help ensure the safety of individuals by requiring providers and suppliers to adequately plan for and respond to both natural and man-made disasters. CMS projected the total costs of this rule to be \$373 million in the first year and annual costs in subsequent years to be approximately \$25 million. CMS estimated that these costs annualized over the period 2016 to 2020 would be \$104 million at a 7 percent discount rate and \$99 million at a 3 percent discount rate. CMS also noted the qualitative costs of performing life-saving and morbidity-reducing activities during emergency events.

(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. CMS also determined that the 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 will not mandate any new requirements for state, local, or tribal governments. For the private sector facilities, CMS explained that the final rule contains a regulatory impact section which addressed the requirements of the Act.

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

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

On December 27, 2013, CMS published a proposed rule. 78 Fed. Reg. 79,082. CMS received nearly 400 public comments on the proposed rule. Commenters included individuals, healthcare professionals and corporations, national associations, health departments and emergency management professionals, and individual facilities that would be impacted by the rule. CMS responded to comments in the final rule. Additionally, CMS found good cause to waive the requirement of a notice of proposed rulemaking for the provisions related to the 2012 editions of National Fire Protection Association (NFPA) 101, "Life Safety Code" and NFPA 99,

“Health Care Facilities Code” as well as the 2010 edition of NFPA 110, “Standard for Emergency and Standby Power Systems.” Because the December 2013 proposed rule referred to and discussed incorporation of earlier versions of these NFPA documents, CMS believes that engaging in a new round of notice-and-comment rulemaking to propose an update to these codes, which have already been incorporated into its general fire safety regulations, would be both unnecessary and contrary to the public interest.

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

CMS determined this final rule contains multiple information collection requirements under the Act imposing burdens on multiple types of providers and suppliers. CMS estimated that in total, these requirements will impose a burden of 3,089,505 hours for a total cost of \$279,680,069.

Statutory authorization for the rule

CMS promulgated this final rule under the authority of sections 1138, 1819, 1820, 1821, 1832, 1861, 1881, 1891, 1894, 1905, 1913, 1919, 1934 of the Social Security Act and section 371 of the Public Health Service Act. 42 U.S.C. §§ 273, 1320b-8, 1395i-3, 1395i-4, 1395i-5, 1395k, 1395x, 1395rr, 1395bbb, 1395eee, 1396d, 1396f, 1396r, 1396u-4.

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

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

Executive Order No. 13,132 (Federalism)

CMS determined that this final rule will not impose substantial direct requirement costs on state or local governments, preempt state law, or otherwise implicate federalism.