



441 G St. N.W.
Washington, DC 20548

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April 28, 2020

The Honorable Ron Johnson
Chairman
The Honorable Gary C. Peters
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Bennie T. Thompson
Chairman
The Honorable Mike Rogers
Ranking Member
Committee on Homeland Security
House of Representatives

Subject: *Department of Homeland Security, Federal Emergency Management Agency:
Prioritization and Allocation of Certain Scarce or Threatened Health and Medical
Resources for Domestic Use*

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 Homeland Security, Federal Emergency Management Agency (FEMA) entitled "Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use" (RIN: 1660-AB01). We received the rule on April 10, 2020. It was published in the *Federal Register* as a temporary final rule on April 10, 2020. 85 Fed. Reg. 20195. The effective date of the rule is April 7, 2020, until August 10, 2020.

According to FEMA, the temporary rule allocates certain scarce or threatened materials for domestic use, so that they may not be exported from the United States without explicit approval by FEMA. FEMA stated that the rule covers the five following types of personal protective equipment (PPE): (1) N95 Filtering Facepiece Respirators; (2) other Filtering Facepiece Respirators; (3) Elastomeric, air purifying respirators and particulate filters/cartridges; (4) PPE surgical masks; and (5) PPE gloves or surgical gloves. According to FEMA, the temporary rule is effective from April 7, 2020, until August 10, 2020, and prohibits shipments of such designated materials from the United States without FEMA approval, subject to certain exemptions.

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 60-day delay in effective date can be waived, however, if the agency finds for good cause that delay is 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. §§ 553(b)(3)(B), 808(2). According to FEMA, there is no required delay in the effective date of the rule because it is being promulgated under the good

cause exception to notice and comment under the Administrative Procedure Act.
5 U.S.C. § 808(2).

Enclosed is our assessment of FEMA'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 Shari Brewster, Assistant General Counsel, at (202) 512-6398.

A handwritten signature in black ink that reads "Shirley A. Jones". The signature is written in a cursive style with a large initial 'S' and 'J'.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Adrian Sevier
Chief Counsel
Federal Emergency Management Agency
Department of Homeland Security

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF HOMELAND SECURITY,
FEDERAL EMERGENCY MANAGEMENT AGENCY
ENTITLED
“PRIORITIZATION AND ALLOCATION OF CERTAIN SCARCE
OR THREATENED HEALTH AND MEDICAL RESOURCES
FOR DOMESTIC USE”
(RIN: 1660-AB01)

(i) Cost-benefit analysis

In its submission to us, the Federal Emergency Management Agency (FEMA) indicated that it considered preparation of an analysis of the costs and benefits of this final rule to be not applicable.

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

According to FEMA, this is a temporary rule issued without a prior proposed rule under the separate authority of the Defense Production Act of 1950, and so a regulatory flexibility analysis was not required.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

FEMA determined that this temporary rule will not have an effect on state, local, or tribal governments, in the aggregate, or on the private sector, of \$172 million or more in any one year. Additionally, according to FEMA, the rule is excluded from the Unfunded Mandates Act under section 1503 of title 2, United States Code.

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

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

On April 10, 2020, FEMA published a temporary rule. 85 Fed. Reg. 20195. According to FEMA, the temporary rule is exempt from the Administrative Procedures Act under section 4559(a) of title 50 United States Code. FEMA stated that the rule is being issued subject to the provisions of section 4559(a) of title 50 United States Code, and that the Administrator of FEMA has concluded that, based on the facts related to the COVID-19 pandemic, with respect to this temporary rule, urgent and compelling circumstances make compliance with the notice and comment requirements of section 4559(b)(1) of title 50 United States Code, impracticable.

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

FEMA did not address PRA in its submission to us.

Statutory authorization for the rule

FEMA promulgated this temporary rule pursuant to the authority of sections 4511 and 4554 of title 50 United States Code. FEMA also cited the authority of Executive Orders 13,909, 13,910, 13,911; along with the Department of Homeland Security Delegation Number 090502 Rev. 00.1; and The Presidential Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (April 3, 2020).

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

The Office of Management and Budget has designated this temporary rule as an economically significant regulatory action.

Executive Order No. 13,132 (Federalism)

FEMA determined that this final rule does not have federalism implications and will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among various levels of government.