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February 2, 2021

Chair
Ranking Member
Committee on Banking, Housing, and Urban Affairs
United States Senate

The Honorable Peter A. DeFazio
Chairman
The Honorable Sam Graves
Ranking Member
Committee on Transportation and Infrastructure
House of Representatives

Subject: *Department of Homeland Security, Federal Emergency Management Agency: Prioritization and Allocation of Certain Scarce and Critical 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 and Critical Health and Medical Resources for Domestic Use" (RIN: 1660-AB01). We received the rule on January 18, 2021. It was published in the *Federal Register* as a temporary final rule; extension of effective date with modifications on December 31, 2020. 85 Fed. Reg. 86835. The final rule has an effective date of December 31, 2020.

According to FEMA, in April, the agency issued a temporary final rule to allocate certain health and medical resources for domestic use, so that these resources may not be exported from the United States without explicit approval by FEMA. FEMA stated the April rule covered five types of personal protective equipment (PPE). While the April rule remains in effect, and subject to certain exemptions, FEMA stated no shipments of such designated materials may leave the United States without its explicit approval. FEMA stated that, in August, it modified the types of PPE covered and extended the duration of the April rule. According to FEMA, through this interim final rule, the agency again extends and modifies the temporary final rule designating the list of scarce and critical materials that cannot be exported from the United States without explicit approval by FEMA.

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. § 808(2). FEMA determined it had good cause to waive the delay in effective date requirement because the COVID-19 pandemic continues to grow worldwide.

FEMA stated the World Health Organization reports over 71.5 million cases and over 1.6 million deaths in 220 countries as of December 15, 2020. FEMA further stated that the severity of the pandemic has increased significantly in the United States in recent months, with surges of up to 244,007 new cases in a single day. FEMA also stated the United States now leads the world in the total number of COVID-19 cases and deaths and the Centers for Disease Control and Prevention estimates the number of confirmed cases and deaths in the United States will continue to increase. As a result of the surge in U.S. confirmed cases and deaths, FEMA stated demand for PPE used to treat patients with the disease has increased and the domestic supply has been unable to keep pace.

Enclosed is our assessment of the 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.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Shabnaum Q. Amjad
Deputy Associate Chief Counsel
Regulatory Affairs Division
Department of Homeland Security

ENCLOSURE

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 AND
CRITICAL HEALTH AND MEDICAL RESOURCES FOR DOMESTIC USE"
(RIN: 1660-AB01)

(i) Cost-benefit analysis

In its submission to us, the Federal Emergency Management Administration (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

FEMA stated the final rule was not subject to RFA because the final rule was not required to go through notice and comment procedures.

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

FEMA determined the final rule is not expected to result in expenditures by state, local, and tribal governments, or by the private sector, above the statutory threshold in any one year.

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

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

FEMA stated the final rule was not subject to the notice and comments provisions of APA but subject to the notice and comment procedures of the Defense Production Act, 50 U.S.C. § 4501 *et seq*. FEMA waived those procedures for good cause. FEMA determined it had good cause because the COVID-19 pandemic continues to grow worldwide. FEMA stated the World Health Organization reports over 71.5 million cases and over 1.6 million deaths in 220 countries as of December 15, 2020. FEMA further stated the severity of the pandemic has increased significantly in the United States in recent months, with surges of up to 244,007 new cases in a single day. FEMA also stated the United States now leads the world in the total number of COVID-19 cases and deaths and the Centers for Disease Control and Prevention estimates the number of confirmed cases and deaths in the United States will continue to increase. As a result of the surge in U.S. confirmed cases and deaths, FEMA stated demand for personal protective equipment used to treat patients with the disease has increased and the domestic supply has been unable to keep pace.

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

FEMA did not discuss PRA in the final rule.

Statutory authorization for the rule

FEMA promulgated the final rule pursuant to sections 4511 *et seq.* of title 50, United States Code.

Executive Order No. 12866 (Regulatory Planning and Review)

FEMA stated the Office of Management and Budget determined the final rule was economically significant.

Executive Order No. 13132 (Federalism)

FEMA determined the final rule will not have a substantial direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.