U.S. GOVERNMENT ACCOUNTABILITY OFFICE

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

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August 27, 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 G. 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 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 August 10, 2020. It was published in the *Federal Register* as a temporary final rule on August 10, 2020. 85 Fed. Reg. 48113. The stated effective date of the temporary final rule is August 10, 2020. *Id.*

The temporary final rule, according to FEMA, modifies the types of personal protective equipment (PPE) covered by and extends the duration of a temporary final rule, promulgated in April 2020. 85 Fed. Reg. 20195 (Apr. 10, 2020); s*ee also* 85 Fed. Reg. 22622 (Apr. 23, 2020) (correcting the date filed from ''4–8–20'' to ''4–7–20''). According to FEMA, the temporary final rule it issued in April allocated 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 that the rule covered five types of personal PPE. FEMA further stated that while that rule remains in effect, and subject to certain exemptions, no shipments of such designated materials may leave 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 stated that because this rule contains

FEMA's finding for good cause that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, there is not a required delay in the effective date. Specifically, FEMA stated that the exigent need for this rule is related to the COVID–19 pandemic. According to FEMA, although the federal government, along with state and local governments, have taken preventative and proactive measures to slow the spread of COVID–19, and to treat those affected, the ongoing spread of COVID–19 within the nation's communities is straining the nation's healthcare systems. FEMA stated that it is imperative that health and medical resources needed to respond to the spread of COVID–19, including the PPE affected by this rule, continue to be allocated for domestic use as appropriate. FEMA further stated that given the evolving nature of this pandemic and the frequently changing supply of and demand for the health and medical resources needed to combat it, full public notice and comment proceedings are impracticable.

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.

Shirley A. Jones
Managing Associate General Counsel

Enclosure

cc: Adrian Sevier
Chief Counsel
Federal Emergency Management Agency
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 Department of Homeland Security (DHS), 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 neither a proposed rule, nor a final rule that the agency has issued under 5 U.S.C. § 553 after being required by that section or any other law to publish a general notice of proposed rulemaking. FEMA stated that this is a temporary final rule issued without a prior proposed rule, under the separate authority of the Defense Production Act of 1950. FEMA further stated that, as a result, a regulatory flexibility analysis is 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 rule is not expected to result in expenditures by state, local, and tribal governments, or by the private sector, of $172 million or more in any one year. According to FEMA, this rule imposes no requirements on state, local, and tribal governments and, therefore, cannot require them to expend any funds. FEMA stated that, to the extent this rule affects the private sector, it only prohibits conduct, namely certain exports. FEMA further stated that this temporary final rule does not require any private sector expenditures within the meaning of the Act. Further, according to FEMA, the rule is excluded from the Act under 2 U.S.C. §§ 1503(4) and (5).

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

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

FEMA stated that pursuant to 50 U.S.C. § 4559(a), this rule is exempt from the Administrative Procedure Act (APA), and is instead subject to the notice requirements of 50 U.S.C. § 4559(b), compliance with which FEMA determined to be impracticable. FEMA claimed the same basis for this determination would constitute good cause to dispense with the requirements of APA. In particular, according to FEMA, notice and public comment are impractical, unnecessary, or contrary to the public interest, and the temporary final rule should become effective on August 10, 2020, the date on which the original temporary final rule would expire. FEMA stated that the exigent need for this rule is related to the COVID–19 pandemic. According to FEMA,

although the federal government, along with state and local governments, have taken preventative and proactive measures to slow the spread of COVID–19, and to treat those affected, the ongoing spread of COVID–19 within the nation's communities is straining the nation's healthcare systems. FEMA stated that it is imperative that health and medical resources needed to respond to the spread of COVID–19, including the personal protective equipment (PPE) affected by this rule, continue to be allocated for domestic use as appropriate. FEMA further stated that given the evolving nature of this pandemic and the frequently changing supply of and demand for the health and medical resources needed to combat it, full public notice and comment proceedings are impracticable. According to FEMA, this immediate action is needed to continue to ensure that such resources are appropriately allocated for domestic use, and to tailor the scope of such allocation to current needs as of the prior temporary final rule's scheduled end-date. FEMA stated that given the national and international emergency caused by COVID–19 and the continuously evolving nature of the situation, FEMA finds that urgent and compelling circumstances have made it impracticable and contrary to the public health—and, by extension, the public interest—to delay these implementing regulations until a full public notice and comment process is completed. FEMA further stated that this temporary final rule modification and extension is needed to appropriately allocate scarce and critical materials for domestic use, based on current needs. According to FEMA, the measures described in this rule are being issued on a temporary basis. FEMA stated that this temporary final rule will cease to be in effect on December 31, 2020, unless sooner modified or terminated by the Administrator.

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

In its submission to us, FEMA indicated that it considered PRA to be not applicable.

Statutory authorization for the rule

FEMA promulgated this final rule pursuant to sections 101 and 704 of the Defense Production Act of 1950, as amended, 50 U.S.C. §§ 4511, 4554.

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

According to FEMA, the Office of Management and Budget has designated this temporary final rule as an economically significant regulatory action. FEMA stated that given that the temporary final rule is a significant regulatory action, FEMA proceeds under the emergency provision, under section 6(a)(3)(D) of the Order, based on the need for immediate action to ensure the health and medical resources subject to the temporary final rule are appropriately allocated for domestic use.

Executive Order No. 13,132 (Federalism)

FEMA determined that this temporary 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. DHS stated that there are no provisions in the rule that impose direct compliance costs on state and local governments. FEMA further stated that, accordingly, it believes that the rule does not warrant additional analysis under the Order.