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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 328

Docket ID FEMA-2020-0018

RIN 1660-AB01

Prioritization and Allocation of Certain Scarce or Threatened Health and Medical Resources for Domestic Use

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Temporary final rule.

SUMMARY: The Federal Emergency Management Agency (FEMA) is issuing a temporary rule to allocate certain scarce or threatened materials for domestic use, so that these materials may not be exported from the United States without explicit approval by FEMA. The rule covers five types of personal protective equipment (PPE), outlined below. While this rule remains in effect, and subject to certain exemptions stated below, no shipments of such designated materials may leave the United States without explicit approval by FEMA.

DATES: *Effective date:* This rule is effective from [INSERT DATE OF FILING FOR PUBLICATION IN THE FEDERAL REGISTER] until [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may review the docket by searching for Docket ID FEMA-2020-0018, via the Federal eRulemaking Portal: <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Daniel McMasters, Office of Policy and Program Analysis, 202-709-0661, FEMA-DPA@fema.dhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Current COVID-19 Pandemic

COVID-19 is a communicable disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), that was first identified as the cause of an outbreak of respiratory illness that began in Wuhan, Hubei Province, People's Republic of China. The virus is thought to be transmitted primarily by person-to-person contact through respiratory droplets produced when an infected person coughs, sneezes, or talks. Some recent studies have suggested that COVID-19 may be spread by people who are not showing symptoms. It also may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose, or possibly their eyes. Older adults and people of all ages with underlying medical conditions, particularly if not well controlled, are at higher risk for more serious COVID-19 illness.¹

On January 30, 2020, the Director-General of the World Health Organization (WHO) declared that the outbreak of COVID-19 is a Public Health Emergency of International Concern under the International Health Regulations.² The following day, the Secretary of Health and Human Services (HHS) declared COVID-19 a public health emergency under Section 319 of the

¹ Information obtained from <https://www.coronavirus.gov> (accessed April 2, 2020).

² Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV) (January 30, 2020), *available at* [https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-\(2019-ncov\)](https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)).

Public Health Service (PHS) Act.³ On March 11, 2020, the WHO declared COVID-19 a pandemic. On March 13, 2020, the President issued a Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak under sections 201 and 301 of the National Emergencies Act, 50 U.S.C. 1601 *et seq.*, and consistent with section 1135 of the Social Security Act, 42 U.S.C. 1320b-5.⁴ On March 13, 2020, the President declared a nationwide emergency under section 501(b) of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, authorizing FEMA to provide assistance for emergency protective measures to respond to the COVID-19 pandemic.⁵

As of April 7, 2020, there were over 333,000 cases of COVID-19 in the United States, resulting in over 9,500 deaths due to the disease, with new cases being reported daily. Worldwide, there have been over 1.28 million confirmed cases, resulting in over 72,600 deaths.⁶ At this time, there is no vaccine that can prevent infection with COVID-19, nor is there currently any FDA-approved post-exposure prophylaxis for people who may have been exposed to COVID-19. Treatment is currently limited to supportive (or palliative) care for patients who need it. Clinical management for hospitalized patients with COVID-19 is focused on supportive care for complications, including supplemental oxygen and advanced organ support for respiratory failure, septic shock, and multi-organ failure.⁷

³ HHS, “Determination that a Public Health Emergency Exists,” *available at* <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx> (Jan. 31, 2020).

⁴ “Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak,” March 13, 2020, *available at* <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

⁵ COVID-19 Emergency Declaration *available at* <https://www.fema.gov/news-release/2020/03/13/covid-19-emergency-declaration> (accessed April 6, 2020).

⁶ Information obtained from <https://www.who.int/> (accessed April 7, 2020).

⁷ Information obtained from <https://www.coronavirus.gov> (accessed April 7, 2020).

Within the United States, widespread transmission of COVID-19 has occurred.

Widespread transmission of COVID-19 has resulted and will continue to result in large numbers of people needing medical care at the same time. Public health and healthcare systems may become overloaded, with elevated rates of hospitalizations and deaths, as well as elevated demand for PPE, including the PPE covered by this rule.

B. Legal Authorities

FEMA is issuing this temporary rule as part of its response to the COVID-19 pandemic.

The rule is issued pursuant to the following authorities, among others:

- The Defense Production Act of 1950, as amended (“DPA” or “the Act”), and specifically sections 101 and 704 of the Act, 50 U.S.C. 4511, 4554;
- Executive Order 13909, 85 FR 16227 (Mar. 23, 2020);
- Executive Order 13910, 85 FR 17001 (Mar. 26, 2020);
- Executive Order 13911, 85 FR 18403 (Apr. 1, 2020);
- DHS Delegation Number 09052 Rev. 00.1, “Delegation of Defense Production Act Authority to the Administrator of the Federal Emergency Management Agency” (Apr. 1, 2020); and
- The Presidential Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (April 3, 2020).⁸

FEMA describes each authority in turn. The President has broadly delegated authority to make determinations and take action with respect to health and medical resources for COVID-19

⁸ See Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use for the Secretary of Health and Human Services, the Secretary of Homeland Security, and the Administrator of the Federal Emergency Management Agency (Apr. 3, 2020), <https://www.whitehouse.gov/presidential-actions/memorandum-allocating-certain-scarce-threatened-health-medical-resources-domestic-use/> (last visited Apr. 5, 2020).

response under Section 101 of the DPA to the Secretary of Homeland Security in Executive Order 13911. This authority has in turn been delegated to the FEMA Administrator in DHS Delegation 09052, Rev. 00.1 (Apr. 1, 2020).

First, under subsection 101(a) of the Act, 50 U.S.C. 4511(a), the President may (1) require that performance under contracts or orders (other than contracts of employment) which he deems necessary or appropriate to promote the national defense shall take priority over performance under any other contract or order, and, for the purpose of assuring such priority, require acceptance and performance of such contracts or orders in preference to other contracts or orders by any person he finds to be capable of their performance. The President may also (2) allocate materials, services, and facilities in such manner, upon such conditions, and to such extent as he shall deem necessary or appropriate to promote the national defense. FEMA refers to these authorities as relating to “priority ratings” and “allocation,” respectively.

Under subsection 101(b) of the Act, 50 U.S.C. 4511(b), the President may not use the aforementioned authorities to control the general distribution of any material in the civilian market unless the President finds (1) that such material is a scarce and critical material essential to the national defense, and (2) that the requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship.

Under subsection 101(d) of the Act, 50 U.S.C. 4511(d), the head of each Federal agency to which the President delegates authority under section 101 of the Act (1) shall issue, and annually review and update whenever appropriate, final rules, in accordance with 5 U.S.C. 553, that establish standards and procedures by which the priorities and allocations authority under section 101 is used to promote the national defense, under both emergency and nonemergency

conditions; and (2) as appropriate and to the extent practicable, consult with the heads of other Federal agencies to develop a consistent and unified Federal priorities and allocations system.⁹

Second, on March 18, 2020, the President signed Executive Order 13909, which delegated to the Secretary of HHS authority under the DPA for the prioritization and allocation of health and medical resources to respond to the spread of COVID-19. The President determined that to ensure that our healthcare system is able to surge capacity and capability to respond to the spread of COVID-19, it is critical that all health and medical resources needed to respond to the spread of COVID-19 are properly distributed to the Nation's healthcare system and others that need them most at this time. The President found that health and medical resources needed to respond to the spread of COVID-19, including personal protective equipment and ventilators, meet the criteria specified in section 101(b) of the Act (50 U.S.C. 4511(b)).¹⁰

Third, on March 23, 2020, the President signed Executive Order 13910, in which the President delegated to the Secretary of HHS the authority under section 102 of the Act to prevent hoarding and price gouging with respect to health and medical resources necessary to respond to the spread of COVID-19. On March 25, 2020, the Secretary of Health and Human Services

⁹ FEMA has not yet issued comprehensive regulations on its implementation of section 101 of the Act. As noted below, FEMA was only recently delegated authority under section 101 of the Act. As described in greater detail below, this temporary final rule implements section 101(a) of the Act and related authority for a specific purpose and for a limited period of time. FEMA anticipates issuing comprehensive regulations under section 101 of the Act in the near future. In addition to section 101 of the Act, this rule implements FEMA's broad delegated authority under section 704 of the Act, 50 U.S.C. 4554, to prescribe such regulations and issue such orders as FEMA may determine appropriate to carry out its delegated authorities under the Act. The President has delegated this authority to the Secretary of Homeland Security under sections 2 and 5 of Executive Order 13911, who in turn delegated it to the Administrator of FEMA in DHS Delegation 09052, Rev. 00.1 (Apr. 1, 2020).

¹⁰ The Executive Order delegates to the Secretary of Health and Human Services the President's authority under section 101 of the Act, 50 U.S.C. 4511, including the authority to identify additional specific health and medical resources that meet the criteria of section 101(b). The Executive Order allows the Secretary of Health and Human Services, using the delegated authority under section 101 of the Act, to determine, in consultation with the Secretary of Commerce and the heads of other executive departments and agencies as appropriate, the proper nationwide priorities and allocation of all health and medical resources needed to respond to the spread of COVID-19 within the United States.

designated under section 102 of the Act 15 categories of health and medical resources as scarce materials or materials the supply of which would be threatened by accumulation in excess of the reasonable demands of business, personal, or home consumption, or for the purpose of resale at prices in excess of prevailing market prices (“scarce or threatened materials”). *See* 85 FR 17592 (Mar. 30, 2020). These designated items include certain PPE materials that are the subject of this rulemaking.

Fourth, on March 27, 2020, the President signed Executive Order 13911, which (among other things) delegated to the Secretary of Homeland Security the President’s authority under section 101 of the Act with respect to health and medical resources needed to respond to the spread of COVID-19 within the United States. The Executive Order provides that the Secretary of Homeland Security may use the authority under section 101 of the Act to determine, in consultation with the heads of other executive departments and agencies as appropriate, the proper nationwide priorities and allocation of health and medical resources, including by controlling the distribution of such materials (including applicable services) in the civilian market, for responding to the spread of COVID-19 within the United States.¹¹ The Secretary of Homeland Security has delegated his authorities under Executive Order 13911 to FEMA. *See* DHS Delegation 09052, Rev. 00.1 (Apr. 1, 2020).

Finally, on April 3, 2020, the President signed a Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use. The Memorandum reaffirmed the delegations and findings contained in Executive Orders 13909, 13910, and 13911, including that health and medical resources needed to respond to the spread of COVID-19,

¹¹ The Executive Order also delegated to the Secretary of Homeland Security the authority under section 102 of the Act to prevent hoarding and price gouging with respect to such resources, and requires that before exercising the authority under section 102 of the Act, the Secretary of Homeland Security shall consult with the Secretary of Health and Human Services.

including personal protective equipment (PPE) and ventilators, meet the criteria specified in section 101(b) of the Act, *i.e.*, that (1) such material is a scarce and critical material essential to the national defense, and (2) that the requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship. The President further stated that to ensure that these scarce or threatened PPE materials remain in the United States for use in responding to the spread of COVID-19, it is the policy of the United States to prevent domestic brokers, distributors, and other intermediaries from diverting such material overseas.

In furtherance of such policy, the President directed that the Secretary of Homeland Security, through the FEMA Administrator, and in consultation with the Secretary of HHS, shall use any and all authority available under section 101 of the Act to allocate to domestic use, as appropriate, the following scarce or threatened materials designated by the Secretary of HHS under Section 102 of the DPA:

- N95 Filtering Facepiece Respirators, including devices that are disposable half-face-piece non-powered air-purifying particulate respirators intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates;
- Other Filtering Facepiece Respirators (e.g., those designated as N99, N100, R95, R99, R100, or P95, P99, P100), including single-use, disposable half-mask respiratory protective devices that cover the user's airway (nose and mouth) and offer protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181;
- Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges;

- PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials; and
- PPE gloves or surgical gloves, including those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such gloves intended for the same purposes.

Pursuant to this Memorandum, and with the authority delegated to the Secretary of Homeland Security in EO 13911 and re-delegated to the FEMA Administrator in DHS Delegation 09052 Rev. 00.1, FEMA now issues this allocation order as a temporary rule.

II. Provisions of the Temporary Final Rule

Following consultation with the Secretary of HHS; pursuant to the President's direction; and as an exercise of the Administrator's priority order, allocation, and regulatory authorities under the Act, the Administrator has determined that the scarce or threatened materials identified in the April 3, 2020 Presidential Memorandum ("covered materials") shall be allocated for domestic use, and may not be exported from the United States without explicit approval by FEMA. *See* new 44 CFR 328.102(a).

The rule is necessary and appropriate to promote the national defense with respect to the covered materials because the domestic need for them exceeds the supply. Under this temporary rule, before any shipments of such covered materials may leave the United States, CBP will detain the shipment temporarily, during which time FEMA will determine whether to return for domestic use, issue a rated order for, or allow the export of part or all of the shipment under section 101(a) of the Act, 50 U.S.C. 4511(a). FEMA will make such a determination within a reasonable time of being notified of an intended shipment and will make all decisions consistent with promoting the national defense. *See* new 44 CFR 328.102(b). FEMA will work to review and make determinations quickly and will endeavor to minimize disruptions to the supply chain.

In determining whether it is necessary or appropriate to promote the national defense to purchase covered materials, or allocate materials for domestic use, FEMA may consult other agencies and will consider the totality of the circumstances, including the following factors: (1) the need to ensure that scarce or threatened items are appropriately allocated for domestic use; (2) minimization of disruption to the supply chain, both domestically and abroad; (3) the circumstances surrounding the distribution of the materials and potential hoarding or price-gouging concerns; (4) the quantity and quality of the materials; (5) humanitarian considerations; and (6) international relations and diplomatic considerations.

This rule contains an exemption that the Administrator has determined to be necessary or appropriate to promote the national defense. *See* new 44 CFR 328.102(c). Specifically, the Administrator has determined that FEMA will not purchase covered materials from shipments made by or on behalf of U.S. manufacturers with continuous export agreements with customers in other countries since at least January 1, 2020, so long as at least 80 percent of such manufacturer's domestic production of covered materials, on a per item basis, was distributed in the United States in the preceding 12 months. The Administrator decided that this exemption is necessary or appropriate to promote the national defense because it would limit the impact of this order on pre-existing commercial relationships, in recognition of the importance of these commercial relationships to the international supply chain, and for humanitarian reasons, in consideration of the global nature of the COVID-19 pandemic. If FEMA determines that a shipment of covered materials falls within this exemption, such materials may be transferred out of the United States without further review by FEMA, provided that the Administrator may waive this exemption and fully review shipments of covered materials subject to this exemption for further action by FEMA, if the Administrator determines that doing so is necessary or

appropriate to promote the national defense. FEMA may develop additional guidance regarding which exports are covered by this exemption, and encourages manufacturers to contact FEMA with specific information regarding their status under this exemption.

The Administrator may establish, in his discretion, additional exemptions that he determines are necessary or appropriate to promote the national defense and will announce any such exemptions by notice in the *Federal Register*.

FEMA will implement this rule with the cooperation and assistance of other U.S. Government agencies, including CBP, and will work with manufacturers, brokers, distributors, exporters, and shippers to ensure that the applicable requirements are carried out. Any covered materials intended for export may be detained by CBP while FEMA conducts its review of the shipment. FEMA will review the shipment and provide notification as soon as possible regarding the disposition of the covered materials under this order, provided that any goods that have been detained by CBP and are subsequently made subject to a DPA-rated order will be consigned to FEMA pending further distribution or agency direction. FEMA may provide additional guidance regarding the application of any exemptions to this temporary rule, as appropriate.

FEMA may conduct such investigations and issue such requests for information as may be necessary for the enforcement of the Act, including this rule. *See* new 44 CFR 328.104(a); *see also* section 705 of the Act, 50 U.S.C. 4555; Executive Order 13911, 85 FR 18403 (Apr. 1, 2020). FEMA may seek an injunction or other order whenever, in the Administrator's judgment, a person has engaged or is about to engage in any acts or practices which constitute or will constitute a violation of the Act or any rule or order issued thereunder. *See* new 44 CFR 328.104(b); *see also* section 706 of the Act, 50 U.S.C. 4556. In addition to an injunction, failure

to comply fully with this rule is a crime punishable by a fine of not more than \$10,000 or imprisonment for not more than one year, or both. *See* new 44 CFR 328.104(c); *see also* section 103 of the Act, 50 U.S.C. 4513. In addition, pursuant to 18 U.S.C. 554, whoever fraudulently or knowingly exports or sends from the United States, or attempts to export or send from the United States, any merchandise, article, or object contrary to any U.S. law or regulation, or receives, conceals, buys, sells, or in any manner facilitates the transportation, concealment, or sale of such merchandise, article, or object, prior to exportation, knowing the same to be intended for exportation contrary to any U.S. law or regulation, faces up to 10 years' imprisonment, a fine, or both, if convicted.

At any point in time, and to the extent consistent with United States policy, the FEMA Administrator may determine additional materials to be subject to this allocation order. Upon a determination under section 101(b) of the DPA that an additional material is a scarce and critical material essential for national defense, and that being allocated to domestic use under this allocation order is the only way to meet national defense requirements without significant disruption to the domestic markets, the Administrator will include these additional materials in this allocation order, and will provide notification of this decision through publication in the *Federal Register*.

III. Regulatory Procedure and Analyses

A. Temporary Rule with Immediate Effective Date

Agency rulemaking is generally governed by the agency rulemaking provisions of the Administrative Procedure Act (APA). *See* 5 U.S.C. 553. Such provisions generally require that, unless the rule falls within one of a number of enumerated exceptions, or unless another statute exempts the rulemaking from the requirements of the APA, FEMA must publish a notice of

proposed rulemaking in the *Federal Register* that provides interested persons an opportunity to submit written data, views, or arguments, prior to finalization of regulatory requirements. Section 553(b)(B) authorizes a department or agency to dispense with the prior notice and opportunity for public comment requirement when the agency, for “good cause,” finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest.

This rule is exempt from the APA under section 709(a) of the Act, 50 U.S.C. 4559(a). Instead, this rule is issued subject to the provisions of section 709(b). Pursuant to section 709(b)(2) of the Act, the Administrator has concluded, based on the facts related to the COVID-19 pandemic, which already have been summarized in this document, that, with respect to this temporary rule, urgent and compelling circumstances make compliance with the notice and comment requirements of section 709(b)(1) of the Act, 50 U.S.C. 4559(b)(1), impracticable. If final regulations become necessary, an opportunity for public comment will be provided for not less than 30 days before such regulations become final, pursuant to section 709(b)(2)(C) of the Act, 50 U.S.C. 4559(b)(2)(C).

Furthermore, the same facts that warrant waiver under section 709(b)(2) of the Act would constitute good cause for FEMA to determine, under the APA, that notice and public comment thereon are impractical, unnecessary, or contrary to the public interest, and that the temporary rule should become effective upon display at the *Federal Register*.

As the President has noted, although the Federal Government, along with State and local governments, have taken preventative and proactive measures to slow the spread of the virus SARS-CoV-2, and the disease it causes, COVID-19, and to treat those affected. The spread of COVID-19 within the Nation’s communities threatens to strain the Nation’s healthcare

systems. It is imperative that health and medical resources needed to respond to the spread of COVID-19, including the PPE affected by this rule, are allocated for domestic use as appropriate. This temporary rule is needed to appropriately allocate scarce or threatened items for domestic use.

The measures described in this rule are being issued on a temporary basis. This temporary rule will cease to be in effect on [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

B. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a regulation (1) having an annual effect on the economy of \$100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

The Office of Management and Budget has designated this temporary rule as an economically significant regulatory action. Given that the temporary rule is a significant regulatory action, FEMA proceeds under the emergency provision of Executive Order 12866, section 6(a)(3)(D) based on the need for immediate action, as described above.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that when an agency issues a proposed rule, or a final rule that the agency issues under 5 U.S.C. 553 after being required by that section or any other law to publish a general notice of proposed rulemaking, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the Federal Register. 5 U.S.C. 603, 604.

This is neither a proposed rule, nor a final rule that the agency has issued under 5 U.S.C. 553 of this title after being required by that section or any other law to publish a general notice of proposed rulemaking. This is a temporary rule issued without a prior proposed rule, under the separate authority of the Defense Production Act of 1950. Accordingly, a regulatory flexibility analysis is not required.

D. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act), 2 U.S.C. 1532, requires that covered agencies prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately \$172 million. If a budgetary impact statement is required, section 205 of the Unfunded Mandates Act also requires covered agencies to identify and consider a reasonable number of regulatory

alternatives before promulgating a rule. DHS has 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. This rule imposes no requirements on State, local, and tribal governments and, therefore, cannot require them to expend any funds, let alone \$172 million. To the extent that this rule affects the private sector, it only prohibits conduct, namely certain exports. It does not require any private sector expenditures within the meaning of the Unfunded Mandates Act. Further, the rule is excluded from the Unfunded Mandates Act under 2 U.S.C. 1503(4) and (5).

E. National Environmental Policy Act (NEPA)

Under the National Environmental Policy Act of 1969 (NEPA), as amended, 42 U.S.C. 4321 *et seq.*, an agency must prepare an environmental assessment or environmental impact statement for any rulemaking that significantly affects the quality of the human environment. FEMA has determined that this rulemaking does not significantly affect the quality of the human environment and consequently has not prepared an environmental assessment or environmental impact statement.

Rulemaking is a major Federal action subject to NEPA. Categorical exclusion A3 included in the list of exclusion categories at Department of Homeland Security Instruction Manual 023–01–001–01, Revision 01, Implementation of the National Environmental Policy Act, Appendix A, issued November 6, 2014, covers the promulgation of rules, issuance of rulings or interpretations, and the development and publication of policies, orders, directives, notices, procedures, manuals, and advisory circulars if they meet certain criteria provided in A3(a-f). This interim final rule meets Categorical Exclusion A3(a), “Those of a strictly administrative or procedural nature”.

F. Executive Order 13132: Federalism

This rule has been reviewed under Executive Order 13132, Federalism, 64 FR 43255 (August 4, 1999). That Executive Order imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. DHS has determined that this temporary 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. Furthermore, there are no provisions in this rule that impose direct compliance costs on State and local governments. Accordingly, DHS believes that the rule does not warrant additional analysis under Executive Order 13132.

G. Congressional Review Act

Under the Congressional Review of Agency Rulemaking Act (CRA), 5 U.S.C. 801-808, before a rule can take effect, the Federal agency promulgating the rule must: submit to Congress and to the Government Accountability Office (GAO) a copy of the rule; a concise general statement relating to the rule, including whether it is a major rule; the proposed effective date of the rule; a copy of any cost-benefit analysis; descriptions of the agency's actions under the Regulatory Flexibility Act and the Unfunded Mandates Reform Act; and any other information or statements required by relevant executive orders.

FEMA has sent this rule to the Congress and to GAO pursuant to the CRA. The Office of Information and Regulatory affairs has determined that this rule is a "major rule" within the meaning of the CRA. As this rule is being promulgated under the good cause exception to notice and comment under the Administrative Procedure Act, there is not a required delay in the effective date. *See* 5 U.S.C. 808.

List of Subjects in 44 CFR Part 328

Administrative practice and procedure, Business and industry, Government contracts, Health or medical resource, Hoarding, Investigations, Materials, National defense, Scarce materials, Strategic and critical materials, Threatened materials

Accordingly, for the reasons set forth in the preamble, and effective from [INSERT DATE OF FILING FOR PUBLICATION IN THE *FEDERAL REGISTER*] until [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], chapter I of title 44 of the Code of Federal Regulations is amended by adding part 328 to read as follows:

PART 328—COVID-19 ALLOCATION ORDERS AND PRIORITY ORDER REVIEW UNDER THE DEFENSE PRODUCTION ACT

Sec.

328.101 Basis and purpose.

328.102 Requirements.

328.103 Designation of covered materials.

328.104 Investigations and injunctions; penalties.

AUTHORITY: Sections 101 et seq. of the Defense Production Act of 1950, 50 U.S.C. 4511, et seq.; Executive Order 13909, 85 FR 16227 (Mar. 23, 2020); Executive Order 13911, 85 FR 18403 (Apr. 1, 2020); DHS Delegation 09052, Rev. 00.1 (Apr. 1, 2020); Presidential Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to

Domestic Use (April 3, 2020).

§ 328.101 Basis and purpose.

(a) *Basis.* These rules are issued pursuant to section 101 of the Defense Production Act of 1950, as amended, 50 U.S.C. 4511, and complementary authorities, including such authorities as are contained in subchapter III of chapter 55 of title 50, United States Code (50 U.S.C. 4554, 4555, 4556, and 4559), which have been delegated to FEMA.

(b) *Purpose.* The purpose of these rules is to aid the response of the United States to the spread of COVID-19 by ensuring that scarce or threatened health and medical resources are appropriately allocated for domestic use.

§ 328.102 Requirements.

(a) *Allocation Order and Requirement for the Administrator's Approval.* All shipments of covered materials, as designated in § 328.103, shall be allocated for domestic use, and may not be exported from the United States without explicit approval by FEMA.

(b) *Procedures.* U.S. Customs and Border Protection (CBP), in coordination with such other officials as may be appropriate, will notify FEMA of an intended export of covered materials. CBP must temporarily detain any shipment of such covered materials, pending the Administrator's determination whether to return for domestic use or issue a rated order for part or all of the shipment, pursuant to the Administrator's delegated authorities. The Administrator will make such a determination within a reasonable timeframe after notification of an intended export.

(c) *Administrator's Determination.* In making the determination described in paragraph (b) of this section, the Administrator may consult other agencies and will consider the totality of the circumstances, including the following factors:

- (1) the need to ensure that scarce or threatened items are appropriately allocated for domestic use;
- (2) minimization of disruption to the supply chain, both domestically and abroad;
- (3) the circumstances surrounding the distribution of the materials and potential hoarding or price-gouging concerns;
- (4) the quantity and quality of the materials;
- (5) humanitarian considerations; and
- (6) international relations and diplomatic considerations.

(d) *Exemption.*

(1) The Administrator has determined in the interest of promoting the national defense to generally allow the export of covered materials from shipments made by or on behalf of U.S. manufacturers with continuous export agreements with customers in other countries since at least January 1, 2020, so long as at least 80 percent of such manufacturer's domestic production of such covered materials, on a per item basis, was distributed in the United States in the preceding 12 months. If FEMA determines that a shipment of covered materials falls within this exemption, such materials may be exported without further review by FEMA, provided that the Administrator may waive this exemption and fully review shipments of covered materials under paragraph (b) of this section, if the Administrator determines that doing so is necessary or appropriate to promote the national defense. FEMA

will communicate to CBP regarding the application of this exemption to shipments identified by CBP.

(2) The Administrator may establish, in his discretion, additional exemptions that he determines necessary or appropriate to promote the national defense and will announce any such exemptions by notice in the *Federal Register*.

(e) *Exportations prohibited.* The exportation of covered materials other than in accordance with this section is prohibited.

§ 328.103 Designation of covered materials.

(a) The Administrator has designated the following materials as “covered materials” under this part:

- (1) N95 Filtering Facepiece Respirators, including devices that are disposable half-face-piece non-powered air-purifying particulate respirators intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates;
- (2) Other Filtering Facepiece Respirators (e.g., those designated as N99, N100, R95, R99, R100, or P95, P99, P100), including single-use, disposable half-mask respiratory protective devices that cover the user’s airway (nose and mouth) and offer protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181;
- (3) Elastomeric, air-purifying respirators and appropriate particulate filters/cartridges;
- (4) PPE surgical masks, including masks that cover the user’s nose and mouth and provide a physical barrier to fluids and particulate materials; and
- (5) PPE gloves or surgical gloves, including those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such gloves intended for the same purposes.

(b) Upon determination that additional items are scarce and necessary for national defense, and that consideration under this allocation order is the only way to meet national defense requirements without significant disruption to the domestic markets, the Administrator may designate additional materials as “covered materials” in the list provided above. The Administrator will publish notice of these additional “covered materials” in the *Federal Register*.

§ 328.104 Investigations and injunctions; penalties.

(a) To administer or enforce this subpart, the Administrator may exercise the authorities available under section 705 of the Defense Production Act of 1950, as amended, 50 U.S.C. 4555, including the conduct of investigations, requests for information or testimony, and inspections of records or premises. Before such authorities are utilized, the Administrator will determine the scope and purpose of the investigation, inspection, or inquiry, and be assured that no adequate and authoritative data are available from any Federal or other responsible agency.

(b) Whenever, in the judgment of the Administrator, any person has engaged or is about to engage in any acts or practices that constitute or will constitute a violation of any provision of this subpart, or order issued thereunder, the Administrator may exercise the authorities available under section 706 of the Defense Production Act of 1950, as amended, 50 U.S.C. 4556, including applying for a preliminary, permanent, or temporary injunction, restraining order, or other order to enforce compliance with this subpart.

(c) Any person who willfully engages in violations of this part is subject to penalties available under section 103 of the Defense Production Act of 1950, as amended, 50 U.S.C. 4513, or other available authority.

Pete Gaynor,

Administrator,

Federal

Emergency

Management

Agency

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