anticipate any impacts to the Medicare program, beneficiaries, or other stakeholders.

There are three primary aspects of the provision that could affect its cost and the amount saved. The most immediate cost comes from the one-time implementation cost for the few EHR vendors that need to need to change their programming to use two standards; the NCPDP SCRIPT standard version 2017071 for Part D ePA and the HIPAA standard for other contexts. Based on our conversations with EHR vendors, we believe that it will take the EHR vendors approximately 200 developing hours and 800 programming hours to enable the EHRs to utilize two standards.

We also estimated what it will cost plan sponsors to implement this standard. After consulting with industry stakeholders, we have concluded that implementing or building to the SCRIPT standard can vary, but $6,500 is the approximate amount per plan and $100,000 is the approximate amount for the industry. We estimate that only 2 percent of the 774 plans will have to make changes to their ePA process to implement the NCPDP SCRIPT standard version 2017071 ePA transactions, which gives us an approximate one time implementation cost of $100,000 (15 * $6,500).

E. Alternatives Considered

We considered requiring the adoption of the standard by January 1, 2021 to ensure that this important mandate was implemented quickly. However, we want to help ensure that plans have as much time to comply with the statutory mandate as possible.

F. Accounting Statement and Table

The following table summarizes overall costs for this rule. The cost comes from implementing the new standard.

	2022	2023	2024	2025	2026
Total Costs	$100,000				
Net Savings					

List of Subjects in 42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Incorporation by reference, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 423 as set forth below:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 1. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 2. Section 423.160 is amended by adding paragraph (b)(8) to read as follows:

§ 423.160 Standards for electronic prescribing.

* * * * *

(b) * * *

(8) *Electronic prior authorization.* (i) Beginning January 1, 2021, Part D sponsors and prescribers may use the National Council for Prescription Drug Programs SCRIPT standard, Implementation Guide Version 2017071 approved July 28, 2017 (incorporated by reference in paragraph (c)(1)(vii) of this section), to provide for the communication of a prescription or prescription-related information between prescribers and Part D sponsors for the following transactions:

(A) PAInitiationRequest and PAInitiationResponse.

(B) PARequest and PAResponse.

(C) PAAppealRequest and PAAppealResponse.

(D) PACancelRequest and PACancelResponse.

(ii) Beginning January 1, 2022, Part D sponsors and prescribers must use the standard specified in paragraph (b)(8)(i) of this section for the transactions listed in paragraphs (b)(8)(i)(A) through (D) of this section.

* * * * *

Dated: February 6, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: March 13, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

Editorial note: This document was received for publication by the Office of the Federal Register on December 23, 2020.

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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 and Critical Health and Medical Resources for Domestic Use

AGENCY: Federal Emergency Management Agency, Department of Homeland Security (DHS).

ACTION: Temporary final rule; extension of effective date with modifications.

SUMMARY: In April, the Federal Emergency Management Agency (FEMA) 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. The rule covered 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. In August, FEMA modified the types of PPE covered and extended the duration of the temporary rule. Through this action, FEMA 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.

DATES: *Effective date:* This rule is effective from December 31, 2020 until June 30, 2021.

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, Program Analyst, Office of Policy and Program Analysis, 202–709–0661, *FEMA-DPA@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On April 10, 2020, FEMA published a temporary final rule in the **Federal Register** allocating 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.[1] The rule aids the response of the United States to the spread of Coronavirus Disease 2019 (COVID–19) by ensuring that certain health and medical resources are appropriately allocated for domestic use. On April 21, 2020, FEMA published a notification of exemptions to the rule.[2] With the continued goal of ensuring that these resources are appropriately allocated for domestic use, FEMA extended the date through which the allocation in the temporary final rule would be in effect, including the exemptions published on April 21, 2020, and modified the list of covered materials under the rule to reflect domestic supply needs as of August 10, 2020.[3] FEMA is now further extending and modifying this rule to reflect current domestic supply needs of health and medical resources to promote the national defense. The temporary final rule, as extended and modified, will remain in effect until June 30, 2021, unless sooner modified or terminated by the Administrator.

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. 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.[4] The following day, the Secretary of Health and Human Services (HHS) declared COVID–19 a public health emergency under Section 319 of the Public Health Service (PHS) Act.[5] 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.[6] 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.[7] FEMA subsequently issued 57 major disaster declarations in response to COVID–19, including for every State, 5 territories, the Seminole Tribe of Florida, and the District of Columbia.[8]

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 have become overwhelmed in some areas, with elevated rates of hospitalizations and deaths, as well as elevated demand for PPE, including the PPE covered by this rule. Due to a surge in confirmed COVID–19 cases and hospitalizations in October, November, and December 2020,[9] domestic supply of the allocated PPE has not kept pace with demand and is not anticipated to do so. Additionally, given the high rate of influenza vaccination administrations in 2020,[10] along with the recent developments in COVID–19 vaccines and vaccine trials,[11] the projected domestic supply of syringes and hypodermic needles is not expected to meet demand.

B. Legal Authorities

FEMA is extending and modifying this temporary final 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 13911, 85 FR 18403 (Apr. 1, 2020);
- Department of Homeland Security (DHS) Delegations, including DHS Delegation Number 09052 Rev. 00, ''Delegation of Defense Production Act Authority to the Administrator of the Federal Emergency Management Agency'' (Jan. 3, 2017) and 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 (Apr. 3, 2020).[12]

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 the President 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 the President shall deem necessary or appropriate to promote the national defense. FEMA refers to these authorities as relating to ''priority ratings'' and ''allocation,'' respectively.

[1] 85 FR 20195 (Apr. 10, 2020). *See also* 85 FR 22622 (Apr. 23, 2020) (correcting the date filed from ''4–8–20'' to'' 4–7–20'').

[2] 85 FR 22021 (Apr. 21, 2020).

[3] 85 FR 48113 (Aug. 10, 2020).

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

[5] HHS, ''Determination that a Public Health Emergency Exists,'' (Jan. 31, 2020) *available at https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx* (accessed December 2, 2020).

[6] ''Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak,'' Mar. 13, 2020, *available at https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/* (accessed December 15, 2020).

[7] COVID–19 Emergency Declaration *available at https://www.fema.gov/news-release/2020/03/13/covid-19-emergency-declaration* (accessed December 15, 2020).

[8] See *https://www.fema.gov/disasters/* (accessed December 15, 2020).

[9] As of December 22, 2020, the United States has over 17.79 million reported cases and over 300,000 deaths attributed to COVID–19. *See https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days* (accessed December 22, 2020). As of December 7, 2020, the number of reported weekly cases and weekly deaths are forecast to increase. *See https://covid.cdc.gov/covid-data-tracker/#forecasting_weeklycases* (accessed December 22, 2020) and *https://covid.cdc.gov/covid-data-tracker/#forecasting_weeklydeaths* (accessed December 22, 2020).

[10] *See https://www.cdc.gov/flu/prevent/vaccine-supply-distribution.htm* (accessed December 15, 2020).

[11] *See https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html* (accessed December 22, 2020).

[12] *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/* (accessed December 15 2020).

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.

On March 18, 2020, the President signed Executive Order 13909, which (among other things) contained a finding 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)).[13]

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.[14] The Secretary of Homeland Security has redelegated the Secretary's DPA authorities to the FEMA Administrator. *See* DHS Delegation Number 09052, Rev. 00 (Jan. 3, 2017) and DHS Delegation Number 09052, Rev. 00.1 (Apr. 1, 2020).

Additionally, on April 3, 2020, the President signed a Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (the Memorandum). The Memorandum reaffirmed the delegations and findings contained in Executive Orders 13909 and 13911, including that health and medical resources needed to respond to the spread of COVID–19, including personal protective equipment (PPE), 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 Memorandum identified certain categories of PPE materials that the Secretary of HHS had previously designated as ''scarce or threatened'' for purposes of section 102 of the DPA, and further stated that to ensure that these 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 PPE materials overseas.

In furtherance of such policy, the President directed the Secretary of Homeland Security, through the FEMA Administrator, and in consultation with the Secretary of HHS, to use any and all authority available under section 101 of the Act to allocate to domestic use, as appropriate, the five types of PPE identified in the Memorandum. On April 10, 2020, FEMA executed this direction by issuing the allocation order as a temporary final rule pursuant to the Memorandum, and with the authority delegated to the Secretary of Homeland Security in E.O. 13911 and re-delegated to the FEMA Administrator.[15] The temporary final rule was modified and extended on August 10, 2020, to ensure certain health and medical resources were appropriately allocated for domestic use.[16]

Finally, on May 13, 2020, FEMA published an interim final rule to 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.[17]

As the COVID–19 pandemic continues in the United States, the FEMA Administrator, in consultation with other agencies as appropriate, has determined that FEMA must continue to allocate some materials contained in the August 10, 2020, temporary final rule for domestic use, and to incorporate other health and medical resources due to changes in domestic supply and demand, surges in the number of confirmed COVID–19 cases and deaths in the United States, forecasts anticipating the increased number of COVID–19 cases and deaths, the current and projected volume of influenza vaccination doses, and future COVID–19 vaccination predictions. FEMA has determined, consistent with the Memorandum and FEMA's authorities under section 101 of the DPA, that it is appropriate to designate, with modification, the PPE previously designated and to include syringes and hypodermic needles (whether distributed separately or attached together) to ensure domestic supply is

[13] Executive Order 13909 also delegated to the Secretary of Health and Human Services (HHS) authority under the DPA for the prioritization and allocation of health and medical resources to respond to the spread of COVID–19. Further, 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 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 (''anti-hoarding designation''). *See* 85 FR 17592 (Mar. 30, 2020). The Secretary of HHS later modified and extended this designation. *See* 85 FR 45895 (July 30, 2020). The anti-hoarding designation relates to domestic hoarding and price-gouging activity, and is conceptually distinct from, and serves different purposes than, this rulemaking.

[14] 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.

[15] *See* 85 FR 20195 (Apr. 10, 2020).

[16] *See* 85 FR 48113 (Aug. 10, 2020).

[17] *See* 85 FR 28500 (May 13, 2020) (codified at 44 CFR part 333). In that interim final rule, FEMA noted that although FEMA effectuated the April allocation order via a temporary rule that predated the interim final rule, FEMA retains authority to administer and enforce that allocation order according to its terms, and to issue future allocation orders consistent with the procedures announced in the interim final rule. *See* 85 FR at 28505. As noted above, in August, FEMA opted to extend the April allocation, with modifications, consistent with the form of the April order. FEMA does the same here.

able to meet the continuing demand for these materials. In short, FEMA has determined that the original temporary final rule must be extended, and the list of covered materials under such rule must be modified.

Consistent with the authority delegated to the Secretary of Homeland Security in E.O. 13911 and re-delegated to the FEMA Administrator, FEMA now issues this temporary final rule to extend and modify the allocation order.

II. Provisions of the Temporary Final Rule

Following consultation with the appropriate Federal agencies; 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 April 10, 2020, temporary final rule (''covered materials'') shall be extended temporarily, and that the list of scarce and critical materials identified in such temporary final rule shall be modified to reflect current domestic needs. The materials identified in this rule will continue to be allocated for domestic use and may not be exported from the United States without explicit approval by FEMA. *See* 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 final rule extension, before any shipments of such covered materials may leave the United States, U.S. Customs and Border Protection (CBP) will continue to 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 continue to 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* 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 continue to consult other agencies and will consider the totality of the circumstances, including the following factors: (1) The need to ensure that such 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 extension to the rule continues the eleven exemptions that the Administrator has determined to be necessary or appropriate to promote the national defense. *See* 44 CFR 328.102(d).

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.

On April 21, 2020, FEMA published notification of 10 additional exemptions to the original temporary final rule.[18] These exemptions will remain in effect for the new effective period of this rule, subject to the Administrator's discretion to waive, modify, or terminate such exemptions at any time in the future. The Administrator has determined that it continues to be necessary and appropriate to promote the national defense to exempt these categories of covered materials from the requirements of 44 CFR 328.102(a) and (b). 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 continue to 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 final rule, as appropriate.

FEMA is modifying the original temporary final rule's authority citation to include both DHS Delegation Number 09052, Rev. 00 (Jan. 3, 2017) and DHS Delegation Number 09052, Rev. 00.1 (Apr. 1, 2020), and to update the formatting of other citations previously included. FEMA is making a number of non-substantive revisions throughout part 328 to correct formatting errors and improve clarity and readability. FEMA is also modifying the original temporary final rule at § 328.101 to reflect the appropriate statutory language from section 101 of the Act. FEMA is further modifying § 328.103(a) to update the designation of covered materials under the rule. FEMA is further clarifying the types of PPE surgical masks subject to the allocation order and is adding specific syringes and hypodermic needles (whether distributed separately or attached together). The continued allocation of certain PPE materials reflects current domestic demand, as indicated by the number of open requests for such materials from State, local, Tribal, and territorial (SLTT) jurisdictions. Specifically—

- FEMA is continuing the designation of Surgical N95 Filtering Facepiece Respirators as covered materials. Surgical N95 respirators for medical use are still subject to high demand within the United States, and supply is not expected to catch up with demand at this time given the current forecasts of

[18] 85 FR 22021 (Apr. 21, 2020).

increases in confirmed cases and hospitalizations.

• FEMA is continuing the designation of PPE surgical masks as covered materials due to the continued inability of domestic supply to meet current demands, with modification. In the original temporary final rule, FEMA designated ''PPE surgical masks, including masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials.'' This temporary final rule clarifies the existing language regarding the PPE surgical masks subject to this order. As revised, 44 CFR 328.103(a)(2) now specifically designates PPE surgical masks as described by 21 CFR 878.4040, including masks that cover the user's nose and mouth providing a physical barrier to fluids and particulate materials that meet fluid barrier protection standards pursuant to ASTM F 1862 [19] and to Class I or Class II flammability tests under CPSC CS 191–53,[20] NFPA Standard 702–1980,[21] or UL 2154 standards.[22] As of December 9, 2020, FEMA had open requests for over 13 million surgical masks from SLTT jurisdictions.

• FEMA is also continuing the designation of PPE nitrile gloves as covered materials with one minor edit to clarify the specific types of gloves subject to the order. There is still a significant shortage of nitrile gloves. As of December 9, 2020, FEMA had open requests for over 168 million nitrile gloves from SLTT jurisdictions.

• FEMA is continuing the designation of Level 3 and 4 Surgical Gowns and Surgical Isolation Gowns that meet all of the requirements in ANSI/AAMI PB70 [23] and ASTM F2407–06 [24] and are classified by Surgical Gown Barrier Performance based on AAMI PB70. At this time, domestic supply is not meeting demand. As of December 9, 2020, FEMA had open requests for over 1.2 million of these gowns from SLTT jurisdictions.

• FEMA is adding designations for specific syringes and hypodermic needles (whether distributed separately or attached together) to the covered materials list. The designated materials are piston syringes and hypodermic needles that are either: Piston syringes that allow for the controlled and precise flow of liquid as described by 21 CFR 880.5860, that are compliant with ISO 7886–1:2017,[25] and use only Current Good Manufacturing Practice (CGMP) processes; [26] or hypodermic single lumen needles as described by 21 CFR 880.5570 that have engineered sharps injury protections as described in the Needlestick Safety and Prevention Act.[27] Due to the current high rate of influenza vaccine administration, in conjunction with the development of COVID–19 vaccines, the projected domestic supply of these materials is not anticipated to meet demand. As of the week of December 4, 2020, more than 189.4 million influenza vaccine doses had been distributed in the United States for this influenza season [28] compared to the 2019–2020 influenza season, where approximately 174.5 million influenza vaccine doses were distributed for the entire season,[29] representing an increase of over 14.9 million vaccine doses so far in the 2020–2021 influenza season. A record number of influenza vaccine doses is being produced and distributed this influenza season, and production and distribution will occur over a longer period of time as a result,[30] further reducing the domestic supply of syringes. Additionally, as of December 22, 2020, the United States has authorized for emergency use two COVID–19 vaccines, with multiple other vaccines in large clinical trials.[31] As of December 16, 2020, the United Kingdom and Canada have also already approved the use of one vaccine for COVID–19.[32] As vaccination efforts expand, FEMA anticipates that these materials will be in short supply.

Consistent with the DPA and the original temporary final rule, FEMA may continue to conduct such investigations and issue such requests for information as may be necessary for the enforcement of the Act, including this rule. *See* 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* 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* 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

[19] The American Society for Testing and Materia (ASTM) F 1862 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) is the test method used to evaluate the resistance of medical face masks to penetration by the impact of a small volume ((~2 mL) of a high-velocity stream of synthetic blood. Medical face mask pass/fail determinations are based on visual detection of synthetic blood penetration.

[20] The Consumer Protection Safety Commission (CPSC) CS 191–53 standard is the flammability standard for clothing textiles pursuant to 16 CFR part 1610.

[21] The National Fire Protection Association (NFPA) Standard 702–1980 is the standard for classification of the flammability of wearing apparel.

[22] UL (previously Underwriters Laboratories) is a global independent safety science company with expertise in innovating safety solutions. The UL 2154 is the standard for safety fire tests of surgical fabrics.

[23] ANSI/AAMI PB70 is the second edition of the standard for liquid barrier performance of protective apparel.

[24] The American Society for Testing and Material (ASTM) F2407 is an umbrella document which describes testing for surgical gowns: Tear resistance, seam strength, lint generation, evaporative resistance, and water vapor transmission.

[25] ISO 7886–1:2017 specifies requirements and test methods for verifying the design of empty sterile single-use hypodermic syringes, with or without needle, made of plastic or other materials and intended for the aspiration and injection of fluids after filling by the end-users.

[26] More information on CGMP processes can be found on the Food and Drug Administration (FDA) website, Facts About the Current Good Manufacturing Practices (CGMPs) (June 25, 2018), *https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmps.*

[27] Public Law 106–430, 114 Stat. 1901 (Nov. 6, 2000).

[28] *https://www.cdc.gov/flu/prevent/vaccine-supply-distribution.htm* (accessed December 15, 2020). As of November 27, 2020, 188 million doses of influenza vaccine had been distributed in the United States, the highest number of influenza doses distributed in the United States during a single influenza season. *https://www.cdc.gov/flu/fluvaxview/dashboard/vaccination-distribution.html* (accessed December 15, 2020).

[29] *https://www.cdc.gov/flu/prevent/vaccine-supply-historical.htm* (accessed December 15, 2020).

[30] *https://www.cdc.gov/flu/prevent/vaccine-supply-distribution.htm* (accessed December 15, 2020).

[31] *See https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html* (accessed December 22, 2020).

[32] *https://www.gov.uk/government/news/uk-medicines-regulator-gives-approval-for-first-uk-covid-19-vaccine* (accessed December 15, 2020) and *https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/vaccines.html* (accessed December 15, 2020).

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 Final 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, that, with respect to this temporary final rule, urgent and compelling circumstances continue to make compliance with the notice and comment requirements of section 709(b)(1) of the Act, 50 U.S.C. 4559(b)(1), impracticable. The COVID–19 pandemic continues to grow worldwide. The World Health Organization reports over 71.5 million cases and over 1.6 million deaths in 220 countries as of December 15, 2020.[33] 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.[34] The United States now leads the world in the total number of COVID–19 cases and deaths [35] and the Centers for Disease Control and Prevention (CDC) estimates the number of confirmed cases and deaths in the United States will continue to increase.[36] As a result of the surge in U.S. confirmed cases and deaths, demand for PPE used to treat patients with the disease has increased and the domestic supply has been unable to keep pace. As explained above, FEMA continues to have a high volume of open requests for the specific types of PPE listed in this allocation order and anticipates this volume will increase given the COVID–19 forecasts from the CDC. The historic increase in the number of influenza vaccine doses manufactured and distributed this influenza season combined with the authorization for emergency use of vaccines for COVID–19 and the demand for the same by those who wish to be vaccinated against the disease means the projected domestic supply of syringes and hypodermic needles will not meet demand in the upcoming months.[37] 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 final rule should become effective immediately upon publication in the **Federal Register**. The exigent need for this rule is related to the COVID–19 pandemic.

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 current surge of confirmed COVID–19 cases and deaths within the Nation's communities is straining 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 and other health and medical resources affected by this rule, continue to be allocated for domestic use as appropriate. Given the evolving nature of this pandemic, the current surge in confirmed COVID–19 cases and deaths, 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. As explained earlier in the preamble, the volume of requests for certain health and medical resources continues to outpace domestic supply. FEMA is continuously monitoring SLTT jurisdictions' demand for these scarce and critical health and medical resources and is taking this immediate action to continue to ensure that such resources are appropriately allocated for domestic use to continue to combat the current surge of confirmed COVID–19 cases and deaths, the forecasted increase in both, and the projected shortages of supplies to ensure the effective distribution of influenza vaccine doses and COVID–19 vaccine doses for those who wish to be vaccinated against these diseases.

In short, given the national and international emergency caused by COVID–19 and the current surge of confirmed cases and deaths, 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. Based on current needs, this temporary final rule modification and extension is needed to appropriately allocate scarce and critical materials for domestic use. Specifically, FEMA seeks to continue designation of certain PPE materials with minor modifications based on current demand and to add other health and medical resources based on projected domestic supply not meeting demand.

The measures described in this rule are being issued on a temporary basis. This temporary final rule with

[33] *https://www.who.int/emergencies/diseases/novel-coronavirus-2019* (accessed December 15, 2020).

[34] *https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases* (accessed December 15, 2020).

[35] *https://covid19.who.int/* (accessed December 15, 2020). The United States has over 16 million confirmed cases compared to over 9.9 million confirmed cases in India as of December 15, 2020. The United States has over 296,000 deaths from COVID–19 compared to over 181,000 deaths in Brazil from COVID–19 as of December 15, 2020.

[36] *https://covid.cdc.gov/covid-data-tracker/#forecasting_weeklycases* (accessed December 15, 2020) and *https://covid.cdc.gov/covid-data-tracker/#forecasting_weeklydeaths* (accessed December 15, 2020).

[37] A record number of influenza vaccine doses is being produced and distributed this influenza season, and production and distribution will occur over a longer period as a result. *https://www.cdc.gov/flu/prevent/vaccine-supply-distribution.htm* (accessed December 15, 2020). As of December 22, 2020, the United States has authorized for emergency use two COVID–19 vaccines, with multiple other vaccines in large clinical trials. *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html* (accessed December 22, 2020).

modification remains in effect until June 30, 2021, unless sooner modified or terminated by the Administrator.

B. Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the 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 any regulatory action that is likely to result in a regulation that may (1) have an annual effect on the economy of $100 million or more, or adversely affect in a material way 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) create a serious inconsistency or otherwise interfere 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) raise 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 final rule as an economically significant regulatory action. Given that the temporary final 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, to ensure these health and medical resources are appropriately allocated for domestic use.

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 after being required by that section or any other law to publish a general notice of proposed rulemaking. This is a temporary final 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. 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, in that amount 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 in excess of the threshold. 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. 1532(a) and 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 temporary 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 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. Furthermore, there are no provisions in this rule that impose direct compliance costs on State and local governments. Accordingly, DHS is not providing the additional analysis as the rule does not warrant additional analysis under Executive Order 13132.

G. Congressional Review Act

Under the Congressional Review 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 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. *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 December 31, 2020 until June 30, 2021, chapter I of title 44 of the Code of Federal Regulations is amended by revising 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: 50 U.S.C. 4511, *et seq.;* E.O. 13909, 85 FR 16227; E.O. 13911, 85 FR 18403; DHS Delegation Number 09052, Rev. 00 (Jan. 3, 2017); DHS Delegation Number 09052, Rev. 00.1 (Apr. 1, 2020); Presidential Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (Apr. 3, 2020).

§ 328.101 Basis and purpose.

(a) *Basis.* The rules in this part 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 the Federal Emergency Management Agency (FEMA).

(b) *Purpose.* The purpose of the rules in this part are to aid the response of the United States to the spread of COVID–19 by ensuring that scarce and critical 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 the exemption in this paragraph (d), such materials may be exported without further review by FEMA, provided that the Administrator may waive the exemption in this paragraph (d) 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 the exemption in this paragraph (d) to shipments identified by CBP.

(2) The Administrator may establish, in his or her discretion, additional exemptions that he or she 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) Surgical 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) PPE surgical masks as described by 21 CFR 878.4040, including masks that cover the user's nose and mouth providing a physical barrier to fluids and particulate materials, that meet fluid barrier protection standards pursuant to—

(i) ASTM F 1862; and

(ii) Class I or Class II flammability tests under CPSC CS 191–53, NFPA Standard 702–1980, or UL 2154 standards;

(3) PPE nitrile gloves, specifically those defined at 21 CFR 880.6250 (exam gloves) and 878.4460 (surgical gloves) and such nitrile gloves intended for the same purposes;

(4) Level 3 and 4 Surgical Gowns and Surgical Isolation Gowns that meet all of the requirements in ANSI/AAMI PB70 and ASTM F2407–06 and are classified by Surgical Gown Barrier Performance based on AAMI PB70; and

(5) Syringes and hypodermic needles (whether distributed separately or attached together) that are either:

(i) Piston syringes that allow for the controlled and precise flow of liquid as described by 21 CFR 880.5860, that are compliant with ISO 7886–1:2017 and use only Current Good Manufacturing Practices (CGMP) processes; or

(ii) Hypodermic single lumen needles that have engineered sharps injury protections as described in the Needlestick Safety and Prevention Act, Pub. L. 106–430, 114 Stat. 1901 (Nov. 6, 2000).

(b) Upon determination that additional items are scarce and necessary for national defense, and that consideration under the allocation order in this part 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 in paragraph (a) of this section. 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 part, 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 part, 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 part.

(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.

[FR Doc. 2020–29060 Filed 12–30–20; 8:45 am]

BILLING CODE 9111–19–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

49 CFR Part 389

[Docket No. FMCSA–2016–0341]

RIN 2126–AB96

Rulemaking Procedures Update

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Final rule.

SUMMARY: FMCSA amends its rulemaking procedures by revising the process for preparing and adopting rules and petitions. Also, the Agency adds new definitions, and makes general administrative corrections throughout its rulemaking procedures. These actions are authorized under the Fixing America's Surface Transportation (FAST) Act and the Administrative Procedure Act (APA).

DATES: This final rule is effective March 1, 2021.

Petitions for Reconsideration of this final rule must be submitted to the FMCSA Administrator no later than February 1, 2021. You may use today's amended procedures below in 49 CFR 389.35.

FOR FURTHER INFORMATION CONTACT: Mr. Steven J. LaFreniere, Regulatory Ombudsman, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 366–0596, *steven.lafreniere@dot.gov*. If you have questions on viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION: This final rule is organized as follows:

I. Rulemaking Documents

A. Availability of Rulemaking Documents

For access to docket FMCSA–2016–0341 to read background documents and comments received, go to *http://www.regulations.gov* at any time, or to Dockets Operations at U.S. Department of Transportation, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

II. Legal Basis for the Rulemaking

The FAST Act requires FMCSA to address its rulemaking and petitions procedures. Specifically, section 5202 provides requirements for the Agency to follow regarding the development of proposed rulemakings [49 U.S.C. 31136(f)–(h)]. Section 5204 also directs the Agency to be more transparent to the public regarding how FMCSA prioritizes and defines petitions.

The APA (5 U.S.C. 551–706) established procedures for all Federal agencies to use in developing rules and regulations. It also established the standards that allow the public to participate in a rulemaking as well as the opportunity to petition the Federal government for the issuance, amendment, or repeal of a rule. The APA authorizes changes to 49 CFR part 389, beyond what is required by the FAST Act.

DOT's regulatory procedures, codified at 49 CFR part 5, also describe how persons may petition a departmental Operating Administration, like FMCSA, for a new rulemaking, an exemption from an existing rule, or a retrospective review. These departmental procedures apply unless a statute or an Operating Administration's regulations or procedures provide alternate procedures for processing petitions. FMCSA's procedures are housed in 49 CFR part 389, and are the subject of this rulemaking.