



## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

#### 44 CFR Part 328

[Docket ID FEMA-2020-0018]

### Prioritization and Allocation of Certain Scarce and Critical Health and Medical Resources for Domestic Use; Additional Exemptions

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

**ACTION:** Notification of additional exemptions.

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**SUMMARY:** The Federal Emergency Management Agency (FEMA) announces additional exemptions from a temporary final rule that FEMA published in the *Federal Register* on December 31, 2020.

**DATES:** *Applicability date:* This notification applies beginning on [INSERT DATE OF FILING FOR PUBLIC INSPECTION AT 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, Program Analyst, Office of Policy and Program Analysis, 202-212-2900, [FEMA-DPA@fema.dhs.gov](mailto:FEMA-DPA@fema.dhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

On April 10, 2020, the Federal Emergency Management Agency (FEMA) published a temporary final rule (the “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.<sup>1</sup> The rule aids the response of the United States to the spread of COVID-19 by ensuring that certain health and medical resources are appropriately allocated for domestic use. The rule was modified and extended on August 10, 2020 and December 31, 2020, respectively.<sup>2</sup>

FEMA issued the rule under the authority of the Defense Production Act of 1950, as amended (DPA),<sup>3</sup> and related Executive orders and delegations.<sup>4</sup> Most prominently, on April 3, 2020, the President signed a Memorandum on Allocating Certain Scarce or Threatened Health and Medical Resources to Domestic Use (Memorandum).<sup>5</sup> In the Memorandum, the President directed the Secretary of Homeland Security, through the FEMA Administrator, and in consultation with the Secretary of Health and Human Services (HHS), to use any and all authority available under section 101 of the DPA to allocate to domestic use, as appropriate, the five types of personal protective equipment (PPE) materials identified in the Memorandum. FEMA executed this direction by publishing an allocation order on April 10, 2020, as a temporary final rule pursuant to the Memorandum. On April 21, 2020, FEMA published notification of 10 exemptions in addition to the exemption listed in the original temporary final rule.<sup>6</sup> The temporary final rule was modified and extended on August 10, 2020, and again on December 31, 2020, to ensure certain health and medical resources were appropriately allocated for domestic use.<sup>7</sup>

Consistent with the Memorandum, the December 31, 2020 rule provides that until June 30, 2021, and subject to certain exemptions, no shipments of covered materials may leave the United States without explicit approval by FEMA.<sup>8</sup> The rule requires U.S. Customs and Border

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<sup>1</sup> 85 FR 20195 (Apr. 10, 2020) (codified at 44 CFR part 328). *See also* 85 FR 22622 (Apr. 23, 2020) (correcting the date filed from “4–8–20” to “4–7–20”).

<sup>2</sup> 85 FR 48113 (Aug. 10, 2020) and 85 FR 86835 (Dec. 31, 2020) (codified at 44 CFR part 328).

<sup>3</sup> 50 U.S.C. 4501 *et seq.*

<sup>4</sup> *See* 85 FR 20195 at 20196–20197.

<sup>5</sup> *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://trumpwhitehouse.archives.gov/presidential-actions/memorandum-allocating-certain-scarce-threatened-health-medical-resources-domestic-use/> (last accessed May 12, 2021).

<sup>6</sup> 85 FR 22021 (Apr. 21, 2020).

<sup>7</sup> *See* 85 FR 48113 (Aug. 10, 2020); 85 FR 86835 (Dec. 31, 2020).

<sup>8</sup> 44 CFR 328.102(a).

Protection (CBP), in coordination with such other officials as may be appropriate, to notify FEMA of an intended export of covered materials.<sup>9</sup> CBP must temporarily detain any shipment of such covered materials pending the Administrator's determination whether to return for domestic use, issue a rated order for, or allow the export of part or all of the shipment.<sup>10</sup> In making such determination, the Administrator may consult other agencies and will consider the totality of the circumstances, including: (1) the need to ensure that scarce or critical 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.<sup>11</sup>

In addition to providing for the determination described above, the rule includes eleven exemptions to the requirement that covered materials not leave the United States without explicit approval by FEMA. In the interest of promoting the national defense, the Administrator 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 such covered materials, on a per item basis, was distributed in the United States in the preceding 12 months.<sup>12</sup> 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, if the Administrator determines that doing so is necessary or appropriate to promote the national defense.<sup>13</sup> Additionally, the Administrator determined that it is necessary

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<sup>9</sup> 44 CFR 328.102(b).

<sup>10</sup> *Id.*

<sup>11</sup> 44 CFR 328.102(c).

<sup>12</sup> 44 CFR 328.102(d)(1).

<sup>13</sup> *Id.*

and appropriate to promote the national defense to continue the 10 additional exemptions to the original temporary final rule that were published on April 21, 2020.<sup>14</sup>

Pertinent to this notification, the rule also provides that 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*. This notification announces additional exemptions.

### **Notice of Additional Exemptions**

Pursuant to 44 CFR 328.102(d)(2), section 101 of the DPA, and related authorities, the Administrator has determined that it is necessary and appropriate in order to promote the national defense to exempt certain categories of covered materials from the requirements of 44 CFR 328.102(a) and (b). The Administrator may waive any of these exemptions at any time and fully review shipments of covered materials under 44 CFR 328.102(b) if the Administrator determines that doing so is necessary or appropriate to promote the national defense. In addition, if CBP believes that any manufacturer, broker, distributor, exporter, or shipper of any covered materials is intentionally modifying its shipments in a way to take advantage of one or more of these exemptions, diverting materials from the United States market, or otherwise trying to circumvent the FEMA review requirements in 44 CFR 328.102(b) through application of any of the exemptions, CBP may detain a shipment and forward information about that shipment (including the basis for CBP's belief) to FEMA for determination.

The additional exemptions are as follows:

- (1) *Exports of Industrial N95 Respirators*. The Administrator issues this exemption to narrow the scope of the allocation order to exempt shipments of industrial N-95 respirators from the allocation order. The Administrator believes that this exemption is necessary to narrow the scope of the allocation order to be limited to surgical N95 filtering facepiece respirators that are single-use, disposable respiratory protective

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<sup>14</sup> See 85 FR 86835, 86838 (Dec. 31, 2020).

devices used in a healthcare setting that are worn by healthcare personnel during procedures to protect both the patient and healthcare personnel from the transfer of microorganisms, body fluids, and particulate material at an N95 filtration efficiency level per 42 CFR 84.171. A surgical N95 respirator is a class II device, regulated by the U.S. Food and Drug Administration under 21 CFR 878.4040. Narrowing the scope of the covered materials ensures that only those items that are scarce or critical items in the domestic supply chain are affected by the allocation order. The Administrator believes that industrial N95 respirators are in sufficient domestic supply<sup>15</sup> and that worldwide demand for these items remains high. As such, it is necessary and appropriate to promote the national defense and consistent with the purposes of the Presidential Memorandum and the subsequent allocation order to exempt these items from the list of covered materials.

(2) *Exports of PPE Surgical Masks.* The Administrator believes it is necessary and appropriate to promote the national defense to exempt these items from the list of covered materials to support the efforts of domestic manufacturing to combat COVID-19 around the world and consistent with the position of the United States as a world leader. A key element of national defense is the ability of the United States to convey international leadership during times of crisis, including the COVID-19 pandemic. This includes our ability to assist in meeting the global demand for items where domestic supply needs have been met, help those in need, and to remain stalwarts of the international community. The Administrator also recognizes the international nature of many U.S. companies, and believes that allowing these companies to continue to produce at a high level is crucial to promoting the U.S. economy. One of the factors specifically identified in the allocation order that the Administrator considers in determining whether to return

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<sup>15</sup> FEMA fills requests from state, local, tribal, and territorial partners for respirators through the standard Resource Request Form process. The agency does not have any open requests for industrial N95 respirators and is equipped to fill requests as they are received.

for domestic use, issue rated order for, or allow the export of a shipment is minimization of disruption of the supply chain, both domestically and abroad. The Administrator believes that this exemption would not disrupt the domestic supply chain,<sup>16</sup> nor cause a detrimental shortage of covered materials to Americans.

(3) *Exports of Specific Syringes and Needles.* The Administrator believes it is necessary and appropriate to promote the national defense to exempt the specific syringes and needles covered under the current rule given the worldwide efforts to provide COVID-19 vaccinations. Similar to PPE surgical masks above, the Administrator believes these items should be exempted from the list of covered materials to support the efforts to combat COVID-19 around the world and consistent with the position of the United States as a world leader. A key element of national defense is the ability of the United States to convey international leadership during times of crisis, including the COVID-19 pandemic. This includes our ability to assist in meeting the global demand for items where domestic supply needs have been met, help those in need, and to remain stalwarts of the international community. The Administrator also recognizes the international nature of many U.S. companies, and believes that allowing these companies to continue to produce at a high level is crucial to promoting the U.S. economy. One of the factors specifically identified in the allocation order that the Administrator considers in determining whether to return for domestic use, issue rated order for, or allow the export of a shipment is minimization of disruption of the supply chain, both domestically and abroad. The Administrator believes that this exemption would not disrupt the domestic supply chain, nor cause a detrimental shortage to Americans given the current state of vaccination rates in the United States.<sup>17</sup>

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<sup>16</sup> FEMA fills requests from state, local, tribal, and territorial partners for respirators through the standard Resource Request Form process. The agency does not have any open requests for PPE surgical masks.

<sup>17</sup> As of May 11, 2021, approximately 35.1 percent of the U.S. population has been fully vaccinated, while 46.2 percent of the U.S. population has received at least one dose of a vaccine. Over 71 percent of the U.S. population 65 years of age or older (one of the highest at-risk segments of the U.S. population) have now been fully vaccinated. See [www.covid.cdc.gov/covid-data-tracker/#vaccinations](https://www.covid.cdc.gov/covid-data-tracker/#vaccinations) (last accessed May 12, 2021 at 1:30 pm).

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**Deanne Criswell,**

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