



# FedEx Regulatory Alerts & Updates

## **Regulatory Alert: Actions Taken to Protect Scarce Personal Protective Equipment in the U.S.**

April 13, 2020

### **Background**

The Coronavirus (COVID-19) pandemic has resulted in a scarcity of personal protective equipment (PPE) in the U.S. A Presidential Memorandum was issued on April 3, 2020, and a Federal Emergency Management Agency (FEMA) Temporary Final Rule (TFR) was published in the Federal Register on April 10, 2020, addressing the situation.

### **What are the details of these two actions?**

CBP personnel at all U.S. ports of exit will be actively reviewing export shipment details to segregate any PPE that is considered scarce or threatened. Once a shipment is identified, the shipment details will be provided to the FEMA national center in Washington, D.C. for review and decision. The FEMA center operates 24/7.

This "PPE export review" process is effective immediately.

### **Here are the specific PPE items that are considered scarce or threatened based upon the FEMA TFR:**

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's 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 material
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

This PPE export review process will apply to all U.S. export shipments of the above listed articles valued at \$2,500USD and above and containing 10,000 units or more. Additionally, there are certain other shipment types receiving an exclusion.

### **Exclusions to the PPE export review:**

- Exports to Canada or Mexico

- Exports to U.S. government entities such as U.S. military bases overseas
- Exports by U.S. government agencies
- Exports by U.S. charities
- Exports by critical infrastructure industries for the protection of their workers;
- Exports by the 3M company
- Express or mail parcels that do not meet the commercial quantity definition above
- In-transit shipments

## **Q&A**

### **Q1: How long do these protective actions of exported PPE last?**

A1: The FEMA TFR states that this temporary rule will cease to be in effect on August 10, 2020.

### **Q2: If FEMA determines a shipment should not be exported, what happens with the intended shipment?**

A2: If FEMA makes the decision a shipment detained by CBP at a port of exit is NOT to be exported, there are two actions that can be taken:

- FEMA will have the shipment returned for domestic use
- FEMA will issue a "rated order" for part or all of the shipment

### **Q3: Are U.S. shippers allowed to export any of these scarce items to family members, friends or associates overseas for their personal use during the COVID-19 pandemic?**

A3: Yes, as long as the \$2,500 value threshold and 10,000 unit threshold are both adhered to. The commercial invoice for the shipment should clearly indicate the reason for the shipment (e.g., - "500 surgical masks for personal use by consignee").

### **Q4: What are "critical infrastructure industries" and how were those determined?**

A4: The U.S. federal government determined that functioning critical infrastructure is imperative during the response to the COVID-19 emergency for both public health and safety as well as community well-being. Sixteen specific critical infrastructure industries were identified to have a special responsibility in these times to continue operations. Please see the CISA link below in the Resources section for additional details and explanations (as well as a FAQ section).

### **Q5: Are there penalties for violations of this new FEMA rule?**

A5: Yes, FEMA can seek an injunction or other order if they suspect a person may have or is considering committing an action in violation of the act. Additionally, failing to fully comply with this rule is considered a crime punishable by a fine not to exceed \$10,000, up to a year in prison or both.

## **References:**

April 3 Presidential Memo

<https://www.whitehouse.gov/presidential-actions/memorandum-allocating-certain-scarce-threatened-health-medical-resources-domestic-use/>

April 10 FEMA Temporary Final Rule

<https://www.federalregister.gov/documents/2020/04/10/2020-07659/prioritization-and-allocation-of-certain-scarce-or-threatened-health-and-medical-resources-for>

Cyber & Infrastructure Security Agency (CISA) website

<https://www.cisa.gov/identifying-critical-infrastructure-during-covid-19>