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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Extension of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures Under Executive Order 13910 and Section 102 of the Defense Production Act of 1950

AGENCY: Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) provides notice of the extension of the designation issued March 25, 2020 under Executive Order 13910 (Executive Order) and section 102 of the Defense Production Act of 1950 (the Act), 50 U.S.C. 4512, as amended, designating health and medical resources necessary to respond to the spread of the virus associated with Coronavirus Disease 2019 (COVID-19) that are scarce or the supply of which would be threatened by excessive accumulation by people or entities not needing the excess supplies (March 25 Designation Notice). These designated materials are subject to the hoarding prevention measures authorized under the Executive Order and the Act. The March 25 Designation Notice was subsequently published in the Federal Register on March 30, 2020. *See* 85 FR 17592. On June 30, 2020, HHS updated the March 25 Designation Notice to change the information contact and to remove chloroquine phosphate and hydroxychloroquine HCl as a scarce or threatened material. This update was published in the Federal Register on July 7, 2020. *See* 85 FR 40667. Without extension, the March 25 Designation Notice would terminate 120 days from publication. This notice, issued on July 23, 2020, extends the March 25 Designation Notice for an additional 120 days. This notice also includes modifications and additions to the original list of scarce or threatened materials.

DATES: This action took effect July 23, 2020 and terminates January 19, 2021.

FOR FURTHER INFORMATION CONTACT: Paige Ezernack: 202-260-0365; Paige Ezernack@hhs.gov

SUPPLEMENTARY INFORMATION: On March 23, 2020, and in response to the spread of the virus associated with COVID-19, President Trump signed Executive Order 13910 (Executive Order) to prevent hoarding of health and medical resources necessary to respond to the spread of COVID-19 within the United States. As provided in the Executive Order, it is the policy of the United States that health and medical resources needed to respond to the spread of COVID-19, such as personal protective equipment and sanitizing and disinfecting products, are appropriately distributed. This policy furthers the goal of protecting the Nation's healthcare systems from undue strain.

Through the Executive Order, the President delegated, to the Secretary of Health and Human Services (the Secretary), his authority under section 102 of the Defense Production Act of 1950, 50 U.S.C. 4512, as amended (the Act), to prevent hoarding of health and medical resources necessary to respond to the spread of COVID-19 within the United States, and his authority to implement the Act in subsection III of chapter 55 of title 50, United States Code (50 U.S.C. 4554, 4555, 4556, and 4660). Under this delegation and the Act, the Secretary may designate such resources as scarce materials or materials the supply of which would be threatened by such accumulation (threatened materials). The Secretary may also prescribe conditions with respect to accumulation of such materials in excess of the reasonable demands of business, personal, or home consumption. The Act prohibits any person or entity from accumulating designated materials (1) in excess of the reasonable demands of business, personal,

or home consumption, or (2) for the purpose of resale at prices in excess of prevailing market prices.

The March 25 Designation Notice issued by HHS designates scarce materials or threatened materials that are subject to the hoarding prevention measures authorized under the Executive Order and the Act. *See* 85 FR 17592 (Mar. 30, 2020). Under 50 U.S.C. § 4552(13), the term “materials” includes “(A) any raw materials (including minerals, metals, and advanced processed materials), commodities, articles, components (including critical components), products, and items of supply; and (B) any technical information or services ancillary to the use of any such materials, commodities, articles, components, products, or items.” For purposes of the March 25 Designation Notice, the term “scarce materials or threatened materials” means health or medical resources, or any of their essential components, determined by the Secretary to be needed to respond to the spread of COVID-19 and which are, or are likely to be, in short supply or the supply of which would be threatened by hoarding. 85 FR at 17592. Designated scarce materials or threatened materials are subject to periodic review by the Secretary.

The designation is not a “regulation” under the Administrative Procedure Act (APA). *See* 50 U.S.C. 4559 (providing an exemption from the APA). To the extent that it were, the Secretary finds that, in light of the current global pandemic, urgent and compelling circumstances make compliance with public comment requirements impracticable. *See id.*

The March 25 Designation Notice was scheduled to terminate after 120 days from the date of publication, unless superseded by a subsequent notice. Given the ongoing pandemic, the Secretary finds good cause to extend the March 25 Designation Notice, as modified by the June 30, 2020 notice, for an additional 120 days. The Secretary also finds good cause to include the following modifications and additions to list of scarce or threatened materials:

1. Add “laboratory reagents and materials used for isolation of viral genetic material and testing, such as transport media, collection swabs, test kits and reagents specific to those kits, and consumables such as plastic pipette tips and plastic tubes”;
2. Add “drug products currently recommended by the NIH COVID-19 Treatment Guidelines Panel, including (as of July 23, 2020) remdesivir and dexamethasone”; and
3. Add “alcohol-based hand sanitizer and rubs.”

A copy of the Notice of the March 25 Designation, including the above modifications and additions and as modified by the June 30, 2020 notice, is provided below and also can be found on HHS’s website.

**NOTICE OF DESIGNATION OF
SCARCE MATERIALS OR THREATENED MATERIALS**

Health or medical resources, or any of their essential components, determined by the Secretary of HHS to be needed to respond to the spread of COVID-19 and which are, or are likely to be, in short supply (scarce materials) or the supply of which would be threatened by hoarding (threatened materials). Designated scarce materials or threatened materials are subject to periodic review by the Secretary.

The following materials are designated pursuant to section 102 of the Defense Production Act (50 U.S.C. § 4512) and Executive Order 13190 of March 23, 2020 (Preventing Hoarding of Health and Medical Resources to Respond to the Spread of COVID-19) as scarce materials or threatened materials:

1. N-95 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. Powered Air Purifying Respirator (PAPR)
5. Portable Ventilators, including portable devices intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas
6. Sterilization services for any device as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act and sterilizers as defined in 21 CFR 880.6860, 880.6870, and 880.6880, including devices that already have FDA marketing authorization and those that do not have FDA marketing authorization but are intended for the same uses
7. **Disinfecting devices** intended to kill pathogens and other kinds of microorganisms by chemical means or physical means, including those defined in 21 CFR 876.1500, 880.6992, and 892.1570 and other sanitizing and disinfecting products suitable for use in a clinical setting
8. Medical gowns or apparel, e.g., surgical gowns or isolation gowns
9. Personal protective equipment (PPE) coveralls, e.g., Tyvek Suits
10. PPE face masks, including any masks that cover the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels
11. PPE surgical masks, including masks that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials
12. PPE face shields, including those defined at 21 CFR 878.4040 and those intended for the same purpose
13. 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
14. Ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories as those terms are described in FDA's March 2020 Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency located at <https://www.fda.gov/media/136318/download>
15. Laboratory reagents and materials used for isolation of viral genetic material and testing, such as transport media, collection swabs, test kits and reagents specific to those kits, and consumables such as plastic pipette tips and plastic tubes

16. Drug products currently recommended by the NIH COVID-19 Treatment Guidelines Panel, including (as of July 23, 2020) remdesivir and dexamethasone
17. Alcohol-based hand sanitizer and rubs

Authority

The authority for this Notice is Executive Order 13910 and section 102 of the Defense Production Act of 1950, 50 U.S.C. 4512, as amended.

Date: July 23, 2020.

Ann C. Agnew,

Executive Secretary, Department of Health and Human Services.

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