

DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Notice 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) announces the issuance of a Notice 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 Coronavirus Disease 2019 (COVID-19) that are scarce or the supply of which would be threatened by excessive accumulation. These designated materials are subject to the hoarding prevention measures authorized under the Executive Order and the Act. The Notice was issued on March 25, 2020.

DATES: This action took effect March 25, 2020.

FOR FURTHER INFORMATION CONTACT: Bryan Shuy: 202-703-8610;

Bryan.Shuy@hhs.gov

SUPPLEMENTARY INFORMATION:

On March 23, 2020, and in response to the spread of 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 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.

HHS is issuing this Notice designating scarce materials or threatened materials that are subject to the hoarding prevention measures authorized under the Executive Order and the Act. 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 this 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. Designated scarce materials or threatened materials are subject to periodic review by the Secretary.

This designation is not a “regulation” under the Act. *See* 50 U.S.C. 4559. 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.* This designation shall terminate after 120 days from the date of publication, unless superseded by a subsequent notice.

A copy of the 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. Drug product with active ingredient chloroquine phosphate or hydroxychloroquine HCl
7. 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
8. 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
9. Medical gowns or apparel, e.g., surgical gowns or isolation gowns
10. Personal protective equipment (PPE) coveralls, e.g., Tyvek Suits
11. 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
12. PPE surgical masks, including masks that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials
13. PPE face shields, including those defined at 21 CFR 878.4040 and those intended for the same purpose
14. 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
15. 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>

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.