

# PUBLICATION

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## HHS Issues Notice of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures

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**On March 25, 2020, the Department of Health and Human Services (HHS) issued a 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. This Notice designates certain health and medical resources as scarce or threatened materials that are subject to hoarding prevention measures authorized under Executive Order 13910 and the Defense Production Act (the Act).**

The President signed Executive Order 13910 on March 23, 2020 in response to the rapid spread of COVID-19. This Executive Order delegated to the Secretary of HHS the authority under Section 102 of the Act to prevent hoarding and price gouging of health and medical supplies.

The Act, 50 U.S.C. § 4501 *et seq.*, originally signed by President Harry S. Truman in 1950, authorizes the President to direct industries to produce critical equipment for national defense. Section 102 of the Act prohibits any person from accumulating any 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." 50 U.S.C. § 4512 (emphasis added). For additional information on the Defense Production Act, see Baker Donelson's March 18, 2020 Alert, [linked here](#).

Under the Executive Order and the Act, the Secretary of HHS may designate resources as *scarce materials* or *threatened materials* and prescribe conditions with respect to the accumulation of these materials. On March 25, the Secretary issued a Notice designating 15 materials as "scarce materials or threatened materials." Under the 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." The designation of these materials is subject to periodic review by the Secretary and will terminate after 120 days.

Individuals and businesses alike need to be aware of these designations because violations of the Act may result in criminal penalties and the Department of Justice (DOJ) has indicated a commitment to preventing hoarding and price gouging. In a March 24, 2020 memorandum to U.S. Attorneys, Attorney General Barr explained that the DOJ "will aggressively pursue bad actors who amass critical supplies either far beyond what they could use or for the purpose of profiteering. Scarce medical supplies need to be going to hospitals for immediate use in care, not to warehouses for later overcharging."

The following is a comprehensive list of the designated materials:

1. N95 Filtering Facepiece Respirators, including devices that are disposable half-facepiece 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. 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 cover the user's nose and mouth and provide 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 [here](#).

Indeed, on April 1, 2020, under the authority of the Act, the DOJ and HHS seized 192,000 N95 respirator masks, 598,000 gloves, and 130,000 other personal protective equipment and disinfectant from someone hoarding the supplies. Pursuant to the Act, fair market value will be paid to the owner of the confiscated supplies. Peter Navarro, the federal government's Act coordinator, also announced that "many such

investigations are underway" and [warned of further seizures from individuals or companies hoarding supplies or selling them above market prices.](#)

Businesses in the supply chain should closely monitor these designations, particularly when it comes to supplies such as ventilators and personal protective equipment. Hardly a day goes by when shortages of these materials are not reported in the news. Baker Donelson, with its vast and varied legal experience, is particularly positioned to help guide your company through these complex developments.

If you have any questions, please contact one of the authors or any member of [Baker Donelson's Government Enforcement and Investigations Group](#). Also, please visit the [Coronavirus \(COVID-19\): What You Need to Know information page](#) on our website.