WINSTON & STRAWN LLP

CLIENT ALERT

DHHS Secretary Azar Takes Steps to Prevent Hoarding of Essential COVID-19 Medical Supplies and Equipment

MARCH 26, 2020

On March 25, 2020, the Secretary of the U.S. Department of Health and Human Services ("DHHS") ("the Secretary") issued his "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" ("the Notice").

The Notice follows the President's Executive Order 13910 pursuant to the Defense Production Act (the Act). Section 102 of the Act [50 U.S.C. §4512] provides for a designation of "Scarce Materials" and is designed to prevent hoarding. The Act provides "[i]n order to prevent hoarding, no person shall accumulate (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, materials which have been designated by the President as scarce materials or materials the supply of which would be threatened by such accumulation."

Additionally, Section 103 of the Act [50 U.S.C. §4513] provides for penalties for "[a]ny person who willfully performs any act prohibited, or willfully fails to perform any act required, by the provisions of this title [sections 4511 to 4518 of 50 U.S.C.] or any rule, regulation, or order thereunder, shall, upon conviction, be fined not more than $10,000 or imprisoned for not more than one year, or both." These penalties would apply to anyone found to be hoarding "Scarce Materials" as defined by the Secretary's Notice.

The Notice defines 15 specific items as "Scarce Materials." These items are:

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 Respirators ("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 Food and Drug Administration ("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 at https://www.fda.gov/media/136318/download.

****

The Secretary's action is designed to ensure an appropriate and effective supply of needed medical supplies and equipment to address the COVID-19 pandemic. The list of "Scarce Materials" may change over time and additional measures may be taken by the federal government to oversee the distribution and use of these identified supplies and equipment.

If you have additional questions or need further assistance, please feel free to reach out to our Health Care & Life Sciences Industry Group or your Winston relationship attorney.

View all of our COVID-19 perspectives here. Contact a member of our COVID-19 Legal Task Force here.

3 Min Read

Related Locations

Charlotte | Chicago | Dallas | Houston | Los Angeles | New York | San Francisco | Silicon Valley | Washington, DC

Related Topics

COVID-19 | Health Care | Private Equity

Related Capabilities

Health Care

Related Regions

North America