

#### IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. Such standards are those that FDA has recognized by notice published in the **Federal Register** or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the **Federal Register**). FDA will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often if necessary.

#### V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to [CDRHStandardsStaff@fda.hhs.gov](mailto:CDRHStandardsStaff@fda.hhs.gov). To be considered, such recommendations should contain, at a minimum, the information listed on FDA's website, which is specifically available at <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/recognition-standard>.

Dated: March 24, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

**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), 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](mailto: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 any raw materials (including minerals, metals, and advanced processed materials), commodities, articles, components (including critical components), products, and items of supply; and 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.

#### Wilma M. Robinson,

*Deputy Executive Secretary, Department of Health and Human Services.*

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## DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA-2020-0002]

### Notice of Request for Extension of a Currently Approved Information Collection for Chemical-Terrorism Vulnerability Information (CVI)

**AGENCY:** Cybersecurity and Infrastructure Security Agency, DHS.

**ACTION:** 60-Day notice and request for comments; extension of Information Collection Request: 1670-0015.

**SUMMARY:** The Infrastructure Security Division (ISD) within the Cybersecurity and Infrastructure Security Agency (CISA) will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The submission proposes to renew the information collection for an additional three years and update the burden estimates.

**DATES:** Comments are encouraged and will be accepted until May 29, 2020.

**ADDRESSES:** You may send comments, identified by docket number through the Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for sending comments.

*Instructions:* All submissions received must include the agency name "CISA" and docket number CISA-2020-0002. All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

Comments that include trade secrets, confidential commercial or financial information, Chemical-terrorism Vulnerability Information (CVI),<sup>1</sup>

<sup>1</sup> For more information about CVI see 6 CFR 27.400 and the CVI Procedural Manual at [www.dhs.gov/publication/safeguarding-cvi-manual](http://www.dhs.gov/publication/safeguarding-cvi-manual).

Sensitive Security Information (SSI),<sup>2</sup> or Protected Critical Infrastructure Information (PCII)<sup>3</sup> should not be submitted to the public docket.

Comments containing trade secrets, confidential commercial or financial information, CVI, SSI, or PCII should be appropriately marked and packaged in accordance with applicable requirements and submitted by mail to the DHS/CISA/Infrastructure Security Division, CFATS Program Manager at CISA, 245 Murray Lane SW, Mail Stop 0610, Arlington, VA 20528-0610. Comments must be identified by docket number CISA-2020-0002.

#### FOR FURTHER INFORMATION CONTACT:

Lona Saccomando, 703-235-5263, [cfats@hq.dhs.gov](mailto:cfats@hq.dhs.gov).

**SUPPLEMENTARY INFORMATION:** The CFATS Program identifies and regulates the security of high-risk chemical facilities using a risk-based approach. Congress initially authorized the CFATS Program under Section 550 of the Department of Homeland Security Appropriations Act of 2007, Public Law 109-295 (2006) and reauthorized it under the Protecting and Securing Chemical Facilities from Terrorist Attacks Act of 2014<sup>4</sup> or "CFATS Act of 2014" (Pub. L. 113-254, 6 U.S.C. 621 *et seq.*). The Department implemented the CFATS Program through rulemaking and issued an Interim Final Rule (IFR) on April 9, 2007 and a final rule on November 20, 2007. See 72 FR 17688 and 72 FR 65396.

Pursuant to 6 U.S.C. 623, the CFATS regulations establish the requirements under 6 CFR 27.400 that covered persons must follow to safeguard certain documents and other information developed under the regulations from unauthorized disclosure. This information is identified as CVI and, by law, receives protection from public disclosure and misuse. This collection will be used to manage the CVI program in support of CFATS. The current information collection for the CVI program (IC 1670-0015) will expire on January 31, 2021.<sup>5</sup>

CISA proposes one revision from the previously approved collection. Specifically, to increase the loaded

<sup>2</sup> For more information about SSI see 49 CFR part 1520 and the SSI Program web page at [www.tsa.gov/for-industry/sensitive-security-information](http://www.tsa.gov/for-industry/sensitive-security-information).

<sup>3</sup> For more information about PCII see 6 CFR part 29 and the PCII Program web page at [www.dhs.gov/pcii-program](http://www.dhs.gov/pcii-program).

<sup>4</sup> The CFATS Act of 2014 codified the CFATS program into the Homeland Security Act of 2002. See 6 U.S.C. 621 *et seq.*, as amended by Public Law 116-2.

<sup>5</sup> The current information collection for CVI (*i.e.*, IC 1670-0015) may be viewed at [https://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=201704-1670-002](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201704-1670-002).