

Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* The Maternal, Infant, and Early Childhood Home Visiting Program Quarterly Performance Report, OMB No. 0906-0016, Revision

*Abstract:* This clearance request is for continued approval of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Program Quarterly Performance Report. The MIECHV Program, administered by HRSA in partnership with the Administration for Children and Families, supports voluntary, evidence-based home visiting services during pregnancy and to parents with young children up to kindergarten entry. States, certain non-profit organizations, and tribal entities are eligible to receive funding from the MIECHV Program and have the flexibility to tailor the program to serve the specific needs of their communities. HRSA is revising the data collection forms for the MIECHV Program by making the following changes:

- *Form 4, reporting guidance:* Revise reporting instructions to reflect updated reporting requirements

- *Form 4, Definition of Key Terms:* Update definitions for Table A.1
- *Form 4, Definition of Key Terms:* Add definitions for Table A.2

HRSA is also requesting approval to expand the use of Form 4 in order to collect quarterly performance data from awardees who receive MIECHV funding appropriated by section 9101 of the American Rescue Plan Act (Pub. L. 117-2).

*Need and Proposed Use of the Information:* HRSA uses quarterly performance information to demonstrate program accountability and continuously monitor and provide oversight to MIECHV Program awardees. The information is also used to provide quality improvement guidance and technical assistance to awardees and help inform the development of early childhood systems at the national, state, and local level. HRSA is seeking to revise reporting instructions and definitions of key terms and to expand the use of Form 4 in order to collect distinct quarterly performance data related to the use of the American Rescue Plan Act funds. This notice is subject to the appropriation of funds, and is a contingency action taken to

ensure that, should funds become available for this purpose, information can be collected in a timely manner.

*Likely Respondents:* MIECHV Program awardees that are states, territories, and, where applicable, nonprofit organizations receiving MIECHV funding to provide home visiting services within states.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

**TOTAL ESTIMATED ANNUALIZED BURDEN HOURS**

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Form 4: Section A—Quarterly Performance Report .....	56	8	448	24	10,752
Form 4: Section B Quarterly Benchmark Performance Measures .....	10	4	40	200	8,000
Total .....	* 56	.....	488	.....	18,752

\*The 10 responses for Section B are a sub-set of 56 total awardees funded through the MIECHV Program.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2021-14412 Filed 7-6-21; 8:45 am]

**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Office of the Secretary**

**Extension of Designation of Scarce Materials or Threatened Materials Subject to COVID-19 Hoarding Prevention Measures; Extension of Effective Date With Modifications**

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

**ACTION:** Temporary notice; solicitation of comments.

**SUMMARY:** The Department of Health and Human Services (HHS) provides notice of the extension of the designation issued on February 1, 2021, 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 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. These designated materials are subject to the hoarding prevention measures authorized under the Executive Order and the Act.

**DATES:** This action took effect on July 1, 2021, and terminates on November 15, 2021. To be assured consideration, comments on this extension and update to the list of scarce or threatened materials must be received at the address provided below by August 6, 2021.

**ADDRESSES:** In commenting, please refer to Paige Ezernack: 202-260-0365;

[paige.ezernack@hhs.gov](mailto:paige.ezernack@hhs.gov). Comments, including mass comment submissions, must be submitted electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>.

Follow the "Submit a comment" instructions.

**FOR FURTHER INFORMATION CONTACT:**

Paige Ezernack: 202-260-0365;

[paige.ezernack@hhs.gov](mailto: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 4560). 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 subject to the Administrative Procedure Act (APA). See 50 U.S.C. 4559(a) (providing an exemption from the APA). Pursuant to 50 U.S.C. 4559(b)(2), the Secretary finds that, in light of the current pandemic and need to ensure Americans have access to critical and life-saving health resources, urgent and compelling circumstances make compliance with public comment requirements impracticable prior to issuance. This temporary Notice is therefore effective immediately upon issuance, but the Secretary will provide an opportunity for 30 days of public comment before finalizing. See *id.*

The March 25 Designation Notice was scheduled to terminate 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, July 30, 2020, and February 1, 2021 notices, through November 15, 2021. The Secretary also finds good cause to remove the following materials from the list because they are no longer scarce or threatened materials:

1. In FR Doc. 2020-06641 of March 30, 2020 (85 FR 17592), remove the following text:

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 (FD&C 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, or are authorized by FDA under section 564 of the FD&C Act for purposes of decontamination
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.
9. Personal protective equipment (PPE) coveralls, *e.g.*, Tyvek Suits
10. 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. 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.

17. Alcohol-based (over 60 percent) hand sanitizer and rubs.

**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. Medical gowns or apparel, *e.g.*, surgical gowns or isolation gowns
2. 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
3. Drug products currently recommended by the National Institutes of Health COVID–19 Treatment Guidelines Panel, including (as of April 21, 2021) remdesivir and dexamethasone
4. Syringes and hypodermic needles (whether distributed separately or attached together) generally used in the United States for vaccinations that are either:

(i) Piston syringes in 1 ml or 3 ml sizes that allow for the controlled and precise flow of liquid as described by 21 CFR 880.5860, that are compliant with ISO 7886–1:2017 and use only Current Good Manufacturing Practices (CGMP) processes; or

(ii) Hypodermic single lumen needles between 1” and 1.5” and 22 to 25 gauge between 1” and 1.5” and 22 to 25 gauge that have engineered sharps injury protections as described in the Needlestick Safety and Prevention Act, Public Law 106–430, 114 Stat. 1901 (Nov. 6, 2000) and OSHA standard 29 CFR 1910.1030, Bloodborne Pathogens.”

**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.

Dated: June 30, 2021.

**Xavier Becerra**

*Secretary, Department of Health and Human Services.*

[FR Doc. 2021–14383 Filed 7–2–21; 4:15 pm]

**BILLING CODE 4150–37–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

[Document Identifier: OS–4040–0001]

**Agency Information Collection Request: 60-Day Public Comment Request**

**AGENCY:** Office of the Secretary, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before September 7, 2021.

**ADDRESSES:** Submit your comments [sagal.musa@hhs.gov](mailto:sagal.musa@hhs.gov) or by calling (202) 205–2634.

**FOR FURTHER INFORMATION CONTACT:** When submitting comments or requesting information, please include the document identifier 4040–0001–Revision–60D and project title for reference, to Sagal Musa, email: [sagal.musa@hhs.gov](mailto:sagal.musa@hhs.gov), or call (202) 205–2634 the Reports Clearance Officer.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* SBIR/STTR Information.

*Type of Collection:* Revision of A Currently Approved Collection.

*OMB No.:* 4040–0001.

*Abstract:* The SBIR (Small Business Innovation Research)/STTR (Small Business Technology Transfer) program is designed to stimulate technological innovation in the private sector by strengthening the role of small business, increasing the commercial application of federally supported research results, as well as fostering and encouraging participation by socially and economically disadvantaged and women-owned small businesses. This form is used by grant applicants to apply for SBIR/STTR-related grants. *Grants.gov* seeks to include a question regarding the use of SBIR/STTR funds for Technical and Business Assistance (TABAs).

**ANNUALIZED BURDEN HOUR TABLE**

Forms (If necessary)	Respondents (If necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
SBIR/STTR Information .....	Grant Applicants .....	6,376	1	1	6,376
Total .....	.....	6,376	1	1	6,376