

consequences of proposed actions, and any reasonable alternatives. Under FDA regulations, FDA will prepare an EIS when data or information in an environmental assessment or otherwise available to the Agency leads to a finding that the proposed agency action may significantly affect the quality of the human environment.<sup>2</sup> Because of questions raised about the extent to which two sunscreen active ingredients (oxybenzone and octinoxate) may affect coral and/or coral reefs, FDA is initiating the public scoping process to consider any potential environmental impacts associated with the use of oxybenzone and octinoxate in sunscreens so that an EIS, if necessary, can be completed prior to issuance of a final sunscreen order addressing sunscreens containing these ingredients.

We note the Agency's docket to the 2019 proposed rule "Sunscreen Drug Products for Over-the-Counter Human Use" (84 FR 6204 February 26, 2019) received comments that raised concerns about the potential impacts from sunscreens containing oxybenzone or octinoxate on coral and/or coral reefs. FDA is also aware that the National Oceanic and Atmospheric Administration (NOAA) Coral Reef Conservation Program is currently evaluating research related to coral reef health, including the potential impacts of sunscreen products that include oxybenzone and octinoxate on coral reefs and other aquatic systems.<sup>3</sup> The Agency is also aware that at least one state has restricted the sale of sunscreens that include the active ingredients oxybenzone or octinoxate. On July 3, 2018, the state of Hawaii signed into law S. 2571, Act 104, prohibiting the sale, offer of sale, and distribution of sunscreens that contain oxybenzone and/or octinoxate, to protect Hawaii's marine ecosystems, including coral reefs. This law became effective January 1, 2021. All of these actions raise questions about the potential environmental impacts of sunscreens containing oxybenzone and/or octinoxate on coral and/or coral reefs that warrant further evaluations.

The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, including potential alternatives and the extent to which those issues and impacts will be analyzed. At this initial stage of the

scoping process, we have identified the following four alternatives: (1) FDA will conclude that the inclusion of oxybenzone and octinoxate in sunscreens marketed without an NDA is impermissible; (2) FDA will conclude that the inclusion of oxybenzone and octinoxate in sunscreens marketed without an NDA is permissible; (3) FDA will conclude that inclusion of oxybenzone in sunscreens marketed without an NDA is permissible but that the inclusion of octinoxate in sunscreens marketed without an NDA is impermissible; or (4) FDA will conclude that inclusion of octinoxate in sunscreens marketed without an NDA is permissible but that the inclusion of oxybenzone in sunscreens marketed without an NDA is impermissible.

The EIS will be prepared in accordance with section 102(2)(C) of NEPA, 42 U.S.C. 4332(2)(C), FDA's NEPA implementing regulations (21 CFR part 25), and the CEQ regulations for implementing NEPA (40 CFR parts 1500–1508).<sup>4</sup> Federal, State, and local agencies, along with Tribes and other stakeholders that may be interested in or affected by the sunscreen proposed order are invited to participate in the scoping process. Some Federal agencies may request or be requested by the FDA to participate in the development of the environmental analysis as a cooperating agency. FDA encourages other stakeholders to comment on this scoping process, on what specific issues, alternatives, mitigation measures, or other information FDA should include for further analysis in the EIS.

Dated: May 7, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Black Lung Clinics Program, OMB No. 0915–0292—Revision

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR should be received no later than July 12, 2021.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the ICR title for reference.

*Information Collection Request Title:* Black Lung Clinics Program Performance Measures, OMB No. 0915–0292—Revision.

*Abstract:* HRSA's Federal Office of Rural Health Policy conducts an annual data collection of user information for the Black Lung Clinics Program (BLCP), which has been ongoing with OMB approval since 2004. The BLCP is authorized by Sec. 427(a) of the Federal Mine Safety and Health Act of 1977, as amended (30 U.S.C. 937), and accompanying regulations at 42 CFR part 55a, to reduce the morbidity and mortality associated with occupationally-related coal mine dust lung disease through the screening, diagnosis, and treatment of active, inactive, retired, and/or disabled coal

<sup>2</sup> See 21 CFR 25.22(b); 40 CFR 1508.27.

<sup>3</sup> See NOAA's Coral Reef Information article "The effects of ultraviolet filters and sunscreen on corals and aquatic ecosystems," available at the NOAA web page <https://www.coris.noaa.gov/activities/effects-ultraviolet-filters-sunscreen-corals/welcome.html>.

<sup>4</sup> FDA began activities relating to the environmental assessment of the use of oxybenzone and octinoxate in sunscreens marketed without an NDA before September 14, 2020. Consistent with 40 CFR 1506.13, FDA will apply the regulations in place prior to implementation of the new CEQ regulations. See the Council on Environmental Quality's final rule, "Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act" (40 CFR 1506.13, 85 FR 43304 at 43372 (July 16, 2020)).

miners. Collecting this data provides HRSA with information on how well each grantee is meeting the needs of these miners in their communities.

*Need and Proposed Use of the Information:* Data from the annual performance measures report provides quantitative information about the clinics, specifically: (a) The characteristics of the patients they serve (age, diagnoses, occupation type); (b) the characteristics of services provided (clinical services and benefits counseling); and (c) the number of patients served. This programmatic performance measure enables HRSA to provide data required by Congress under the Government Performance and Results Act of 1993. It also ensures that

funds are effectively used to provide services that meet the target population needs.

The proposed changes to the BLCP measures are a result of the accumulation of grantee and stakeholder feedback and information gathered from the previously approved BLCP measures. The proposed changes include revisions of current measures for better usability and additional questions about screening program participation, smoking, pulmonary function testing, referral for services, and COVID-19 vaccination.

*Likely Respondents:* Respondents will likely be award recipients of the Black Lung Clinics Program.

*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
Black Lung Clinics Program Measures .....	15	1	15	10	150
Total .....	15	.....	15	.....	150

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.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Advisory Committee on Individuals With Disabilities and Disasters**

**AGENCY:** Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Office of the Assistant Secretary for Preparedness and Response (ASPR), in the Department of Health and Human Services (HHS) Office of the Secretary announces establishment of the National Advisory

Committee on Individuals with Disabilities and Disasters (NACIDD). The Advisory Committee will provide advice and consultation to the HHS Secretary with respect to the medical, public health, and accessibility needs of individuals with disabilities related to preparation for, response to, and recovery from all-hazards emergencies. The Office of the Assistant Secretary for Preparedness and Response (ASPR) shall provide management and administrative oversight to support the activities of the Advisory Committee. The Office of the Secretary is accepting application submissions from qualified individuals who wish to be considered for membership on the NACIDD. Up to seven voting members with expertise disability accessibility, disaster planning, preparedness, response, or recovery will be selected for the Committee. Please visit the NACIDD website at [www.phe.gov/nacidd](http://www.phe.gov/nacidd) for all application submission information and instructions. Application submissions will be accepted for 30 calendar days from the date this posting is published in the **Federal Register**.

**DATES:** *Application Period:* The application submissions will be accepted for 30 calendar days from the date this posting is published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Maxine Kellman, DVM, Ph.D., PMP,

Alternate Designated Federal Official for National Advisory Committees, Washington, DC, Office (202) 260-0447 or email [maxine.kellman@hhs.gov](mailto:maxine.kellman@hhs.gov).

**SUPPLEMENTARY INFORMATION:** The Office of the Assistant Secretary for Preparedness and Response provides management and administrative oversight to support the activities of the NACIDD.

*Description of Duties:* The NACIDD shall evaluate issues and programs and provide findings, advice, and recommendations to the Secretary of HHS, in accordance with FACAA, to support and enhance all-hazards public health and medical preparedness, response activities, and recovery aimed at meeting the unique needs of individuals with disabilities across the entire spectrum of their wellbeing. The NACIDD shall (1) provide advice and consultation with respect to activities carried out pursuant to section 2814 of the PHS Act (at-risk individuals), as applicable and appropriate; (2) evaluate and provide input with respect to the medical, public health, and accessibility needs of individuals with disabilities related to preparation for, response to, and recovery from all-hazards emergencies; and (3) provide advice and consultation with respect to State emergency preparedness and response activities, including related drills and exercises pursuant to the preparedness