

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Application for Health Center Program Award Recipients for Deemed Public Health Service Employment With Liability Protections Under the Federal Tort Claims Act, OMB No. 0906–0035—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 Information Collection Request must be received no later than February 22, 2022.

ADDRESSES: Submit your comments to 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 or call Samantha Miller, the acting HRSA Information Collection Clearance Officer at (301) 443–9094.

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

Information Collection Request Title: Application for Health Center Program Award Recipients for Deemed Public

Health Service (PHS) Employment with Liability Protections under the Federal Tort Claims Act (FTCA), OMB No. 0906–0035—Revision.

Abstract: Section 224(g)–(n) of the PHS Act (42 U.S.C. 233(g)–(n)), as amended, authorizes the Secretary to “deem” entities receiving funds under section 330 of the PHS Act as PHS employees for the purposes of establishing eligibility for liability protections for covered activities and individuals under the FTCA. The Health Center Program and the Health Center FTCA Program are administered by HRSA’s Bureau of Primary Health Care (BPHC). Health centers submit deeming applications annually to BPHC in the prescribed form and manner in order to obtain deemed PHS employee status for this purpose.

Need and Proposed Use of the Information: Deeming applications are required by law and must address certain specified criteria in order for deeming determinations to be issued. The application submissions provide BPHC with the information essential for evaluation of compliance with legal requirements and making a deeming determination under Section 224(g)–(n) of the PHS Act (42 U.S.C. 233(g)–(n)).

The FTCA Program uses a web based application system within HRSA’s Electronic Handbooks system. These electronic application forms decrease the time and effort required to complete the older, paper-based approved FTCA application forms. The application includes: Contact information; Section 1: Review of Risk Management Systems; Section 2: Quality Improvement/Quality Assurance; Section 3: Credentialing and Privileging; Section 4: Claims Management; and Section 5: Additional Information, Certification, and Signatures.

HRSA is proposing several changes to the Application for Health Center Program Award Recipients for Deemed PHS Employment with Liability Protections Under the FTCA, to be used for Health Center deeming applications for Calendar Year 2022 and thereafter, to clarify questions posed and required documentation. Specifically, the

Application includes the following proposed changes:

- Updated application language: Throughout the application, revised terminology was utilized to provide greater clarity and specificity. These changes were based on stakeholder feedback and inquiries received from HRSA’s Health Center Program Support. These changes are not substantive in nature.

- Some questions were removed from the application’s Quality Improvement/Quality Assurance Section, as these questions were similar to questions collected in the Risk Management Section. This change is intended to reduce duplicative information collection.

- For the Credentialing and Privileging Section, the application will return to the previous process of requiring the submission of a Credentialing List with providers’ credentialing and privileging information. This change is intended to enhance HRSA’s oversight and verification capabilities as it relates to continuous compliance with the FTCA statute.

Likely Respondents: Respondents include recipients of Health Center Program funds seeking deemed PHS employee status under Section 224(g)–(n) of the PHS Act (42 U.S.C. 233(g)–(n)).

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 |
|--|-----------------------|------------------------------------|-----------------|--|--------------------|
| Application for Health Center Program Deemed Public Health Service Employment Status (Initial) | 35 | 1 | 35 | 2.5 | 87.5 |
| Application for Health Center Program Deemed Public Health Service Employment Status (Redeeming) | 1,125 | 1 | 1,125 | 2.5 | 2,812.5 |
| Total | 1,160 | 2 | 1,160 | 5 | 2,900 |

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 Institutes of Health

Request for Data and Information on New Approach Methodologies for Efficacy Testing of Ectoparasiticide Products To Meet Regulatory Data Requirements

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) requests available data and information on approaches and/or technologies currently used for efficacy testing of ectoparasiticide products. Submitted information will be used to assess the state of the science and determine technical needs for non-animal test methods used to evaluate the efficacy of ectoparasiticides on dogs and cats and to facilitate their incorporation into a testing strategy for regulatory purposes.

DATES: Receipt of information: Deadline for receipt of information is January 28, 2022.

ADDRESSES: Data and information should be submitted electronically to niceatm@niehs.nih.gov.

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Kleinstreuer, Acting Director, NICEATM; email: nicole.kleinstreuer@nih.gov; telephone: (984) 287-3150.

SUPPLEMENTARY INFORMATION:

Background: NICEATM fosters the evaluation and promotion of alternative test methods for regulatory use. As part of this activity, NICEATM supports efforts to develop, validate, and implement alternative approaches for chemicals and medical products. These include approaches used to evaluate the efficacy of ectoparasiticides on dogs and cats, such as products to prevent flea and tick infestations. Tests on such products are required by multiple federal agencies for regulatory and other decision contexts. Currently, the standard tests for this endpoint use animals that can experience significant discomfort and distress during the study.

Request for Information: NICEATM requests available data and information on approaches and/or technologies currently used to predict the efficacy of ectoparasiticides without using animals. Respondents should provide information on any activities relevant to the development or validation of alternatives to in vivo test methods currently used by federal agencies for regulatory and other decision contexts.

Respondents to this request for information should include their name, affiliation (if applicable), mailing address, telephone, email, and sponsoring organization (if any) with their communications. The deadline for receipt of the requested information is January 28, 2022. Responses to this notice will be posted at: <https://ntp.niehs.nih.gov/go/niceatm-data>. Persons submitting responses will be identified on the web page by name and affiliation or sponsoring organization, if applicable.

Responses to this request are voluntary. No proprietary, classified, confidential, or sensitive information should be included in responses. This request for information is for planning purposes only and is not a solicitation for applications or an obligation on the

part of the U.S. Government to provide support for any ideas identified in response to the request. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

Background Information on NICEATM: NICEATM conducts data analyses, workshops, independent validation studies, and other activities to assess new, revised, and alternative test methods and strategies. NICEATM also provides support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) provides authority for ICCVAM and NICEATM involvement in activities relevant to the development of alternative test methods. Information about NICEATM and ICCVAM can be found at <https://ntp.niehs.nih.gov/go/niceatm> and <https://ntp.niehs.nih.gov/go/iccvam>.

Dated: December 13, 2021.

Brian R. Berridge,

Associate Director, National Toxicology Program.

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2021-0002; Internal Agency Docket No. FEMA-B-2185]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth,