

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Health Resources and Services Administration****Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request; Federal Tort Claims Act Program Deeming Applications for Health Centers, 0906–0035, Extension**

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

**ACTION:** Notice.

**SUMMARY:** In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

**DATES:** Comments on this ICR should be received no later than May 3, 2021.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–1984.

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

*Information Collection Request Title:* Federal Tort Claims Act Program Deeming Application for Health Centers, OMB No. 0906–0035—Extension.

*Abstract:* Section 224(g)-(n) of the Public Health Service (PHS) Act (42 U.S.C. 233(g)-(n)), as amended, authorizes the "deeming" of entities receiving funds under section 330 of the PHS Act as PHS employees for the purposes of receiving Federal Tort Claims Act (FTCA) coverage. The Health Center Program is administered by HRSA's Bureau of Primary Health Care. Health centers submit deeming applications annually to HRSA in the prescribed form and manner in order to obtain deemed PHS employee status, with the associated FTCA coverage.

Deemed PHS employment provides the covered individual with immunity from lawsuits and related civil actions resulting from the performance of medical, surgical, dental, and related functions within the scope of deemed employment.

The FTCA Program has a web-based application system, the Electronic Handbooks (EHBs). These electronic application forms decrease the time and effort required to complete the older, paper-based OMB approved FTCA application forms. The application includes: Contact Information; Section 1: Review of Risk Management Systems; Section 2: Quality Improvement/Quality Assurance (QI/QA) Attestations; Section 3: Credentialing and Privileging; Section 4: Claims Management; and Section 5: Additional Information, Certification, and Signatures.

HRSA is proposing no changes to the Application for Health Center Program Deemed Public Health Service Employment Status, to be used for

Health Center deeming applications for Calendar Year 2021 and thereafter.

A 60-day notice published in the **Federal Register** on February 5, 2021, Vol. 86, No. 23; pp. 8364–65. There were no public comments.

*Need and Proposed Use of the Information:* Deeming applications must address certain specified criteria required by law in order for deeming determinations to be issued, and FTCA application forms are critical to HRSA's deeming determination process. This form provides HRSA with information that is essential for evaluating health center adherence to FTCA program requirements and making a determination as to whether a health center meets the statutory requirements for deemed PHS employee status for the purposes of FTCA coverage. The application information is also used to determine whether a site visit is appropriate to assess issues relating to the health center's quality of care and to determine technical assistance needs.

*Likely Respondents:* Respondents include Health Center Program funds recipients seeking deemed PHS employee status for purposes of FTCA coverage.

*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
FTCA Health Center Program Initial Application .....	35	1	35	2.5	87.5
FTCA Health Center Program Redeeming Application .....	1,125	1	1,125	2.5	2,812.5
Total .....	1,160	.....	1,160	.....	2,900.0

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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**BILLING CODE 4165-15-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the National Vaccine Advisory Committee

**AGENCY:** Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a virtual meeting. The meeting will be open to the public and public comment will be heard during the meeting.

**DATES:** The meeting will be held June 16–17, 2021. The confirmed meeting times and agenda will be posted on the NVAC website at <http://www.hhs.gov/nvpo/nvac/meetings/index.html> as soon as they become available.

**ADDRESSES:** Instructions regarding attending this meeting will be posted online at: <http://www.hhs.gov/nvpo/nvac/meetings/index.html> at least one week prior to the meeting. Pre-registration is required for those who wish to attend the meeting or participate in public comment. Please register at <http://www.hhs.gov/nvpo/nvac/meetings/index.html>.

**FOR FURTHER INFORMATION CONTACT:** Ann Aikin, Acting Designated Federal Officer, at the Office of Infectious Disease and HIV/AIDS Policy, U.S. Department of Health and Human Services, Mary E. Switzer Building, Room L618, 330 C Street SW, Washington, DC 20024. Email: [nvac@hhs.gov](mailto:nvac@hhs.gov). Phone: 202-695-9742.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa-1), the Secretary of HHS was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters

related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

During this NVAC meeting, NVAC will hear presentations on vaccine safety, communication activities for COVID-19 vaccines, and immunization equity. Please note that agenda items are subject to change, as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: <http://www.hhs.gov/nvpo/nvac/index.html>.

Members of the public will have the opportunity to provide comment at the NVAC meeting during the public comment period designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Individuals are also welcome to submit written comments in advance. Written comments should not exceed three pages in length. Individuals submitting comments should email their written comments or their request to provide a comment during the meeting to [nvac@hhs.gov](mailto:nvac@hhs.gov) at least five business days prior to the meeting.

**Ann Aikin,**

*Acting Designated Federal Official, Office of the Assistant Secretary for Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine or Oral Fluid (Mandatory Guidelines).

**FOR FURTHER INFORMATION CONTACT:** Anastasia Donovan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240-276-

2600 (voice); [Anastasia.Donovan@samhsa.hhs.gov](mailto:Anastasia.Donovan@samhsa.hhs.gov) (email).

**SUPPLEMENTARY INFORMATION:** In accordance with Section 9.19 of the Mandatory Guidelines, a notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at <https://www.samhsa.gov/workplace/resources/drug-testing/certified-lab-list>.

The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020.

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100-71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three