

clinics seeking FTCA coverage for their employees, officers, board members, contractors, and volunteers must submit deeming applications in the specified form and manner on behalf of named individuals for review and approval, resulting in a “deeming determination” that includes associated FTCA coverage for these individuals.

HRSA is proposing several changes to the FTCA Program Deeming Applications for Free Clinics, to be used for Free Clinic deeming sponsorship applications for Calendar Year 2021 and thereafter, to improve question clarity and clarify required documentation. Specifically, the Application includes the following proposed changes:

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

- Added Service Type and clarifications regarding professional designation: Specifically, section VI of the application was updated to include service type which will allow HRSA to verify whether an individual is performing clinical or non-clinical services. In addition to the inclusion of service type, a note was added to request that free clinics include the professional designation for each individual.

- Deleted remark in section IX: It has been determined that the information requested in this section, which related to offsite events and particularized determinations is no longer necessary to evaluate eligibility for deeming.

The FTCA Program has a web based application system, the Electronic Handbooks. 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, Site Information, Information on the Sponsoring Free Clinic Eligibility, Information on the Credentialing and Privileging Systems, Information on the Risk Management Systems, Information on the Free Clinic Volunteer Health Care Professionals, Board Members, Officers, Employees, and Individual Contractors and Patient Visit Data.

A 60-day notice was published in the **Federal Register** on August 6, 2020, vol. 85, No. 152; pp. 47803–04. HRSA received one public comment regarding FTCA coverage of Urban Indian Organizations, which is outside of the scope of this ICR.

**Need and Proposed Use of the Information:** Deeming applications must address certain criteria required by law in order for the Secretary to deem an individual sponsored by a qualifying free clinic as a PHS employee for purposes of liability protections, including FTCA coverage. This determination cannot be made without

the collection of this information. Specifically, the deeming sponsorship application form seeks information verifying that the free clinic meets the criteria to sponsor a deeming application and that the individual being sponsored is eligible to be deemed as a PHS employee. The FTCA application form for free clinics has been updated to improve clarity and thereby improve applicants' and deemed individuals' compliance with applicable requirements.

**Likely Respondents:** Respondents include free clinics seeking deemed PHS employee status on behalf of their sponsored individuals for purposes of liability protections including 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 Program Deeming Application for Free Clinics .....	374	3	1,122	2	2,244
Total .....	374	.....	1,122	.....	2,244

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, Division of the Executive Secretariat.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Health Resources and Services Administration

##### National Vaccine Injury Compensation Program: Revised Amount of the Average Cost of a Health Insurance Policy

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

**ACTION:** Notice.

**SUMMARY:** HRSA is publishing an updated monetary amount of the

average cost of a health insurance policy as it relates to the National Vaccine Injury Compensation Program (VICP).

##### FOR FURTHER INFORMATION CONTACT:

Tamara Overby, Acting Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, HHS by mail at 5600 Fishers Lane, 08N186B, Rockville, Maryland 20857; or call (301) 443-9350.

**SUPPLEMENTARY INFORMATION:** Section 100.2 of VICP's implementing regulation (42 CFR part 100) states that the revised amount of an average cost of a health insurance policy, as determined by the Secretary of HHS (the Secretary), is effective upon its delivery by the

Secretary to the United States Court of Federal Claims (the Court), and will be published periodically in a notice in the **Federal Register**. The Secretary delegated this responsibility to the HRSA Administrator. This figure is calculated using the most recent Medical Expenditure Panel Survey-Insurance Component data available as the baseline for the average monthly cost of a health insurance policy. This baseline is adjusted by the annual percentage increase/decrease obtained from the most recent annual Kaiser Family Foundation Employer Health Benefits Survey or other authoritative source that may be more accurate or appropriate.

In 2020, Medical Expenditure Panel Survey-Insurance Component, available at [www.meps.ahrq.gov](http://www.meps.ahrq.gov), published the annual 2019 average total single premium per enrolled employee at private-sector establishments that provide health insurance. The figure published was \$6,972. This figure is divided by 12 to determine the cost per month of \$581. The \$581 figure is increased or decreased by the percentage change reported by the most recent Kaiser Family Foundation Employer Health Benefits Survey, available at [www.kff.org](http://www.kff.org). The increase from 2019 to 2020 was 4.0 percent. By adding this percentage increase, the calculated average monthly cost of a health insurance policy for a 12-month period is \$604.24.

Therefore, the Secretary announces that the revised average cost of a health insurance policy under the VICP is \$604.24 per month. In accordance with § 100.2, the revised amount was effective upon its delivery by the Secretary to the Court. Such notice was delivered to the Court on October 29, 2020.

Thomas J. Engels,  
Administrator.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Review and Revision of the Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA

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

**ACTION:** Notice.

**SUMMARY:** Synthetic biology is a multidisciplinary field of research that involves the design, modification, and

creation of biological systems and holds broad promise to advance both basic and applied research in areas ranging from materials science to molecular medicine. However, synthetic nucleic acids and associated technologies may also pose risks if misused. To reduce the risk that individuals with ill intent may exploit the application of nucleic acid synthesis technology to obtain genetic material derived from or encoding Select Agents and Toxins and, as applicable, agents on the Export Administration Regulations' (EAR's) Commerce Control List (CCL), the U.S. Government issued guidance in 2010 providing a framework for screening synthetic double-stranded DNA (dsDNA). This document, the *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA* (Guidance), sets forth recommended baseline standards for the gene and genome synthesis industry and other providers of synthetic dsDNA products, regarding the screening of orders, so they are filled in compliance with U.S. regulations prohibiting the possession, use, and transfer of specific pathogens and biological toxins. The other goals of the Guidance are to encourage best practices in addressing biosecurity concerns associated with the potential misuse of these products to inflict harm or bypass existing regulatory controls and to minimize any negative impacts on the conduct of research and business operations. Rapid and continued advances in nucleic acid synthesis technologies and synthetic biology applications necessitate periodic reevaluation of associated risks and mitigation measures. We invite public comments on whether and, if so, how the Guidance should be modified to address new and emerging challenges posed by advances in this area.

Please submit all comments related to this request for information (RFI) through the web form on the Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA website at <https://www.phe.gov/syndna/update2020>.

**DATES:** Responses to this RFI must be received no later than 12 p.m. (ET) on the revised submission deadline of January 4, 2021. This notice was originally published with an earlier date. Please note that the close date for comments has been changed from the original notice.

**FOR FURTHER INFORMATION CONTACT:** Dr. C. Matthew Sharkey; Division of Policy; Office of Strategy, Policy, Planning, and Requirements; Office of the Assistant Secretary for Preparedness and Response; U.S. Department of Health

and Human Services; phone: 202-401-1448; email: [Matthew.Sharkey@hhs.gov](mailto:Matthew.Sharkey@hhs.gov); website: <https://www.phe.gov/syndna/update2020>.

#### SUPPLEMENTARY INFORMATION:

*Disclaimer and Important Notes:* The U.S. Government is seeking feedback from life sciences stakeholders, including from the commercial, health care, academic, and non-profit sectors; federal and state, local, tribal, and territorial (SLTT) law enforcement organizations; SLTT governments; and others, including the members of the public. The focus of this RFI is to help inform whether updates or modifications of the Guidance are needed and, if so, what updates or modifications are desired. The U.S. Government will review and consider all responses to this RFI. The U.S. Government will not provide reimbursement for costs incurred in responding to this RFI. Respondents are advised that the U.S. Government is under no obligation to acknowledge receipt of the information received or to provide feedback to respondents with respect to any information submitted under this RFI. Responses to this RFI do not bind the U.S. Government to any further actions related to this topic. Respondents are welcome to answer all or any subset of the questions and are strongly advised to not include any information in their responses that might be considered attributable, business sensitive, proprietary, or otherwise confidential, as comments may be made available for public review.

#### Categories and Questions

##### Scope of the Guidance

*Nucleic acid synthesis technologies are fundamental for biomedical research and allow for the generation and modification of some viruses, bacteria, and toxins. Such technologies serve as tools to advance important research to understand such agents better as well as in developing medical countermeasures. Additionally, dsDNA synthesis could pose biosecurity risks, including enabling individuals with ill intent or who are not authorized to possess Select Agents and Toxins (or, for international orders, items listed on the CCL) to obtain them using materials ordered from providers of synthetic dsDNA.*

*The Guidance sets forth recommended baseline standards for the gene and genome synthesis industry and other providers of synthetic dsDNA, regarding the screening of orders, to ensure they are filled in compliance with Select Agent Regulations (SAR)*