

I. General Description of the Genetic Metabolic Diseases Advisory Committee's Duties

The Committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drug and biologic products for use in the treatment of genetic metabolic diseases and makes appropriate recommendations to the Commissioner of Food and Drugs.

II. Qualifications

Persons nominated for the Committee should be full-time employees of firms that develop human drug and biologic products, or consulting firms that represent human drug and biologic product developers or have similar appropriate ties to industry.

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interest must send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 60 days, FDA will send a letter to each organization that has expressed an interest, attaching a complete list of all such organizations; and a list of all nominees along with their current résumés or *curriculum vitae*. The letter will also state that it is the responsibility of the interested organizations to confer with one another and to select a candidate, to represent industry interest for the committee, within 60 days after the receipt of the FDA letter. The interested organizations are not bound by the list of nominees in selecting a candidate. However, if no individual is selected within 60 days, the Commissioner will select temporary nonvoting members to represent industry interests.

IV. Nomination Procedure

Individuals may self-nominate and/or an organization may nominate one or more individuals to serve as a temporary nonvoting industry representative. Nominations must include a cover letter and a current, complete résumé or *curriculum vitae* for each nominee, including current business and/or home address, telephone number, and email address if available; and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Membership Nomination Portal (see **ADDRESSES**). Nominations should specify the advisory committee for which the nominee is recommended within 60 days of publication of this

document (see **DATES**). Nominations should also acknowledge that the nominee is aware of the nomination, unless self-nominated. FDA will forward all nominations to the organizations expressing interest in participating in the selection process for the committee. Only interested industry organizations participate in the selection process. Persons who nominate themselves as nonvoting industry representatives will not participate in the selection process.

FDA seeks to include the views of members of all gender groups, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to advisory committees.

Dated: December 7, 2023.

Lauren K. Roth,

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: Applications for Deemed Public Health Service Employment With Liability Protections Under the Federal Tort Claims Act for Health Centers, Deemed Health Center Volunteers, and Free Clinic Sponsored Individuals, OMB No. 0906-XXXX-New

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 February 12, 2024.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland 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 Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

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

Information Collection Request Title: Applications for Deemed Public Health Service (PHS) Employment with Liability Protections Under the Federal Tort Claims Act (FTCA) for Health Centers, Deemed Health Center Volunteers, and Free Clinic Sponsored Individuals, OMB No. 0906-XXXX-New.

Abstract: Section 224(g)-(n) of the PHS Act (42 U.S.C. 233(g)-(n)) states that entities receiving funds under section 330 of the PHS Act and specified individuals of that entity may be deemed to be PHS employees for the purpose of eligibility for liability protections, including FTCA coverage, for the performance of medical, surgical, dental, and related functions within the scope of deemed employment upon approval of an application for deemed employment. The Health Center Program and Health Center FTCA Program are administered by HRSA. 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 eligibility for FTCA coverage. Such applications must be approved by HRSA in a Notice of Deeming Action. Deemed health centers must resubmit applications annually meeting all deeming requirements in order to maintain deemed status.

Volunteer Health Professionals (VHPs)

Section 224(q) of the PHS Act (42 U.S.C. 233(q)) extends eligibility for deemed PHS employee status to VHPs sponsored by deemed health centers upon approval of an individual sponsorship application for deemed PHS employment. The Health Center VHP FTCA Program is administered by HRSA. In order to maintain deemed status for VHPs, deemed health centers must submit to HRSA an annual deeming sponsorship application on behalf of individually named VHPs. For liability protections to apply, such

applications must be approved by HRSA in a Notice of Deeming Action applicable to the individual VHP, which, absent other intervening facts, generally is applicable to covered activities within the scope of such deemed PHS employment for a calendar year.

Free Clinics

Section 224(o) of the PHS Act (42 U.S.C. 233(o)) extends eligibility for deemed PHS employee status to free clinic health professionals, including employees, officers, board members, contractors, and volunteer health professionals, at qualifying free clinics. The Free Clinics FTCA Program is administered by HRSA. Free clinics must submit deeming sponsorship applications to HRSA in the specified form and manner on behalf of named individuals for HRSA's review and approval. In order to continue to participate in the Free Clinics FTCA Program and maintain deemed status for individuals, free clinics must submit to HRSA an annual deeming sponsorship application on behalf of named individuals. For liability protections to apply, such applications must be approved by HRSA in a Notice of Deeming Action applicable to the sponsored individual, which, absent other intervening facts, generally is applicable to covered activities within the scope of such deemed PHS employment for a calendar year. Approvals are reflected, resulting in a "deeming determination" that includes associated FTCA coverage for these individuals.

HRSA proposes combining the three existing ICRs for these programs into a single ICR consisting of the three application forms. The three existing ICRs are: (1) Application for Health Center Program Recipients for Deemed PHS Employment with Liability Protections Under the FTCA (OMB No. 0906-0035); (2) Application for Deemed Health Center Program Award Recipients to Sponsor VHPs for Deemed PHS Employment (OMB No. 0915-0032); and (3) FTCA Program Deeming Sponsorship Applications for Free Clinics (OMB No. 0915-0293). HRSA recognizes that the content of these three FTCA applications differs but proposes combining these three separate ICRs in order to increase efficiencies, decrease burden on stakeholders, and allow commentors to provide feedback more easily where applicable to commonalities that may impact all three ICRs. Pursuant to Section 224(g)-(o), and (q) of the PHS Act (42 U.S.C. 233(g)-(o) and (q)), as amended, all three collections are done for the

purpose of collecting information from certain health centers that receive grant funding under Section 330 of the PHS Act and free clinics to determine eligibility for liability protections, including FTCA coverage. Applications for these programs must be submitted through HRSA's 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. In order to make the terminology more consistent, the names of the applications are now as follows: (1) Application for Health Center Program Recipients for Deemed PHS Employment with Liability Protections Under the FTCA; (2) Application for Deemed Health Center Program Recipients to Sponsor VHPs for Deemed PHS Employment with Liability Protections Under the FTCA; and (3) Application for Free Clinics to Sponsor Individuals for Deemed PHS Employment with Liability Protections Under the FTCA. In this single ICR, HRSA proposes updating the content of the applications forms, which OMB has previously approved as three individual ICRs. The revisions are described below.

Proposed Revisions

1. Application for Health Center Program Recipients for Deemed PHS Employment With Liability Protections Under the FTCA

HRSA is proposing several changes to the content of the Application for Health Center Program Recipients for Deemed PHS Employment with Liability Protections Under the FTCA, to be used for health center deeming applications for calendar year (CY) 2024 and thereafter, to improve question clarity and clarify required documentation. 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. In addition to minor changes made for clarity, the application includes the following proposed changes:

- A disclaimer regarding training for health center staff was added to the beginning of the Review of Risk Management Systems, Quality Improvement/Quality Assurance, Credentialing and Privileging, and Claims Management sections.

Review of Risk Management Systems:

- Questions related to required FTCA trainings for Obstetrics, Infection Control, the Health Insurance Portability and Accountability Act, and other specific areas of risk were separated into four questions, and detailed guidance for Obstetrics training was added for clarity.

- To facilitate the verification of compliance with training requirements, applicants will be required to enter their training tracking information in a Word or PDF document that will be part of the information collection tool.

- To enhance clarity and ensure accurate uploading of information, the quarterly assessments have been divided into four separate questions. This change aims to outline the required elements and information necessary for each risk assessment.

Credentialing and Privileging:

- The credentialing and privileging section was revised to include clarification regarding policy and procedure requirements for temporary privileging.

- A new attestation question was added to clearly outline the requirements of Chapter 5 of the Health Center Compliance Manual, Clinical Staffing regarding for Credentialing and Privileging of health care practitioners.

- A new question was added to ensure health centers ensure credentialing and privileging for all provider types, including Licensed Independent Practitioners, Other Licensed or Certified Practitioners, and Other Clinical Staff.

Claims Management:

- A new claims management question was added to ensure documents relating to potential tort claims are in the correct format when transmitted to the Department of Health and Human Services, Office of the General Counsel's General Law Division.

2. Application for Deemed Health Center Program Recipients To Sponsor VHPs for Deemed PHS Employment With Liability Protections Under the FTCA

HRSA is proposing several changes to the content of the Application for Deemed Health Center Program Recipients to Sponsor VHPs for Deemed PHS Employment with Liability Protections Under the FTCA, to be used for deeming sponsorship applications for CY 2024 and thereafter, to improve question clarity, clarify required documentation, and support HRSA's analysis and understanding of program impact. The application includes the following sections: Acknowledgments of Deemed Status Requirements, Acknowledgment of Required

Performance Conditions, and Information on the Volunteers Sponsored for Deeming. Specifically, the application includes the following proposed changes:

• *Volunteers Sponsored for Deeming:*

A new question has been added to better assist health centers sponsoring VHPs who perform activities during declared emergencies. The question asks if the submitted application relates to services provided during a declared emergency.

• *Credentialing and Privileging:*

Language has been added to ensure grantees understand the 2-year requirement for credentialing and privileging.

3. *Application for Free Clinics To Sponsor Individuals for Deemed PHS Employment With Liability Protections Under the FTCA*

HRSA is proposing several changes to the content of the Applications for Free Clinics to Sponsor Individuals for Deemed PHS Employment with Liability Protections Under the FTCA, to be used for deeming sponsorship applications for CY 2024 and thereafter, to improve question clarity and clarify required documentation. Specifically,

the application includes the following proposed changes:

• In Section III, “Sponsoring Free Clinic Eligibility,” a note was added to clarify the non-profit status documentation requirements for free clinics; and

• In Section VII, “Patient Visit Data,” clarifying language was added to ensure that free clinics provide precise and accurate data.

Need and Proposed Use of the Information: Deeming applications must address certain specified criteria required by law to be approved, and FTCA application forms are critical to HRSA’s deeming determination process. The application submissions provide HRSA with the information essential to evaluate the application and make a deeming determination. Moreover, the application information is also used to determine whether a site visit is appropriate to assess issues relating to quality of care and to determine technical assistance needs.

Likely Respondents: Respondents include Health Center Program funding recipients seeking deemed PHS employee status for purposes of eligibility for liability protections,

including FTCA coverage; Health Center Program funding recipients that have been deemed as PHS employees and that seek to sponsor VHPs for deemed PHS employee status for purposes of eligibility for liability protections, including FTCA coverage; and free clinics that seek to sponsor individuals for deemed PHS employee status for purposes of eligibility for 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
Application for Health Center Program Recipients for Deemed PHS Employment with Liability Protections Under the FTCA	1,160	1	1,160	2.5	2,900
Application for Deemed Health Center Program Recipients to Sponsor Volunteer Health Professionals (VHPs) for Deemed PHS Employment with Liability Protections Under the FTCA	1,156	3	3,468	2.0	6,936
Application for Free Clinics to Sponsor Individuals for Deemed PHS Employment with Liability Protections Under the FTCA	374	3	1,122	2.0	2,244
Total	2,655	7	5,705	9	12,080

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

Announcement of the Fourth Meeting of the 2025 Dietary Guidelines Advisory Committee

AGENCY: Office of Disease Prevention and Health Promotion, Department of Health and Human Services (HHS), Office of the Assistant Secretary for Health (OASH); Department of Agriculture (USDA), Food, Nutrition, and Consumer Services (FNCS).

ACTION: Notice.

SUMMARY: The Departments of Health and Human Services and Agriculture announce the fourth meeting of the 2025 Dietary Guidelines Advisory Committee

(Committee). This meeting will be open to the public virtually.

DATES: The fourth Committee meeting will be held on January 19, 2024, from 8:30 a.m. to 3:00 p.m. Eastern Time.

ADDRESSES: The meeting will be accessible online via livestream and recorded for later viewing. Registrants will receive the livestream information prior to the meeting.

FOR FURTHER INFORMATION CONTACT: Designated Federal Officer, 2025 Dietary Guidelines Advisory Committee, Janet M. de Jesus, MS, RD; Office of Disease Prevention and Health Promotion, 1101 Wootton Parkway, Suite 420, Rockville, MD 20852; Phone: 240–453–8266; Email DietaryGuidelines@hhs.gov. Additional information is at DietaryGuidelines.gov.