

and how do they affect your daily life? Examples of downsides may include going to the clinic for treatment, time devoted to treatment, side effects of treatment, route of administration, etc.

4. What specific things would you look for in an ideal treatment for your condition?

- What would you consider to be a meaningful improvement in your condition that a treatment could provide?

5. What factors do you take into account when making decisions about selecting a course of treatment?

### III. Meeting Attendance and Participation

If you wish to attend this meeting, visit <https://alopeciaareata.eventbrite.com>. Persons interested in attending this public meeting must register by August 28, 2017. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations due to a disability, please contact Meghana Chalasani (see **FOR FURTHER INFORMATION CONTACT**) no later than September 1, 2017.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to [PatientFocused@fda.hhs.gov](mailto:PatientFocused@fda.hhs.gov) a brief summary of responses to the topic questions by August 21, 2017. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

*Transcripts:* Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available at <https://www.fda.gov/ForIndustry/>

*UserFees/PrescriptionDrugUserFee/ucm554443.htm*.

Dated: June 20, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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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: Federal Tort Claims Act (FTCA) Program Deeming Applications for Free Clinics, OMB No. 0915-0293—Extension

**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, the Health Resources and Services Administration (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 August 22, 2017.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N39, 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 the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

*Information Collection Request Title:* Federal Tort Claims Act (FTCA)

Program Deeming Applications for Free Clinics, OMB No. 0915-0293—Extension.

*Abstract:* Section 224(o) of the Public Health Service (PHS) Act (42 U.S.C. 233(o)), as amended, authorizes the “deeming” of certain individuals as PHS employees for the purposes of receiving Federal Tort Claims Act (FTCA) coverage. Section 224(o) relates to employees, officers, and contractors at qualifying free clinics. The Free Clinics FTCA Program is administered by HRSA’s Bureau of Primary Health Care (BPHC). Sponsoring free clinics are required by law to 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.

*Need and Proposed Use of the Information:* Deeming applications must address certain specified criteria required by law for deeming determinations to be issued, and FTCA application forms are critical to BPHC’s deeming determination process. These forms provide BPHC with the information necessary to evaluate an application and determine whether an individual meets the requirements for deemed PHS employee status for the purposes of FTCA coverage. FTCA application forms for free clinics do not require any changes with this extension other than to update the applicable dates.

*Likely Respondents:* Respondents include free clinics seeking deemed PHS employee status on behalf of their sponsored individuals 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 Information Collection Request 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 Free Clinics Program Application .....	228	3	684	2	1368
Total .....	228	3	684	2	1368

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.

**Jason E. Bennett,**  
 Director, Division of the Executive Secretariat.  
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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: Federal Tort Claims Act (FTCA) Program Deeming Applications for Health Centers, 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 must be received no later than August 22, 2017.

**ADDRESSES:** Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 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 the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

*Information Collection Request Title:* Federal Tort Claims Act (FTCA) Program Deeming Applications for Health Centers, OMB No. 0906-XXXX—New

*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 (BPHC). Health centers submit deeming applications to BPHC in the prescribed form and manner to obtain deemed PHS employee status with the associated FTCA coverage.

*Need and Proposed Use of the Information:* Deeming applications must address certain specified criteria required by law for deeming determinations to be issued, and FTCA application forms are critical to BPHC’s deeming determination process. These forms provide BPHC with the information necessary to evaluate an application and make a deeming determination 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 Information Collection Request 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 .....	1125	1	1125	2.5	2812.5
Total .....	1160	.....	1160	.....	2900