

Supporting Statement A

Federal Tort Claims Act (FTCA) Program Deeming Applications for Free Clinics

OMB Control No. 0915-0293 - Extension

Terms of Clearance: None

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA), Bureau of Primary Health Care (BPHC) is requesting an extension of Office of Management and Budget (OMB) approval for the FTCA Program Deeming Applications for Free Clinics. The current application has OMB Number 0915-0293 and expires October 31, 2017.

Congress enacted FTCA medical malpractice protection for volunteer Free Clinic health professionals through Section 194 of HIPAA of 1996 (Public Law 104-191) by amending Section 224 of the Public Health Service (PHS) Act (42 U.S.C. 233). However, Congress appropriated funds for the Free Clinic FTCA Program for the first time in late January 2004. In 2010, the Patient Protection and Affordable Care Act (Affordable Care Act) (Public Law 111-148) expanded eligible individuals to include employees, officers, board members, and contractors, in addition to volunteers.

2. Purpose and Use of Information Collection

Deeming applications must address certain specified criteria required by law in order for deeming determinations to be issued, and FTCA application forms (Attachment A) are critical to BPHC's deeming determination processes. These forms provide BPHC with the information essential for application evaluation and determination of whether an individual meets the requirements for deemed PHS employee status for the purposes of FTCA coverage. BPHC uses the FTCA Program deeming applications for Free Clinics to determine if the Free Clinic and health care professional to be deemed meet the statutory requirements for deeming the health care professional as a federal employee for the purpose of FTCA medical malpractice protection.

3. Use of Improved Information Technology and Burden Reduction

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 paper-based application forms.

4. Efforts to Identify Duplication and Use of Similar Information

The application form is unique to this requirement. The information requested is specific to this

activity and is needed to make FTCA deeming decisions for Free Clinic professionals.

5. Impact on Small Businesses or Other Small Entities

This activity does not have a substantial impact on small entities or small businesses.

6. Consequences of Collecting the Information Less Frequently

As required by statute, the FTCA Program deeming applications for Free Clinics must be submitted annually. If free clinics do not submit an annual deeming application, their covered individuals will not be eligible for FTCA coverage for purposes of medical malpractice.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

The request fully complies with the regulation.

8. Comments in Response to the Federal Register Notice/ Outside Consultation

A Federal Register notice announcing the FTCA Program deeming applications for Free Clinics was published on June 23, 2017 (Vol. 82, No. 120, pages 28667 - 28668). BPHC received several public comments requesting that FTCA eligibility be extended to free clinics as entities. In response, BPHC notes that per Section 224(o) of the PHS Act (42 U.S.C. 233(o)), FTCA coverage cannot be extended to the free clinic as an entity. Rather, coverage is only available to eligible and approved free clinic-sponsored individuals. All public comments and BPHC responses to the comments can be found in Attachments B and C, respectively.

In 2017, BPHC consulted with multiple people familiar with the FTCA deeming process during the development of the FTCA Program deeming application for Free Clinics. Overall, these outside consultants noted that the information requested should be readily available to the free clinic; an annual collection of this information is appropriate; and the application instructions are clear. Some suggested requesting that the free clinic provide additional documentation for each individual. However, BPHC believes such a collection of information would be overly burdensome for respondents and not essential for making a deeming determination. BPHC used feedback from these outside consultants to estimate the burden hours required for gathering information and completing this application.

Name: Amelia Broussard, PhD, RN, MPH
Title: FTCA Reviewer and Site Visitor, Independent Consultant
Home phone: 706-692-5663; cell phone: 404-234-9227
Email: broussardco1@msn.com
Company: KEPRO

Name: Jeffrey Reck

Title: Subcontractor
Phone: 508-533-0493
Email: reckja@gmail.com
Company: KEPRO

Name: Felicia Eshragh
Title: KEPRO Consultant – FTCA Deeming
Phone: 616-240-8286
Email: Felicia.eshragh@gmail.com
Company: KEPRO

Name: James P. Kelly
Title: Reviewer
Phone: 717-314-4511
Email: jpkelly179@aol.com
Company: KEPRO

Name: Courtney D. Pavona
Title: Subcontractor
Phone: 330-338-9252
Email: cpavona@outlook.com
Company: KEPRO

9. Explanation of any Payment/Gifts to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

Data will be kept private to the extent allowed by law. Please see attached Privacy Impact Assessment.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour and Cost Burden

BPHC has designed the FTCA Program deeming applications for Free Clinics as a user-friendly mechanism for Free Clinics to apply for deemed status on behalf of their eligible health professionals.

The burden estimates for completing the FTCA Program deeming applications for Free Clinics

have been determined based on the experience of the program since its implementation. Individual Free Clinic burden is estimated to be two (2) hours per respondent for completing the FTCA Program deeming application for Free Clinics. BPHC estimates that there will be approximately 228 respondents annually. BPHC notes that the estimated number of responses per respondent increased from one to three annually due to sponsoring free clinics submitting a greater number of supplemental applications on behalf of individuals who on-board throughout a calendar year. As such, the current burden inventory of 454 hours will increase to 1,368 hours.

Estimated Annualized Burden Hours:

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Private Sectors (Free Clinics)	FTCA Program Deeming Application	228	3	684	2	1,368
Total		228		684		1,368

The estimated annualized burden costs for this collection is \$71,929.44.

Estimated Annualized Burden Costs:

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Medical and Health Services Manager ¹	1368	\$52.58	\$71,929.44
Total	1368	\$52.58	\$71,929.44

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

Other than their time, there is no cost to respondents.

¹ Wages for Medical and Health Services Managers are based on Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Employment Statistics*, Medical and Health Services Managers, at <https://www.bls.gov/oes/current/oes119111.htm>.

14. Annualized Cost to the Federal Government

The estimated annual cost to the government is approximately \$126,117 (2 Contractors, 1 GS-12, 1 GS-14, 1 GS-15, 1 SES FTEs – 11% time of work) for reviewing the forms, and for processing and providing notification to applicants.

15. Explanation for Program Changes or Adjustments

There is a change to the estimate of burden from 454 hours to 1,368 hours annually. This change results largely from the number of responses per respondent increasing from one to three annually due to sponsoring free clinics submitting a greater number of supplemental applications on behalf of individuals who on-board throughout a calendar year. One additional respondent results from net growth of the Free Clinics submitting deeming applications.

While the estimated annualized burden has increased, there are no revisions to the application forms.

16. Plans for Tabulation, Publication, and Project Time Schedule

At this time, no statistical analysis will be conducted with the information collected. At this time, no information collected will be published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB number and Expiration date will be displayed on every page of every form/instrument.

18. Exceptions to Certifications for Paperwork Reduction Act Submissions

There are no exceptions to the certification.