

Supporting Statement
Health Resources and Services Administration, Bureau of Primary Health Care
Free Clinics FTCA Program Application

OMB Control No. 0915-0293

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA), Bureau of Primary Health Care (BPHC) is requesting a revision of Office of Management and Budget (OMB) approval for the Free Clinics Federal Tort Claims Act (FTCA) Program deeming application. The current application has OMB Number 0915-0293 and expires December 31, 2014..

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 Act (the 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 (Public Law 111-148) (Affordable Care Act) expanded eligible individuals to include employees, officers, board members, and contractors, in addition to volunteers.

If an eligible individual meets all the requirements of the Act, the related Free Clinic can sponsor him/her to be a “deemed” federal employee for the purpose of FTCA medical malpractice coverage. FTCA deemed status provides the covered individual with immunity from medical malpractice lawsuits resulting from his/her subsequent performance of medical, surgical, dental or related functions within the scope of his/her deemed employment. Claimants alleging acts of medical malpractice by the deemed health care professional must file their claims against the United States according to FTCA requirements. Free Clinics must submit an annual FTCA deeming application on behalf of their covered individuals to HRSA, BPHC, which administers the program.

Free Clinics have evolved into an increasingly important part of the Nation’s safety net for uninsured and medically underserved populations. Although Free Clinics desire to increase the number of health care professionals serving patients in their facilities, the high cost of medical malpractice insurance limits the number of providers that Free Clinics can support. Moreover, in cases when retired physicians and other health care professionals are willing and able to provide needed services, without FTCA coverage, Free Clinics typically must turn them away because neither they nor the physicians have a feasible means to obtain medical malpractice protection.

The program expands access to care by making it possible for Free Clinics to offer comprehensive malpractice coverage to clinicians at no cost who seek to provide services at the clinic.

The attached Free Clinic FTCA deeming application does not have any revisions. However the number of respondents' has changed. The Affordable Care Act expanded eligibility for the Free Clinics FTCA Program to include employees, board members, officers, and contractors. Program policies and the application reflect this change, allowing clinics to sponsor all eligible individuals. Additionally, the application form is now electronic, allowing for faster submission, processing, and decrease of the public burden to fill out the applications.

2. Purpose and Use of Information

HRSA uses the Free Clinics FTCA Program application 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.

A Free Clinic is a health care facility operated by a nonprofit private entity that:

- (1) In providing health care, does not accept reimbursement from any third-party payor (including reimbursement from any insurance policy, health plan, or Federal or State health benefits program);
- (2) In providing health care, does not impose charges on patients to whom service is provided OR imposes charges on patients according to their ability to pay¹;
- (3) May accept patients' voluntary donations for health care service provision; and
- (4) Is licensed or certified to provide health services in accordance with applicable law.

A volunteer [and other eligible] Free Clinic health professional:

- 1) Provides services to patients at a Free Clinic or through offsite programs or events carried out by a Free Clinic;
- 2) Is sponsored by a Free Clinic;
- 3) Provides a qualifying health service (i.e., any medical assistance required or authorized to be provided under Title XIX of the Social Security Act (42 U.S.C. 1396 et. seq.)) without regard to whether the medical assistance is included in the plan submitted by the State in which the health care practitioner provides the service;
- 4) Does not receive compensation for provided services from patients directly or from any third-party payor;
- 5) May receive repayment from a Free Clinic for reasonable expenses incurred in service provision to patients;
- 6) Is licensed or certified to provide health care services at the time of service² provision in accordance with applicable law; and

¹ If the free clinic imposes charges based on a patient's ability to pay, this will negate the FTCA coverage of the volunteer(s) for the specific services for which the clinic received payment.

² A licensed or certified health care practitioner is an individual required to be licensed, registered, or certified by the State, Commonwealth or territory in which a Free Clinic is located. These individuals include, but are not limited to, physicians, dentists, registered nurses, and others required to be licensed, registered, or certified (e.g., laboratory technicians, social workers, medical assistants, licensed practical nurses, dental hygienists, and nutritionists). The definition will vary dependent upon legal jurisdiction.

- 7) Provides patients with written notification before service provision of the extent to which his/her liability is limited pursuant to the PHS Act if his/her associated Free Clinic has not already provided such notification.

In addition, HRSA uses the Free Clinics FTCA Program application to verify that the Free Clinic has satisfied the other program requirements related to credentialing, privileging, and risk management policies and procedures, patient notification of limited liability pursuant to FTCA, and periodic review of medical malpractice claims history. The credentialing and privileging requirements for the Free Clinic FTCA Program have been modeled after those utilized in the Health Center FTCA Program and are based on nationally accepted and recognized standards set forth by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) in its *Comprehensive Accreditation Manual for Ambulatory Care*.

In summary, per the statutory requirements, HHS provides eligible individuals at Free Clinics with FTCA coverage if the:

- 1) Free Clinic meets the legislative definition of a Free Clinic and satisfies requirements related to credentialing, privileging, and risk management systems, patient notification of limited liability, and periodic review of medical malpractice claims history; and
- 2) Individual meets the statutory eligibility requirements.

Free Clinic FTCA coverage is not available for:

- 1) Health care services not required or authorized to be provided under Title XIX of the Social Security Act (i.e., Medicaid Program);
- 2) Health care services not provided at a Free Clinic site or through offsite programs or events carried out by the Free Clinic;
- 3) Health care services provided before the effective date of HHS approval of the FTCA deeming application; or
- 4) Situations normally protected by general liability and directors' and officers' insurance policies.

The Free Clinics FTCA application gathers information about the Free Clinic's credentialing, privileging, and other risk management systems and requires that the Free Clinic submit a: (1) list of its sites; (2) list of prior medical malpractice claims; (3) copy of the Free Clinic's quality assurance plan; (4) copy of the Free Clinic's credentialing, privileging and risk management policies if they are not included in the quality assurance plan; and (5) list of its sponsored volunteer Free Clinic health care professionals. The list of sponsored health care professionals contains the name, professional designation, specialty, address and phone number of each licensed or certified health care worker and his/her dates of last credentialing and privileging. A copy of the guidance and application are provided in a separate attachment.

A Free Clinic must sponsor each Free Clinic professional that participates in the Free Clinic FTCA Program. A Free Clinic can apply to sponsor individuals by submitting a FTCA deeming application to the HHS Secretary through the Free Clinics FTCA Program. Free ClinicAn application with minor or easily resolved deficiencies results in HRSA, BPHC contacting the Free Clinic to notify it of the missing information and to request the submission of the required information. An application with significant deficiencies is returned to the Free Clinic with a statement that indicates the missing requirements and requests that the Free Clinic resubmit a

complete application.

HRSA, BPHC approves of FTCA deemed status for the sponsored Free Clinic individual(s) if the application documents that the professional(s) and related Free Clinic have met the statutory and implementation requirements of the Free Clinic FTCA Program. The Associate Administrator for the Bureau of Primary Health Care issues a deeming letter within 30 days of receipt of complete applications. Free Clinics must submit an annual deeming renewal application in order to maintain FTCA coverage for their volunteer health care professionals. FTCA coverage is effective for the period stated in the letter (i.e., the remainder of the calendar year for original deeming or the upcoming calendar year for annual deeming renewals).

FTCA technical assistance is provided to Free Clinics via: (1) a FTCA help line staffed by BPHC employees and supported by the FTCA program; and (2) technical assistance presentations at the national and regional conferences of HRSA's Free Clinic partners (e.g., National Association of Free Clinics).

If a claim is made against a Free Clinic, it is processed in the same manner as one made against a FTCA deemed health center. The claim is filed with the HHS Office of the General Counsel (OGC), which will gather information from the Free Clinic, make a preliminary determination of coverage and forward the claim to the HRSA, BPHC. HRSA will have an expert medical reviewer review the claim and provide an opinion on whether the standard of care was met. The HHS Office of the General Counsel will review all records and make a determination, in consultation with the HRSA, BPHC, regarding disposition of the claim. At this point, the claim could be resolved without litigation, settled or denied. If the claimant files suit in Federal Court, the claim will be turned over to the Department of Justice (DOJ) for further attempts at settlement or defense of the Federal Government. Claim settlements or judgments will be paid via a congressionally appropriated Free Clinic FTCA judgment fund.

As of July 2014, HRSA/BPHC has deemed Free Clinics Free Clinic resulting in a current total of over 10,000 individuals having been deemed under the program.

3. Use of Improved Information Technology

The FTCA Program has a web based application system, the Electronic Handbooks (EHBs). It is anticipated that these modifications will decrease the time and effort required to complete the current OMB approved FTCA 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 Entities

This activity does not have a significant impact on small entities.

6. Consequences of Information Collected Less Frequently

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

7. Consistency with Guidelines in 5 CFR 1320.5(d)(2)

The request fully complies with the regulation.

8. Consultation outside the Agency

A Federal Register notice announcing a revision to this application approval was published on June 18, 2014 (Vol. 79, No. 117, pages 34765 - 34766). There were no public comments.

HRSA, BPHC consulted with multiple Free Clinic organizations during the development of the Free Clinics FTCA Program guidance and application (National Association of Free Clinics, Volunteers in Health Care, Volunteers in Medicine Institute, Vermont Free Clinic Association and the Ohio Free Clinic Association). HRSA, BPHC has also communicated with several organizations that provided input when the program was implemented, including: the Tri-County Health Care Safety Net Enterprise, located in Oregon; Partners in Health, located in Texas, and We Care of Polk County, located in Florida. To calculate the new burden hours, the Program contacted Salem Free Clinic, Volunteers in Medicine Southern Nevada, Burlington Free Clinic, and Conejo Free Clinic. These clinics represented different sizes of Free Clinics with various types of resources. The program conducts on-going technical assistance, outreach and training activities that obtain clinic inputs regarding the application form, guidance, and process.

9. Explanation of any Payment/Gifts to Respondents

Respondents will not be receiving any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

Sponsoring Free Clinics are required to provide personal identifiers for each sponsored individual to include: home address, and phone number. However, this information is not available to the public and is considered confidential.

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature.

12. Estimates of Annualized Hour Burden

HRSA, BPHC has designed the Free Clinic FTCA Program application as a user-friendly mechanism for Free Clinics to document their existing policies and procedures related to

credentialing, privileging and risk management systems. The hour burden estimates presume that the Free Clinic indeed has credentialing, privileging and risk management systems that are consistent with health care industry standards (e.g., Joint Commission on Accreditation of Healthcare Organizations).

The annual burden estimate is as follows:

Type of Respondents	Number of Respondent	Responses Per Respondent	Average Burden Per Response	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Medical Directors (Physicians)	227	1	2	454	\$92.25	\$41,881

The burden estimates for completing the Free Clinic FTCA Program deeming application have been determined based on the experience of the program since its implementation. Individual Free Clinic burden is estimated to be 2 hours per respondent for completing the Free Clinic FTCA Program deeming application. The program estimates that there will be approximately 227 respondents annually.

Application burden for Free Clinics might vary in listing the required information for volunteer health care professional, i.e., name, professional designation, specialty, address, phone number and dates of last credentialing and privileging. If the Free Clinic has credentialing and privileging systems consistent with health care industry standards, Free Clinics should collect and list existing information for each sponsored volunteer health care professional.

The application forms are available electronically, and the application completion can be performed by a staff person with an average wage rate of \$92.25 per hour. (Retrieved from: http://www.bls.gov/oes/current/oes_nat.htm#29-0000)

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

There is no capital or start up costs for this activity.

14. Annualized Cost to the Federal Government

The estimated annual cost to the federal government for data processing is: \$77,368 (Grade 12, Step 2) (Retrieved from: <http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2013/general-schedule/washington-baltimore-northern-virginia-dc-md-va-wv-pa-annual-rates-by-grade-and-step>)

Also, we use contractors to review our redeeming applications two (2) months out of every year.

The estimated annual cost during that two month time frame is: 10,215.00

Number of Applications Reviewed	Average Amount of Time Needed to Review an Application (Hours)	Contractors Hourly Rate	Total
227	1	\$45	\$10,215.00

Therefore, the total annualized cost to the federal government is: \$87, 583.00

15. Explanation for Program Changes or Adjustments

There is a change to the estimate of burden. The number of hours per Free Clinic application has been reduced from fourteen (14) to two (2) hours due to the Free Clinic deeming application module, which is the new electronic application submitted to HRSA through the Electronic Handbooks. The number of respondents has also increased to 227. As a result the total number of burden hours has decreased to 454.

16. Plans for Tabulation, Publication and Project Time Schedule

There will be no statistical analysis done on the information received on these application forms. In addition, there will be no publication of the information being reported on the application forms.

17. Exemption for Display of Expiration Date

The expiration date will be displayed.

18. Certifications

This project fully complies with CFR 1320.9. The certifications are included in this package.