

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

JUSTIFICATION

1. Circumstances of Information Collection

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 Torts Claim Act (FTCA) Program deeming application. The current application has OMB Number 0915-0293 and expires August 31, 2008.

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.

If a volunteer health care professional 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 volunteer health care professional 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 work at the free clinic. Claimants alleging acts of medical malpractice by the deemed volunteer 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 volunteer free clinic health care professionals to HRSA, BPHC that 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, 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 volunteer their services at the clinic.

The attached Free Clinic FTCA deeming application has one substantive revision. The Free Clinic FTCA program had a PART review in 2006, and, based upon the OMB PART review, the program has added the following new element to the application: Patient visits provided by free clinics sponsoring volunteer FTCA-deemed clinicians. OMB has noted that the purpose of the program is

to encourage health professionals to volunteer to expand access to medical services to low-income individuals. This measure seeks to determine if patient capacity is increasing at free clinics that choose to sponsor volunteer health professionals for FTCA coverage. Responding to OMB's suggestion following the PART review, the program has revised its application materials to collect this information.

2. Purpose and Use of Information

HRSA uses the Free Clinics FTCA Program application to determine if the free clinic and volunteer health care professional meet the statutory requirements for deeming the health care professional as a federal employee for the purposes 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 pay;²
- (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 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 services¹ at the time of service

² 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.

¹ 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.

- provision in accordance with applicable law; and
- 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 a volunteer free clinic health care professional 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) Health care professional meets the legislative definition of a volunteer free clinic health care professional and is sponsored by a free clinic.

Free Clinic FTCA coverage is not be available for:

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

The free clinic 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; (5) copy of the free clinic's patient notice of limited liability; and (6) 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 volunteer free clinic health care professional that participates in

the Free Clinic FTCA Program. A free clinic can sponsor volunteer free clinic health care professionals by submitting a FTCA deeming application to the HHS Secretary through the Free Clinics FTCA Program. Free clinics can download the application from the HRSA, BPHC website (<http://www.bphc.hrsa.gov/freeclinicsftca>). Completed applications are submitted to the HRSA, BPHC, where they are reviewed by program staff or appropriately trained contract staff. An 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 cover letter that enumerates the missing requirements and requests that the free clinic resubmit a complete application.

HRSA approves of FTCA deemed status for the sponsored volunteer health care professional(s) if the application documents that the health care professional(s) and related free clinic have met the statutory 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). A flow chart of the application review processes is attached.

FTCA technical assistance is provided to free clinics via: (1) a FTCA help line staffed by a HRSA-funded contractor to provide general FTCA information and referrals to a free clinic staff person, as needed; 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 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 the practitioner's FTCA coverage. 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. A flowchart of this process is attached. Claim settlements or judgments will be paid via a Congressionally appropriated free clinic FTCA judgment fund.

As of July 28, 2008, HRSA/BPHC has received deeming applications from 119 free clinics. Of these 119 clinics, 96 free clinics have had their applications approved, resulting in a current 2,708 volunteers having been deemed under the program.

3. Use of Improved Information Technology

The application form and guidance are fully electronic and can be accessed at the following web

address: <http://www.bphc.hrsa.gov/policy/pin0424.htm>.

4. Efforts to Identify Duplication

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 volunteer health care professionals.

5. Involvement of Small Entities

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

6. Consequences if 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 volunteer health care professionals will not maintain FTCA coverage for purposes of medical malpractice.

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

The data are collected in a manner consistent with guidelines contained in 5 CFR 1320.5(d)(2).

8. Consultation Outside the Agency

A Federal Register notice announcing the continuation of this application approval was published on September 6, 2007 (Vol. 72, No. 172, pages 51233-51234). No comments were received.

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. The program conducts on-going technical assistance, outreach and training activities that obtain clinic inputs regarding the application form, guidances, and process.

9. Remuneration of Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality

The sponsoring free clinic is required to provide the name, professional designation, address,

phone number and dates of last credentialing and privileging for each sponsored volunteer health care professional. This type of personal information about individual health care volunteers is generally publicly available for health care professionals.

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 Application Form	Number of Respondents	Hours per Response	Total Burden Hours	Total Wage Rate	Total Cost Burden Hours
Free Clinic FTCA Program Deeming Application	150	16	2,400	35.00	\$84,000

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 16 hours per respondent for completing the Free Clinic FTCA Program deeming application. The program estimates that there will be approximately 150 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 senior staff person with an average wage rate of \$35 per hour.

13. Estimates of Annualized Cost Burden to Respondents

There are no capital or start up costs for this activity. The guidance and required application forms are posted on the HRSA, BPHC web site for easy access by free clinics.

14. Estimated Cost to the Federal Government

The estimated annual cost to the federal government for data processing is \$9,291.00. This figure is the sum of the following cost categories:

(1)	Data entry, review, processing of the application forms and deeming notification Number of respondents – 150 Average cost per hour - \$30.24	\$4,536.00
(2)	Notifying the Health Center – \$31.70 Number of respondents – approx. 150	\$4,755.00
	Total	\$9,291.00

15. Changes in Burden

There is **no change** to the estimate of burden. The current inventory of burden hours for this activity is 2,400 hours and this request is for 2,400 annual burden hours.

16. Time Schedule, Publication and Analysis Plans

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.