

Federal Tort Claims Act Coverage of Free Clinic Volunteer Health Care Professionals

I. PURPOSE

This Program Information Notice (PIN) supersedes PIN 2004-24 and provides detailed information regarding the implementation of the *Free Clinic Federal Tort Claims Act (FTCA) Medical Malpractice Program (the Program)* as described in Section 194 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This PIN provides information on:

- 1) Who is covered;
- 2) What services are covered;
- 3) What are the Program requirements;
- 4) How are claims processed;
- 5) What is the application process; and
- 6) Other types of recommended insurance.

II. OVERVIEW

Congress enacted FTCA medical malpractice protection for volunteer free clinic health care professionals through Section 194 of HIPAA (Public Law 104-191) by amending Section 224 of the Public Health Service (PHS) Act (42 U.S.C. § 233). If a volunteer health care professional meets all the requirements of the Program, the related free clinic can sponsor him/her to be a “deemed” PHS employee for the purpose of FTCA medical malpractice coverage. FTCA deemed status provides the volunteer licensed or certified 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. The payment of claims will be subject to Congressional appropriations for the program. Free clinics must submit an annual FTCA deeming application on behalf of their volunteer free clinic health care professionals to the Department of Health and Human Services’ (HHS) Health Resources and Services Administration, Bureau of Primary Health Care (HRSA, BPHC) that administers the Program.

III. WHO IS COVERED?

HHS will deem a volunteer free clinic health care professional to be a PHS employee for the purposes of FTCA coverage for medical malpractice claims if the free clinic and health care professional meet certain requirements.

A free clinic is a health care facility operated by a non-profit¹ 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 that is individually determined);

¹ The IRS under section 501(c) (3) of the Internal Revenue Code should have conferred the non-profit status of the health care facility operating the free clinic.

- 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.³

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 services³ at the time of service provision in accordance with applicable law; and
- 7) Provides patients with written notification before service provision of the extent to which his/her legal liability is limited pursuant to the PHS Act if his/her associated free clinic has not already provided such notification (see Section V(B)).

An example of a FTCA covered offsite program or event carried out by a free clinic is a health fair sponsored by the free clinic. If a free clinic is unsure whether an offsite program or event is covered by FTCA, the free clinic may apply to the HRSA Associate Administrator for Primary Care (through the Free Clinic FTCA Program) for a determination of coverage. The request must sufficiently detail:

- 1) What service(s) is being provided;
- 2) Who is providing the service;
- 3) Where the service is being provided; and
- 4) Why the free clinic volunteer(s) is providing the 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.

³ 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.

IV. WHAT SERVICES ARE COVERED?

FTCA deemed volunteer free clinic health care professionals are eligible for medical malpractice coverage for health care service acts or omissions that:

- 1) Arise from services required or authorized to be provided under Title XIX of the Social Security Act (i.e., Medicaid Program) regardless of whether the service is included in the State Medicaid plan in effect for the volunteer free clinic health care professional's work site(s);
- 2) Arise from the provision of medical, surgical, dental or related services at a free clinic site or through offsite programs or events carried out by the free clinic; and
- 3) Occur on or after the effective date that the HHS Secretary approves the FTCA deeming application submitted by the free clinic on behalf of its volunteer free clinic health care professionals.

V. WHAT ARE THE PROGRAM REQUIREMENTS?

Free clinics and their FTCA deemed volunteer health care professionals must satisfy various program requirements. The requirements related to credentialing and privileging systems and patient notification of limited liability are described in detail in this PIN. The Program applications outline other Program requirements related to risk management systems and periodic review of medical malpractice claims history (see Appendices A & B).

A. Credentialing and Privileging

Credentialing and Privileging Definitions

HHS will deem a volunteer free clinic health care professional to be a PHS employee for purposes of FTCA coverage for medical malpractice claims if specific credentialing and privileging requirements are met. For the purposes of the Program:

- 1) Credentialing is the process of *assessing and confirming the qualifications* (e.g., licensure, certification, and/or registration) of a licensed or certified health care practitioner; and
- 2) Privileging is the process of *authorizing the specific scope and content of patient care services* of a licensed or certified health care practitioner. This is performed in conjunction with an evaluation of the health care practitioner's clinical qualifications and/or performance.

Free clinics can satisfy many of the credentialing and privileging requirements by utilizing primary and secondary source verification. For the purposes of the Program:

- 1) Primary source verification is *verification of an individual health care practitioner's reported qualification by the original source or an approved agent*. Examples of primary source verification of credentials include direct correspondence, telephone verification, or internet verification from the original qualification source or reports from credentials verification organizations (CVOs). For example, the Education Commission for Foreign Medical Graduates (ECFMG), the American Board of Medical Specialties (ABMS), the American Osteopathic

Association (AOA) Physician Database, or the American Medical Association (AMA) Masterfile can be used for primary source verification of health care practitioners' education and training. Hospitals also can serve as CVOs to conduct primary source verification for free clinics. When using a CVO for primary source verification, the free clinic is relieved from the process of gathering the information, but it is not relieved from the responsibility of having complete and accurate information. Therefore, a free clinic that bases its decisions in part on information obtained from a CVO should achieve a level of confidence in the information provided by the CVO (For more information, consult *Credentialing and Granting of Privileges, 2004 Comprehensive Accreditation Manual for Ambulatory Care*, Joint Commission on Accreditation of Healthcare Organizations (JCAHO), pg. HR-10).

- 2) Secondary source verification is *verification by methods not considered acceptable for primary source verification*. Examples of secondary source verification of credentials include viewing the original credential, a notarized copy of the credential, or a copy of the credential (when the copy was made from an original by an authorized participant of the organization's credentialing process).

Only volunteer health care professionals who are currently licensed or certified are eligible for FTCA deemed status (see Section III). Licensed or certified health care practitioners can be divided into two categories:

- 1) A licensed independent practitioner (LIP) is a physician, dentist, nurse practitioner, nurse midwife, or any other *individual permitted by law and the organization to provide care and services without direction or supervision*, within the scope of the individual practitioner's license and consistent with individually granted clinical privileges; and
- 2) Another licensed or certified health care practitioner is an individual who is licensed, registered, or certified but is *not permitted by law to provide patient care services without direction or supervision*. Examples include, but are not limited to, laboratory technicians, social workers, medical assistants, licensed practical nurses, and dental hygienists.

Credentialing and Privileging Requirements

The free clinic must determine whether each volunteer health care professional meets the definition of a LIP or other licensed or certified health care practitioner based on State law and the free clinic's policies. Further, the free clinic must assure that these licensed or certified health care practitioners are credentialed and privileged. Credentialing and privileging requirements differ depending on whether the volunteer health care professional is a LIP or other licensed or certified health care practitioner.

Initial Credentialing of LIPs

The initial credentialing of LIPs should include:

- 1) *Primary source verification of:*
 - a) Current licensure;
 - b) Relevant education, training, or experience; and
 - c) Health fitness or the ability to perform the requested privileges (This can be determined by a statement from the individual that is confirmed either by the director of a training program, chief of staff/service of a hospital where the individual has privileges, or a licensed physician designated by the organization);
- 2) *Secondary source verification of:*
 - a) Identification (via a government issued picture id);
 - b) Drug Enforcement Administration registration, as applicable;
 - c) Hospital admitting privileges, as applicable;
 - d) Immunization and TB skin test result status; and
 - e) Life support training, as applicable; and
- 3) *Querying the National Practitioner Data Bank (NPDB), as applicable (If the free clinic is ineligible to query the NPDB, it should have the LIP provide the results of a self-query).*

The free clinic should complete the credentialing process for the LIP prior to the practitioner providing patient care services at the free clinic.

Initial Privileging of LIPs

The initial privileging of a LIP involves the assessment of his/her current competence in the specific scope or content of patient care services he/she is to provide at the free clinic. The free clinic should assure that the specific assessment procedures utilized are appropriate for the LIP's specialty, breadth of clinical services to be provided to patients, and accessibility to ancillary and tertiary medical practitioners. A free clinic could assess a LIP's competence by any combination of:

- 1) Primary source verification of a course of study from a recognized and certifying educational institution showing that the LIP met or passed a level of training required to perform a defined procedure or management protocol;
- 2) Documentation of first hand, one-on-one review of the LIP's competence in particular procedures or management protocols by a supervising clinician who possesses privileges in the particular procedures or management protocols; and/or
- 3) Direct proctoring of the LIP in particular procedures or management protocols by a qualified clinician possessing a degree of expertise in the particular procedures or protocols beyond the level of expertise of most newly practicing primary care providers.

Approval Authority for Initial LIP Credentialing and Privileging

The free clinic's governing board should state in writing its determination that a LIP meets credentialing and privileging requirements. This determination can be based on the recommendation of the Medical Director or the combined recommendation of medical staff (including the Medical Director) and the Executive Director. Alternatively, the governing board may delegate this responsibility (via resolution or bylaws) to an appropriate individual to be implemented based on approved policies and procedures (including methods to assess compliance with these policies and procedures).

Examples of cases in which a free clinic could grant temporary privileges to a LIP in order to meet important patient care needs for a limited period of time include:

- 1) A current LIP becomes ill or takes a leave of absence, and another LIP is needed to cover patient care until the current LIP returns; or
- 2) A current LIP does not have the necessary skills to provide needed patient care.

Temporary Privileging Requirements for LIPs

The free clinic should strive to complete the privileging process prior to the LIP being allowed to provide patient care services. However, if the free clinic has established temporary privileging policies and procedures, it can grant temporary privileges to a LIP:

- 1) To meet important patient care needs for a limited period of time⁴ (requires verification, which can be done by phone, of the provider's current licensure and current competence in the specific scope or content of patient care services he/she is to provide at the free clinic); or
- 2) To issue privileges for new volunteer free clinic health care professionals for a period not to exceed 120 days when the following has been verified:
 - a) Current licensure and lack of any history of current or previously successful challenges to licensure (can be done by phone);
 - b) Relevant training and experience (can be done by phone);
 - c) Current competence in the specific scope or content of patient care services he/she is to provide at the free clinic and ability to perform the privileges requested (can be done by phone);
 - d) NPDB history;
 - e) Lack of any history of involuntary termination of medical staff membership at another organization;
 - f) Lack of any history of involuntary limitations, reduction, denial, or loss of clinical privileges; and
 - g) Other criteria required by the policies and procedures of the free clinic (can be done by phone).

Free clinics should not provide temporary privileges for situations in which:

- 1) The LIP fails to provide all information necessary for the privileging process; or

- 2) Free clinic staff fails to verify performance data and other information in a timely manner.

In these situations, the free clinic must require that the LIP cease providing patient care in the free clinic until the privileging process is completed.

Initial Credentialing of Other Licensed or Certified Practitioners

The initial credentialing of other licensed or certified practitioners should include:

- 1) *Primary source verification* current licensure, registration, or certification;
- 2) *Secondary source verification* of:
 - a) Education and training;
 - b) Identification (via a government issued picture id);
 - c) Drug Enforcement Administration registration, as applicable;
 - d) Hospital admitting privileges, as applicable;
 - e) Immunization and PPD status; and
 - f) Life support training, as applicable; and
- 3) *Querying the NPDB*, as applicable (If the free clinic is ineligible to query the NPDB, it must have the licensed or certified practitioner provide the results of a self-query).

A free clinic also may choose to credential other licensed or certified health care practitioners via similar requirements utilized for LIPs. Free clinics must complete the credentialing process for other licensed or certified health care practitioners prior to the practitioners providing patient care services at the free clinic.

Initial Privileging of Other Licensed or Certified Practitioners

The initial privileging of another licensed or certified practitioner involves the assessment of his/her current competence in the specific scope or content of patient care services he/she is to provide at the free clinic. A free clinic can assess current competency through an orientation process during which a supervisor evaluates the practitioner's clinical qualifications and performance based on his/her job description.

Approval Authority for Initial Credentialing and Privileging of Other Licensed or Certified Health Care Practitioners

The Executive Director should state in writing his/her determination that an other licensed or certified health care practitioner meets credentialing and privileging requirements. This determination should be based on the Medical Director's review of credentialing information and the supervisor's evaluation of the practitioner's clinical qualifications and performance.

Alternatively, the Executive Director may delegate this responsibility (via resolution or bylaws) to an appropriate individual to be implemented based on approved policies and procedures (including methods to assess compliance with these policies and procedures).

Reassessment of the Credentials and Privileges of LIPs and Other Licensed or Certified Health Care Practitioners

The free clinic should reassess the credentials and privileges of LIPs and other licensed or certified health care practitioners at least every 2 years. Renewed credentialing and privileging processes should include:

- 1) Primary source verification of current licensure, registration or certification;
- 2) Secondary source verification of:
 - a) Adherence to the free clinic's policies, procedures and rules;
 - b) Relevant education training and experience (if changed since initial appointment);
 - c) The practitioner's ability to perform the care, treatment and services he/she has been providing and will be providing in the future at the free clinic; and
 - d) Lack of any restrictions on privileges at any other health care organization.
- 3) An assessment of current competency to include:
 - a) A synopsis of peer review results from the prior 2 year period and/or any relevant performance improvement information (for LIPs); or
 - b) The supervisor's evaluation of performance (for other licensed or certified health care practitioners); and
- 4) Querying the NPDB, as applicable.

The free clinic should notify each LIP and other licensed or certified health care practitioner in writing of its conclusions regarding the reassessment of the practitioner's credentials and privileges.

The free clinic should have an appeal process that a LIP can undertake if the free clinic decides to discontinue or deny his/her clinical privileges. An appeal process is optional for other licensed or certified health care practitioners.

B. Patient Notice of Limited Legal Liability of FTCA Deemed Health Care Professionals

A FTCA deemed volunteer free clinic health care professional or the free clinic must provide each patient with written notification of the limited liability of the health care professional pursuant to FTCA. The volunteer health care professional and/or free clinic can satisfy this statutory requirement by having each patient review a notification document prior to the first encounter between the patient and the health care professional. It is preferable that the health care practitioner or free clinic obtain the patient's signature on the notice and include the notice in the patient's medical record. If the volunteer health care professional is providing emergency care, the health care professional or free clinic may provide the written notice as soon thereafter as is practicable. The health care professional or free clinic should provide the notice to a parent or legal guardian when the patient lacks legal responsibility for his/her care under the law of the State where care is provided.

A sample patient notice can be found in Appendix C. Free clinics also may choose to develop their own patient notice form. The free clinic's form must at a minimum address all of the requirements listed in the sample.

VI. HOW ARE CLAIMS PROCESSED?

Claimants alleging acts of medical malpractice by a FTCA deemed volunteer free clinic health care professional must file their claims against the United States according to FTCA requirements. FTCA requires that the alleged injured party file an administrative claim with HHS prior to instituting any court action.

Upon receipt of the claim, HHS will determine whether FTCA medical malpractice coverage applies to the particular claim by considering if the alleged act or omission giving rise to the claim:

- 1) Involved a volunteer free clinic health care professional with deemed FTCA status pursuant to the PHS Act;
- 2) Involved a health care service qualifying for FTCA coverage; and
- 3) Occurred at a free clinic or a covered offsite program or event carried out by the free clinic.

If HHS denies the claim or HHS action is pending after 6 months, the claimant can file suit against the United States. FTCA medical malpractice cases are heard in Federal district court without a jury and are defended by the Department of Justice with the assistance of the Office of General Counsel, Department of Health and Human Services. No punitive damages are allowed.

VIII. WHAT IS THE APPLICATION PROCESS?

A. Overview

A free clinic must sponsor each volunteer free clinic health care professional that participates in the Program. A free clinic can sponsor volunteer free clinic health care professionals by submitting a FTCA deeming application to the HHS Secretary thru the Free Clinic FTCA Program. The free clinic can download deeming applications from the web at <http://www.bphc.hrsa.gov/freeclinicsftca/application.htm>. Free clinics should submit:

- 1) One electronic copy and one hard copy of all application materials to: freeclinicsFTCA@hrsa.gov; or
- 2) One copy of all application materials to:
Free Clinic FTCA Program
Division of Clinical Quality
Bureau of Primary Health Care, HRSA
5600 Fishers Lane, Room 15C-26
Rockville, MD 20857

Failure to submit any of the requested information will render the application incomplete. The application will not be considered until the missing information is provided.

B. Original Deeming Application

A free clinic may submit an original FTCA deeming application at any time after the effective date of this notice. The original deeming application requires information fulfilling statutory and programmatic requirements, including (see Appendix A):

- 1) Contact information of the sponsoring free clinic;
- 2) Location and managers of free clinic sites;
- 3) Description of the free clinic's credentialing and privileging systems;
- 4) Description of the free clinic's risk management systems;
- 5) List of all volunteer health care professionals that the free clinic is sponsoring for FTCA deemed status (no handwritten lists, please);
- 6) Description of all medical malpractice claims alleged against the free clinic and/or its sponsored volunteer health care professionals occurring prior to the submission of this FTCA application (including pending claims) and a description of all disciplinary actions against any of the sponsored volunteer health care professionals;
- 7) Requested effective date of FTCA coverage; and
- 8) Approval signatures of senior free clinic managers.

HRSA's Associate Administrator for Primary Care will make final decisions regarding FTCA deeming of volunteer free clinic health care professionals within 30 days of receipt of a complete application. The HRSA Associate Administrator will provide the free clinic with written notification of the effective date of its volunteer health care professionals' FTCA deemed status. Original deeming will be valid through the remainder of the calendar year.

C. Annual Renewal Deeming Application

The free clinic subsequently can sponsor volunteer health care professionals annually by submitting a FTCA annual renewal application in the month corresponding with its original deeming application submission.

The HRSA Associate Administrator will make final decisions regarding FTCA deeming renewal of volunteer free clinic health care professionals. If the renewal application is approved, in December, the HRSA Associate Administrator will provide the free clinic with written notification of its volunteer health care professionals' FTCA deemed status that will be valid through the subsequent calendar year.

D. Supplemental Deeming Application

If a free clinic desires FTCA coverage of additional volunteer free clinic health care professionals prior to the due date for the annual renewal application, the free clinic must submit a supplemental deeming application (see Appendix B) that contains:

- 1) Contact information of the sponsoring free clinic;
- 2) Location and managers of any new free clinic sites since its last FTCA application submission;
- 3) Certification that the free clinic has maintained its credentialing, privileging, and risk management systems or a description as to how the system(s) has been modified;

- 4) List of all new volunteer health care professionals that the free clinic is sponsoring for FTCA deemed status;
- 5) A description of all medical malpractice claims alleged against the free clinic's newly sponsored volunteer health care professionals and a description of all disciplinary actions against any of the sponsored volunteer health care professionals;
- 6) Requested effective date of FTCA coverage; and
- 7) Approval signatures of senior free clinic managers.

Supplemental deeming will be valid through the remainder of the calendar year.

VIII. TYPES OF RECOMMENDED INSURANCE

The Program provides protection only from allegations of medical negligence for volunteer free clinic health professionals as defined in Section III of this PIN. Other free clinic staff and the free clinic corporation are not covered under FTCA. Additionally, the Program does not provide protection against perils normally protected by general liability and directors and officers' insurance policies. Free clinics should consult with their insurance agents to determine their needs for protection beyond the Program.

IX. PUBLIC BURDEN STATEMENT

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0293. Public reporting burden for this collection of information is estimated to average 16 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 10-33, Rockville, Maryland, 20857.

X. APPENDICES

Appendix A Deeming Application – Original or Annual Renewal

A.1 – Application Form

A.2 - Application Checklist

Appendix B Deeming Application – Supplemental

B.1 – Application Form

B.2 –Application Checklist

Appendix C Sample Patient Notice of Limited Liability of FTCA Deemed Volunteer Free Clinic Health Professionals

Appendix D Free Clinic FTCA Deeming Application Feedback Form

Appendix A.1
FREE CLINIC FEDERAL TORT CLAIMS ACT (FTCA) PROGRAM

Volunteer Free Clinic Health Professional Deeming Application – Original or Annual Renewal (Please note that the free clinic will need to in the future file the annual renewal applications by July 11.)

| SECTION I –SPONSORING FREE CLINIC |
|---|
| <p>Free Clinic FTCA Number: (Leave blank if original deeming application)</p> <p>Corporate Name of Free Clinic or Sponsoring Entity: (If there has been a legal name change since the last application submission, please attach the appropriate state document indicating the change.)</p> <p>List any “doing business as” (dba) name:</p> <p>Corporate Address: Chief Executive Officer’s Name: Telephone Number: Fax Number: E-mail: Free Clinic Medical Director’s Name: Telephone Number: Fax Number: E-mail: Risk Management Coordinator’s Name:</p> |
| SECTION II –FREE CLINIC SITES |
| <p><i>List all free clinic sites where volunteer health care professionals will be providing services.</i></p> <p><i>Please make additional copies of this page to list any additional sites.</i></p> |
| <p>Free Clinic Site - main or additional (circle one): Name: Address: Telephone Number: Fax Number: E-mail: Days/Hours of Operations: Executive Director’s Name: Telephone Number: Medical Director’s Name: Telephone Number:</p> |

Free Clinic Site - main or additional (circle one):
 Name:
 Address:
 Telephone Number:
 Fax Number:
 E-mail:
 Days/Hours of Operations:
 Executive Director's Name: Telephone Number:
 Medical Director's Name: Telephone Number:

| SECTION III – CREDENTIALING AND PRIVILEGING SYSTEMS | | |
|---|------------|-----------|
| <i>Please answer YES or NO to the following questions by marking in the appropriate box.</i> | | |
| <i>“NO” answers require an explanation in Section V.</i> | | |
| <i>Note that the credentialing and privileging activities specified below may be done through the free clinic's own efforts or through its reasonable reliance on information provided to it by a credible third party such as a credentialing verification organization.</i> | | |
| Item | Yes | No |
| A. The free clinic periodically verifies licensure, certification and/or registration of each volunteer health care professional according to the instructions in PIN 2004-24 (Revised). | | |
| B. The free clinic has a copy of each volunteer health care professional's current license, certification, and/or registration on file at the free clinic. | | |
| C. The free clinic periodically verifies board eligibility or certification for each volunteer health care professional, when applicable, according to instructions in PIN 2004-24 (Revised). | | |
| D. The free clinic utilizes peer review activities when it periodically privileges volunteer health care professionals according to the instructions in PIN 2004-24 (Revised). | | |
| E. During the credentialing processes, the free clinic requires each volunteer health care practitioner to submit a personal statement or other evidence of fitness to perform expected health care duties according to the instructions in PIN 2004-24 (Revised). | | |

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| <p>F. The free clinic has a copy of each volunteer health care professional’s hospital privileges, when applicable, on file.</p> |
| <p>G. The free clinic annually reviews each volunteer health care professional’s history of prior and current FTCA medical malpractice claims.</p> |
| <p>H. During the credentialing process of volunteer health care professionals, the free clinic queries the National Practitioner Data Bank according to the instructions in PIN 2004-24 (Revised).</p> |

| <p>SECTION IV – RISK MANAGEMENT SYSTEMS</p> <p><i>Please answer YES or NO to the following questions by marking in the appropriate box.</i></p> <p>“NO” answers require an explanation in Section V.</p> | | |
|--|-----|----|
| Item | Yes | No |
| <p>A. The free clinic has policies and procedures in place for the provision of appropriate supervision and back-up of clinical staff.</p> | | |
| <p>B. The free clinic maintains a medical record for every patient receiving care from its organization.</p> | | |
| <p>C. The free clinic has policies and procedures that address triage, walk-in patients and telephone triage.</p> | | |
| <p>D. The free clinic has protocols that define appropriate treatment and diagnostic procedures for selected medical conditions based on current standards of care.</p> | | |
| <p>E. The free clinic has a tracking system for patients who miss appointments or require follow-up of referrals, hospitalization, x-rays, or laboratory results.</p> | | |
| <p>F. The free clinic periodically reviews patients’ medical records to</p> | | |

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|--|
| determine quality, completeness and legibility. |
| G. The free clinic has a written, current quality assurance plan (please attach a copy). |
| H. The free clinic has regular, periodic meetings to review and assess quality assurance issues. |
| I. The free clinic considers findings from its peer review activities when reviewing and/or revising its quality assurance plan. |
| J. The free clinic utilizes quality assurance finding to modify policies to improve patient care. |
| K. The free clinic's volunteer health care professionals annually participate in risk management continuing education activities. |
| L. The free clinic has assured that each volunteer health care professional has a copy of PIN 2004-24 (Revised) and that his/her questions regarding FTCA medical malpractice coverage have been addressed. |
| M. The free clinic has attached a copy of the clinic's IRS 501©(3) documentation. |

SECTION V – ADDITIONAL INFORMATION REGARDING CREDENTIALING, PRIVILEGING, AND RISK MANAGEMENT SYSTEMS

*Explanations of each “No” answer from Sections III & IV.
(Please identify each response with the corresponding section number and letter.)*

Please attach additional pages, if needed.

SECTION VI - FREE CLINIC VOLUNTEER HEALTH CARE PROFESSIONALS

List of all volunteer free clinic licensed or certified health care professionals that the free clinic wants to sponsor for FTCA deemed status.

For Renewal Applications, please also include separate (typed) lists for (1) currently covered clinicians to be continued, (2) any requested new supplemental clinicians, and (3) for clinicians to be dropped from FTCA coverage.

| Name | Professional designation (e.g., MD, RN, CNM) | Specialty Training | Specialty to be Practiced at the Free Clinic | Home Address | Home Phone | Date of Last Credentialing Person and Organization Conducting | Credentialing | Date of Last Privileging |
|------|--|--------------------|--|--------------|------------|---|---------------|--------------------------|
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

Please attach additional sheets, if needed.

Person and Organization Conducting Privileging

(Annual renewal deeming) Describe all medical malpractice claims against the free clinic, its deemed health care professionals, and/or its newly sponsored volunteer health care professionals since the last FTCA application submission.

SECTION VII – HISTORY OF MEDICAL MALPRACTICE CLAIMS

(Original deeming) Describe all medical malpractice claims against the free clinic. Also, describe all malpractice claims against its sponsored volunteer health care professionals (for at least the last 10 years) occurring prior to the submission of this FTCA application (unless reported on a previous application).

Also include a list of any disciplinary actions taken by a State medical licensing authority (or a professional society) for the relevant volunteer health care clinicians. Note that clinics should usually avoid applying for coverage for volunteers who have had prior disciplinary actions.

Please make additional copies of this page to list additional claims.

Specialty Involved:

Allegation:

Action taken by the free clinic to prevent such claims in the future:

Specialty Involved:

Allegation:

Action taken by the free clinic to prevent such claims in the future:

Specialty Involved:

Allegation:

Action taken by the free clinic to prevent such claims in the future:

SECTION VIII – SIGNATURES

REQUESTED EFFECTIVE DATE OF FTCA COVERAGE

(No sooner than 30 days from the date of application submission)

We certify that this sponsoring free clinic meets the definition of a free clinic found in Section III of HRSA/BPHC PIN 2004-24 (Revised) and that the information in this application and the related attachments is complete and accurate.

CHIEF EXECUTIVE OFFICER:

(Print or type)

SIGNATURE: _____ **Date:** _____

FREE CLINIC MEDICAL DIRECTOR:

(Print or type)

SIGNATURE: _____ **Date:** _____

(Note: When filing electronically, an electronic signature is sufficient.)

**Appendix A.2
FREE CLINIC FEDERAL TORT CLAIMS ACT (FTCA) PROGRAM**

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|--|---|
| APPLICATION CHECKLIST | Volunteer Free Clinic Health Professional Deeming Application – Original or Annual Renewal |
| ITEM COMPLETED AND/OR ATTACHED | |
| <i>(annual renewal application only)</i> | |
| <i>(original deeming)</i> Descriptions of all medical malpractice claims occurring prior to the submission of this deeming application are included. | |
| Other | |

APPLICATION SECTION

Section I – Sponsoring Free Clinic

State document indicating legal name change is attached if legal name change occurred since last deeming application was submitted.

Section II –Free Clinic Sites

All free clinic sites are listed, using additional copies of Section II, if needed.

Each site is appropriately identified as the main or an additional site.

Section III –Credentialing and Privileging Systems

An explanation of all “No” answers is provided in Section V.

The free clinic’s credential and privileging policies are included in the attached quality assurance plan or as a separate document.

Section IV–Risk Management Systems

An explanation of all “No” answers is provided in Section V.

The free clinic’s risk management policies are included in the attached quality assurance plan or as a separate document. A copy of the free clinic’s quality assurance plan is attached.

Section V–Additional Information Regarding Credentialing, Privileging and Risk Management Systems

An explanation for each “No” answer from Sections III & IV is included.

Section VI – Free Clinic Volunteer Health Care Professionals

All free clinic volunteer health professionals that the free clinic wants to sponsor for FTCA deemed status are listed.

Section VII– History of Medical Malpractice Claims

(Annual renewal deeming) Descriptions of all medical malpractice claims since the last deeming application submission are included.

Section VIII– Signatures

Original signatures are included for the Chief Executive Officer and Free Clinic Medical Director. A copy of the free clinic’s patient notice of limited liability of FTCA deemed volunteer health care professionals is attached.

Appendix B.1

| FREE CLINIC FEDERAL TORT CLAIMS ACT (FTCA) PROGRAM |
|--|
| <p>SECTION I –SPONSORING FREE CLINIC</p> <p>Free Clinic FTCA Number:</p> <p>Corporate Name of Free Clinic or Sponsoring Entity: (If there has been a legal name change since the last application submission, please attach the appropriate state document indicating the change.)</p> <p>Corporate Address:</p> <p>Chief Executive Officer’s Name:</p> <p>Telephone Number:</p> <p>Fax Number:</p> <p>E-mail:</p> <p>Free Clinic Director’s Name:</p> <p>Telephone Number:</p> <p>Risk Management Coordinator’s Name:</p> |
| <p>E-mail:</p> <p>SECTION II –FREE CLINIC SITES</p> |
| <p><i>Please make additional copies of this page to list any additional sites.</i></p> <p>Free Clinic Site - main or additional (circle one):</p> <p>Name:</p> <p>Address:</p> <p>Telephone Number:</p> <p>Fax Number:</p> <p>E-mail:</p> <p>Days/Hours of Operations:</p> |
| <p>Medical Director’s Name: Telephone Number:</p> <p>Free Clinic Site - main or additional (circle one):</p> <p>Name:</p> <p>Address:</p> <p>Telephone Number:</p> <p>Fax Number:</p> <p>E-mail:</p> <p>Days/Hours of Operations:</p> <p>Executive Director’s Name: Telephone Number:</p> |

Volunteer Free Clinic Health Professional Deeming Application - Supplemental Fax Number:

List all new free clinic sites where volunteer health care professionals have been/will be providing services (i.e., sites not included in the last deeming application).

Executive Director’s Name: Telephone Number:

Medical Director’s Name: Telephone Number:

**SECTION III- CREDENTIALING, PRIVILEGING & RISK MANAGEMENT
SYSTEMS CERTIFICATION**

Has modified the credentialing, privileging, and/or risk management systems since the submission of its last FTCA deeming application.

Please attach additional sheets, if needed.

_____ Free Clinic:

(Print or type free clinic's name)

(Check appropriate box)

Has maintained the credentialing, privileging, and risk management systems documented in its last FTCA deeming application

OR

Please explain any changes in the free clinic's credentialing, privileging, and risk management systems.

SECTION IV - FREE CLINIC VOLUNTEER HEALTH CARE PROFESSIONALS

SECTION IV - FREE CLINIC VOLUNTEER HEALTH CARE PROFESSIONALS
List of all volunteer free clinic licensed or certified health care professionals that the free clinic wants to sponsor for FTCA deemed status.

| Name | Professional designation (e.g., MD, RN, CNM) | Specialty Training | Specialty to be Practiced at the Free Clinic | Home Address | Home Phone | Date of Last Credentialing Person and Organization Conducting | Credentialing | Date of Last Privileging |
|------|--|--------------------|--|--------------|------------|---|---------------|--------------------------|
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

SECTION V – HISTORY OF MEDICAL MALPRACTICE CLAIMS

(Original deeming) Describe all medical malpractice claims against the free clinic. Also, describe all malpractice claims against its sponsored volunteer health care professionals (for at least the last 10 years) occurring prior to the submission of this FTCA application (unless reported on a previous application).

Also include a list of any disciplinary actions taken by a State medical licensing authority (or a professional society) for the relevant volunteer health care clinicians. Note that clinics should usually avoid applying for coverage for volunteers who have had prior disciplinary actions.

Please make additional copies of this page to list additional claims.

Specialty Involved:

Allegation:

Action taken by the free clinic to prevent such claims in the future:

Specialty Involved:

Allegation:

Action taken by the free clinic to prevent such claims in the future:

Specialty Involved:

Allegation:

Action taken by the free clinic to prevent such claims in the future:

SECTION VI – SIGNATURES
REQUESTED EFFECTIVE DATE OF FTCA COVERAGE FOR
ADDITIONAL VOLUNTEER HEALTH CARE PROFESSIONALS

(No sooner than 30 days from the date of application submission)

We certify that this sponsoring free clinic meets the definition of a free clinic found in Section III of HRSA/BPHC PIN 2004-24 (Revised) and that the information in this application and the related attachments is complete and accurate.

CHIEF EXECUTIVE OFFICER:

(Print or type)

SIGNATURE: _____ **Date:** _____

FREE CLINIC MEDICAL DIRECTOR:

(Print or type)

SIGNATURE: _____ **Date:** _____

(Note: When filing electronically, an electronic signature is sufficient.)

Appendix B.2

**FREE CLINIC FEDERAL TORT CLAIMS ACT (FTCA) PROGRAM
ITEM COMPLETED AND/OR ATTACHED**

Original signatures are included for the Chief Executive Officer and Free Clinic Director.

| | |
|--|---|
| APPLICATION CHECKLIST | Volunteer Free Clinic Health Professional Deeming Application - Supplemental |
| APPLICATION SECTION | |
| Section I – Sponsoring Free Clinic | |
| State document indicating legal name change is attached if legal name change occurred since last deeming application was submitted. | |
| Section II –Free Clinic Sites | |
| Free clinic sites that were not included in the last deeming application are listed, using additional copies of Section II, if needed. | |
| Each site is appropriately identified as the main or an additional site. | |
| Section III –Credentialing, Privileging, and Risk Management Systems Certification | |
| An explanation of any changes in the free clinic’s credentialing, privileging and/or risk management systems since the last deeming application submission is included, if applicable. | |
| Section IV – Free Clinic Volunteer Health Care Professionals | |
| All free clinic health professionals not listed in the last deeming application that the free clinic wants to sponsor for FTCA deemed status are listed. | |
| Section V– History of Medical Malpractice Claims | |
| Descriptions of all medical malpractice claims occurring since the last deeming application submission are included. | |
| Section VI– Signatures | |

Appendix C

FREE CLINIC FEDERAL TORT CLAIMS ACT (FTCA) PROGRAM

Sample Patient Notice of Limited Liability of FTCA Deemed Volunteer Free Clinic Health Care Professionals

Notice to Patients

To be provided to the individual patient before health care services are provided, except in emergency cases when notice may be provided as soon after the emergency as is practicable or to a parent or legal guardian when the patient lacks legal responsibility for his/her care under State law.

This is to notify you that under Federal law relating to the operation of free clinics, the Federal Tort Claims Act (FTCA), (See 28 U.S.C. §§ 1346(b), 2401(b), 2671-80) provides the exclusive remedy for damage from personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions by any free clinic volunteer health care practitioner who the Department of Health and Human Services has deemed to be an employee of the Public Health Service. This FTCA medical malpractice coverage applies to deemed free clinic volunteer health care practitioners who have provided a required or authorized service under Title XIX of the Social Security Act (i.e., Medicaid Program) at a free clinic site or through offsite programs or events carried out by the free clinic (See 42 U.S.C. § 233(a), (o)).

The above Federal law and other State and Federal laws including the Federal Volunteer Protection Act of 1997 may cover certain free clinic health care professionals providing health care services to patients at this free clinic.

Acknowledged:

_____ (Patient signature)

_____ (Patient name, printed legibly)

Date: _____

Proposed Project: Free Clinic FTCA Deeming Application (OMB No. 0915-0293)

Revision

Appendix D

FREE CLINIC FEDERAL TORT CLAIMS ACT (FTCA) PROGRAM Annual Number of Free Clinic Patient Visits Which Are Covered by FTCA

Malpractice Coverage

Free Clinic FC # _____

Please list the annual number of the free clinic's patient visits which are covered by the FTCA malpractice coverage. This data should be reported for the calendar year. This data should be sent to The Bureau of Primary Health Care by February 28 for the prior calendar year. (I.e., the annual number of the free clinic's patient visits which are covered by the FTCA malpractice coverage for the year 2009, should be reported to The Bureau of Primary Health Care by February 28, 2010.)

For the year _____, the annual number of the free clinic's patient visits, which are covered by the FTCA malpractice coverage, is _____ patient visits.

This annual data should preferably be sent by email to the Bureau Free Clinic FTCA Program, FTCA Patient Visits Data Report, c/o Mike Chellis at mchellis@hrsa.gov with an email cc to freeclincsFTCA@hrsa.gov. (Please always include your free clinic FTCA # (FC00xx) in the subject line of these emails other communications with the Free Clinic FTCA Program.