U.S. Department of Health and Human Services
HRSA
Health Resources and Services Administration

POLICY INFORMATION NOTICE

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Revision (November 18, 2014): Updated OGC/GLD/CELB contact information (page 15)

TO: Free Clinics
Free Clinic Associations
Primary Care Associations
Primary Care Offices
National Cooperative Agreements

The purpose of this Policy Information Notice (PIN) is to explain and outline the Free Clinics Federal Tort Claims Act (FTCA) Program. The Free Clinics FTCA Program (the Program) was created by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and expanded by the Patient Protection and Affordable Care Act (Public Law 111-148) (Affordable Care Act) granting FTCA coverage for volunteer health professionals, board members, officers, employees, and contractors. In light of this new expansion, the Health Resources and Services Administration (HRSA) issued this PIN to expand and clarify guidance for the Program. This PIN, therefore, supersedes PIN 2004-24 and Program Assistance Letter (PAL) 2010-08. Guidance that has been provided regarding the application process (PAL 2010-11) and data collection processes (PAL 2011-03) remains in effect and therefore supplements this PIN.

This PIN includes an explanation of the Program including covered individuals, covered services and activities, and the claims process. It also clarifies program requirements such as credentialing and privileging systems, risk management activities, data reporting, and providing patients a notice of limited liability. More information on the application process and form can be found at http://bphc.hrsa.gov/ftca/freeclinics/.

A draft version of this PIN was released in July 2010 with a comment period running through October 22, 2010. Three organizations commented on the draft PIN. One commenter was concerned about data collection and the ability of free clinics to collect data on patients when many free clinics operate a drop-in clinic and do not have established patients. This concern was taken into consideration in developing revised data requirements. There was also a comment requesting clarification of the definitions of covered individuals. The final PIN was re-

worded in order to provide more clarity in defining Board Members and Officers for purposes of the Free Clinics FTCA Program. Finally, a comment noted the inability of some free clinics to fully comply with the credentialing and privileging requirements. These concerns were considered, though no change has been made to the current requirements.

If you have any questions or require further guidance, please contact the Bureau of Primary Health Care at 877-974-BPHC (877-974-2742).

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I. PURPOSE

This Program Information Notice (PIN) supersedes PIN 2004-24 and Program Assistance Letter (PAL) 2010-08 and provides detailed information regarding the implementation of the **Free Clinics Federal Tort Claims Act (FTCA) Program (the Program)** as authorized by Section 194 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and extended by the Patient Protection and Affordable Care Act (Public Law 111-148) (Affordable Care Act). This PIN provides information on:

1) Covered Individuals;
2) Covered Services and Activities;
3) Program Requirements;
4) Claims Process; and
5) Other Recommended Insurance.

II. OVERVIEW

Congress afforded medical malpractice liability insurance protection under the FTCA, 28 U.S.C. §§ 1346(b), 2401(b), 2671-80, to volunteer free clinic health care professionals through enactment of Section 194 of HIPAA (Public Law 104-191), which added a new subsection to Section 224 of the Public Health Service (PHS) Act (42 U.S.C. § 233(o)). Congress later extended FTCA medical malpractice liability protection to free clinic board members, officers, employees, and contractors through Section 10608 of the Affordable Care Act, which amended 42 U.S.C. 233(o). If a volunteer health care professional, board member, officer, employee, or contractor meets all statutory and implementing Program requirements, the related free clinic may sponsor him/her to become, upon approval by the Secretary, a "deemed" PHS employee (i.e., "covered individual").

Eligible free clinic volunteer health care professionals, board members, officers, employees, and/or contractors do not receive deemed PHS employee status automatically. Free clinics must submit an annual application for deeming on behalf of their volunteer health care professionals, board members, officers, employees and contractors to the Department of Health and Human Services' (HHS) Health Resources and Services Administration, Bureau of Primary Health Care (HRSA, BPHC), which administers the Program. An annual Program Assistance Letter (PAL) specifies the yearly form of the application, which must be approved by HRSA and effected through a documented deeming determination. Deemed PHS employee status provides the covered individual with immunity from medical malpractice lawsuits and related civil actions resulting from the performance of qualifying health services within the scope of his/her work on behalf of the sponsoring free clinic. Persons alleging acts of medical malpractice by covered individuals must file their claims against the United States according to FTCA and applicable HHS regulatory requirements.

III. COVERED INDIVIDUALS

In order for a free clinic volunteer health care professional, board member, officer, employee and/or contractor to become a deemed PHS employee (i.e., a covered individual), the sponsoring free clinic entity and the individual to be covered by the deeming must meet certain statutory and implementing Program requirements, as further described below.

Free Clinic: A "free clinic," as defined by applicable law and Program requirements, is a health care facility operated by a non-profit private entity that:

1) In providing health services, does not accept reimbursement from any third-party payor (including reimbursement from any insurance policy, health plan, or Federal or State health benefits program);[1]
2) In providing health care, does not impose charges on patients to whom service is provided or impose charges on patients according to their ability to pay;
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.[2,3]

The PHS Act forbids free clinic volunteer health professionals and the sponsoring free clinic from receiving "***any compensation for the service*** from the individual or from any third-party payor" for a health service to be covered for medical malpractice insurance purposes by the Free Clinics FTCA Program. If a free clinic or deemed individual imposes a charge upon a patient for a service provided by a deemed individual at the free clinic, FTCA will not apply to the provision of these services. [4]

Volunteer free clinic health professional: A volunteer free clinic health professional, as defined by applicable law and Program requirements:

1) Provides services to patients at a free clinic or through offsite programs or events carried out by a sponsoring free clinic;
2) Is sponsored by the 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,

[1] Grant funding that applies to reimbursement, payment, or compensation for the delivery of health services to patients falls within the statutory prohibition, while grant funding that is not intended for or applied to this purpose does not.

[2] The requirements are those applicable to health care facilities under applicable Federal and State laws.

[3] For purposes of the Free Clinics FTCA program, a licensed or certified health care practitioner is an individual required to be licensed, registered, or certified, as applicable, to practice or provide health services by the State, Commonwealth, or territory in which the free clinic is located and services are being provided. These individuals may 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).

[4] The non-availability of FTCA coverage applies even if the charge is based on a sliding scale and the free clinic later elects not to pursue the charge, unless it can be demonstrated that the imposition of a charge was done through an administrative error and/or that the decision not to pursue payment was not occasioned in bad faith (i.e., for purposes of gaining FTCA coverage). This applies to all eligible individuals.

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 (including reimbursement from any insurance policy, health plan, or Federal or State health benefits program);[5]
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[6] 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)).

Board Members and Officers: HRSA accords these terms their ordinary meaning as set forth in standard business practice and state law. As is the case with free clinic volunteer health professionals, to be eligible for deemed PHS status with resulting FTCA coverage for purposes of medical malpractice protection, these individuals must be sponsored by a free clinic and have documentation that confirms their relationship with the sponsoring free clinic and that specifies their roles and duties.

Employees: HRSA generally applies the Internal Revenue Service (IRS) definitions and standards in determining who is an employee under the statute for purposes of FTCA coverage. To be considered as an employee by the IRS, the individual ordinarily must receive a salary from the employing entity (here, the sponsoring free clinic) with applicable taxes and benefits withheld, and the salary and withholdings should be documented by a W-2 form. As is the case with volunteer health professionals, to be eligible for deemed PHS status with resulting FTCA coverage for purposes of medical malpractice protection, employees must be sponsored by a free clinic, licensed in accordance with applicable State law, and credentialed and privileged to the extent applicable in accordance with this PIN. All employee health professionals must also comply with the above definition components listed for volunteer health professionals.

Contractor: For purposes of this Program, eligibility for coverage extends only to those individual contractors of the free clinic who are licensed or certified health care practitioners and comply with the above components listed for volunteer health professionals. The threshold requirement for deeming is a contract between the individual practitioner and the free clinic. A contract between a sponsoring free clinic and a corporation, including a contract with an eponymous professional corporation (defined as a professional corporation to which one has given one's name, e.g., John Doe, LLC, and consisting of only one health provider) does not provide sufficient basis for deemed status under the Free Clinics FTCA Program. As is the case with volunteer health professionals, to be eligible for deemed PHS employee status with resulting FTCA coverage for purposes of medical malpractice protection, individual contractors

[5] See footnote 4, above.
[6] See footnote 3, above.

must be sponsored by a free clinic, licensed in accordance with applicable State law, and credentialed and privileged to the extent applicable in accordance with this PIN to be eligible for coverage.

IV. COVERED SERVICES AND ACTIVITIES

Deemed PHS employees, for purposes of the Free Clinics FTCA Program, have FTCA coverage for negligent acts or omissions that:

1) Arise from services required or authorized to be provided under Title XIX of the Social Security Act, regardless of whether the service is included in the State plan then in effect for that State;
2) Arise from the provision of medical, dental, or related services at a free clinic site or through offsite programs or events carried out by the free clinic;
3) Occur during the effective deeming period after a FTCA deeming application submitted by the free clinic on behalf of its eligible individuals (i.e., volunteer health professionals, board members, officers, employees, and/or contractors) is approved; and
4) Arise from services provided at a free clinic or through offsite programs or events carried out by the free clinic in which no charge was imposed on a patient.

HRSA considers offsite programs and/or events to include health fairs or similar events where the sponsoring free clinic provides routine health screenings and educational activities. For other offsite programs, HRSA strongly encourages the free clinic to seek clarification regarding FTCA coverage from the Free Clinics FTCA Program. This request should include:

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

V. PROGRAM REQUIREMENTS

To be eligible for deemed PHS status, sponsoring free clinics and their FTCA covered individuals must satisfy statutory and Program requirements. The requirements related to free clinic health care professionals, credentialing and privileging systems, risk management system, patient notification of limited liability, review of medical malpractice claims history, and annual data reporting are described in detail in this PIN.

A. Credentialing and Privileging

Individuals who are required to be licensed or certified are eligible to be deemed as PHS employees for purposes of FTCA coverage for medical malpractice claims only if certain credentialing and privileging requirements are fulfilled by the sponsoring free clinic.

Definitions

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.

Sponsoring free clinics must satisfy 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.
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 health care professionals who are currently licensed or certified as applicable under State law 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 System[7]

The free clinic must determine whether each individual for whom deemed status is desired 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 sponsoring free clinic must provide acceptable assurances that these licensed or certified health care practitioners are properly credentialed and privileged. Credentialing and privileging requirements differ depending on whether the covered individual is a LIP or other licensed or certified health care practitioner.

Credentialing and Privileging of LIPs

Initial Credentialing of LIPs

The initial credentialing of LIPs should include:

1) Primary source verification of:
   a) Current licensure; and
   b) Relevant education, training, or experience.
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.
3) Additional verification by:
   a) 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); and
   b) Determining practitioner's 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);

For FTCA coverage to apply, the sponsoring free clinic must have completed the required 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 an 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 sponsoring 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

[7] For an overview of credentialing requirements, please see Appendix A – Credentialing Table.

accessibility to ancillary and tertiary medical practitioners. A free clinic could assess an 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).

Temporary Privileging Requirements for LIPs

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.

Although the free clinic should complete the privileging process prior to the LIP being allowed to provide patient care services, the following principles can be applied in cases where a free clinic has established temporary privileging policies and procedures. However, if the free clinic has established temporary privileging policies and procedures, it can apply these to grant temporary privileges to a LIP:

1) To meet important patient care needs for a limited period of time (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 sixty (60) 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 only provide temporary privileges when the LIP provides all information necessary for the privileging process and the free clinic staff successfully verifies 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.

Reassessment of the Credentials and Privileges of LIPs
The free clinic should reassess the credentials and privileges of LIPs at least every two (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).
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.

Credentialing and Privileging of Other Licensed of Certified Practitioners

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. In either case, the chosen credentialing process must be completed 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

While LIPs should be approved by the governing board, other licensed or certified health care practitioners may be approved by the Executive Director or his/her designee. The Executive Director should state in writing his/her determination that the 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. 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 Other Licensed or Certified Health Care Practitioners (Re-credentialing)

The free clinic should reassess the credentials and privileges of other licensed or certified health care practitioners at least every two (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).
4) Querying the NPDB, as applicable.

B. Risk Management Requirements

A sponsoring free clinic shall provide HRSA with a copy of the clinic's Quality Improvement/ Quality Assurance (QI/QA) plan that has been signed and approved by the Board of Directors. The QI/QA plan should be reviewed, approved, and signed by the Board of Directors every three (3) years. These plans identify each sponsoring free clinic's plan to mitigate risk and improve quality of care for its patients. The clinic should identify a plan for identification and evaluation of concerns, education plans for staff members regarding the QI/QA plan, and the responsibilities of management to ensure the implementation of the plan. This QI/QA plan should also address the free clinic's credentialing and privileging processes and risk management system in order to assure that they meet all program requirements.

C. Patient Notice of Limited Legal Liability

A free clinic covered individual or the free clinic itself must provide each patient with written notification of the limited liability of the health care professional pursuant to FTCA. The covered individual and/or free clinic can satisfy this 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 covered individual or free clinic obtains the patient's signature on the notice and includes the notice in the patient's medical record. If the covered individual is providing emergency care, either the covered individual or free clinic may provide the written notice as soon as practicable. The covered individual 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 on the Free Clinics FTCA website (http://bphc.hrsa.gov/ftca/freeclinics/). Free clinics also may choose to develop their own patient notice form. The free clinic's form should at a minimum address all of the requirements listed in the sample.

D. Review of Medical Malpractice Claims

HRSA reviews each application according to the requirements in § 224(h) of the PHS Act. Requested disclosures of medical malpractice claims and subsequent measures taken by the free clinic and eligible individuals are used to determine that appropriate policies and procedures are in place to reduce the risk of medical malpractice and lawsuits.

For each individual seeking FTCA coverage, the sponsoring free clinic shall include information about medical malpractice claims for the past ten years. In an attached form, information about each medical malpractice claim should include, but need not be limited to, an explanation about the suit, medical specialty involved, allegation, and any risk management actions taken by the free clinic and eligible individual to prevent such claims in the future.

E. Annual Data Reporting for Sponsoring Free Clinics

Each year, BPHC collects data on the sponsoring free clinics. Each sponsoring free clinic shall submit data on the number of deemed health care professionals at the clinic, the number of patients seen, and the number of visits each year. The reporting forms and submission information can be found each year on the Free Clinics FTCA website (http://bphc.hrsa.gov/ftca/freeclinics/). Reporting is conducted annually in the first quarter to report on the previous year's data.

VI. CLAIMS PROCESS

A. Operation of FTCA for Free Clinics

As previously discussed in this PIN, deemed volunteer health care professionals, board members, officers, employees, and/or individual contractors of free clinics are considered to be PHS employees and covered individuals for the purposes of FTCA coverage for medical malpractice claims. As such, they are immune from personal liability for claims of medical malpractice and related civil actions arising from their deemed PHS employee status. Should they be sued in State courts for actions arising within the scope of this deemed employment, they should ensure prompt notification of the litigation to the U.S. Department of Health and Human Services' (HHS) Office of the General Counsel (OGC) so that the action may be removed to Federal district court and the United States substituted as the named defendant. The covered individuals will not be financially liable for any civil actions arising from their covered activities. However, this immunity does not preclude related actions by Federal, State and other licensing and certifying bodies, including reporting of claims payments to the National Practitioner Data Bank.

FTCA coverage is comparable to an occurrence type of malpractice policy and does not have a specific coverage limit with a monetary cap. Therefore, any coverage limits required by other organizations, such as hospitals, are met under FTCA. For example, a local hospital requirement of $1 million per claim and $3 million annual aggregate occurrence is met since FTCA would, as appropriate, provide for the payment of any damages awarded as a result of a settlement or judgment sums in excess of that amount. Under the FTCA, however, no punitive damages are allowed.

B. Overview of Claim Filings

The requirements for the filing of a FTCA claim are found in Federal law, implementing regulations, and case law. The FTCA is found at 28 U.S.C. §§ 1346(b), 2401(b), 2671-80.
To begin the process of filing a FTCA claim, a claimant must pursue the following:

- **Administrative Remedy:** A claimant must first seek an administrative remedy by presenting his or her claim with the HHS Office of the General Counsel (OGC), General Law Division (GLD), Claims and Employment Law Branch (CELB). Under the FTCA, if the claim is denied or a settlement is not reached within six months of such presentment, the claimant can sue the United States in the appropriate Federal district court. Alternatively, a claimant may request reconsideration of the denial of an administrative tort claim within six months after issuance of the denial.
- **Litigation:** Once an administrative claim (or a reconsideration request, if applicable) has been denied by HHS, the claimant must file suit within six months in the appropriate Federal district court or the action will be barred. Cases are heard in Federal district court without a jury, and are defended by the Department of Justice (DOJ) with the assistance of HHS OGC.

Occasionally, a claimant erroneously files a lawsuit in State court in lieu of filing an administrative claim with HHS or less than six months after filing an administrative claim with HHS. These lawsuits are termed premature lawsuits. In the event that a claimant erroneously files a claim or serves premature lawsuit documentation directly with the covered individual, that person should fax a copy of the documentation to OGC/GLD/CELB at the address below:

U.S. Department of Health and Human Services
Office of the General Counsel
General Law Division
Claims and Employment Law Branch
330 C Street, SW
Attention: CLAIMS
Switzer Building, Suite 2600
Washington, D.C., 20201
Phone: (202) 619-2155
Fax: 202-619-2922
HHS-FTCA-Claims@hhs.gov

: :

With regard to premature lawsuits in which a claimant files a lawsuit against a covered individual in State court, the sponsoring free clinic or its private counsel should make arrangements to obtain at least a sixty (60) day extension from the court to answer the complaint.

A covered individual representative should also immediately call or email OGC/GLD/CELB and ask to speak to any of the CELB FTCA attorneys for advice on how to proceed.

C. Required Documentation for Claims Processing and Certification of Scope of Employment

The applicability of FTCA to a particular claim or case will depend upon verification by HHS OGC and/or certification by the United States Attorney, as appropriate, that:

1) The individual is covered by the Act (see **Section III: Covered Individuals);**
2) The act or omission giving rise to the claim was within the covered services (see **Section IV: Covered Services and Activities);** and
3) The act or omission giving rise to the claim occurred during the provision of services to sponsoring free clinic patients.

Such certification or failure to certify is subject to judicial review.

The documents identified below are used by OGC/GLD/CELB to verify a covered individual's FTCA claim eligibility. The verification process also confirms that the covered individuals were performing at a free clinic site or an approved off site event and within the scope of the statute. Upon HHS OGC request, the covered individual must provide to HHS OGC, as applicable, required documentation, with tabs matching each of the individual items below, and retain copies for filing. A covered individual should ensure that the dates of the documents correspond to the dates of the incident.

Required Documents for Premature Lawsuits and Claims Disposition

a) Three copies of the summons and complaint.
b) Three copies of the covered individual's initial deeming letter and all subsequent redeeming documentation including Notices of Deeming Award (NDAs) containing re-deeming language or re-deeming letters, as appropriate.
c) Three copies of the sponsoring clinic's nonprofit status documentation.
d) Three copies of a statement, on sponsoring clinic letterhead, identifying which providers are involved or named in the claim and their dates of employment, dates of contract, or dates of volunteer activities at the sponsoring clinic (if not already provided for a premature lawsuit relating to the same incident).
e) Evidence that the named providers were licensed physicians or licensed or certified health care providers at the time of the incident, including documentation of the specialty of all named providers.
f) If the alleged incident arises from acts or omissions that occurred outside of the sponsoring clinic's approved service sites, the name and address of the outside facility and information as to the nature of the affiliation between the outside facility, free clinic and its personnel.
g) Three copies of any written agreements between the free clinic and the covered individual.
h) Three copies of the Wage and Tax statements (W-2) for each employed individual involved in the alleged incident for the period of time covered by the claim.

i) If the provider whose care is at issue was a licensed or certified health care provider contractor at the time of the alleged incident, three copies of the 1099 form, and a contract for services covering the period of the alleged incident.
j) Three copies of a declaration verifying the association of each individual involved in the alleged incident on the free clinic's letterhead, signed by each provider whose care is at issue.
k) Three copies of any professional liability or gap insurance policy that provides coverage to the free clinic and/or the named provider. The policies must cover the dates of the alleged incident. If neither the sponsoring free clinic nor the covered individual involved in the alleged incident has medical malpractice coverage other than that provided under FTCA, the covered individual should submit a statement on free clinic letterhead addressing that fact. However, if the covered individual has purchased his/her own individual professional liability medical malpractice insurance coverage, which was in effect during the allegation time period, the covered individual must provide evidence of this coverage.
l) All correspondence received from the claimant pertaining to the claim.
m) The name and telephone number of a contact at the free clinic familiar with the certification information described above.
n) Three copies of all of the claimant's medical records including x-rays, laboratory reports, and other results and treatments from the sponsoring free clinic and any private facility that might be involved. (Note: The original medical records should be sequestered by the health center and retained until instructed to do so by OGC.)

Note: If a claim or lawsuit involving covered activities is presented or filed, it is essential that the covered individual notify and cooperate with the sponsoring free clinic and OGC so that all potentially relevant documents are preserved. Once a covered individual reasonably anticipates litigation—and it is reasonable to anticipate litigation once a claim or lawsuit is filed, whether administratively or in state or Federal district court—the individual must suspend any routine destruction and hold any documents relating to the claimant or plaintiff so as to ensure their preservation.

Additional and more detailed information regarding document retention will be provided after a claim or lawsuit is filed. However, covered individuals and sponsoring free clinics should be aware of this requirement, act accordingly whenever a claim or lawsuit is filed, and seek further guidance from HHS OGC before destroying any potentially relevant documents.

D. Statute of Limitations

An FTCA claim must be presented within two years after the claim accrues. Generally, accrual occurs on the date of the injury. However, Federal case law also incorporates a discovery rule for determining claim accrual or starting date for the statute of limitations. Under the discovery rule, the statute of limitations commences when a person discovers, or in the exercise of reasonable care should discover, injury due to another's negligence. State statute of limitations periods do not apply to claims filed under the FTCA.

E. Medical Claims Review Panel (MCRP)

If a payment is made on an FTCA claim, the claim is then reviewed by the MCRP to identify the providers and to determine whether the standard of care was met for purposes of reporting to the National Practitioner Data Bank (NPDB).

F. Other Considerations within the Litigation Process

Litigation of FTCA Cases

Malpractice claims filed against the Public Health Service under the FTCA are handled by HHS OGC and DOJ. The delegated authority for HHS lies with the General Law Division's CELB, whose FTCA attorneys are experienced in medical malpractice tort law.

DOJ is responsible for the defense of all litigation arising from acts or omissions covered under the FTCA. Within DOJ, a case ordinarily is assigned to a U.S. Attorney's Office where it is handled by an Assistant U.S. Attorney, with litigation support from HHS. In addition, DOJ Torts Branch attorneys may provide guidance to U.S. Attorney's Offices in consultation with attorneys from HHS OGC.

Subpoenas and Other Requests for Testimony

If a covered individual or others associated with a sponsoring free clinic are requested to provide testimony in litigation pertaining to medical malpractice cases, please contact BPHC and/or the HHS OGC. These requests or questions can be forwarded to bphchelpline@hrsa.gov or the address for the Office of the General Counsel listed above.

VII. CONTACT INFORMATION

For more information on the free clinics deeming application requirements and related questions, please contact:

- By Email — FreeclinicsFTCA@hrsa.gov
  (Please **always** include your free clinic FTCA # (FC XXXX) in the subject line of these emails or other communications with the Free Clinics FTCA Program.)
- By Phone — BPHC Helpline 877-974-BPHC (877-974-2742) – 8:30 AM to 5:00 PM (ET)

VIII. OTHER RECOMMENDED INSURANCE

The Program provides protection against allegations of medical negligence for volunteer free clinic health professionals, board members, officers, employees, and/or contractors as defined in Section III of this PIN and who have been deemed to be PHS employees. **Other free clinic personnel and the free clinic entity or corporation are not eligible to be covered under FTCA.** Additionally, the Program does not provide protection against perils normally protected by general liability and directors' and officers' insurance policies (beyond medical malpractice). Sponsoring 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.

APPENDIX A
Credentialing Table*

Provider/Credentialing	Primary Source Verification	Secondary Source Verification	Other Verification	Approval
Licensed Independent Practitioner – *Initial Credentialing*	• Current licensure • Relevant education, training, and experience	• Identification • DEA registration (as applicable) • Hospital admitting privileges (as applicable) • Immunization and TB skin test results status • Life support training (as applicable)	• Health fitness or ability to perform requested privileges • National Practitioner Data Bank (practitioner may self query and provide clinic with report)	Written approval by governing board or board's designee
Licensed Independent Practitioner – *Re-Credentialing*	• Current licensure	• Adherence to free clinic policies, procedures and rules • Relevant education training and experience (if changed) • Practitioner's ability to perform the care, treatment, services expected	• Synopsis of peer review results OR relevant performance improvement information • NPDB query	Written approval by governing board or board's designee
Other Practitioners – *Initial Credentialing*	• Current licensure, registration, or certification	• Education and training • Identification • DEA registration (as applicable) • Hospital admitting privileges (as applicable) • Immunization and TB skin test results • Life support training (as applicable)	• National Practitioner Data Bank (practitioner may self query and provide clinic with report)	Written approval by Executive Director or designee
Other Practitioners – *Re-Credentialing*	• Current licensure, registration, or certification	• Adherence to free clinic policies, procedures and rules • Relevant education training and experience (if changed) • Practitioner's ability to perform the care, treatment, services expected	• Supervisor's evaluation of performance • NPDB query	Written approval by Executive Director or designee

* In addition to credentialing, free clinics must also privilege providers according to Section V(A): Credentialing and Privileging