



PROGRAM ASSISTANCE LETTER

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Federal Tort Claims Act (FTCA) Deeming
Application for Free Clinics

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

I. PURPOSE

This Program Assistance Letter (PAL) supplements Policy Information Notice (PIN) 2011-02, "Free Clinics Federal Tort Claims Act (FTCA) Program Policy Guide" (<http://bphc.hrsa.gov/ftca/freeclinics/pin1102.html>), and provides guidance on the Calendar Year (CY) 2016 deeming application process for liability coverage under the provisions of section 224(o) of the PHS Act and the Federal Tort Claims Act (FTCA). This PAL contains instructions for free clinics on how to apply to HRSA for coverage under the FTCA for CY 2016 on behalf of their volunteer free clinic health care professionals, board members, officers, employees, and/or contractors. **The Electronic Handbook (EHB) system will be available to begin receiving CY 2016 applications on August 10, 2015.** Redeeming applications for CY 2016 coverage are due no later than September 7, 2015.

FTCA coverage is provided to certain qualified free clinic volunteer health care professionals, board members, officers, employees, and/or contractors (covered individuals) under section 224(o) of the Public Health Service (PHS) Act, as amended (42 U.S.C. 233(o)). PIN 2011-02 details the process through which the United States Department of Health and Human Services' (HHS) Health Resources and Services Administration (HRSA) may deem such individuals to be a PHS employee for the purposes of FTCA coverage for medical malpractice claims if the eligible individual meets certain statutory and program requirements.

Free clinics must submit an annual FTCA deeming application on behalf of their eligible individuals to HRSA, which administers the Free Clinic FTCA Program. With the amendment of PHS Act section 224(o) by the Affordable Care Act, free clinic board

members, officers, employees, and/or individual contractors, as well as volunteer health care professionals, whose deeming applications are approved by HRSA, may be deemed as PHS employees for purposes of FTCA liability coverage. FTCA coverage for these individuals extends only to coverage for negligent acts and omissions that arise from the performance of medical, surgical, dental, or related functions within the scope of the covered individual's employment (generally speaking, work on behalf of the sponsoring free clinic). Section 224(o) does not provide coverage beyond this form of liability protection. **FTCA coverage also does not extend to free clinic entities, as these entities are not eligible for coverage under PHS Act section 224(o).**

Under section 224(o)(5)(e) (42 U.S.C. 233(o)(5)(e)), FTCA coverage applies to eligible individuals for the provision of services only to the extent that certain conditions specified in section 224(o)(2) (42 U.S.C. 233(o)(2)) are met.¹ Other requirements under this section also pertain.

II. APPLICATION PROCEDURES AND THE FREE CLINIC ELECTRONIC HANDBOOK SYSTEM

Coverage under the Free Clinic FTCA Program does not occur automatically. FTCA coverage requires that HRSA approve a deeming application submitted by a sponsoring free clinic on behalf of specifically named eligible individuals. (See 42 U.S.C. 233(o); PIN 2011-02) It is important to note, **HRSA requires that all free clinic applications be submitted using HRSA's Web-based Electronic Handbook (EHB) system.**

¹ Section 224(o)(2) requires, in providing health services to an individual, that certain conditions be present. These include the following:

- (A) The service is provided to the individual at a free clinic, or through offsite programs or events carried out by the free clinic.
- (B) The free clinic is sponsoring the health care practitioner pursuant to paragraph (5)(C).
- (C) The service is a qualifying health service (as defined in paragraph (4)).
- (D) Neither the health care practitioner nor the free clinic receives any compensation for the service from the individual or from any third-party payor (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program). With respect to compliance with such condition:
 - (i) The health care practitioner may receive repayment from the free clinic for reasonable expenses incurred by the health care practitioner in the provision of the service to the individual.
 - (ii) The free clinic may accept voluntary donations for the provision of the service by the health care practitioner to the individual.
- (E) Before the service is provided, the health care practitioner or the free clinic provides written notice to the individual of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection (or in the case of an emergency, the written notice is provided to the individual as soon after the emergency as is practicable). If the individual is a minor or is otherwise legally incompetent, the condition under this subparagraph is that the written notice be provided to a legal guardian or other person with legal responsibility for the care of the individual.
- (F) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable law regarding the provision of the service.

As a part of continued efforts to streamline and automate data reporting processes, the Bureau of Primary Health Care (BPHC) developed a Free Clinic FTCA Program deeming module within the HRSA EHB.

Free clinics that experience technical difficulties preventing them from submitting an application using the EHB system may request a waiver to submit their application using the Microsoft Excel application. Waiver requests must be submitted before September 7, 2015, the Redeeming Cycle deadline, and should be sent to freeclinicsFTCA@hrsa.gov. HRSA will review all requests for waiver, and if approved, will provide the free clinic with an alternate application and instructions for submission.²

A. INITIAL APPLICATIONS

Free clinics must complete a deeming application in order to sponsor eligible individuals for FTCA coverage. (See 42 U.S.C. 233(o); PIN 2011-02) Applications require that the appropriate free clinic representative(s) electronically sign by typing his or her name in the appropriate field, upload documentation of the sponsoring free clinic's nonprofit status, upload the free clinic's quality improvement/quality assurance (QI/QA) plan, and include an explanation of any medical malpractice claims or any disciplinary actions taken against an eligible individual during the past ten (10) years. The required information must be uploaded as attachment files within the online EHB application form.

The initial deeming EHB application requires a free clinic to provide information as evidence that it has fulfilled statutory and programmatic requirements, including:

- 1) Contact information for the sponsoring free clinic;
- 2) Location and manager(s) of free clinic sites;
- 3) Confirmation that the sponsoring free clinic and individuals for whom deeming is sought meet the statutory eligibility criteria;
- 4) Description of the free clinic's credentialing and privileging systems;
- 5) Description of the free clinic's risk management systems;
- 6) List of all individuals (i.e., volunteer health care professionals, board members, officers, employees, and individual contractors) whom the free clinic is sponsoring for deemed employment status;
- 7) Evidence that each licensed or certified individual was credentialed and privileged by the sponsoring free clinic within the last two (2) years, including the specific dates such actions were taken; and
- 8) Requested effective date of FTCA coverage (which may not be less than 30 days following submission of a complete application).

In addition to addressing the requirements noted above, an application will not be considered complete without the following attachments:

- a. Documentation of non-profit status;

² Explanations that may be considered permissible include, but are not limited to, natural disasters or a serious emergency at the free clinic that makes it impossible for the free clinic to submit its application in the EHB system.

- b. Quality Improvement/Quality Assurance plan (QI/QA) with either a signature of an authorized board representative indicating date of board approval or a copy of board minutes documenting approval;
- c. Description of any and all disciplinary actions and malpractice claims alleged against the free clinic and/or its sponsored eligible individuals within **ten (10) years prior** to the submission of this FTCA application (including pending claims), and a brief statement of whether the clinic implemented appropriate risk management activities as needed in response to allegations, and to prevent further claims from occurring in the future; and
- d. Affirmation signatures (entered as electronic signatures) by the Chief Executive Officer and Medical Director of the sponsoring free clinic that all statements and assertions made by the application are true under penalty of perjury.

HRSA will accept initial EHB deeming applications at any time a free clinic and its eligible individuals wish to pursue FTCA liability coverage. The EHB application form can be found at <https://grants.hrsa.gov/webExternal/>.

B. REDEEMING APPLICATIONS

Free clinics that currently sponsor deemed individuals must reapply annually for continued FTCA coverage. (See 42 U.S.C. 233(o); PIN 2011-02) The annual redeeming application should be submitted through the EHB at <https://grants.hrsa.gov/webExternal/>.

The EHB redeeming application requires a free clinic to provide information to demonstrate that it has fulfilled statutory and program requirements, including:

- 1) Contact information for the sponsoring free clinic;
- 2) Location and manager(s) of free clinic sites;
- 3) Confirmation that the sponsoring free clinic and individuals for whom deeming is sought meet the statutory eligibility criteria;
- 4) Description of the free clinic's credentialing and privileging systems;
- 5) Description of the free clinic's risk management systems;
- 6) List of all individuals (i.e., volunteer health care professionals, board members, officers, employees, and individual contractors) whom the free clinic is sponsoring for deemed employment status;
- 7) Evidence that each licensed or certified individual was credentialed and privileged by the sponsoring free clinic within the last two (2) years, including the specific dates such actions were taken; and
- 8) Requested preferred effective date of FTCA coverage (which may not be less than 30 days following submission of a complete application).

In addition to addressing the requirements noted above, an application will not be considered complete without the following attachments:

- a. Quality Improvement/Quality Assurance plan (QI/QA) with either a signature of an authorized board representative **that notes the date of board approval or a dated copy of board minutes, with appropriate signature(s), documenting approval (either method of submission must evidence that approval was**

undertaken within the last three (3) years);

- b. Description of any and all disciplinary actions and medical malpractice claims alleged against any sponsored eligible individuals within **five (5) years prior** to the submission of this FTCA application (including pending claims), and a brief explanation of each medical malpractice claim or disciplinary action including explanations of the suit, allegation, medical specialty involved, and a statement of whether appropriate action was taken by the clinic to reduce the risk of malpractice and future such claims; and
- c. Affirmation signatures (entered as electronic signatures) by the Chief Executive Officer and Medical Director of the sponsoring free clinic.

EHB Redeeming applications for CY 2016 coverage are due on or before **September 7, 2015**.

C. SUPPLEMENTAL APPLICATIONS

During the course of the calendar year, sponsoring free clinics may wish to add additional eligible individuals for FTCA coverage. In order to supplement the free clinic's list of covered individuals, an EHB supplemental application must be completed and submitted. This application can be found at <https://grants.hrsa.gov/webExternal/>. Please note that supplemental applications received before the end of the calendar year, and after the submission of the annual redeeming application, will continue to be treated as both a supplemental application and an effective redeeming application for those individuals listed in the supplemental application. For example, a free clinic submits a redeeming application on September 7, 2015, and then submits a supplemental application for Dr. Smith on August 31, 2015. After both applications are reviewed, and if both are approved, Dr. Smith would then be deemed as of August 31, 2015, through December 31, 2016, as per the supplemental application, and for all of calendar year 2016, as per the redeeming application.

A supplemental EHB application form requires:

- 1) Contact information for the sponsoring free clinic;
- 2) Location and managers of any new free clinic sites that have been added since the free clinic's last FTCA application submission;
- 3) Confirmation that the sponsoring free clinic and individuals for whom deeming is sought meet the statutory eligibility criteria;
- 4) 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;
- 5) List of all additional individuals (i.e., volunteer health care professionals, board members, officers, employees, and individual contractors) whom the free clinic is sponsoring for deemed employment status;
- 6) Requested effective date of FTCA coverage (which may be not less than 30 days following submission of a complete application).

In addition to a completed EHB supplemental application form, an overall supplemental

application will not be considered complete without the following:

- a. An uploaded copy of the new QI/QA plan **only** if it has changed since the most recent original or redeeming deeming application;
- b. Description of any and all disciplinary actions and malpractice claims alleged against any **new** sponsored eligible individuals within **ten (10) years prior** to the submission of this FTCA application (including pending claims), and a brief explanation of each medical malpractice claim or disciplinary action including explanations of the suit, allegation, medical specialty involved, and a statement of whether appropriate action was taken by the clinic to reduce the risk of malpractice and future such claims; and
- c. Affirmation signatures (entered as electronic signatures) by the Chief Executive Officer and Medical Director of the sponsoring free clinic.

III. CALENDAR YEAR DATA COLLECTION

As of calendar year (CY) 2015, FTCA Free Clinics are required to submit their annual data report within their annual redeeming application within the EHB online system. Redeeming applications will not be considered complete if the annual data report section is not completed. As in previous years, free clinics are required to report the total number of FTCA deemed individuals in the recently closed calendar year, total number of FTCA deemed providers in the recently closed calendar year, and total number of “FTCA-covered” patient visits conducted by FTCA deemed individuals in the recently closed calendar year. FTCA patient visits must be those that were conducted by FTCA deemed providers. Patient visits, solely for purposes of reporting under this section, are defined as documented, face-to-face contacts between a patient and an FTCA deemed provider who exercises independent professional judgment³ in the provision of services to the patient.⁴ To be included as a visit for this purpose, services rendered must be documented in a medical record in the possession of the free clinic. In addition, this number should represent only the number of FTCA-covered patient visits. FTCA deemed providers are defined as licensed or certified, healthcare practitioner clinicians that have been deemed as “Public Health Service” employees for FTCA coverage purposes. FTCA deemed providers include licensed and non-licensed, and/or certified and non-certified healthcare practitioners that have been deemed as “Public Health Service” employees for FTCA coverage purposes. For a patient visit to be “FTCA covered,” under this section, the provider must be FTCA-deemed, and the encounter must comply with all applicable Free Clinic FTCA Program requirements. The annual data report is due by the end of the application cycle following the close of that calendar year. For example, the annual data report on the number of FTCA patient visits by deemed individuals in 2014 is due on or before **September 7, 2015**.

³ To meet the criterion for “independent professional judgment,” the provider must be acting on his/her own when serving the patient and not assisting another provider. For example, a nurse assisting a physician during a physical examination by taking vital signs, taking a history, or drawing a blood sample, even when acting within the approved scope of project, is not credited with a separate visit for reporting purposes.

⁴ This does not mean that a specific encounter or activity, while not constituting a “patient visit” for reporting purposes under this section, has not occurred within the approved scope of project and therefore is not eligible for FTCA coverage.

IV. GENERAL APPLICATION SUBMISSION INSTRUCTIONS

To streamline the FTCA deeming application submission and processing, free clinics should submit the deeming application within the EHB online system. Please do not submit a printed and scanned version of the application form. Supplemental EHB applications should contain new names of individuals requested to be added to a sponsoring free clinic and not currently deemed individuals.

All Initial, Redeeming, and Supplemental applications require an uploaded attachment explaining any and all disciplinary actions and medical malpractice claims alleged against the eligible individuals applying for deeming. Documentation related to a disciplinary action must include: nature and reason for the disciplinary action; timeframe (where applicable); documentation from the appropriate professional board that states the volunteer is approved to volunteer or work at the sponsoring free clinic (where applicable). This information is required for the past ten (10) years for new applicants and five (5) years for renewal applicants. Do not upload a report from the National Practitioner Data Bank (NPDB), as these reports do not describe the actions taken by the sponsoring free clinic or the applicant in response to the claims. Additionally, an NPDB report may disclose information exceeding the time frame requested.

Should review of the application reveal that the required application information supplied by the sponsoring free clinic is incomplete or additional verification is required, the CEO and FTCA Contact listed on the application will both be contacted via email. The sponsoring free clinic will have ten (10) business days from the date of notification to submit the requested information to complete its application. If the requested information is not received within the 10-day time period, individuals sponsored by the free clinic may not be deemed by January 1, 2016, and may experience a gap in coverage.

V. CONTACT INFORMATION

For more information on the free clinic deeming application requirements and related questions, please call the Office of Quality Improvement at (301) 594-0818, email freeclinicsFTCA@hrsa.gov, or call the BPHC Helpline at 1-877-974-2742.

James Macrae
Associate Administrator for Primary Health Care

APPENDIX A

FREE CLINIC FTCA PROGRAM APPLICATION CHECKLIST

APPLICATION CHECKLIST	<ul style="list-style-type: none"> – Free Clinic Deeming Application for Volunteer Health Care Professionals, Board Members, Officers, Employees, and/or Individual Contractors – Deeming Application – Original and/or Annual Renewal
<p>ITEMS TO BE UPLOADED in the EHB:</p> <ol style="list-style-type: none"> 1) Copy of nonprofit documentation (Initial Application Only) 2) Copy of clinic’s Quality Improvement/Quality Assurance (QI/QA) plan 3) Descriptions of all medical malpractice claims occurring within (ten) 10 years prior to the submission of this deeming application for initial applications or (five) 5 years prior for renewal applications. 	

APPLICATION NOTES BY SECTION

*** Please note that one or more application questions for the sections marked with an asterisk have been slightly revised**

Section I – Sponsoring Free Clinic

- Send state documentation indicating legal name change if legal name change occurred since last deeming application.

Section II – Free Clinic Sites

- All free clinic sites must be listed. Each site must be appropriately identified as the main site or as an additional site.

Section III – Sponsoring Free Clinic Eligibility

- Provide an explanation of any “No” answers in the box below the question.
- Attach IRS nonprofit documentation to application (if Initial Application).

***Section IV – Credentialing and Privileging Systems**

- Provide an explanation of any “No” answers in the box below the question.

***Section V– Risk Management Systems**

- Provide an explanation of any “No” answers in the box below the question.
- Attach a copy of the free clinic’s QI/QA plan, including an explanation of the clinic’s risk management policies. QI/QA plans must be signed and approved by an authorized board member within three (3) years of the date of the application.

Section VI – Free Clinic Volunteer Health Care Professionals, Board Members, Officers, Employees, and Individual Contractors

- Provide a list of ALL free clinic volunteer health professionals, board members, officers, employees, and individual contractors on whose behalf the free clinic is submitting an application for FTCA deemed status.
- Provide a physical address for ALL free clinic volunteer health professionals, board members, officers, employees, and individual contractors on whose behalf the free

clinic is submitting an application for FTCA deemed status. Addresses provided for individuals must be personal mailing addresses that are different than that of the clinic.

- Specify the person's role in the free clinic for any individual the free clinic is sponsoring for FTCA deemed status.
- Disclose if the individual has had any past medical malpractice claims or disciplinary actions for the past ten (10) years if submitting an original application or for the past five (5) years for renewal applicants.
- Attach an explanation of each medical malpractice claim or disciplinary action (to include probationary actions) including explanations of the suit, allegation, medical specialty involved, and a brief statement of whether the clinic implemented appropriate risk management actions as needed in response to allegations to reduce the risk of future malpractice and future such claims. Documentation related to a disciplinary action must include: nature and reason for the disciplinary action; timeframe (where applicable); documentation from the appropriate professional board that states the volunteer is approved to volunteer or work at the sponsoring free clinic (where applicable).