



PROGRAM ASSISTANCE LETTER

DOCUMENT NUMBER: 2019-02

DOCUMENT NAME: Calendar Year 2020 Requirements for Federal Tort Claims Act (FTCA) Coverage for Health Centers and Their Covered Individuals

DATE: April 10, 2019

TO: Health Center Program Award Recipients
National Cooperative Agreements
Primary Care Associations
Primary Care Offices

I. PURPOSE

The purpose of this Program Assistance Letter (PAL) is to inform Health Center Program stakeholders of the process and requirements for submitting Federal Tort Claims Act (FTCA) Program initial deeming and annual redeeming applications for calendar year (CY) 2020. This PAL supersedes PAL 2018-01, "Calendar Year 2019 Requirements for Federal Tort Claims Act (FTCA) Coverage for Health Centers and their Covered Individuals." This PAL does not address the specifics of the deeming process for Health Center Volunteer Health Professionals (VHPs), which are addressed in the VHP PAL on the Health Center VHP FTCA Program website <https://bphc.hrsa.gov/ftca/about/health-center-volunteers.html>.

Health Center Program award recipients applying for FTCA deeming for the entity and any covered individuals (not including VHPs) must demonstrate to the Health Resources and Services Administration (HRSA), the Secretary's designee for this purpose, that they have met applicable requirements for implementing appropriate policies and procedures for risk management and quality improvement (QI)/quality assurance (QA), conducting credentialing and privileging, and complying with claims management requirements.

This PAL contains the instructions for applicants submitting:

1. An FTCA application requesting initial deeming; or
2. An annual FTCA redeeming application for coverage for CY 2020 (January 1, 2020 - December 31, 2020).

II. PROGRAM UPDATES

In order to be deemed or redeemed for the upcoming calendar year, applicants must demonstrate via their FTCA application that they meet FTCA requirements for risk management, QI/QA, credentialing and privileging, and claims management. The CY 2020 FTCA deeming application questions and required submissions have been revised to reduce burden on applicants and clarify how applicants can meet these requirements.

Note: The presence of an active (unresolved) condition based on noncompliance with the Health Center Program requirements for credentialing and privileging and/or QI/QA may be deemed to demonstrate noncompliance with the corresponding FTCA Program requirements and may therefore result in disapproval of a deeming application.¹ The deeming application at the end of this document provides further clarification.

III. BACKGROUND

Eligible entities (including Health Center Program award recipients and subrecipients, as defined in grants regulations² and the Health Center FTCA regulations³) may be deemed by HRSA as employees of the Public Health Service (PHS) for purposes of liability protections for the performance of medical, surgical, dental, and related functions pursuant to the Federally Supported Health Centers Assistance Acts (FSHCAA) of 1992 (Pub. L. 102-501) and 1995 (Pub. L. 104-73), as amended.

Eligible Health Center Program award recipients and subrecipients -- hereafter “award recipients,” “entities,” or “health centers” -- in order to receive deemed employment status under FSHCAA, must demonstrate compliance with all Health Center FTCA Program requirements including, where applicable, implementation of applicable policies and procedures. Each entity seeking FTCA coverage (including award recipients and subrecipients) must submit an initial deeming application or redeeming application in the form and manner prescribed by HRSA. Deeming applications must demonstrate that the entity seeking FTCA coverage has successfully met all FTCA requirements set forth in law.

Section 224(h) of the PHS Act requires the Secretary, as a condition of deeming, to make certain determinations. Under section 224(h)(1), the Secretary must determine that the entity has implemented “appropriate policies and procedures to reduce the risk of malpractice and the risk of lawsuits arising out of any health or health-related functions performed by the entity.” Similarly, under section 224(h)(2), the Secretary must determine that the entity has reviewed and verified “the professional credentials, references, claims history, fitness, professional review organization findings, and license status of its physicians and other licensed or certified health

¹ Health centers that are noncompliant with Health Center Program requirements also may be subject to grant conditions and/or enforcement actions, as further provided for in the Health Center Program Compliance Manual and other authorities.

² 45 CFR 75.2

³ 42 CFR 6.2, 6.3

care practitioners and, where necessary, has obtained the permission from these individuals to determine that an entity “has no history of claims having been filed against the United States ... or if such history of claims exists, has fully cooperated with the Attorney General in defending against any such claim and has either taken, or will take, any necessary corrective steps to assure against such claims in the future.” Finally, section 224(h)(4) requires that the Secretary determine that the entity “will fully cooperate with the Attorney General in providing information relating to an estimate described under subsection (k).”

IV. APPLICABILITY

This PAL applies to eligible entities (including award recipients and subrecipients) receiving grant funding under section 330 of the PHS Act, including sections 330(e), (g), (h), and/or (i).

Under 42 C.F.R. 6.2, eligible subrecipients for purposes of FTCA coverage are those entities receiving funds from a covered section 330 award recipient under a grant or contract to provide a full range of services on behalf of the covered entity and only for those services carried out within the scope of deemed employment, which includes but is not limited to those activities carried out under the grant-funded project. All subrecipient entities seeking deemed employment status must be identified as a service site on the award recipient of record’s approved Form 5B and must submit a deeming application to HRSA through the award recipient of record.

Please note that only the award recipient of record (the entity named on the Notice of Award) can transmit a request to HRSA for deeming, with resultant FTCA coverage, through HRSA’s electronic communication tool, the Electronic Handbooks (EHBs). Health centers requesting FTCA coverage on behalf of a subrecipient must submit a complete deeming application on the subrecipient’s behalf in accordance with the initial deeming and redeeming application procedures specified within this PAL and other FTCA Program requirements. The subrecipient deeming application ordinarily must be completed along with the award recipient’s deeming application package. Moreover, the award recipient’s deeming does not apply to the subrecipient entity. Subrecipient applications are subject to the same requirements as those applicable to award recipients, and only subrecipients of deemed entities are eligible for deeming.

Approval by HRSA of a deeming application submitted in accordance with this PAL will result in issuance of a Notice of Deeming Action (NDA) issued to the health center or, where appropriate, to the subrecipient. The NDA also extends to the actions of *any* employee, officer, board member, or qualified contractor of the entity meeting the statutory requirements and acting within the scope of deemed employment. ***The NDA issued to the entity does not extend deeming/coverage to VHPs. Deeming/coverage for VHPs is solely made available through a distinct, individual sponsorship process, as required by section 224(q) of the PHS Act.***

V. COORDINATION WITH DEEMING PROCEDURE FOR VOLUNTEER HEALTH PROFESSIONALS (VHPs)

Eligible health center VHPs do not receive deemed PHS employee status automatically, nor, as noted above, do they receive it derivatively, through the deeming of the health center pursuant to this PAL. Instead, health center VHPs must be individually deemed by HRSA in response to a

sponsorship application by the health center. The entity's VHP sponsorship application must be submitted through the EHBs in addition to the entity's organizational deeming application.

The EHBs FTCA module will allow health centers to submit a separate VHP sponsorship application in addition to its entity initial deeming and/or redeeming application. If the health center's entity deeming application is not approved, the health center's VHPs will be ineligible for deeming and associated FTCA coverage, and any associated VHP sponsorship application, will be denied.

Guidance on the VHP sponsorship application instructions and program requirements can be found in the VHP PAL on the VHP website <https://bphc.hrsa.gov/ftca/about/health-center-volunteers.html>.

VI. SUBMITTING FTCA APPLICATIONS

All FTCA deeming applications must be submitted electronically through the FTCA deeming module within the EHBs. The EHBs system will be available to begin receiving CY 2020 deeming applications on May 17, 2019.

When a health center submits an FTCA application, the EHBs will assign a tracking number. Health centers may create and submit an FTCA application in one session, or create and save part of the application and return as many times as necessary to complete it before submitting it for HRSA review. The health center will receive an email confirming that HRSA has received its FTCA application through the EHBs. Each health center is responsible for ensuring that its deeming application(s) has been received by HRSA through the EHBs.

All deeming applicants must:

1. Submit required FTCA application information and materials in a timely manner (including responding within specified time frames to all clarification and additional information requests from HRSA, which may include an FTCA-specific site visit); and
2. Demonstrate compliance with all Health Center FTCA Program requirements (including, as appropriate, implementation of applicable policies).

Entities that submit an incomplete application will be notified of the incomplete application through the EHBs via a change request notification and afforded an opportunity to complete the application. The EHBs support electronic web-based functionality for the deeming process, including award recipient completion and submission of applications, HRSA review and processing of applications, and electronic notification of deeming status to award recipients. Applications that do not appropriately address all application questions and/or fail to attach all required documents will be considered incomplete and will not be approved. Additional information about applications that are incomplete or fail to appropriately address program requirements is found below, in subsections VII and VIII.

There must be an electronic signature from the **Executive Director/CEO of the health center** certifying the contents of the application. If the FTCA application is not signed/certified by such an individual, the application will be returned to the award recipient as described in Section VII:

Initial Deeming Applications and Section VIII: Redeeming Applications. All subrecipient applications must be signed/certified separately by an authorizing official for the subrecipient.

Note: Documentation submitted to HRSA must be redacted of all patient identifiers and other sensitive material that is not needed for HRSA to make a deeming determination. Please also note that redaction to the point that it renders the document impractical for purposes of review may result in an unfavorable deeming determination or request for additional information. Applicants may wish to consult with private legal counsel to address any associated privacy concerns, including questions about redactions.

For additional information or technical assistance on how to submit an FTCA application, please visit <http://www.bphc.hrsa.gov/ftca/healthcenters/hcappprocess.html>. Additional technical assistance for the EHBs and this PAL will be made available prior to the application submission deadline.

VII. INITIAL DEEMING APPLICATIONS

Health centers may submit an initial deeming application via the electronic, web-based EHBs system at any time during the year when the system is open to accept applications. However, HRSA suggests that award recipients request initial deeming well in advance of their desired coverage start date.

After reviewing the technical assistance resources (available at: <https://bphc.hrsa.gov/ftca/index.html>), award recipients submitting an initial deeming application should consult with Health Center FTCA Program staff (contact information can be found in section X below) if they have any additional questions.

Once a complete initial deeming application is submitted, HRSA will conduct its review within 30 days. Please note that an FTCA deeming application is not considered complete until all required documentation has been completed and submitted through the EHBs, and, if required by HRSA, a site visit has been completed. Entities are responsible for ensuring that the information needed to complete their application has been successfully submitted to HRSA through the EHBs. Entities that do not submit a complete application in a timely manner may not receive deemed status, with associated FTCA coverage, on the date desired. If additional information or clarification is needed, HRSA may notify the entity through the EHBs, and the entity will be given **10 business days from the date of the EHBs notification** to provide the requested information to complete its application. **Should requested information not be submitted within 10 business days of notification, the FTCA application may be determined incomplete and voided.** After being notified that an application has been voided, entities must submit an initial deeming application if they wish to obtain deemed status at a later date.

Within 30 days after a complete initial deeming application has been received by HRSA, HRSA will notify the contact person(s) identified by the health center of a final determination through the EHBs. FTCA coverage will begin on the effective date identified by HRSA on the NDA. Initial deeming applicants are advised to maintain private malpractice insurance until they receive written documentation confirming the deeming determination from HRSA.

VIII. REDEEMING APPLICATIONS

Each currently deemed entity must submit a redeeming application for itself and any subrecipients (as applicable) by **July 1, 2019**, in order to be eligible to be deemed during CY 2020 without a gap in coverage. *Eligible entities that do not submit a redeeming application by the deadline may experience a gap in anticipated FTCA coverage and may wish to consider purchasing private malpractice liability insurance for CY 2020.*

Award recipients are responsible for ensuring that the information needed to complete their redeeming application has been successfully submitted to HRSA through the EHBs. If additional information or clarification is needed to support an application, HRSA may notify the award recipient through the EHBs. The award recipient will be given **10 business days from the date of such EHBs notification** to resubmit the application with the requested information. *Award recipients that do not provide a responsive submission within 10 business days after receiving notice may have their application deemed incomplete and voided. If the application is voided, the award recipient will receive notification and will be required to submit an initial deeming application if they wish to obtain deemed status.*

During the application review process, if HRSA determines that the applicant has not successfully demonstrated compliance with the FTCA deeming requirements and, therefore, is in danger of being disapproved for CY 2020 coverage, the award recipient will be notified and will be given a final opportunity to provide additional information to demonstrate compliance.

Once the additional information is submitted, HRSA will review the documentation and make a final FTCA deeming determination. After a final FTCA deeming determination is made for each application, HRSA will notify the contact person(s) identified by the health center of their deeming status through the EHBs.

IX. SITE VISITS

HRSA may conduct a site visit, either randomly or as a result of other factors, to any health center seeking deeming to ensure compliance with deeming application requirements. A site visit finding of a lack of implementation of the FTCA deeming requirements may lead to denial of the entity's application for initial deeming or redeeming.

Factors that may prompt a site visit include, but are not limited to:

1. Submission of an initial deeming application;
2. Documentation submitted that indicates possible non-compliance with deeming requirements during the review of the health center's FTCA application;
3. The need for follow-up based on prior site visit findings or other identified issues;
4. History of repeated conditions or current conditions placed by HRSA on the health center's Health Center Program grant, as documented on the health center's associated Notice of Award and/or through enforcement action; and/or
5. History of medical malpractice claims.

Please note that HRSA also conducts regularly scheduled site visits as part of its oversight responsibilities to ensure that QI/QA, credentialing and privileging, risk management, and claims management requirements have been appropriately implemented. The results of such site visits may be incorporated into HRSA's assessment of the completeness of an FTCA application. **Site visit findings indicating non-compliance with FTCA Program requirements may result in a deeming application being considered incomplete or non-compliant and at risk of disapproval. Please visit the HRSA website for more information related to operational site visits and FTCA site visits: <https://bphc.hrsa.gov/programrequirements/syguide.html>.**

X. CONTACT INFORMATION

Award recipients and subrecipients are encouraged to carefully review the FTCA policies and technical assistance resources found on the HRSA website at <https://bphc.hrsa.gov/ftca/index.html>, as well as the Health Center Program requirements page found at <https://www.bphc.hrsa.gov/programrequirements/index.html>.

For programmatic support regarding the Health Center FTCA Program, application requirements, and technical/EHBs support, please contact:

Health Center Program Support

Phone: 1-877-464-4772, Option 1

Web form: https://bphccommunications.secure.force.com/ContactBPHC/BPHC_Contact_Form

7:00 a.m. to 8:00 p.m. ET, Monday through Friday (except Federal holidays)

/James Macrae/

James Macrae

Associate Administrator

Bureau of Primary Health Care

**Application for Health Center Program Award Recipients for
Liability Protections Under the
Federal Tort Claims Act (FTCA)**

**(This application is illustrative and the actual application may appear differently in the HRSA
Electronic Handbook (EHBs) System)**

DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration	FOR HRSA USE ONLY	
	Award Recipient Name	Application Type
CONTACT INFORMATION	Application Tracking Number	Grant Number

CONTACT INFORMATION (Please include a preferred title next to the name) All the fields marked with * are required.	
EXECUTIVE DIRECTOR <i>(Must electronically sign and certify the FTCA application prior to submission)</i> * Name: * Email: * Direct Phone: Fax:	
GOVERNING BOARD CHAIRPERSON * Name: * Email: * Direct Phone: Fax:	
MEDICAL DIRECTOR * Name: * Email: * Direct Phone: Fax:	
RISK MANAGER * Name: * Email: * Direct Phone: Fax:	

CONTACT INFORMATION (Please include a preferred title next to the name)

All the fields marked with * are required.

<p>PRIMARY DEEMING CONTACT <i>(Individual responsible for completing application)</i> * Name: * Email: * Direct Phone: Fax:</p>	
<p>ALTERNATE DEEMING CONTACT <i>(Individual responsible for assisting with the application)</i> * Name: * Email: * Direct Phone: Fax:</p>	
<p>CREDENTIALING/PRIVILEGING CONTACT <i>(Individual responsible for managing the credentialing and privileging process)</i> * Name: * Email: * Direct Phone: Fax:</p>	
<p>CLAIMS MANAGEMENT CONTACT <i>(Individual responsible for the management and processing of FTCA and other medical malpractice claims)</i> * Name: * Email: * Direct Phone: Fax:</p>	
<p>QUALITY IMPROVEMENT/QUALITY ASSURANCE CONTACT <i>(Individual responsible for overseeing the QI/QA program)</i> * Name: * Email: * Direct Phone: Fax:</p>	

DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration	FOR HRSA USE ONLY	
	Award Recipient Name	Application Type
REVIEW OF RISK MANAGEMENT SYSTEMS	Application Tracking Number	Grant Number

REVIEW OF RISK MANAGEMENT SYSTEMS All questions in this section are required.
<p>1(A). I attest that my health center has implemented an ongoing risk management <u>program</u> to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation and that requires the following:</p> <ul style="list-style-type: none"> i. Risk management across the full range of health center activities (for example, patient management including scheduling, triage, intake, tracking, and follow-up); ii. Health care risk management training for health center staff; iii. Completion of quarterly risk management assessments by the health center; and iv. Annual reporting to the board of: completed risk management activities; status of the health center’s performance relative to established risk management goals; and proposed risk management activities that relate and/or respond to identified areas of high organizational risk. <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If “No”, provide an explanation.</p> <p>[2,000 character comment box]</p>
<p>1(B). I also acknowledge that failure to implement an ongoing risk management program and provide documentation of such implementation may result in disapproval of this deeming application and/or other remedies.</p> <p>Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If “No”, provide an explanation.</p> <p>[2,000 character comment box]</p>

REVIEW OF RISK MANAGEMENT SYSTEMS

All questions in this section are required.

2(A). I attest that my health center has implemented risk management procedures to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation. At a minimum, these procedures specifically address the following:

- i. Identifying and mitigating (for example, through clinical protocols, medical staff supervision) the health care areas/activities of highest risk within the health center’s HRSA-approved scope of project, including but not limited to tracking referrals, diagnostics, and hospital admissions ordered by health center providers;
- ii. Documenting, analyzing, and addressing clinically-related complaints, and “near misses” reported by health center employees, patients, and other individuals;
- iii. Setting and tracking progress related to annual risk management goals;
- iv. Developing and implementing an annual health care risk management training plan for all staff members based on identified areas/activities of highest clinical risk for the health center (including, but not limited to obstetrical procedures, infection control) and any non-clinical trainings appropriate for health center staff (including Health Insurance Portability and Accountability Act (HIPAA) medical record confidentiality requirements); and
- v. Completing an annual risk management report for the board and key management staff.

Yes No

If “No”, provide an explanation.

[2,000 character comment box]

2(B). I also acknowledge that failure to implement and maintain risk management procedures to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation, as further described above, may result in disapproval of this deeming application.

Yes No

If “No”, provide an explanation.

[2,000 character comment box]

2(C). Upload the risk management procedures that address the items outlined in question 2(A).i above, specifically risk management procedures that address mitigating risk in referral tracking, diagnostics, and hospital admissions ordered by health center providers or initiated by the patient.

[Attachment control named ‘Referral Tracking’]

[Attachment control named ‘Hospitalization Tracking’]

[Attachment control named ‘Diagnostic Tracking (must include labs and x-rays)’]

REVIEW OF RISK MANAGEMENT SYSTEMS

All questions in this section are required.

3(A). I attest that my health center has developed and implemented an annual health care risk management training plan for staff members based on identified areas/activities of highest clinical risk for the health center. These training plans include detailed information related to the health center’s tracking/documentation methods to ensure that trainings have been completed by the appropriate staff, including all clinical staff, at least annually. I attest that the training plans at a minimum also incorporate the following:

- i. Obstetrical procedures (for example, continuing education for electronic fetal monitoring (such as the online course available through ECRI Institute), dystocia drills). Please note: Health centers that provide obstetrical services through health center providers need to include obstetrical training as part of their risk management training plans to demonstrate compliance. This includes health centers that provide prenatal and postpartum care through health center providers, even if they do not provide labor and delivery services;
- ii. Infection control and sterilization (for example, Blood Borne Pathogen Exposure protocol, Infection Prevention and Control policies, Hand Hygiene training and monitoring program, dental equipment sterilization);
- iii. HIPAA medical record confidentiality requirements; and
- iv. Specific trainings for groups of providers that perform various services which may lead to potential risk (for example, dental, pharmacy, family practice).

Yes [] No []

If “No”, provide an explanation.

[2,000 character comment box]

3(B). Upload the health center’s current annual risk management training plans for all staff, including all clinical and non-clinical staff, based on identified areas/activities of highest clinical risk for the health center and that include the items outlined in risk management question 3(A).i-iv of this application. The risk management training plans should also document completion of all required training.

All documents must be from the current or previous calendar year. Any documents dated outside of this period will not be accepted.

[Attachment control named ‘Risk Management Training Plan’]

3(C). Upload all tracking/documentation tools used to ensure trainings have been completed by all staff, at least annually (for example, excel sheet, Relias training reports).

All documents must be from the current or previous calendar year. Any documents dated outside of this period will not be accepted.

[Attachment control named ‘Risk Management Training Plan Tracking and Documentation Tool’]

REVIEW OF RISK MANAGEMENT SYSTEMS

All questions in this section are required.

4. Upload documentation (for example, data/trends, reports, risk management committee minutes) that demonstrates that the health center has completed quarterly risk management assessments.

[Attachment control named 'Risk Management Quarterly Assessments Documentation']

5(A). Upload the most recent report provided to the board and key management staff on health care risk management activities and progress in meeting goals at least annually, and documentation provided to the board and key management staff showing that any related follow-up actions have been implemented. **The report must be from the current or previous calendar year and must be reflective of the activities related to risk over a 12-month period. Any documents dated outside of this period will not be accepted.** The report must include:

- i. Completed risk management activities (for example, risk management projects, assessments),
- ii. Status of the health center's performance relative to established risk management goals (for example, data and trends analyses, including, but not limited to, sentinel events, adverse events, near misses, falls, wait times, patient satisfaction information, other risk management data points selected by the health center), and
- iii. Proposed risk management activities for the next 12-month period that relate and/or respond to identified areas of high organizational risk.

[Attachment control named 'Annual Risk Management Report to Board and Key Management Staff']

5(B). Upload proof that the health center board has received and reviewed the report uploaded for risk management question 5(A) of this application (for example, minutes signed by the board chair/board secretary, minutes and signed letter from board chair/board secretary).

All documents must be from the current or previous calendar year. Any documents dated outside of this period will not be accepted.

[Attachment control named 'Proof of Board Review of Annual Risk Management Report']

6. Upload the relevant Position Description of the risk manager who is responsible for the coordination of health center risk management activities and any other associated risk management activities. The job description must clearly detail that the risk management activities are a part of the risk manager's daily responsibilities.

[Attachment control named 'Risk Management Position Description']

7(A). Has the health center risk manager completed health care risk management training in the last 12 months (CY2018 or CY2019)?

Yes No

If "No", provide an explanation.

[2,000 character comment box]

REVIEW OF RISK MANAGEMENT SYSTEMS

All questions in this section are required.

7(B). Upload evidence that the risk manager has completed health care risk management training in the last 12 months (CY2018 or CY2019).

[Attachment control named 'Annual Risk Manager Training']

DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration	FOR HRSA USE ONLY	
	Award Recipient Name	Application Type
QUALITY IMPROVEMENT/QUALITY ASSURANCE PLAN (QI/QA)		
	Application Tracking Number	Grant Number

QUALITY IMPROVEMENT/QUALITY ASSURANCE (QI/QA)

All questions in this section are required.

1(A). I attest that my health center has board-approved policies (for example, a QI/QA plan) that demonstrate that the health center has an established QI/QA program. Such documentation must, at a minimum, demonstrate that the QI/QA program addresses the following:

- i. The quality and utilization of health center services;
- ii. Patient satisfaction and patient grievance processes; and
- iii. Patient safety, including adverse events.

Yes [] No []

If “No”, provide an explanation.

[2,000 character comment box]

1(B). I attest that my health center has QI/QA program operating procedures or processes that, at a minimum, address the following:

- i. Adhering to current evidence-based clinical guidelines, standards of care, and standards of practice in the provision of health center services, as applicable;
- ii. Identifying, analyzing, and addressing patient safety and adverse events and implementing follow-up actions, as necessary;
- iii. Assessing patient satisfaction;
- iv. Hearing and resolving patient grievances;
- v. Completing periodic QI/QA assessments on at least a quarterly basis to inform the modification of the provision of health center services, as appropriate; and
- vi. Producing and sharing reports on QI/QA to support decision-making and oversight by key management staff and by the governing board regarding the provision of health center services.

Yes [] No []

If “No”, provide an explanation.

[2,000 character comment box]

2. Upload documentation that the health center has performed QI/QA assessments on a quarterly basis (for example, through QI/QA report(s), QI/QA committee minutes, or QI/QA assessments).

All documents must be from the current or previous calendar year. Any documents dated outside of this period will not be accepted. Such documentation must, at a minimum,

QUALITY IMPROVEMENT/QUALITY ASSURANCE (QI/QA)

All questions in this section are required.

demonstrate the following:

- i. QI/QA assessments have been completed on at least a quarterly basis over the past calendar year by the health center’s physicians or other licensed health care professionals; and
- ii. QI/QA assessments over the past calendar year that include assessing the following:
 - a. Provider adherence to current evidence-based clinical guidance, standards of care, and standards of practice in the provision of health center services, as applicable; and
 - b. The identification of any patient safety and adverse events and the implementation of related follow-up actions, as necessary.

[Attachment control named ‘QI/QA Assessments’]

If you are unable to upload documentation that demonstrates the above, provide an explanation:

[2,000 character comment box]

3(A). Upload the most recent QI/QA report that has been provided to key management staff and to the governing board. **The report must be from the current calendar year or the previous calendar year.**

[Attachment control named ‘QI/QA Report’]

3(B). Upload governing board minutes or other documentation to demonstrate that the QI/QA report uploaded for question 3(A) was shared with and discussed by key management staff and by the governing board to support decision-making and oversight regarding the provision of health center services. The minutes should include reference to the report uploaded for QI/QA question 3(A) in this application. **The minutes must be from the current calendar year or the previous calendar year.**

[Attachment control named ‘Governing Board Minutes’]

4. Upload the relevant Position Description(s) that describe the responsibilities of the individual(s) who oversee the QI/QA program, including ensuring the implementation of QI/QA operating procedures and completion of QI/QA assessments, monitoring QI/QA outcomes, and updating QI/QA operating procedures. The job description must clearly detail that the QI/QA activities are a part of the individual’s daily responsibilities.

[Attachment control named ‘QI/QA Position Descriptions’]

QUALITY IMPROVEMENT/QUALITY ASSURANCE (QI/QA)

All questions in this section are required.

5. Has the health center implemented a certified Electronic Health Record for all health center patients?

Yes No

If No, describe the health center's systems and procedures for maintaining a retrievable health record for each patient, the format and content of which is consistent with both federal and state law requirements.

[4,000 character comment box]

6(A). I attest that my health center has implemented systems and procedures for protecting the confidentiality of patient information and safeguarding this information against loss, destruction, or unauthorized use, consistent with federal and state requirements.

Yes No

If "No", provide an explanation.

[2,000 character comment box]

6(B). I also acknowledge and agree that failure to implement and maintain systems and procedures for protection the confidentiality of patient information and safeguarding this information against loss, destruction, or unauthorized use, consistent with federal and state requirements, may result in disapproval of this deeming application.

Yes No

If "No", provide an explanation.

[2,000 character comment box]

7. Indicate whether you currently have an active condition or any other enforcement action on your Health Center Program award related to QI/QA.

Yes No

If Yes, indicate the date that the condition was imposed and its source (for example, Operational Site Visit, Service Area Competition application) through which your entity received this condition. Also indicate the specific nature of the condition, including the finding and reason why the condition was imposed. Describe your entity's plan to remedy the deficiency that led to imposition of the condition and the anticipated timeline by which the plan is expected to be fully implemented.

[2,000 character comment box]

Please note: The presence of certain award conditions and/or enforcement actions related to quality improvement/quality assurance may demonstrate noncompliance with FTCA Program requirements and may result in disapproval of deemed status.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration	FOR HRSA USE ONLY	
	Award Recipient Name	Application Type
CREDENTIALING AND PRIVILEGING		
	Application Tracking Number	Grant Number

CREDENTIALING AND PRIVILEGING
All questions in this section are required.

1(A). I attest that my health center has implemented a credentialing process for all clinical staff members (including for licensed independent practitioners and other licensed or certified health care practitioners who are health center employees, individual contractors, or volunteers). I also attest that my health center has operating procedures for the initial and recurring review of credentials, and responsibility for ensuring verification of all of the following:

- i. Current licensure, registration, or certification using a primary source;
- ii. Education and training for initial credentialing, using:
 - a. Primary sources for licensed independent practitioners;
 - b. Primary or other sources for other licensed or certified practitioners and any other clinical staff;
- iii. Completion of a query through the National Practitioner Databank (NPDB);
- iv. Clinical staff member’s identity for initial credentialing using a government issued picture identification;
- v. Drug Enforcement Administration registration (if applicable); and
- vi. Current documentation of Basic Life Support training.

Yes No

If “No”, provide an explanation.

[2,000 character comment box]

1(B). I also acknowledge and agree that failure to implement and maintain a credentialing process as further described above may result in disapproval of this deeming application.

Yes No

If “No”, provide an explanation.

[2,000 character comment box]

2(A). I attest that my health center has implemented privileging procedures for the initial granting and renewal of privileges for clinical staff members (including for licensed independent practitioners and other licensed or certified health care practitioners who are health center employees, individual contractors, and volunteers). I also attest that my health center has privileging procedures that address all of the following:

- i. Verification of fitness for duty, immunization, and communicable disease status;

CREDENTIALING AND PRIVILEGING
All questions in this section are required.

- ii. For initial privileging, verification of current clinical competence via training, education, and, as available, reference reviews;
- iii. For renewal of privileges, verification of current clinical competence via peer review or other comparable methods (for example, supervisory performance reviews); and
- iv. Process for denying, modifying or removing privileges based on assessments of clinical competence and/or fitness for duty.

Yes No

If “No”, provide an explanation.

[2,000 character comment box]

2(B). I also acknowledge and agree that failure to implement and maintain a privileging process for the initial granting and renewal of privileges for clinical staff members, including operating procedures as further described above, may result in disapproval of this deeming application.

Yes No

If “No”, provide an explanation.

[2,000 character comment box]

3. Upload the health center’s credentialing and privileging operating procedures that address all credentialing and privileging components listed in questions 1(A) & 2(A) above. (Please note: Procedures that are missing any of the components referenced in the credentialing and privileging section questions 1(A) & 2(A) of this application will be interpreted as the health center not implementing those missing components.)

[Attachment control named ‘Credentialing and Privileging Operating Procedures’]

4. I attest that my health center maintains files or records for our clinical staff (for example, employees, individual contractors, and volunteers) that contain documentation of licensure, credentialing verification, and applicable privileges, consistent with the health center’s operating procedures.

Yes No

If “No”, provide an explanation.

[2,000 character comment box]

5. I attest that if my health center has contracts with provider organizations (for example, group practices, staffing agencies) or formal, written referral agreements with other provider organizations that provide services within its scope of project, the health center ensures (for example, through provisions in formal, written referral agreements, contracts, other documentation) that such providers are:

CREDENTIALING AND PRIVILEGING
All questions in this section are required.

- i. Licensed, certified, or registered as verified through a credentialing process, in accordance with applicable federal, state, and local laws; and
- ii. Competent and fit to perform the contracted or referred services, as assessed through a privileging process.

Select N/A if the health center does not contract with provider organizations or have any formal, written referral agreements with other provider organizations.

Yes No N/A

If No, provide an explanation.

[2,000 character comment box]

Please note: “A contract between a covered entity and a provider's corporation does not confer FTCA coverage on the provider. Services provided strictly pursuant to a contract between a covered entity and any corporation, including eponymous professional corporations (defined as a professional corporation to which one has given one’s name, for example, John Doe, LLC, and consisting of only one health care provider), are not covered under FSHCAA and the FTCA.” See FTCA Health Center Policy Manual, Section B.3.

6. Indicate whether you currently have an active condition or any other enforcement action on your Health Center Program award related to credentialing or privileging.

Yes No

If Yes, indicate the date and source (for example, Operational Site Visit, Service Area Competition application) through which you received this condition or other enforcement action. Also indicate the specific nature of the condition or other enforcement action, including the finding and reason why it was imposed, such as failure to verify licensure, etc. Describe your entity’s plan to remedy the deficiency that led to imposition of the condition or enforcement action and the anticipated timeline by which the plan is expected to be fully implemented.

[2,000 character comment box]

Please note: The presence of certain award conditions and/or enforcement actions related to credentialing and privileging may demonstrate noncompliance with FTCA Program requirements and may result in disapproval of deemed status.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration	FOR HRSA USE ONLY	
	Award Recipient Name	Application Type
CLAIMS MANAGEMENT		
	Application Tracking Number	Grant Number

CLAIMS MANAGEMENT
All questions with an * in this section are required.

Please note: Health centers are expected to maintain their own records of medical malpractice claims as part of their risk management systems and in accordance with local practice requirements and guidelines.

If a claim or lawsuit involving covered activities is presented to the covered entity/individual or filed in court, it is essential that the covered entity preserve all potentially relevant documents. Once a covered entity or 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 entity or individual must suspend any routine destruction and hold any documents relating to the claimant or plaintiff so as to ensure their preservation for purposes of claim disposition or litigation.

1(A). *I attest that my health center has a claims management process for addressing any potential or actual health or health-related claims, including medical malpractice claims, which may be eligible for FTCA coverage. My health center’s claims management process includes information related to how my health center ensures the following:

- i. The preservation of all health center documentation related to any actual or potential claim or complaint (for example, medical records and associated laboratory and x-ray results, billing records, employment records of all involved clinical providers, clinic operating procedures); and
- ii. That any service of process/summons that the health center or its provider(s) receives relating to any alleged claim or complaint is promptly sent to the HHS, Office of the General Counsel, General Law Division, per the process prescribed by HHS and as further described in the FTCA Health Center Policy Manual.

Yes [] No []

If “No”, provide an explanation.

[2,000 character comment box]

CLAIMS MANAGEMENT

All questions with an * in this section are required.

1(B). *I also acknowledge and agree that failure to implement and maintain a claims management process as described above may result in disapproval of this deeming application.

Yes [] No []

If “No”, provide an explanation.

[2,000 character comment box]

1(C). *Upload documentation of the health center’s claims management process (for example, claims management procedures) for addressing any potential or actual health or health-related claims, including medical malpractice claims, that may be eligible for FTCA coverage. In addition, this process includes the items outlined in Claims Management question 1(A).a-b of this application.

[Attachment control named ‘Claims Management Procedures’] (If answer to 1(A) is Yes, attachment required; if answer to 1(A) is No, no attachment is required.)

2(A). *Has the health center had any history of claims under the FTCA? (Health centers should provide any medical malpractice claims or allegations that have been presented during the past 5 years.)

Yes [] No []

If Yes, provide a list of the claims. For each claim, include:

- i. Name of provider(s) involved;
- ii. Area of practice/Specialty;
- iii. Date of occurrence;
- iv. Summary of allegations;
- v. Status or outcome of claim;
- vi. Documentation that the health center cooperated with the Attorney General for this claim, as further described in the FTCA Health Center Policy Manual; and
- vii. Summary of health center internal analysis and implemented steps to mitigate the risk of such claims in the future (Only submit a summary if the case is closed. If the case has not been settled do not include the summary. Do not submit a copy of the NPDB report in this section.).

[Attachment control named ‘History of Claims’]

2(B). *I agree that the health center will cooperate with all applicable Federal government representatives in the defense of any FTCA claims.

Yes [] No []

If “No”, provide an explanation.

[2,000 character comment box]

CLAIMS MANAGEMENT

All questions with an * in this section are required.

3(A). *I attest that my health center informs patients using plain language that it is a deemed Federal PHS employee via its website, promotional materials, and/or within an area(s) of the health center that is visible to patients. For example: “This health center receives HHS funding and has Federal PHS deemed status with respect to certain health or health-related claims, including medical malpractice claims, for itself and its covered individuals.”

Yes No

If No, provide an explanation.

[2,000 character comment box]

3(B). Include a link to the exact location where this information is posted on your health center website, or attach the relevant promotional material or pictures.

[Free Response Control to type in link]

[Attachment control named ‘FTCA Promotional Materials’]

(If answer to 3(A) is Yes, either free response control or attachment required; if answer to 3(A) is No, no free response control or attachment is required.)

3(C). *Upload the relevant Position Description(s) that describe the health center’s designated individual(s) who is responsible for the management and processing of claims-related activities and serves as the claims point of contact. The job description must clearly detail that the claims management activities are a part of the individual’s daily responsibilities.

[Attachment control named ‘Claims Management Position Descriptions’]

DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration	FOR HRSA USE ONLY	
	Award Recipient Name	Application Type
ADDITIONAL INFORMATION		
	Application Tracking Number	Grant Number

CERTIFICATION AND SIGNATURES Completion of this section by a typed name will constitute signature on this application. This field is required.
<p>I [] declare under the penalty of perjury that all statements contained in this application and any accompanying documents are true and correct, with full knowledge that all statements made in this application are subject to investigation and that any material false statement or omission in response to any question may result in denial or subsequent revocation of coverage.</p> <p>I understand that by printing my name I am signing this application.</p> <p><i>Please note – this must be signed by the Executive Director, as indicated in the Contact Information Section of the FTCA application. If not signed by the Executive Director, the application will be returned to the health center.</i></p>