

PROGRAM ASSISTANCE LETTER

DOCUMENT NUMBER: 2018-01

DOCUMENT NAME: Calendar Year 2019 Requirements for Federal Tort Claims Act (FTCA) Coverage for Health Centers and their Covered Individuals

DATE: March 26, 2018

TO: Health Center Program Grantees
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 initial deeming or annual redeeming applications for calendar year (CY) 2019 and highlight updates to the Federal Tort Claims Act (FTCA) deeming application requirements. This PAL supersedes Program Assistance Letter (PAL) 2017-03, "Calendar Year 2018 Requirements for Federal Tort Claims Act (FTCA) Coverage for Health Centers." This PAL does not address the specifics of the deeming process for Health Center Volunteer Health Professionals (VHPs). The VHP deeming procedure and guidance is outlined in PAL 2018-01.

Health Center Program grantees seeking 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 implemented policies meeting applicable requirements for risk management, claims management, quality improvement (QI)/quality assurance (QA), and credentialing and privileging.

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 2019 (January 1, 2019 December 31, 2019).

II. PROGRAM UPDATES

In order to be deemed or redeemed for the upcoming calendar year, applicants must demonstrate via their FTCA deeming application that they meet FTCA requirements for risk management, claims management, QI/QA, and credentialing and privileging. The CY 2019 FTCA deeming application questions and required submissions have been further synthesized in an effort to reduce burden on applicants and clarify how applicants can meet these requirements.

III. BACKGROUND

Eligible non-federal entities (including Health Center Program grantees and certain grant subrecipients)¹ and other subrecipient entities described in the Health Center FTCA regulations² may be deemed by HRSA as employees of the Public Health Service (PHS) for purposes of liability protections for the performance of medical, dental, surgical, 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 grantees and subrecipients -- hereafter "grantees," "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 grantees and subrecipients, as further defined below) must submit an initial FTCA 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 implemented all deeming requirements set forth in law. Section 224(h) of the PHS Act requires the Secretary, as a condition of deeming, to make certain required 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 care practitioners and, where necessary, has obtained the permission from these individuals to gain access to this information." In addition, section 224(h)(3) requires that the Secretary 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 has 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)."

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¹ 45 CFR 75.2

² 42 CFR 6.2, 6.3

IV. APPLICABILITY

This PAL applies to eligible non-federal entities (grantees and certain subrecipients), as well as subrecipients as defined in 42 CFR 6.2, receiving grant funding under section 330 of the PHS Act, including sections 330(e), (g), (h), and/or (i).

As defined in 42 C.F.R. 6.2, eligible subrecipients for purposes of FTCA coverage are those entities receiving funds from a covered section 330 grantee 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 on the grantee of record's current Scope of Project/Services Site (i.e., the grantee of record's approved Form 5B) and must submit a deeming application to HRSA through the grantee of record.

Please note that only the grantee of record (the organization 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 (EHB). Health centers requesting FTCA coverage on behalf of a subrecipient must submit a <u>complete</u> deeming application in accordance with the initial and redeeming application procedures specified within this PAL and other FTCA Program requirements. The subrecipient deeming application ordinarily, absent good cause, must be completed along with the grantee of record's deeming application package. Subrecipient applications are subject to the same requirements as those applicable to grantees, 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 and, where appropriate, to the subrecipient. The NDA also extends to the actions of any employee, officer, board member, or qualified contractor of the entity acting within the scope of deemed employment. The NDA does not, however, extend to the actions of any volunteer health professionals (VHPs), for whom deeming/coverage is made available through a distinct 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 volunteers must be sponsored by the health center through submission of an annual application for deeming on behalf of their individually named VHPs to HRSA. The VHP deeming application must be submitted through the EHB in addition to the health center deeming application.

Beginning in CY 2019, the FTCA EHB module will allow health centers to submit a separate VHP deeming application in addition to its entity initial and/or redeeming application. If the health center's entity deeming application is not approved, the health center's volunteers will become ineligible for deeming and associated FTCA coverage, and any associated VHP deeming

application will be denied.

Guidance on the VHP application instructions and program requirements can be found in PAL 2018-01 and 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 EHB. <u>The EHB system will be available to begin receiving CY 2019</u> <u>deeming applications on May 4, 2018</u>.

When a health center submits an FTCA application, the EHB 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 a verification email confirming that it has submitted the FTCA application through EHB. Health centers are responsible for ensuring that their deeming application(s) have been successfully submitted to HRSA through the EHB.

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 related to the FTCA application, 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).

Health Center Program grantees that submit an incomplete application will be notified of the incomplete application through EHB, via a change request notification, and afforded an opportunity to complete the application. EHB supports electronic web-based functionality for the deeming process, including grantee completion and submission of applications, HRSA review and processing of applications, and electronic notice of deeming status to grantees. Submissions that do not appropriately address all application questions and/or fail to attach all required documents will be considered incomplete. Applicants that do not submit a complete application or that do not meet all applicable deeming application requirements will not be approved and will not receive FTCA deeming or renewal of deeming (i.e., redeeming). For example, the presence of an active condition based on noncompliance with Health Center Program requirements for credentialing and privileging and/or QI/QA may also demonstrate noncompliance with FTCA Program requirements and may therefore result in disapproval of deemed status. Health centers that are noncompliant with Health Center Program requirements also may be subject to enforcement actions under the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, at 45 CFR part 75.

<u>Please note that all documentation submitted to HRSA must be redacted of all patient identifiers and other sensitive material that is not needed to make a deeming determination. Please also</u>

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.

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 by such an individual, the application will be returned to the grantee as described in Section VI: Initial FTCA Applications and Section VII: FTCA Redeeming Applications. All subrecipient applications must be signed separately by an authorizing official for the subrecipient.

Deeming applications for any subrecipient(s) that appear on the grantee's most recent Form 5B and for which FTCA coverage is requested must, absent good cause, be included in the grantee of record's annual FTCA application. If a subrecipient's deeming application is incomplete, HRSA will notify the grantee through the EHB, and the grantee will have 10 business days to respond. If the grantee does not respond within 10 days, the entire application package may be deemed incomplete and voided. Please see Section VI: Initial FTCA Applications and Section VII: FTCA Redeeming Applications for more information. If the application is voided based on lack of completeness, the grantee will receive notification and will be required to resubmit their application in order to obtain deemed status.

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 EHB and this PAL will be made available prior to the application submission deadline.

VII. INITIAL FTCA APPLICATIONS

Health centers may submit an initial deeming application via the electronic, web-based EHB system at any time during the year when the system is open to accept applications. However, we strongly suggest that grantees request initial FTCA 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), grantees submitting an initial deeming application should consult with the FTCA Program (contact information can be found in section X below) if they have any additional questions.

Once a complete initial FTCA application is submitted, HRSA will conduct its review within 30 days of receiving a complete application. Please note that an FTCA deeming application is not considered complete until <u>all</u> required documentation has been completed and submitted through EHB, and if required by HRSA, a site visit has been completed. Grantees are responsible for ensuring that the information needed to complete their application has been successfully submitted to HRSA through the EHB. Grantees 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 grantee through the EHB, and the grantee will be given 10 business days from the date of the EHB

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 to be incomplete and voided. After being notified that an application has been voided, grantees must submit an initial application if they wish to obtain deemed status at a later date.

Within 30 days after a complete initial FTCA deeming application has been received by HRSA, HRSA will notify the contact person(s) identified by the health center of a final determination through EHB. 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. FTCA REDEEMING APPLICATIONS

All currently deemed grantees must submit an FTCA redeeming application for itself and any subrecipients (as applicable) by June 4, 2018 in order to be eligible to be deemed for the entirety of CY 2019 without a gap in coverage. Grantees who fail to submit a redeeming application by the deadline date may be required to reapply for coverage. Eligible entities (grantees and grantees on behalf of subrecipients, as further described above) that do not submit a redeeming application by the June 4, 2018 deadline may experience a gap in anticipated FTCA coverage and should consider purchasing private liability insurance for CY 2019.

Grantees are responsible for ensuring that the information needed to complete their redeeming application has been successfully submitted to HRSA through the EHB. If additional information or clarification is needed to support an application, HRSA may notify the grantee through the EHB. The grantee will be given 10 business days from the date of such EHB notification to resubmit the application with the requested information. Grantees 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 grantee will receive notification and will be required to resubmit their redeeming 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 2019 coverage, the grantee will be notified and provided a final opportunity to demonstrate compliance.

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

IX. SITE VISITS

HRSA may conduct a site visit, randomly or for cause, to any initial applicant or deemed grantee to ensure compliance with the deeming requirements in 42 U.S.C. 233(h). If a site visit results in

a finding of a lack of implementation of the FTCA Program requirements, this may lead to denial of the entity's application for FTCA deeming or redeeming.

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

- 1. Submission of an initial FTCA deeming application;
- 2. Documentation submitted that indicates possible non-compliance with 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
- 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 an application being considered incomplete or non-compliant, depending on the circumstances, and at risk of not receiving FTCA deeming or redeeming. As stated earlier, health centers that are found non-compliant with credentialing and privileging or QI/QA requirements may receive conditions upon their Health Center Program award in addition to having their FTCA deeming application denied.

X. CONTACT INFORMATION

Grantees are encouraged to carefully review the FTCA policies and technical assistance resources found on the HRSA website at http://www.bphc.hrsa.gov/FTCA/ as well as the Health Center Program requirements page found at https://www.bphc.hrsa.gov/programrequirements/index.html.

For programmatic support regarding the FTCA Program, application requirements (including credentialing, QI/QA, etc.), and technical/EHB support, please contact:

Health Center Program Support

Phone: 877-464-4772

Web form: http://www.hrsa.gov/about/contact/bphc.aspx

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

/S/

James Macrae Associate Administrator Bureau of Primary Health Care

Application for Health Center Program Grantees for Medical Malpractice Coverage Under the Federal Tort Claims Act

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

| DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration | FOR HRSA USE ONLY | | |
|--|--------------------------------|------------------|--|
| | Grantee 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 (Must electronically sign | | |
| and certify the FTCA application prior to | | |
| submission) | | |
| * 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 inclu All the fields marked | • |
|--|---|
| PRIMARY DEEMING CONTACT | |
| (Individual responsible for completing | |
| application) | |
| * Name: | |
| * Email: | |
| * Direct Phone: | |
| Fax: | |
| ALTERNATE DEEMING CONTACT | |
| (Individual responsible for assisting with the | |
| application) | |
| * Name: | |
| * Email: | |
| * Direct Phone: | |
| Fax: | |
| CREDENTIALING CONTACT | |
| (Individual responsible for managing updating | |
| credentialing information) | |
| * Name: | |
| * Email: | |
| * Direct Phone: | |
| Fax: | |
| CLAIMS MANAGEMENT CONTACT | |
| (Individual responsible for the management and | |
| processing of FTCA and other medical | |
| malpractice claims) | |
| * Name: | |
| * Email: | |
| * Direct Phone: | |
| Fax: | |
| QUALITY IMPROVEMENT/QUALITY ASSURANCE | |
| CONTACT | |
| (Individual responsible for overseeing the QI/QA | |
| program) | |
| * Name: | |
| * Email: | |
| * Direct Phone: | |
| Fax: | |
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| REVIEW OF RISK MANAGEMENT SYSTEMS | Application Tracking Number | Grant Number |
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REVIEW OF RISK MANAGEMENT SYSTEMS All fields marked with * are required.

1. *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. I also acknowledge and agree that failure to implement an ongoing risk management program and provide documentation of such implementation may result in disapproval of this deeming application.

Yes [] No []

If "No", please enter an explanation.

| DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration | FOR HRSA USE ONLY | | |
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| | Grantee Name Application Typ | | |
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| REVIEW OF RISK MANAGEMENT SYSTEMS | Application Tracking Number | Grant Number | |
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REVIEW OF RISK MANAGEMENT SYSTEMS All fields marked with * are required.

- 2. *I attest that my health center has implemented and maintains risk management <u>policies</u> to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation. At a minimum, these policies specifically address the following:
 - 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.

| I also acknowledge and agree that failure to implement and maintain a risk management policy as |
|--|
| further described above to reduce the risk of adverse outcomes that could result in medical |
| malpractice or other health or health-related litigation may result in disapproval of this deeming |
| application. |

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If "No", please enter an explanation.

- 3. *I attest that my health center has implemented risk management <u>operating procedures</u> to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation. At a minimum, these operating procedures specifically address the following:
 - i. Identifying the areas/activities of highest risk for health center patient safety consistent with the health center's HRSA-approved scope of project;
 - ii. Mitigating the areas/activities of highest risk for health center patient safety consistent with the health center's HRSA-approved scope of project, through clinical protocols, training, and medical staff supervision);
 - iii. Documenting, analyzing, and addressing clinically-related complaints, and "near misses" reported by health center employees, patients, and other individuals;
 - iv. Setting and tracking progress related to annual risk management goals;
 - v. 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
 - vi. Completing an annual risk management report for the board and key management staff.

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

Yes [] No []

If "No", please enter an explanation.

[2,000 character comment box]

- 4. *Upload policies or procedures for the following, in order to demonstrate how the health center has mitigated risk for health center patient safety in these areas/activities consistent with the health center's HRSA-approved scope of project:
 - Referral tracking
 - Hospitalization tracking
 - Diagnostic tracking (x-ray, labs)

[Attachment control named 'Referral Tracking']

[Attachment control named 'Hospitalization Tracking']

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

5(A). *I attest that my health center has developed and implemented health care risk management training plans for staff members based on identified areas/activities of highest clinical risk for the health center. These training plans include 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 incorporate the following:

- Obstetrical procedures (e.g., continuing education for electronic fetal monitoring (such as, online course available through ECRI Institute), and dystocia drills);
- ii. Infection control (e.g., Blood Borne Pathogen Exposure protocol, InfectionPrevention and Control policies, Hand Hygiene training and monitoring program);
- iii. HIPAA medical record confidentiality requirements.

| Yes | ١N | lo | [] | l |
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If "No", please enter an explanation.

[2,000 character comment box]

5(B). *Upload the health center's current risk management training plans for staff members based on identified areas/activities of highest clinical risk for the health center, as well as any and all tracking/documentation methods or tools used to ensure trainings have been completed by the appropriate staff, including all clinical staff, at least annually.

[attachment control named 'Risk Management Training Plans']

*6. Upload the most recent report to the board/key management staff on risk management activities, progress in meeting risk management goals and evidence that related follow up actions have been implemented.

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 'Reports to Board and Key Management Staff']

- 7. *Upload the relevant Position Description(s) describing the person responsible for the coordination of health center risk management activities and any other associated activities. [Attachment control named 'Risk Management Position Descriptions']
- 8. Has the designated individual(s) who oversees and coordinates the health center's risk management activities completed health care risk management training in the last 12 months?

| [] | Yes | [] | No |
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If "No", please enter an explanation.

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QUALITY IMPROVEMENT/QUALITY ASSURANCE (QI/QA) All fields marked with * are required

- 1. *Upload the health center's policies and supporting documentation to demonstrate that the health center has established an ongoing QI/QA Program and supporting operating procedures. All supporting documentation must be from the current calendar year or the previous calendar year. Examples of supporting documentation include, but are not limited to QI/QA minutes and QI/QA reports. The policies and other documentation must, at a minimum, demonstrate that the health center's QI/QA program's operating procedures address:
 - a. Adherence to current evidence-based clinical guidelines, standards of care, and standards of practice, as applicable;
 - b. A process for identifying, analyzing, and addressing patient safety and adverse events and for implementing follow-up actions, as necessary;
 - c. A process for assessing patient satisfaction;
 - d. A process for hearing and resolving patient grievances;
 - e. Completion of periodic QI/QA assessments on at least a quarterly basis; and
 - f. A process for modifying the provision of health center services based on the findings of QI/QA assessments, as appropriate.

[Attachment control named 'Supporting QI/QA Documents] [Attachment control named 'QI/QA Plan']

If you are unable to upload the QI/QA Plan and/or other documentation that demonstrates the above, please explain:

[2,000 character comment box]

2. *Upload documentation that the health center has performed QI/QA assessments (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, demonstrate the following:

- A. QI/QA assessments have been completed on at least a quarterly basis over the past calendar year;
- B. QI/QA assessments over the past calendar year that include assessing the following:
 - 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; and
 - ii. 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, please explain: [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 that document that the report uploaded for question 3(A) was shared with and discussed by the governing board to support decision-making and oversight regarding the provision of health center services. 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'] |
| 5. *Has the health center implemented a certified Electronic Health Record for all health center patients? |
| [] Yes [] No |
| If No, please 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. *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. |
| 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", please enter an explanation. |
| [2,000 character comment box] |
| 7. *Please indicate whether you currently have an active condition on your Health Center Program award related to QI/QA. |
| [] Yes [] No |
| If Yes, please indicate the date that the condition was imposed and its source (for example, Operational Site Visit, Service Area Competition application) through which your organization received this condition. Please also indicate the specific nature of the condition, including the finding and reason why the condition was imposed. Please also describe your organization'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. |
| |

<u>Please note</u>: The presence of certain award conditions related to Quality Improvement / Quality Assurance may demonstrate noncompliance with FTCA Program requirements and may result in disapproval of deemed status.

CREDENTIALING AND PRIVILEGING All fields marked with * are required

- 1. *I attest that my health center has implemented a credentialing process for all clinical staff members 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:
 - a. Current licensure, registration, or certification using a primary source;
 - b. Education and training for initial credentialing, using:
 - Primary sources for licensed independent practitioners;
 - Primary or other sources for other licensed or certified practitioners and any other clinical staff;
 - c. Completion of a query through the National Practitioner Databank (NPDB);
 - d. Clinical staff member's identity for initial credentialing using a government issued picture identification;
 - e. Drug Enforcement Administration registration (if applicable); and
 - f. Current documentation of Basic Life Support skills.

| I also acknowledge a | and agree that f | ailure to imp | lement and | maintain a | credentialing | process as |
|----------------------|------------------|---------------|---------------|-------------|---------------|------------|
| further described ab | ove may result | in disapprova | al of this de | eming appli | cation. | |

| [2,000 character comment box] |
|--|
| If "No", please enter an explanation. |
| [] Yes [] No |
| Turther described above may result in disapproval of this decriming application. |

- 2.*I attest that my health center has implemented a privileging process for the initial granting and renewal of privileges for clinical staff members (including health center employees, individual contractors, and volunteers). I also attest that my health center has operating procedures that address all of the following:
 - a. Verification of fitness for duty, immunization, and communicable disease status;
 - b. For initial privileging, verification of current clinical competence via training, education, and, as available, reference reviews;
 - c. For renewal of privileges, verification of current clinical competence via peer review or other comparable methods (for example, supervisory performance reviews); and
 - d. Process for denying, modifying or removing privileges based on assessments of clinical competence and/or fitness for duty.

| 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", please enter an explanation.

[2,000 character comment box]

3. * Please upload the health center's credentialing and privileging operating procedures that address all credentialing and privileging elements listed in questions 1 & 2 above.

[attachment control named 'Credentialing and Privileging Operating Procedures']

| 4. *I attest that my health center ensures that the files or records for our clinical staff (employees, |
|---|
| individual contractors, and volunteers) contain documentation of licensure and credentialing |
| verification and recording of privileges, consistent with the health center's operating procedures. |

| Γ | 1 | Yes | Γ. | lΝ | lc |
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| | | | | | |

If "No", please enter an explanation.

- 5. *I attest that if my health center contracts with provider organizations (for example, group practices, staffing agencies) or has formal, written referral agreements with other provider organizations, such contracts and/or formal, written referral agreements contain provisions that:
 - a. Ensure that the providers are licensed, certified, or registered as verified through a credentialing process, in accordance with applicable federal, state, and local laws; and
 - b. Ensure that the providers are assessed as competent to perform the contracted or referred services 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, please enter an explanation.

[2,000 character comment box]

<u>Please note</u>: "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, e.g., 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.*Please indicate whether you currently have a condition on your Health Center Program award related to credentialing or privileging.

[] Yes []No

If Yes, please indicate the date and source (for example, Operational Site Visit, Service Area Competition application) through which your received this condition. Please also indicate the specific nature of the condition, including the finding and reason why the condition was imposed, such as failure to verify licensure, etc. Please also describe your organization'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]

<u>Please note</u>: The presence of certain award conditions 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 | | |
|--|--------------------------------|--------------|--|
| | Grantee Name Application Ty | | |
| | | | |
| CLAIMS MANAGEMENT | Application Tracking Number | Grant Number | |
| | | | |

CLAIMS MANAGEMENT All fields marked with * 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. *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, that may be eligible for FTCA coverage. My health center's claims management process includes information related to how my health center ensures the following:
 - a. The preservation of all health center documentation related to any actual or potential claim or complaint (e.g. medical records and associated laboratory and x-ray results, billing records, employment records of all involved clinical providers, clinic operating procedures); and
 - b. 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.

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", please enter an explanation. | |

| DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration | FOR HRSA USE ONLY | | |
|--|--------------------------------|--------------|--|
| | Grantee Name Application Ty | | |
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| CLAIMS MANAGEMENT | Application Tracking Number | Grant Number | |
| | | | |

CLAIMS MANAGEMENT All fields marked with * are required

2. *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, Upload a list of the claims. For <u>each</u> claim, include:
 - a. Name of provider(s) involved
 - b. Area of practice/Specialty
 - c. Date of occurrence
 - d. Summary of allegations
 - e. Status or outcome of claim
 - f. Documentation that the health center cooperated with the Attorney General for this claim, as further described in the FTCA Health Center Policy Manual
 - g. Summary of health center internal analysis and implemented steps to mitigate the risk of such claims in the future (Please only submit a summary if the case is closed. If the case has not been settled do not include the summary.)

[Attachment control called 'History of Claims']

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

CLAIMS MANAGEMENT All fields marked with * are required

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

| ſ | 1 | Yes | Γ. | lNo |
|---|---|-----|----|-----|
| | | | | |

If No, please enter an explanation.

[2,000 character comment box]

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

[Attachment control named 'Claims Management Position Descriptions']

| DEPARTMENT OF HEALTH AND HUMAN SERVICES Health Resources and Services Administration | FOR HRSA USE ONLY | |
|--|--------------------------------|------------------|
| | Grantee 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.

* 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.

I understand that by printing my name I am signing this application.

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.