Federal Tort Claims Act (FTCA)
Health Center Program
Site Visit Protocol

Contents

Purpose

The Health Resources and Services Administration (HRSA) conducts Health Center Federal Tort Claims Act (FTCA) Program site visits to support its responsibility to ensure compliance with the FTCA deeming requirements found in 42 U.S.C. 233(h) and (q) with particular respect to credentialing and privileging, risk management, claims management, and quality improvement/quality assurance (QI/QA). These deeming requirements are also addressed within the annual FTCA Health Center Deeming Program Assistance Letter (PAL), the FTCA Health Center Policy Manual, and pertinent chapters of the Health Center Program Compliance Manual. HRSA may conduct FTCA site visits on a regularly scheduled basis, to provide information related to a deeming application, and/or as otherwise determined by HRSA to be needed or appropriate.

Factors that may prompt an FTCA site visit include, but are not limited to, the following:

- Submission of an initial FTCA deeming application;
- Documentation submitted on the FTCA deeming application that indicates possible non-compliance with deeming requirements;
- A 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(s) of Award[1];
- The need for follow-up based on prior site visit findings or other identified issues; and/or
- A history of medical malpractice claims.

FTCA site visits are distinct from Health Center Program Operational Site Visits (OSVs) under section 330 of the Public Health Service Act. FTCA site visits enable HRSA to objectively assess and verify the implementation of FTCA deeming requirements and provide technical assistance (TA) to health centers as needed and appropriate. In contrast, OSVs assess a health center's compliance with Health Center Program requirements described in the Health Center Program Compliance Manual.[2] Health centers that are currently FTCA deemed or applying for initial FTCA deeming may also be assessed during an OSV for compliance with FTCA Program credentialing and privileging, risk management, claims management, and quality improvement/quality assurance (QI/QA) deeming requirements.

To prepare for an FTCA site visit, HRSA encourages all health centers to review the FTCA Health Center Policy Manual, the annual FTCA Health Center Deeming PAL and relevant chapters (e.g., chapters 5, 10, and 21) of the Health Center Program Compliance Manual.

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[1] Unresolved Health Center Program conditions related to clinical staffing and/or quality improvement/assurance, requirements that apply to both Health Center Program and FTCA deeming, may impact FTCA deeming if they are not resolved by the time that HRSA makes annual FTCA deeming determinations.

[2] For more information on the statutory and regulatory requirements of the Health Center Program, please see the Health Center Program Compliance Manual.

FTCA Site Visit Structure

The FTCA site visit team consists of both HRSA staff and consultants. During an FTCA site visit, the team will typically assess whether the health center 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;
- Reviewed and verified the professional credentials, references, claims history, fitness, professional review organization findings, and licensure 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; and
- Should a history of claims exist, fully cooperated with the Attorney General in defending against any such claims and either has taken, or will take, any necessary corrective steps to assure against such claims in the future.

HRSA uses the deeming requirements found in 42 U.S.C. 233(h) and (q), as implemented in the FTCA regulations in 42 CFR part 6, the FTCA Health Center Policy Manual, and the annual FTCA Health Center Deeming PAL as the basis for determining whether health centers have demonstrated compliance with the statutory deeming requirements of the FTCA Health Center Program. Consultants and/or HRSA staff also may share best practice recommendations or TA on various areas observed during the site visit.

HRSA primarily conducts FTCA site visits between the months of May and October, although they may be conducted at any time throughout the year. Generally, health centers that have been selected for an FTCA site visit will be notified at the beginning of the calendar year. However, in the event that an FTCA site visit is scheduled due to an emergent need (such as a patient safety concern arising from issues with credentialing and privileging, risk management or QI/QA), HRSA may schedule a site visit with the health center at any time.

FTCA Site Visit Process Overview

Once on site, the health center can expect the team to conduct document reviews, staff and board interviews and facility tours depending on schedules and availability. FTCA site visits are generally conducted in a 2.5-day timeframe. All details are discussed prior to the site visit during the pre-site visit call. The steps below include pre-site and on-site planning activities during a typical FTCA Site Visit.

Pre-Site Activities

1. HRSA staff notifies selected health center Chief Executive Officer (CEO) and Project Officer (PO) about their health center's selection.
2. HRSA will assemble a site visit team to conduct the FTCA site visit. The team generally consists of a HRSA staff member and two consultants.
3. HRSA staff will coordinate and schedule a pre-site visit call with the health center and site visit team to introduce the site visit process and clarify roles, responsibilities, and logistics.

4. Consultants will request specific documents from the FTCA Document Review Checklist as noted in Section I below, for review prior to the visit.
5. During the call, consultants will work with the health center to identify appropriate staff to be interviewed onsite.
6. The health center will update the FTCA Site Visit Agenda as noted in Section II below, and return requested documents to HRSA staff. HRSA will confirm receipt of documents and follow up as needed.

On-Site Activities

1. While on site, the site visit team will review the previously requested health center policies and procedures pertinent to credentialing and privileging, risk management, claims management, and QI/QA with the grantee. This review typically focuses on questions that may have arisen during the team's review of the documents prior to arriving on site.
2. The site visit team will follow the finalized FTCA Site Visit Agenda as noted in Section II below, while reviewing documents, conducting interviews and touring facilities to ensure tasks are completed on time and within the 2.5-day timeframe.
3. During the site visit, the site visit team will utilize the FTCA Health Center Site Visit Protocol to conduct the on-site analysis. Possible areas of deficiency are identified using the annual FTCA Health Center Deeming PAL, the FTCA Health Center Policy Manual, the annual Health Center FTCA Deeming Application and pertinent chapters of the Health Center Program Compliance Manual (e.g., chapters 5, 10, and 21) to assess and verify implementation of FTCA deeming requirements.
4. Any identified areas of deficiency are listed in the FTCA Site Visit Report (see below for additional details regarding the report process).
5. The FTCA site visit will conclude with an exit conference where the site visit team will present any site visit findings to health center staff. At this time, the health center staff will have an opportunity to ask questions and engage in review and discussion of the site visit team's findings.

FTCA Site Visit Report

HRSA will develop and share an FTCA site visit report with the health center, typically within 4-6 weeks of the site visit. The report will convey the site visit findings and determinations regarding the health center's implementation of FTCA deeming requirements.

The report will include both findings of non-compliance, if any, as well as suggestions for improvement. Findings of non-compliance will not affect a health center's current calendar year FTCA deeming status. **However, health centers that are found to be non-compliant with Health Center Program requirements, specifically credentialing and privileging and/or QI/QA, may be subject to enforcement actions under the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards, at 45 CFR part 75. These enforcement actions are further described in the Health Center Program Compliance Manual, specifically, Chapter 2: Health Center Program Oversight. In addition, any areas of non-compliance still present at the time of the subsequent calendar year FTCA deeming cycle may result in a negative deeming determination.**

The FTCA site visit report will include a description of health center actions required to comply with FTCA

deeming requirements and cure any identified deficiencies. The report will note specific dates or deadlines for submission of information and/or documentation to HRSA.

Section I – Document Review Checklist

The consolidated Document Review Checklist contains documents used to assess compliance with FTCA program requirements during the FTCA site visit. While on-site, the consultant(s) may request additional documentation and information. The consultants may also ask to speak to specific staff members that work in each of the areas listed below.

Many of the documents addressed in this section are requested in advance of the site visit in order for the site visit team to best service the health center. The lead consultant will reach out to the health center to request specific pre-site visit documents. Notification of these pre-site visit documents will occur on or before the pre-site visit call with the health center. Pre-site visit documents will be transmitted to the identified team electronically by the health center. Health centers have varying names for different policies and procedures. Please review the documents and follow up with the site visit team if you need clarification to determine which of your health center documents would be most appropriate. In general, the health center is encouraged to prepare any documents related to the areas of review (risk management, QI/QA, credentialing and privileging, and claims management) in order to demonstrate evidence of health center compliance.

Risk Management		
Requested Documents	**Health Center Provides Pre-Site Visit**	**Health Center Provides On-Site**
Risk Management Policy and Operating Procedures	✓	
Annual Risk Management Report to the governing board. This is the comprehensive report that covers clinical risk management issues including but not limited to, risk management goals, progressing in meeting goals, completed risk management activities, proposed activities, completed assessments, number of incidents, and trainings	✓	
Quarterly Risk Management Assessments (within the past 12-24 months)	✓	

Risk Management		
Minutes of Risk Management meetings (within the past 12-24 months)	✓	
Staffing HIPAA (Privacy) Policy	✓	
Medical Records Retention Policy	✓	
Infection Control Policies and Procedure	✓	
Sterilization Policies and Procedures	✓	
Adverse Occurrence Policy or Incident Management Policy	✓	
Patient Satisfaction Survey Results		✓
Patient Complaint Policy and Procedure	✓	
If applicable, active and resolved patient complaints		✓
Medical Record Documentation and Completeness Standards		✓
Medical Record Archiving Procedures		✓
Safety Protocols Policy and Procedures (i.e., Sharps use/disposal procedures and Emergency plans)	✓	

Risk Management		
Risk Management Training		
Risk Management Training Plan (This plan outlines the trainings that will be required for the current calendar year, health center staff/provider types required to take the trainings, the date the training will occur, the deadline to complete the training. In addition, the plan should outline the process for tracking training progress, and the tools used to ensure adherence.)	✓	
Risk Management Training documentation (Including but not limited to training plans, policies and procedures, Sign-in sheets or other tracking documentation)		✓
Record of governing board risk management training (within the past 12 months)	✓	
Record of staff risk management and safety training (within the past 12 months)	✓	

Tracking		
Requested Documents	**Health Center Provides Pre-Site Visit**	**Health Center Provides On-Site**
Walk-in Patients Policy	✓	
Specialty Referral Tracking Policy	✓	

Tracking		
Specialist Referral Tracking Log (or other means to demonstrate referral tracking and follow-up)		✓
Hospitalization Tracking Policy	✓	
ER Tracking Policy	✓	
Hospital and ER Referral Tracking Log (or other means to demonstrate tracking and follow-up)		✓
Diagnostic Tracking Policy (x-ray, labs) and either log or workflow regarding closing loop of patient lab results from health center back to the patient	✓	
Diagnostic Tracking Log (or other means to demonstrate tracking and follow-up)		✓
No Show Appointments Policy and Follow-up	✓	
Phone Triage Policy	✓	
Urgent Care Visit Triage Policy and Procedure	✓	
Specialty Referral Tracking Policy	✓	
Specialist Referral Tracking Log (or other means to demonstrate referral tracking and follow-up)		✓

Quality Improvement and Quality Assurance (QI/QA)		
Requested Documents	**Health Center Provides Pre-Site Visit**	**Health Center Provides On-Site**
QI/QA Plan and/or policy(ies) that establish the QI/QA program	✓	
QI/QA Committee Meeting Minutes (within the last 12-24 months)	✓	
Board Minutes (six most current governing board minutes)	✓	
Health center bylaws	✓	
Governing board roster	✓	
Clinical guidelines and references used to develop guidelines/protocols, (i.e., UpToDate.com specialty guidelines, Academy of Pediatrics, American College of Obstetrics, Gynecology, Academy of Family Practitioners, etc.)		✓
Clinical protocols		✓
Sample clinical performance reports presented to the QI/QA Committee(s) and Board (most recent)	✓	
Minutes of provider staff meetings (within the past 6 months)	✓	

Credentialing and Privileging		
Requested Document	**Health Center Provides Pre-Site Visit**	**Health Center Provides On-Site**
List of clinical staff members with indicated professional designation including (but not limited to) relevant credentialing/privileging information, name, and FTE status	✓	
Provider Contracts, Agreements and Subrecipient Arrangements (if applicable based on service delivery methods on Form 5A)	✓	
Credentialing and Privileging Policies and Procedures	✓	
Credentialing and Privileging files available for examination (specific files to be pulled by health center will be determined by consultant team on-site)		✓
If applicable, contract or agreement with Credentialing Verification Organization (CVO) or other entity if used to perform credentialing functions, such as primary source verification, on behalf of the health center	✓	
Peer review procedures or other applicable mechanism(s) (results to be available on site)	✓	
Documentation the governing board or designee has approved the staff members who are credentialed or re-credentialed and privileged		✓

Credentialing and Privileging		
Health center organizational chart(s) with name of key management staff	✓	

Claims Management		
Requested Document	**Health Center Provides Pre-Site Visit**	**Health Center Provides On-Site**
Policies and procedures for internal handling, analyzing, and tracking claims or potential claims	✓	
Document(s) showing evidence the health center informs patients, using plain language, it is a deemed federal Public Health Service employee via its website, promotional materials, and/or within area(s) of the health center visible to patients		✓
Claims files for all potential and actual claims		✓

Section II – Sample FTCA Site Visit Agenda

Creation of Site Visit Agenda

When creating the agenda for an FTCA site visit, the goal is to work in coordination with the health center in a flexible and collaborative manner. The FTCA site visit agenda is created based on a standard template that is utilized for all FTCA site visits and from the recommendations and availability of staff that is submitted by the health center. Prior to the site visit, an FTCA staff member will e-mail a copy of the FTCA agenda template to the health center contact. The health center will edit the agenda in the following ways:

1) Make any changes to the base of the template.
    a. Example: In circumstances where the facility tour cannot be accomplished on the first day or from 10:00 am – 11:00 am, the health center can reschedule the tour to another date or time.
2) Select an hour timeslot for the team to meet with the governing board.
    a. Please note that the meeting with the governing board does not include other health center staff or health center management.
    b. While it is nice to have governing board members attend in person, it is acceptable for members to attend via telephone, skype, or any other means of telecommunication that the health center has available.
3) In the timeslots slated for interviews with staff, if there are key staff members with limited availability, please include specific times those individuals will be available for meetings. The key staff members typically include:

    a. Risk Manager
    b. Quality Coordinator
    c. Chief Medical Officer
    d. Claims Manager
    e. Credentialing Officer and Human Resource Manager
    f. Other staff that the health center determines has an integral role in any of the areas that will be reviewed by the site visit team

Please Note: During the site visit, schedules may change or certain sessions may run longer than intended. In the event that there are required changes, the FTCA staff and the site visit consultants will keep an open line of communication and make any needed adjustments.

Sample FTCA Site Visit Agenda

Health Center
Health Center Address

_____, 20XX

Point of Contact
_____
(Phone Number)

Wednesday, _____, 20XX

	Arrival at Health Center
9:00-10:00	Entrance Conference with site visit team, key management staff and board members; Other staff attends at pleasure of CEO
	Review of site visit, overview of health center, site visit logistics, information request and schedule
10:00 - 11:00	Tour of Facility
11:00 - 12:00	Begin document review from requested list of on-site documents and files
12:00 - 1:00	Break for Lunch
	Lead Consultant Schedule
1:00 - 2:00	Discuss Credentialing and Privileging - Consultant and Health Center staff
2:00 - 3:00	Discuss Quality - Consultant and Health Center staff
3:00 - 4:00	Discuss Peer Review with Health Center staff
	2nd Consultant Schedule
1:00 – 4:00	Discuss Clinical Tracking with Health Center staff Discuss Risk Management – Infection Control, Safety, and Training with Health Center staff

Thursday, _____, 20XX

	Arrival at Health Center
9:00 – 12:00	Continue Risk Management discussion with Health Center staff
12:00 - 1:00	Interview governing board members

1:00 – 2:00	Claims Management review with Health Center staff

Friday, _____, 20XX

	Arrival at Health Center
9:00 – 10:30	Completion of site visit team review
10:30 - 12:00	Exit conference with key management staff. Site visit team presents oral report of findings and recommendations.

Section III – Sample Report

The site visit report will identify HRSA/FTCA compliance determinations for each area of review (credentialing, privileging, risk management, QI/QA, and claims management). FTCA program requirement issues are monitored with an action plan as noted below in the Sample Compliance Actions section. The site visit team may also identify performance improvement opportunities. Federal representatives and consultants will engage health center staff onsite about areas of improvement as identified during the review process.

FTCA Program Requirements	**Sample Compliance Actions** [***Actions required to come into compliance***]
Credentialing Authority- 42 U.S.C 233(h)(2); Health Center Compliance Manual; PAL 2018-01 pg.19-21	
CP. 1 The health center has operating procedures for the initial and recurring review (clearly indicates period of review) of credentials for all clinical staff members (licensed independent practitioners (LIPs), other licensed or certified practitioners (OLCPs), and other clinical staff providing services on behalf of the health center) who are health center employees, individual contractors, or volunteers. ☐ No compliance issue noted ☐ Compliance issues noted Remarks:	Provide updated operating procedures for initial and recurring review of credentials for all clinical staff members (LIPs and OLCPs). These operating procedures must clearly detail the following as indicated below: 1. ☐ Time period for review and 2. Procedures for: ☐ Employees, ☐ Individual contractors, and ☐ Volunteers Due Date:

FTCA Program Requirements	Sample Compliance Actions [*Actions required to come into compliance*]
CP. 2 The credentialing procedures ensure verification of the following, as applicable: a) Current licensure, registration, or certification using a primary source; b) Education and training for initial credentialing, using: c) Primary sources for LIPs d) Primary or other sources (as determined by the health center) for OLCPs and any other clinical staff; e) Completion of a query through the National Practitioner Databank (NPDB); f) Clinical staff member's identity for initial credentialing using a government-issued picture identification; g) Drug Enforcement Administration (DEA) registration; and h) Current documentation of basic life support training. ☐ No compliance issue noted ☐ Compliance issues noted <u>Remarks</u>:	Provide updated operating procedures for initial and recurring review of credentials for all clinical staff members (LIPs and OLCPs). These operating procedures must clearly detail the following for the clinical staff indicated below: ☐ LIPs ☐ OLCPs a) ☐ Current licensure, registration, or certification using a primary source; ☐ b) ☐ Education and training for initial credentialing, using: i. Primary sources for LIPs ii. Primary or other sources (as determined by the health center) for OLCPs and any other clinical staff; c) ☐ Completion of a query through the NPDB; d) ☐ Clinical staff member's identity for initial credentialing using a government-issued picture identification; e) ☐ DEA registration; and f) ☐ Current documentation of basic life support training. Due Date:

FTCA Program Requirements	Sample Compliance Actions [*Actions required to come into compliance*]
Privileging Authority- 42 U.S.C 233(h)(2); Health Center Compliance Manual; PAL 2018-01 pg.19-21	
CP. 3 The health center has operating procedures for the initial granting and renewal (for example, every two years) of privileges for clinical staff members (LIPs, OLCPs, and other clinical staff providing services on behalf of the health center) who are health center employees, individual contractors, or volunteers. ☐ No compliance issue noted ☐ Compliance issues noted Remarks:	Provide updated operating procedures for initial granting and renewal of privileges for clinical staff members (LIPs and OLCPs). These operating procedures must clearly detail the following as indicated below: ☐ LIPs ☐ OLCPs 1. Privileges procedures for ☐ employees, ☐ individual contractors, and ☐ volunteers. Due Date:

FTCA Program Requirements	**Sample Compliance Actions** [***Actions required to come into compliance***]
CP. 4 The health center has privileging procedures to address 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. ☐ No compliance issue noted ☐ Compliance issues noted <u>Remarks</u>:	Provide updated operating procedures for initial granting and renewal of privileges for clinical staff members (LIPs and OLCPs). These operating procedures must clearly detail the following for the groups indicated below: Group: ☐ LIPs ☐ OLCPs 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. Due Date:

FTCA Program Requirements	**Sample Compliance Actions** [***Actions required to come into compliance***]
CP. 5 The health center maintains files or records for its clinical staff (for example, employees, individual contractors, and volunteers) that contain documentation of licensure, credentialing verification, and applicable privileges, consistent with operating procedures. ☐ No compliance issue noted ☐ Compliance issues noted <u>Remarks</u>:	Health center must ensure all provider files and/or records contain the appropriate documentation of licensure, credentialing verification, and applicable privileges, consistent with operating procedures. Due Date:

FTCA Program Requirements	**Sample Compliance Actions** [***Actions required to come into compliance***]
CP. 6 If the health center has contracts with provider organizations (for example, group practices, locum tenens staffing agencies, training programs) or formal, written referral agreements with other provider organizations that provide services within its scope of project, the health center has ensured that such providers are: a) Licensed, certified, or registered as verified through a credentialing process, in accordance with applicable Federal, state, and local laws; and b) Competent and fit to perform the contracted or referred services, as assessed through a privileging process. ☐ No compliance issue noted ☐ Compliance issues noted <u>Remarks</u>:	Provide contracts from your provider organizations (for example, group practices, locum tenens staffing agencies, training programs) or formal, written referral agreements with provider organizations that ensure and require the following: a) ☐ A credentialing process for all licensed, certified, or registered providers in accordance with applicable Federal, state, and local laws; and b) ☐ A process to verify that all licensed, certified, or registered providers are competent and fit to perform the contracted or referred services, as assessed through a privileging process. Due Date:

FTCA Program Requirements	Sample Compliance Actions [*Actions required to come into compliance*]
Risk Management Authority- 42 U.S.C 233(h)(1); Health Center Compliance Manual; PAL 2018-01 pg.10-14	
RM. 1 The health center is implementing an ongoing health care risk management program 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: a) Risk management across the full range of health center health care activities; b) Health care risk management training for health center staff; c) Completion of quarterly risk management assessments by the health center; and d) Annual reporting to the health center board which includes: 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. ☐ No compliance issue noted ☐ Compliance issues noted <u>Remarks</u>**:**	Provide ongoing documentation of your health care risk management program to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation. a) ☐ Policies and procedures for risk management across the full range of health center health care activities and risk management minutes or other documentation that clearly indicates risk management is occurring within the health center b) ☐ The health center risk management training plan for all levels of staff and other documentation that evidences risk management training within the health center (Example: Training Sources, Sign-in sheets, registration forms, session outlines); and c) ☐ The most recent risk management report that was presented to the health center board, and minutes that clearly indicate the report was presented to the health center board. Due Date:
RM. 2 The health center has risk management procedures that address the following areas for	Provide risk management procedures that address the items listed below. Also, include any additional

FTCA Program Requirements	Sample Compliance Actions [*Actions required to come into compliance*]
health center services and operations: a) Identifying and mitigating 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; b) Documenting, analyzing, and addressing clinically-related complaints and "near misses" reported by health center employees, patients, and other individuals; c) Setting and tracking progress related to annual risk management goals; d) 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 and infection control) and any non-clinical trainings appropriate for health center staff (including HIPAA medical record confidentiality requirements); and e) Completing an annual risk management report for the board and key management staff. ☐ No compliance issue noted ☐ Compliance issues noted	documents requested for each item. a) ☐ Identifying and mitigating 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; b) ☐ Documenting, analyzing, and addressing clinically-related complaints and "near misses" reported by health center employees, patients, and other individuals; c) ☐ Setting and tracking progress related to annual risk management goals; d) ☐ 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 and infection control) and any non-clinical trainings appropriate for health center staff (including HIPAA medical record confidentiality requirements); and; e) ☐ Completing an annual risk management report for the board and key management staff. Due Date:

FTCA Program Requirements	**Sample Compliance Actions** [***Actions required to come into compliance***]
Remarks:	
RM. 3 The health center has designated an individual(s) (for example, a risk manager) who oversees and coordinates the health center's health care risk management activities and completes risk management training annually. ☐ No compliance issue noted ☐ Compliance issues noted Remarks:	Provide the name of the individual(s) responsible for the management of the health center's health care risk management activities and risk management training. Also, include position descriptions and job agreements (if applicable). Due Date:

FTCA Program Requirements	Sample Compliance Actions [*Actions required to come into compliance*]
Quality Assurance and Quality Improvement (QI/QA) Authority- 42 U.S.C 233(h)(1); Health Center Compliance Manual; PAL 2018-01 pg.15-18	

QM. 1 The health center has an ongoing quality improvement/assurance (QI/QA) system that includes clinical services and [clinical] management and maintains the confidentiality of patient records.
 	
☐ No compliance issue noted
 	
☐ Compliance issues noted
 	
Remarks:
	Provide the following documentation:
	
	a. Board-approved policy(ies) that establishes a QI/QA program. This QI/QA program addresses the following:
	  a. ☐ The quality and utilization of health center services;
	  b. ☐ Patient satisfaction and patient grievance processes; and
	  c. ☐ Patient safety, including adverse events;
	b. ☐ Position description for the individual(s) designated to oversee the QI/QA program established by board-approved policy(ies). This individual's responsibilities would include, but would not be limited to, ensuring the implementation of QI/QA operating procedures and related assessments, monitoring QI/QA outcomes, and updating QI/QA operating procedures.
	c. ☐ The most recent QI/QA report that has been provided to key management staff and to the governing board. and
	d. ☐ Governing board minutes that document that the most recent QI/QA report was shared with and discussed by the governing board to support decision-making and oversight regarding the provision of health center services.
	
	Due Date:

QM. 2 The health center's ongoing QI/QA system provides the following:	Provide the following documentation:

FTCA Program Requirements	Sample Compliance Actions [*Actions required to come into compliance*]
a) Organizational arrangements, including a focus of responsibility, to support the quality assurance program and the provision of high quality patient care; and b) Periodic assessment of the appropriateness of the utilization of services and the quality of services provided or proposed to be provided to individuals served by the center. Such assessments must: 1. Be conducted by physicians or by other licensed health professionals under the supervision of physicians; 2. Be based on the systematic collection and evaluation of patient records; 3. Assess patient satisfaction, achievement of project objectives, and include a process for hearing and resolving patient grievances; and 4. Identify and document the necessity for change in the provision of services by the center and result in the institution of such change, where indicated. ☐ No compliance issue noted ☐ Compliance issues noted	a. Operating procedures or processes that address the following: 1. ☐ Adhering to current evidence-based clinical guidelines, standards of care, and standards of practice in the provision of health center services, as applicable; 2. ☐ Identifying, analyzing, and addressing patient safety and adverse events and implementing follow-up actions, as necessary; 3. ☐ Assessing patient satisfaction; 4. ☐ Hearing and resolving patient grievances; 5. ☐ 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 6. ☐ 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; and b. QI/QA assessments conducted on at least a quarterly basis by the health center's physicians or other licensed health care professionals, using data systematically collected from patient records, to ensure: 1. ☐ Provider adherence to current evidence-based clinical guidelines, standards of care, and standards of practice in the provision of health center services, as applicable; and 2. ☐ The identification of any patient safety and adverse events and the implementation of related follow-up actions, as necessary.

FTCA Program Requirements	Sample Compliance Actions [*Actions required to come into compliance*]
Remarks:	Due Date:
QM. 3 The health center maintains the confidentiality of patient records, including all information as to personal facts and circumstances obtained by the health center staff about recipients of services. Specifically, the health center must not divulge such information without the individual's consent except as may be required by law or as may be necessary to provide service to the individual or to provide for medical audits by the Secretary of HHS or his/her designee with appropriate safeguards for confidentiality of patient records. ☐ No compliance issue noted ☐ Compliance issues noted Remarks:	Provide the following documentation: a. ☐ Operating procedures on maintaining a retrievable health record (for example, the health center has implemented a certified Electronic Health Record (EHR)) for each patient, the format and content of which is consistent with both Federal and state laws and requirements; and b. ☐ Operating procedures on implemented systems (for example, certified EHRs and corresponding standard operating procedures) for protecting the confidentiality of patient information and safeguarding this information against loss, destruction, or unauthorized use, consistent with Federal and state requirements. Due Date:
Claims Management Authority- 42 U.S.C 233(h)(1); Health Center Compliance Manual; PAL 2018-01 pg.22-24	
CM. 1 The 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. In addition, this process ensures: a) The preservation of all health center documentation related to any actual or potential claim or complaint (for example, medical records and	Provide claims management document(s) that details a process for addressing potential or actual medical malpractice claims that may be eligible for FTCA coverage. The policies must detail and ensure the following: a) ☐ The preservation of all health center documentation related to any actual or potential claim or complaint (for example, medical records and associated laboratory

FTCA Program Requirements	Sample Compliance Actions [*Actions required to come into compliance*]
associated laboratory and x-ray results, billing records, employment records of all involved clinical providers, clinic operating procedures); and b) 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. ☐ No compliance issue noted ☐ Compliance issues noted <u>Remarks</u>:	and x-ray results, billing records, employment records of all involved clinical providers, clinic operating procedures); and b) ☐ 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. Due Date:

FTCA Program Requirements	**Sample Compliance Actions** [***Actions required to come into compliance***]
CM. 2 The health center has designated individual(s) who is responsible for the management and processing of claims-related activities and serves as the claims point of contact. ☐ No compliance issue noted ☐ Compliance issues noted <u>Remarks</u>:	Provide the name of the individual(s) responsible for the management and processing of medical malpractice claims-related activities and relevant position description documents and/or job agreement. Due Date:
CM. 3 The health center informs patients using plain language that it is a deemed Federal Public Health Service (PHS) employee via its website, promotional materials, and/or within an area(s) of the health center that is visible to patients. ☐ No compliance issue noted ☐ Compliance issues noted <u>Remarks</u>:	Provide pictures, materials, website links, and/or documentation that clearly demonstrates the health center has informed patients using plain language the health center is a deemed Federal PHS employee. Due Date:

FTCA Program Requirements	**Sample Compliance Actions** [***Actions required to come into compliance***]
CM. 4 If a history of claims under the FTCA exists, the health center has: a) Cooperated with the Attorney General, as further described in the FTCA Health Center Policy Manual; and b) Implemented steps to mitigate the risk of such claims in the future. ☐ No compliance issue noted ☐ Compliance issues noted <u>Remarks</u>:	Provide the following: 1. ☐ A detailed action plan that outlines how the health center will ensure cooperation with relevant HHS offices and the Attorney General in the defense of all eligible FTCA Claims, and 2. ☐ A statement signed by the Chair of the Health Center governing board acknowledging that that a failure to not cooperate with the U.S. Department of Health and Human Services and or the Attorney General in the defense of eligible FTCA claims may and can result in the denial of future FTCA Deeming applications. 3. ☐ Submit a plan for each FTCA claim noted that details what actions the health center has taken or will take to mitigate the risk of such claims in the future. The document should clearly indicate how this plan will be implemented prior to the next deeming application submission. Due Date:

Section IV - Resources

If your organization is a Federally Qualified Health Center, please email Clinical_RM_Program@ecri.org to request access to ECRI Clinical Risk Management resources. A sample of the tools and resources available through ECRI are listed below. Please visit www.ecri.org or call 610-825-6000 ext. 5891 for more information.

Credentialing and Privileging and Peer Review Tools and Resources
• Credentialing Toolkit (includes sample credentialing policies, step-by-step processes, credentialing application packet and flowcharts, and more): www.ecri.org/components/HRSA/Pages/CredentialingToolkit.aspx • Credentialing and Privileging Guide for Health Centers: https://www.ecri.org/components/HRSA/Documents/CredentialingandPrivilegingGuide.pdf • Get Safe: Back to Basics: Effective Credentialing: www.ecri.org/components/HRSA/Pages/GetSafe_113016.aspx • Get Safe: Credentialing and Privileging Non-Physician Providers and Clinical Staff: www.ecri.org/Components/HRSA/Pages/GetSafe_042114.aspx • Get Safe: Assessing Clinical Competence: www.ecri.org/Components/HRSA/Pages/GetSafe_123113.aspx • Get Safe: Peer Review Improves Patient Safety and Quality of Care: www.ecri.org/Components/HRSA/Pages/GetSafe091412.aspx • Get Safe: Effective Processes for Granting Clinical Privileges: www.ecri.org/Components/HRSA/Pages/GetSafe102612.aspx
Risk Management Tools and Resources
• Risk Management Toolkit (includes sample plan, checklists, dashboard, risk management training tools, risk assessment tools, and more): www.ecri.org/Components/HRSA/Pages/RMToolkit.aspx • Test Tracking and Follow-Up Toolkit (includes sample policy, logs, and more): www.ecri.org/Components/HRSA/Pages/TestTrackToolkit.aspx • Ambulatory Care Risk Management Certificate Program: www.ecri.org/Components/HRSA/Pages/rmbasics.aspx • E-Learn Courses for Continuing Education Credit: www.ecri.org/Components/HRSA/Pages/eLearn.aspx • Get Safe: Developing a Risk Management Training Program: www.ecri.org/Components/HRSA/Pages/GetSafe_042815.aspx • Get Safe: Handling Patient Complaints: Feedback for Quality Improvement: www.ecri.org/Components/HRSA/Pages/GetSafe_082616.aspx • Practice Alert: Conducting Risk Assessments: A Checklist: www.ecri.org/Components/HRSA/Pages/PracticeAlerts033018.aspx

Quality Assurance and Quality Improvement Tools and Resources

- Quality Improvement/Quality Assurance Toolkit (includes sample QI plans, meeting agendas and minutes, program checklists, and more): www.ecri.org/components/HRSA/Pages/QAToolkit.aspx
- Webinar: Data-Driven Quality Improvement: www.ecri.org/Components/HRSA/Pages/AC_DataDriven.aspx
- Webinar: A Measure of Quality: Implementing a QI/QA Program: www.ecri.org/Components/HRSA/Pages/AC_QualityImprove.aspx
- Webinar: The Use of EHRs for Quality Improvement: www.ecri.org/Components/HRSA/Pages/AC_EHRsforQI.aspx
- Virtual Conference: Continuous Quality Improvement: Learning from Events: www.ecri.org/Components/HRSA/Pages/HRSAWebinar_090816_ContinuousQualityImprovement.aspx
- Get Safe: Employing Data-Driven Quality Improvement Measures: www.ecri.org/Components/HRSA/Pages/GetSafe_061915.aspx
- Get Safe: Using Valid Quality Improvement (QI) Methodologies: www.ecri.org/Components/HRSA/Pages/GetSafe_123014.aspx

Claims Management Tools and Resources

- Event Reporting Toolkit: www.ecri.org/Components/HRSA/Pages/EventReportToolkit.aspx
- Event Response Toolkit: www.ecri.org/Components/HRSA/Pages/EventResponseToolkit.aspx
- Infographic: Proactive Management of Potential Claims: www.ecri.org/Components/HRSA/Pages/LBPol4.aspx.
- Virtual Conference: After an Event: Understanding the Claims Process: www.ecri.org/Components/HRSA/Pages/AC_AfterEventUnderstandClaimsProcess.aspx
- Virtual Conference: After an Event: Consider the Patient, Provider, and Practice: www.ecri.org/Components/HRSA/Pages/AC_AfterEventConsider.aspx