Federal Tort Claims Act Site Visit Training for Health Centers

Bureau of Primary Health Care (BPHC)
Health Resources and Services Administration (HRSA)
U.S. Department of Health and Human Services (HHS)

Current as of April 20, 2022
Agenda

- FTCA Site Visit Purpose.
- Virtual Site Visit Overview.
- Site Visit Selection Criteria.
- FTCA Site Visit Roles and Responsibilities.
- Site Visit Process.
- FTCA Site Visit Activities/Areas for Review.
- FTCA Site Visit Report.
Learning Objectives

- Describe the FTCA site visit purpose, overview, and selection criteria.
- Highlight FTCA site visit processes to promote understanding and compliance.
- Identify elements required to achieve compliance with FTCA programmatic requirements.
- Review the health center response to the site visit report findings.
What is the Federal Tort Claims Act?


- Medical malpractice coverage is provided to deemed entities.

- Health centers must apply annually to be granted deemed status.
Purpose of FTCA Site Visit

- Provides an objective evaluation and verification of deemed health center compliance with programmatic requirements related to:
  - Risk management.
  - Quality improvement/quality assurance (QI/QA).
  - Credentialing and privileging.
  - Claims management.
FTCA Site Visit Overview

- Approximately 20 to 25 health centers are selected annually.
- Emergency site visit may occur during the year depending on circumstances.
- Three full days in length.
- Team consists of one or two FTCA representative(s) and two contracted consultants.
- Pre-site visit readiness tool utilized to assess health center readiness.
FTCA Site Visit Selection Criteria

- Submission of a FTCA initial deeming application.
- Potential non-compliance on annual deeming application.
- History of repeated conditions or current conditions on Health Center Program grant placed by HRSA operational site visit (OSV).
- Need for follow-up on prior site visit.
- History of medical malpractice claims.
- Other issues as identified by HRSA.
FTCA Site Visit Team Responsibilities

- FTCA representatives:
  - Lead and provide oversight of FTCA site visit team.
  - Provide programmatic guidance and address issues that may arise during the site visit.

- Consultants:
  - Evaluate health center’s compliance with FTCA programmatic requirements in consultation with FTCA representative.
  - Provide technical assistance, as needed.
Health Center Responsibilities

- Participate in the pre-site visit conference call.
- Confirm staff availability to participate in interviews and document reviews.
- Invite board members to board meeting, entrance conference, or exit conference.
- Provide requested documents to site visit team.
- Coordinate site visit activities such as virtual tour, meetings, interviews, and document review.
- Arrange for meeting space and internet connectivity.
Programs and Platforms Used During FTCA Site Visits

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Technology Used During FTCA Site Visits

- **Overview of Citrix ShareFile:**
  - Program used for uploading files to a shared folder.
  - Provides access to all documents needed for site visit.

- **Overview of GoToMeeting:**
  - Video conference platform used for virtual site visit.
  - Used for virtual tour and all meetings.
FTCA Site Visit Process

- Pre-site visit planning
- Pre-site visit call
- Site visit review
- Site visit report
Pre-Site Visit Planning and Pre-Site Visit Call
Pre-Site Visit Planning

- Health centers notified through electronic handbook (EHB).
- Health centers confirm participation via email to HRSA.
- Initial contact will be made by HRSA, but thereafter, contact may be with FTCA representative(s) or consultant(s).
Health Center Notification Letter

- Notification letter sent five to eight weeks prior to site visit.
- The letter includes:
  - Names and contact information for site visit team.
  - Sample agenda.
  - Details regarding pre-site visit call and logistics.
  - List to assist in gathering documents required for site visit.
  - Three proposed dates for pre-site visit call.
Pre-Site Visit Call

- Introduce site visit team.
- Discuss purpose of FTCA site visit.
- Review and edit site visit agenda.
- Discuss document review/submission.
- Discuss site visit report.
- Provide answers to questions.
Site Visit Agenda

- Provides a road map for the site visit.
  - Includes entrance conference, exit conference, board meeting, and tour.
- Should be completed with names and contact information for key staff members who will participate in meetings and interviews.
- Final agenda emailed and uploaded into Citrix ShareFile three days prior to site visit.
Site Visit Review
Site Visit Meetings and Interviews (Slide 1 of 2)

- Health center staff and board members should participate in site visit meetings and interviews.
- Key management staff are expected to participate in all site visit activities.
- It is not appropriate for health center counsel or Primary Care Association (PCA) representatives to attend meetings and interviews.
Site Visit Meetings and Interviews (Slide 2 of 2)

- Entrance conference: Introductions, review of agenda/logistics, presentation of general organizational overview by the health center.
- Exit conference: Presentation of preliminary findings by the site visit team.
- Interviews/meetings will be conducted with health center staff and include review of documents.
- Meeting with board of directors should include only board members and site visit team.
Site Visit Activities/Areas for Review

- Virtual Tour
- Risk Management
- Credentialing and Privileging
- Quality Improvement/Quality Assurance
- Claims Management
Virtual Site Visit Tour (Slide 1 of 2)

- Conducted via GoToMeeting.
- Key staff should be present to answer questions.
- Site visit team may request to speak informally with staff as they tour.
Examples of areas that will be included in tour:

- Vacant treatment room.
- Medication room/storage and management.
- Dedicated space for the separation of contagious patients from the general population.
- Clinical areas, including laboratory, radiology, pharmacy, and dental (as applicable).
- Eye wash stations.
FTCA Programmatic Requirements
Risk Management
Sample of five to 10 patient records that include clinic visit note(s) and/or summary of care.

Patient satisfaction survey results.

Patient complaint policy and procedure.

Active and resolved patient complaints and/or grievances.

Risk management training documentation.
  - e.g., policies and procedures, training plans, sign-in sheets.
Policies and procedures, training, monitoring, and tracking for the following:

- Infection control and prevention.
- Sterilization/surgical practices.
  - Dental, OB/GYN, podiatry, minor surgery.
- Medication management/control.
  - Medication management and safe handling and storage practices.
- Point of care testing (POCT) equipment.
  - Glucometers, centrifuges, etc.
- Policies and procedures for documenting, analyzing, and addressing the following:
  - Clinically-related complaints and grievances.
  - Sentinel events.
  - Adverse events.
  - Near misses.
- Evidence that systems are in place to track, trend, and analyze events.
- Evidence that process improvements are implemented.
Risk Management Training
A comprehensive risk management training plan should describe:

- How the program works and is implemented on an annual basis.
- Required trainings and sources utilized for training.
- Levels of staff required to participate in each training and time frame for completion.
- Tracking and documentation process to ensure training has been completed.
- Compliance enforcement and monitoring methods to ensure completion.
At a minimum, trainings must include areas/activities of highest clinical risk and incorporate the following:

- Obstetrical procedures.
- Infection control and sterilization.
- HIPAA medical record confidentiality requirements.
- Specific trainings for groups of providers that perform various services, which may lead to potential risk.
Health centers that provide obstetrical services through health center providers need to include obstetrical training as part of their risk management training plans.

- This includes health centers that provide prenatal and postpartum care through health center providers, even if they do not provide labor and delivery services.
Risk Management Training: Tracking Tool

- Tracking tool should include title and position of staff members.
- Tracking tool should clearly demonstrate that all staff members (clinical and non-clinical) have completed all required trainings.
- If all staff have not completed training in a timely manner, the tracking tool or other submissions should demonstrate remediation actions that have been implemented.
Test Your Knowledge
ABC Community Health Center has developed an annual risk management training plan. Handwashing and HIPAA training is provided each year for clinical staff. The charge nurse is responsible for providing the education, which includes a combination of one-on-one training with a return demonstration of handwashing technique. An article regarding medical record confidentiality is handed out, and staff are responsible to read it on their own time and complete 10 test questions. Staff have all year to complete the required training. Completion rates are reported to the board of directors. Obstetrics training is not included in the annual risk management training plan, as only prenatal and postpartum care is rendered at the health center, and labor and delivery services are not provided by health center employees.
Polling Question #1

- Question: Is ABC Community Health Center in compliance with risk management training requirements?

- Answer Choices:
  - Yes
  - No

- Correct Answer: No
Diagnostic, Referral, and Hospitalization Tracking
Document Review for Diagnostic, Referral, and Hospitalization Tracking

- Written policies and procedures.
- Uploaded tracking logs.
Referral and Hospitalization Tracking Procedures

- Tracking procedures should demonstrate a closed loop process that clearly addresses:
  - Time frames for follow-up.
  - Types and number of communications.
  - Individuals responsible for each step within the process.
  - Documentation.
Diagnostic Tracking Procedure

- Tracking procedure should demonstrate a closed loop process that clearly addresses:
  - Abnormal and critical test results.
  - Time frames for follow-up.
  - Types and number of communications.
  - Individuals responsible for each step within the process.
  - Documentation.
Test Your Knowledge
<table>
<thead>
<tr>
<th>Patient Name</th>
<th>DOB</th>
<th>Date of Admission/ED Visit</th>
<th>Date Notified</th>
<th>Name of Person Who Notified Health Center</th>
<th>Reason for Admission</th>
<th>Hospital/ED Records Received (Y/N) Date</th>
<th>Date of Office Follow-Up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Martha Week</td>
<td>3/5/16</td>
<td>2/15/22</td>
<td>2/18/22</td>
<td>Meg Signy</td>
<td>Abdominal mass</td>
<td></td>
<td>2/22/22</td>
</tr>
<tr>
<td>Stewart Long</td>
<td></td>
<td></td>
<td></td>
<td>Paul Fine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Matthew Peach</td>
<td>4/21/54</td>
<td>1/16/21</td>
<td></td>
<td>Mary Roberts</td>
<td></td>
<td>Y - 1/30/21</td>
<td>1/19/21</td>
</tr>
<tr>
<td>Susie Day</td>
<td>1/12/21</td>
<td></td>
<td></td>
<td>John</td>
<td>Vomiting &amp; diarrhea</td>
<td></td>
<td>3/12/22</td>
</tr>
</tbody>
</table>
Polling Question #2

- Question: Did the health center upload a complete and accurate hospital admission/emergency department tracking report?
- Answer choices:
  - Yes
  - No
- Correct Answer: No
Quarterly Risk Assessments
Quarterly Risk Assessments

- Documentation should provide detailed information that allows a clear understanding of methodology and outcomes of the assessments.
- Risk assessments should focus on areas that can potentially prevent or decrease the likelihood of medical malpractice claims.
  - e.g., patient safety, clinically focused assessments.
  - Do not include non-clinical elements such as building maintenance and parking lot inspections.
Annual Report to the Board of Directors
The annual report should be reflective of risk management activities over a 12-month period.

- Do not submit standalone minutes as evidence of an annual report to the board.
- While environment of care issues may impact the safety of patients, the annual report should be primarily focused on clinical elements of risk management and patient safety.
The annual report should include:

- Completed risk management activities.
- Status of the health center’s performance relative to established risk management goals.
- Proposed risk management activities for the next 12-month period that relate and/or respond to identified areas of high organizational risk.
Test Your Knowledge
ABC Community Health Center uploaded the past 12 months of meeting minutes, reflecting completed risk management activities reported to and discussed with the board of directors.
Polling Question #3

- **Question:** Did ABC Community Health Center’s submission meet the annual board report requirement?

- **Answer choices:**
  - Yes
  - No

- **Correct Answer:** No
Risk Manager
Job description should clearly detail duties that would typically be conducted by a risk manager.

Risk management training is required within 12 months prior to the submission of the FTCA application.
- Quality improvement/quality assurance (QI/QA) plan.
- Six months of QI/QA meeting minutes (within previous 12 months).
- Samples of QI/QA projects.
- Data used in conducting QI/QA projects.
Document Review for Quality Improvement (Slide 2 of 2)

- Clinical guidelines/protocols.
- Provider peer review.
- Health center bylaws.
- Board meeting minutes (most recent six months).
- Governing board roster.
Components of a Quality Improvement Plan

- Statement of purpose or intent.
- Scope of plan.
- Administrative responsibility.
- Risk management systems (some make this separate plan).
- Role of peer review in QI/QA.
- Committee composition.
- Committee accountability.
- Methods for conducting QI/QA activities.
- Tracking of QI/QA activities.
- Approval and review.
QI/QA Committee Meeting Minutes

- Should provide enough information for reviewer to verify successful implementation of QI/QA program.
- Should provide written documentation of QI/QA activities.
- Should include information on monitoring activities for measures listed in QI/QA plan.
- Should document multidisciplinary team by name and title during attendance.
- Should report on QI/QA activities conducted during meeting interval.
- Should include data used to measure objectives of QI/QA plan and track improvement activities.
Test Your Knowledge
ABC Community Health Center submitted its peer review policies and procedures, and discussion took place with its CMO and Quality Improvement Director. The policy and procedure indicated that the health center would conduct periodic assessments of the appropriateness of the utilization of services and the quality of services provided. During the interview, the CMO indicated that peer review was conducted twice a year.
Polling Question #4

- Question: Is the health center in compliance with the Health Center Program Compliance Manual Chapter 10 requirements?
- Answer choices:
  - Yes
  - No
- Correct Answer: No
Credentialing and Privileging
Health center: Employee list of full-time, part-time, and contractual clinical staff uploaded into Citrix ShareFile.

Consultant: Selects specific providers’ files to be reviewed from the list of clinical staff and uploads into Citrix ShareFile.
Consultants review:
- Licensed independent practitioners (LIPs) and other licensed and certified practitioners (OLCPs) - no fewer than 10 files.
- Other Clinical Staff (OCS) - no fewer than five files.

Staff who should be present during document review:
- Human resources (HR) employees, if applicable.
- Chief medical officer, chief dental officer, behavioral health director.
Document Review for Contracted or Referral Providers

- Documents reviewed to determine providers are credentialed and privileged:
  - Form 5 A, Column II.
    - Formal Written Contract Agreements.
  - Form 5A, Column III.
    - Formal Written Referral Arrangements.
Definitions

- Licensed Independent Practitioner (LIP): Any individual permitted by law and the organization to provide care and services without supervision and within scope of individual license and consistent with clinical privileges.

- Other Licensed or Certified Health Care Practitioner (OLCP): Individuals not permitted to provide patient care and services without supervision.

- Other Clinical Staff (OCS): Individuals for whom licensure, registration, or certification are not required.
Credentialing files should ensure verification of the following, as applicable:

- Identity using government-issued picture identification (initial credentialing only).
- Current licensure, registration, and certification.
- Education and training (initial credentialing only).
- Completion of query through the National Practitioner Database (NPDB).
- Drug Enforcement Administration (DEA) registration.
- Current documentation of Basic Life Support (BLS) training.
Privileging files should include:

- Verification of current clinical competence.
- Verification of fitness for duty.
- Verification of immunization and communicable disease status.
- Contractual/cooperative agreements, if applicable.

Privileging files should include delineation of privileges granted by health center and hospital.
Test Your Knowledge
Scenario: Credentialing and Privileging

ABC Community Health Center uploaded its credentialing and privileging policies and procedures. The policy indicated BLS and verification of immunization and communicable disease occurred upon hire, and an NPDB query occurred for LIPs upon hire and on a recurring basis.
Polling Question #5

- Question: The health center’s policy and procedure meet FTCA requirements and Health Center Program Compliance Manual Chapter 5 requirements.

- Answer choices:
  - True
  - False

- Correct Answer: False
Document Review for Claims Management

- Claims procedure.
- List of current and previous malpractice claims.
- Description of process for reviewing malpractice claims.
  - Internal analysis and implementation of steps to mitigate the risk of such claims in the future (regardless of outcome).
  - Only submit summary for closed claims.
Claims Procedure

- Claims procedure to include the following:
  - Notification of Office of General Council when health center receives notice of claim.
  - Preservation of all records associated with the claim, including medical records, billing records, laboratory reports, imaging reports, and consult reports.
Professional Liability History

- Brief description of closed claims:
  - Name of provider(s) involved.
  - Area of practice/specialty.
  - Date of occurrence.
  - Summary of allegations.
  - Status/outcome of claim.

- Remove patient information and conclusions of liability.
Closed Claims

- Closed claims consist of any of the following:
  - Settlement is reached.
  - Lawsuit is decided by a federal judge without a jury.
  - Case is dismissed with prejudice.
FTCA Site Visit Report
Site Visit Report (Slide 1 of 3)

- Conveys findings and determinations regarding health center implementation of FTCA programmatic requirements.
- Used to support programmatic decisions.
- Used to identify risk and claims management findings that require follow-up and corrective action.
- Used to identify technical assistance needs for FTCA deemed health centers.
Site visit report will identify HRSA/FTCA compliance determinations for each element reviewed as:

- No compliance issue noted.
- Compliance issue noted.

Report may include performance improvement opportunities.

- Health center is not required to provide written response to suggestions for performance improvement.
Site Visit Report (Slide 3 of 3)

- Site visit report will be delivered and stored in EHB.
- HRSA sends action plans via EHB with recommendations for changes.
- Actions required to come into compliance will be highlighted and due dates will be provided.
- Health centers must respond and demonstrate compliance with FTCA programmatic requirements to maintain deeming status.
Key Takeaways
Tips for a Successful Site Visit (Slide 1 of 2)

- Review policies and ensure all elements are in alignment with the Health Center Program Compliance Manual, FTCA Policy Manual, and Program Assistance Letter (PAL) for the upcoming deeming year.

- Agenda should be completed with names and contact information for all key staff members who will participate in meetings and interviews.

- Virtual tour should be practiced in advance to identify and resolve any problems with internet connectivity.
- All documents should be uploaded in Citrix ShareFile at least two weeks before the site visit.
- All requested credentialing and privileging documents should be organized by staff member name and uploaded as directed.
HRSA Resources for Risk Management Training (Slide 1 of 2)

- FTCA Application Demonstration of Compliance Tool: Risk Management Training Plan Edition

- Risk Management Training (webinar) bphc.hrsa.gov/ftca/hcap-process

- FTCA Deeming Application Tracking Policies
HRSA Resources for Risk Management Training (Slide 2 of 2)

- Tracking, Monitoring, & Addressing Near Misses, Adverse Events and Sentinel Events (webinar) bphc.hrsa.gov/ftca/hcap-process
- Quarterly Risk Assessment (webinar) bphc.hrsa.gov/ftca/hcap-process
- Annual Report to Governing Board (webinar) bphc.hrsa.gov/ftca/hcap-process
HRSA Resources for Credentialing and Privileging (Slide 1 of 2)

- Health Center Program Compliance Manual - Chapter 5

  bphc.hrsa.gov/sites/default/files/bphc/programrequirements/pdf/credentialing-privileging-file-review.pdf

- The FTCA Program and the National Practitioner Data Bank (webinar)
  youtube.com/watch?v=SKzlwyYWhy4
- FTCA Application Procedural Demonstration of Compliance Tool: Credentialing and Privileging Edition
HRSA Resources for Claims Management

- FTCA Health Center Policy Manual
  bphc.hrsa.gov/sites/default/files/bphc/ftca/pdf/ftcahcppolicymanualpdf.pdf
- FTCA Health Center Policy Manual
  bphc.hrsa.gov/sites/default/files/bphc/ftca/pdf/ftcahcppolicymanualpdf.pdf

- FTCA Health Center Deeming Program Assistance Letter (PAL)

- Health Center Program Compliance Manual, e.g., Chapters 5, 10, and 21

- FTCA Health Center Program Site Visit Protocol
  bphc.hrsa.gov/sites/default/files/bphc/ftca/pdf/ftca-hcp-svp.pdf
Supplement for FTCA Virtual Site
bphc.hrsa.gov/ftca/supplement-ftca-virtual-site-visits
ECRI Resources
ECRI Resources for Risk Management

- Sample Risk Management Plan for a Community Health Center (ecri.org)
- Risk Management Manual for Health Centers (ecri.org)
- Just the “FAQs”: Your Risk Management Questions, Answered (ecri.org) (webinar)
- Ambulatory Care Risk Management Certificate Course | ECRI Learning
- Clinical Risk Management Program eLearning | ECRI Learning
ECRI Resources for Quality Improvement

- Tracking a Sample QI/QA Initiative (ecri.org) *(sample tool)*
- Ready, Set, Go - Quality-of-Care Measures.pdf (ecri.org) *(tool for leadership)*
- Data-Driven Quality Improvement (ecri.org) *(webinar)*
- Employing Data-Driven Quality Improvement (QI) Measures (ecri.org) *(self-assessment tool)*
- See all QI/QA resources in the Quality Improvement/Quality Assurance Resource Collection.
ECRI Resources for Credentialing and Privileging

- Credentialing and Privileging Guide for Health Centers (ecri.org)
- FTCA Application Procedural Demonstration of Compliance Tool: Credentialing and Privileging Edition (ecri.org)
- A Brief Case for Safety: Credentialing and Privileging to Meet Staffing Needs (ecri.org) (self-assessment tool)
- Assessing Clinical Competence (ecri.org) (self-assessment tool)
- See all credentialing and privileging resources in the Credentialing and Privileging Resource Collection and the Peer Review Resource Collection.
ECRI Resources for Claims Management

- ECRI Guidance on the FTCA Program for Health Center Providers and Staff
- Checklist: Health Center Responsibilities When Responding to a State Court Lawsuit or Notice of Intent to File a Lawsuit (ecri.org)
- Claims Management: You Have Been Sued, Now What? (ecri.org) (webinar)
- Proactive Management of Potential Claims (ecri.org) (infographic)
- See all claims management resources in the Claims Management Resource Collection.
ECRI Resources for Other Topics

- **Obstetrics Care**
  - Maternal and Perinatal Health and Safety Resource Collection
  - Obstetrics: Safe, Equitable Care for All Women - 3-part series | ECRI Learning
  - Obstetrics Training Suite (ecri.org)

- **Infection Control**
  - Infection Control Resource Collection
  - Fundamental Elements of Standard Precautions - 6 Credit Series | ECRI Learning

- **Medication Management**
  - Medication Safety Resource Collection
Final Reminder

- Health centers that have questions regarding the FTCA Program or FTCA deeming requirements may contact Health Center Program Support or call 1–877–464–4772.