

Health Center Program Site Visit Protocol:

Federal Tort Claims Act (FTCA) Deeming Requirements

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FEDERAL TORT CLAIMS ACT (FTCA) DEEMING REQUIREMENTS

ONLY TO BE COMPLETED FOR HEALTH CENTERS THAT ARE CURRENTLY FTCA DEEMED

Primary Reviewer: Clinical Expert

Secondary Reviewer: N/A

Notes:

- Please find below observations regarding the review of FTCA requirements regarding Risk and Claims Management.
- The FTCA Program uses the site visit report to support programmatic decisions, including but not limited to FTCA deeming decisions, and to identify technical assistance needs for FTCA deemed health centers. In circumstances where the site visit report contains FTCA risk and claims management findings that require follow-up, the FTCA Program will develop and share a Corrective Action Plan (CAP) with the health center. HRSA expects the health center to respond to the CAP and address findings.
- 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 decisions.
- Health centers that have questions regarding the FTCA Program or FTCA deeming requirements may contact Health Center Program Support at 1-877-464-4772 or <https://www.hrsa.gov/about/contact/bphc.aspx>.

Authority: Section 224(g)-(n), 224(q) of the Public Health Service (PHS) Act (42 U.S.C. 233(g)-(n) and (q)); and 42 CFR Part 6

Document Checklist for Health Center Staff

Documents Provided Prior to Site Visit:

- Risk management policy(ies) and related operating procedures or protocols (including but not limited to procedures for tracking referrals, diagnostics, and hospital admissions ordered by health center providers, incident reporting for clinically-related complaints, and “near misses”)
Note: Health centers may have distinct “risk management” operating procedures OR these may be included or integrated within other health center operating procedures or protocols (for example, Human Resources, Quality Improvement/Quality Assurance, Admin, Clinical, Infection Control)
- Claims management process policy(ies)/procedures
- Most recent HRSA-approved FTCA deeming application
- Risk management training plan and documentation of completed training

- Example(s) of methods used to inform patients of the health center's deemed status (for example, website, promotional materials, statements posted within an area(s) of the health center visible to patients)

Documents Provided at the Start of the Site Visit:

- Documentation (for example, board/committee minutes, supporting data, reports) of the last two quarterly risk management assessments of health center activities designed to reduce the risk of adverse outcomes (for example, environment of care, incident tracking, infection control, patient safety) that could result in medical malpractice or other health or health-related litigation
- Board meeting minutes and/or most recent report(s) (within past 12 months) to the board that include the status of risk management activities
- For health centers with **closed** claims from within the past 5 years under the FTCA: For each **closed** claim, documentation of steps implemented to mitigate the risk of such claims in the future (for example, targeted staff training, improved records management, implementation of new clinical protocols)

Demonstrating Compliance

Is the health center currently deemed under the Health Center Federal Tort Claims Act (FTCA) Program?

- YES NO

NOTE: IF "NO" WAS SELECTED, NONE OF THE QUESTIONS FOR ANY OF THE ELEMENTS IN THIS FTCA SECTION ARE APPLICABLE.

Risk Management

Element a: Risk Management Program

The health center has and currently implements 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:

- Risk management across the full range of health center health care activities;
- Health care risk management training for health center staff;
- Completion of quarterly risk management assessments by the health center; and
- 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.

Element b: Risk Management Procedures

The health center has risk management procedures that address the following areas for health center services and operations:

- 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;
- Documenting, analyzing, and addressing clinically-related complaints and "near misses" reported by health center employees, patients, and other individuals;
- Setting and tracking progress related to annual risk management goals;
- 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 Health Insurance Portability and Accountability Act (HIPAA) medical record confidentiality requirements); and
- Completing an annual risk management report for the board and key management staff.

Element c: Reports on Risk Management Activities

The health center provides reports to the board and key management staff on health care risk management activities and progress in meeting goals at least annually, and provides documentation to the board and key management staff showing that any related follow-up actions have been implemented.

Element d: Risk Management Training Plan

The health center has a health care risk management training plan for all staff members and documentation showing that such trainings have been completed by the appropriate staff, including all clinical staff, at least annually.

Element e: Individual who Oversees Risk Management

The health center designates 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.

Site Visit Team Methodology

- Review risk management policy(ies), procedure(s), and/or protocols.
- Review health care risk management training plan.
- Review training records to verify that appropriate staff, including all clinical staff, completed risk management training at least annually.
- Review documentation of last two quarterly risk management assessments that address one or more areas of risk.
- Review relevant board meeting minutes and most recent report(s) (within past 12 months) to the board on the status of risk management activities.

- Interview the health center individual(s) (for example, health center risk manager) who oversees and coordinates the health center’s risk management activities on implementation of related policies, procedures, training, assessment, reporting, and follow-up actions.
- Interview other health center clinical leadership and individuals as necessary.

Site Visit Findings

1. Does the health center currently have an individual(s) who oversees and coordinates the health center’s risk management activities?

YES NO

If No, an explanation is required:

2. Do the health center’s risk management policies or procedures apply to all services and sites within the health center’s scope of project?

YES NO

If No, an explanation is required:

3. How does the health center identify and mitigate areas/activities of highest patient safety risk? Describe if and how this informs or aligns with the health center’s overall risk management program (for example, staff training, establishment of risk management goals, changes in clinical safety practices).

An explanation is required, including one to two examples:

4. Was the health center able to provide examples of how it documents, analyzes, and addresses clinically-related complaints and “near misses” reported by health center employees, patients, and other individuals?

YES NO

If Yes OR No, an explanation is required, including describing the examples:

5. Was the health center able to produce documentation of its last two quarterly risk management assessments?

YES NO

If No, an explanation is required:

6. Was the health center able to provide a copy of a report on the status of risk management activities and progress in meeting risk management goals that was presented within the past 12 months to the board and key management staff?

YES NO

If No, an explanation is required:

7. What follow-up actions has the health center implemented based on its risk management assessments and its reporting to the board and key management staff?

An explanation is required, including explaining the health center's reasoning if no related follow-up actions have been implemented:

8. Does the health center's training plan require risk management training for relevant clinical staff on obstetrical services?

Notes:

- *Health centers that do not directly provide obstetrical services such as labor and delivery but provide prenatal and postpartum care must provide relevant training to clinical staff.*
- *Select "Not Applicable" if the health center provides all obstetrical services including prenatal and postpartum care to patients through direct referral to another provider.*

YES NO NOT APPLICABLE

If No, an explanation is required as to why such trainings are not included in the training plan:

9. Does the health center's training plan require risk management training for clinical staff on infection prevention and control for all departments?

YES NO

If No, an explanation is required:

10. Does the health center's training plan also require training for all relevant staff on HIPAA medical record confidentiality requirements?

YES NO

If No, an explanation is required.

11. Does the health center have documentation that all relevant staff completed training in accordance with the health center's annual risk management training plan?

YES NO

If No, an explanation is required, including stating what follow-up actions, if any, the health center has or will implement to assure all relevant staff complete training:

Claims Management

Element a: Claims Management Process

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:

- The preservation of all health center documentation related to any actual or potential claim or complaint (for example, medical records and associated laboratory and x-ray results, billing records, employment records of all involved clinical providers, clinic operating procedures); and
- 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](#).

Element b: Claims Activities Point-of-Contact

The health center has a designated individual(s) who is responsible for the management and processing of claims-related activities and serves as the claims point of contact.

Element c: Informing Patients of FTCA Deemed Status

The health center informs patients using plain language that it is a deemed federal PHS employee¹ via its website, promotional materials, and/or within an area(s) of the health center that is visible to patients.

Element d: History of Claims: Cooperation and Mitigation

If a history of claims under the FTCA exists, the health center can document that it:

- Cooperated with the Attorney General, as further described in the FTCA Health Center Policy Manual; and
- Implemented steps to mitigate the risk of such claims in the future.

Site Visit Team Methodology

- Interview designated individual(s) responsible for claims management.
- Review claims management process policy(ies)/procedures.
- Review claims management and claims history section of the FTCA application.

¹ For example: “This health center receives HHS funding and has federal PHS deemed status with respect to certain health or health-related claims, including medical malpractice claims, for itself and its covered individuals.” For more information, see <http://www.bphc.hrsa.gov/ftca/>.

- Review example(s) of language used to inform patients that the health center is a deemed federal PHS employee.
- For health centers with **closed** claims from within the past 5 years under the FTCA: Review for each **closed** claim documentation of steps implemented to mitigate the risk of such claims in the future.

Site Visit Findings

1. Does the health center currently have an individual(s) who is responsible for the management and processing of claims-related activities and who serves as the claims point of contact?

YES NO

If No, an explanation is required:

2. Was the health center able to describe how it has (if health center has a history of claims under FTCA) or would (if no claims history) manage health or health-related claims? Specifically, was the health center able to demonstrate how it has or would:

- o Preserve claims-related documentation (for example, medical records and associated laboratory and x-ray results, billing records, employment records of all involved clinical providers, clinic operating procedures); and
- o Promptly communicate with HHS Office of the General Counsel, General Law Division regarding any actual or potential claim or complaint?

YES NO

If No, an explanation is required:

3. Does the health center inform patients (using plain language) that it is a deemed federal PHS employee via its website, promotional materials, and/or within an area(s) of the health center that is visible to patients?

YES NO

If No, an explanation is required:

4. **For health centers with a history of closed claims under the FTCA within the past 5 years:** For each **closed** claim, what steps has the health center implemented to mitigate the risk of such claim in the future?

NOT APPLICABLE

An explanation is required:
