The Federal Tort Claims Act (FTCA) Deeming Application

A Step-by-Step Guide for Completing the 2025 Application for Coverage in CY 2026

Disclaimer

FTCA Deeming Application: A Step-by-Step Guide **is a descriptive reference tool, not a legal document. Organizations should consult legal counsel for specific guidance and develop clinical guidance in consultation with their clinical staff and other experts as circumstances warrant. This handbook includes various suggested best practices but is not intended to indicate a legal standard of care.**

Official federal government policy issuances relating to HRSA's implementation of the Health Center FTCA Program are found in the Health Center FTCA Policy Manual, currently applicable Program Assistance Letters (PALs), and Chapter 21 of the Health Center Program Compliance Manual.

The information and guidance provided in this technical assistance document are intended to support and assist in understanding applicable FTCA application and procedures. In the event of any conflict between the content of this document and the agency's official policies, the agency's official policies shall prevail and must be deferred to as the authoritative source. Any differences or inconsistencies in this handbook or in external references as compared to the FTCA Policy Manual, Health Center Compliance Manual, the FTCA Federally Supported Health Center Assistance Act (FSHCAA) statute, and HRSA program guidance should be resolved by deferring to those HRSA/FTCA sources.

The references provided or linked to in this handbook are based on the best available information at the time it was published. External resources are referenced in this handbook for informational purposes and should not be construed as an endorsement for a particular product. Readers should also take into account the dates resources were published, and always refer directly to HRSA for current FTCA requirements.

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Introduction

This guide is intended to help health centers complete the annual Application for Health Center Program Award Recipients for Deemed Public Service Employment with Liability Protections Under the Federal Tort Claims Act (FTCA) ("FTCA deeming application"). Official HRSA policy guidance and FTCA deeming requirements are found in HRSA's Health Center FTCA Policy Manual, annual deeming Program Assistance Letters (PALs) and application instructions, and Chapter 21 of the Health Center Program Compliance Manual. Check the Health Resources and Services Administration (HRSA) Bureau of Primary Health Care (BPHC) website for the most up-to-date FTCA policies and program guidance.

This handbook covers each section of the FTCA deeming application:

- Review of Risk Management Systems
- Quality Improvement/Quality Assurance (QI/QA)
- Credentialing and Privileging
- Claims Management

In addition, an Appendix is included that summarizes key resources referred to throughout the document.

Health centers are encouraged to have this guide on hand as you complete the deeming application and to cross-reference for each question. It includes guidance on what each question in the application means, why it is important, and how to answer each question, along with helpful resources. In addition, helpful "do's" and "don'ts" for completing the application are provided.

Look for these symbols throughout this guide:

	Tips for documents and materials to have ready before beginning the application
	Important reminder
	Key resources and tools
	**Do:** Practices that health centers should do when completing the application
	**Don't:** Practices that health centers should not do when completing the application
	Application question. This symbol is included next to each application question so that users of this guide can more quickly find questions when scrolling through the document.

Key FTCA Application Dates

This step-by-step guide has been updated to compliment the Program Assistance Letter (PAL) 2025-01: Calendar Year 2026 Requirements for Federal Tort Claims Act (FTCA) Coverage for Health Centers and Their Covered Individuals. This PAL, along with the deeming application process, has a number of important dates that health centers should be aware of.

Reporting Period:

The FTCA application requires information from the health center covering the period from January 1st to December 31st of the previous year of submission of the application. **For applications submitted in 2025, the information submitted must cover January 1st, 2024, to December 31st, 2024.** Submitting information that does not cover this reporting period, or includes dates beyond the reporting period, will be considered noncompliant. Information submitted for this time frame should include:

- The annual risk management educational training plan and all associated FTCA education training tracking forms for clinical staff (topics include obstetrical training, infection control training, HIPAA training, and areas of high-risk training)
- Proof that the risk manager has received risk management training
- Quarterly risk assessments (one risk assessment must be completed within each calendar quarter):
    - Quarter 1: January 1, 2024 – March 31, 2024
    - Quarter 2: April 1, 2024 – June 30, 2024
    - Quarter 3: July 1, 2024 – September 30, 2024
    - Quarter 4: October 1, 2024 – December 31, 2024
- The data within the annual report provided to the board and key management staff on health care risk management activities

Redeeming Application Coverage Date Range:

The 2025-01 PAL covers both FTCA applications requesting initial deeming and an annual FTCA redeeming application for coverage for CY 2026 (January 1, 2026 – December 31, 2026).

Application Submission Dates:

All FTCA deeming applications must be submitted electronically through the FTCA deeming module within the EHBs. The EHBs system will be available to begin receiving CY 2026 deeming applications on **February 27, 2025**. Each currently deemed entity must submit a redeeming application for itself and any subrecipients (as applicable) by **June 27, 2025**, to be eligible to be deemed during CY 2026 without a gap in coverage. Health centers should submit their applications well in advance of the deadline if possible.

General Do's and Don'ts of Filling Out the Deeming Application

While this guide reviews each section and question of the Deeming Application in detail, there are some general Do's and Don'ts that applicants should familiarize themselves with before starting the application process:

General Do's

Do: Refer to relevant chapters of the Health Center Program Compliance Manual, the FTCA Health Center Policy Manual, and current Program Assistance Letters when updating policies and procedures.

Do: Double-check that all documents are complete, accurate, and aligned with reporting requirements.

Do: Used approved templates and tools where applicable (e.g., FTCA Educational Training Tracking form for reporting required risk management training).

General Don'ts

Don't: Upload blank templates, incomplete documents, or outdated materials.

Don't: Assume compliance without verifying alignment with all required elements.

Important: Required Actions for Noncompliance in FTCA Application

If you determine that you did not meet certain FTCA requirements during the prior reporting period (CY 2024), please take the following actions as part of your application:

1. **Identify the Noncompliance Issue**: Specify the exact area of noncompliance and the requirement that was unmet.

2. **Provide an Explanation**: Outline the reasons for noncompliance, detailing any events or circumstances that led to this issue.

3. **Describe Corrective Actions**: Clearly describe the actions you are taking or have taken to achieve compliance. Note that these actions must be completed within 30 days of your application submission.

4. **Submit Supporting Documentation**: Include documentation that demonstrates corrective actions are in progress or have been completed. This could include records, meeting notes, or other evidence of compliance efforts.

This process is essential for ensuring your application reflects current compliance, even if requirements from the prior year were not fully met.

Questions? Need Help? Contact:

HRSA:

- **For questions about FTCA deeming requirements or interpretations of requirements**
    - Submit questions to Health Center Program Support
    - Call 1-877-464-4772 between 8:00 a.m. to 8:00 p.m. Eastern time, Monday-Friday (except federal holidays)

ECRI Clinical Risk Management Services:

- **ECRI Clinical Risk Management Program resources are available at no cost to all HRSA-funded health centers on behalf of HRSA. To activate your account and access the resources:**
    - Email Clinical_rm_program@ecri.org

Review of Risk Management Systems

A robust risk management program is an ongoing activity, not a quarterly task, and includes the following essential elements:

- The foundation of a strong culture of safety, which encourages all members of the organization to prioritize patient safety
- One or more designated risk managers, with written job descriptions for each position
- A written, organization-wide risk management plan that is reviewed at least annually
- Governing board approval for the risk management plan
- Risk management committee(s) appropriate to the organization's scope of services
- Event reporting processes, analysis, resolution, and follow-up
- An organizational self-assessment process that identifies areas of highest clinical risk
- Risk management training for all staff, pertinent to their job role and focusing on identified areas of high risk

To be deemed, health centers must demonstrate that they have actively implemented an ongoing healthcare risk management program, across the full range of the organization's healthcare activities, to reduce the risk of adverse outcomes that could result in medical malpractice or other health-related litigation. For this section, health centers will upload various policies, procedures, and documents that demonstrate compliance with risk management requirements (see "Prepare Documents" box) and should take steps before beginning the application process to ensure these documents are complete and up to date.

Prepare Documents

Before beginning the application, have the following documents available **and ready to upload into the application**:

- Referral tracking procedures
- Hospitalization tracking procedures
- Diagnostic tracking procedures (including tracking for labs and x-rays)
- Current risk management training plan (including programs for obstetrics, infection control and sterilization, HIPAA medical record confidentiality, and specific training for specialty services) that documents completion of all required training
- Tracking/documentation tools showing that all staff have completed required training
- Four completed risk assessment tools and action plans (one for each calendar quarter) covering activities from **January 1 to December 31 of CY 2024**
- Annual risk management report provided to the board and key management staff
- Proof that health center board has received and reviewed the annual risk management report (e.g., meeting minutes signed by the board or signed letter from the board chair/board secretary)
- Risk manager job description
- Proof that the risk manager has completed risk management training between **January 1 and December 31 of CY 2024.**

Review of Risk Management Systems: Key Resources and Tools

- ECRI Guidance on the FTCA Program for Health Center Providers and Staff: Information about the Federal Tort Claims Act and the Federally Supported Health Centers Assistance Act
- FTCA Technical Assistance Resources
- Health Center Program Compliance Manual (Chapter 21: Federal Tort Claims Act (FTCA) Deeming Requirements
- Resource Collection: Risk Management Fundamentals
- Resource Collection: Risk Management Operations
- Resource Collection: Risk Management Training

1. Ongoing Risk Management Program

Risk Management Question 1(A). I attest that my health center has implemented an ongoing 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 this program requires the following:

i. Risk management across the full range of health center activities (for example, patient management including scheduling, triage, intake, tracking, and follow-up);

ii. Health care risk management training for health center staff;

iii. Completion of quarterly risk management assessments by the health center; and

iv. Annual reporting to the governing 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 areas of high organizational risk.

What is it asking for?

This question asks for you to confirm that your risk management program has all the elements listed. If you are missing any of these elements, or a part of any element, you will need to answer "no" and explain what actions your health center will take to meet requirements.

What does it mean?

The role of risk management in any business or operation is to protect the organization from any and all losses. Risk management accomplishes this task by identifying, evaluating, and reducing the likelihood of losses from the various risks encountered by the organization.

The first step in risk management is establishing a risk management program, or the guidance and framework that sets forth the health center's objectives and goals for managing risks in the organization. This is often documented in a written risk management plan. The risk management plan is a high-level, strategic governance document that is reviewed and signed by the board. It is separate from operating procedures (which describe how health centers will accomplish risk management objectives and goals; discussed in more detail under question 2 below).

Health centers can ensure that risk management programs are ongoing by continually assessing and identifying risks (i.e., through quarterly risk assessments), taking steps to correct identified risks, monitoring changes to ensure improvements, and conducting risk management training throughout the year on areas identified as highest risk. Because all clinical care and functional areas in the health center have risks and will need to identify and manage those risks:

- Risk managers will coordinate with other functions such as QI/QA, claims management, compliance, credentialing and privileging, patient safety, event reporting, infection control, and other areas on risk management activities; and
- Everyone in the health center, no matter their role or department, must be trained on basic risk management functions and responsibilities.

Why is it important?

Healthcare risk management supports patient safety and quality of care by systematically and proactively identifying, preventing, and mitigating adverse patient safety events, which in turn protects the organization from subsequent medical malpractice lawsuits, financial liability, threats to regulatory compliance, and reputational damage. Effective risk management processes, which often overlap with quality improvement and regulatory compliance functions, also encourage clinical best practices, improve patient satisfaction, and prevent future risks.

How do you answer the question?

Read through your written risk management plan or other risk management program documents to ensure that they address risk management across the range of health center activities, risk management training for all health center staff, completion of quarterly risk assessments by the health center, and annual reporting to the governing board on risk management activities, progress toward meeting goals, and proposed activities that relate to identified areas of high risk.

If your health center has an ongoing risk management program that addresses these elements, select “yes” to answer this question. If your health center does not have a plan or any of the required elements are missing, select “no.”

If you select “no,” follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide.

Reminder: When completing questions that ask for you to attest to a particular action or understanding, make sure that your response corresponds with actions being taken in your health center. **Even if you do not need to submit proof or supporting documentation along with the application, keep in mind that you may be asked to produce proof or supporting documentation as part of a site visit or at the request of FTCA during later stages of the application process.**

Key Resources

- Building an Effective Risk Management Program (webinar)
- Healthcare Risk Management Programs (assessment tool)
- Patient Safety and Risk Management Plan Informational Flowchart
- Patient Safety and Risk Management Plan Operational Checklist
- Sample Risk Management Plan for a Community Health Center

Risk Management Question 1(B)**. **By clicking "Yes" below, I also acknowledge that failure to implement an ongoing risk management program and provide documentation of such implementation upon request may result in disapproval of this deeming application and/or other administrative remedies.

What is it asking for?

This question asks the health center to confirm their understanding that failure to implement an ongoing risk management program including all the elements listed under 1(A) above may result in their application being denied.

How do you answer the question?

Select "yes" to answer and confirm acknowledgment of this question.

2. Ongoing Risk Management Procedures

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

i.** **Identifying and mitigating (for example, through clinical protocols, medical staff supervision) the health care areas/activities of highest risk within the health center's HRSA-approved scope of project, including but not limited to tracking referrals, diagnostics, and hospital admissions ordered by health center providers;

ii.** **Documenting, analyzing, and addressing clinically related complaints, "near misses," and sentinel events reported by health center employees, patients, and other individuals;

iii.** **Setting annual risk management goals and tracking progress toward those goals;

iv.** **Developing and implementing an annual health care risk management training plan for all staff members that addresses the following identified areas/activities of clinical risk: medical record documentation, follow-up on adverse test results, obstetrical procedures, and infection control, as well as training in Health

Insurance Portability and Accountability Act (HIPAA) and other applicable medical record confidentiality requirements; and

v. Completing an annual risk management report for the governing board and key management staff that addresses the risk management program activities, goals, assessments, trainings, incidents, and procedures.

What is it asking for?

This question asks for your confirmation that all listed elements have been implemented in your health center's ongoing risk management program to reduce clinical risk to the patients your health center serves.

What does it mean?

As noted above, the risk management plan is the high-level, strategic document that sets forth the health center's objectives and goals for managing risks in the organization. Risk management procedures, on the other hand, describe how and when these objectives and goals will be accomplished and who will accomplish them. Procedures provide step-by-step instructions on a process, tend to have a narrower focus, and tend to have more frequent changes as processes and steps change.

How do you answer the question?

Collect and review risk management procedures to ensure that, at a minimum, they address the following activities:

- Referral tracking (must include a closed-loop process)
- Hospitalization tracking (must include a closed-loop process)
- Diagnostic tracking (must include a closed-loop process for laboratory results and x-rays)
- Other areas identified in the health center as high-risk (e.g., medication safety, vaccine administration) based on risk assessments, claims, event reports, patient complaints, and other information
- Processes for documenting, analyzing, and addressing reports of events, near misses, and patient or staff complaints
- Annual risk management goals and tracking progress toward goals
- Annual risk management training plan for all staff members that address areas identified in the health center as high-risk AND the following areas: medical record documentation, obstetrical procedures, infection control, and HIPAA and confidentiality requirements
- Annual completion and documentation of risk management report to the board, including documentation that the board received and reviewed the report

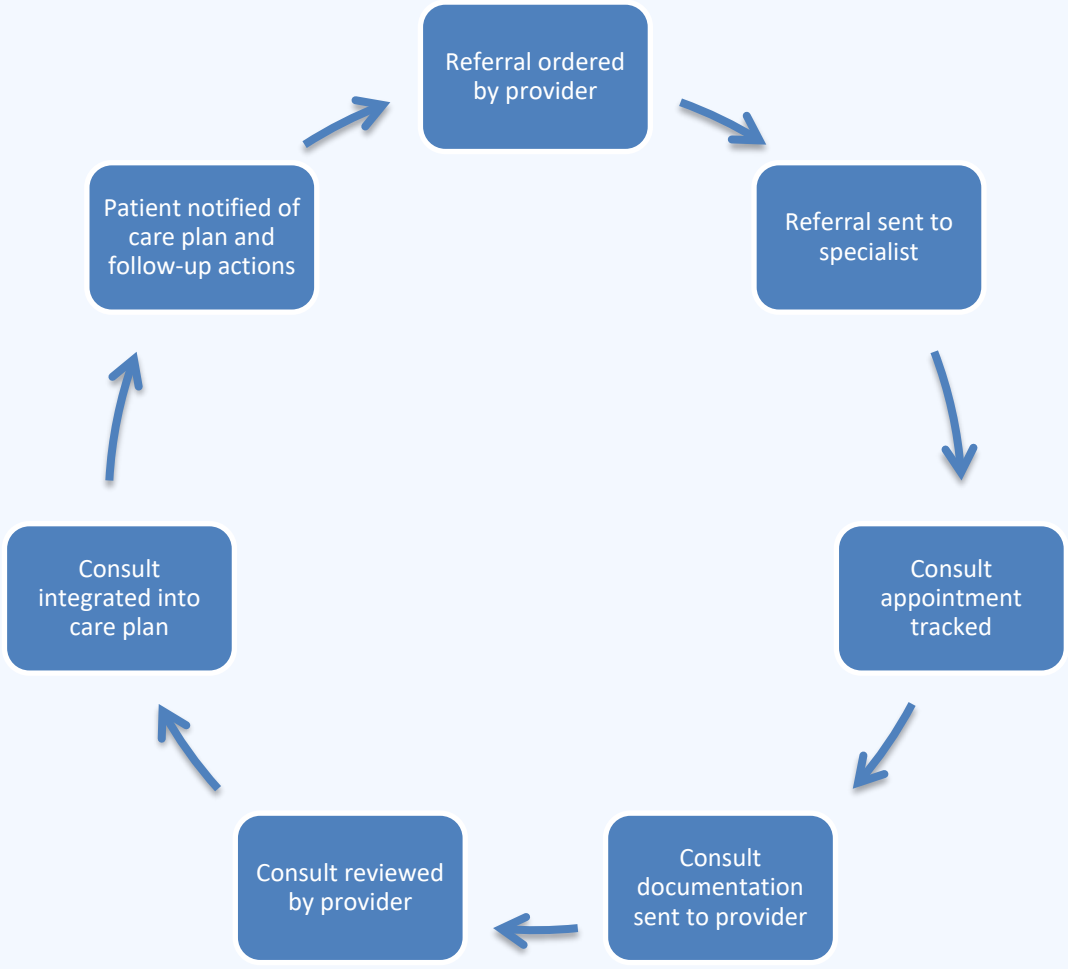
Closed Loop Process:

Closing the loop includes all mechanisms* that ensure that all patient data and information that may require an action:

- Are delivered and communicated to the right individuals, at the right time, through the right mode
- Allow interpretation, critical review, reconciliation, initiation of action, acknowledgement, and appropriate documentation

  * Mechanisms include workflow management tools, interventions, electronic and verbal notifications, checklists, alerts, and dashboards

Example Action Steps for Closed-Loop Referral Tracking



In addition to confirming that your health center has procedures addressing the above areas, your health center should review the procedures to ensure they are comprehensive. See the Key Resources box below for guidance and resources that can be used to help develop or check your procedures against best practices.

If your health center has comprehensive procedures that address the above activities, select "yes" to answer this question. If your health center does not have these procedures, select "no."

If you select "no," follow the instructions under the Important: Required Actions for Noncompliance in FTCA Application section of this guide.

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

What is it asking for?

This question asks the health center to confirm their understanding that failure to implement and maintain risk management procedures, including all the elements listed under 2(A) above, may result in their application being disapproved.

How do you answer the question?

Select "yes" to answer and confirm acknowledgment of this question.

If you select "no," follow the instructions under the Important: Required Actions for Noncompliance in FTCA Application section of this guide.

Risk Management Question 2(C). Upload the risk management procedures that address mitigating risk in tracking of referrals, diagnostics, and hospital admissions ordered by the health center providers or initiated by the patient.

What is it asking for?

This question asks the health center to upload the health center's implemented tracking procedures as specified under Risk Management Question 2(A), bullet i.

What does it mean?

Health centers must have policies and procedures for tracking referrals, diagnostic test results, and hospitalizations. Note that the policies must provide HRSA with enough information to

understand the procedures and processes that have been implemented within the health center. Failure to provide sufficient detail and to address how the health center addresses the key points that comprise these procedures may be viewed as noncompliance with FTCA requirements.

The following guidance is derived from the guidance document on FTCA Deeming Application Tracking Policies and is based on best practices.

Referral Tracking. Referral tracking procedures should include all elements listed in the checklist below.

How to use this checklist: *Determine whether your health center's procedures include the following elements and document "Yes" or "No." Yes = 1, No = 0. Add up your total score in the last row. The higher your score, the more likely your process is in alignment with FTCA requirements.*

Yes	No	Elements of a Referral Tracking Policy
[ ]	[ ]	A system to track all referrals from their origin until they are returned or evaluated by a provider. This system should include the origin of the referral, status of the referral, and the administrative and clinical details of the referral.
[ ]	[ ]	Processes for follow-up with the referral provider(s) in a timely manner to ensure that information is received back from the referral provider(s). This includes specific processes and time frames for transmission, receipt, and follow-up of referral results.
[ ]	[ ]	Identified titles of staff who are responsible for each of the duties throughout the referral process.
[ ]	[ ]	Processes for documenting all patient referrals in the patient's medical record and for documenting efforts to follow up with patients who miss referral appointments. This includes the number of attempts made to reach the patient and the way those attempts were made (e.g., phone calls, certified letter with delivery confirmation).
[ ]	[ ]	Policy approval and signature by the governing board or the individual/committee designed by the board for approval (see Health Center Program Compliance Manual Chapter 19: Board Authority).
[ ]	[ ]	**TOTALS**

Hospitalization Tracking. Hospitalization tracking procedures should include all elements listed in the checklist below.

How to use this checklist: *Determine whether your health center's procedures include the following elements and document "Yes" or "No." Yes = 1, No = 0. Add up your total score in the last row. The higher your score, the more likely your process is in alignment with FTCA requirements.*

Yes	No	Elements of a Hospitalization Tracking Policy
[ ]	[ ]	Tracking and monitoring system for receiving information regarding hospital or emergency department (ED) admissions. This applies to cases where the health center sends a patient to the ED and where the patient has entered the ED on their own. This system includes: • Patient information • Date of admission or visit • Date of notification • Reason for visit (if known) • Documentation received • Documentation requested (including date requested) • Follow-up initiated with the hospital and/or patient (including date initiated)
[ ]	[ ]	Identified staff members, by title, who are responsible for receiving ED and hospital admission information and monitoring the mechanism that is used for receiving hospital and ED admission information.
[ ]	[ ]	Mechanism for follow-up with the patient, provider, or outside facility to request pertinent medical information (e.g., diagnostic studies, discharge summary) related to a hospital or ED visit.
[ ]	[ ]	Policy approval and signature by the governing board or the individual/committee designed by the board for approval (see Health Center Program Compliance Manual Chapter 19: Board Authority).
[ ]	[ ]	**TOTALS**

Diagnostic Tracking. Diagnostic tracking procedures should include all elements listed in the checklist below.

How to use this checklist: *Determine whether your health center's procedures include the following elements and document "Yes" or "No." Yes = 1, No = 0. Add up your total score in the last row. The higher your score, the more likely your process is in alignment with FTCA requirements.*

Yes	No	Elements of a Diagnostic Tracking Policy
[ ]	[ ]	A tracking and monitoring system for all diagnostic tests that includes, at a minimum: • Patient information • Date test was ordered • Ordering provider • List of tests ordered • Date results were received • Provider who reviewed the results • Follow-up recommended by the provider • Communication of results to the patient, including unsuccessful communication attempts and follow-up
[ ]	[ ]	Agreements with lab vendors that clearly define "critical lab values" and processes for contacting the health center providers. If the health center provides on-site lab services, the policy speaks to the lab policies and procedures, clearly defining "critical lab values" and notification procedures.
[ ]	[ ]	For critical test results: • Time frame for communication of results to providers • Acceptable means of communication to provider and patient (e.g., verbal contact only) • Procedures for contacting back-up or surrogate providers if the ordering provider is not immediately available to receive results • Procedures for making every effort to contact the patient for follow-up (e.g., visiting shelter, enlisting help from authorities) • Documentation of successful and unsuccessful attempts to contact the patient • Tracking critical lab results, monitoring to ensure no problems arise, and audits reported to QI/QA committee as part of the program

(Table continues on next page)

Yes	No	Elements of a Diagnostic Tracking Policy
[ ]	[ ]	For abnormal tests: • Acceptable means of communication to provider and patient (e.g., verbal, electronic) • Time frame for communicating results to the patient (e.g., not to exceed 14 days) • Efforts made to contact the patient for follow-up (e.g., visiting shelter, enlisting help from authorities) • Documentation of successful and unsuccessful attempts to contact the patient (notification should include more than just a certified letter)
[ ]	[ ]	Assigned responsibility for documenting all pertinent diagnostic tracking activities and maintaining documentation as part of the patient's medical record. Documentation should include the following: • Acknowledgment of receipt of result • Actions taken related to the patient • Patient notification, including date and time of notification, means used to communicate results (e.g., phone call, letter), and person spoken to (if applicable) • All attempts to contact the patient if the patient cannot be reached • Other clinical information as appropriate
[ ]	[ ]	Policy approval and signature by the governing board or the individual/committee designed by the board for approval (see Health Center Program Compliance Manual Chapter 19: Board Authority).
[ ]	[ ]	**TOTALS**

How do you answer the question?

For this question, follow the instructions for uploading and attaching your referral tracking, hospitalization tracking, and diagnostic tracking procedures to the application. Use the checklists above and determine which items are not present. For those items, update your policies and procedures to address them. Review the policies and procedures and obtain the appropriate approval. As noted above, you can use the Key Resources box below to access resources on these topics and fill in any necessary gaps in your procedures.

Do: Ensure referral tracking procedures include:

- Time frames for transmitting referrals and receiving results
- Patient follow-up efforts and time frames (number/method of attempts, e.g., phone calls, certified letters)
- A closed-loop process

Do: Ensure diagnostic tracking procedures include:

- Tracking processes for laboratory and imaging results
- Actions to notify and respond to abnormal and critical results
- Defined communication methods and frequency
- A closed-loop process

Do: Ensure hospitalization tracking procedures include:

- Guidelines for actions post-discharge
- Clear timelines, responsible individuals, and documentation requirements
- A closed-loop process

Don't: Submit identical tracking policies for referrals, diagnostics, and hospitalizations.

Don't: Submit a general risk management plan or unrelated procedures in place of referral, diagnostic, or hospitalization tracking.

Don't: Upload incomplete tracking procedures (e.g., missing closed-loop elements or follow-up guidelines).

Don't: Include policies that lack key elements, as this may result in a returned or disapproved application.

Key Resources

- FTCA Deeming Application Tracking Policies
- Risk Management Manual for Health Centers
- Resource Collection: Diagnosis: Test, Referral, and Hospitalization Tracking
- Sample Diagnostic Test Tracking Procedure
- Sample Hospitalization and Emergency Department Visit Tracking Procedure
- Sample Specialty Referral Tracking Procedure
- Resource Collection: Event Reporting
- Resource Collection: Event Response
- Resource Collection: Patient Complaints and Grievances

3. Annual Healthcare Risk Management Training Plan

***Risk Management Question 3(A)**. I attest that my health center has developed and implemented an annual health care risk management training plan for staff members based on identified areas/activities of highest clinical risk for the health center. These training plans include detailed information related to the health center's tracking/documentation methods to ensure that trainings have been completed by the appropriate staff, including clinical staff, at least annually. I attest that the training plans at a minimum incorporate obstetrical procedures (for example, continuing education for electronic fetal monitoring, such as the online course available through ECRI, and shoulder dystocia drills).*

Note: Health centers that provide obstetrical services directly or through individual health center contractors need to include obstetrical training as part of their risk management training plans to demonstrate compliance. All health centers that are currently deemed as PHS employees, as well as those seeking deemed or redeemed status, must conduct OB training on an annual basis if they provide clinical services to any of the following individuals (even if they do not provide labor and delivery services):

1. ***Prenatal patients***
2. ***Postpartum patients***
3. ***Patients who are of reproductive age***

All health centers that provide any health services to patients of reproductive age, even if they do not offer obstetrical services directly, must include obstetrical training as part of their annual required trainings to demonstrate compliance.

Health centers should consider the following:

1. ***Which staff must complete the OB training: The health center should consider each staff member's role, responsibilities, and their level of clinically related contact with patients of reproductive age in determining the employee's specific training needs. The health center must clearly document which staff members are required to complete OB training and the process used to determine inclusion or exclusion from the OB training requirement.***
2. ***Source of the training: Health centers may choose from various training sources, such as HRSA trainings, HRSA-supported ECRI trainings, in-house trainings, or other public or private training resources.***
3. ***Delivery method and format: Health centers have the flexibility to choose the delivery method and format of the OB training. Options may include in-person, virtual, or hybrid trainings. Additionally, health centers may utilize different training formats, such as lectures, videos, presentations, labs, or online modules.***
4. ***Content covered during OB training: Health centers can determine the specific content covered during each OB training session. OB topics and content must be selected based on health center data, assessments, and other available health center information.***

What is it asking for?

This question asks the health center to confirm that the health center has developed and implemented an annual health care risk management training plan that includes all specified elements listed in the question for both a general training plan and specific obstetrics training.

What does it mean?

Health centers must develop and implement an annual written risk management training plan. This training plan must specify that all providers and staff in the health center will receive risk management training, must specify which topics will be covered by training programs, and must

include detailed information outlining how health centers will track and document that trainings are completed by all providers and staff. Please note that obstetrics training must include training for all clinical staff, including licensed independent practitioners (LIPs), other licensed or certified practitioners (OLCPs), and other clinical staff (OCS).

Reminder: Check your state laws and practice acts to determine whether there are any state-specific credentialing requirements, and whether staff qualify as LIPs, OCLPs, or OCS:

- **LIPs:** Professionals who can practice without clinical supervision, including physicians, dentists, nurse practitioners, nurse-midwives, physician assistants, and psychiatrists.
- **OLCPs:** Professionals who practice under clinical supervision, including registered nurses, licensed practical nurses, social workers, certified medical assistants, certified dental assistants, and dental hygienists.
- **OCS:** Medical assistants, dental assistants, or community health workers in states, territories, and jurisdictions that do not require licensure or certification.

Although the training topics listed in this section are examples of topics for obstetrical training, health centers should not limit training to just these topics and should incorporate any additional training topics based on areas identified as highest clinical risk. Health centers can identify these areas of high risk through risk assessments, claims trends, event reports, patient complaints and grievances, patient and staff satisfaction surveys, quality measures and data, and other information sources.

Other than the required trainings noted, health centers are given flexibility in determining the content, format, and approach for the trainings. For example, health centers may conduct in-service or “lunch and learn” training programs, may assign providers and staff to complete specific online courses, may schedule time for groups to view an educational webinar, or may provide other training options.

Reminder for obstetrics training: Health centers must include obstetrics training as part of their annual risk management training plan for all clinical staff (LIPs, OLCPs, and OCS) who have contact with prenatal patients, postpartum patients, and individuals of reproductive age, even if the health center does not provide labor and delivery services. This includes health centers that provide obstetrical services through FTCA-deemed providers and health centers that provide prenatal and postpartum care through FTCA-deemed providers. In addition, regardless of the provision of obstetrical services, **if an FTCA-deemed health center has contact with reproductive-age patients for other clinical services through FTCA-deemed providers (health center**

employees or individual contractor providers), the health center is required to include obstetrical training as part of the health center risk management training plan to demonstrate compliance. This is because there are specific risks for reproductive-age patients and postpartum patients for up to one year after childbirth, and health center providers and staff should be aware of potential risks and complications associated with pregnancy and childbirth. ECRI has several obstetrics training options based on job roles and types of services provided.

Reminder for obstetrics training: Health centers should consider each clinical staff member's roles, responsibilities, and their level of clinical contact with patients of reproductive age when determining each employee's specific training. All clinical staff members who have contact with prenatal patients, postpartum patients, and individuals of reproductive age are required to have OB training. Health centers should document the process used to determine what OB training clinical staff members are required to take. For example, health centers may require that obstetricians and OB nurses complete specialized OB training tailored to professionals who provide direct obstetric services. The health center may also require that all providers complete training on prenatal and postpartum risks, and that all clinical staff complete training on responding to obstetric emergencies in the medical office. Meanwhile, other specialty providers, such as dentists and behavioral health providers, would undergo OB training specific to the services they offer within their fields. Optionally, a health center may also include OB training for nonclinical staff members, but this is not required. Health centers should also maintain a list of all employees required to complete OB training and monitor for timely training completion.

Reminder for obstetrics training: Health centers have the flexibility to choose the delivery method and format of the OB training. Options may include in-person, virtual, or hybrid trainings. Additionally, health centers may utilize different training formats, such as lectures, videos, presentations, labs, or online modules. Multiple options may be utilized that best meet the needs of health centers.

Reminder for obstetrics training: Health centers can determine the specific content covered during each OB training session. Topics and content should be based on areas identified as highest clinical risk. Health centers can identify these areas of high risk through risk assessments, claims trends, event reports, patient complaints and grievances, patient and staff satisfaction surveys, quality measures and data, and other information sources. For example, a health center may include clinical staff training on postpartum depression after identifying a need to increase screening rates. Be sure to document the process by which the topics and content were chosen for training.

Why is it important?

Because all clinical care and functional areas in the health center have risks and need to identify and manage those risks, everyone in the health center, no matter their role or department, must be trained on basic risk management functions and responsibilities. A robust risk management training plan improves patient safety; minimizes errors, system breakdowns, and harm; minimizes clinical risks and liability losses; and supports regulatory, accreditation, and compliance needs.

There are specific risks for reproductive-age patients and postpartum patients for up to one year after childbirth, and health center providers and staff should be aware of potential risks and complications associated with pregnancy and childbirth, including urgent pregnancy-related warning signs, and be prepared to deliver care with those risks in mind.

How do you answer the question?

Read through your annual risk management training plan to ensure that it addresses the required obstetrical training topics and all of the required elements noted above.

If your health center has an annual risk management training plan that includes these elements, select “yes” to answer this question.

If you select “no,” follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide.

Key Resources

- ECRI Learning Online Education
- Resource Collection: Risk Management Training
- Policy and Procedure Builder: Risk Management Training Plan
- FTCA Demonstration of Compliance Tool: Risk Management Training Plan Edition
- Risk Management Training: Requirements, Resources, and Strategies
- Obstetrics Education
- Primary Care of the Postpartum Patient: A High-Risk Year
- Resource Collection: Obstetric and Maternal Health and Safety
- Best Practices for Obstetric Training and Competencies in Primary Care Settings (webinar)

***Risk Management Question 3(B)**. I attest that my health center has developed and implemented an annual health care risk management training plan for staff members based on identified areas/activities of highest clinical risk for the health center. These training plans include detailed information related to the health center's tracking/documentation methods to ensure that trainings have been completed by the appropriate staff, including all clinical staff, at least annually. I attest that the training plans at a minimum incorporate infection control and sterilization (for example, Blood Borne Pathogen Exposure protocol, Infection Prevention and Control policies, Hand Hygiene training and monitoring program, dental equipment sterilization).*

What is it asking for?

This question asks the health center to confirm that the health center has developed and implemented an annual health care risk management training plan that includes specific training for staff members based on your health center's areas and activities of highest clinical risk in regard to infection control and sterilization.

What does it mean?

Health centers must develop and implement an annual written risk management training plan. This training plan should specify that all providers and staff in the health center will receive risk management training; should specify which topics will be covered by training programs, including infection control and sterilization; and should include detailed information outlining how health centers will track and document that trainings are completed by all providers and staff.

Although the training topics listed in this section are examples of topics for infection control training, health centers should not limit training to just these topics and should incorporate additional training topics based on areas identified as highest clinical risk. Health centers can identify these areas of high risk through risk assessments, claims trends, event reports, patient complaints and grievances, patient and staff satisfaction surveys, quality measures and data, and other information sources.

ECRI has several options for infection control training (see "Key Resources" box below).

Health centers are given flexibility in determining the content, format, and approach for the trainings. For example, health centers may conduct in-service or "lunch and learn" training programs, may assign providers and staff to complete specific online courses, may schedule time for groups to view an educational webinar, or may provide other training options.

How do you answer the question?

Read through your annual risk management training plan to ensure that it addresses the required training topics and all of the required elements noted above.

If your health center has an annual risk management training plan that includes these elements, select “yes” to answer this question.

If you select “no,” follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide.

Key Resources

- Bloodborne Pathogen Training Program
- The Chain of Infection: Know the Links, Break the Chain
- Hand Hygiene Training Program
- Infection Prevention and Control Starts at the Top
- Resource Collection: Infection Control
- Sharps Injury Prevention Training Program

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

What is it asking for?

This question asks the health center to confirm that the health center has developed and implemented an annual health care risk management training plan that includes specific training for staff members based on your health center’s areas and activities of highest clinical risk in regard to HIPAA medical record confidentiality.

What does it mean?

Health centers must develop and implement an annual written risk management training plan. This training plan should specify that all providers and staff in the health center will receive risk management training; should specify which topics will be covered by training programs, including HIPAA medical record confidentiality requirements; and should include detailed information outlining how health centers will track and document that trainings are completed by all providers and staff.

Although the training topics listed in this section are examples of topics for HIPAA medical record confidentiality requirements training, health centers should not limit training to just these topics and should incorporate additional training topics based on areas identified as highest clinical risk.

Health centers can identify these areas of high risk through risk assessments, claims trends, event reports, patient complaints and grievances, patient and staff satisfaction surveys, quality measures and data, and other information sources.

Health centers are given flexibility in determining the content, format, and approach for the trainings. For example, health centers may conduct in-service or "lunch and learn" training programs, may assign providers and staff to complete specific online courses, may schedule time for groups to view an educational webinar, or may provide other training options.

How do you answer the question?

Read through your annual risk management training plan to ensure that it addresses the required training topics and all of the required elements noted above.

If your health center has an annual risk management training plan that includes these elements, select "yes" to answer this question. If your health center does not have a plan or any of the required elements are missing, select "no."

If you select "no," follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide.

Key Resources

- HIPAA FAQs: Real Life HIPAA Challenges in Primary Care
- Resource Collection: Laws, Regulations, and Compliance

***Risk Management Question 3(D)**. I attest that my health center has developed and implemented an annual health care risk management training plan for staff members based on identified areas/activities of highest clinical risk for the health center. These training plans include detailed information related to the health center's tracking/documentation methods to ensure that trainings have been completed by the appropriate staff, including all clinical staff, at least annually. I attest that the training plans, at a minimum, incorporate specific trainings for groups of providers that perform various services which may lead to potential risk (for example, dental, pharmacy, family practice).*

What is it asking for?

This question asks the health center to confirm that the health center has developed and implemented an annual health care risk management training plan that includes specific training for staff members based on your health center's areas and activities of highest clinical risk in regard to specific specialty services.

What does it mean?

Health centers must develop and implement an annual written risk management training plan. This training plan should specify that all providers and staff in the health center will receive risk management training; should specify which topics will be covered by training programs, including specific trainings for groups of providers that perform various services which may lead to potential risk; and should include detailed information outlining how health centers will track and document that trainings are completed by all providers and staff.

Although the training topics listed in this section are examples of topics for specific trainings for groups of providers that perform various services which may lead to potential risk, health centers should not limit training to just these topics and should incorporate additional training topics based on areas identified as highest clinical risk. Health centers can identify these areas of high risk through risk assessments, claims trends, event reports, patient complaints and grievances, patient and staff satisfaction surveys, quality measures and data, and other information sources.

Health centers are given flexibility in determining the content, format, and approach for the trainings. For example, health centers may conduct in-service or "lunch and learn" training programs, may assign providers and staff to complete specific online courses, may schedule time for groups to view an educational webinar, or may provide other training options.

How do you answer the question?

Read through your annual risk management training plan to ensure that it addresses the required training topics and all of the required elements noted above.

If you select “no,” follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide.

Key Resources

- Resource Collection: Behavioral Health
- Resource Collection: Dental
- Resource Collection: Medication Safety
- Resource Collection: Special Clinical Considerations

***Risk Management Question 3(E)**. Upload the health center’s current annual risk management training plans for all staff, including all clinical and non-clinical staff, based on identified areas/activities of highest clinical risk for the health center and that include the items outlined in risk management question 3(A) – 3(D) of this application. The annual risk management training plan must clearly include OB, Infection Control, HIPAA, and specific training for areas of high-risk.*

What is it asking for?

This question asks the health center to upload the health center’s implemented annual risk management training plan with all required trainings for all staff types as listed above.

How do you answer the question?

Make sure that your annual risk management training plan **covers the period from January 1, 2024, to December 31, 2024,** and that it only includes courses completed during this time period.

Then, select the option to upload your annual risk management training plan and follow the prompts for attaching the document. You can use the Policy and Procedure Builder: Risk Management Training Plan and the FTCA Application Demonstration of Compliance Tool: Risk Management Training Plan Edition to compare with your current plan and fill in any necessary gaps.

Do: Ensure that the risk management training plan **covers the period only from January 1, 2024, to December 31, 2024.**

Do: Include all required training topics: OB, Infection Control, HIPAA, and high-risk areas.

Do: Customize OB training topics (e.g., prenatal/postpartum care, reproductive-age patients) based on clinical staff roles (LIPs, OCLPs, OCS).

Do: Submit a comprehensive training plan that covers all required trainings and ensure that it aligns with the FTCA Educational Training Tracking Form (see below).

Do: Use the FTCA Educational Training Tracking Form exclusively for documentation.

Don't: Submit training plans missing required topics or with incomplete documentation.

Don't: Upload unrelated documents (e.g., training flyers or plans from outside the reporting period).

Don't: Overlook remediation for staff who failed to complete training timely; ensure corrective actions are documented.

***Risk Management Question 3(F)**. Enter the following information for one completed obstetrical training for clinical and non-clinical staff who provide any health services to patients of reproductive age (even if not OB services).*

i. Title of Training

ii. Topic Area

iii. Brief description of training

iv. Date training initially offered

Note: FTCA may request additional information about course completion (for example, proof of training certificates, attendance records, continuing education documentation, and/or training completion reports).

Note: Non-clinical staff should only be included if the health center has determined that they are required to complete OB training because of clinically related contact with patients of reproductive age.

Note: All training must cover the period from January 1st to December 31st of the previous calendar year of submission of the application (for example, applications submitted in 2025 must demonstrate training was completed in 2024).

Upload your OB training tracking documentation that demonstrates attendance and training completion of the training entered above. Please use the FTCA Educational Training Tracking Form to demonstrate compliance.

If multiple OB training courses are offered at your health center, please use a separate FTCA Educational Training Tracking Form for each additional course to document completion.

What is it asking for?

This question asks the health center to upload the health center's completed FTCA Educational Training Tracking Form for obstetrics training (the form is available in PDF and XLS formats).

How do you answer the question?

Enter the title of the training and other required information in the application form, then click the link provided to download a copy of the FTCA Educational Training Tracking Form.

Make sure to complete a separate FTCA Educational Training Tracking Form for each obstetrical training course or program offered by your health center. You may also need to complete an additional FTCA Educational Training Tracking Form if you need additional rows for the same training beyond page 2 of the form.

Reminder: The training dates entered must only cover the period from January 1, 2024, to December 31, 2024.

Reminder: Fields 1-7 are required, and forms missing any information will be considered noncompliant.

On the Tracking Form, be sure to select **Obstetrical Training** from the drop-down field as the Topic Area (Field 1) and include the full Training Title in Field 2. The Brief Description of Training (Field 3) should include the training's learning objectives. Under Staff Member Information, be sure to include First Name, Last Name, Staff Type, and Date Training Completed (Fields 4–7). If you do not have a Date Training Completed (Field 7) for a staff member, provide the status and explanation in the Comments (Field 8). Enter any other applicable comments. Be sure to save a copy of each completed form before clearing or closing the form. Follow all the instructions carefully on the FTCA Educational Training Tracking Form and review for completeness prior to submission.

Select the "Attach File" button in the application to upload your obstetrical training tracking form(s) and follow the prompts for attaching the document(s).

Do: When preparing your application, only use the FTCA Educational Training Tracking Form. **All other tracking tools will be considered noncompliant.**

Do: Ensure that your completed tracking form(s) demonstrate remediation actions that have been implemented for staff who have not completed training in a timely manner.

Do: Ensure that your documentation of OB training completion and remediation should align with the number of clinical staff listed on your Credentialing and Privileging List (see the Credentialing and Privileging Section for more information).

Do: Ensure that OB training for ALL clinical staff who provide clinical services to prenatal, postpartum, and patients of reproductive age is included in the FTCA Educational Training Tracking Form.

Do: Ensure that the FTCA Educational Training Tracking Form **only covers the period from January 1, 2024, to December 31, 2024.**

Don't: Upload blank or incomplete FTCA Educational Training Tracking Forms. The

tracking documents provided must be complete, showing proof of completed trainings by all providers and staff.

Don't: Don't upload a FTCA Educational Training Tracking Form that includes training completed in years other than the previous calendar year of your application submission.

Don't: Upload tracking forms that include training topics not related to OB training.

***Risk Management Question** 3(G). Enter the following information for one completed infection control training for clinical and non-clinical staff.*

i. Title of Training

ii. Topic Area

iii. Brief description of training

iv. Date training initially offered

Note: FTCA may request additional information about course completion (for example, proof of training certificates, attendance records, continuing education documentation, and/or training completion reports).

Note: All training must cover the period from January 1st to December 31st of the previous calendar year of submission of the application (for example, applications submitted in 2025 must demonstrate training was completed in 2024).

Upload your Infection Control training tracking documentation that demonstrates attendance and training completion of the training entered above. Please use the FTCA Educational Training Tracking Form to demonstrate compliance.

If multiple Infection Control training courses are offered at your health center, please use a separate FTCA Educational Training Tracking Form for each additional course to document completion.

What is it asking for?

This question asks the health center to upload the health center's completed FTCA Educational Training Tracking Form for infection control training (the form is available in PDF and XLS formats).

How do you answer the question?

Enter the title of the training and other required information in the application form, then click the link provided to download a copy of the FTCA Educational Training Tracking Form.

Make sure to complete a separate FTCA Educational Training Tracking Form for each infection control training course or program offered by your health center. You may also need to complete an additional FTCA Educational Training Tracking Form if you need additional rows for the same training beyond page 2 of the form.

Reminder: The training dates entered must only cover the period from January 1, 2024, to December 31, 2024.

Reminder: Fields 1-7 are required, and forms missing any information will be considered noncompliant.

On the Tracking Form, be sure to select **Infection Control Training** from the drop-down field as the Topic Area (Field 1) and include the full Training Title in Field 2. The Brief Description of Training (Field 3) should include the training's learning objectives. Under Staff Member Information, be sure to include First Name, Last Name, Staff Type, and Date Training Completed (Fields 4–7). If you do not have a Date Training Completed (Field 7) for a staff member, provide the status and explanation in the Comments (Field 8). Enter any other applicable comments. Be sure to save a copy of each completed form before clearing or closing the form. Follow all the instructions carefully on the FTCA Educational Training Tracking Form and review for completeness prior to submission.

Select the "Attach File" button in the application to upload your infection control training tracking form(s) and follow the prompts for attaching the document(s).

Do: When preparing your application, only use the FTCA Educational Training Tracking Form. **All other tracking tools will be considered noncompliant.**

Do: Ensure that your completed tracking form(s) demonstrate remediation actions that have been implemented for staff who have not completed training in a timely manner.

Don't: Upload blank or incomplete FTCA Educational Training Tracking Forms. The tracking documents provided must be complete, showing proof of completed trainings by all providers and staff.

Don't: Don't upload a FTCA Educational Training Tracking Form that includes training completed in years other than the previous calendar year of your application submission.

Don't: Upload tracking forms that include training topics not related to infection control.

Risk Management Question 3(H). Enter the following information for one completed HIPAA training for clinical and non-clinical staff.

i. Title of Training

ii. Topic Area

iii. Brief description of training

iv. Date training initially offered

Note: FTCA may request additional information about course completion (for example, proof of training certificates, attendance records, continuing education documentation, and/or training completion reports).

Note: All training must cover the period from January 1st to December 31st of the previous calendar year of submission of the application (for example, applications submitted in 2025 must demonstrate training was completed in 2024).

Upload your HIPAA training tracking documentation that demonstrates attendance and training completion of the training entered above. Please use the FTCA Educational Training Tracking Form to demonstrate compliance.

If multiple HIPAA training courses are offered at your health center, please use a separate FTCA Educational Training Tracking Form for each additional course to document completion.

What is it asking for?

This question asks the health center to upload the health center's completed FTCA Educational Training Tracking Form for HIPAA training (the form is available in PDF and XLS formats).

How do you answer the question?

Enter the title of the training and other required information in the application form, then click the link provided to download a copy of the FTCA Educational Training Tracking Form.

Make sure to complete a separate FTCA Educational Training Tracking Form for each HIPAA training offered by your health center. You may also need to complete an additional FTCA Educational Training Tracking Form if you need additional rows for the same training beyond page 2 of the form.

Reminder: The training dates entered must only cover the period from January 1, 2024, to December 31, 2024.

Reminder: Fields 1-7 are required, and forms missing any information will be considered noncompliant.

On the Tracking Form, be sure to select **HIPAA Training** from the drop-down field as the Topic Area (Field 1) and include the full Training Title in Field 2. The Brief Description of Training (Field 3) should include the training's learning objectives. Under Staff Member Information, be sure to include First Name, Last Name, Staff Type, and Date Training Completed (Fields 4–7). If you do not have a Date Training Completed (Field 7) for a staff member, provide the status and explanation in the Comments (Field 8). Enter any other applicable comments. Be sure to save a copy of each completed form before clearing or closing the form. Follow all the instructions carefully on the FTCA Educational Training Tracking Form and review for completeness prior to submission.

Select the "Attach File" button in the application to upload your HIPAA training tracking form(s) and follow the prompts for attaching the document(s).

Do: When preparing your application, only use the FTCA Educational Training Tracking Form. All other tracking tools will be considered noncompliant.

Do: Ensure that your completed tracking form(s) demonstrate remediation actions that have been implemented for staff who have not completed training in a timely manner.

Don't: Upload blank or incomplete FTCA Educational Training Tracking Forms. The tracking documents provided must be complete, showing proof of completed trainings by all providers and staff.

Don't: Don't upload a FTCA Educational Training Tracking Form that includes training completed in years other than the previous calendar year of your application submission.

Don't: Upload tracking forms that include training topics not related to HIPAA training.

Risk Management Question 3(l). Enter the following information for one completed areas of high-risk training for clinical and non-clinical staff.

i. Title of Training

i. Topic Area

ii. Brief description of training

iii. Date training initially offered

Note: FTCA may request additional information about course completion (for example, proof of training certificates, attendance records, continuing education documentation, and/or training completion reports).

Note: All training must cover the period from January 1st to December 31st of the previous calendar year of submission of the application (for example, applications submitted in 2025 must demonstrate training was completed in 2024).

Upload your areas of high-risk training tracking documentation that demonstrates attendance and training completion of the training entered above. Please use the FTCA Educational Training Tracking Form to demonstrate compliance.

If multiple areas of high-risk training courses are offered at your health center, please use a separate FTCA Educational Training Tracking Form for each additional course to document completion.

What is it asking for?

This question asks the health center to upload the health center's completed FTCA Educational Training Tracking Form for specific areas of high risk training (the form is available in PDF and XLS formats).

How do you answer the question?

Enter the title of the training and other required information in the application form, then click the link provided to download a copy of the FTCA Educational Training Tracking Form.

Make sure to complete a separate FTCA Educational Training Tracking Form for each specific area of high-risk training offered by your health center. You may also need to complete an additional FTCA Educational Training Tracking Form if you need additional rows for the same training beyond page 2 of the form.

Reminder: The training dates entered must only cover the period from January 1, 2024, to December 31, 2024.

Reminder: Fields 1-7 are required, and forms missing any information will be considered noncompliant.

On the Tracking Form, be sure to select **Specific areas of High-Risk Training** from the drop-down field as the Topic Area (Field 1) and include the full Training Title in Field 2. The Brief Description of Training (Field 3) should include the training's learning objectives. Under Staff Member Information, be sure to include First Name, Last Name, Staff Type, and Date Training Completed (Fields 4–7). If you do not have a Date Training Completed (Field 7) for a staff member, provide the status and explanation in the Comments (Field 8). Enter any other applicable comments. Be sure to save a copy of each completed form before clearing or closing the form. Follow all the instructions carefully on the FTCA Educational Training Tracking Form and review for completeness prior to submission.

Select the "Attach File" button in the application to upload your high-risk training tracking form(s) and follow the prompts for attaching the document(s).

Do: When preparing your application, only use the FTCA Educational Training Tracking Form. All other tracking tools will be considered noncompliant.

Do: Ensure that your completed tracking form(s) demonstrate remediation actions that have been implemented for staff who have not completed training in a timely manner.

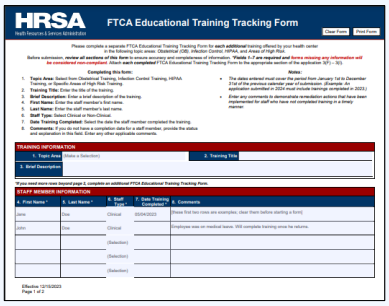
Do: Ensure that the FTCA Educational Training Tracking Form only **covers the period from January 1, 2024, to December 31, 2024**

Don't: Upload blank or incomplete FTCA Educational Training Tracking Forms. The tracking documents provided must be complete, showing proof of completed trainings by all providers and staff.

Don't: Upload tracking forms that include training topics not related to specific areas of high risk.

Key Resources

- FTCA Educational Training Tracking Form (available in PDF and XLS formats)



4. Quarterly Risk Assessments

***Risk Management Question 4**. Upload documentation for each quarter (for example, completed assessment tool or completed assessment checklist with detailed information, outcomes, and follow-up action) that demonstrates that the health center has completed quarterly risk management assessments reflective of health center activities that covers the period from January 1st to December 31st of the previous calendar year of submission.*

What is it asking for?

This question asks the health center to upload the health center's ***completed risk assessment and associated action plan for*** **each calendar quarter within the period from January 1, 2024, to December 31, 2024:**

- Quarter 1: January 1, 2024 – March 31, 2024
- Quarter 2: April 1, 2024 – June 30, 2024
- Quarter 3: July 1, 2024 – September 30, 2024
- Quarter 4: October 1, 2024 – December 31, 2024

What does it mean?

A risk assessment involves collecting and analyzing information about the health center's practices, policies, and culture in order to identify deficiencies and take action to improve. Note that a complete risk assessment involves several steps. Health centers can use a variety of tools for the first step in the risk assessment process, including surveys of staff to evaluate overall safety culture; completion of a targeted questionnaire or checklist that assesses a particular area of concern such as test tracking, obstetrics, or medication safety; a failure mode and effects analysis (FMEA); or leadership walk-arounds to give executive staff the opportunity to hear from employees about potential risks and concerns. **Please note, however, that using these tools is only part of the process and is not a complete risk assessment.**

When conducting a risk assessment, health centers should also document results, evaluate results (e.g., through data analysis, discussion), implement action plans that list changes to address identified risks, test changes (e.g., Plan, Do, Study, Act), and monitor changes. Health centers must be able to provide clear documentation in the application of all these elements (i.e., assessment tool used, results, evaluation of results, action plans, and monitoring of action plans). **Although health centers have flexibility to determine which risk assessment method works best for their organization, at minimum, they must provide documentation of these key elements and be able to provide supporting documentation of each element when requested.**

Health centers must conduct risk assessments, including all the steps noted above, at least quarterly. See “Figure. Anatomy of the Risk Assessment Process” for a description of what elements are included in a complete risk assessment, along with what would be considered an incomplete risk assessment.

Figure. Anatomy of the Risk Assessment Process

Identify Topic	Conduct Assessment	Evaluate Results	Implement Change	Reassess
High risk Patient safety-focused Based on sources of information (e.g., complaints, claims)	Organize team Select methodology and risk assessment tools (e.g., checklist) Collect data and information based on the tool used	Analyze data Discuss with the team Create an action plan with timelines and responsibility	Implement new practices, policies, or procedures Use a framework to test changes (e.g., PDSA) Set SMART goals	Timeline Responsibility Outcome (and possible need to re-visit assessment and/or evaluation process)

Why is it important?

Collecting data on practices, policies, and safety cultures in various areas generates information that can be used to proactively target patient safety activities and prioritize risk prevention and reduction strategies. In addition, health centers can select risk management training topics based on high-risk areas identified through quarterly risk assessments.

How do you answer the question?

Choose a risk assessment and corresponding action plan that demonstrates completion of a risk assessment for **each calendar quarter within the period from January 1, 2024, to December 31, 2024:**

- Quarter 1: January 1, 2024 – March 31, 2024
- Quarter 2: April 1, 2024 – June 30, 2024
- Quarter 3: July 1, 2024 – September 30, 2024
- Quarter 4: October 1, 2024 – December 31, 2024

Please note that your corresponding action plan is tied to the same calendar quarter that the risk assessment is conducted in. For example, your health center may choose to include a self-assessment questionnaire or checklist that has been completed by the risk manager or

another staff member in Quarter 1 of the calendar year, along with the action plan that was created as a result of analyzing the questionnaire's or checklist's findings. Even though the action plan may have been started after Quarter 1 concluded, it is still considered an action plan for Q1 since that is when you first identified the need to create an action plan.

When selecting the four quarterly risk assessments to upload into the application, make sure that each one is primarily clinical patient care and safety focused—in other words, that they focus on areas that can potentially prevent or decrease the likelihood of medical malpractice claims. For example, your health center should submit a risk assessment that focuses on clinical areas such as tracking diagnostic test results, following up on referrals, or storing and handling medications, rather than nonclinical concerns (e.g., building security, parking lot safety, lighting functionality). Although these nonclinical concerns are still significant for the health center's overall risk management program, they are not the primary focus of FTCA.

Once you've selected the risk assessment documents you will include in the application, select the option to upload your risk assessment documents and follow the prompts for attaching the documents. Be sure to include the name of the assessment, the area assessed, the date the assessment was completed, the findings of the assessment, the assessment itself, and the corresponding action plan for each quarter listed. You can refer to the What Is a Risk Assessment? and Key Resources boxes listed below for guidance on conducting and documenting a risk assessment. See also Risk Assessment Evaluation Tool.

What Is a Risk Assessment?

Definition: A risk assessment is a systematic process used to identify, analyze, and evaluate potential hazards inherent in clinical processes that may negatively impact patient health and safety. Risk assessments enable health centers to prioritize areas for improvement and actively engage in implementing actions to mitigate clinical risks and enhance patient outcomes. Use the below checklist to determine whether your risk assessment is complete.

Yes	No	Does your completed risk assessment:
[ ]	[ ]	Focus on a clinical process?
[ ]	[ ]	Identify, analyze, and evaluate potential hazards?
[ ]	[ ]	Prioritize areas of improvement?
[ ]	[ ]	Include an action plan with actions listed to mitigate the risks identified?
[ ]	[ ]	Define SMART goals for improvement as part of the action plan?
[ ]	[ ]	List associated measures of effectiveness to determine improvement outcomes?
[ ]	[ ]	Document progress in a way that can be shared with key stakeholders (e.g., governing board)?
[ ]	[ ]	**TOTALS**

Yes = 1, No = 0. The higher your score, the more likely your process is in alignment with FTCA requirements.

What Is NOT a Risk Assessment?

Although the below elements may play a role in a risk assessment, these alone are NOT considered a complete risk assessment:

- Peer review information for one or several providers
- Quality improvement/quality assurance minutes or documentation
- A risk assessment form or completed tool (without documentation of action plan and monitoring)
- Policies, procedures, and other documents that do not demonstrate completion of an actual assessment

Do: Focus risk assessments on areas that can prevent or reduce medical malpractice claims, prioritizing clinical activities.

Do: Use available tools (e.g., checklists or assessment templates) for guidance.

Do: Ensure assessments include action plans and relevant outcomes.

Don't: Upload blank or incomplete risk assessment tools or action plans. The documents must show a completed risk assessment along with an action plan that corresponds to the appropriate **calendar quarter within the period from January 1, 2024, to December 3, 2024**.

Don't: Upload unrelated documents (e.g., meeting minutes or policies) as evidence of risk assessments.

Don't: Include risk assessments focused only on nonclinical issues, such as building safety.

Key Resources

- Ambulatory Medical and Dental Risk Assessment Tool
- Managing Risks in Ambulatory Care: Clinical Management
- Managing Risks in Ambulatory Care: Human Resources
- Managing Risks in Ambulatory Care: Office Administration
- Practice Alert: Conducting Risk Assessments: A Checklist
- Using Risk Assessments to Implement Positive Change

5. Annual Report to the Board

***Risk Management Question** 5(A). Upload the annual report provided to the board and key management staff on health care risk management activities and progress in meeting goals at least annually, and documentation provided to the board and key management staff showing that any related follow-up actions have been implemented. The report must cover the period from January 1st to December 31st of the previous calendar year of submission and must be reflective of the activities related to risk from the previous calendar year (for example, applications submitted in 2025 must demonstrate training was completed in 2024). Any documents dated outside of this period will not be accepted.*

Note: A consolidated report covering the previous calendar year is required. Separate quarterly or monthly reports are not acceptable. The report must include the following information:

i. Completed risk management activities (for example, risk management projects, assessments),

ii. Status of the health center's performance relative to established risk management goals (for example, data and trends analyses, including, but not limited to, sentinel events, adverse events, near misses, falls, wait times, patient satisfaction information, other risk management data points selected by the health center), and

iii. Proposed risk management activities that cover the previous calendar year (January 1st to December 31st) of submission for the next calendar year period that relate and/or respond to identified areas of high organizational risk.

What is it asking for?

This question asks the health center to upload the health center's completed annual clinical risk management board report.

What does it mean?

Health centers must report to the board and key management staff on health care risk management activities and progress meeting goals at least annually. The format of the report (e.g., dashboard, narrative summary, bullet points, graphs, and charts) may vary depending on board preferences and the purpose of the report (e.g., recognize achievements, inform, seek approval). No matter what format health centers use, they must ensure that the following information is included:

Elements of Annual Risk Management Board Report

Yes	No	Does your completed board report:
[ ]	[ ]	Include all completed clinical risk management activities conducted by the health center (e.g., quarterly risk assessments, risk management projects) from **January 1, 2024, to December 30, 2024**?
[ ]	[ ]	Cover the status of the health center's progress related to established annual risk management goals? (This should include **data trends and analysis** in regard to topics including, but not limited to, sentinel events, adverse events, near misses, falls, wait times, patient satisfaction information, trainings completed, and other clinical risk management data points selected by the health center.)
[ ]	[ ]	List all proposed risk management activities that relate and/or respond to identified areas of high organizational risk as determined from the data presented?
[ ]	[ ]	Document when the report was presented to the board?
[ ]	[ ]	Document any findings or actions taken by the board in response to the report?
[ ]	[ ]	Document the date the report was approved by the board?
[ ]	[ ]	**TOTALS**

Yes = 1, No = 0. The higher your score, the more likely your process is in alignment with FTCA requirements.

The report should also include details about how the health center has established policies and procedures to minimize the possibility of legal action resulting from any health-related activities performed by the health center. This includes risk management training.

Health centers must report to the board on an annual basis, at minimum, but can decide whether to report to the board more frequently (e.g., monthly, quarterly, as requested). Even if health centers report to the board more frequently, they should summarize all key activities and progress toward goals in a single, comprehensive annual summary report.

Why is it important?

The board and key management staff oversee the organization's performance related to safety and quality. They should be informed of the health center's risk management activities and performance related to risk management goals, provide input and recommendations to the chief executive officer and leadership on the safety plan and goals, and keep quality and safety in mind when making decisions for the organization. In addition, reporting to the board is a great opportunity to show the value of the health center's risk management program.

How do you answer the question?

Make sure that your annual report to the board and key management staff is detailed, that it **covers the period from January 1, 2024, to December 31, 2024,** and that it is reflective of the activities related to clinical risk management. The annual report is a summary report including narratives and data points; **it is not a series of board meeting minutes.** If you submit monthly or quarterly reports to the board, these reports and any other data and analysis for the calendar year must be reconciled into a single, comprehensive annual summary document before submitting.

Read the annual report to ensure it includes the required elements listed above (i.e., completed risk management activities, status of progress related to goals, proposed risk management activities) and the information is clear and easy to understand. Select the option to upload your board report and follow the prompts for attaching the document. You can refer to FTCA Application Procedural Demonstration of Compliance Tool: Risk Management—Annual Report to the Board Edition and Risk Management Report to the Board: Sample Report and Dashboard for a sample report and guidance.

Do: Ensure the report covers clinical risks for the reporting period (**January 1, 2024, to December 31, 2024**).

Do: Submit one comprehensive report covering all required information.

Do: Focus on activities preventing medical malpractice claims and avoid nonclinical concerns.

Don't: Upload partial reports (e.g., monthly or quarterly summaries).

Don't: Submit general board meeting minutes, PowerPoint slides, or data without context.

Key Resources

- FTCA Application Procedural Demonstration of Compliance Tool: Risk Management—Annual Report to the Board Edition
- Risk Management Report to Board: Sample Report and Dashboard
- Sample Risk Management Dashboard

Risk Management Question 5(B)**. **Upload proof that the health center board has received and reviewed the report uploaded for risk management question 5(A) of this application (for example, minutes signed by the board chair/board secretary, or minutes and a signed letter from the board chair/board secretary that clearly indicate that the board received and reviewed the report and took any necessary actions).

All documents must cover the period from January 1st to December 31st of the previous calendar year of submission. Any documents dated outside of this period will not be accepted.

What is it asking for?

This question asks the health center to upload documentation proving that the completed annual clinical risk management board report has been reviewed by the board and that the board has taken any necessary actions.

How do you answer the question?

For this question, you will submit a document demonstrating that the board has received and reviewed the annual report that you uploaded for the previous question. As noted in the question, this documentation could be meeting minutes from a board meeting that show the report was received and reviewed at the meeting or a letter signed by the board chair or board secretary that attests that the board received and reviewed the annual report. The document you upload must indicate that the board not only received and reviewed the report, but also took any necessary actions. Be sure to select the option to upload and follow the prompts for attaching the document.

6. Risk Manager Position Description

Risk Management Question 6**. **Upload the relevant position description of the risk manager who is responsible for the coordination of health center

risk management activities and any other associated risk management activities. Note: The job description must clearly detail that the risk management activities are a part of the risk manager's daily responsibilities.

What is it asking for?

This question asks the health center to upload the comprehensive job description for the health center's risk manager.

What does it mean?

Health centers must designate an individual(s) (e.g., the risk manager) who oversees and coordinates health care risk management activities and who completes risk management training annually. The risk manager also ensures implementation of and updates to policies and operating procedures, conducts risk assessments, and reports to the board and key management staff on risk management activities. Depending on the size and needs of the organization, the health center may designate one person who is solely the risk manager, may have multiple risk managers for different sites, or may combine risk management with other job functions (e.g., QI/QA). To meet deeming requirements, health centers must have a job description for the risk manager, or the individual(s) designated as performing risk management activities, and this job description must clearly detail that risk management activities are part of the daily responsibilities.

How do you answer the question?

Review your job description for the risk manager or individual(s) designated as performing risk management activities to ensure it includes the required elements described above. Select the option to upload and follow the prompts for attaching the document. You can refer to sample job descriptions and tools available in Resource Collection: Risk Management Fundamentals for guidance.

Do: Ensure the submitted risk manager position description clearly details that risk management activities are part of the risk manager's daily responsibilities.

Key Resources

- Resource Collection: Risk Management Fundamentals (see Sample Policies and Tools section for sample job descriptions)
- The Many Hats of a Risk Manager: Preventing Harm and Improving Patient Safety

7. Risk Training for the Risk Manager

Risk Management Question 7(A). Has the health center risk manager completed health care risk management training between January 1st to December 31st of the previous calendar year of submission?

What is it asking for?

This question asks if the risk manager has completed risk management training between **January 1, 2024, to December 1, 2024.**

How do you answer the question?

The individual(s) designated as the health center's risk manager must complete risk management training annually. For this question, your health center will attest that your risk manager has completed risk management training **between January 1, 2024, to December 1, 2024**. Risk management training options are available from ECRI or from other organizations like the American Society for Healthcare Risk Management.

Note: Risk management trainings that the risk manager conducts cannot be used as the source of their own training.

If your health center's risk manager has completed risk management training **between January 1, 2024, to December 31, 2024**, select "yes" to answer this question.

If you select "no," follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide.

Reminder: You must demonstrate that the health center's risk manager completed risk management training **between January 1, 2024, to December 31, 2024.**

Key Resources

- Ambulatory Care Risk Management and Patient Safety Training Program
- Clinical Risk Management Program eLearning
- Resource Collection: Risk Management Training
- American Society for Healthcare Risk Management Education

Risk Management Question 7(B)**. **Upload evidence that the risk manager has completed health care risk management training between January 1st to December 31st of the previous calendar year of submission.

What is it asking for?

This question asks the health center to upload documentation proving that the risk manager has completed health care risk management training between **January 1, 2024, to December 31, 2024.**

How do you answer the question?

Evidence of risk management training may include certificates of completion for online courses, certificates of attendance for in-person training or webinars, or other official documentation from the training provider that includes the risk manager's name, tittle of the training program, and date. The date on the documentation must be **between January 1, 2024, to December 31, 2024.** Select the option to upload and follow the prompts for attaching the document.

Don't: Upload certificates from training programs or courses that do not relate to healthcare risk management (e.g., retail loss prevention training certificate).

Don't: Upload certificates from training programs or courses that the risk manager also teaches to staff. Risk management trainings that the risk manager conducts cannot be used as the source of their own training.

General Risk Management Do's and Don'ts

Risk Management Do's

Do: Refer to Chapter 10 and Chapter 21 of the Health Center Program Compliance Manual and the most up-to-date Program Assistance Letter when creating, reviewing, or updating risk management plans and operating procedures.

Do: Ensure that all necessary elements (as outlined in FTCA policy guidance and the questions in the deeming application) are included in your risk management operating procedures, risk management training plan, annual report to the board, risk manager job description, and other documents before attesting and/or uploading them to the application.

Do: Include obstetrics training for ALL clinical staff (LIPs, OCLPs, and OCS). Ensure that ALL clinical staff who see prenatal patients, postpartum patients, and patients who are of reproductive age are part of the health center's training plan.

Do: Use resources referenced throughout this section for guidance when creating or updating operating procedures and other documents.

Risk Management Don'ts

Don't: Wait until the application process to ensure all providers and staff have completed risk management training. Health centers should monitor and document staff training throughout the year using a tracking tool or tracking document and upload that document to the application.

Don't: Upload completed risk assessments, risk management training plans, training tracking documents, proof of annual risk management training for the risk manager, and annual reports to the board with dates outside of those specified in the application **(e.g., within the period from January 1, 2024, to December 31, 2024).**

Don't: Upload blank templates, samples, or incomplete documents. Risk assessments, risk management training tracking tools, annuals report to the board, and other required documents must be complete and specific to the health center.

Quality Improvement/Quality Assurance

Health centers must have an established QI/QA program that addresses quality and utilization of healthcare services, patient satisfaction and patient grievances, and patient safety, including adverse events. The program must be reviewed and approved by the governing board at least every three years.

Healthcare risk management and QI/QA functions commonly overlap; as long as core program and deeming requirements are met, the health center has discretion regarding how to structure these programs.

For this section of the application, you will need to attest that you have an established board-approved QI/QA policies, that your QI/QA policies and operating procedures address core program requirements (described in more detail below), that your health center has implemented a certified electronic health record (EHR) for all patients, and that your health center protects the confidentiality of patient information. You will not need to upload or attach any documents or materials in this section of the application.

QI/QA: Key Resources and Tools

- Health Center Program Compliance Manual (Chapter 10: Quality Improvement/ Assurance)
- HRSA Clinical Quality Improvement webpage
- ECRI Guidance on the FTCA Program for Health Center Providers and Staff: Information about the Federal Tort Claims Act and the Federally Supported Health Centers Assistance Act
- Resource Collection: Quality Improvement/Quality Assurance

1. Board-Approved QI/QA Policies

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

i. The quality and utilization of health center services;

ii. Patient satisfaction and patient grievance processes; and

iii. Patient safety, including adverse events.

What is it asking for?

This question asks the health center to confirm that the health center has a written QI/QA plan or policy that has been approved by the governing board.

What does it mean?

Health centers must implement a QI/QA program and carry out ongoing QI/QA activities. This should be documented in a written plan or policy that is reviewed and signed by the governing board.

Health centers must also designate an individual(s) to oversee the QI/QA program (e.g., a quality director, or other title/descriptor of the health center's choosing). Depending on the size and needs of the health center, the QI/QA designee may be full-time, part-time, or combined with another position (e.g., risk manager). Health centers can also determine the appropriate professional background for the QI/QA designee (e.g., physician, registered nurse, nurse practitioner, an individual with a Master of Public Health or a Master of Health Care Administration degree, or another qualified individual). When looking at clinical quality measures or the utilization and quality of clinical services, physician involvement in or oversight of these efforts is helpful as a best practice.

For this question, health centers will attest that they have a written QI/QA plan that is approved and signed by the board. While requirements for QI/QA and risk management are distinct, many risk and quality activities are complementary, and some overlap. Because of this overlap, health centers no longer need to upload QI/QA policies or documents to the application. Keep in mind, though, that health centers may be asked to provide QI/QA plans, policies, or documents to HRSA as part of a site visit or during later stages of the application process.

Why is it important?

Robust QI/QA programs are intended to improve patient care and patient satisfaction, maintain staff safety and satisfaction, and improve the overall efficiency and effectiveness of the organization. As noted above, QI/QA and risk management functions go hand in hand. Collaboration among individuals responsible for QI/QA, risk management, infection control, patient safety, and compliance can help ensure the organization delivers safe, high-quality patient care while minimizing risks.

How do you answer the question?

Read through your QI/QA plan or QI/QA policy to ensure that it addresses the quality and utilization of health center services, patient satisfaction and grievance processes, and patient safety, including adverse events. As noted above, the health center has some discretion regarding how to structure the QI/QA program and how these functions are carried out.

If your health center has a QI/QA plan or policy that includes these elements, select "yes" to answer this question. If your health center does not have a plan or any of the required elements are missing, select "no."

If you select "no," follow the instructions under the Important: Required Actions for Noncompliance in FTCA Application section of this guide.

Reminder: When completing questions that ask you to attest to a particular action or understanding, make sure that your response corresponds with actions being taken in your health center. **Even if you do not need to submit proof or supporting documentation along with the application, keep in mind that you may be asked to produce proof or supporting documentation as part of a site visit or at the request of FTCA during later stages of the application process.**

Do: Maintain policies covering:

- Evidence-based clinical guidelines
- Patient safety and adverse events
- Patient satisfaction and grievances
- Quarterly QI/QA assessments
- Reports for management and board oversight

Don't: Wait until the application period to review QI/QA plans and procedures. Routine updates are essential.

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

i. Adhering to current evidence-based clinical guidelines, standards of care, and standards of practice in the provision of health center services, as applicable;

ii. ***Identifying, analyzing, and addressing patient safety and adverse events and implementing follow-up actions, as necessary;***

iii. ***Assessing patient satisfaction;***

iv. ***Hearing and resolving patient grievances;***

v. ***Completing periodic QI/QA assessments on at least a quarterly basis to inform the modification of the provision of health center services, as appropriate; and***

vi. ***Producing and sharing reports on QI/QA to support decision-making and oversight by key management staff and by the governing board regarding the provision of health center services.***

What is it asking for?

This question asks the health center to confirm that the health center an ongoing QI/QA program that addresses all the required elements listed.

What does it mean?

This question goes a step further and asks health centers to attest that they have operating procedures that address important elements of QI/QA. As noted above, health centers have some flexibility and discretion regarding determining how to set up the QI/QA program. For example, health centers have the freedom to determine the following:

- Structure of QI/QA committees and agendas for QI/QA meetings
- Which QI/QA approaches to use, including processes for data collection as well as quality measures and methodologies such as SMART objectives (specific, measurable, achievable, realistic, time-phased) or SWOT analysis (strengths, weaknesses, opportunities, threats)
- Type of patient health record system
- Format, content, and focus of QI/QA report

How do you answer the question?

Read through your QI/QA operating procedures to ensure that they address the necessary elements listed in the question.

If your health center has QI/QA operating procedures that include these elements, select “yes” to answer this question. If your health center does not have a plan or any of the required elements

are missing, select “no.” If you select “no,” follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide.

Don’t: Wait until the application submission period to review the QI/QA plan and QI/QA operating procedures for necessary elements. Health centers should review policies and procedures on a regular basis and make updates as needed.

Key Resources

- Continuous Quality Improvement: Learning from Events
- Resource Collection: Event Reporting
- Resource Collection: Event Response
- Resource Collection: Patient Complaints and Grievances
- Resource Collection: Quality Improvement/Quality Assurance Tools

2. Electronic Health Records

QI/QA Question 2. Has the health center implemented a certified Electronic Health Record for all health center patients?

What is it asking for?

This question asks if the health center has implemented an EHR for all patients the health center serves.

What does it mean?

Health centers must maintain a “retrievable health record” for each patient (e.g., a certified EHR that complies with applicable federal and state laws and requirements). Certified EHRs meet technological, capability, functionality, and security requirements set by the U.S. Department of Health and Human Services. When selecting an EHR vendor, make sure the system is certified and meets all applicable federal and state laws and requirements.

Why is it important?

EHRs should improve quality, safety, efficiency, patient and family engagement, care coordination, and public health. Appropriate use of EHRs requires significant planning and workflow assessment. Health centers should involve providers and staff in evaluating,

implementing, and migrating EHRs, as well as in ongoing monitoring and continuous improvement strategies. Health centers should also work collaboratively with vendors and Health Center Controlled Networks to optimize EHRs.

How do you answer the question?

If your health center has a certified EHR for all health center patients, select "yes" to answer this question. If your health center does not have a certified EHR for all health center patients, select "no."

If you select "no," follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide.

Key Resources

- EHR Vendor Checklist
- Electronic Health Records: Functionality
- Electronic Health Records: Operational Issues
- Get Safe! A Brief Case for Safety: Managing Unintended Consequences of EHRs
- Resource Collection: Health Information Technology
- Resource Collection: Medical Records and Documentation

3. Protecting the Confidentiality of Patient Information

QI/QA Question 3. I attest that my health center has implemented and maintains systems and procedures for protecting the confidentiality of patient information and safeguarding this information against loss, destruction, or unauthorized use, and that such systems and procedures are consistent with federal and state requirements.

What is it asking for?

This question asks the health center to confirm that it has systems and procedures in place to protect the confidentiality of patient information.

What does it mean?

The general duty of confidentiality means that any information received from a patient in the course of medical treatment is protected from disclosure, except under certain narrow circumstances. The Health Insurance Portability and Accountability Act provides a detailed roadmap for ensuring the confidentiality of protected health information and specifies who is obligated to ensure that records are protected. States have requirements related to the privacy and confidentiality of patient information as well.

Health centers should ensure that systems and procedures for protecting patient confidentiality meet both HIPAA and state requirements and should consult with legal counsel regarding state-specific considerations and legal concerns. Systems and procedures will include designating a privacy and security officer who is knowledgeable regarding confidentiality practices and requirements, conducting annual risk assessments related to confidentiality practices, following up on problem areas identified through risk assessments, documenting these efforts, and ensuring that all staff and providers complete required HIPAA training at hire and annually.

Why is it important?

Health centers are required by both federal and state laws to protect the privacy and confidentiality of patient information. Failure to comply with these laws can lead to hefty fines and other enforcement actions against health centers.

How do you answer the question?

Review your health center's privacy, security, and confidentiality policies to ensure they are compliant with federal and state requirements. Your health center's privacy and security officer will be a helpful resource.

If your health center has systems and procedures that meet federal and state patient confidentiality requirements, select "yes" to answer this question. If your health center does not have systems and procedures that meet these requirements, select "no."

If you select "no," follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide.

Key Resources

- Get Safe: A Brief Care for Safety: The HIPAA Privacy Rule in Clinical Practice
- Health Information Privacy (HHS.gov)
- HIPAA FAQs: Real-Life HIPAA Challenges in Primary Care
- The HIPAA Privacy Rule
- The HIPAA Security Rule
- Resource Collection: Laws, Regulations, and Compliance

4. Protecting the Confidentiality of Patient Information (cont.)

***QI/QA Question 4**. I also acknowledge and agree that failure to implement and maintain systems and procedures for protecting the confidentiality of patient information and safeguarding this information against loss, destruction, or unauthorized use may result in disapproval of this deeming application.*

What is it asking for?

This question asks the health center to confirm it understands the consequences of failing to maintain the systems and procedures to protect patient confidentiality as required by QI/QA question 3 can include disapproval of the deeming application.

How do you answer the question?

This question asks the health center to confirm their understanding that failure to implement and maintain systems and procedures for protecting the confidentiality of patient information as described above may result in their application being denied. Select “yes” to answer and confirm acknowledgment of this question.

5. Active Conditions or Enforcement Actions

***QI/QA Question 5**. Indicate whether you currently have an active condition or any enforcement action on your Health Center Program award related to QI/QA.*

What is it asking for?

This question asks if the health center has any QI/QA related active conditions or enforcements on your Health Center Program award.

Why is it important?

Robust QI/QA programs are intended to improve patient care and patient satisfaction, maintain staff safety and satisfaction, and improve the overall efficiency and effectiveness of the organization. Insufficient QI/QA programs may leave patients and staff at serious risk.

The presence of certain active conditions and/or enforcement actions related QI/QA may demonstrate noncompliance with FTCA Program requirements and may result in disapproval of deemed status.

How do you answer the question?

If your health center has an active condition or any enforcement action on your Health Center Program award related to QI/QA, select “yes” for this question. Only conditions that may impact FTCA coverage should be included. Then, in the comment box (limit of 2,000 characters), include the following information:

- Date of condition or enforcement action
- Source (e.g., operational site visit, service-area competition application)
- Reason the condition was imposed
- Health center’s plan to remedy the deficiency that led to the condition or enforcement action
- Timeline for when the remedy will be fully implemented

Note: Health centers must have any active conditions resolved or they may not be deemed based on the presence of that condition.

Do: Include a corrective plan with timelines for any active conditions or enforcement actions reported.

Don’t: Document active conditions without a corrective plan, as this may lead to disapproval.

General QA/QI Do's and Don'ts

QI/QA Do's

Do: Refer to Chapter 10 of the Health Center Program Compliance Manual and the most up-to-date Program Assistance Letter when creating, reviewing, or updating QI/QA plans and operating procedures.

Do: Ensure that all necessary elements (as outlined in FTCA policy guidance and the questions in the deeming application) are included in your QI/QA plan and operating procedures before attesting to these questions in the application. **Keep in mind that you may be asked to produce proof or supporting documentation as part of a site visit or at the request of FTCA during later stages of the application process.**

Do: Ensure that your QI/QA plan or policy is approved and signed by the governing board.

QI/QA Don'ts

Don't: Assume your health center is in compliance with QI/QA requirements simply because you have met FTCA requirements for risk management. Although risk management and QI/QA processes may overlap, there are distinct health center requirements for each of these activities. Review your QI/QA processes for required elements prior to application submission.

Don't: Document information about an active condition in the application without including the health center's plan for correcting the deficiency and a timeline for when the plan will be implemented. According to HRSA, the presence of certain conditions and/or enforcement actions may demonstrate noncompliance with FTCA program requirements and may result in disapproval of deemed status.

Credentialing and Privileging

Credentialing is the process of assessing and confirming the license, certification, education, training, and other qualifications of a healthcare professional and is the first step in the credentialing and privileging process. In other words, credentialing verifies that individuals are who they say they are and have the qualifications that they say they do.

Privileging is the process of authorizing a professional's specific scope and content of patient care services and is the second step in the credentialing and privileging process. It involves an assessment of the professional's skills, competencies, and performance, along with verification of fitness for duty, immunizations, communicable disease status, and current clinical competence.

Prepare Documents

Before beginning the application, have the following documents available:

- Credentialing and privileging operating procedures **(will be uploaded in the application)**
- List of all staff including first and last names, title, clinical staff type (LIP, OLCP, OCS), most recent credentialing date, most recent privileging date **(this information must be entered into a form within the application; it is not attached as a separate document)**

Reminder: Check your state laws and practice acts to determine whether there are any state-specific credentialing requirements, and whether staff qualify as licensed independent practitioners (LIPs), other licensed or certified practitioners (OLCPs), or other clinical staff (OCS):

- **LIPs:** Professionals who can practice without clinical supervision, including physicians, dentists, nurse practitioners, nurse-midwives, physician assistants, and psychiatrists.
- **OLCPs:** Professionals who practice under clinical supervision, including registered nurses, licensed practical nurses, social workers, certified medical assistants, certified dental assistants, and dental hygienists.
- **OCS:** Medical assistants, dental assistants, or community health workers in states, territories, and jurisdictions that do not require licensure or certification.

Credentialing and Privileging: Key Resources and Tools

- Health Center Program Compliance Manual (Chapter 5: Clinical Staffing)
- FTCA Application Procedural Demonstration of Compliance Tool: Credentialing and Privileging Edition
- Initial Credentialing Process (infographic)
- Initial Privileging Process (infographic)
- Renewal of Credentials and Privileges (infographic)
- Resource Collection: Credentialing and Privileging

1. Credentialing Process for All Clinical Staff Members

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

i. Current licensure, registration, or certification using a primary source;

ii. Education and training for initial credentialing, using:

a. Primary sources for licensed independent practitioners;

b. Primary or other sources for other licensed or certified practitioners and any other clinical staff;

iii. Completion of a query through the National Practitioner Databank (NPDB);

iv. Clinical staff member's identity for initial credentialing using a government issued picture identification;

v. Drug Enforcement Administration registration (if applicable);

vi. Current documentation of Basic Life Support training; and

vii. Any other credentialing information required by applicable law to be completed for health care providers (e.g., state laws requiring

background checks).

What is it asking for?

This question asks the health center to confirm that it has implemented a credentialing process for all clinical staff that includes an initial review and verification of credentials as well as recredentialing on an ongoing basis.

What does it mean?

All health centers must have written policies and operating procedures that outline the processes for credentialing all clinical staff members, including processes for initial and recurring review of credentials. The requirement includes *any* clinical staff member in the health center, including providers, nurses, pharmacists, dentists, social workers, community health workers, medical and dental assistants, medical residents, students, volunteers, and other clinical staff.

Why is it important?

Credentialing and privileging are important for a few reasons:

- **Quality care:** Ensures that healthcare professionals have the education, knowledge, and competence to provide quality patient care.
- **Patient safety:** Filters out potentially troublesome professionals before they begin practicing in a health center.
- **Risk management:** Reduces the risk of lawsuits that result from failures related to credentialing, as well as the risk of medical errors.
- **Compliance:** Helps ensure compliance with Health Center Program and FTCA Program requirements.

Reminder

All clinical staff members in the health center must be credentialed and privileged. This includes providers, nurses, pharmacists, dentists, social workers, community health workers, medical and dental assistants, medical residents, students, volunteers, and other clinical staff.

How do you answer the question?

Read through your written credentialing operating procedures and determine: (1) whether they include all of the following elements and (2) whether someone (e.g., credentialing coordinator) is designated as responsible for all of the following elements:

- Verification of current licensure, registration, and certification for all clinical staff using a primary source, or the original source of the specified credential. Primary sources may include:
    - Direct correspondence (e.g., telephone, email) with the licensing or certifying body (for example, the health center calls the licensing body to confirm the professional obtained the licenses listed on his or her application)
    - Confirmation through a state database that a provider's licensure, registration, and certifications are current
    - Confirmation using profiles for professional organizations (e.g., American Medical Association, American Osteopathic Association, Educational Commission for Foreign Medical Graduates, American Nurses Credentialing Center)
    - Use of credentials verification organization for primary source verification
- Verification of education and training using:
    - Primary sources (as noted above) for LIPs
    - Primary or other sources (e.g., photocopies of credentials) for OLCPs and OCS
- Completion of query through the NPDB using either of the following processes:
    - Continuous query through NPDB; as new information is reported, it is placed in the provider's credentials file
    - Individual query for each provider at their initial appointment and at the renewal of credentials and privileges
- For initial credentialing, verification of the professional's identity using a copy of his or her government-issued picture identification (e.g., driver's license)
- Verification of Drug Enforcement Administration registration (if applicable, for providers who prescribe controlled dangerous substances)
- Verification of current basic life support (BLS) training (e.g., photocopy of unexpired BLS training certificate)
- Verification of any other information required by the health center's applicable laws. For example, if the health center's state requires criminal background checks, that information should be included.

If your health center has all of the above elements included in your operating procedures, select "yes" to answer this question. If any of the above elements are missing, select "no."

If you select "no," follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide.

Reminder: Health centers should ensure that all clinical staff members, including students and residents, are included in their credentialing and privileging policies and procedures. For nonclinical staff (e.g., office managers, billing staff), they would not be included in credentialing and privileging policies and procedures since they do not participate in direct patient care; however, as a best practice, health centers should still verify information included in their application to ensure it is accurate and they are who they say they are.

Key Resources

- National Practitioner Data Bank (including the continuous query option)
- Sample Credentialing and Privileging Policy

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

What is it asking for?

This question asks the health center to confirm their understanding that failure to implement and maintain all the elements listed under 1(A) above may result in their application being disapproved.

How do you answer the question?

Select “yes” to answer and confirm acknowledgment of this question.

Reminder: When completing questions that ask for you to attest to a particular action or understanding, make sure that your response corresponds with actions being taken in your health center. **Even if you do not need to submit proof or supporting documentation along with the application, keep in mind that you may be asked to produce proof or supporting documentation as part of a site visit or at the request of FTCA during later stages of the application process.**

2. Privileging Process for All Clinical Staff Members

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

*i. **Verification of fitness for duty, which may include immunization, and communicable disease status to the extent applicable to health care providers by applicable law;***

ii. ***For initial privileging, verification of current clinical competence via training, education, and, as available, reference reviews;***

iii. ***For renewal of privileges, verification of current clinical competence via peer review or other comparable methods (for example, supervisory performance reviews); and***

iv. ***Process for denying, modifying or removing privileges based on assessments of clinical competence and/or fitness for duty.***

Note: If the health center chooses to submit a policy and procedure that incorporates temporary credentialing and/or privileges, those temporary credentialing and privileging procedures must align with the guidelines in the current Temporary Privileging of Clinical Providers by Federal Tort Claims Act (FTCA) Deemed Health Centers in Response to Certain Declared Emergency Situations - PAL 2024-01. Use of temporary credentialing and privileging is not allowed for situations not outlined in PAL 2017-07 and therefore should not appear in the health center's general policies and procedures. Language that indicates use of temporary credentialing and privileging that is not aligned with PAL 2024-01 may be considered as non-compliant with FTCA credentialing and privileging requirements.

What is it asking for?

This question asks the health center to confirm that it has implemented a privileging process for all clinical staff that includes an initial review and approval of privileges as well as re-privileging an ongoing basis.

What does it mean?

All health centers must have written procedures that outline the processes for granting and renewing privileges of all clinical staff. When a healthcare provider initially applies for a position in the health center, they will request privileges for specific procedures and services they may perform (e.g., removing skin lesions, performing gynecological procedures) and specific populations for whom they will provide care (e.g., obstetric patients, infants). The health center will confirm that the requested privileges are appropriate for the professional's training, specialty, and services that they will provide at the health center.

On an ongoing basis, the health center will also verify each professional's current clinical competence for the delineated scope and content of patient services, fitness for duty, immunization, and communicable disease status.

Why is it important?

Privileging ensures that providers and staff possess the skills and expertise to manage and treat patients and that they are able to perform the medical procedures required to provide authorized services within the health center's scope of project. In addition, verifying fitness for duty ensures that healthcare providers have the physical and cognitive ability to perform their job duties in a safe, secure, productive, and effective manner.

How do you answer the question?

Read through your written privileging procedures and determine: (1) whether they include all of the following elements and (2) whether someone (e.g., credentialing coordinator) is designated as responsible for all of the following elements:

- Verification of fitness for duty. This can be done using a few different methods:
  - Complete a fitness for duty form for all LIPs, OLCPs, and OCS as best practice
  - Request an attestation of fitness for duty from a provider that is confirmed either by the director of a training program, chief of staff/services at a hospital where privileges exist, or a licensed physician designated by the health center
- Verification of current immunization and communicable disease status
  - Refer to the Centers for Disease Control and Prevention Recommended Vaccines for Healthcare Workers
  - Refer to state immunization laws for healthcare workers
- For initial privileging, verification of current clinical competence using training records, education, and, as available, reference reviews
  - For example, ensuring that providers who perform deliveries satisfactorily complete training in electronic fetal monitoring
- For renewal of privileges, verification of current clinical competence using peer review records, supervisory performance reviews, or other comparable methods
- Process for denying, modifying, or removing privileges based on assessments of clinical competence and/or fitness for duty

If your health center has all of the above elements included in your operating procedures, select “yes” to answer this question. If any of the above elements are missing, select “no.”

If you select “no,” follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide.

Don't: Wait until the application period to review credentialing policies. Routine updates are critical.

Don’t: Use outdated PALs or guidance when updating credentialing and privileging policies.

Temporary Credentialing and Privileging in Certain Declared Emergency Situations. The use of temporary privileges is determined by HRSA on a case-by-case basis to support healthcare professionals, including volunteers, in responding to certain declared public health emergencies and extraordinary circumstances affecting the health center's population or community at large**.** Once determined by HRSA, deemed health centers can use an expedited credentialing and privileging process to ensure temporary FTCA coverage for healthcare providers (including volunteers) during such an emergency. The process includes verification of identity, professional credentials and licensure, claims history, and other requirements.

Temporary privileges can be granted for no more than 90 days. After the 90-day period, the impacted health center should have completed all the necessary verification for standard credentialing and privileging and granted full privileges based on that information.

Refer to the current PAL: PAL 2024-01: Temporary Privileging of Clinical Providers by Deemed Public Health Service Employee Health Centers Impacted by Certain Declared Emergencies of Other Emergency Situations and ensure that any written policies and procedures related to temporary privileging meet the requirements outlined in the PAL.

Do: Align temporary privileging clauses in the policies and procedures with guidance outlined in PAL 2024-01: Temporary Privileging of Clinical Providers by Deemed Public Health Service Employee Health Centers Impacted by Certain Declared Emergencies of Other Emergency Situations

Key Resources

- Ask ECRI: Health Attestation Forms for Providers Being Credentialed
- Get Safe: Assessing Clinical Competence
- Get Safe: Effective Processes for Granting Clinical Privileges
- Get Safe: Fitness for Duty: Providing Safe Patient Care
- Recommended Vaccines for Healthcare Workers (CDC)
- State Healthcare Worker and Patient Vaccination Laws (CDC)
- Sample Fitness for Duty Form
- PAL 2024-01: Temporary Privileging of Clinical Providers by Deemed Public Health Service Employee Health Centers Impacted by Certain Declared Emergencies of Other Emergency Situations

Credentialing and Privileging Question 2(B)**. **I also acknowledge that and agree that failure to implement and maintain an ongoing 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.

What is it asking for?

This question asks the health center to confirm their understanding that failure to implement and maintain all the elements listed under 2(A) above may result in their application being disapproved.

How do you answer the question?

Select “yes” to answer and confirm acknowledgment of this question.

3. Upload of Credentialing and Privileging Operating Procedures

Credentialing and Privileging Question 3**. **Upload the health center’s credentialing and privileging operating procedures that address all credentialing and privileging components listed in questions 1(A) and 2(A) above.

Note: Procedures that are missing any of the components referenced in the credentialing and privileging section questions 1(A) and 2(A) of this application will be interpreted as the health center not implementing those missing components.

What is it asking for?

This question asks the health center to upload the health center’s credentialing and privileging procedures which include all the required elements.

How do you answer the question?

For questions 1 and 2, you already have reviewed your credentialing and privileging operating procedures to ensure they include the required elements listed above. For this question, select the option to upload your credentialing and privileging operating procedures and follow the prompts for attaching the document. You can use the Sample Credentialing and Privileging Policy and FTCA Application Procedural Demonstration of Compliance Tool: Credentialing and Privileging Edition to compare with your current policy and fill in any necessary gaps.

Key Resources

- FTCA Application Procedural Demonstration of Compliance Tool: Credentialing and Privileging Edition
- Sample Credentialing and Privileging Policy

Do: Use a checklist based on the Health Center Program Compliance Manual requirements to verify policies cover all clinical staff roles.

Do: Ensure all required elements for LIPs, OCLPs, and OCS are addressed.

Don't: Submit credentialing and privileging operating procedures with missing components.

Don't: Upload unrelated documents (e.g., meeting minutes or general staffing lists).

4. Review of Credentials and Privileges

***Credentialing and Privileging Question 4**. I certify that my health center reviews the credentials and privileges of all Licensed Independent Practitioners (LIP), Other Licensed or Certified Practitioners (OLCP), and Other Clinical Staff (OCS) at least every two years, in compliance with the FTCA credentialing and privileging requirements. I understand that failure or refusal to demonstrate compliance will result in the denial of this application for FTCA deemed status.*

What is it asking for?

This question asks the health center to confirm that credentialing and privileging of all clinical staff is completed, at minimum, every two years, and that the health center understands that failure to do so may result in disapproval of the application.

What does it mean?

The health center must review each clinical staff member's credentials and current clinical competence at least every two years in accordance with FTCA requirements and renew credentials and privileges according to this time period. The renewal process involves notifying the individual that his or her credentials and privileges are due for renewal; reviewing licensures and certifications to ensure they are not expired; reviewing new education or trainings completed; confirming fitness for duty; verifying current clinical competence using peer review records, supervisory performance reviews, or other comparable methods; and forwarding

recommendations to the board or board designee for approval.

Reminder: Health centers should have processes in place for collecting performance data (e.g., chart review, direct observation, peer review) on an ongoing basis, not just every two years, and should make sure they are verifying documents that expire prior to the two-year renewal period.

Why is it important?

Review and renewal of credentials and privileges is important for the same reasons initial credentialing is important: to advance patient safety, enhance quality of patient care, minimize risks and lawsuits, and ensure compliance with Health Center Program and FTCA Program requirements. Health care professional performance may change, particularly in the areas of current clinical competence and health fitness, and health centers must ensure that all clinical providers and staff have the appropriate training, experience, and competence to provide safe, high-quality care.

How do you answer the question?

Check your credentialing and privileging operating procedures to ensure they include processes for reviewing the credentials and privileges of all LIPs, OLCPs, and OCS at least every two years.

If your credentialing and operating procedures include processes for reviewing credentials and privileges every two years, select “yes” to answer this question. If they do not, select “no.”

If you select “no,” follow the instructions under the Important: Required Actions for Noncompliance in FTCA Application section of this guide.

5. Credentialing Files and Records

***Credentialing and Privileging Question 5**. I attest that my health center maintains files or records for our clinical staff (for example, employees, individual contractors, and volunteers) that contain documentation of the verification, at least every two years, of credentialing and privileging requirements outlined in Chapter 5 of the Health Center Program Compliance Manual, consistent with the health center’s operating procedures.*

What is it asking for?

This question asks the health center to confirm that health center maintains credentialing and privileging documentation on all clinical staff as required by HRSA.

What does it mean?

The health center must keep credentialing files or records for each clinical staff member and include all documents related to credentialing and privileging in that file. Each file should be complete and organized. As new information (e.g., NPDB continuous query results, proof of new trainings and certifications) is gathered, it should be added to the professional's credentialing files.

As a best practice, the health center may want to designate an individual who is responsible for reviewing each file on an ongoing basis to identify any items that might be missing or expired. All documentation must be verified as current at least every two years as part of the credentialing renewal process.

Health centers can refer to Guide for Preparing Credentialing Files to double-check that all necessary documentation is included in each file and as a guide for organizing file contents.

Why is it important?

HRSA may ask for proof of credentialing files or records during the application process. In addition, during an operational site visit or FTCA site visit, reviewers will check credentialing files to ensure that all documentation is included and is up to date.

Maintaining complete and accurate files, and reviewing the files on an ongoing basis, will also make the renewal process easier for the credentialing coordinator—when each provider is due for renewal of credentials and privileges (at least every two years), the coordinator can check the files to ensure that documentation is current, follow up on any information that is expired or missing, and forward to the approving authority for signature to complete the renewal process. Health centers may also need to retrieve files or records at a later date during litigation or for coverage verification.

How do you answer the question?

Check your credentialing files to ensure that they meet the following requirements:

- Include all the elements listed in questions 1 and 2
- Are set up in an organized manner
    - Use folders or file tabs for each section of the file (e.g., application; clinical privileges; education, registration, and certification; licenses)
- Are reviewed and verified at least every two years, and that no information in the file is expired

If your credentialing files meet those requirements, select "yes" to answer this question. If any of the above requirements are not met, select "no."

If you select “no,” follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide.

Key Resources

- Guide for Preparing Credentialing Files

6. Contract or Referral Agreements

Credentialing and Privileging Question 6. I attest that if my health center has contracts with provider organizations (for example, group practices, staffing agencies) or formal, written referral agreements with other provider organizations that provide services within the health center’s scope of project, the health center ensures (for example, through provisions in formal, written referral agreements, contracts, other documentation) that such providers are:

i. Licensed, certified, or registered as verified through a credentialing process, in accordance with applicable federal, state, and local laws; and

ii. Competent and fit to perform the contracted or referred services, as assessed through a privileging process.

Note: A contract between a covered entity and a provider's corporation does not confer FTCA coverage on the provider. Services provided strictly pursuant to a contract between a covered entity and any corporation, including eponymous professional corporations (defined as a professional corporation to which one has given one’s name, for example, John Doe, LLC), are not eligible for coverage under FSHCAA and the FTCA. This is further described in the FTCA Health Center Policy Manual.

What is it asking for?

This question asks the health center to confirm that health center maintains credentialing and privileging documentation on all clinical staff as required by HRSA.

What does it mean?

Health centers must ensure appropriate staffing and resources to provide required primary services (as defined in Section 330(b)(1) of the Public Health Service Act) and approved additional services to patients. If the health center does not have sufficient staffing and resources to provide these services, it may use contracts or referral agreements with provider organizations.

In these cases, the health center must ensure that professionals who provide services for the health center are appropriately credentialed and privileged according to applicable federal, state, and local laws. This can be done by including language regarding credentialing and privileging of these providers in the contract, agreement, or other documentation. Health centers should also clarify these processes in their policies and procedures and should have access to the credentialing documents from the outside organization, if requested by HRSA.

Reminder: For contracts between a covered entity and a provider organization, the provider is *not* covered by FTCA, and services provided strictly related to a contract between a covered entity and any organization are not covered under FSHCAA and the FTCA (see the FTCA Health Center Policy Manual).

How do you answer the question?

If your health center does not have any contracts or referral agreements with provider organizations for staffing, select "N/A" for this question.

If your health center does have contracts or referral agreements with provider organizations, review the contracts, agreements, or documentation to determine whether appropriate credentialing and privileging procedures are being followed by the provider organization and whether these are spelled out in the documentation and in the health center's policies and procedures. If so, select "yes" to answer this question. Keep in mind that health centers still need to approve and grant privileges.

If you select "no," follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide.

7. Active Conditions or Enforcement Actions

Credentialing and Privileging Question 7**. **Indicate whether you currently have an active condition or any enforcement action on your Health Center Program award related to credentialing and privileging.

What is it asking for?

This question asks if the health center has any credentialing or privileging related active

conditions or enforcements on your Health Center Program award.

How do you answer the question?

If your health center has an active condition or any enforcement action on your Health Center Program award related to credentialing and privileging, select “yes” for this question. Only conditions that may impact FTCA coverage should be included. Then, in the comment box (limit of 2,000 characters), include the following information:

- Date of condition or enforcement action
- Source (e.g., operational site visit, service-area competition application)
- Specific nature of the condition or enforcement action
    - Finding (e.g., failure to verify licensure for clinical providers, incomplete credentialing files)
    - Reason enforcement was imposed
- Health center’s plan to remedy the deficiency that led to the condition or enforcement action
- Timeline for when the remedy will be fully implemented

Note: Health centers must have any active conditions resolved or they may not be deemed based on the presence of that condition.

Don’t: Document information about an active condition in the application without including the health center’s plan for correcting the deficiency and a timeline for when the plan will be implemented.

Credentialing and Privileging List

Credentialing and Privileging information must be entered into the EHB system. This information should not be uploaded as an attachment. Please enter all Licensed Independent Practitioners (LIP), Other Licensed or Certified Practitioners (OLCP), and Other Clinical Staff (OCS) at all health center sites, including employed or individual contracted practitioners (which the health center is responsible for credentialing and privileging), and volunteers. Health Center FTCA Program Credentialing and Privileging requirements are described in the Health Center Program Compliance Manual, Chapter 5: Clinical Staffing.

What is it asking for?

This question instructs the health center to enter all clinical staff credentialing and privileging information as required of HRSA directly into the application form via the EHB system.

What does it mean?

Health centers must conduct initial credentialing and privileging for all clinical staff upon hire (before they start working in the health center) and must renew credentials and privileges at least every two years. For this question, the health center will need to complete a Credentialing List in the application form confirming that the most recent dates for renewal of credentials and privileges occurred within two years prior to the application date.

How do you answer the question?

For this question, health centers will input a list of all currently active clinical staff (including employed staff, contractors, volunteers, and locum tenens providers) within a form in the application. Health centers must include all the following information for each staff member:

- First name
- Last name
- Professional designation (e.g., staff pediatrician, nurse)
- Clinical staff type (i.e., LIP, OLCP, OCS)
- Most recent credentialing date **(within two years of date of application submission)**
- Most recent privileging **(within two years of date of application submission)**
- Credentialing type (i.e., initial credentialing or recredentialing)

Note: Health centers will complete a fillable, structured list within the application with this information; they will *not* attach a file to the application. Health centers that have entered staff information in prior years can transfer that information automatically without having to reenter the information. Any new individuals or updates to information from the previous year will need to be added manually.

Health centers should prepare a list of their staff, including all the above information, ahead of time so the information is on hand and easy to retrieve while completing the application. Only people who are working at the health center at the time of application submission should be included. A sample Credentialing List for internal use is also included under “Key Resources” (note this sample includes more information than what is required in the application).

The most recent credentialing and privileging dates must be within two years of the date of application submission. For the purposes of the application, documentation of the most recent credentialing and privileging dates within two years indicates that the health center has properly credentialed and privileged according to program requirements. The list must be complete and accurate. Any clinical staff omissions or dates outside of this time frame will be viewed as not being in compliance with FTCA Program requirements and may result in disapproval of the application. The health center does not need to submit any supporting materials at this time. For information on how to fill out the Credentialing List in EHB, please see the Health Centers Quick

Reference Guide for Completing the FTCA Credentialing and Privileging List in EHB.

Do: Complete all fields in the structured, fillable list within the application and ensure the information is complete and accurate. Include all staff in the list—for example, if there are 90 providers, ensure your completed list includes the same number.

Don't: Attach a Credentialing List in other sections of the application in place of completing the structured, fillable list within the application. This may result in your application being returned or disapproved.

Don't: Submit credentials verification documents or supporting materials in the Credentialing List.

1. I attest that the documents as outlined in Chapter 5 of the Health Center Compliance Manual, have been collected and verified in the form and manner prescribed by HRSA and the individual is fully credentialed and privileged. Furthermore, I am able to provide documented proof of full credentialing and privileging upon request.

What is it asking for?

This question asks the health center to confirm that the Credentialing and Privileging List is complete as required by HRSA for all clinical staff, and that the health center can provide documentation of such upon request.

How do you answer the question?

Check the information entered into the Credentialing and Privileging List to ensure that it is complete and that all clinical staff members listed have been fully credentialed and privileged within the past two years.

If credentialing information is complete and accurate, select "yes" to answer this question. If not, select "no." If you select "no," follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide.

Key Resources

- Credentialing List
- Renewal of Credentials and Privileges

General Credentialing Do's and Don'ts

Credentialing Do's

Do: Refer to Chapter 5 of the Health Center Program Compliance Manual and the most up-to-date Program Assistance Letter when creating, reviewing, or updating credentialing and privileging operating procedures.

Do: Ensure the credentialing and privileging process encompasses all staff members, including OLCPs and OCS.

Do: Ensure operating procedures include a process for denying, modifying, or removing privileges based on assessments of clinical competence and/or fitness for duty.

Do: Ensure the credentialing and privileging dates for each staff member in the structured, fillable Credentialing List are **within a two-year period** of the application submission date.

Do: Double-check the credentialing operating procedure and Credentialing List before submitting to ensure all sections are complete and there are no errors.

Credentialing Don'ts

Don't: Upload or include documents other than the credentialing and privileging operating procedures and Credentialing List (e.g., meeting minutes, general staffing list without credentialing dates) to the application.

Don't: Submit sample policies and documents (like the ones included in this guide). Ensure documents reflect your health center's current processes.

Don't: Submit incomplete Credentialing Lists.

Don't: Submit policies and procedures that incorporate temporary privileging clauses that do not align with the guidance outlined in PAL 2024-01: Temporary Privileging of Clinical Providers by Deemed Public Health Service Employee Health Centers Impacted by Certain Declared Emergencies of Other Emergency Situations

Claims Management

Health centers must be able to demonstrate that they have a process in place for addressing any potential or actual health-related claims that may be eligible for FTCA coverage. This process should ensure that the health center:

- Preserves all files and documents related to any actual or potential claim or complaint.
- Promptly sends to the U.S. Department of Health and Human Services (HHS) Office of General Counsel (OGC) all court filings, demand letters, or communications from a patient or attorney relating to a potential claim or lawsuit.
- Designates an individual(s) to be the claims point of contact and to manage claims-related activities.
- 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 of the health center that is visible to patients.
- Demonstrates that, if there is a history of claims, it cooperated with the attorney general in handling the claims and implemented steps to mitigate the risk of such claims in the future.

Prepare Documents

Before beginning the application, have the following documents available and **ready to upload into the application**:

- Documentation of the claims management process (e.g., claims management operating procedures)
- A list of all claims presented under FTCA within five years of the date of application submission (if applicable)
- Screenshot of health center website or other promotional materials that state the health center is a deemed Federal PHS employee
- Position description for the individual designated as responsible for management and processing of claims-related activities (e.g., claims manager)

Claims Management: Key Resources and Tools

- Health Center Program Compliance Manual (Chapter 21: FTCA Deeming Requirements)
- ECRI Guidance on the FTCA Program for Health Center Providers and Staff: Information about the Federal Tort Claims Act and the Federally Supported Health Centers Assistance Act
- FTCA Health Center Policy Manual (Section II: Claims and Lawsuits)
- Resource Collection: Claims Management
- Resource Collection: Event Reporting
- Resource Collection: Event Response

1. Claims Management Process

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

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

ii. That any service of process/summons that the health center or its provider(s) receives relating to any alleged claim or complaint is promptly sent to the HHS, Office of the General Counsel, General Law Division, per the process prescribed by HHS and as further described in the FTCA Health Center Policy Manual.

What is it asking for?

This question asks the health center to confirm that the health center has written procedures and process to manage potential and actual claims received that includes all elements as listed as required by FTCA.

What does it mean?

If a claim or lawsuit involving a health center's covered activities is filed in court, or the health center reasonably anticipates litigation, the health center must preserve all potentially relevant documents and suspend any routine destruction of such documents. Situations that may indicate a credible threat of potential litigation include receipt of a demand letter, formal complaint, records subpoena, court notice, or the occurrence of an event that typically results in litigation.

The health center's claims management process should specify how the health center ensures preservation of documentation and submission of any claim or notice of potential claim to HHS OGC General Law Division. Health centers should confirm receipt of all documents that they email or fax.

This process should be documented (for example, in written claims management policies and procedures) and should include the specific instructions prescribed by HHS and as further described in Section II of the FTCA Health Center Policy Manual.

Health centers can use Checklist: Health Center Responsibilities when Responding to a State Court Lawsuit or Notice of Intent to File a Lawsuit to ensure all steps are completed.

Why is it important?

Once a party reasonably anticipates litigation, they have a duty to preserve evidence. Failure to preserve evidence can result in allegations of spoilation of evidence, which makes defense of the case more difficult, and may lead to adverse rulings.

How do you answer the question?

Review your health center's written claims management process (e.g., claims management operating procedures) to ensure that it addresses the following:

- Preservation of all health center documentation related to any actual or potential claim or complaint (e.g., medical records, laboratory or x-ray results, billing records, employment records of all involved clinical providers, clinic operating procedures)
- Prompt submission of any service of process/summons that the health center or its provider(s) receives relating to any alleged claim or complaint to HHS OGC General Law Division according to HHS process

If your health center has all of the above elements included in the claims management process, select "yes" to answer this question. If any of the above elements are missing, select "no."

If you select "no," follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide. If you do not have a policy and procedure that addresses these elements, HRSA will view this as not having implemented these practices and may return or disapprove the application.

Key Resources

- FTCA Health Center Policy Manual
- After An Event: Understanding the Claims Process (webinar)
- Checklist: Health Center Responsibilities when Responding to a State Court Lawsuit or Notice of Intent to File a Lawsuit
- FTCA Frequently Asked Questions - Claims and Lawsuits (HRSA)
- Claims Management: You Have Been Sued, Now What? (webinar)
    - Questions and Answers: Claims Management: You Have Been Sued, Now What?
- Sample Claims Management Policy and Procedure

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

What is it asking for?

This question asks the health center to confirm it understands the consequences of failing to implement and maintain the systems and procedures to manage claims as required by Claims Management question 1A can include disapproval of the deeming application.

How do you answer the question?

This question asks the health center to confirm their understanding that failure to implement and maintain a claims management process that includes all the elements listed under 1(A) above may result in their application being denied. Select “yes” to answer and confirm acknowledgment of this question.

Reminder: When completing questions that ask for you to attest to a particular action or understanding, make sure that your response corresponds with actions being taken in your health center. **Even if you do not need to submit proof or supporting documentation along with the application, keep in mind that you may be asked to produce proof or supporting documentation as part of a site visit or at the request of FTCA during the application review process.**

***Claims Management Question 1(C)**. Upload documentation of the health center’s claims management process (for example, claims management procedures) for addressing any potential or actual health or health-related claims, including medical malpractice claims, that may be eligible for FTCA coverage.*

Note: This process must include the items outlined in Claims Management question 1(A) of this application.

What is it asking for?

This question asks the health center to upload documentation of the health center’s claims management process.

How do you answer the question?

For question 1(A), you already have reviewed your written claims management process (e.g.,

claims management operating procedures) to ensure it includes the required elements listed above. For this question, select the option to upload your claims management procedure and follow the prompts for attaching the document. You can use the Sample Claims Management Policy and Procedure to compare with your current policy and fill in any necessary gaps.

Do: Included processes for promptly sending summons or service of process to HHS Office of General Law Division.

Do: Detail procedures for preserving all documents related to claims.

Don't: Submit procedures with missing components.

Don't: Upload unrelated documents (e.g., notice of intent for a lawsuit).

Key Resources

- Checklist: Health Center Responsibilities when Responding to a State Court Lawsuit or Notice of Intent to File a Lawsuit
- Claims Files Tracking Tool
- Sample Claims Management Policy and Procedure
- Tracking Process Tool for Claims Files

2. FTCA Claims History

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

What is it asking for?

This question asks if the health center has had a medical malpractice claim or allegation within the past five years.

How do you answer the question?

If your health center has not had a medical malpractice claim or allegation within the past five years from the date of application submission, select "no" to answer this question.

If your health center has had a medical malpractice claim or allegation within the past five years from the date of application submission, select "yes" **and** attach a document that lists all claims filed during that period of time.

For each claim listed, you must include the following information:

- Name of provider(s) involved
- Role(s) in health center
- Area of practice/specialty
- Others involved
- Nature of allegations
- Date of occurrence
- Date claim filed
- Summary of allegations
- Status or outcome of the claim (e.g., in progress, settled, resolved)
- Summary of health center internal analysis and steps taken to mitigate the risk of such claims in the future. Health centers should only include this summary if the case is closed. Health centers also should not submit a copy of the NPDB report in this section.

Reminder: For each closed claim included in the claims history list, make sure you include a description of mitigating actions you have taken to prevent similar events or claims from occurring in the future. Such actions may include investigations and root cause analysis, credentialing and privileging actions, trainings, risk management/quality improvement projects or assessments, or policy and procedure development or revisions. Failure to do so may result in disapproval of the FTCA application. Dates and time frames for follow-up and resolution should also be included.

Do: Provide complete documentation for all claims from the past five years.

Do: Include summaries of closed cases with corrective actions taken to mitigate future risks.

Don't: Submit unrelated documents (e.g., NPDB reports or meeting minutes).

Don't: Include non-FTCA-related claims (e.g., workers' compensation claims).

Key Resources

- FTCA Health Center Policy Manual
- Claims Files Tracking Tool
- Resource Collection: Event Reporting
- Resource Collection: Event Response

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

What is it asking for?

This question asks the health center to confirm it will cooperate with all applicable federal government representatives in the defense of any FTCA claims.

What does it mean?

Patients and their attorneys cannot directly sue a deemed health center or covered individuals in state court. They are required to file the claim against the United States government, following specific procedures. However, health center malpractice claims often start out (erroneously) naming individuals and the health center as defendants in state court. The health center and covered individuals will not remain defendants for an FTCA-related malpractice claim—the federal government assumes responsibility.

At all stages in the claims process, including the administrative claims process (e.g., receipt of demand letter, court notice, or filing) and federal court process (e.g., subpoenas or requests for testimony in litigation), health centers and covered individuals must cooperate with and follow instructions from applicable federal government representatives.

Why is it important?

HHS OGC will advise the health center on actions and next steps during the administrative claims process. HHS OGC will determine whether the claim is covered by FTCA and will make the final determination on whether to settle or deny the claim.

If the claim is denied, the patient may file a lawsuit in federal court. At this point, the U.S. Department of Justice (DOJ) will take over to defend the case, and HHS OGC will transfer all files to DOJ.

It is important for the health center to cooperate with both HHS OGC and DOJ representatives in order to ensure that the agencies have the information they need to make determinations about the claim or case and that the process proceeds efficiently.

How do you answer the question?

For this question, select “yes” to verify that you will cooperate with all applicable federal government representatives in the defense of any FTCA claims. Even if your health center has not yet had a claim filed under FTCA, selecting “yes” verifies that you will cooperate for any future

claims. Select “no” if you will not cooperate with federal government representatives in the defense of any FTCA claims. If you select “no,” type an explanation in the comment box (limit of 2,000 characters) for why you will not cooperate.

Key Resources

- FTCA Health Center Policy Manual
- Checklist: Health Center Responsibilities when Responding to a State Court Lawsuit or Notice of Intent to File a Lawsuit

Claims Management Question 2(C).* I attest and agree that upon HHS OGC request, the health center will provide requested documentation, in a separate PDF or electronic file for each of the individual items outlined in Section K.1 (1-13) of the FTCA Health Center Policy Manual and will retain copies. I will keep all records until HHS OGC notifies the health center that an administrative claim or lawsuit has been finally resolved either by settlement, denial, or final judgment in litigation, including any post-judgment reconsideration request or appeal. I will use the method to transmit the records that HHS OGC requests, including a secure digital portal for electronic submission of the requested documents. I will ensure that the dates of the documents correspond to the dates of the incident.

What is it asking for?

This question asks the health center to confirm it will provide, upon HHS OGC request, all required documents listed in Section K.1 Required Documents for Premature Lawsuits and Claims Disposition of the FTCA Health Center Policy Manual.

What does it mean?

Upon HHS OGC request, the health center must provide to HHS OGC, as applicable, all required documents as outlined in Section K.1 Required Documents for Premature Lawsuits and Claims Disposition of the FTCA Health Center Policy Manual. These documents are used to verify FTCA claim eligibility.

Why is it important?

HHS OGC will advise the health center on actions and next steps during the administrative claims process. HHS OGC will determine whether the claim is covered by FTCA and will make the final determination on whether to settle or deny the claim.

If the claim is denied, the patient may file a lawsuit in federal court. At this point, the DOJ will take over to defend the case, and HHS OGC will transfer all files to DOJ.

It is important for the health center to cooperate with both HHS OGC and DOJ representatives in order to ensure that the agencies have the information they need to make determinations about the claim or case and that the process proceeds efficiently.

How do you answer the question?

For this question, select "yes" to verify that you will cooperate with all applicable federal government representatives in the defense of any FTCA claims. Even if your health center has not yet had a claim filed under FTCA, selecting "yes" verifies that you will cooperate for any future claims.

Select "no" if you will not cooperate with federal government representatives in the defense of any FTCA claims. If you select "no," type an explanation in the comment box (limit of 2,000 characters) for why you will not cooperate.

Key Resources

- FTCA Health Center Policy Manual
- Checklist: Health Center Responsibilities when Responding to a State Court Lawsuit or Notice of Intent to File a Lawsuit

3. Notice of Deemed Status

Claims Management Question 3(A)**. **I attest that my health center informs patients using plain language that it is a deemed Federal PHS employee via its website, promotional materials, and/or within an area(s) of the health center that is visible to patients. For example: "This health center receives HHS funding and has Federal 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."

What is it asking for?

This question asks the health center to confirm that it informs, in plain language, that it is a deemed Federal PHS employee in areas visible to patients.

What does it mean?

Health centers should take steps to inform patients and the public of their federal status by including language on public-facing websites, promotional materials provided to the public, or signs posted in an easily visible location in the health center. Some examples of potential language include the following options:

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.

This health center is a Health Center Program grantee under 42 U.S.C. 245b and a deemed PHS employee under 42 U.S.C. 233(g)-(n).

Health centers may also display the FSHCAA FTCA Deemed Status Badge, according to guidelines for use, on websites, nametags, promotional materials, brochures, signs, and posters to demonstrate deemed PHS employment status to the public and patients.
While displaying the badge is optional, HRSA strongly encourages display of the badge as the standard for showing deemed status.

Why is it important?

As noted above, health center malpractice claims often start out (erroneously) naming individuals and the health center as defendants in state court rather than filing the claim against the United States government. This may be because the claimant is unaware that the individuals and health center have FTCA coverage. Clearly notifying the public of the health center's deemed federal status will help ensure that claimants know to file medical malpractice claims against the United States government.

How do you answer the question?

If your health center informs patients of its deemed federal status in locations that are easily visible to patients, either by posting language with this information or including the FSHCAA FTCA Deemed Status Badge, select "yes" to answer this question.

If you select "no," follow the instructions under the **Important: Required Actions for Noncompliance in FTCA Application** section of this guide. Be sure to clearly state what aspects of this requirement are not in place (e.g., language is not included on the website, in promotional materials, or in the health center; language is included but is not visible to patients) and why.

Don't: Obscure language notifying the public of the health center's federal deeming status. Post in areas of the website that are easily visible. As a best practice, include the language on the main page of the website.

Claims Management Question 3(B)**. **Include a screenshot to the exact location where the information is posted on your health center website or attach the relevant promotional material or pictures.

What is it asking for?

This question asks the health center to include screenshot proof showing the where the Notice of Deemed Status has been posted.

How do you answer the question?

Before beginning to complete the application, you should have on hand a screenshot of the health center's website that shows the statement informing the public of the health center's deeming status or the FSHCAA FTCA Deemed Status Badge (including the webpage's URL and where it appears on the website), copies of promotional materials that include this statement or badge, and/or pictures of signs posted in the health center that include this statement or badge. For this question, follow the prompts to upload and attach all available screenshots, documents, or pictures to the application.

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

What is it asking for?

This question asks the health center to upload the comprehensive job description for the health center's claims manager.

What does it mean?

Health centers must designate an individual or multiple individuals to manage claims-related activities and serve as the claims point of contact. This person may be the risk manager, corporate compliance staff, QI/QA staff, finance personnel, or may hold another position. Whoever the health center designates as the claims coordinator and claims point of contact, the health center must ensure that the individual's job description includes roles and responsibilities related to claims management (see Get Safe: Roles and Responsibilities of the Claims Coordinator for a list of responsibilities).

Why is it important?

Health centers have various responsibilities related to claims management, including preservation of all documentation related to a claim, potential claim, or complaint; prompt submission of any service of process/summons to HHS OGC; communication and coordination with HHS OGC and DOJ; internal investigations of events or complaints that may lead to a claim; and mitigation actions (e.g., root cause analysis) in response to closed claims. Designating an individual(s) in the health center as responsible for these actions, and documenting these actions in that person's job description, is important for ensuring that all required claims management activities are carried out effectively and that all instructions from HHS OGC and DOJ are followed.

How do you answer the question?

Review the job description for the individual(s) designated as responsible for claims-related activities (e.g., risk manager) and ensure that roles and responsibilities for claims management are included. Make sure that roles and responsibilities are clearly stated in the job description; vague or missing responsibilities may result in the application being returned. You can review the roles and responsibilities outlined in Get Safe: Roles and Responsibilities of the Claims Coordinator as a comparison. Follow the prompts to upload and attach the job description to the application.

Key Resources

- Get Safe: Roles and Responsibilities of the Claims Coordinator

General Claims Management Do's and Don'ts

Claims Management Do's

Do: Refer to the FTCA Health Center Policy Manual (Section II: Claims and Lawsuits) and Chapter 21 of the Health Center Program Compliance Manual when creating, reviewing, or updating claims management operating procedures.

Do: As a best practice, include language clearly stating the health center's deemed status on the main page of the health center's website, or in another easily visible location. Ensure that screenshots, pictures, or other documents submitted show where this information is located (e.g., ensure screenshot captures URL of webpage).

Do: Double-check the claims management process/operating procedures, claims history list, job descriptions, and other documents before submitting to ensure all sections are complete and there are no errors.

Do: Ensure that claims management procedures include processes related to the prompt sending of any service of process/summons to the HHS General Law Division as well as preservation of health center records and documentation.

Claims Management Don'ts

Don't: Submit claims management procedures with missing components (see question 1(A) above).

Don't: Upload or include documents that are not claims management processes or claims management procedures (e.g., notice of intent for lawsuit).

Don't: Send non-FTCA-related claims history information (e.g., workers' compensation claims).

Don't: Submit sample claims management procedures or job descriptions. Ensure documents reflect your organization's current processes.

Don't: Upload position descriptions that do not include claims management responsibilities (e.g., risk manager job description that fails to include claims management responsibilities).

Appendix A: Summary of Resources

This Appendix includes a summary of resources included throughout the document.

ECRI Clinical Risk Management Program resources are available at no cost to all HRSA-funded health centers on behalf of HRSA. To activate your account and access the resources, please email Clinical_RM_Program@ecri.org.

General Resources

ECRI. ECRI Guidance on the FTCA Program for Health Center Providers and Staff: Information about the Federal Tort Claims Act and the Federally Supported Health Centers Assistance Act. https://members.ecri.org/assets/document/ecri-guidance-on-the-ftca-program-for-health-center-providers-and-staff-inf

HRSA Bureau of Primary Health Care. Federal Tort Claims Act Health Center Policy Manual. https://bphc.hrsa.gov/sites/default/files/bphc/compliance/ftcahc-policy-manual.pdf

HRSA Bureau of Primary Health Care. FTCA Policies and Program Guidance. https://bphc.hrsa.gov/initiatives/ftca/policies-program-guidance

HRSA Bureau of Primary Health Care. FTCA Technical Assistance Resources. https://bphc.hrsa.gov/initiatives/ftca/technical-assistance-resources

HRSA Bureau of Primary Health Care. Health Center Program Compliance Manual. https://bphc.hrsa.gov/compliance/compliance-manual

Review of Risk Management Systems

Key Resources

- ECRI. FTCA Application Demonstration of Compliance Tool: Risk Management Training Plan Edition.
  - https://members.ecri.org/assets/document/ftca-application-demonstration-of-compliance-tool-risk-management-training-
  - https://bphc.hrsa.gov/sites/default/files/bphc/initiatives/ftca-compliance-tool-risk-management-training-plan.pdf
- ECRI. FTCA Application Procedural Demonstration of Compliance Tool: Risk Management— Annual Report to Board Edition.
  - https://members.ecri.org/assets/document/ftca-application-procedural-demonstration-of-compliance-tool-risk-managemen
  - https://bphc.hrsa.gov/sites/default/files/bphc/compliance/ftca-compliance-tool-risk-management-annual-report.pdf

ECRI. Ambulatory Medical and Dental Risk Management Assessment Tool (assessment tool). https://members.ecri.org/assets/document/ambulatory-medical-and-dental-risk-management-assessment-tool

ECRI. Building an Effective Risk Management Program (webinar). https://members.ecri.org/event/building-an-effective-risk-management-program

ECRI. FTCA Application Procedural Demonstration of Compliance Tool: Risk Management—Annual Report to Board Edition. https://members.ecri.org/assets/document/ftca-application-procedural-demonstration-of-compliance-tool-risk-managemen

ECRI. Healthcare Risk Management Programs (assessment tool). https://members.ecri.org/selfassessment/healthcare-risk-management-programs

ECRI. Hiding in Plain Sight: Free Resources for Risk Management Training (webinar). https://members.ecri.org/event/hiding-in-plain-sight-free-resources-for-risk-management-training

ECRI Obstetrics Education. https://members.ecri.org/education/obstetrics-education

ECRI Learning Online Course Library. https://learning.ecri.org/

ECRI. Managing Risks in Ambulatory Care: Clinical Management (assessment tool).
https://members.ecri.org/selfassessment/managing-risks-in-ambulatory-care-clinical-management

ECRI. Managing Risks in Ambulatory Care: Human Resources (assessment tool).
https://members.ecri.org/selfassessment/managing-risks-in-ambulatory-care-human-resources

ECRI. Managing Risks in Ambulatory Care: Office Administration (assessment tool).
https://members.ecri.org/selfassessment/managing-risks-in-ambulatory-care-office-administration

ECRI. Patient Safety and Risk Management Plan Informational Flowchart.
https://members.ecri.org/assets/document/patient-safety-and-risk-management-plan-informational-flowchart-

ECRI. Patient Safety and Risk Management Plan Operational Checklist.
https://members.ecri.org/assets/document/patient-safety-and-risk-management-plan-operational-checklist

ECRI. Policy and Procedure Builder: Risk Management Training Plan.
https://members.ecri.org/assets/document/policy-and-procedure-builder-risk-management-training-plan

ECRI. Practice Alert: Conducting Risk Assessments: A Checklist.
https://members.ecri.org/selfassessment/practice-alert-conducting-risk-assessments-a-checklist

ECRI. Resource Collection: Behavioral Health.
https://members.ecri.org/guidance/behavioral-health-4818

ECRI. Resource Collection: Dental.
https://members.ecri.org/guidance/dental

ECRI. Resource Collection: Diagnosis: Test, Referral, and Hospitalization Tracking.
https://members.ecri.org/guidance/diagnosis-test-referral-and-hospitalization-tracking

ECRI. Resource Collection: Event Reporting.
https://members.ecri.org/guidance/event-reporting

ECRI. Resource Collection: Event Response.
https://members.ecri.org/guidance/event-response

ECRI. Resource Collection: Infection Control.
https://members.ecri.org/guidance/infection-control-dc2b

ECRI. Resource Collection: Laws, Regulations, and Compliance.

https://members.ecri.org/guidance/laws-regulations-and-compliance-42aa

ECRI. Resource Collection: Obstetric and Maternal Health and Safety. https://members.ecri.org/guidance/obstetric-and-maternal-health-and-safety-hrsa

ECRI. Resource Collection: Patient Complaints and Grievances. https://members.ecri.org/guidance/patient-complaints-and-grievances

ECRI. Resource Collection: Risk Management Fundamentals. https://members.ecri.org/guidance/risk-management-fundamentals-e28c

ECRI. Resource Collection: Risk Management Operations. https://members.ecri.org/guidance/risk-management-operations

ECRI. Resource Collection: Risk Management Training. https://members.ecri.org/guidance/risk-management-training

ECRI. Resource Collection: Special Clinical Considerations. https://members.ecri.org/guidance/special-clinical-considerations-hrsa

ECRI. Risk Management Manual for Health Centers. https://members.ecri.org/assets/document/risk-management-manual-for-health-centers

ECRI. Risk Management Report to Board: Sample Report and Dashboard. https://members.ecri.org/assets/document/risk-management-report-to-board-sample-report-and-dashboard

ECRI. Risk Management Training: Creating a Plan and Making It Work (webinar). https://members.ecri.org/event/risk-management-training-creating-a-plan-and-making-it-work

ECRI. Risk Management Training: Requirements, Resources, and Strategies (webinar). https://members.ecri.org/event/risk-management-training-requirements-resources-and-strategies

ECRI. Sample Diagnostic Test Tracking Procedure. https://members.ecri.org/assets/document/sample-diagnostic-test-tracking-procedure

ECRI. Sample Hospitalization and Emergency Department Visit Tracking Procedure. https://members.ecri.org/assets/document/sample-hospitalization-and-emergency-department-visit-tracking-procedure

ECRI. Sample Risk Management Dashboard. https://members.ecri.org/assets/document/sample-risk-management-dashboard

ECRI. Sample Risk Management Plan for a Community Health Center. https://members.ecri.org/assets/document/sample-risk-management-plan-for-a-community-health-center

ECRI. Sample Specialty Referral Tracking Procedure. https://members.ecri.org/assets/document/sample-specialty-referral-tracking-procedure

ECRI. The Many Hats of a Risk Manager: Preventing Harm and Improving Patient Safety (infographic). https://members.ecri.org/assets/document/the-many-hats-of-a-risk-manager-preventing-harm-and-improving-patient-safet

ECRI. Using Risk Assessments to Implement Positive Change (webinar). https://members.ecri.org/event/using-risk-assessments-to-implement-positive-change

Quality Improvement/Quality Assurance

ECRI. Continuous Quality Improvement: Learning from Events (webinar). https://members.ecri.org/event/continuous-quality-improvement-learning-from-events-

ECRI. EHR Vendor Checklist (assessment tool). https://members.ecri.org/selfassessment/ehr-vendor-checklist

ECRI. Electronic Health Records: Functionality (guidance article). https://members.ecri.org/guidance/electronic-health-records-functionality-

ECRI. Electronic Health Records: Operational Issues (guidance article). https://members.ecri.org/guidance/electronic-health-records-operational-issues

ECRI. Get Safe: A Brief Case for Safety: Managing Unintended Consequences of EHRs (assessment tool). https://members.ecri.org/selfassessment/get-safe-a-brief-case-for-safety-managing-unintended-consequences-of-ehrs

ECRI. Get Safe: A Brief Case for Safety: The HIPAA Privacy Rule in Clinical Practice (assessment tool). https://members.ecri.org/selfassessment/get-safe-a-brief-case-for-safety-the-hipaa-privacy-rule-in-clinical-practic

ECRI. HIPAA FAQs: Real-Life HIPAA Challenges in Primary Care (webinar). https://members.ecri.org/event/hipaa-faqs-real-life-hipaa-challenges-in-primary-care

ECRI. Resource Collection: Event Reporting. https://members.ecri.org/guidance/event-reporting

ECRI. Resource Collection: Event Response. https://members.ecri.org/guidance/event-response

ECRI. Resource Collection: Health Information Technology. https://members.ecri.org/guidance/health-information-technology

ECRI. Resource Collection: Medical Records and Documentation. https://members.ecri.org/guidance/medical-records-and-documentation

ECRI. Resource Collection: Laws, Regulations, and Compliance. https://members.ecri.org/guidance/laws-regulations-and-compliance-42aa

ECRI. Resource Collection: Patient Complaints and Grievances. https://members.ecri.org/guidance/patient-complaints-and-grievances

ECRI. Resource Collection: Quality Improvement/Quality Assurance.

https://members.ecri.org/guidance/quality-improvement-quality-assurance

ECRI. The HIPAA Privacy Rule (guidance article).
https://members.ecri.org/guidance/the-hipaa-privacy-rule-d0e6

ECRI. The HIPAA Security Rule (guidance article).
https://members.ecri.org/guidance/the-hipaa-security-rule-21c9

HRSA Bureau of Primary Health Care. Clinical Quality Improvement.
https://bphc.hrsa.gov/technical-assistance/clinical-quality-improvement

U.S. Department of Health and Human Services. Health Information Privacy.
https://www.hhs.gov/hipaa/index.html

Credentialing and Privileging

Key Resources

- ECRI. FTCA Application Procedural Demonstration of Compliance Tool: Credentialing and Privileging Edition.
  - https://members.ecri.org/assets/document/ftca-application-procedural-demonstration-of-compliance-tool-credentialing
  - https://bphc.hrsa.gov/sites/default/files/bphc/initiatives/ftca-compliance-tool-credentialing-privileging.pdf

Centers for Disease Control and Prevention. What Vaccines are Recommended for You – Healthcare Workers.
https://www.cdc.gov/vaccines-adults/recommended-vaccines/index.html#heading-h5zyqhhpjw

Centers for Disease Control and Prevention. Vaccination Laws.
https://www.cdc.gov/phlp/php/publications/vaccination-laws.html

ECRI. Ask ECRI: Health Attestation Forms for Providers Being Credentialed.
https://members.ecri.org/guidance/ask-ecri-health-attestation-forms-for-providers-being-credentialed

ECRI. Credentialing List.
https://members.ecri.org/assets/document/credentialing-list

ECRI. FTCA Application Procedural Demonstration of Compliance Tool: Credentialing and Privileging Edition.
https://members.ecri.org/assets/document/ftca-application-procedural-demonstration-of-compliance-tool-credentialing-

ECRI. Get Safe: Assessing Clinical Competence (assessment tool).
https://members.ecri.org/selfassessment/get-safe-assessing-clinical-competence

ECRI. Get Safe: Effective Processes for Granting Clinical Privileges (assessment tool).
https://members.ecri.org/selfassessment/get-safe-effective-processes-for-granting-clinical-privileges

ECRI. Get Safe: Fitness for Duty: Providing Safe Patient Care (assessment tool).
https://members.ecri.org/selfassessment/get-safe-fitness-for-duty-providing-safe-patient-care

ECRI. Guide for Preparing Credentialing Files.
https://members.ecri.org/assets/document/guide-for-preparing-credentialing-files

ECRI. Initial Credentialing Process (infographic).
https://members.ecri.org/assets/document/initial-credentialing-process

ECRI. Initial Privileging Process (infographic). https://members.ecri.org/assets/document/initial-privileging-process

ECRI. Renewal of Credentials and Privileges (infographic).
https://members.ecri.org/assets/document/renewal-of-credentials-and-privileges

ECRI. Resource Collection: Credentialing and Privileging.
https://members.ecri.org/guidance/credentialing-and-privileging

ECRI. Sample Credentialing and Privileging Policy.
https://members.ecri.org/assets/document/sample-credentialing-and-privileging-policy

ECRI. Sample Fitness-for-Duty Form.
https://members.ecri.org/assets/document/fitness-for-duty-form

U.S. Department of Health and Human Services. National Practitioner Data Bank.
https://www.npdb.hrsa.gov/index.jsp

Claims Management

ECRI. After an Event: Understanding the Claims Process (webinar).
https://members.ecri.org/event/after-an-event-understanding-the-claims-process-

ECRI. Checklist: Health Center Responsibilities when Responding to a State Court Lawsuit or Notice of Intent to File a Lawsuit.
https://members.ecri.org/assets/document/checklist-health-center-responsibilities-when-responding-to-a-state-court-l

ECRI. Claims Files Tracking Tool. https://members.ecri.org/assets/document/claims-files-tracking-tool

ECRI. Claims Management: You Have Been Sued, Now What? (webinar)
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