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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.

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 (FSCHAA) 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 <u>Health Resources and Services Administration (HRSA)</u>
<u>Bureau of Primary Health Care (BPHC) website</u> 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:

\triangle	Tips for documents and materials to have ready before beginning the application
\bigcirc	Important reminder
%	Key resources and tools
	Do: Practices that health centers should do when completing the application

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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.

Questions? Need help? Contact:

HRSA:

- For questions about FTCA deeming requirements or interpretations of requirements
- Submit questions to <u>Health Center</u> 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:

- For access to ECRI Clinical Risk Management Program resources (referred to throughout this document) provided on behalf of HRSA
- Email Clinical rm program@ecri.org
- Call (610) 825-6000 ext. 5200



ECRI Clinical Risk Management Program Resources

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



Summary of New and Modified Requirements: 2024

Review of Risk Management Systems

Question 3(A): Health centers attest that they have developed and implemented an annual health care risk management training plan based on identified areas/activities of highest clinical risk. The training plan, at minimum, incorporates obstetrics procedures if the health center provides 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

Question 3(B): Health centers attest that they have developed and implemented an annual health care risk management training plan based on identified areas/activities of highest clinical risk. The training plan, at minimum, incorporates **infection control and sterilization**.

Question 3(C): Health centers attest that they have developed and implemented an annual health care risk management training plan based on identified areas/activities of highest clinical risk. The training plan, at minimum, incorporates **HIPAA medical record confidentiality requirements**.

Question 3(D): Health centers attest that they have developed and implemented an annual health care risk management training plan based on identified areas/activities of highest clinical risk. The training plan, at minimum, incorporates specific trainings for groups of providers that perform services that may lead to potential risk (e.g., dental, pharmacy, family practice).

Question 3(E). The annual risk management training plan must cover the period from January 1 to December 31 of the previous calendar year of submission of the application.

Questions 3(F) to 3(I). Health centers will enter information on one completed training for each required topic: obstetrics, infection control, HIPAA, and areas of high-risk. Health centers will then download and use the provided FTCA Educational Training Tracking Form to document attendance and training completed for each staff member. All training must cover the period from January 1 to December 31 of the previous calendar year of submission of the application.



Summary of New and Modified Requirements: 2024 (cont.)

Review of Risk Management Systems

Question 4. Health centers will upload documentation that demonstrates the health center completed quarterly risk assessments and associated action plans for each quarter during the period of January 1 to December 31 of the previous calendar year of submission.

Question 5. Health centers will submit an annual report to the board that covers the period of January 1 to December 31 of the previous calendar year of submission and that is reflective of activities related to risk from the previous calendar year.

Question 7(A). Health centers will upload evidence that the risk manager has completed health care risk management training between January 1 and December 31 of the previous calendar year of submission.

Credentialing and Privileging

Question 2(A). As part of verification of privileging procedures, health centers must verify that policies and procedures that include temporary credentialing and/or privileging align with current guidelines in *Temporary Privileging of Clinical Providers by Federal Tort Claims Act (FTCA) Deemed Health Centers in Response to Certain Declared Emergency Situations - PAL 2017-07.*

Question 4. Health centers certify that they **renew the credentials and privileges** of all LIPs, OLCPs, and OCS **at least every two years**.

Credentialing and Privileging List. This question was moved to a stand-alone section of the application and health centers enter information for each practitioner directly into the system. Health centers attest they can provide proof of full credentialing and privileging upon request.

Claims Management

Question 2(C): Health centers attest and agree that upon HHS OGC request, they will provide requested documentation in separate PDF or electronic files for each of the individual items outlined in Section K.1 of the FTCA Health Center Policy Manual.

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 of the application, health centers will need to upload various policies, procedures, and documents that demonstrate compliance with risk management requirements (see "Prepare Documents" box)



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 xrays)
- 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 or checklists covering activities from January 1 to **December 31** of the previous year
- 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 the previous year

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and should take steps before beginning the application process to ensure these documents are complete and up-to-date.

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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.

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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.

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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," type an explanation in the comment box (limit of 2,000 characters), including which elements are missing from risk management program, why they are missing, and how the health center will address the missing elements.

At this time, you need to attest through the application that you have an ongoing risk management program in place; you do not need to upload your written plan or policy into the application.



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.



- 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.

How do you answer the question?

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

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in their application being denied. Select "yes" to answer and confirm acknowledgement 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 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

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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
- Hospitalization tracking
- Diagnostic tracking (must include tracking 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

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," type an explanation in the comment box (limit of 2,000 characters), including which procedures are missing or are deficient, why they are missing or deficient, and how the health center will address the missing or deficient elements.



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.

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How do you answer the question?

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 denied. Select "yes" to answer and confirm acknowledgement of this question.



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 does it mean?

Health centers must have policies and procedures for tracking referrals, diagnostic test results, and hospitalizations. 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 the following elements:

- 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 manner in which 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 <u>Health Center Program Compliance Manual Chapter 19:</u> Board Authority).

Hospitalization Tracking. Hospitalization tracking procedures should include the following elements:

- 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 entered the ED on their own. This system includes:
 - Patient information
 - Date of admission or visit

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- 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 <u>Health Center Program Compliance Manual Chapter 19:</u> <u>Board Authority</u>).

Diagnostic Tracking. Diagnostic tracking procedures should include the following elements:

- A tracking and monitoring system for all diagnostic orders that includes, at a minimum:
 - Patient information
 - o Date test was ordered
 - Ordering provider
 - List of tests ordered
 - Date results were received
 - Provider who reviewed the results
 - o 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)
 - o 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
- For abnormal test results:

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- Acceptable means of communication to provider and patient (e.g., verbal, electronic)
- o 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:
 - Acknowledgement 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 <u>Health Center Program Compliance Manual Chapter 19:</u> <u>Board Authority</u>).

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. 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: Make sure your hospitalization tracking procedures include a closed-loop process that comprehensively covers timelines for subsequent actions, frequency and kinds of correspondence, individuals responsible for every stage of the process, and documentation.



Do: Make sure your diagnostic tracking procedures include processes for tracking both laboratory and x-ray testing results, processes for addressing abnormal and critical tests, and types and frequency of communication regarding results.

Do: Make sure your referral tracking procedures include the following required elements: time frames for transmitting and receiving results, following up within appropriate time frames, demonstrating a closed-loop process, and documenting efforts to follow up with patients who miss referral appointments, including number and method of attempts (e.g., phone calls, certified letters with delivery confirmation).



Do: Make sure tracking policies and procedures have sufficient clarity and detail.

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Don't: Submit your general risk management plan or general risk management procedures (not covering referral, hospitalization, or diagnostic tracking) in place of attaching your referral, hospitalization, and diagnostic tracking procedures.



Don't: Submit hospitalization tracking procedures that do not include guidelines for follow-up after the patient's discharge.



Don't: Submit diagnostic tracking procedures that do not include a well-defined process for handling results, specific time frames for follow-up, and the number and types of follow-up attempts needed to ensure accurate and effective management.



Don't: Submit referral tracking, hospitalization tracking, and diagnostic tracking procedures without checking to make sure they are comprehensive and include necessary elements. Even if a health center uploads these three procedures into the application, your application may be returned or disapproved if these procedures are found to be deficient by HRSA.



Don't: Submit the same tracking policy for all three tracking policies. Each policy should address a specific aspect of the tracking and referral process, ensuring clarity and relevance to the corresponding area of focus.



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

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).

Please 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. This requirement applies to all health centers that are currently deemed as PHS employees, as well as those seeking deemed or redeemed status. All health centers 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, 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 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

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- 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 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, 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 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 inservice 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.

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Reminder for obstetrics training: Health centers must include obstetrics training as part of their annual risk management training plan, even if they do 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 staff member's role, responsibilities, and their level of contact with patients of reproductive age in determining the employee's specific training. Health centers should document the process used to determine how staff members are included or excluded from the OB training requirement. Health centers should also maintain a list of all employees required to complete OB training and monitor for timely training completion. For example, health centers may require that obstetricians and OB nurses complete electronic fetal monitoring training, that all providers and clinical staff complete training on prenatal and postpartum risks, and that all staff, including non-clinical staff, complete training on responding to obstetric emergencies in the medical office.



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

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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.

Health centers also play a crucial role in providing pre-conception, prenatal, obstetric, and postpartum care services. 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 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 your health center does not have a plan or any of the required elements are missing, select "no."

If you select "no," type an explanation in the comment box (limit of 2,000 characters), including which elements are missing from the annual risk management training plan, why they are missing, and how the health center will address the missing elements.



- Obstetrics Education
- Obstetrics: Safe, Equitable Care for All Women 3-Part Series
- Primary Care of the Postpartum Patient: A High-Risk Year
- Resource Collection: Maternal and Perinatal Health and Safety

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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 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 your health center does not have a plan or any of the

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required elements are missing, select "no." If you select "no," type an explanation in the comment box (limit of 2,000 characters), including which elements are missing from the annual risk management training plan, why they are missing, and how the health center will address the missing elements.

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 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.

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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," type an explanation in the comment box (limit of 2,000 characters), including which elements are missing from the annual risk management training plan, why they are missing, and how the health center will address the missing elements.



- 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

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that perform various services which may lead to potential risk (for example, dental, pharmacy, family practice).

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 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," type an explanation in the comment box (limit of 2,000 characters), including which elements are missing from the annual risk management training plan, why they are missing, and how the health center will address the missing elements.

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.

How do you answer the question?

Make sure that your annual risk management training plan **covers the period from January 1 to December 31** of the previous calendar year of submission of the application (for example, an application submitted in 2024 must be a complete training plan covering calendar year 2023 and only include courses completed during that 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 <u>Policy and Procedure Builder: Risk Management Training Plan</u> and <u>FTCA Application Demonstration of Compliance Tool: Risk Management Training Plan Edition</u> to compare with your current plan and fill in any necessary gaps.

Reminder: Transition Period: Your annual risk management training plan should cover trainings completed from January 1 to December 31 of the previous calendar year. However, for applications submitted in 2024, you may include an explanation for any issues related to the reporting period, and the explanations will be reviewed and considered by FTCA on

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a case-by-case basis. For applications submitted in 2025, all health centers should have fully transitioned to the new reporting period (**January 1 to December 31** of the previous calendar year).

Do: Include obstetric training for ALL clinical staff who see prenatal patients, postpartum patients, and patients who are of reproductive age. Determine obstetric training based on the type of care and interaction with patients and keep in mind that training may vary based on these factors.



Do: Ensure that the risk management training plan only **covers the period from January 1 to December 31** of the previous calendar year of submission of the application.



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).



Don't: Submit a risk management training plan that does not include all required trainings and don't overlook any essential components.



Don't: Submit other types of documents (e.g., training flyers, procedures unrelated to the risk management training plan) in place of the risk management training plan.



Don't: Submit training plans with trainings completed outside of the calendar year **January 1 to December 31** time frame.



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).

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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 2024 must demonstrate training was completed in 2023).

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.

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 cover the period from January 1 to December 31 of the previous calendar year of submission. (Example: An application submitted in 2024 must include trainings completed in 2023.) You may include a written explanation in the application for consideration by FTCA if your training dates do not meet this requirement. This is only for applications completed in 2024; for future years, there will be no exceptions.



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

On the Tracking Form, be sure to select **Obstetrical Training** from the dropdown 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

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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).



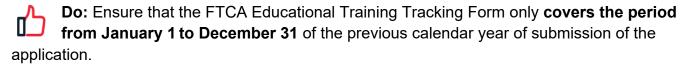
Do: When preparing your application, only use the FTCA Educational Training Tracking Form. All other tracking tools will be considered non-compliant.



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 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.





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

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example, applications submitted in 2024 must demonstrate training was completed in 2023).

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.

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 cover the period from January 1 to December 31 of the previous calendar year of submission. (Example: An application submitted in 2024 must include trainings completed in 2023.) You may include a written explanation in the application for consideration by FTCA if your training dates do not meet this requirement. This is only for applications completed in 2024; for future years, there will be no exceptions.



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

On the Tracking Form, be sure to select **Infection Control Training** from the dropdown 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.

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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 non-compliant.



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 to December 31** of the previous calendar year of submission of the application.



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 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 2024 must demonstrate training was completed in 2023).

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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.

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 cover the period from January 1 to December 31 of the previous calendar year of submission. (Example: An application submitted in 2024 must include trainings completed in 2023.) You may include a written explanation in the application for consideration by FTCA if your training dates do not meet this requirement. This is only for applications completed in 2024; for future years, there will be no exceptions.



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

On the Tracking Form, be sure to select **HIPAA Training** from the dropdown 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.

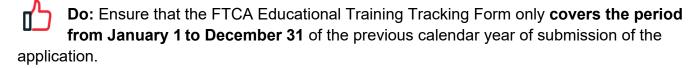
Select the "Attach File" button in the application to upload your HIPAA training tracking form(s) and follow the prompts for attaching the document(s).



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



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



Risk Management Question 3(I). 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 2024 must demonstrate training was completed in 2023).

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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.

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 cover the period from January 1 to December 31 of the previous calendar year of submission. (Example: An application submitted in 2024 must include trainings completed in 2023.) You may include a written explanation in the application for consideration by FTCA if your training dates do not meet this requirement. This is only for applications completed in 2024; for future years, there will be no exceptions.



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

On the Tracking Form, be sure to select **Specific areas of High-Risk Training** from the dropdown 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 non-compliant.



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 to December 31** of the previous calendar year of submission of the application.



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.



- FTCA Educational Training Tracking Form PDF
- ECRI Learning Online Education
- FTCA Demonstration of Compliance Tool: Risk Management Training Plan Edition
- Policy and Procedure Builder: Risk Management Training Plan
- Resource Collection: Risk Management Training
- Risk Management Training: Requirements, Resources, and Strategies

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

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the period from January 1st to December 31st of the previous calendar year of submission.

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. Risk assessments can include a variety of strategies, 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.

Health centers must conduct risk assessments at least quarterly. When conducting a risk assessment, health centers should 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.

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 quarter within the period from January 1 to December 31** of the previous calendar year of submission. 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, along with the action plan that was created as a result of analyzing the questionnaire's or checklist's findings.

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 non-clinical concerns (e.g., building security, parking lot safety, lighting functionality).

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Although these non-clinical 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 Key Resources listed below for guidance on conducting and documenting a risk assessment.

Reminder: Transition Period: Your risk assessments and action plans should demonstrate completion for each quarter within the period from January 1 to December 31 of the previous calendar year. However, for applications submitted in 2024, you may include an explanation for any issues related to the reporting period, and the explanations will be reviewed and considered by FTCA on a case-by-case basis. For applications submitted in 2025, all health centers should have fully transitioned to the new reporting period (January 1 to December 31 of the previous calendar year).



Do: Ensure that the risk assessments focus on areas that can potentially prevent or decrease the likelihood of medical malpractice claims. It is important to prioritize clinical areas when conducting risk assessments for your health center.



Do: Refer to available assessment tools, such as those noted in Key Resources below.



Do: Ensure that all relevant information is included in the quarterly risk assessment and include the corresponding action plan for each quarterly risk assessment.



Don't: Upload a blank risk assessment tool or action plan. The documents must show a completed risk assessment along with an action plan that corresponds to the appropriate quarter within the period from January 1 to December 31 of the previous calendar year of submission.



Don't: Upload or include documents (e.g., meeting minutes, policies, procedures) that do not demonstrate completion of an actual assessment focusing on a particular risk or safety area.



Don't: Submit a quarterly risk assessment that does not require significant improvements on at least a quarterly basis.



Don't: Submit a quarterly risk assessment that focuses on incidents unrelated to clinical patient care or patient safety. For example, do not submit risk assessments focused on

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building safety and security or other non-clinical issues. (While non-clinical concerns are still important for the health center's overall risk management program, they are not the primary focus of FTCA.)

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 (January 1st to December 31st). Any documents dated outside of this period will not be accepted. Please note that separate quarterly or monthly reports are not acceptable for this report, which must be a consolidated report covering the previous calendar year. 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

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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 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:

- Completed risk management activities (e.g., quarterly risk assessments, risk management projects)
- Status of the health center's progress related to established annual risk management goals. This may include data trends and analysis (e.g., sentinel events, adverse events, near misses, falls, wait times, patient satisfaction information, number of incidents, trainings completed, and other data points selected by the health center)
- Proposed risk management activities that cover the previous calendar year (January 1 to December 31) of submission for the next calendar year period that relate and/or respond to identified areas of high organizational risk.

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 an 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.

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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 to December 31 of the previous calendar year of submission, and that it is reflective of the activities related to risk from the previous calendar year (January 1 to December 31). 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, make sure that these reports are consolidated into an 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
Edition and Risk Management Report to the Board: Sample Report and Dashboard for a sample report and guidance.

Reminder: Transition Period: Your annual board report should cover the period from January 1 to December 31 of the previous calendar year. However, for applications submitted in 2024, you may include an explanation for any issues related to the reporting period, and the explanations will be reviewed and considered by FTCA on a case-by-case basis. For applications submitted in 2025, all health centers should have fully transitioned to the new reporting period (January 1 to December 31 of the previous calendar year).



Do: Submit a detailed report that encompasses all risk management activities, the health center's current performance related to pre-established risk management goals, and proposed risk management activities that address and/or respond to areas of high clinical organizational risk. Include detailed performance analysis (e.g., data and trends) that provide evidence of the health center's awareness and proactive management of risks.



Do: Make sure that the board report covers the 12-month period of the previous calendar year (January 1 to December 31).



Do: When submitting reports, avoid using copies of board minutes alone. Instead, provide a comprehensive annual report that encompasses all necessary information.



Do: Make sure the annual report focuses on areas of clinical risk/activities to prevent medical malpractice claims and does not only focus on non-clinical concerns such as building safety or maintenance.

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Don't: Upload monthly or quarterly board reports. The report must be consolidated into an annual report and **cover the period from January 1 to December 31 of the previous calendar year of submission**.



Don't: Use vague generalizations or leave activities incomplete. The scope of the risk management activities undertaken by the health center should be clear and complete.



- <u>FTCA Application Procedural Demonstration of Compliance Tool: Risk Management—</u>
 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.

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.

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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. Please note: The job description must clearly detail that the risk management activities are a part of the risk manager's daily responsibilities.

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

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

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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?

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 to December 31** of the previous calendar year of submission. Risk management training options are available <u>from ECRI</u> or from other organizations like the American Society for Healthcare Risk Management.

If your health center's risk manager has completed risk management training **between January 1 to December 31** of the previous calendar year of submission, select "yes" to answer this question. If your risk manager has not completed this training, select "no."

If you select "no," type an explanation in the comment box (limit of 2,000 characters) including why the health center's risk manager has not completed training and what the health center will do to address this.

Reminder: Transition Period: You must demonstrate that the health center's risk manager completed risk management training between January 1 to December 31 of the previous calendar year. However, for applications submitted in 2024, you may include an explanation for any issues related to the reporting period, and the explanations will be reviewed and considered by FTCA on a case-by-case basis. For applications submitted in 2025, all health centers should have fully transitioned to the new reporting period (January 1 to December 31 of the previous calendar year).

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

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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.

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 to December 31 of the previous calendar year of submission**. 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.

Risk Management Do's



Do: Refer to <u>Chapter 10</u> and <u>Chapter 21</u> of the Health Center Program Compliance Manual and the <u>most up-to-date Program</u> <u>Assistance Letter</u> 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. 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 make sure 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 to December 31 of the previous calendar year of submission).

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 boardapproved 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

- Delineation of Risk and Quality Functions
- 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;
- Patient satisfaction and patient grievance processes; and ii.

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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.

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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," type an explanation in the comment box (limit of 2,000 characters), including which elements are missing from the QI/QA plan or policy, why they are missing, and how the health center will address the missing elements.



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.



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:

- 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 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

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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," type an explanation in the comment box (limit of 2,000 characters), including which elements are missing from QI/QA plan or policy, why they are missing, and how the health center will address the missing elements.



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.



- 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 (see Sample Policies and Tools)

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2. Electronic Health Records



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

What does it mean?

Health centers must maintain a "retrievable health record" for each patient (e.g., a certified electronic health record that complies with applicable federal and state laws and requirements). Certified electronic health records 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," type an explanation in the comment box (limit of 4,000 characters) explaining what systems you use to maintain a retrievable health record for each patient. Ensure you include in the explanation how the retrievable record meets applicable federal and state requirements.

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 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.

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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," type an explanation in the comment box (limit of 2,000 characters), including which elements are missing from your privacy, security, and confidentiality policies, why they are missing, and how the health center will address the missing elements.



- 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.

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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 acknowledgement 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.

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 non-compliance 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



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.

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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.

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.



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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
- <u>Initial Credentialing Process</u> (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.

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.



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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.



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 <u>primary source</u>, 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
 - o Primary or other sources (e.g., photocopies of credentials) for OLCPs and OCS
- Completion of query through the National Practitioner Data Bank (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

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- 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 non-expired 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," type an explanation in the comment box (limit of 2,000 characters), including which elements are missing from credentialing operating procedures, why they are missing, and how the health center will address the missing elements.



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 non-clinical 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.



- <u>National Practitioner Data Bank</u> (including the <u>continuous query</u> 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.

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How do you answer the question?

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 denied. Select "yes" to answer and confirm acknowledgement 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).

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 2017-07. 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 2017-07 may be considered as non-compliant with FTCA credentialing and privileging requirements.

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

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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 <u>fitness for duty form</u> for all LIPs, OLCHPs, and other clinical staff 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 <u>Recommended Vaccines</u> for <u>Healthcare Workers</u>
 - 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."

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If you select "no," type an explanation in the comment box (limit of 2,000 characters), including which elements are missing from credentialing-operating procedures, why they are missing, and how the health center will address the missing elements.



Don't: Wait until the application submission period to review credentialing processes and operating procedures for necessary elements. Health centers should review policies and procedures on a regular basis and make updates as needed.



Don't: Refer to outdated Program Assistance Letters or Policy Information Notices when checking to ensure that credentialing and privileging processes include necessary elements.

Temporary Credentialing and Privileging in Certain Declared Emergency Situations. In cases of certain government-declared emergency or disaster situations (e.g., environmental disasters, civil disturbances, infectious disease outbreaks), or as determined on a case-by-case basis 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 outlining <u>Temporary Privileging of Clinical Providers by Federal Tort Claims Act (FTCA) Deemed Health Centers in Response to Certain Declared Emergency Situations</u> and ensure that any written policies and procedures related to temporary privileging meet the requirements outlined in the PAL.

Do: Review and align any temporary privileging clauses in the policies and procedures with guidance outlined in Temporary Privileging of Clinical Providers by Federal Tort Claims Act (FTCA) Deemed Health Centers in Response to Certain Declared Emergency Situations.



- 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)
- Sample Fitness for Duty Form
- <u>Temporary Privileging of Clinical Providers by Federal Tort Claims Act (FTCA) Deemed</u> Health Centers in Response to Certain Declared Emergency Situations (HRSA)
- Vaccination Laws (CDC)



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.

How do you answer the question?

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 denied. Select "yes" to answer and confirm acknowledgement 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. Please 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.

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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: Have a checklist of all credentialing and privileging elements that are required from the Health Center Program Compliance Manual. Cross check to ensure that your policies and operating procedures have all the required elements for LIPs, OLCPs, and OCS.



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



Don't: Submit credentialing and privileging operating procedures with missing components (listed in 1(A) and 2(A) above).



Don't: Upload or include documents other than the credentialing and privileging operating procedures (e.g., meeting minutes, 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.

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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," type an explanation in the comment box (limit of 2,000 characters), including why the credentialing files do not meet the requirements and how the health center will address the missing elements.

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 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 <u>Guide for Preparing Credentialing Files</u> 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.

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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," type an explanation in the comment box (limit of 2,000 characters), including why the credentialing files do not meet the requirements and how the health center will address the missing elements.



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:

- 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.

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What does it mean?

Health centers must ensure appropriate staffing and resources to provide <u>required primary</u> <u>services</u> (as defined in <u>Section 330(b)(1) of the Public Health Service Act</u>) and <u>approved</u> <u>additional services</u> 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 heath centers still need to approve and grant privileges.

If not, select "no" for this question and include an explanation in the comment box (limit of 2,000 characters).

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.

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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)
 - o 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



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 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.

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How do you answer the question?

For this question, health centers will input a list of all 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. 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. Any 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.



Do: Complete all fields in the structured, fillable list within the application and make sure the information is complete and accurate. Include all staff in the list—for example, if there are 90 providers, make sure the 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.

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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.

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," type an explanation in the comment box (limit of 2,000 characters), including what information is missing and how the health center will address the missing elements.



- Credentialing List
- Renewal of Credentials and Privileges

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: Make sure the credentialing and privileging process encompasses all staff members, including OLCPs and OCS.

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

Do: Make sure 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) without checking to make sure they reflect your current processes and adapting them to your organization.

Don't: Submit Credentialing Lists that are incomplete.

Don't: Submit policies and procedures that incorporate temporary privileging clauses that do not align with the guidance outlined in Temporary Privileging of Clinical Providers by Federal Tort Claims Act (FTCA) Deemed Health Centers in Response to Certain Declared 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 claimsrelated 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

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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 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 <u>Checklist: Health Center Responsibilities when Responding to a State</u> Court Lawsuit or Notice of Intent to File a Lawsuit to ensure all steps are completed.

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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," type an explanation in the comment box (limit of 2,000 characters), including which elements are missing from the claims management process, why they are missing, and how the health center will address the missing elements. 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
- Claims Filing: Health Centers (HRSA)
- Claims Management: You Have Been Sued, Now What? (webinar)
 - o Questions and Answers: Claims Management: You Have Been Sued, Now What?
- Sample Claims Management Policy and Procedure

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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.

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

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: Ensure that claims management procedures include processes for promptly sending any service of process/summons that the health center or its provider(s) receives to the HHS Office of General Law Division.



Do: Ensure that claims management procedures specify how the health center will maintain all records that are related to any actual or potential claim or complaint.



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

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Don't: Upload or include documents other than the written claims management process or claims management procedures (e.g., notice of intent for 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.)

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.

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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: Ensure that the health center produces comprehensive documentation and information addressing all claims indicated in the application. Review the list of claims before submitting to ensure the information is complete and correct.



Do: Ensure that the health center includes a summary of the internal analysis and clearly articulates the corrective steps taken or planned to mitigate the risk of claims in the future (only for closed cases; do not submit this information if the case has not been settled).



Don't: Submit a copy of the NPDB report or meeting minutes. Only a summary of analysis and mitigation steps that have been taken or will take place is needed.



Don't: Send information on 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 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)

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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.



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

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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 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 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.

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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
- <u>Checklist: Health Center Responsibilities when Responding to a State Court Lawsuit or Notice of Intent to File a Lawsuit</u>

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 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 Public Health Service employee under 42 U.S.C. 233(g)-(n).

Health centers may also display the <u>FSHCAA FTCA Deemed Status Badge</u>, according to <u>guidelines for use</u>, on websites, nametags, promotional materials, brochures, signs, and posters to demonstrate deemed Public Health Service 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.

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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 your health center does not do this, select "no." Then, type an explanation in the comment box (limit of 2,000 characters) that clearly says 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: Post language notifying the public of the health center's federal deeming status in areas of the website that are not 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.

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.

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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 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.



Get Safe: Roles and Responsibilities of the Claims Coordinator

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 other than the written claims management process or claims management procedures (e.g., notice of intent for lawsuit)

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

Don't: Submit sample claims management procedures or job descriptions without checking to make sure they reflect your current processes and adapting them to your organization.

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).

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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://www.ecri.org/components/HRSA/Documents/ECRI Guidance FTCA Health Center Providers Staff.pdf

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

ECRI. Ambulatory Medical and Dental Risk Management Assessment Tool (assessment tool). https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/AmbulatoryMedicalDentalRiskM anagementAssessmentTool.doc

ECRI. Building an Effective Risk Management Program (webinar). https://www.ecri.org/components/HRSA/Pages/HRSAWebinar 031517 RiskManagement.aspx

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

https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/508_FTCA_Compliance_tool_Risk_Management_Training_Plan.pdf

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ECRI. FTCA Application Procedural Demonstration of Compliance Tool: Risk Management—Annual Report to Board Edition.

https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/508 FTCA Compliance tool Risk Management Annual Report Board.docx

ECRI. Healthcare Risk Management Programs (assessment tool).

https://www.ecri.org/components/HRC/Pages/SAQ47.aspx

ECRI. Hiding in Plain Sight: Free Resources for Risk Management Training (webinar).

https://www.ecri.org/components/HRSA/Pages/HRSAWebinar 041321 Hiding.aspx

ECRI Obstetrics Education. https://www.ecri.org/components/HRSA/Pages/OBEducation.aspx

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

ECRI. Managing Risks in Ambulatory Care: Clinical Management (assessment tool).

https://www.ecri.org/components/HRSA/Pages/SAQ2 2.aspx

ECRI. Managing Risks in Ambulatory Care: Human Resources (assessment tool).

https://www.ecri.org/components/HRSA/Pages/SAQ2 1.aspx

ECRI. Managing Risks in Ambulatory Care: Office Administration (assessment tool).

https://www.ecri.org/components/HRSA/Pages/SAQ2.aspx

ECRI. Patient Safety and Risk Management Plan Informational Flowchart.

https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/PSRMPol51.pdf

ECRI. Patient Safety and Risk Management Plan Operational Checklist.

https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/PSRMPol54.doc

ECRI. Policy and Procedure Builder: Risk Management Training Plan.

https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/PolicyProcedure_RMTraining.docx

ECRI. Practice Alert: Conducting Risk Assessments: A Checklist.

https://www.ecri.org/components/HRSA/Pages/PracticeAlerts033018.aspx

ECRI. Resource Collection: Behavioral Health.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection BehavioralHealth.aspx

ECRI. Resource Collection: Dental.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection Dental.aspx

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ECRI. Resource Collection: Diagnosis: Test, Referral, and Hospitalization Tracking.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection_DiagnosisTestReferralandHospitalizationTracking.aspx

ECRI. Resource Collection: Event Reporting.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection EventReporting.aspx

ECRI. Resource Collection: Event Response.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection EventResponse.aspx

ECRI. Resource Collection: Infection Control.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection InfectionControl.aspx

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

https://www.ecri.org/components/HRSA/Pages/ResourceCollection_LawsRegulationsandCompliance.aspx

ECRI. Resource Collection: Maternal and Perinatal Health and Safety.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection MaternalandPerinatalHealthandSafety.aspx

ECRI. Resource Collection: Patient Complaints and Grievances.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection PatientComplaintsandGrievances.aspx

ECRI. Resource Collection: Risk Management Fundamentals.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection_RiskManagementFundament_als.aspx

ECRI. Resource Collection: Risk Management Operations.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection_RiskManagementOperations.aspx

ECRI. Resource Collection: Risk Management Training.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection RiskManagementTraining.as https://www.ecri.org/components/HRSA/Pages/ResourceCollection RiskManagementTraining.as

ECRI. Resource Collection: Special Clinical Considerations.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection SpecialClinicalConsideration s.aspx

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ECRI. Risk Management Manual for Health Centers.

https://www.ecri.org/components/HRSA/Documents/RiskManagementManual.pdf

ECRI. Risk Management Report to Board: Sample Report and Dashboard.

https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/RMSamplereportdashboard.pdf

ECRI. Risk Management Training: Creating a Plan and Making It Work (webinar).

https://www.ecri.org/components/HRSA/Pages/HRSAWebinar 091422 Risk-Management-Training.aspx

ECRI. Risk Management Training: Requirements, Resources, and Strategies (webinar).

https://www.ecri.org/components/HRSA/Pages/HRSAWebinar 041420 RMTraining.aspx

ECRI. Sample Diagnostic Test Tracking Procedure.

https://www.ecri.org/components/HRSA/Documents/SPT/508-Diagnostic-Test-Tracking-Policy-Procedure-Builder-Template.docx

ECRI. Sample Hospitalization and Emergency Department Visit Tracking Procedure.

https://www.ecri.org/components/HRSA/Documents/SPT/508 Hospitalization Tracking-Policy-Procedure-Builder-Template.docx

ECRI. Sample Risk Management Dashboard.

https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/PSRMPol48.xls

ECRI. Sample Risk Management Plan for a Community Health Center.

https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/PSRMPol10.doc

ECRI. Sample Specialty Referral Tracking Procedure.

https://www.ecri.org/components/HRSA/Documents/SPT/508-Referral-Test-Tracking-Policy-Procedure-Builder-Template.docx

ECRI. Staff Training Completion Tracking Tool.

https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/PSRMPol35.xls

ECRI. The Many Hats of a Risk Manager: Preventing Harm and Improving Patient Safety (infographic). https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/PSRMPol61.pdf

ECRI. Using Risk Assessments to Implement Positive Change (webinar).

https://www.ecri.org/components/HRSA/Pages/HRSAWebinar_091422_Using-Risk-Assessments.aspx

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Quality Improvement/Quality Assurance

ECRI. Continuous Quality Improvement: Learning from Events (webinar).

https://www.ecri.org/components/HRSA/Pages/HRSAWebinar 090816 ContinuousQualityImprovement.aspx

ECRI. Delineation of Risk and Quality Functions.

https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/PSRMPol53.pdf

ECRI. EHR Vendor Checklist (assessment tool).

https://www.ecri.org/components/HRSA/Pages/SAQ8.aspx

ECRI. Electronic Health Records: Functionality (guidance article).

https://www.ecri.org/components/HRSA/Pages/EHR2.aspx

ECRI. Electronic Health Records: Operational Issues (guidance article).

https://www.ecri.org/components/HRSA/Pages/EHR1.aspx

ECRI. Get Safe: A Brief Case for Safety: Managing Unintended Consequences of EHRs (assessment tool). https://www.ecri.org/components/HRSA/Pages/GetSafe 121319.aspx

ECRI. Get Safe: A Brief Case for Safety: The HIPAA Privacy Rule in Clinical Practice (assessment tool). https://www.ecri.org/components/HRSA/Pages/getsafe 113018.aspx

ECRI. HIPAA FAQs: Real-Life HIPAA Challenges in Primary Care (webinar).

https://www.ecri.org/components/HRSA/Pages/HRSAWebinar 121218 HIPAA.aspx

ECRI. Resource Collection: Event Reporting.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection EventReporting.aspx

ECRI. Resource Collection: Event Response.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection EventResponse.aspx

ECRI. Resource Collection: Health Information Technology.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection_HealthInformationTechnologvaspx

ECRI. Resource Collection: Medical Records and Documentation.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection_MedicalRecordsandDocumentation.aspx

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

https://www.ecri.org/components/HRSA/Pages/ResourceCollection_LawsRegulationsandCompliance.aspx

ECRI. Resource Collection: Patient Complaints and Grievances.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection PatientComplaintsandGrievances.aspx

ECRI. Resource Collection: Quality Improvement/Quality Assurance.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection QualityImprovementQualityAssurance.aspx

ECRI. The HIPAA Privacy Rule (guidance article).

https://www.ecri.org/components/HRSA/Pages/RS5.aspx

ECRI. The HIPAA Security Rule (guidance article).

https://www.ecri.org/components/HRSA/Pages/RS5 1.aspx

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

Centers for Disease Control and Prevention. Recommended Vaccines for Healthcare Workers.

https://www.cdc.gov/vaccines/adults/rec-vac/hcw.html

Centers for Disease Control and Prevention. Vaccination Laws.

https://www.cdc.gov/phlp/publications/topic/vaccinationlaws.html

ECRI. Ask ECRI: Health Attestation Forms for Providers Being Credentialed.

https://www.ecri.org/components/HRSA/Pages/AskECRI031517.aspx

ECRI. Credentialing List. https://www.ecri.org/components/HRSA/Documents/SPT/Credentialing-List.xls

ECRI. FTCA Application Procedural Demonstration of Compliance Tool: Credentialing and Privileging Edition.

https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/508 FTCA Compliance Tool C redentialing Privileging.pdf

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ECRI. Get Safe: Assessing Clinical Competence (assessment tool).

https://www.ecri.org/components/HRSA/Pages/GetSafe 123113.aspx

ECRI. Get Safe: Effective Processes for Granting Clinical Privileges (assessment tool).

https://www.ecri.org/components/HRSA/Pages/GetSafe 102612.aspx

ECRI. Get Safe: Fitness for Duty: Providing Safe Patient Care (assessment tool).

https://www.ecri.org/components/HRSA/Pages/GetSafe 042922.aspx

ECRI. Guide for Preparing Credentialing Files.

https://www.ecri.org/components/HRSA/Documents/SPT/HR/HRPol20.doc

ECRI. Initial Credentialing Process (infographic).

https://www.ecri.org/components/HRSA/Documents/SPT/HR/HRPol14.pdf

ECRI. Initial Privileging Process (infographic).

https://www.ecri.org/components/HRSA/Documents/SPT/HR/HRPol15.pdf

ECRI. Renewal of Credentials and Privileges (infographic).

https://www.ecri.org/components/HRSA/Documents/SPT/HR/HRPol16.pdf

ECRI. Resource Collection: Credentialing and Privileging.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection_CredentialingandPrivileging.aspx

ECRI. Sample Credentialing and Privileging Policy.

https://www.ecri.org/components/HRSA/Documents/SPT/HR/HRPol6.doc

ECRI. Sample Fitness-for-Duty Form.

https://www.ecri.org/components/HRSA/Documents/SPT/HR/HRPol19.doc

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://www.ecri.org/components/HRSA/Pages/AC AfterEventUnderstandClaimsProcess.aspx

ECRI. Checklist: Health Center Responsibilities when Responding to a State Court Lawsuit or Notice of Intent to File a Lawsuit.

https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/ChecklistHealthCenterResponsibilitiesRespondingStateCourtLawsuit.pdf

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ECRI. Claims Files Tracking Tool.

https://www.ecri.org/components/HRSA/Documents/SPT/LB/LBPol5.doc

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

https://www.ecri.org/components/HRSA/Pages/HRSAWebinar 091218 ClaimsManagement.aspx

ECRI. Get Safe: Roles and Responsibilities of the Claims Coordinator (assessment tool).

https://www.ecri.org/components/HRSA/Pages/GetSafe 110122.aspx

ECRI. Resource Collection: Claims Management.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection ClaimsManagement.aspx

ECRI. Resource Collection: Event Reporting.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection EventReporting.aspx

ECRI. Resource Collection: Event Response.

https://www.ecri.org/components/HRSA/Pages/ResourceCollection EventResponse.aspx

ECRI. Sample Claims Management Policy and Procedure.

https://www.ecri.org/components/HRSA/Documents/SPT/Sample-Claims-Management-Policy-Procedure.docx

ECRI. Tracking Process Tool for Claims Files.

https://www.ecri.org/components/HRSA/Documents/SPT/LB/LBPol6.doc

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

Appendix B: Sample Template Risk Management Training Plan: Demonstration of Compliance Tool

This sample compliance tool is intended as an example. Health centers should refer to <u>Chapter 21: Federal Tort Claims Act (FTCA) Deeming Requirements</u> for standards that must be met for health center risk management programs. Free clinics should refer to <u>Policy Information Notice (PIN) 2011-02: Free Clinics FTCA Program Policy Guide.</u>

Name of health center:
Location:
Contact name:
Contact phone and email:
Document Purpose
The risk management training plan supports the health center's philosophy that patient safety and risk management are everyone's responsibility. Risk management education and training are critical for clinical and nonclinical staff to improve safety and mitigate risk related to patient care. All staff are expected to be knowledgeable about and participate in risk management activities.
The purpose of this document is for health centers and free clinics to record and validate the components of their risk management training plan in order to meet Health Center Program requirements and best practices. Use this document to select which risk management training processes and procedures are used in your organization. Please select all options that apply to your health center and provide additional details in free text where prompted.
Oversight of Risk Management Training Plan
The following staff member is responsible for developing and carrying out the health center's risk management training plan:
Risk manager
Education manager
Executive director/chief executive officer (CEO)
Chief medical officer
Other—please specify:

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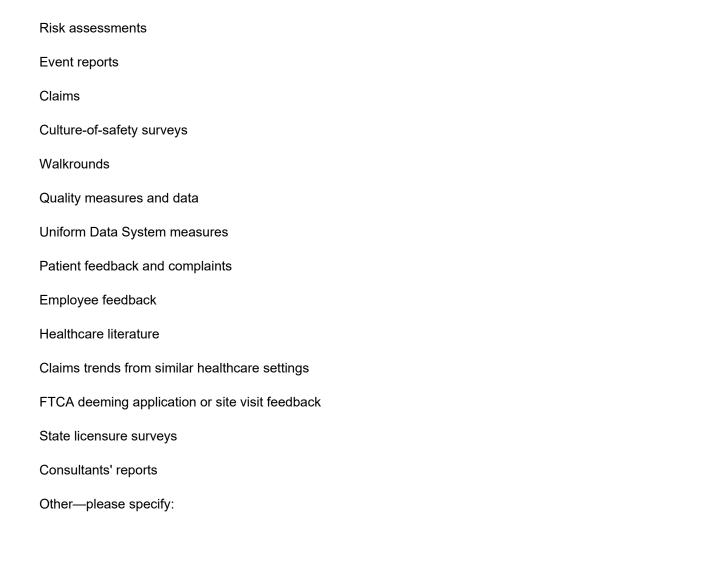
Please provide any other information about oversight of the risk management training plan (optional):
The governing board reviews and approves the risk management training plan.
Yes
No
If "no," please specify who reviews and approves the risk management training plan:
Time Frame
New employees: New employees receive risk management training within days of hire.
30
60
90
Other—please specify:
Existing employees: The health center sets the plan for ongoing risk management training on the following schedule:
Annually
Annually, but we may revise the training plan throughout the year based on new risks or priorities
Every six months
Every quarter
Other:

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If "Other" was selected, please provide information regarding the risk management plan time frame:

Training Topics

The risk manager identifies areas of risk within the context of the health center's risk management plan and selects risk management training topics. The following sources of information are used for determining training topics (select all that apply):



All Health Center Staff

The required trainings for all health center staff include the following topics based on <u>Chapter 21 of the Health Center</u> Program Compliance Manual:

Health Insurance Portability and Accountability Act (HIPAA) medical record confidentiality requirements

Infection control and sterilization

Other topics included in the annual risk management training plan for all health center staff include the following (not required):

Event reporting

Sexual harassment and misconduct in healthcare

Cultural sensitivity

Communication

Culture of safety

Teamwork strategies

Other—please specify:

Please provide any additional information about annual risk management training topics for all staff (optional):

Clinical Staff

The required trainings for staff serving in clinical roles include the following topics based on Center Program Compliance Manual:

Obstetrics training (including care for prenatal patients, postpartum patients, and patients who are of reproductive age)

Specific trainings for groups of providers that perform various services that may lead to potential risk (for example, dental, pharmacy, family practice)

Other topics included in the annual risk management training plan for staff serving in clinical roles include the following (not required):

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Tracking referrals	
Tracking diagnostic tests	
Tracking hospital admissions ordered by health center providers	
Other—please specify:	
Please provide any additional information about annual risk management training topics for clinical sta	aff (optional):
Managing and Monitoring Training	
Supervisors allocate time for staff to complete required trainings (not required):	
Yes	
No	
When possible	
If "no" or "when possible," please specify when staff complete trainings:	
The health center uses the following format for training programs (select all that apply) (not required):	
Instructor-led training	
Train-the-trainer programs	
Online training (e-learning)	
Webinar training	
Other—please specify:	
The health center tracks staff completion of training using the following method (select all that apply):	
The health center uses a centralized Excel file or Microsoft Word file to record and track training	
The health center uses a web-based program to record and track training	Dogo 00 -f 440
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The health center has a learning management system where staff completion of trainings is either automatically or manually uploaded
Employees are responsible for tracking their own training and signing an attestation to verify completion
Other—please specify:
Please provide any additional information about processes for tracking staff completion of training (optional):
The health center has processes to address cases in which providers or staff do not complete training by required deadlines.
Yes
No
Please provide any additional information regarding addressing cases in which providers or staff do not complete training by required deadlines (optional):
The health center sets metrics for staff training (100% completed trainings by December 31) and monitors progress toward meeting goals.
Yes
No
Please provide any additional information about metrics for staff training (optional):
The health center includes the following information in reports to the board (select all that apply):
List of required trainings by area or department
Metrics related to risk management training (e.g., percentage of courses completed)
Challenges identified related to the risk management training plan
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Information provided by ECRI is intended as guidance to be used consistent with the internal needs of your organization. This information is not to be viewed as required by ECRI or the Health Resources and Services Administration.

Other—please specify:
Please provide any additional information about reporting risk management training information to the board (optional):
Information provided by ECRI is intended as guidance to be used consistent with the internal needs of your organization. This information is not to be viewed as required by ECRI or the Health Resources and Services Administration.

Plans for changes to the risk management training plan, when applicable

Appendix C: Sample Template: Risk Management Report to the Board: Guide for Report Preparation

This sample guide is intended as an example. Health centers should refer to <u>Chapter 21: Federal Tort Claims Act</u> (FTCA) <u>Deeming Requirements</u> and <u>Chapter 10: Quality Improvement/Assurance</u> in the <u>Health Center Program</u> <u>Compliance Manual</u> for standards that must be met in order to meet FTCA deeming requirements related to risk management.

Introduction

Each health center has external regulations regarding how to conduct board functions. Such rules and requirements are likely a combination of FTCA, federal, state, accreditation, and legal requirements.

The health center establishes internal rules and processes regarding how the center's board conducts business, the format for written reports such as dashboards and/or narrative reports, processes for submitting reports, and the schedule of reports during the calendar year.

The following is a comprehensive selection of information that can be customized for your health center's written risk management report to the board. Choose the information that applies to your organization when developing the report format. Revise the sample language to meet your organization's needs. See also Risk Management Report to Board: Sample Report and Dashboard for a template that can be used when developing the report.

Report Objectives

[Provide a statement about the report. Note that health centers may set their own schedule for providing reports on risk management activities throughout the year, with the annual report a summary of activities for the entire year.]

Sample Text

To complete an annual report as directed by the governing board and key management staff that addresses the risk management program activities, goals, assessments, trainings, incidents, and procedures. Quarterly reports are provided throughout the year, and the annual report summarizes risk management activities for the entire year.

To evaluate, demonstrate, and validate that the [name of 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-related litigation. This program requires the following:

- Risk management across the full range of health center activities
- Healthcare risk management training
- Completion of quarterly risk management assessments
- 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 identified areas of high organizational risk

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Purpose of the Report

[Describe the reason for the report.]

Sample Text

- To establish an effective system for staff to communicate to the board about the risk management program
 and progress for improvement and for the board to communicate with staff about key expectations and
 recommendations
- To provide the board with pertinent information so that they can perform their duty for oversight of risk management
- To inform the board members about current risk assessments and established risk mitigation strategies
- To evaluate the effectiveness of the risk management plan and to identify risks; how risk management tasks are completed; and resource consumption for risk management
- To ensure all staff are adequately trained, at least annually, on [name of health center's] identified areas of risk and strategies for risk reduction
- To support regulatory/accreditation compliance and meet requirements for deeming under FTCA

Board Report Submission Documentation

[Provide the following information for each report to the board.]

Sample Text

Title: (Quarterly, Semi-annual, or Annual) Risk Management Report to the Health Center Board

Date: (Time period that covers events, assessments, etc.; should be from January 1 to December 31 of previous calendar year)

Submitted by: (Risk manager, CEO)

Reviewed/approved by: (Medical director, COO)

Date submitted to the board: (Meeting date when discussion regarding the report is on the agenda)

Date recorded in the board minutes: (Meeting date when the report was reviewed and discussed)

Report Structure

[Refer to (name of health center's) board procedures for the preferred report format. Sample formats are described below.]

- A narrative report includes descriptions that explain the risk management activities and progress toward goals.
- A dashboard is a visual tool for monitoring health center performance that provides a snapshot of what the board needs to know to fulfill its oversight responsibilities. Board members can see which activities are on track and which activities are not.
- A graphic display involves data displayed with self-explanatory, easy-to-interpret quality tools, such as graphs, charts, and tables.

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 A risk management story may highlight a good catch or an identified gap and make a dashboard and spreadsheet more impactful.

Opening Statement

[Include a brief summary that describes activities for the stated report period. Potential content is listed below.]

- Quantified and identified risks and priorities
- · Critical issues and emerging concerns
- Key points

Report Contents

[Report the required level of detail to meet regulatory and board requirements. Content may vary based on committee structure and job assignments.]

- Risk management training: annual and identified risk
- · Risk management activities
- Quarterly risk management assessments
- Identification and mitigation of areas/activities of highest risk
- Monitoring of known areas of high risk: infection control, sterilization, obstetrics, test and referral tracking,
 Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules
- Monitoring of risks for specific service groups: dental, pharmacy, laboratory
- Analysis of and response to complaints, adverse events, unsafe conditions, and near misses
- · Identification of trends
- Risk mitigation strategies and policy and procedure improvements
- Performance toward established risk management goals
- Lessons learned from risk management activities
- Review of claims and lawsuits
- Collaborative efforts with quality improvement, peer review, and regulatory compliance
- Annual risk management goals and tracking progress toward those goals

Types of Risk Areas and Activities

- Triage
- Scheduling
- Wait times
- Adverse test results
- Adherence to evidence-based clinical guidelines
- Clinical protocols
- Falls
- Medical staff supervision
- Tracking referrals, hospitalizations, and diagnostics
- Medical record confidentiality
- HIPAA
- Obstetrics, including electronic fetal monitoring and shoulder dystocia drills
- Infection control, including sterilization, hand hygiene, and protections for bloodborne pathogens
- · Credentialing and privileging

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- Quarterly risk assessments
- Establishment of risk management goals
- Complaints and grievances
- Patient satisfaction
- Patient safety, including processes for responding to adverse events, near misses, and unsafe conditions
- Claims summary
- Provider-specific risks: dental, pharmacy, laboratory

Appendices to the Report

[Attach relevant policies and procedures, plans, and documents as directed by the board report format.]

- Risk management plan
- · Risk management staff training plan and attendance at staff trainings
- Claims files report
- Risk assessment topics and calendar
- Related policies, documents, and forms

Report Conclusion

[Include one or two sentences to conclude the report.]

Sample Text

In conclusion, this report is respectfully submitted to the governing board of [name of health center] to demonstrate the ongoing risk management program to reduce the risk of adverse outcomes and provide safe, efficient, and effective care and services.

ECRI Resources

- Ambulatory Care Risk Management and Patient Safety Training Program
- Developing a Risk Management Training Program
- Resource Collection: Credentialing and Privileging
- Obstetrics Education
- Sample Risk Management Plan for a Community Health Center
- Staff Training Completion Tracking Tool
- Claims Files Tracking Tool
- Quality Measure Sources

External Resources

- A Nonprofit Dashboard and Signal Light for Boards
- Displaying the Data in a Health Care Quality Report

References

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[List all references applicable to this policy, including any relevant federal and state laws and regulations and accreditation standards.]

Bureau of Primary Health Care. Health center program site visit protocol: Federal Tort Claims Act (FTCA) deeming requirements. Updated 2020 Feb 27 [cited 2020 Mar 31].

Bureau of Primary Health Care. Health center program compliance manual: chapters 10 and 21: Federal Tort Claims Act (FTCA) deeming requirements. Reviewed 2018 Jan [cited 2020 Mar 31]. https://bphc.hrsa.gov/programrequirements/compliancemanual/chapter-21.html

This model plan is intended as guidance to be adapted consistent with the internal needs of your organization. This plan is not to be viewed as required by ECRI or the Health Resources and Services Administration.

All policies, procedures, and forms reprinted are intended not as models, but rather as samples submitted by ECRI member and nonmember institutions for illustration purposes only. ECRI is not responsible for the content of any reprinted materials. Healthcare laws, standards, and requirements change at a rapid pace, and thus, the sample policies may not meet current requirements. ECRI urges all members to consult with their legal counsel regarding the adequacy of policies, procedures, and forms.

Appendix D: Sample Template: Credentialing and Privileging: Procedural Demonstration of Compliance Tool

This sample procedures document is intended as an example. Health centers should refer to <u>Chapter 5: Clinical Staffing</u> in the <u>Health Center Program Compliance Manual</u> for standards that must be met in order to meet Federal Tort Claims Act (FTCA) deeming requirements related to credentialing and privileging. Free clinics should refer to <u>Policy Information Notice (PIN) 2011-02: Free Clinics FTCA Program Policy Guide.</u>

name of nealth center:
Location:
Contact name:
Contact phone and email:
Document Purpose
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. Privileging nvolves authorizing the specific scope and content of patient care services that a professional may provide. These processes help ensure that professionals have the education, knowledge, and competence to provide safe patient care and that the health center maintains compliance with Health Center Program and FTCA Program requirements.
The purpose of this document is for health centers and free clinics to record and validate the steps in the credentialing and privileging process in order to meet Health Center Program requirements and best practices. Use this document to select which credentialing and privileging processes and procedures are used in your organization. Please select all options that apply to your health center and provide additional details in free text where prompted.
Staffing Types
The health center utilizes the following staff types (select all that apply):
☐ Licensed independent practitioners (LIPs) (e.g., physician, dentist, nurse practitioner, nurse-midwife, physician assistant)
☐ Other licensed or certified practitioners (OLCPs) (e.g., registered nurse, licensed practical nurse, social worker, certified medical assistant, dental hygienist)
☐ Other clinical staff providing services on behalf of the health center (e.g., medical assistants or community health workers in states, territories, and jurisdictions that do not require licensure or certification) Page 104 of 11
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Please provide any other information about staffing types (optional):

Time Frame

Initial credentialing. The health center conducts initial credentialing and privileging prior to the provider beginning work in the health center.

Renewal of credentials and privileges. Credentials and privileges are renewed on the following time frame:		
□ Every year		
□ Every two years		
☐ Other—please specify: If "Other" was selected, please provide detailed information regarding the organization's renewal time frame:		
Renewal is initiated at least prior to the expiration of current credentials and privileges.		
□ 30 days		
□ 60 days		
□ 90 days		
☐ Other—please specify: Credentials that expire prior to the next renewal date are verified prior to expiration.		
□Yes		
☐ No Please provide any other information about the renewal process (optional):		

Credentialing

Licensed Independent Practitioners

The required verifications for LIPs include the following information based on <u>Chapter 5 of the Health Center</u> <u>Program Compliance Manual.</u>

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Current licensure, registration, and certification are verified using primary sources. The health center uses the	
following verification processes (select all that apply):	
$\hfill\square$ The health center confirms through a state database that a provider's licensure, registration, and certifications are current.	
\Box The health center directly corresponds (e.g., telephone, email) with the licensing or certifying body to confirm credentials.	
☐ The health center verifies using the American Medical Association (AMA), American Osteopathic Association (AOA), or Educational Commission for Foreign Medical Graduates (ECFMG) profile (for physicians).	
☐ The health center verifies using the American Nurses Credentialing Center (ANCC), American Midwifery Certification Board (AMCB), or National Commission on Certification of Physician Assistants (NCCPA) (for nonphysician LIPs).	
\square The health center uses a credentials verification organization for primary source verification.	
☐ The health center uses another method of source verification. If another method of source verification is used, please specify below:	
Education and training are verified using primary sources. The health center uses the following verification processes (select all that apply):	
$\hfill\square$ The health center confirms a provider's education and training credentials through a state or local database.	
\Box The health center directly corresponds (e.g., telephone, email) with the educational institution to confirm credentials.	
☐ The health center verifies using the AMA, AOA, or ECFMG profile (for physicians).	
☐ The health center verifies using the ANCC, AMCB, or NCCPA (for nonphysician LIPs).	
☐ The health center uses a credentials verification organization for primary source verification.	
☐ The health center uses another method of source verification. If another method of source verification is used, please specify below:	
National Practitioner Data Bank (NPDB). The health center queries the NPDB using the following method:	
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	☐ The health center conducts a continuous query for each provider who is hired. As new information is reported, it is placed in the provider's file and reported to the appropriate health center officers. All reports are reviewed at renewal of credentials and privileges.
	\Box The health center performs an individual query for each provider at initial appointment and at renewal of credentials and privileges.
If anoth	☐ The health center uses another method. ner method of NPDB query is used, please specify below:
Clinica	Il staff member identity is verified by the following process:
	\Box The health center receives a copy of the provider's government-issued picture identification (e.g., driver's license, passport).
If anoth	☐ The health center uses another method. ner method of identity verification is used, please specify below:
Drug E	inforcement Administration (DEA) registration is verified by the following process:
	☐ The health center receives a photocopy of the provider's DEA certificate.
	\square The health center views the original DEA certificate and documents verification in the credentials file.
	\square The health center directly corresponds (e.g., telephone, email) with the DEA to confirm registration.
	☐ The health center verifies using the AMA, AOA, or ECFMG profile (for physicians).
	☐ The health center verifies using the ANCC, AMCB, or NCCPA (for nonphysician LIPs).
If anoth	☐ The health center uses another method. ner method of DEA registration verification is used, please specify below:
Basic I	Life Support (BLS) training is verified by the following process:
	☐ The health center receives a photocopy of the provider's BLS training certificate.
	\square The health center views the original BLS training certificate and documents verification in the credentials file.
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☐ The health center checks with the American Heart Association or other professional training program to confirm completed training.
☐ The health center uses another method. If another method of BLS training verification is used, please specify below:
Other Licensed or Certified Practitioners
The required verifications for OLCPs include the following information based on Chapter 5 of the Health Center Program Compliance Manual.
Current licensure, registration, and certification are verified using primary sources. The health center uses the following verification processes (select all that apply):
\Box The health center confirms through a state database that a provider's licensure, registration, and certifications are current.
\Box The health center directly corresponds (e.g., telephone email) with the licensing or certifying body to confirm credentials.
☐ The health center verifies using the ANCC, AMCB, or NCCPA.
☐ The health center uses a credentials verification organization for primary source verification.
☐ The health center uses another method of source verification. If another method of source verification is used, please specify below:
Education and training are verified using primary or other sources. The health center uses the following verification processes (select all that apply):
\Box The health center confirms a provider's education and training credentials through a state or local database.
\Box The health center directly corresponds (e.g., telephone, email) with the educational institution to confirm credentials.
☐ The health center verifies using the ANCC, AMCB, or NCCPA.
☐ The health center uses a credentials verification organization for source verification.
☐ The health center receives photocopies of diplomas and/or other applicable education/training confirmation.
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☐ The health center uses another method of source verification. If another method of source verification is used, please specify below:		
National Practitioner Data Bank (NPDB): The health center queries the NPDB using the following method:		
☐ The health center conducts a continuous query for each provider who is hired. As new information is reported, it is placed in the provider's file and reported to the appropriate health center officers. All reports are reviewed at renewal of credentials and privileges.		
\Box The health center performs an individual query for each provider at initial appointment and at renewal of credentials and privileges.		
☐ The health center uses another method. If another method of NPDB query is used, please specify below:		
Clinical staff member identity is verified by the following process:		
\Box The health center receives a copy of the provider's government-issued picture identification (e.g., driver's license, passport).		
☐ The health center uses another method. If another method of identity verification is used, please specify below:		
Basic Life Support (BLS) training is verified by the following process:		
☐ The health center receives a photocopy of the provider's BLS training certificate.		
\Box The health center views the original BLS training certificate and documents verification in the credentials file.		
\Box The health center checks with the American Heart Association or other professional training program to confirm completed training.		
☐ The health center uses another method. If another method of BLS training verification is used, please specify below:		

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Other Clinical Staff

The required verifications for other clinical staff include the following information based on <u>Chapter 5 of the Health</u> <u>Center Program Compliance Manual</u>.

Education	on and training are verified using primary or other sources. The health center uses the following verification
processe	es (select all that apply):
	☐ The health center confirms a provider's education and training credentials through an online database.
	☐ The health center directly corresponds (e.g., telephone, email) with the educational institution to confirm credentials.
	☐ The health center uses a credentials verification organization for source verification.
	☐ The health center receives photocopies of diplomas and/or other applicable education/training confirmation.
	□ The health center uses another method of source verification. r method of source verification is used, please specify below:
	Practitioner Data Bank (NPDB): The health center queries the NPDB using the following method:
r	☐ The health center conducts a continuous query for each provider who is hired. As new information is reported, it is placed in the provider's file and reported to the appropriate health center officers. All reports are reviewed at renewal of credentials and privileges.
	☐ The health center performs an individual query for each provider at initial appointment and at renewal of credentials and privileges.
	□ The health center uses another method. r method of NPDB query is used, please specify below:
Clinical	staff member identity is verified by the following process:
	☐ The health center receives a copy of the provider's government-issued picture identification (e.g., driver's icense, passport).
	□ The health center uses another method. r method of identity verification is used, please specify below:

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Basic Life Support (BLS) training is verified by the following process:		
	☐ The health center receives a photocopy of the provider's BLS training certificate.	
	\Box The health center views the original BLS training certificate and documents verification in the credentials file.	
	\Box The health center checks with the American Heart Association or other professional training program to confirm completed training.	
lf anoth	☐ The health center uses another method. ner method of BLS training verification is used, please specify below:	
Othe	r Verifications	
Verifica	ation of the following information is recommended for completeness, but not required.	
Please	indicate which verifications below are conducted in the health center.	
	□ Criminal background checks	
	□ Curriculum vitae	
	☐ Current health insurance participation	
	☐ Office of Inspector General exclusion query	
	☐ Claims history (e.g., summary of professional liability claims and lawsuits over the past 10 years)	
	□ Controlled Dangerous Substances registration (as applicable)	
	□ Advanced Cardiovascular Life Support training (as applicable)	
	□ Advanced Trauma Life Support training (as applicable)	
	□ Pediatric Advanced Life Support training (as applicable)	
	□ Neonatal Resuscitation Life Support training (as applicable)	
	□ Professional references	
	☐ Affiliation attestation	
	□ Collaborative practice agreement	
	☐ Hospital admitting privileges (e.g., provider employment contracts from hospitals as applicable)	

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Please provide any additional information about the verifications noted above (optional):
If any other verifications are conducted, please indicate:
Privileging
Licensed Independent Practitioners
The required verifications for initial privileging include the following information based on Center Program Compliance Manual .
Fitness for duty is verified using the following process:
☐ The health center receives a completed statement or attestation of fitness for duty from the provider that is confirmed by either 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.
☐ The health center uses another method. If another method of confirming fitness for duty is used, please specify below:
Immunizations and communicable disease status: The health center verifies the following immunizations and communicable disease status (make sure to follow state recommendations and standards and check the Centers for Disease Control and Prevention's Recommended Vaccines for Healthcare Workers):
☐ Recent tuberculin skin test (PPD; purified protein derivative) results
□ Hepatitis B
□ Influenza (flu)
☐ MMR (measles, mumps, and rubella)
□ Varicella (chicken pox)
☐ Tdap (tetanus, diphtheria, pertussis)
□ Meningococcal
☐ Other—please specify:
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Immunizations and communicable disease status are confirmed using the following process:
\Box The health center receives a photocopy of immunization records and communicable disease screenings.
☐ The health center receives a completed statement or attestation from the provider.
☐ The health center uses another method. If another method of confirming immunizations and communicable disease status is used, please specify:
Current clinical competence is verified using the following process for initial privileging (select all that apply):
\Box The health center receives certificates of completion from the provider verifying completion of applicable education and training.
\Box The health center receives a list of supervisor and peer references from the provider and corresponds wit those references for verification.
☐ The health center uses another method. If another method is used for verifying current clinical competence for initial privileging, please specify:
For renewal of privileges, current clinical competence is verified using the following process (select all that apply):
\Box The health center evaluates the provider's peer review records over a specified time frame (e.g., two years).
\Box The health center evaluates supervisory performance reviews over a specified time frame (e.g., two years).
$\hfill\square$ The health center conducts direct observation of the provider during clinical practice and documents results.
☐ The health center uses another method.
If another method is used for verifying current clinical competence for renewal of privileges, please specify:

Other Licensed or Certified Practitioners and Other Clinical Staff

The required verifications for initial privileging include the following information based on <u>Chapter 5 of the Health</u> <u>Center Program Compliance Manual</u>.

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Fitness for duty is verified using the following process:
☐ The health center receives a completed statement or attestation of fitness for duty from the provider that is confirmed by either 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.
☐ The health center uses another method.
If another method of confirming fitness for duty is used, please specify below:
Immunizations and communicable disease status: The health center verifies the following immunizations and
communicable disease status (make sure to follow <u>state recommendations and standards</u> and check the <u>Centers for</u>
Disease Control and Prevention's Recommended Vaccines for Healthcare Workers):
☐ Recent tuberculin skin test (PPD; purified protein derivative) results
☐ Hepatitis B
□ Influenza (flu)
☐ MMR (measles, mumps, and rubella)
□ Varicella (chicken pox)
☐ Tdap (tetanus, diphtheria, pertussis)
☐ Meningococcal
☐ Other—please specify: Immunizations and communicable disease status are confirmed using the following process:
☐ The health center receives a photocopy of immunization records and communicable disease screenings.
☐ The health center receives a completed statement or attestation from the provider.
☐ The health center uses another method. If another method of confirming immunizations and communicable disease status is used, please specify:
Current clinical competence is verified using the following process for initial privileging (select all that apply):
☐ The health center receives certificates of completion from the provider verifying completion of applicable education and training.

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☐ The health center receives a list of supervisor and peer references from the provider and corresponds with those references for verification.
☐ The health center uses another method. If another method is used for verifying current clinical competence for initial privileging, please specify:
For renewal of privileges, current clinical competence is verified using the following process (select all that apply):
\Box The health center evaluates the provider's peer review records over a specified time frame (e.g., two years).
$\hfill\Box$ The health center evaluates supervisory performance reviews over a specified time frame (e.g., two years).
$\hfill\Box$ The health center conducts direct observation of the provider during clinical practice and documents results.
☐ The health center uses another method. If another method is used for verifying current clinical competence for renewal of privileges, please specify:
Approval, Modification, or Denial of Privileges
Approval authority for credentialing and privileging clinical staff is the responsibility of
☐ The health center board of directors
☐ An individual or entity designated by the board. Please specify:
☐ Other—please specify: Please describe the health center's process for approval of credentials and privileges:
The health center has an appeals process in conjunction with credentialing and privileging determinations (not required):
□Yes
□ No
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If an appeals process is used, please specify:
The health center implements corrective action plans in conjunction with the denial, modification, or removal of privileges (not required):
□Yes
□ No If a corrective action plan is used, please specify:
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