

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

Sample Report

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

Credentialing

Authority- 42 U.S.C 233(h)(2); Health Center Compliance Manual; PAL 2018-01 pg.19-21

FTCA Program Requirements	Sample Compliance Actions <i>[Actions required to come into compliance]</i>
<p>CP. 1 The health center has operating procedures for the initial and recurring review (clearly indicates period of review) of credentials for all clinical staff members (licensed independent practitioners (LIPs), other licensed or certified practitioners (OLCPs), and other clinical staff providing services on behalf of the health center) who are health center employees, individual contractors, or volunteers.</p> <p><input type="checkbox"/> No compliance issue noted</p> <p><input type="checkbox"/> Compliance issues noted</p> <p>Remarks:</p>	<p>Provide updated operating procedures for initial and recurring review of credentials for all clinical staff members (LIPs and OLCPs). These operating procedures must clearly detail the following as indicated below:</p> <ol style="list-style-type: none"> 1. <input type="checkbox"/> Time period for review and 2. Procedures for: <ul style="list-style-type: none"> <input type="checkbox"/> Employees, <input type="checkbox"/> Individual contractors, and <input type="checkbox"/> Volunteers <p>Due Date:</p>
<p>CP. 2 The credentialing procedures ensure verification of the following, as applicable:</p> <ol style="list-style-type: none"> a) Current licensure, registration, or certification using a primary source; b) Education and training for initial credentialing, using: c) Primary sources for LIPs 	<p>Provide updated operating procedures for initial and recurring review of credentials for all clinical staff members (LIPs and OLCPs). These operating procedures must clearly detail the following for the clinical staff indicated below:</p> <p><input type="checkbox"/> LIPs <input type="checkbox"/> OLCPs</p> <ol style="list-style-type: none"> a) <input type="checkbox"/> Current licensure, registration, or certification using a primary source; <input type="checkbox"/>

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<p>d) Primary or other sources (as determined by the health center) for OLCPs and any other clinical staff;</p> <p>e) Completion of a query through the National Practitioner Databank (NPDB);</p> <p>f) Clinical staff member's identity for initial credentialing using a government-issued picture identification;</p> <p>g) Drug Enforcement Administration (DEA) registration; and</p> <p>h) Current documentation of basic life support training.</p> <p><input type="checkbox"/> No compliance issue noted</p> <p><input type="checkbox"/> Compliance issues noted</p> <p>Remarks:</p>	<p>b) <input type="checkbox"/> Education and training for initial credentialing, using:</p> <ul style="list-style-type: none"> i. Primary sources for LIPs ii. Primary or other sources (as determined by the health center) for OLCPs and any other clinical staff; <p>c) <input type="checkbox"/> Completion of a query through the NPDB;</p> <p>d) <input type="checkbox"/> Clinical staff member's identity for initial credentialing using a government-issued picture identification;</p> <p>e) <input type="checkbox"/> DEA registration; and</p> <p>f) <input type="checkbox"/> Current documentation of basic life support training.</p> <p>Due Date:</p>

Privileging

Authority- 42 U.S.C 233(h)(2); Health Center Compliance Manual; PAL 2018-01 pg.19-21

FTCA Program Requirements	Sample Compliance Actions <i>[Actions required to come into compliance]</i>
<p>CP. 3 The health center has operating procedures for the initial granting and renewal (for example, every two years) of privileges for clinical staff members (LIPs, OLCPs, and other clinical staff providing services on behalf of the health center) who are health center employees, individual contractors, or volunteers.</p> <p><input type="checkbox"/> No compliance issue noted</p> <p><input type="checkbox"/> Compliance issues noted</p> <p>Remarks:</p>	<p>Provide updated operating procedures for initial granting and renewal of privileges for clinical staff members (LIPs and OLCPs). These operating procedures must clearly detail the following as indicated below:</p> <p><input type="checkbox"/> LIPs <input type="checkbox"/> OLCPs</p> <p>1. Privileges procedures for</p> <p><input type="checkbox"/> employees,</p> <p><input type="checkbox"/> individual contractors, and</p> <p><input type="checkbox"/> volunteers.</p> <p>Due Date:</p>
<p>CP. 4 The health center has privileging procedures to address the following:</p> <p>a) Verification of fitness for duty, immunization, and communicable disease status;</p> <p>b) For initial privileging, verification of current clinical competence via training, education, and, as available, reference reviews;</p> <p>c) For renewal of privileges, verification of current clinical competence via peer review or other comparable methods (for example, supervisory performance reviews); and</p>	<p>Provide updated operating procedures for initial granting and renewal of privileges for clinical staff members (LIPs and OLCPs). These operating procedures must clearly detail the following for the groups indicated below:</p> <p>Group:</p> <p><input type="checkbox"/> LIPs <input type="checkbox"/> OLCPs</p> <p>a) <input type="checkbox"/> Verification of fitness for duty, immunization, and communicable disease status;</p> <p>b) <input type="checkbox"/> For initial privileging, verification of current clinical competence via training, education, and, as available, reference reviews;</p>

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<p>d) Process for denying, modifying or removing privileges based on assessments of clinical competence and/or fitness for duty.</p> <p><input type="checkbox"/> No compliance issue noted</p> <p><input type="checkbox"/> Compliance issues noted</p> <p>Remarks:</p>	<p>c) <input type="checkbox"/> For renewal of privileges, verification of current clinical competence via peer review or other comparable methods (for example, supervisory performance reviews); and</p> <p>d) <input type="checkbox"/> Process for denying, modifying or removing privileges based on assessments of clinical competence and/or fitness for duty.</p> <p>Due Date:</p>
<p>CP. 5 The health center maintains files or records for its clinical staff (for example, employees, individual contractors, and volunteers) that contain documentation of licensure, credentialing verification, and applicable privileges, consistent with operating procedures.</p> <p><input type="checkbox"/> No compliance issue noted</p> <p><input type="checkbox"/> Compliance issues noted</p> <p>Remarks:</p>	<p>Health center must ensure all provider files and/or records contain the appropriate documentation of licensure, credentialing verification, and applicable privileges, consistent with operating procedures.</p> <p>Due Date:</p>
<p>CP. 6 If the health center has contracts with provider organizations (for example, group practices, locum tenens staffing agencies, training programs) or formal, written referral agreements with other provider organizations that provide services within its scope of project, the health center has ensured that such</p>	<p>Provide contracts from your provider organizations (for example, group practices, locum tenens staffing agencies, training programs) or formal, written referral agreements with provider organizations that ensure and require the following:</p>

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<p>providers are:</p> <ul style="list-style-type: none"> a) Licensed, certified, or registered as verified through a credentialing process, in accordance with applicable Federal, state, and local laws; and b) Competent and fit to perform the contracted or referred services, as assessed through a privileging process. <p><input type="checkbox"/> No compliance issue noted</p> <p><input type="checkbox"/> Compliance issues noted</p> <p>Remarks:</p>	<ul style="list-style-type: none"> a) <input type="checkbox"/> A credentialing process for all licensed, certified, or registered providers in accordance with applicable Federal, state, and local laws; and b) <input type="checkbox"/> A process to verify that all licensed, certified, or registered providers are competent and fit to perform the contracted or referred services, as assessed through a privileging process. <p>Due Date:</p>

Risk Management

Authority- 42 U.S.C 233(h)(1); Health Center Compliance Manual; PAL 2018-01 pg.10-14

FTCA Program Requirements	Sample Compliance Actions <i>[Actions required to come into compliance]</i>
<p>RM. 1 The health center is implementing an ongoing health care risk management program to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation and that requires the following:</p> <ul style="list-style-type: none"> a) Risk management across the full range of health center health care activities; b) Health care risk management training for health center staff; 	<p>Provide ongoing documentation of your health care risk management program to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation.</p> <ul style="list-style-type: none"> a) <input type="checkbox"/> Policies and procedures for risk management across the full range of health center health care activities and risk management minutes or other documentation that clearly indicates risk

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<p>c) Completion of quarterly risk management assessments by the health center; and</p> <p>d) Annual reporting to the health center board which includes: completed risk management activities; status of the health center’s performance relative to established risk management goals; and proposed risk management activities that relate and/or respond to identified areas of high organizational risk.</p> <p><input type="checkbox"/> No compliance issue noted</p> <p><input type="checkbox"/> Compliance issues noted</p> <p>Remarks:</p>	<p>management is occurring within the health center</p> <p>b) <input type="checkbox"/> The health center risk management training plan for all levels of staff and other documentation that evidences risk management training within the health center (Example: Training Sources, Sign-in sheets, registration forms, session outlines); and</p> <p>c) <input type="checkbox"/> The most recent risk management report that was presented to the health center board, and minutes that clearly indicate the report was presented to the health center board.</p> <p>Due Date:</p>
<p>RM. 2 The health center has risk management procedures that address the following areas for health center services and operations:</p> <p>a) Identifying and mitigating the health care areas/activities of highest risk within the health center’s HRSA-approved scope of project, including but not limited to tracking referrals, diagnostics, and hospital admissions ordered by health center providers;</p> <p>b) Documenting, analyzing, and addressing clinically-related complaints and “near misses” reported by health center employees, patients, and other individuals;</p>	<p>Provide risk management procedures that address the items listed below. Also, include any additional documents requested for each item.</p> <p>a) <input type="checkbox"/> Identifying and mitigating the health care areas/activities of highest risk within the health center’s HRSA-approved scope of project, including but not limited to tracking referrals, diagnostics, and hospital admissions ordered by health center providers;</p> <p>b) <input type="checkbox"/> Documenting, analyzing, and addressing clinically-related complaints and “near misses” reported by health center employees, patients, and other individuals;</p>

FTCA Program Requirements	Sample Compliance Actions [Actions required to come into compliance]
<p>c) Setting and tracking progress related to annual risk management goals;</p> <p>d) Developing and implementing an annual health care risk management training plan for all staff members based on identified areas/activities of highest clinical risk for the health center (including, but not limited to, obstetrical procedures and infection control) and any non-clinical trainings appropriate for health center staff (including HIPAA medical record confidentiality requirements); and</p> <p>e) Completing an annual risk management report for the board and key management staff.</p> <p><input type="checkbox"/> No compliance issue noted</p> <p><input type="checkbox"/> Compliance issues noted</p> <p>Remarks:</p>	<p>c) <input type="checkbox"/> Setting and tracking progress related to annual risk management goals;</p> <p>d) <input type="checkbox"/> Developing and implementing an annual health care risk management training plan for all staff members based on identified areas/activities of highest clinical risk for the health center (including, but not limited to, obstetrical procedures and infection control) and any non-clinical trainings appropriate for health center staff (including HIPAA medical record confidentiality requirements); and;</p> <p>e) <input type="checkbox"/> Completing an annual risk management report for the board and key management staff.</p> <p>Due Date:</p>
<p>RM. 3 The health center has designated an individual(s) (for example, a risk manager) who oversees and coordinates the health center's health care risk management activities and completes risk management training annually.</p> <p><input type="checkbox"/> No compliance issue noted</p>	<p>Provide the name of the individual(s) responsible for the management of the health center's health care risk management activities and risk management training. Also, include position descriptions and job agreements (if applicable).</p> <p>Due Date:</p>

FTCA Program Requirements	Sample Compliance Actions [Actions required to come into compliance]
<input type="checkbox"/> Compliance issues noted Remarks:	

Quality Assurance and Quality Improvement (QI/QA)

Authority- 42 U.S.C 233(h)(1); Health Center Compliance Manual; PAL 2018-01 pg.15-18

FTCA Program Requirements	Sample Compliance Actions [Actions required to come into compliance]
<p>QM. 1 The health center has an ongoing quality improvement/assurance (QI/QA) system that includes clinical services and [clinical] management and maintains the confidentiality of patient records.</p> <p><input type="checkbox"/> No compliance issue noted</p> <p><input type="checkbox"/> Compliance issues noted</p> <p>Remarks:</p>	<p>Provide the following documentation:</p> <ul style="list-style-type: none"> a. Board-approved policy(ies) that establishes a QI/QA program. This QI/QA program addresses the following: <ul style="list-style-type: none"> a. <input type="checkbox"/> The quality and utilization of health center services; b. <input type="checkbox"/> Patient satisfaction and patient grievance processes; and c. <input type="checkbox"/> Patient safety, including adverse events; b. <input type="checkbox"/> Position description for the individual(s) designated to oversee the QI/QA program established by board-approved policy(ies). This individual’s responsibilities would include, but would not be limited to, ensuring the implementation of QI/QA operating procedures and related assessments, monitoring QI/QA outcomes, and updating QI/QA operating procedures. c. <input type="checkbox"/> The most recent QI/QA report that has been provided to key management staff and to the governing board. and d. <input type="checkbox"/> Governing board minutes that document that the most recent QI/QA report was shared with and discussed by the governing board to support decision-making and oversight

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	<p>regarding the provision of health center services.</p> <p>Due Date:</p>
<p>QM. 2 The health center’s ongoing QI/QA system provides the following:</p> <ul style="list-style-type: none"> a) Organizational arrangements, including a focus of responsibility, to support the quality assurance program and the provision of high quality patient care; and b) Periodic assessment of the appropriateness of the utilization of services and the quality of services provided or proposed to be provided to individuals served by the center. Such assessments must: <ul style="list-style-type: none"> 1. Be conducted by physicians or by other licensed health professionals under the supervision of physicians; 2. Be based on the systematic collection and evaluation of patient records; 3. Assess patient satisfaction, achievement of project objectives, and include a process for hearing and resolving patient grievances; and 4. Identify and document the necessity for change in the provision of services by the center and result in the institution of such change, where indicated. 	<p>Provide the following documentation:</p> <ul style="list-style-type: none"> a. Operating procedures or processes that address the following: <ul style="list-style-type: none"> 1. <input type="checkbox"/> Adhering to current evidence-based clinical guidelines, standards of care, and standards of practice in the provision of health center services, as applicable; 2. <input type="checkbox"/> Identifying, analyzing, and addressing patient safety and adverse events and implementing follow-up actions, as necessary; 3. <input type="checkbox"/> Assessing patient satisfaction; 4. <input type="checkbox"/> Hearing and resolving patient grievances; 5. <input type="checkbox"/> Completing periodic QI/QA assessments on at least a quarterly basis to inform the modification of the provision of health center services, as appropriate; and 6. <input type="checkbox"/> Producing and sharing reports on QI/QA to support decision-making and oversight by key management staff and by the governing board regarding the provision of health center services; and b. QI/QA assessments conducted on at least a quarterly basis by the health center’s physicians or other licensed health care professionals, using data systematically collected from patient records, to ensure: <ul style="list-style-type: none"> 1. <input type="checkbox"/> Provider adherence to current evidence-based clinical guidelines,

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<input type="checkbox"/> No compliance issue noted <input type="checkbox"/> Compliance issues noted Remarks:	<p>standards of care, and standards of practice in the provision of health center services, as applicable; and</p> <p>2. <input type="checkbox"/> The identification of any patient safety and adverse events and the implementation of related follow-up actions, as necessary.</p> <p>Due Date:</p>
<p>QM. 3 The health center maintains the confidentiality of patient records, including all information as to personal facts and circumstances obtained by the health center staff about recipients of services. Specifically, the health center must not divulge such information without the individual's consent except as may be required by law or as may be necessary to provide service to the individual or to provide for medical audits by the Secretary of HHS or his/her designee with appropriate safeguards for confidentiality of patient records.</p> <input type="checkbox"/> No compliance issue noted <input type="checkbox"/> Compliance issues noted Remarks:	<p>Provide the following documentation:</p> <p>a. <input type="checkbox"/> Operating procedures on maintaining a retrievable health record (for example, the health center has implemented a certified Electronic Health Record (EHR)) for each patient, the format and content of which is consistent with both Federal and state laws and requirements; and</p> <p>b. <input type="checkbox"/> Operating procedures on implemented systems (for example, certified EHRs and corresponding standard operating procedures) for protecting the confidentiality of patient information and safeguarding this information against loss, destruction, or unauthorized use, consistent with Federal and state requirements.</p> <p>Due Date:</p>

Claims Management

Authority- 42 U.S.C 233(h)(1); Health Center Compliance Manual; PAL 2018-01 pg.22-24

FTCA Program Requirements	Sample Compliance Actions [Actions required to come into compliance]
<p>CM. 1 The health center has a claims management process for addressing any potential or actual health or health-related claims, including medical malpractice claims, that may be eligible for FTCA coverage. In addition, this process ensures:</p> <ul style="list-style-type: none"> a) 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 b) Any service-of-process/summons that the health center or its provider(s) receives relating to any alleged claim or complaint is promptly sent to the HHS, Office of the General Counsel, General Law Division, per the process prescribed by HHS and as further described in the FTCA Health Center Policy Manual. <p><input type="checkbox"/> No compliance issue noted</p> <p><input type="checkbox"/> Compliance issues noted</p>	<p>Provide claims management document(s) that details a process for addressing potential or actual medical malpractice claims that may be eligible for FTCA coverage. The policies must detail and ensure the following:</p> <ul style="list-style-type: none"> a) <input type="checkbox"/> 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 b) <input type="checkbox"/> 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. <p>Due Date:</p>

FTCA Program Requirements	Sample Compliance Actions [Actions required to come into compliance]
Remarks:	
<p>CM. 2 The health center has designated individual(s) who is responsible for the management and processing of claims-related activities and serves as the claims point of contact.</p> <p><input type="checkbox"/> No compliance issue noted</p> <p><input type="checkbox"/> Compliance issues noted</p> <p>Remarks:</p>	<p>Provide the name of the individual(s) responsible for the management and processing of medical malpractice claims-related activities and relevant position description documents and/or job agreement.</p> <p>Due Date:</p>
<p>CM. 3 The health center informs patients using plain language that it is a deemed Federal Public Health Service (PHS) employee via its website, promotional materials, and/or within an area(s) of the health center that is visible to patients.</p> <p><input type="checkbox"/> No compliance issue noted</p> <p><input type="checkbox"/> Compliance issues noted</p> <p>Remarks:</p>	<p>Provide pictures, materials, website links, and/or documentation that clearly demonstrates the health center has informed patients using plain language the health center is a deemed Federal PHS employee.</p> <p>Due Date:</p>
<p>CM. 4 If a history of claims under the FTCA exists, the health center has:</p> <p>a) Cooperated with the Attorney General, as further described in the</p>	<p>Provide the following:</p> <p>1. <input type="checkbox"/> A detailed action plan that outlines how the health center will ensure cooperation with</p>

FTCA Program Requirements	Sample Compliance Actions [<i>Actions required to come into compliance</i>]
<p>FTCA Health Center Policy Manual; and</p> <p>b) Implemented steps to mitigate the risk of such claims in the future.</p> <p><input type="checkbox"/> No compliance issue noted</p> <p><input type="checkbox"/> Compliance issues noted</p> <p>Remarks:</p>	<p>relevant HHS offices and the Attorney General in the defense of all eligible FTCA Claims, and</p> <p>2. <input type="checkbox"/> A statement signed by the Chair of the Health Center governing board acknowledging that that a failure to not cooperate with the U.S. Department of Health and Human Services and or the Attorney General in the defense of eligible FTCA claims may and can result in the denial of future FTCA Deeming applications.</p> <p>3. <input type="checkbox"/> Submit a plan for each FTCA claim noted that details what actions the health center has taken or will take to mitigate the risk of such claims in the future. The document should clearly indicate how this plan will be implemented prior to the next deeming application submission.</p> <p>Due Date:</p>