

**\*SAMPLE DOCUMENT\***

01/31/2024

Sample CEO Name  
Sample Health Center  
Sample H80 No.  
Sample Address  
Sample City, State, Zip Code

Re: Federal Tort Claims Act - Site Visit Report

Dear Sample CEO:

Thank you for participating in the Federal Tort Claims Act (FTCA) site visit conducted on 01/01/2024 – 01/01/2024. The purpose of the site visit was to provide an organizational assessment of FTCA deeming requirements. Below you will find final findings documented during the site visit, which have been reviewed and confirmed by HRSA. This report documents the assessment of organizational with the FTCA programmatic requirements in the areas of risk management systems, credentialing and privileging, quality improvement and assurance, and claims management. Please note that any findings of non-compliance with FTCA program requirements will be transmitted to your organization via the Electronic Handbooks Systems (EHBs). Failure to resolve findings of non-compliance may impact future FTCA deeming status.

Thank you for the critical work of your health center in providing high quality, comprehensive, and patient-centered primary care to your community and its vulnerable populations. We hope the information provided during the site visit will help to strengthen your ongoing quality improvement and risk management efforts.

For additional information and resources regarding FTCA Site Visits, please refer to the [FTCA Health Center Program Site Visit Protocol \(https://bphc.hrsa.gov/ftca/site-visit-protocol\)](https://bphc.hrsa.gov/ftca/site-visit-protocol). If you have any questions about the report, site visit process, or any other related items, please contact [Health Center Program Support \(http://www.hrsa.gov/about/contact/bphc.aspx\)](http://www.hrsa.gov/about/contact/bphc.aspx).

Sincerely,

Office of Quality Improvement  
Federal Tort Claims Act

**\*SAMPLE DOCUMENT\***

## **Sample Health Center**

-

This report has been prepared on behalf of the Health Resources and Services Administration, Bureau of Primary Health Care (HRSA/BPHC), FTCA Program for the purposes of oversight. The report contains HRSA's findings and final compliance determinations. This site visit was conducted in accordance with the [FTCA Health Center Program Site Visit Protocol \(https://bphc.hrsa.gov/ftca/site-visit-protocol\)](https://bphc.hrsa.gov/ftca/site-visit-protocol).

**Bureau of Primary Health Care FTCA Site Visit Report**

**TABLE OF CONTENTS**

1. SITE VISIT INFORMATION
2. BRIEF OVERVIEW OF GRANTEE ORGANIZATION
3. SITE VISIT COMPLIANCE SUMMARY
4. SITE VISIT PROCESS AND PARTICIPANTS
5. SITE VISIT FINDINGS
6. TOOLS AND RESOURCES

**1. SITE VISIT INFORMATION**

**Task Order #**                      Sample TA

**Grantee Address:**                Sample Health Center  
Sample Address  
Sample City, State, Zip Code

**Health Center Contact:**

**Types Of Site Visits:**

**Date(s) of Visit:**                -

**Purpose of Visit:**                The purpose of the site visit is to verify implementation of FTCA program requirements.

**Consultants Information**

1) Lead Consultant:

Focus Areas:

2) Consultant:

Focus Areas:

**Federal Representative Name and Title:**

**Federal Representative Name and Title:**

**Site Visit Location(s):**

<b>Site Toured:</b>	
<b>Site Toured:</b>	

**2. BRIEF OVERVIEW OF GRANTEE ORGANIZATION**

Sample Health Center is based in Sample City, State and provides care at (x) sites. The geographic areas served include (x). The Health Center’s services include (x). The health center served approximately (x) patients in calendar year (x).

**3. SITE VISIT COMPLIANCE SUMMARY**

<b>Program Requirements</b>	<b>Elements</b>	<b>HRSA/BPHC Determination Compliance Demonstrated?</b>
<b>Risk Management</b>	<b>Element A</b>	
<b>Risk Management</b>	<b>Element B</b>	
<b>Risk Management</b>	<b>Element C</b>	
<b>Risk Management</b>	<b>Element D</b>	
<b>Risk Management</b>	<b>Element E</b>	
<b>Credentialing &amp; Privileging</b>	<b>Element A</b>	
<b>Credentialing &amp; Privileging</b>	<b>Element B</b>	
<b>Credentialing &amp; Privileging</b>	<b>Element C</b>	
<b>Credentialing &amp; Privileging</b>	<b>Element D</b>	
<b>Claims Management</b>	<b>Element A</b>	
<b>Claims Management</b>	<b>Element B</b>	
<b>Claims Management</b>	<b>Element C</b>	
<b>Claims Management</b>	<b>Element D</b>	
<b>Quality Improvement and Quality Assurance (QI / QA)</b>	<b>Element A</b>	
<b>QI / QA</b>	<b>Element B</b>	
<b>QI / QA</b>	<b>Element C</b>	
<b>QI / QA</b>	<b>Element D</b>	
<b>QI / QA</b>	<b>Element E</b>	
<b>QI / QA</b>	<b>Element F</b>	

**4. SITE VISIT PROCESS AND PARTICIPANTS**

Specific actions taken by the site visit team during the site visit as follows:

**Table 2. Staff/Reviewer/FTCA Representative Attendance**

<b>Name</b>	<b>Title</b>	<b>Entrance (Y/N)</b>	<b>Exit (Y/N)</b>	<b>Interviewed (Y/N)</b>

## 5. SITE VISIT FINDINGS

### Risk Management Systems

**Authority:** Section 224(g)-(n), 224(q) of the PHS Act (42 U.S.C. 233(g)-(n) and (q)); and 42 CFR ; PAL 2022- 01

#### Documents Reviewed:

Patient Satisfaction Survey Results

Risk Management Training

Tracking Documents

### Element A: Risk Management Program

#### Demonstrating Compliance

##### Description:

The health center has and currently implements an ongoing health care risk management program to reduce the risk of adverse outcomes that could result in medical malpractice or other health or health-related litigation and that requires the following:

- Risk management across the full range of health center health care activities;
- Health care risk management training for health center staff;
- Completion of quarterly risk management assessments by the health center; and
- Annual reporting to the health center board which includes: completed risk management activities; status of the health center's performance relative to established risk management goals; and proposed risk management activities that relate and/or respond to identified areas of high organizational risk.

#### Element A: Questions:

1. Does the health center identify and mitigate areas/activities of highest patient safety risk?

Yes       No

An explanation is required:

**\*SAMPLE DOCUMENT\***

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

- Yes     No

An explanation is required:

3. Does the health center have follow-up actions implemented based on its risk management assessments and its reporting to the board and key management staff?

- Yes     No

An explanation is required:

4. Does the health center's training plan require risk management training for relevant clinical staff on obstetrical services? This includes prenatal and postpartum care. Training should be provided if care includes reproductive age patients for other clinical services. For example, continuing education for electronic fetal monitoring , and shoulder dystocia drills?

- Yes     No

An explanation is required:

5. Does the health center implement procedures to reduce the risk of adverse outcomes, specifically identifying and mitigating risk (for example, clinical protocols, medical staff supervision)?

- Yes     No

An explanation is required:

6. Does the health center 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?

- Yes     No

An explanation is required:



**Element A: HRSA/BPHC Determination: Compliance Demonstrated**

Yes

No

Element A Action Plans:

Please provide the following documentation to address findings of non-compliance:

**Element B: Risk Management Procedures**

**Demonstrating Compliance**

**Description:**

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

- Identifying and mitigating the health care areas/activities of highest risk within the health center's HRSA-approved scope of project, including but not limited to, tracking referrals, diagnostics, and hospital admissions ordered by health center providers;
- Documenting, analyzing, and addressing clinically related complaints and "near misses" reported by health center employees, patients, and other individuals; and
- Setting and tracking progress related to annual risk management goals.

**Element B: Questions:**

1. Does the health center's risk management procedures apply to all services and sites within the health center's scope of project?

Yes     No

An explanation is required:

2. Did the health center provide documentation of analysis and evidence that the health center addresses clinically-related complaints and "near misses" reported by health center employees, patients, and other individuals?

Yes     No

An explanation is required:

**\*SAMPLE DOCUMENT\***

3. Does the health center have policies and procedures in place to mitigate risk of infection and ensure proper sterilization (for example, blood-borne pathogen exposure protocol, hand hygiene training and monitoring program, or dental equipment sterilization) and have provided documentation to verify that this policy/procedure has been implemented?

- Yes     No

An explanation is required:

4. Does the health center have a policy/procedure in place for mitigating risk in tracking referrals (e.g., demonstrate a closed loop process) and have provided documentation to verify that this policy/procedure has been implemented?

- Yes     No

An explanation is required:

5. Does the health center have a policy/procedure in place for mitigating risk in hospitalization tracking and have provided documentation to verify that this policy/procedure has been implemented?

- Yes     No

An explanation is required:

6. Does the health center have a policy/procedure in place for mitigating risk in diagnostic tracking (i.e., the policy should demonstrate a closed loop process) and have provided documentation to verify that this policy/procedure has been implemented?

- Yes     No

An explanation is required:

7. Does the health center have a policy/procedure in place for mitigating risk in medication management and storage and have provided documentation to verify that this policy/procedure has been implemented?

- Yes     No

An explanation is required:

8. Does the health center have a policy/procedure in place for mitigating risk in point-of-care testing equipment and have provided documentation to verify that this policy/procedure has been implemented?

- Yes     No

An explanation is required:

**Element B: HRSA/BPHC Determination: Compliance Demonstrated**                       Yes                        
No

### **Element C: Reports on Risk Management Activities**

#### **Demonstrating Compliance**

##### **Description:**

The health center health center completes and provides an annual risk management report to the board and key management staff on health care risk management activities and progress in meeting goals and provides documentation to the board and key management staff of any related follow-up actions have been implemented.

Please Note: The annual risk management report to the board must be reflective of the activities related to risk over a 12-month period in the current or previous calendar year. This must be a consolidated report covering an entire 12-month period and may not include separate quarterly or monthly reports.

##### **Element C: Questions:**

1. Was the health center able to provide a report on the status of risk management activities and progress in meeting risk management goals, which has been presented within the past 12 months to the board and key management staff?

- Yes     No

An explanation is required:

2. Did the health center implement follow-up actions based on the health center's risk management assessments?

- Yes     No

An explanation is required:

**Element C: HRSA/BPHC Determination: Compliance Demonstrated**

- Yes     No

### **Element D: Risk Management Training Plan**

#### **Demonstrating Compliance**

##### **Description:**

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

The annual health care risk management training plan for all staff members is based on identified areas/ activities of highest clinical risk for the health center (including, but not limited to, obstetrical procedures and infection control) and any non-clinical trainings appropriate for health center staff (including Health Insurance Portability and Accountability Act (HIPAA) and other applicable medical record confidentiality requirements).

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, 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):

- Pre-natal patients
- Post-partum patients
- 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.

The annual risk management educational training plan must cover the period from January 1st to December 31st of the previous calendar year of submission of the application (for example, documentation for 2024 must include the complete training plan that was used in 2023).

**Element A: Questions:**

1. Does the health center have documentation that all relevant staff completed training in accordance with the health center's annual risk management training plan? The annual risk management educational training plan must cover the period from January 1st to December 31st of the previous calendar year of submission of the application (for example, documentation for 2024 must include the complete training plan used in 2023).

Yes     No

An explanation is required:

2. Does the health center have specific trainings for providers based on specialty of care)? (for example, behavioral health, dental, pharmacy, family practice)?

Yes     No

An explanation is required:

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

Yes     No

An explanation is required:

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

Yes     No

An explanation is required:

5. Does the health center's training plan require risk management training for relevant clinical staff on obstetrical services? This includes prenatal and postpartum care. Training should be provided if care includes reproductive age patients for other clinical services. For example, continuing education for electronic fetal monitoring , and shoulder dystocia drills.

Yes     No

An explanation is required:

6. Does the health center's training plan require risk management training for clinical staff on risks associated with the provision of prenatal and postpartum care?

Yes     No

An explanation is required:

**Element D: HRSA/BPHC Determination: Compliance Demonstrated?**       Yes     No

### **Element E: Risk Manager**

#### **Demonstrating Compliance**

##### **Description:**

The health center designates an individual(s) (for example, a risk manager) who oversees and coordinates the health center's health care risk management activities and completes risk management training annually.

##### **Element E: Questions:**

1. Does the health center currently have an individual(s) who oversees and coordinates the health center's risk management activities and duties are reflected in the position description?

Yes     No

An explanation is required:

2. Did the risk manager complete annual risk management training?

Yes     No

An explanation is required:

**Element E: HRSA/BPHC Determination: Compliance Demonstrated?**     Yes     No

### **Credentialing & Privileging**

**Authority:** Health Centers Assistance Acts (FSHCAA) of 1992 (Pub. L. 102-501) and 1995 (Pub. L. 104- 73) (section 224 of the PHS Act) (42 U.S.C. § 233(g)-(n)), Health Center Program Compliance Manual, Chapter 5: Clinical Staffing; PAL 2023- 01, FTCA Health Center Policy Manual.

### **Documents Reviewed**

### **Element A: Procedures for Review of Credentials**

#### **Demonstrating Compliance**

#### **Description:**

The health center has operating procedures for the initial and recurring review (for example, every two years) of credentials for all clinical staff members (licensed independent practitioners (LIPs), other licensed or certified practitioners (OLCPs), and other clinical staff (OCS) providing services on behalf of the health center) who are health center employees, individual contractors, or volunteers.

These credentialing procedures would ensure verification of the following, as applicable:

- Current licensure, registration, or certification using a primary source
- Education and training for initial credentialing, using:
  - Primary sources for LIPs
  - Primary or other sources (as determined by the health center) for OLCPs
  - Any OCS
- Completion of a query of the National Practitioner Data Bank (NPDB)
- Clinical staff member's identity for initial credentialing using a government-issued picture identification
- Drug Enforcement Administration (DEA) registration
- Current documentation of Basic Life Support training

**Staff Composition**

The health center utilizes the following providers:

- |             |                          |     |                          |    |
|-------------|--------------------------|-----|--------------------------|----|
| LIPs:       | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| OLCPs:      | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| OCS:        | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
| Volunteers: | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |

**Element A Questions: Reviewer's responses reflect an evaluation of both the written procedures and the implementation of the procedures.**

1. Initial Credentialing Only: Do the health center's credentialing procedures require verification of the following for all clinical staff (LIPs, OLCPs, and OCS), as applicable, upon hire:

1a. Clinical staff member's identity using a government-issued picture identification?

- |        |                          |     |                          |    |                          |     |
|--------|--------------------------|-----|--------------------------|----|--------------------------|-----|
| LIPs:  | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> | N/A |
| OLCPs: | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> | N/A |
| OCS:   | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No | <input type="checkbox"/> | N/A |

An explanation is required:

1b. Verification by the health center (licensing agency, specialty board, or registry) of the education and training of LIPs using a primary source?

- |       |                          |     |                          |    |
|-------|--------------------------|-----|--------------------------|----|
| LIPs: | <input type="checkbox"/> | Yes | <input type="checkbox"/> | No |
|-------|--------------------------|-----|--------------------------|----|

An explanation is required:



**\*SAMPLE DOCUMENT\***

1c. Verification of the education and/or training of OLCs and, as applicable, OCS using a primary or secondary source as determined by the health center?

OLCs:                Yes        No        N/A

OCS:                Yes        No        N/A

An explanation is required:

2. Initial and Recurring Credentialing Procedures: Do the health center's credentialing procedures require verification of the following for all clinical staff (LIPs, OLCs, and OCS) upon hire and on a recurring basis?

2a. Current licensure, registration, or certification using a primary source for OLCs?

OLCs:                Yes        No        N/A

An explanation is required:

2b. Completion of a query of the NPDB for reportable provider types?

LIPs:                Yes        No        N/A

OLCs:                Yes        No        N/A

OCS:                Yes        No        N/A

An explanation is required:

2c. DEA registration (as applicable)?

LIPs:                Yes        No        N/A

OLCs:                Yes        No        N/A

An explanation is required:

**\*SAMPLE DOCUMENT\***

2d. Current documentation of Basic Life Support training (or comparable training completed through licensure or certification)?

LIPs:                Yes        No        N/A  
OLCPs:             Yes        No        N/A  
OCS:                Yes        No        N/A

An explanation is required:

**Element A: HRSA/BPHC Determination: Compliance Demonstrated?**        Yes        No

**Element B: Procedures for Review of Privileges**

**Demonstrating Compliance**

**Description:**

The health center has operating procedures for the initial granting and renewal (for example, every two years) of privileges for clinical staff members (licensed independent practitioners (LIPs), other licensed or certified practitioners (OLCPs), and other clinical staff (OCS) providing services on behalf of the health center) who are health center employees, individual contractors, or volunteers. These privileging procedures address the following:

- Verification of fitness for duty, immunization, and communicable disease status
- For initial privileging, verification of current clinical competence via training, education, and, as available, reference reviews
- For renewal of privileges, verification of current clinical competence via peer review or other comparable methods (for example, supervisory performance reviews)
- Process for denying, modifying, or removing privileges based on assessments of clinical competence and/or fitness for duty

**Element B Questions: Reviewer’s responses reflect an evaluation of both the written procedures and the implementation of the procedures.**

**\*SAMPLE DOCUMENT\***

1. Do the health center's operating procedures address both the initial granting and renewal of privileges for all clinical staff (LIPs, OLCs, and OCS who are health center employees, individual contractors, or volunteers)?

LIPs:                Yes        No        N/A

OLCPs:            Yes        No        N/A

OCS:               Yes        No        N/A

An explanation is required:

2. Do the health center's privileging procedures require verification of the following for providers upon hire and on a recurring basis?

2a. Fitness for duty?

LIPs:               Yes        No        N/A

OLCPs:            Yes        No        N/A

OCS:               Yes        No        N/A

An explanation is required:

2b. Immunization status?

LIPs:               Yes        No        N/A

OLCPs:            Yes        No        N/A

OCS:               Yes        No        N/A

An explanation is required:

2c. Communicable disease status?

LIPs:                Yes        No        N/A

OLCPs:             Yes        No        N/A

OCS:                Yes        No        N/A

An explanation is required:

2d. Current clinical competence?

LIPs:                Yes        No        N/A

OLCPs:             Yes        No        N/A

OCS:                Yes        No        N/A

An explanation is required:

3. Does the health center have criteria and processes for modifying or removing privileges based on the outcomes of clinical competence assessments?

LIPs:                Yes        No        N/A

An explanation is required:

4. Does the health center have a policy and procedure in place for temporary privileging in alignment with PAL 2017-07: Temporary privileging of clinical providers by FTCA Deemed Health Centers in response to certain declared emergency situations?

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.

**\*SAMPLE DOCUMENT\***

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.

Yes     No     N/A

An explanation is required:

**Element B: HRSA/BPHC Determination: Compliance Demonstrated?**     Yes     No

**Element C: Credentialing and Privileging Records**

**Demonstrating Compliance**

**Description:**

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 that are consistent with operating procedures.

**Element C Questions: Reviewer's responses reflect an evaluation of both the written procedures and the implementation of the procedures.**

1. Based on the review of the sample of current clinical staff files, did the files contain up-to-date (as defined by the health center in its operating procedures) documentation of licensure and credentialing of these clinical staff (employees, individual contractors, and volunteers)?

Number of files reviewed:    LIPs:    OLCPs:    OCS:

1a. LIPs:     Yes     No     N/A

An explanation is required:

1b. OLCPs:     Yes     No     N/A

An explanation is required:

**\*SAMPLE DOCUMENT\***

1c. OCS:             Yes     No     N/A

An explanation is required:

2. Based on the review of the sample of provider files, did the files contain up-to-date (as defined by the health center in its operating procedures) documentation of privileging decisions (e.g., an up-to-date privileging list for each provider) for these clinical staff (employees, individual contractors, and volunteers)?

2a. LIPs:             Yes             No     N/A

An explanation is required:

List the full names of the employee files that were reviewed and missing documents:

2b. OLCPs:         Yes     No     N/A

An explanation is required:

List the full names of the employee files that were reviewed and missing documents:

2c. OCS:             Yes     No     N/A

An explanation is required:

List the full names of the employee files that were reviewed and missing documents:

**Element C: HRSA/BPHC Determination: Compliance Demonstrated?**             Yes     No

## Element D: Credentialing and Privileging of Contracted or Referral Providers

### Demonstrating Compliance

#### Description:

If the health center has contracts with provider organizations (for example, group practices, locum tenens staffing agencies, or training programs) or formal, written referral agreements with other provider organizations that provide services within its scope of project, the health center ensures that such providers are.

- Licensed, certified, or registered as verified through a credentialing process, in accordance with applicable federal, state, and local laws
- Competent and fit to perform the contracted or referred services, as assessed through the privileging process.

#### Element D Questions

1. Was the health center able to ensure through provisions in contracts or through other means that contracted services (Form 5A, Column II) are provided by organizations that?

1a. Verify provider licensure, certification, or registration through a credentialing process?

Yes  No

An explanation is required:

1b. Verify providers are competent and fit to perform the contracted service(s) through a privileging process?

Yes  No

An explanation is required:

Notes: For Column II services that involve a contract with provider organization(s), the credentialing and privileging process for the provider(s) may either be conducted by the provider organization(s) or may be conducted by the health center. Individual contractors are credentialed and privileged by the health center (see demonstrating compliance element "A").

2. Was the health center able to incorporate into its written referral arrangements or through other means (for example, the referral organization provides the health center with documentation of Joint Commission accreditation) the expectation that referred services (Form 5A, Column III) provided by the organizations:

2a. Verify provider licensure, certification, or registration through a credentialing process?

Yes  No

An explanation is required:

2b. Verify providers are competent and fit to perform the contracted service(s) through a privileging process?

Yes     No

An explanation is required:

**Element D: HRSA/BPHC Determination: Compliance Demonstrated?**     Yes     No

Please provide a signed attestation confirming the contracts for the provider organization that addresses the following compliance elements. (Contracts are read only to ensure credentialing and privileging process):

### Claims Management

**Authority:** 42 U.S.C 233(h)(1); Health Center Compliance Manual; PAL 2023-01

Documents Reviewed

### Element A: Claims Management Process

#### Demonstrating Compliance

#### Description:

- 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, 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, and clinic operating procedures)
- 
- 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 Health and Human Services Office of the General Counsel (OGC), General Law Division (GLD), per the process prescribed by Health and Human Services (HHS) and as further described in the FTCA Health Center Policy Manual

#### Element A Questions:



**\*SAMPLE DOCUMENT\***

1. Does the health center have a process for the addressing of all health or health-related claims, including medical malpractice claims that may be eligible for FTCA coverage?

Yes  No

An explanation is required:

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

2a. Preserve claims-related documentation (e.g., medical records and associated laboratory and x-ray results, billing records, employment records of all involved clinical providers, clinic operating procedures)?

Yes  No

An explanation is required:

2b. Promptly communicate with the HHS Office of the General Counsel, General Law Division, regarding any actual or potential claim or complaint?

Yes  No

An explanation is required:

**Element A: HRSA/BPHC Determination: Compliance Demonstrated?**  Yes  No

**Element B: Claims Management Activities Point of Contact**

**Demonstrating Compliance**

**Description:**

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

**Element B Question:**

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

Yes  No

An explanation is required:

**Element B: HRSA/BPHC Determination: Compliance Demonstrated?**      Yes      No

**Element C: Informing Patients of FTCA Deemed status**

**Demonstrating Compliance**

**Description:**

The 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.

**Element C Question:**

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

Yes    No

An explanation is required:

**Element C: HRSA/BPHC Determination: Compliance Demonstrated?**      Yes      No

**Element D: History of Claims – Cooperation and Mitigation**

**Demonstrating Compliance**

**Description:**

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

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

**Element D Question:**

1. For health centers with a history of closed claims under FTCA within the past five years: For each closed claim, has the health center implemented any steps to mitigate the risk of such a claim in the future? If the health center does not have a history of claims within the past five years, have they conducted an internal analysis and implemented steps to mitigate the risk of such claims in the future?

Yes  No

An explanation is required:

**Element D: HRSA/BPHC Determination: Compliance Demonstrated?**  Yes  No

### **Quality Improvement/Quality Assurance**

**Authority:** 42 U.S.C. Section 233 (g) – (n). Health Center Compliance Manual, Chapter 10; PAL 2023-01

#### **Documents Reviewed**

### **Element A: Program Policies**

#### **Demonstrating Compliance**

##### **Description:**

The health center has a board-approved policy(ies) that establishes a QI/QA program. This QI/QA program addresses the following:

- The quality and utilization of health center services;
- Patient satisfaction assessments and patient grievance processes; and
- Patient safety including of adverse events.

#### **Element A Questions:**

1. Does the health center have a QI/QA policy (ies) that addresses the following areas:

1a. The quality of care rendered to patients at the health center?

Yes  No

An explanation is required:

**\*SAMPLE DOCUMENT\***

1b. Assessment of patient satisfaction scores?

Yes     No

An explanation is required:

1c. Assessment of patient grievance processes and resolutions?

Yes     No

An explanation is required:

1d. Patient safety, including adverse events?

Yes     No

An explanation is required:

**Element A: HRSA/BPHC Determination: Compliance Demonstrated?**     Yes     No

**Element B: Designee to Oversee Program**

**Demonstrating Compliance**

**Description:**

The health center designates an individual(s) 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.

**Element B: QI/QA Questions:**

Does the health center have a QI/QA policy (ies) that addresses the following areas:

1. Does the health center have a designated individual(s) to oversee the QI/QA program?

Yes     No

An explanation is required:

2. Based on the interview(s) and review of the job/position description(s) or other documentation, do the responsibilities of this individual(s) include:

2a. Ensuring the implementation of QI/QA operating procedures?

Yes     No

An explanation is required:

2b. Ensuring QI/QA assessments are conducted quarterly?

Yes     No

An explanation is required:

2c. Monitoring QI/QA outcomes?

Yes     No

An explanation is required:

2d. Updating QI/QA operating procedures, as needed?

Yes     No

An explanation is required:

**Element B: HRSA/BPHC Determination: Compliance Demonstrated?**     Yes     No

**Element C: Procedures or Processes:**

**Description:**

- The health center has operating procedures or processes that address all of 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;
- Identifying, analyzing, and addressing patient safety and adverse events and implementing follow-up actions, as necessary; Assessing patient satisfaction; Hearing and resolving patient grievances;
- 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
- 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.

**Element C: Questions:**

Does the health center have operating procedures and/or related systems that address:

1. Adherence to current, applicable evidence-based clinical guidelines, standards of care, and standards of practice (e.g., provider access to Electronic Health Record (EHR) clinical decision making support, job aids, protocols, and/or other sources of evidence-based care)?:

Yes     No

An explanation is required:

2. A process for implementing follow-up actions related to patient safety and adverse events, as necessary?

Yes     No

An explanation is required:

3. A process for the health center to assess patient satisfaction (e.g., fielding patient satisfaction surveys, conducting periodic patient focus groups)?

Yes     No

An explanation is required:

4. Completion of periodic QI/QA assessments on at least a quarterly basis?

Yes     No

An explanation is required:

5. Does the health center share reports on QI/QA, including data on patient satisfaction and patient safety with key management staff and the governing board?

Yes     No

An explanation is required:

**Element C: HRSA/BPHC Determination: Compliance Demonstrated?**

Yes     No

**Element D: Quarterly Assessments of Clinician Care:**

**Description:**

- The health center’s physicians or other licensed health care professionals conduct QI/QA assessments on at least a quarterly basis, using data systematically collected from patient records, to ensure:
- Provider adherence to current evidence-based clinical guidelines, standards of care, and standards of practice in the provision of health center services, as applicable; and
- The identification of any patient safety and adverse events and the implementation of related follow-up actions, as necessary.

**Element D: Questions:**

1. Are the health center’s QI/QA assessments conducted by physicians or other licensed health care professionals (such as nurse practitioner, registered nurse, or other qualified individual) on at least a quarterly basis?:

Yes     No

An explanation is required:

2. Are these QI/QA assessments based on data systematically collected from patient records?:

Yes     No

An explanation is required:

3. Do these assessments demonstrate that the health center is tracking and, as necessary, addressing issues related to the quality and safety of the care provided to health center patients (e.g., use of appropriate medications for asthma, early entry into prenatal care, HIV linkages to care, response initiated as a result of a recent adverse event)?:

Yes     No

An explanation is required:

**Element D: HRSA/BPHC Determination: Compliance Demonstrated?**       Yes     No

**Element E: Retrievable Health Records:**

**Description:**

The health center maintains a retrievable health record (for example, the health center has implemented a certified Electronic Health Record) for each patient, the format and content of which is consistent with both federal and state laws and requirements.

**Element E: Questions:**

1. Does the health center maintain an individual health record that is easily retrievable?:  
 Yes     No

An explanation is required:

2. Does the health center have a process for ensuring that the format and content of its health records are consistent with applicable federal and state laws and requirements (for example, the health center has implemented a certified EHR)?:  
 Yes     No

An explanation is required:

**Element E: HRSA/BPHC Determination: Compliance Demonstrated?**                     Yes     No

**Element F: Confidentiality of Patient Information:**

**Description:**

The health center has 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.

**Element F: QI/QA Questions:**

1. Do the health center's health Information Technology (IT) or other record keeping procedures address current federal and state requirements related to confidentiality, privacy, and security of protected health information (PHI) including safeguards against loss, destruction, or unauthorized use?:  
 Yes     No

An explanation is required:



2. Does the health center ensure its staff are trained in confidentiality, privacy, and security?:

Yes     No

An explanation is required:

**Element F: HRSA/BPHC Determination: Compliance Demonstrated?**

Yes     No

## **6. TOOLS AND RESOURCES**

Appropriate resources will be provided.