REGLANTERN

LIGHTING THE WAY TO HEALTH CENTER EXCELLENCE

LIGHTING THE WAY TO HEALTH CENTER EXCELLENCE

FTCA: Moving Toward Continuous Compliance

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CEO | REGLANTERN

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✚ Each health center should reference **HRSA's CURRENT REFERENCES** to determine your health center's compliance.

✚ Contact the **BPHC CONTACT FORM** at https://hrsa.my.site.com/support/s/.
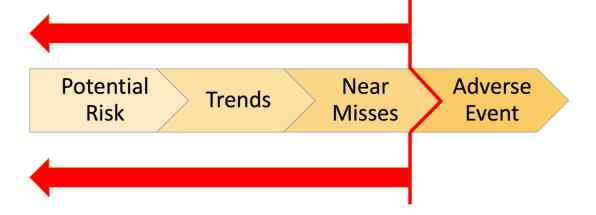
Quality and Risk Management

COMMON HEALTH CENTER AREAS OF RISK

- Patient privacy, confidentiality, HIPAA
- Human Resources: Hiring, interviewing, disciplining, management, termination
- Abuse: Reporting, assessing
- HRSA Program Requirements
- Reputation, public relations
- Health and sanitation, infection control
- Strategic
- Financial risk
- Documentation of services, billing fraud
- Employee injury and illness
- Conflict of interest, corruption, corporate compliance
- Quality/Clinical outcomes
- Patient access

- Medication errors
- Theft
- Cyber risk
- Disruptive staff behavior
- Environmental pollutants
- Telemedicine
- Negligence/misdiagnosis/delay in care
- Violence
- Emergency preparedness
- Alarm fatigue
- Epidemics and pandemics
- Clinical competence/fitness for duty/training
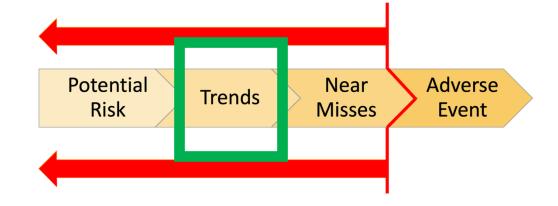- Contract and referral arrangements

COMMON CLINICAL AREAS OF RISK

- **Patient privacy, confidentiality, HIPAA**
- **Human Resources: Hiring, interviewing, disciplining, management, termination**
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- HRSA Program Requirements
- **Reputation, public relations**
- **Health and sanitation, infection control**
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- Financial risk
- **Documentation of services, billing fraud**
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- Conflict of interest, corruption, corporate compliance
- **Quality/Clinical outcomes**
- **Patient access**

- **Medication errors**
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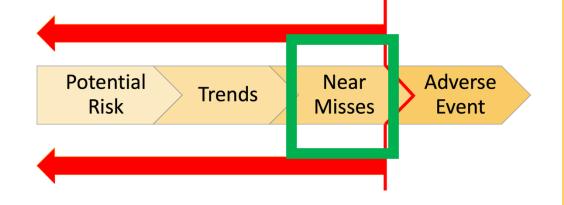- Contract and referral arrangements

COMMON HEALTH CENTER AREAS OF RISK

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- Epidemics and pandemics
- Clinical competence/fitness for duty/training
- Contract and referral arrangements

| Potential Risk | Trends | Near Misses | Adverse Event |

COMMON HEALTH CENTER AREAS OF RISK

FTCA: "Primarily clinical patient care- and safety-focused…"

(Areas that potentially prevent or decrease the likelihood of medical malpractice claims)

RISK TRENDS

+ Patient privacy, confidentiality, HIPAA

+ Human Resources: Hiring, interviewing, disciplining, management, termination

+ Health and sanitation, infection control

+ Employee injury and illness

+ Conflict of interest, corruption, corporate compliance

+ Quality/Clinical outcomes

+ Patient access

| Potential Risk | Trends | Near Misses | Adverse Event |

NEAR MISSES

It was noted that the there were several episodes where the wrong chart was pulled but it was caught before care was provided.

A medication was prescribed though the patient was allergic to it but it was caught before the patient took it.

Potential Risk → Trends → Near Misses → Adverse Event
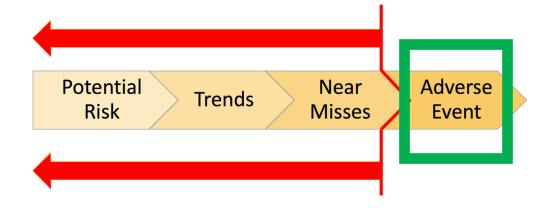
ADVERSE EVENTS

+ HIPAA breach

+ Wrong vaccine given

+ Needle-stick

+ Patient injury or death

Potential Risk → Trends → Near Misses → Adverse Event →

RISK PRIORITIZATION

	Small Impact	Large Impact
Low Likelihood	*Low Likelihood Small Impact*	*Low Likelihood Large Impact*
High Likelihood	*High Likelihood Small Impact*	*High Likelihood Large Impact*

Quality Planning (QP)

"What are we doing to ensure the care we provide is safe, timely, efficient, effective, patient-centered, and with limited variation?"

Quality Management Plan	Risk Management Plan	Quality & Risk Work Plan	Training Plan	Organizational Chart	Job Descriptions

Quality Aims

Risk Management (RM)

"What are we doing to identify and lower risks of not meeting our aims?"

Adverse Outcome Management

"What are we doing to assess, address, correct, and manage adverse outcomes?"

Quality Assurance (QA)

"What assurances are we providing that we are meeting our aims?"

- Aims-Based Policies & Procedures
- Outcome comparison to internal and external benchmarks
- C&P
- Pt Complaints & Grievance Program
- Needs Assessment
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- Job Descriptions and Employment Contracts
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- After Hours Care Service
- Pt Board Member Requirements
- Evidence-based Decision-Support Tools
- Medical Emergency Supplies Daily Check
- Referral, Hospitalization, & Diagnostic Tracking Program
- Hospital Admitting Arrangements
- ONC-certified EHR

(red box) Pt Grievance & Complaint Program / Claims Management / Pt Safety & Adverse Event Program

Quality Improvement (QI) – Internal

"What are we doing internally to improve to meet our aims?"

- RCA
- FMEA
- Process Maps
- Appreciative Inquiry
- Key Driver Diagram
- Run Charts
- PDSA
- Value Stream Map
- Pareto Chart
- Control Chart
- Checklists
- Histogram
- Scatter Plot
- Gantt Chart
- Balanced Scorecard
- Spaghetti Diagram

Model for Improvement

Potential Risk → Trends → Near Misses → Adverse Outcome → Diagnostic Phase → Problem-Solving Phase → Evaluation Phase → Iteration Phase

Model for Improvement

Quality Control (QC)

"How are we verifying/checking whether or not we are meeting our aims?"

- Quarterly Risk Assessments
- Quarterly Peer Review
- Clinical Outcome Reports
- Medical Emergency Drills
- Pt Satisfaction Surveys
- Pt Access Eval./3NAA
- Clinical Staffing Mix Evaluation
- Subrecipient Monitoring
- AHRQ Surveys on Pt Culture (SOPS)
- C/P Audits
- After-Hours Test Call

(red box) Good Catch Forms / Pt Grievance & Complaints / Incident Reports

- Pareto Report of Near Miss and Incident Reports
- Chart Documentation Audits
- Mock OSVs
- Service Contract/ MOU Monitoring Review
- Emp. Sat. Surveys
- Forms 5A & 5B Review

Quality Improvement (QI) – External Advocacy

"What are we doing to improve external factors to help meet our aims?"

- Policy Advocacy
- Voter Advocacy
- Communications

BOLDED areas are HRSA-required.

RISK MANAGEMENT LIFE CYCLE

Annual Risk Management Report

Quarterly Assessments

Risk Management Plan

Risk Management Training Plan
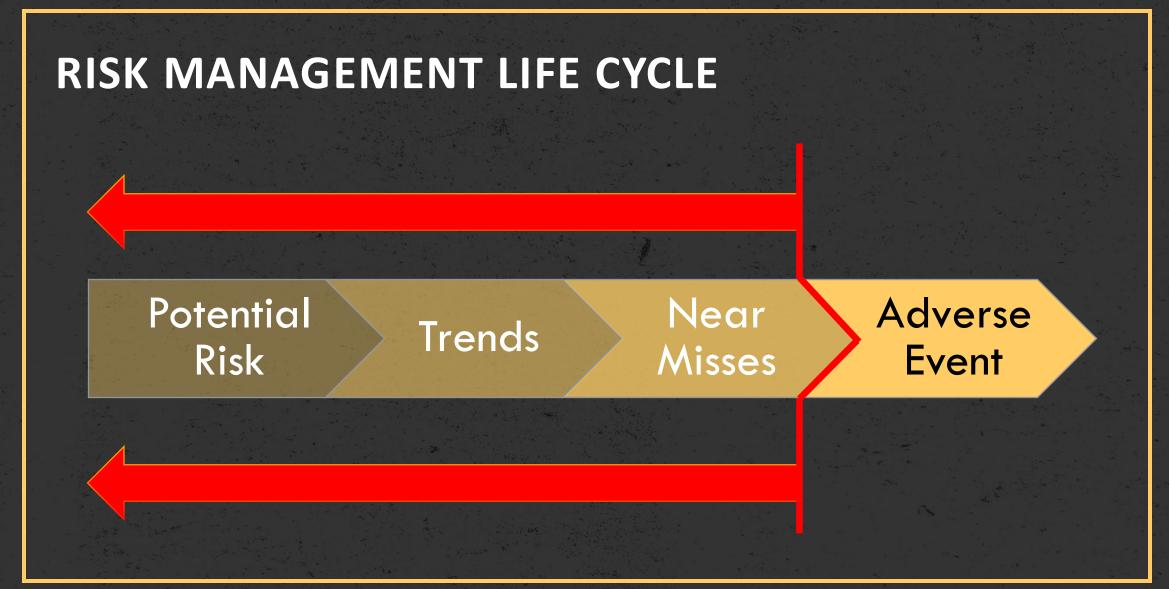
RISK MANAGEMENT LIFE CYCLE

Quarterly Assessments

✚ Patient satisfaction surveys

✚ Incident reports

✚ Patient grievances

✚ Peer review

✚ Training competencies

✚ Process audits

Assess

Do

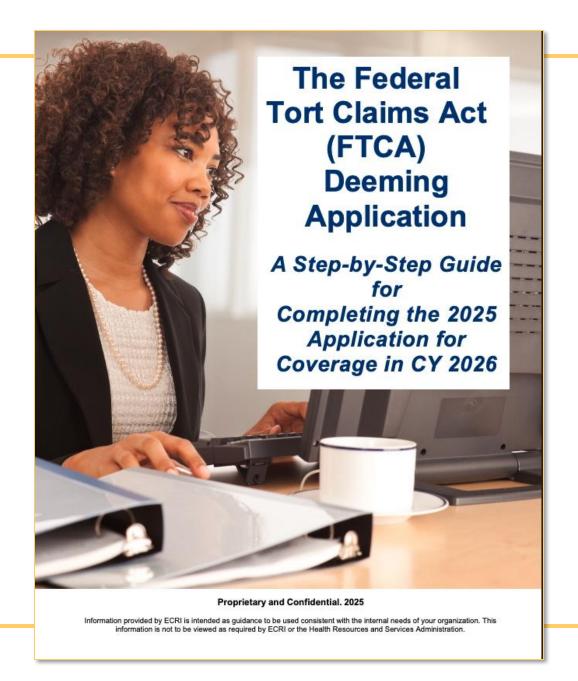Study

Act

Surveillance

Strategies for Continuous FTCA Compliance

IMPORTANT CHANGES

+ Risk Management activities submitted should be reflective of activities completed from **January 1 to December 31** of the previous calendar year.

The Federal Tort Claims Act (FTCA) Deeming Application

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

Proprietary and Confidential. 2025

DOCUMENT EXAMPLES

https://hrsadeemingapplicationclinic.vfairs.com/

MAKE A PLAN

	Current Calendar Year												Next Year						
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
Quarterly RM Assessments			X			X			X			X			X			X	
Report quart. RM Asmts to QI	X			X			X			X			X			X			X
Compile Annual RM Report	X												X						
Present Annual Report to BOD		X												X					
Create RM Training Plan												X							
Complete required trainings	X	X	X	X	X	X	X	X	X				X	X	X	X	X	X	X
Review related Policies/Proc			X	X											X	X			
Ensure Cred/Priv up-to-date	X	X	X	X			X	X	X	X	X	X	X	X	X	X			
Look for new HRSA FTCA PAL	X	X	X										X	X	X				
Complete/Submit FTCA App						X	X										X	X	

MAKE A PLAN

MAKE A PLAN

				Current Calendar Year										Next Year						
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
Quarterly RM Assessments			X			X			X			X			X		X		
Report quart. RM Asmts to QI	X			X			X			X			X			X			X
Compile Annual RM Report	X												X						
Present Annual Report to BOD		X												X					
Create RM Training Plan												X							
Complete required trainings	X	X	X	X	X	X	X	X	X				X	X	X	X	X	X	X
Review related Policies/Proc			X	X											X	X			
Ensure Cred/Priv up-to-date	X	X	X	X			X	X	X	X	X	X	X	X	X			
Look for new HRSA FTCA PAL	X	X	X										X	X	X				
Complete/Submit FTCA App					X	X											X	X	

RISK POLICIES/PROCEDURES CHECKLIST

Required and Additional Health Services (Chapter 4)
- Referral Initiation, Tracking and Management Policy and Procedure (pp. 9, 14)

Clinical Staffing (Chapter 5)
- Credentialing and Privileging Policy and Procedure (pp. 17-24)
- Clinical Staff Recruitment and Retention Policy and Procedure (p. 18)

Coverage for Medical Emergencies During and After Hours (Chapter 7)
- Managing Medical Emergencies During Hours of Operation Policy and Procedure (pp. 29-30)
- Managing Medical Emergencies After Hours of Operation Policy and Procedure (pp. 29-30)

Continuity of Care and Hospital Admitting (Chapter 8)
- Continuity of Care and Hospitalization Tracking Policy and Procedure (p. 35)
- Specialty Referral Tracking Policy (FTCA SVP)

Quality Improvement/Quality Assurance & FTCA (Chapter 10 & 21)
- Clinical Guidelines, Standards of Care, and Standards of Practice Policy and Procedure (p. 53)
- Patient Safety and Adverse Event Policy and Procedure (p. 53)
- Patient Satisfaction Policy and Procedure (p. 53)
- Patient Grievance Policy and Procedure (p. 53)
- Periodic QI/QA Assessments and Peer Review Policy and Procedure (p. 53)
- Confidentiality, Privacy and Security of Patient Records Policy and Procedure (p. 53)
- Quality Plan Policy and Procedures (pp. 54-55)
- Health Information Technology Policy and Procedures (p. 59)
- Risk and Claims Management Policy and Procedures (p. 129)

FTCA
- Medical Records Archiving/Retention Policy (FTCA SVP)
- Medical Records Documentation/Completeness (FTCA SVP)
- Infection Control P/Ps (FTCA SVP)
- Sterilization P/Ps (FTCA SVP)
- Safety Protocols P/Ps (Sharps, etc.) (FTCA SVP)
- Walk-In Patients Policy (FTCA SVP)
- No-Show Appoints/Follow-Up Policy (FTCA SVP)
- Phone Triage Policy (FTCA SVP)
- Urgent Care Visit Triage P/P (FTCA SVP)

General*
- Continuous Compliance Policy and Plan
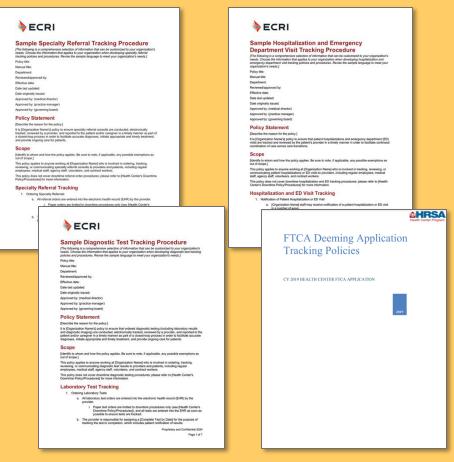
RISK MANAGEMENT PROCEDURES

- Written procedure for identifying and mitigating high-risk activities (**Quarterly Risk Management Assessment Procedure**)

- Written procedure for **setting annual risk management goals** and tracking progress toward those goals

- Written procedure for developing and implementing an **annual RM training plan**

- Written procedure for completing an **annual risk management report to board**

- Documenting, analyzing, and addressing clinically related complaints, "**near misses**", and sentinel events reported by employees, patients, others

RISK MANAGEMENT PROCEDURES

✚ **Referral** Tracking Procedure

✚ **Hospitalization** Tracking Procedure

✚ **Diagnostic** Tracking Procedure

https://bphc.hrsa.gov/sites/default/files/bphc/compliance/ftca-deeming-app-tracking-checklist-cy-19.pdf

RISK MANAGEMENT PROCEDURES

✚ Referral Tracking Procedure

Category	Element of Policy
RT.1	The health center has implemented a system to track all referrals from their origin until they are returned and evaluated by a provider. This tracking system should include: • The origin of the referral • Status of the referral • The administrative and clinical details of the referral
RT.2	The health center follows up with referral provider(s) in a timely manner to ensure that information is received back from the referral provider(s). This must include: • Specific process and timeframes for the transmission and receipt of referral results. • Specific process and times frames for follow-up if results are not received in timely manner.
RT.3	The health center clearly identifies titles of health center staff who are responsible for executing each of the duties throughout the referral tracking process.
RT.4	The heath center documents all patient referrals in the patient's medical records and makes documented efforts to follow up with patients who miss referral appointments. This must include number of attempts that will be made and the manner in which those attempts will be made (i.e., two phone calls, one certified letter with mail delivery confirmation).
RT.5	The policy has been signed and approved by the Governing Board or the individual or the committee that the Governing Board has delegated review and approval authority to. If delegation of authority has occurred, there should be a clear delegation of authority statement within the policy. (See Health Center Compliance Manual, Chapter 19: Board Authority for more information on the health center governing board's role in approving policies.)

RISK MANAGEMENT PROCEDURES

✚ **Hospitalization Tracking Procedure**

Category	Element of Policy
HT.1	The health center has a tracking and monitoring system for receiving information regarding hospital or ED admissions. At a minimum the tracking system must include: • Patient information • Date of admission or visit • Date of notification • Reason for visit, if known • Documentation received • Documentation requested (includes date requested) Follow-up initiated with hospital and or patient (includes date initiated). Note: This relates to admissions where the health center sends the patient to the ED and cases where the patient may have entered the ED on their own.
HT.2	The health center has identified staff members, by title, who are responsible for receiving ED and hospital admission information and monitoring the mechanism that is utilized for receiving hospital and ED admission information.
HT.3	The health center has implemented a mechanism to 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.
HT.4	The policy has been signed and approved by the Governing Board or the individual or the committee that the Governing Board has delegated review and approval authority to. If delegation of authority has occurred, there should be a clear delegation of authority statement within the policy. (See Health Center Compliance Manual, Chapter 19: Board Authority for more information on the health center governing board's role in approving policies.)

RISK MANAGEMENT PROCEDURES

✚ **Diagnostic Tracking Procedure (Labs/Imaging)**

Category	Element of Policy
DT.1	A tracking and monitoring system is maintained for all diagnostic orders. The system must include at a minimum: • Patient information • Date test ordered • Ordering provider • List of tests ordered • Date results received • Provider who reviewed results • Follow-up recommended by provider • Communication of results to patient, including unsuccessful communication attempts and follow-up
DT.2	The policy speaks to agreements with lab vendors which 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.

RISK MANAGEMENT PROCEDURES

✚ **Diagnostic Tracking Procedure (Labs/Imaging)**

DT.3	For **Critical Test Results**:
	• Time frame for communication of results to patients • Acceptable means of communication to provider and patient (e.g., verbal contact only) • Procedures for contacting back-up or surrogate providers if ordering provider is not immediately available to receive results • Every effort is made to contact patient for follow-up (e.g., visiting shelter, enlisting help from authorities) • Documentation of successful and unsuccessful attempts to contact patient • Tracking critical lab tests, monitoring to ensure no problems arise, audits reported to QI/QA committee as part of the program.
DT.4	For **Abnormal Test Results**:
	• Acceptable means of communication to provider and patient (e.g., verbal, electronic) • Timeframe for communicating results to patient (e.g., not to exceed 14 days) • Efforts made to contact patient for follow-up (e.g., visiting shelter, enlisting help from authorities) • Documentation of successful and unsuccessful attempts to contact patient (notification should include more than just a certified letter).

RISK MANAGEMENT PROCEDURES
✚ Diagnostic Tracking Procedure (Labs/Imaging)

Responsibility is assigned for documentation of all pertinent diagnostic tracking activities and is maintained as part of the patient's medical record to include the following items:

- Acknowledgment of receipt of result

- Actions taken related to the patient

- Patient notification, including date and time of notification, means used to communicate results (e.g., phone call, letter), and person spoken to (if applicable)

- All attempts to contact the patient if the patient cannot be reached

- Other clinical information as appropriate

RISK MANAGEMENT PROCEDURES

✚ **Diagnostic Tracking Procedure (Labs/Imaging)**

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RISK MANAGER JOB DESCRIPTION

✚ This should clearly define the key responsibilities that lower risk.

✚ This should be reviewed and updated annually.

RISK ROLES: Risk Manager

"Convenes a team responsible for conducting the risk assessment.

Considers available assessment tools and chooses assessment(s) that best meets the health center's needs.

Conducts, in collaboration with others, risk assessments at least quarterly.

Collaborates with key stakeholders on action plans to address identified risks.

Presents all findings to risk management committees, leadership, the board, and other staff as appropriate."

QI/QA PROCESSES

✚ Ensure the health center maintains board-approved QI/QA program policies that address:

   ✚ **Quality** and **utilization** of health center services

   ✚ **Patient satisfaction** and **patient grievance** processes

   ✚ Patient safety, including **adverse events**

   ✚ Adherence to current **evidence-based** clinical guidelines, etc.

   ✚ **Identifying, analyzing, and addressing patient safety** and adverse events

QI/QA PROCESSES

✚ Ensure the health center maintains board-approved QI/QA program policies that address:

- ✚ Hearing and resolving patient **grievances**

- ✚ Completing quarterly **QI/QA assessments**

- ✚ Producing and sharing **reports on QI/QA with board**

- ✚ Has implemented a **certified EHR** for all health center patients

- ✚ Implements and maintains systems and procedures for protecting **confidentiality**

Quality Planning (QP)

"What are we doing to ensure the care we provide is safe, timely, efficient, effective, patient-centered, and with limited variation?"

Quality Management Plan	Risk Management Plan	Quality & Risk Work Plan	Training Plan	Organizational Chart	Job Descriptions

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"What are we doing internally to improve to meet our aims?"

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- Histogram
- Balanced Scorecard
- Appreciative Inquiry
- PDSA
- Control Chart
- Scatter Plot
- Spaghetti Diagram

Model for Improvement

Potential Risk	Trends	Near Misses	Adverse Outcome	Diagnostic Phase	Problem-Solving Phase	Evaluation Phase	Iteration Phase

Model for Improvement

Quality Control (QC)

"How are we verifying/checking whether or not we are meeting our aims?"

- Quarterly Risk Assessments
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Quality Improvement (QI) – External Advocacy

"What are we doing to improve external factors to help meet our aims?"

- Policy Advocacy
- Voter Advocacy
- Communications

BOLDED areas are HRSA-required.

CLAIMS MANAGEMENT PROCESS

✚ Requires **preservation of documentation** and **coordination with HHS/Office of General Counsel**, etc.

✚ **Informs patients** in plain language

　　✚ *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."*

CLAIMS MANAGEMENT TRACKING

Occurrence Date	Name of provider(s) involved / Area of specialty	Summary of Allegations	Status	Documentation of Cooperation With AG / Mitigation Plan
1/1/2019	Dr. John Doe / Family Pract.	A patient alleged that a health center provider improperly diagnosed her cancer.	*Closed*	1. All providers were re-trained in health center lab follow-up policies. 2. Involved provider disciplined and required to attend related medical continuing education trainings.

MAKE A PLAN

	Current Calendar Year												Next Year						
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
Quarterly RM Assessments			X			X			X			X			X			X	
Report quart. RM Asmts to QI	X			X			X			X			X			X			X
Compile Annual RM Report	X												X						
Present Annual Report to BOD		X												X					
Create RM Training Plan												X							
Complete required trainings	X	X	X	X	X	X	X	X	X				X	X	X	X	X	X	X
Review related Policies/Proc			X	X											X	X			
Ensure Cred/Priv up-to-date	X	X	X	X			X	X	X	X	X	X	X	X	X				
Look for new HRSA FTCA PAL	X	X	X										X	X	X				
Complete/Submit FTCA App					X	X											X	X	

RISK MANAGEMENT TRAINING PLAN

✚ Based on identified areas/activities of **highest clinical risk** for the health center.

✚ 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.

RISK MANAGEMENT TRAINING PLAN

✚ Include required areas:

  ✚ **Obstetrical procedures** (for example, continuing education for electronic fetal monitoring (such as the online course available through ECRI Institute), and shoulder dystocia drills).

  ✚ **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).

  ✚ **HIPAA** medical record confidentiality requirements.

  ✚ **Specific training** for groups of providers that perform various services which may lead to potential risk (for example, dental, pharmacy, family practice).

RISK MANAGEMENT TRAINING PLAN

✚ Include required areas:

  ✚ **Annual Risk Manager Training**

  ✚ **Board Risk Management**

  ✚ **Medical Record Documentation**

  ✚ **Follow-up on Adverse Test Results**

  ✚ **Provider-Specific Risk Training**

RISK MANAGEMENT-OB Training

✚ All Clinical Staff (**LIPs, OLCPs, OCS**)

✚ Based on the **OB risks of the health center** and appropriate for all roles

✚ Must be completed between **January 1-December 31**

MAKE A PLAN

	Current Calendar Year												Next Year						
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
Quarterly RM Assessments			X			X			X			X			X			X	
Report quart. RM Asmts to QI	X			X			X			X			X			X			X
Compile Annual RM Report	X												X						
Present Annual Report to BOD		X												X					
Create RM Training Plan												X							
Complete required trainings	X	X	X	X	X	X	X	X	X				X	X	X	X	X	X	X
Review related Policies/Proc			X	X											X	X			
Ensure Cred/Priv up-to-date	X	X	X	X				X	X	X	X	X	X	X	X	X			
Look for new HRSA FTCA PAL	X	X	X										X	X	X				
Complete/Submit FTCA App					X	X											X	X	

RISK MANAGEMENT TRACKING

MAKE A PLAN

	Current Calendar Year												Next Year						
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
Quarterly RM Assessments			X			X			X			X			X			X	
Report quart. RM Asmts to QI	X			X			X			X			X			X			X
Compile Annual RM Report	X												X						
Present Annual Report to BOD		X												X					
Create RM Training Plan												X							
Complete required trainings	X	X	X	X	X	X	X	X	X				X	X	X	X	X	X	X
Review related Policies/Proc			X	X											X	X			
Ensure Cred/Priv up-to-date	X	X	X	X				X	X	X	X	X	X	X	X	X			
Look for new HRSA FTCA PAL	X	X	X										X	X	X				
Complete/Submit FTCA App					X	X											X	X	

RISK MANGAGEMENT ASSESSMENTS

✚ A risk assessment involves **collecting and analyzing** information about the health center's practices, policies, and culture in order to identify deficiencies and make improvements.

✚ Risk Management Assessments involve: **People**, **Processes**, and **Tools**

✚ Risk assessments can include a variety of strategies, including:

  ✚ **Surveys** to evaluate overall safety culture
  ✚ Targeted **questionnaires** to assess specific areas of concern such as test tracking, obstetrics, or medication safety
  ✚ Impact analyses, including a failure mode and effects analysis (**FMEA**)
  ✚ Leadership **walk-arounds**

Quality Planning (QP)

"What are we doing to ensure the care we provide is safe, timely, efficient, effective, patient-centered, and with limited variation?"

Quality Management Plan	Risk Management Plan	Quality & Risk Work Plan	Training Plan	Organizational Chart	Job Descriptions

Quality Aims

Risk Management (RM)

"What are we doing to identify and lower risks of not meeting our aims?"

Adverse Outcome Management

"What are we doing to assess, address, correct, and manage adverse outcomes?"

Quality Assurance (QA)

"What assurances are we providing that we are meeting our aims?"

- Aims-Based Policies & Procedures
- Quality/RM Training Program
- Evidence-based Decision-Support Tools
- Outcome comparison to internal and external benchmarks
- Job Descriptions and Employment Contracts
- Medical Emergency Supplies Daily Check
- C&P
- CLAS Practices
- Referral, Hospitalization, & Diagnostic Tracking Program
- Pt Complaints & Grievance Program
- Clinical Guidelines
- Needs Assessment
- After Hours Care Service
- Hospital Admitting Arrangements
- ONC-certified EHR
- *Daily Patient Care Huddles*
- Pt Board Member Requirements
- *Good Catch Program*
- *Provider Board Certification Requirements*
- Pt Grievance & Complaint Program
- Claims Management
- Pt Safety & Adverse Event Program

Quality Improvement (QI) – Internal

"What are we doing internally to improve to meet our aims?"

- RCA
- FMEA
- Process Maps
- Appreciative Inquiry
- Key Driver Diagram
- Run Charts
- PDSA
- Value Stream Map
- Pareto Chart
- Control Chart
- Checklists
- Histogram
- Scatter Plot
- Gantt Chart
- Balanced Scorecard
- Spaghetti Diagram

Model for Improvement

Potential Risk	Trends	Near Misses	Adverse Outcome	Diagnostic Phase	Problem-Solving Phase	Evaluation Phase	Iteration Phase

Model for Improvement

Quality Control (QC)

"How are we verifying/checking whether or not we are meeting our aims?"

- Quarterly Risk Assessments
- Medical Emergency Drills
- Clinical Staffing Mix Evaluation
- Quarterly Peer Review
- Pt Satisfaction Surveys
- Subrecipient Monitoring
- Clinical Outcome Reports
- Pt Access Eval./3NAA
- *AHRQ Surveys on Pt Culture (SOPS)*
- *Good Catch Forms*
- *Pareto Report of Near Miss and Incident Reports*
- *C/P Audits*
- Pt Grievance & Complaints
- *Chart Documentation Audits*
- *Mock OSVs*
- *After-Hours Test Call*
- Incident Reports
- *Emp. Sat. Surveys*
- *Forms 5A & 5B Review*
- *Service Contract/ MOU Monitoring Review*

Quality Improvement (QI) – External Advocacy

"What are we doing to improve external factors to help meet our aims?"

- Policy Advocacy
- Voter Advocacy
- Communications

BOLDED areas are HRSA-required.
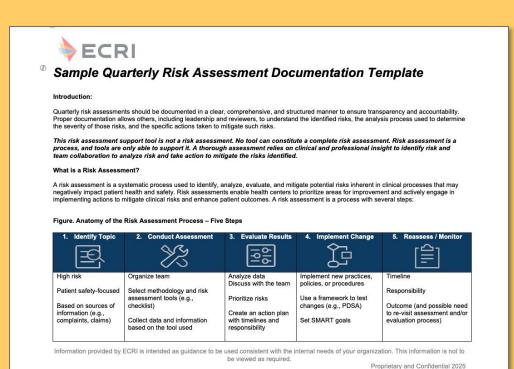
QUARTERLY RISK MANAGEMENT ASSESSMENTS

✚ Completed **quarterly** of calendar year

✚ Use a **standard form** (recommend using updated ECRI forms)

✚ Must be **clinically-focused**
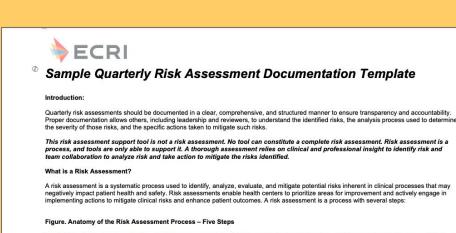
✚ Must have an "**Action Plan**"

QUARTERLY RISK MANAGEMENT ASSESSMENTS

✚ 6 Key Components

   ✚ Purpose Statement

   ✚ Goals

   ✚ Methodology

   ✚ Risk Evaluation

   ✚ Risk Analysis

   ✚ Action Plan

ECRI

Sample Quarterly Risk Assessment Documentation Template

Introduction:

Quarterly risk assessments should be documented in a clear, comprehensive, and structured manner to ensure transparency and accountability. Proper documentation allows others, including leadership and reviewers, to understand the identified risks, the analysis process used to determine the severity of those risks, and the specific actions taken to mitigate such risks.

This risk assessment support tool is not a risk assessment. No tool can constitute a complete risk assessment. Risk assessment is a process, and tools are only able to support it. A thorough assessment relies on clinical and professional insight to identify risk and team collaboration to analyze risk and take action to mitigate the risks identified.

What is a Risk Assessment?

A risk assessment is a systematic process used to identify, analyze, evaluate, and mitigate potential risks inherent in clinical processes that may negatively impact patient health and safety. Risk assessments enable health centers to prioritize areas for improvement and actively engage in implementing actions to mitigate clinical risks and enhance patient outcomes. A risk assessment is a process with several steps:

Figure. Anatomy of the Risk Assessment Process – Five Steps

1. Identify Topic	2. Conduct Assessment	3. Evaluate Results	4. Implement Change	5. Reassess / Monitor
High risk	Organize team	Analyze data	Implement new practices, policies, or procedures	Timeline
Patient safety-focused	Select methodology and risk assessment tools (e.g., checklist)	Discuss with the team	Use a framework to test changes (e.g., PDSA)	Responsibility
Based on sources of information (e.g., complaints, claims)	Collect data and information based on the tool used	Prioritize risks Create an action plan with timelines and responsibility	Set SMART goals	Outcome (and possible need to re-visit assessment and/or evaluation process)

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.

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Page 1 of 6

RISK MANGAGEMENT ASSESSMENTS

✚ Health centers should:
- ✚ **Define the assessment procedure** as part of their Risk Management Plan
- ✚ Conduct risk assessments at least **quarterly** using selected tool(s)
- ✚ **Document** risk assessment results
- ✚ **Evaluate** risk assessment results
- ✚ **Implement changes** to address identified risks
- ✚ **Test** changes
- ✚ **Monitor** changes
- ✚ **Report** all findings to the governing board as part of the annual board report

RISK MANG

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RISK MANGAGEMENT ASSESSMENTS

✚ **Action Plans:**
  ✚ It is not enough to simply assess risk
  ✚ Health centers must show efforts to correct identified risks
  ✚ It is important to monitor and evaluate actions over time

Quality and Risk Management

MAKE A PLAN

					Current Calendar Year									Next Year					
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
Quarterly RM Assessments			X			X			X			X			X			X	
Report quart. RM Asmts to QI	X			X			X			X			X			X			X
Compile Annual RM Report	X												X						
Present Annual Report to BOD		X												X					
Create RM Training Plan												X							
Complete required trainings	X	X	X	X	X	X	X	X	X				X	X	X	X	X	X	X
Review related Policies/Proc			X	X											X	X			
Ensure Cred/Priv up-to-date	X	X	X	X				X	X	X	X	X	X	X	X	X			
Look for new HRSA FTCA PAL	X	X	X										X	X	X				
Complete/Submit FTCA App					X	X												X	X

ANNUAL BOARD RISK MANAGEMENT REPORT

✚ The report must cover the period from **January 1-December 31** of the previous calendar year of submission

✚ Must be reflective of the activities related to risk from the **previous calendar year** (for example, applications submitted in 2026 must demonstrate training was completed in 2025).

✚ Recommend doing this the **same month each year** (February)

ANNUAL BOARD RISK MANAGEMENT REPORT

✚ **Clinical** risk management issues

✚ Risk management **goals**

✚ Progress toward meeting **goals**

✚ Completed risk management **activities**

✚ **Proposed activities** for next CY

✚ Completed **assessments**

✚ Incident **trends**

✚ Patient **satisfaction**

✚ Risk Management **Training Plan**

ANNUAL BOARD RISK MANAGEMENT REPORT

ANNUAL BOARD RISK MANAGEMENT REPORT

✚ Maintain **proof that the health center board has received and reviewed the report.**

MAKE A PLAN

	Current Calendar Year												Next Year						
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
Quarterly RM Assessments			X			X			X			X			X			X	
Report quart. RM Asmts to QI	X			X			X			X			X			X			X
Compile Annual RM Report	X												X						
Present Annual Report to BOD		X												X					
Create RM Training Plan												X							
Complete required trainings	X	X	X	X	X	X	X	X	X				X	X	X	X	X	X	X
Review related Policies/Proc			X	X											X	X			
Ensure Cred/Priv up-to-date	X	X	X	X				X	X	X	X	X	X	X	X	X			
Look for new HRSA FTCA PAL	X	X	X										X	X	X				
Complete/Submit FTCA App					X	X											X	X	

CREDENTIALING/PRIVILEGING

✚ Implemented ongoing Credentialing/Privileging process/procedures
  ✚ *NOTE: New language about PAL 2024-01 (Temporary Privileges)*
✚ Maintains files for all clinical staff that are current and complete
  ✚ *NOTE: FTCA requires credentialing/privileging every 2 years*
✚ Agreements with Column II/III organizations with C/P assurances
✚ Recommend not having C/P files updated in May, June, or July each year

CREDENTIALIN

REGLANTERN
Credentialing and Privileging Policy Checklist

	LIPs Licensed Independent Practitioners *Physician, Dentist, PA, NP*		OLCPs Other Licensed or Certified Practitioners *RN, LPN, CMA, RD, Pharmacist*		Other Clinical Staff *MAs, CHWs where lic. or cert. is not required.*	
Credentialing (Initial Upon Hire)						
Gov't Issued Picture ID (4.1)	X (4.1)		X (4.1)		X (4.1)	
Edu/Training Verification (4.2/4.3/4.3)	X (Primary) (4.2)		X (Prim/Sec*) (4.3)		X (Prim/Sec*) (4.3)	
Credentialing (Upon Hire/Recurring)	*On hire*	*Recurring*	*On hire*	*Recurring*	*On hire*	*Recurring*
Current Lic, Reg, Cert (5.1)	X (Prim)	X (Prim)	X (Prim)	X (Prim)	NA	NA
NPDB Queries (5.2)	X	X	X	X	X	X
DEA (5.3)	X	X	X/If App.	X/If App.	NA	NA
BLS Training Documentation (5.4)	X	X	X	X	X	X
Privileging (Upon Hire/Recurring)	*On hire*	*Recurring*	*On hire*	*Recurring*	*On hire*	*Recurring*
Fitness For Duty* (7)	X	X	X	X	X	X
Immun./Communicable Disease* (8.1)	X / X	X / X	X / X	X / X	X / X	X / X
Current Clinical Competence* (8.2)	X	X	X	X	X	X

General Policy Questions

Frequency of C/P as determined by the health center policies?*	Upon hire and every ___ years.	
Does the policy clearly define the process for documentation of privileging decisions (for example, the completion of a privileging list for each provider)? (11)	Yes / No	Requirements:
Does the privileging policy define how *Fitness For Duty* is determined?* (Describing how physical/ cognitive fitness is verified?	Yes / No	Requirements:
Does the privileging policy define how *Current Clinical Competence* is determined?*	Yes / No	Requirements:
Does the privileging policy define what is included and required for verifying *Immunization and Communicable Disease* status?*	Yes / No	Requirements:
Does the privileging policy cover employees, individual contractors, and volunteers? (6)	Yes / No	
Does the privileging policy have a process for modifying or removing privileges based on the outcomes of clinical competence assessments?* (9)	Yes / No	
Policy board-approved in last 3 years? (Ch. 19, Element d., Question 9.2)	Yes / No	
Temporary privileging FTCA-compliant? (HRSA PAL 2017-07)	Yes / No	

Citations from the Health Center Site Visit Protocol, April 13, 2023, Chapter 5: Clinical Staffing unless specified otherwise.

Primary Source Verification: Verification by the original source of a specific credential of the accuracy of a qualification reported by an individual health care practitioner. Primary source verification could include direct correspondence, telephone, fax, e-mail, or paper or online reports received from original sources (for example, telephone confirmation from an educational institution that the individual graduated with the degree[s] listed on his or her application, confirmation through a state's database that a provider's license is current, reports from credentials verification organizations).

Secondary Source Verification: Verification by sources other than primary sources. Secondary source verification could include verification of the original credential, a notarized copy of credential, a copy of the credential (when copy is made from an original by approved health center staff).

REVISED: 12/21/2023

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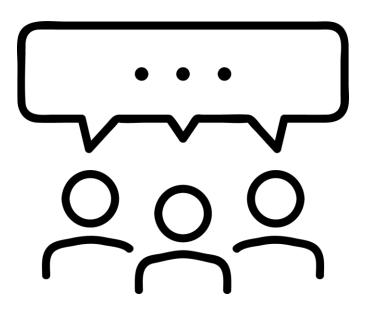
WHO IS COVERED BY FTCA?

+ Employees

+ Officers

+ Directors

+ Governing board members

+ Volunteer Health Professionals (VHPs)
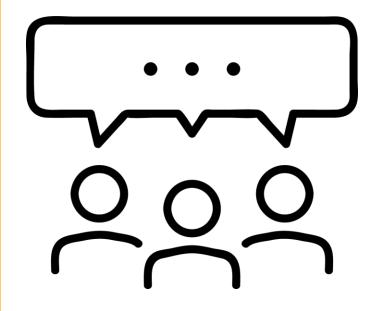
WHO IS COVERED BY FTCA?

✚ Contractors
- ✚ Any full-time licensed or certified contract provider (at least 32.5 hours per week).
- ✚ Part-time licensed or certified contract provider of services in the fields of family practice, ob-gyn, general internal medicine, or general pediatrics.
- ✚ Contract must be between the deemed health center and the individual provider.
- ✚ Contracts between the deemed health center and a corporation (including professional corporations) are not covered.

		Form 5A Column	Any Health Center Employee	Licensed or Certified Providers		
			FT / PT	FT (>32.5hrs/wk)	PT (<32.5hrs/wk)	
			W2 Employees, Officers, Directors, Governing board members	Any licensed or certified provider	In the fields of family practice, ob-gyn, general internal medicine, or general pediatrics	NOT in the fields of family practice, ob-gyn, general internal medicine, or general pediatrics
Employees (W2)		I	YES	YES	YES	YES
Volunteers		I	YES*	YES*	YES*	YES*
Contractor	Individual	II / III	NA	YES	YES	NO
	Organizational	II / III	NA	NO	NO	NO
	Eponoymous	II / III	NA	NO	NO	NO

Need to apply annually for Volunteer Health Providers. See HRSA PAL 2024-04.

MAKE A PLAN

	Current Calendar Year												Next Year						
	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
Quarterly RM Assessments			X			X			X			X			X			X	
Report quart. RM Asmts to QI	X			X			X			X			X			X			X
Compile Annual RM Report	X												X						
Present Annual Report to BOD		X												X					
Create RM Training Plan												X							
Complete required trainings	X	X	X	X	X	X	X	X	X				X	X	X	X	X	X	X
Review related Policies/Proc			X	X											X	X			
Ensure Cred/Priv up-to-date	X	X	X	X			X	X	X	X	X	X	X	X	X	X			
Look for new HRSA FTCA PAL	X	X	X										X	X	X				
Complete/Submit FTCA App					X	X											X	X	

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MAKE A PLAN

FTCA Resources

✚ FTCA Health Center Policy Manual

✚ FTCA Site Visit Protocol

✚ HRSA's FTCA website (https://bphc.hrsa.gov/ftca/index.html)

✚ Current FTCA/HRSA PAL

FTCA Resources

✚ FTCA Application Page: https://bphc.hrsa.gov/initiatives/ftca/application-process

✚ FTCA Application Step-By-Step Guide: https://bphc.hrsa.gov/sites/default/files/bphc/initiatives/ftca-step-step-guide.pdf

✚ HRSA Example (Risk Management Training Plan):
https://bphc.hrsa.gov/sites/default/files/bphc/initiatives/ftca-compliance-tool-risk-management-training-plan.pdf

✚ HRSA Example (Risk Management Tracking Policies):
https://bphc.hrsa.gov/sites/default/files/bphc/initiatives/ftca-deeming-app-tracking-checklist-cy-19.pdf

✚ HRSA Example (Risk Management Annual Report):
https://bphc.hrsa.gov/sites/default/files/bphc/initiatives/ftca-compliance-tool-risk-management-annual-report.pdf

QUESTIONS?

SUPPORT@REGLANTERN.COM