



FTCA DEEMING APPLICATION CLINIC Pre-work Packet

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PRE-WORK INTRODUCTION

FTCA Deeming Application Clinic registrants are required to complete the pre-work packet for specific sessions. The sessions with required pre-work are as follows:

1. HIPAA: Cybersecurity
2. Obstetrics
3. Claims Management
4. Integrating Quarterly Risk Assessments into your Proactive Risk Management Program
5. Reporting Annual Risk Management Activities to the Governing Board

The pre-work documents and instructions for each session will offer needed guidance and materials to be discussed during the training and labs. A checklist has been provided to simplify the completion of the pre-work, and any questions can be directed to hrsasupport@kepro.com.





HIPAA: CYBER SECURITY, OBSTETRICS, & CLAIMS MANAGEMENT

HIPAA: CYBERSECURITY

1. Watch the video on the home (main) page: <https://405d.hhs.gov/>
2. Review the information on the following pages:
 - a. <https://405d.hhs.gov/threats>
 - b. <https://405d.hhs.gov/best-practices>

OBSTETRICS

1. Review article: [Cognitive Bias Article](#)
This article should be considered the “textbook” resource of the presentation because it addresses multiple examples of cognitive bias that create improper clinical decision making resulting in medical errors.
2. Review key definitions and terms: [Obstetrics Pre-Work Terms and Definitions](#)

CLAIMS MANAGEMENT

We will be reviewing these scenarios and associated documents during the presentation. Health centers are encouraged to review these documents prior to the presentation.

1. [Notice of Intent Mrs. Doe](#)
2. [Notice of Intent Patient T](#)
3. [Patient P SF95](#)
4. [Patient W SF95](#)
5. [Employment Contract ABC Health Center](#)
6. [Case Scenario A](#)
7. [Case Scenario B](#)



INTEGRATING QUARTERLY RISK ASSESSMENTS INTO YOUR PROACTIVE RISK MANAGEMENT PROGRAM

1. Review the 2022 FTCA Risk Management Virtual Conference session slides:

[Using Risk Assessments to Implement Positive Change](#)

- a. This information will be helpful in understanding what a risk assessment is and how the risk assessment process fits into your overall risk management program. A short review will be discussed during the presentation.
- b. Optional video presentation and transcripts are available on [ECRI's website](#). ECRI Clinical Risk Management resources are available at no cost to all HRSA-funded health centers on behalf of HRSA. If you don't already have access to the website, please email us at Clinical_RM_Program@ecri.org.

2. Complete the FTCA Sample Quarterly Risk Assessment

Health Centers:

- a. Complete the online version of the [FTCA Sample Quarterly Risk Assessment](#)

b. After completing the online survey, download a summary of your responses in PDF format. To receive credit for all four quarters of the quarterly risk assessment requirement, you must save this PDF and upload the PDF with your application, along with a completed action plan of next steps that focuses on your responses to the assessment findings.

c. We will be practicing with this tool during the presentation. Health centers are encouraged to start using this tool within the organization prior to the presentation.

d. Your risk manager should complete the assessment with support and input from other key subject matter experts as necessary.

Free Clinics and Look-Alikes:

a. Complete the [Quarterly Risk Assessment offline](#) by using the word version of this risk assessment. Do NOT submit the Word document version of this survey to EHB. It is not eligible for credit.

b. The survey includes questions on:

- i. Diagnostic Test Tracking
- ii. Referral Tracking
- iii. Hospitalization Tracking
- iv. Infection Control and Sterilization
- v. Confidentiality (HIPAA)
- vi. Obstetrics
- vii. Preventing Sexual Misconduct
- viii. Cybersecurity

If you have any survey-related questions or need further help with the ECRI Clinical Risk Management Program, please send an email to Clinical_RM_Program@ecri.org.





REPORTING ANNUAL RISK MANAGEMENT ACTIVITIES TO THE GOVERNING BOARD

1. Review the [Risk Management Sample Report to the Board](#)

The sample report is a PDF that contains sample data and analysis. During the presentation, we will be creating a dashboard report from a template. The goal post-presentation is to create a document with your unique data in the format presented, much like this sample document. Note that the document does not just contain data but tells a story of the outcomes of your risk management activities, as well as future proposed actions based on those outcomes.
2. Download the [FTCA Application Procedural Demonstration of Compliance Tool: Risk Management - Annual Report to Board Edition](#)
 - a. The compliance tool is a blank Word document you may adapt for use within your organization.
 - b. This is the tool we will be practicing with during the presentation. Health centers are encouraged to start using this tool within the organization prior to the presentation.
 - c. In order to fill in the report to the board, you will need to gather information specific to your organization as applicable. Please review the Measures/Key Indicators and their summaries described in each section provided. Some measures, particularly for Risk and Patient Safety Activities, may not be applicable to your organization, so you may have no information available that exactly matches what is in the sample report and dashboard. Instead, you will need to report metrics based on the unique clinical risk and patient safety needs of your organization you have previously identified. We will cover the following sections:
 - i. High-Risk and Quarterly Risk Assessments
 - ii. Adverse Event Reporting
 - iii. Risk Management Training
 - iv. Risk and Patient Safety Activities
 - v. Claims Management





PRE-WORK CHECKLIST

PRE-WORK MATERIAL: HIPAA: CYBERSECURITY

1. Watch the video on the home (main) page: <https://405d.hhs.gov/>
2. Review the information on the following page: <https://405d.hhs.gov/threats>
3. Review the information on the following page: <https://405d.hhs.gov/best-practices>

PRE-WORK MATERIAL: OBSTETRICS

1. Review article: [Cognitive Bias Article](#)
2. Review key definitions and terms: [Obstetrics Pre-Work Terms and Definitions](#)

PRE-WORK MATERIAL: CLAIMS MANAGEMENT

1. Review document: [Notice of Intent Mrs. Doe](#)
2. Review document: [Notice of Intent Patient T](#)
3. Review document: [Patient P SF95](#)
4. Review document: [Patient W SF95](#)
5. Review document: [Employment Contract ABC Health Center](#)
6. Review document: [Case Scenario A](#)
7. Review document: [Case Scenario B](#)

PRE-WORK MATERIAL: INTEGRATING QUARTERLY RISK ASSESSMENTS INTO YOUR PROACTIVE RISK MANAGEMENT PROGRAM

1. Review document: [Using Risk Assessments to Implement Positive Change](#)
2. Complete the online version of the [FTCA Sample Quarterly Risk Assessment](#)
3. Download a PDF summary of your FTCA Sample Quarterly Risk Assessment responses

PRE-WORK MATERIAL: REPORTING ANNUAL RISK MANAGEMENT ACTIVITIES TO THE GOVERNING BOARD

1. Review the [Risk Management Sample Report to the Board](#)
2. Download the [FTCA Application Procedural Demonstration of Compliance Tool: Risk Management - Annual Report to Board Edition](#)
3. Complete the report to the board by gathering information specific to your organization.



Terms and Definitions for Pre-Work Risk Management: Obstetrics

Anchoring Bias - prematurely settling on a single diagnosis based on initial data.

Implicit Bias - attitudes that are largely unconscious and may directly contradict the person's expressed beliefs and values.

Cognitive Autopsy - a root cause analysis of medical decision-making and the potential influence of cognitive biases

Omission Bias - the tendency to systematically favor nontreatment.

Zebra Bias - the hesitation to consider a rare diagnosis (zebra) when other, more common diagnoses are part of the differential.

Cognitive Bias - an implicit systematic error in thinking.

January 18, 2023

ABC COMMUNITY HEALTH CENTER
161 Cedar Creek St.
Winchester, VA 22604

Date of Loss: 08/03/2022
Patient: Jane Doe, by her mother Mrs. Doe, and Mrs. Doe, Individually

DEMAND LETTER & Letter of Representation

To ABC Community Health Center,

This law office, Oak Law, has been retained to represent Jane Doe, by her mother Mrs. Doe, and Mrs. Doe, Individually, for injuries they sustained during their August 3, 2022 visit to the ABC Community Health Center. Mrs. Doe was injured when Dr. X roughly opened the door to the examining room causing a clock in the room to fall and hit her head; she was also injured when she stepped on a puddle of water in the parking lot, which caused her to fall and injure herself. During Jane Doe's exam, she fractured her ankle while stepping off a scale that did not have safety handles and/or non-slip mats around the scale.

ABC Community Health Center was negligent in failing to take care of the puddles of water in its parking and in failing to keep the examination room safe for its patients and visitors. ABC Community Health Center was also negligent in failing to place safety handles and non-slip mats around the scale to prevent patients from injuring themselves when stepping on/off the scale. As a result of the negligence, Mrs. Doe suffered a head wound and injuries to her body; Jane Doe has suffered a fractured ankle; and both individuals have also suffered emotional stress due to the injuries. Damages at this time are undetermined.

This letter is intended to comply with the requirements of the FTCA.

Please send all future correspondence to me@oak-law.com, or Oak Law, 567 Rosemont St. #100, Winchester, VA 22601.

Sincerely,

Me Oak

Me Oak
Counsel for Mrs. Doe and Jane Doe

January 14, 2023

ABC COMMUNITY HEALTH CENTER
161 Cedar Creek St.
Winchester, VA 22604

Date of Loss: 2/14/2022
Patient: Patient T

DEMAND LETTER & Letter of Representation

To ABC Community Health Center,

This law office, Oak Law, has been retained to represent Patient T for injuries he sustained on February 14, 2022, while in the Emergency Room of ABC General Hospital. Dr. R negligently performed an intraosseous (IO) line into Patient T's right tibia, which caused him to develop compartment syndrome in the anterior compartment resulting in multiple surgeries and causing Patient T to suffer drop-foot nerve injury and permanent disability.

ABC Community Health Center was negligent in failing to supervise and train Dr. R, and Dr. R was negligent in performing the IO line. As a result of his negligence, Patient T has suffered permanent injuries as well as mental distress. Patient T demands \$1 million in damages.

This letter is intended to comply with the requirements of the FTCA.

Please send all future correspondence to me@oak-law.com, or Oak Law, 567 Rosemont St. #100, Winchester, VA 22601.

Sincerely,

Me Oak

Me Oak
Counsel for Mrs. Doe and Jane Doe

CLAIM FOR DAMAGE, INJURY, OR DEATH		INSTRUCTIONS: Please read carefully the instructions on the reverse side and supply information requested on both sides of this form. Use additional sheet(s) if necessary. See reverse side for additional instructions.			FORM APPROVED OMB NO. 1105-0008	
1. Submit to Appropriate Federal Agency: US Department of Health & Human Services OGC/General Law Division (ATTN: CLAIMS) 330 C Street, SW, Switzer Building, Suite 2100 Washington, DC 20201				2. Name, address of claimant, and claimant's personal representative if any. (See instructions on reverse). Number, Street, City, State and Zip code. <i>Patient P, 8901 Noble Rd, Winchester VA 22604 c/o Barbara Klondike, Esq. 4937 Strauss St. #100 Winchester VA 22601</i>		
3. TYPE OF EMPLOYMENT <input type="checkbox"/> MILITARY <input type="checkbox"/> CIVILIAN	4. DATE OF BIRTH <i>02/13/05</i>	5. MARITAL STATUS <i>S</i>	6. DATE AND DAY OF ACCIDENT <i>8/3/22</i>	7. TIME (A.M. OR P.M.) <i>NA</i>		
8. BASIS OF CLAIM (State in detail the known facts and circumstances attending the damage, injury, or death, identifying persons and property involved, the place of occurrence and the cause thereof. Use additional pages if necessary). <i>Failure to diagnose/timely diagnose appendicitis. Patient P presented to the ER of ABC General Hospital with abdominal pain and discomfort. Dr. X examined Patient P and diagnosed her with a urinary tract infection without an x-ray or consulting a general surgeon. Dr. X discharged Patient P, who then returned to ABC Gen. Hospital with a ruptured appendix.</i>						
9. PROPERTY DAMAGE						
NAME AND ADDRESS OF OWNER, IF OTHER THAN CLAIMANT (Number, Street, City, State, and Zip Code). <i>NA</i>						
BRIEFLY DESCRIBE THE PROPERTY, NATURE AND EXTENT OF THE DAMAGE AND THE LOCATION OF WHERE THE PROPERTY MAY BE INSPECTED. (See instructions on reverse side). <i>NA</i>						
10. PERSONAL INJURY/WRONGFUL DEATH						
STATE THE NATURE AND EXTENT OF EACH INJURY OR CAUSE OF DEATH, WHICH FORMS THE BASIS OF THE CLAIM. IF OTHER THAN CLAIMANT, STATE THE NAME OF THE INJURED PERSON OR DECEDENT. <i>As a result of the above negligence, Patient P was deprived of timely treatment and sustained severe personal injuries including, but not limited to, sepsis and 20 days hospitalization. Patient P has suffered conscious pain and suffering, mental anguish, emotional distress, medical and related expenses, and loss of enjoyment of life.</i>						
11. WITNESSES						
NAME			ADDRESS (Number, Street, City, State, and Zip Code)			
<i>Employees, agents, servants, and/or representatives of ABC Community Health Center Patient P's mother who witnessed her injuries</i>			<i>161 Cedar Creek St. Winchester VA 22604</i>			
12. (See instructions on reverse). AMOUNT OF CLAIM (in dollars)						
12a. PROPERTY DAMAGE <i>NA</i>	12b. PERSONAL INJURY <i>\$1.5 million</i>	12c. WRONGFUL DEATH <i>NA</i>	12d. TOTAL (Failure to specify may cause forfeiture of your rights). <i>\$1.5 million</i>			
I CERTIFY THAT THE AMOUNT OF CLAIM COVERS ONLY DAMAGES AND INJURIES CAUSED BY THE INCIDENT ABOVE AND AGREE TO ACCEPT SAID AMOUNT IN FULL SATISFACTION AND FINAL SETTLEMENT OF THIS CLAIM.						
13a. SIGNATURE OF CLAIMANT (See instructions on reverse side). <i>Barbara Klondike</i>				13b. PHONE NUMBER OF PERSON SIGNING FORM <i>(571) 711-8969</i>	14. DATE OF SIGNATURE <i>8/11/23</i>	
CIVIL PENALTY FOR PRESENTING FRAUDULENT CLAIM The claimant is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages sustained by the Government. (See 31 U.S.C. 3729).				CRIMINAL PENALTY FOR PRESENTING FRAUDULENT CLAIM OR MAKING FALSE STATEMENTS Fine, imprisonment, or both. (See 18 U.S.C. 287, 1001.)		

INSURANCE COVERAGE

In order that subrogation claims may be adjudicated, it is essential that the claimant provide the following information regarding the Insurance coverage of the vehicle or property.

15. Do you carry accident Insurance? Yes If yes, give name and address of insurance company (Number, Street, City, State, and Zip Code) and policy number. No

16. Have you filed a claim with your insurance carrier in this instance, and if so, is it full coverage or deductible? Yes No 17. If deductible, state amount.

18. If a claim has been filed with your carrier, what action has your insurer taken or proposed to take with reference to your claim? (It is necessary that you ascertain these facts).

19. Do you carry public liability and property damage insurance? Yes If yes, give name and address of insurance carrier (Number, Street, City, State, and Zip Code). No

INSTRUCTIONS

Claims presented under the Federal Tort Claims Act should be submitted directly to the "appropriate Federal agency" whose employee(s) was involved in the incident. If the incident involves more than one claimant, each claimant should submit a separate claim form.

Complete all items - Insert the word NONE where applicable.

A CLAIM SHALL BE DEEMED TO HAVE BEEN PRESENTED WHEN A FEDERAL AGENCY RECEIVES FROM A CLAIMANT, HIS DULY AUTHORIZED AGENT, OR LEGAL REPRESENTATIVE, AN EXECUTED STANDARD FORM 95 OR OTHER WRITTEN NOTIFICATION OF AN INCIDENT, ACCOMPANIED BY A CLAIM FOR MONEY DAMAGES IN A SUM CERTAIN FOR INJURY TO OR LOSS OF PROPERTY, PERSONAL INJURY, OR DEATH ALLEGED TO HAVE OCCURRED BY REASON OF THE INCIDENT. THE CLAIM MUST BE PRESENTED TO THE APPROPRIATE FEDERAL AGENCY WITHIN TWO YEARS AFTER THE CLAIM ACCRUES.

Failure to completely execute this form or to supply the requested material within two years from the date the claim accrued may render your claim invalid. A claim is deemed presented when it is received by the appropriate agency, not when it is mailed.

If instruction is needed in completing this form, the agency listed in item #1 on the reverse side may be contacted. Complete regulations pertaining to claims asserted under the Federal Tort Claims Act can be found in Title 28, Code of Federal Regulations, Part 14. Many agencies have published supplementing regulations. If more than one agency is involved, please state each agency.

The claim may be filled by a duly authorized agent or other legal representative, provided evidence satisfactory to the Government is submitted with the claim establishing express authority to act for the claimant. A claim presented by an agent or legal representative must be presented in the name of the claimant. If the claim is signed by the agent or legal representative, it must show the title or legal capacity of the person signing and be accompanied by evidence of his/her authority to present a claim on behalf of the claimant as agent, executor, administrator, parent, guardian or other representative.

If claimant intends to file for both personal injury and property damage, the amount for each must be shown in item number 12 of this form.

The amount claimed should be substantiated by competent evidence as follows:

- (a) In support of the claim for personal injury or death, the claimant should submit a written report by the attending physician, showing the nature and extent of the injury, the nature and extent of treatment, the degree of permanent disability, if any, the prognosis, and the period of hospitalization, or incapacitation, attaching itemized bills for medical, hospital, or burial expenses actually incurred.
(b) In support of claims for damage to property, which has been or can be economically repaired, the claimant should submit at least two itemized signed statements or estimates by reliable, disinterested concerns, or, if payment has been made, the itemized signed receipts evidencing payment.
(c) In support of claims for damage to property which is not economically repairable, or if the property is lost or destroyed, the claimant should submit statements as to the original cost of the property, the date of purchase, and the value of the property, both before and after the accident. Such statements should be by disinterested competent persons, preferably reputable dealers or officials familiar with the type of property damaged, or by two or more competitive bidders, and should be certified as being just and correct.
(d) Failure to specify a sum certain will render your claim invalid and may result in forfeiture of your rights.

PRIVACY ACT NOTICE

This Notice is provided in accordance with the Privacy Act, 5 U.S.C. 552a(e)(3), and concerns the information requested in the letter to which this Notice is attached. A. Authority: The requested information is solicited pursuant to one or more of the following: 5 U.S.C. 301, 28 U.S.C. 501 et seq., 28 U.S.C. 2671 et seq., 28 C.F.R. Part 14.

- B. Principal Purpose: The information requested is to be used in evaluating claims.
C. Routine Use: See the Notices of Systems of Records for the agency to whom you are submitting this form for this information.
D. Effect of Failure to Respond: Disclosure is voluntary. However, failure to supply the requested information or to execute the form may render your claim "invalid."

PAPERWORK REDUCTION ACT NOTICE

This notice is solely for the purpose of the Paperwork Reduction Act, 44 U.S.C. 3501. Public reporting burden for this collection of information is estimated to average 6 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Director, Torts Branch, Attention: Paperwork Reduction Staff, Civil Division, U.S. Department of Justice, Washington, DC 20530 or to the Office of Management and Budget. Do not mail completed form(s) to these addresses.

CLAIM FOR DAMAGE, INJURY, OR DEATH		INSTRUCTIONS: Please read carefully the instructions on the reverse side and supply information requested on both sides of this form. Use additional sheet(s) if necessary. See reverse side for additional instructions.			FORM APPROVED OMB NO. 1105-0008	
1. Submit to Appropriate Federal Agency: US Department of Health & Human Services OGC/General Law Division (ATTN: CLAIMS) 330 C Street, SW, Switzer Building, Suite 2100 Washington, DC 20201				2. Name, address of claimant, and claimant's personal representative if any. (See instructions on reverse). Number, Street, City, State and Zip code. <i>Patient W, 4336 Conifer Rd. Winchester, VA 22602 c/o Donaldson Law Firm, LLC 5400 Cafferty Park Rd. Winchester VA 22601</i>		
3. TYPE OF EMPLOYMENT <input type="checkbox"/> MILITARY <input checked="" type="checkbox"/> CIVILIAN	4. DATE OF BIRTH <i>07/28/2001</i>	5. MARITAL STATUS <i>S</i>	6. DATE AND DAY OF ACCIDENT <i>03/17/2022</i>	7. TIME (A.M. OR P.M.) <i>N/A</i>		
8. BASIS OF CLAIM (State in detail the known facts and circumstances attending the damage, injury, or death, identifying persons and property involved, the place of occurrence and the cause thereof. Use additional pages if necessary). <i>Sexual Assault/medical malpractice by Dr. Q at ABC Community Health Center Dr. Q fondled Patient W's breast while performing a chiropractic exam; Dr. Q did neck manipulation on Patient W.</i>						
9. PROPERTY DAMAGE						
NAME AND ADDRESS OF OWNER, IF OTHER THAN CLAIMANT (Number, Street, City, State, and Zip Code). <i>N/A</i>						
BRIEFLY DESCRIBE THE PROPERTY, NATURE AND EXTENT OF THE DAMAGE AND THE LOCATION OF WHERE THE PROPERTY MAY BE INSPECTED. (See instructions on reverse side). <i>NA</i>						
10. PERSONAL INJURY/WRONGFUL DEATH						
STATE THE NATURE AND EXTENT OF EACH INJURY OR CAUSE OF DEATH, WHICH FORMS THE BASIS OF THE CLAIM. IF OTHER THAN CLAIMANT, STATE THE NAME OF THE INJURED PERSON OR DECEDENT. <i>As a result of Dr. Q's actions, Patient W's world went into a dizzy spin due to nausea and loss of speech; Patient W has permanent damage to her nerve vocal cords and is unable to swallow her food. Patient W also suffered severe insomnia and emotional stress due to Dr. Q's sexual assault. Medical expenses.</i>						
11. WITNESSES						
NAME			ADDRESS (Number, Street, City, State, and Zip Code)			
<i>Dr. Q ABC Community Health Center</i>			<i>161 Cedar Creek St. Winchester VA 22604</i>			
12. (See instructions on reverse). AMOUNT OF CLAIM (in dollars)						
12a. PROPERTY DAMAGE <i>N/A</i>	12b. PERSONAL INJURY <i>\$750,000</i>	12c. WRONGFUL DEATH <i>N/A</i>	12d. TOTAL (Failure to specify may cause forfeiture of your rights). <i>\$750,000</i>			
I CERTIFY THAT THE AMOUNT OF CLAIM COVERS ONLY DAMAGES AND INJURIES CAUSED BY THE INCIDENT ABOVE AND AGREE TO ACCEPT SAID AMOUNT IN FULL SATISFACTION AND FINAL SETTLEMENT OF THIS CLAIM.						
13a. SIGNATURE OF CLAIMANT (See instructions on reverse side). <i>[Signature]</i>			13b. PHONE NUMBER OF PERSON SIGNING FORM <i>(240) 634-7589</i>	14. DATE OF SIGNATURE <i>12/19/22</i>		
CIVIL PENALTY FOR PRESENTING FRAUDULENT CLAIM The claimant is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages sustained by the Government. (See 31 U.S.C. 3729).			CRIMINAL PENALTY FOR PRESENTING FRAUDULENT CLAIM OR MAKING FALSE STATEMENTS Fine, imprisonment, or both. (See 18 U.S.C. 287, 1001.)			

INSURANCE COVERAGE

In order that subrogation claims may be adjudicated, it is essential that the claimant provide the following information regarding the insurance coverage of the vehicle or property.

15. Do you carry accident insurance? Yes If yes, give name and address of insurance company (Number, Street, City, State, and Zip Code) and policy number. No

16. Have you filed a claim with your insurance carrier in this instance, and if so, is it full coverage or deductible? Yes No 17. If deductible, state amount.

18. If a claim has been filed with your carrier, what action has your insurer taken or proposed to take with reference to your claim? (It is necessary that you ascertain these facts).

19. Do you carry public liability and property damage insurance? Yes If yes, give name and address of insurance carrier (Number, Street, City, State, and Zip Code). No

INSTRUCTIONS

Claims presented under the Federal Tort Claims Act should be submitted directly to the "appropriate Federal agency" whose employee(s) was involved in the incident. If the incident involves more than one claimant, each claimant should submit a separate claim form.

Complete all items - Insert the word NONE where applicable.

A CLAIM SHALL BE DEEMED TO HAVE BEEN PRESENTED WHEN A FEDERAL AGENCY RECEIVES FROM A CLAIMANT, HIS DULY AUTHORIZED AGENT, OR LEGAL REPRESENTATIVE, AN EXECUTED STANDARD FORM 95 OR OTHER WRITTEN NOTIFICATION OF AN INCIDENT, ACCOMPANIED BY A CLAIM FOR MONEY

DAMAGES IN A SUM CERTAIN FOR INJURY TO OR LOSS OF PROPERTY, PERSONAL INJURY, OR DEATH ALLEGED TO HAVE OCCURRED BY REASON OF THE INCIDENT. THE CLAIM MUST BE PRESENTED TO THE APPROPRIATE FEDERAL AGENCY WITHIN TWO YEARS AFTER THE CLAIM ACCRUES.

Failure to completely execute this form or to supply the requested material within two years from the date the claim accrued may render your claim invalid. A claim is deemed presented when it is received by the appropriate agency, not when it is mailed.

The amount claimed should be substantiated by competent evidence as follows:

If instruction is needed in completing this form, the agency listed in item #1 on the reverse side may be contacted. Complete regulations pertaining to claims asserted under the Federal Tort Claims Act can be found in Title 28, Code of Federal Regulations, Part 14. Many agencies have published supplementing regulations. If more than one agency is involved, please state each agency.

(a) In support of the claim for personal injury or death, the claimant should submit a written report by the attending physician, showing the nature and extent of the injury, the nature and extent of treatment, the degree of permanent disability, if any, the prognosis, and the period of hospitalization, or incapacitation, attaching itemized bills for medical, hospital, or burial expenses actually incurred.

The claim may be filed by a duly authorized agent or other legal representative, provided evidence satisfactory to the Government is submitted with the claim establishing express authority to act for the claimant. A claim presented by an agent or legal representative must be presented in the name of the claimant. If the claim is signed by the agent or legal representative, it must show the title or legal capacity of the person signing and be accompanied by evidence of his/her authority to present a claim on behalf of the claimant as agent, executor, administrator, parent, guardian or other representative.

(b) In support of claims for damage to property, which has been or can be economically repaired, the claimant should submit at least two itemized signed statements or estimates by reliable, disinterested concerns, or, if payment has been made, the itemized signed receipts evidencing payment.

If claimant intends to file for both personal injury and property damage, the amount for each must be shown in item number 12 of this form.

(c) In support of claims for damage to property which is not economically repairable, or if the property is lost or destroyed, the claimant should submit statements as to the original cost of the property, the date of purchase, and the value of the property, both before and after the accident. Such statements should be by disinterested competent persons, preferably reputable dealers or officials familiar with the type of property damaged, or by two or more competitive bidders, and should be certified as being just and correct.

(d) Failure to specify a sum certain will render your claim invalid and may result in forfeiture of your rights.

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EMPLOYMENT AGREEMENT

This Employment **Agreement** ("Agreement"), effective as of the 8th day of January (2023) is by and between **ABC Community Health Center** ("Employer" or "ABC CHC"), a Virginia not-for-profit corporation having its principal place of business at 161 Cedar Creek St., Winchester, VA, and **Dr. R, by and through TOP PHYSICIAN** ("Physician"), of Great Falls, VA.

WITNESSETH

WHEREAS, **Employer** is currently operating a federally qualified health center, licensed by the Virginia Department of Public Health, in Winchester, Virginia;

WHEREAS, **Physician** possesses a valid and unrestricted license to practice medicine in the Commonwealth of Virginia and is board eligible in Orthopedics;

WHEREAS, **Physician**, throughout the term of this **Agreement**, shall maintain such medical credentials as are necessary to engage in the practice of medicine and Orthopedics in the Commonwealth of Virginia;

WHEREAS, **Physician** represents and warrants to **Employer** that **Physician's** execution and performance of this **Agreement** will not violate or conflict with any other agreement to which **Physician** is a party;

WHEREAS, **Employer** desires to employ **Physician**, and **Physician** desires to be employed by **Employer**;

NOW, THEREFORE, in consideration of the mutual promises and undertakings herein contained, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto mutually agree as follows:

1. DUTIES OF PHYSICIAN

ABC CHC shall employ **Physician** as a part-time Orthopedist who, in addition to the duties described herein, shall have such duties and responsibilities in connection therewith as designated from time to time by **ABC CHC** and as mutually agreed upon by the **Physician**.

A. **Physician** shall provide services to Orthopedic patients of **ABC CHC** in accordance with **ABC CHC's** appointment schedule, which may include weekend and evening hours. **Physician** shall provide direct out-patient care averaging five (5) clinic sessions per week and shall be on-call for the practice on a mutually agreed upon call-schedule per Section 1 B. Each session will be for seven (7) hours. One day of the week or a portion thereof may be set aside for scheduled operative procedures performed at ABC General Hospital (“ABC GH”) in addition to the direct patient care sessions. The direct patient care hours may vary from week-to-week but should average five (5) sessions per week.

B. **Physician** shall participate in the departmental call schedule. Calls shall be at a frequency of one (1) in four (4) weekdays and one (1) in four (4) weekends. The call arrangements will be made with mutual discussion amongst the participating providers within **ABC CHC** and the department staff. The call arrangements will include back up (secondary call) during which **Physician** will be available for any consultative services required by **ABC CHC's** Family Practice providers and **Physician** may be asked to be on primary call wherein the **Physician** will be responsible for addressing all **ABC CHC** patient care responsibilities when such patients seek services either by the telephone or when they present at ABC GH. The number of primary or secondary calls per month can be variable and scheduled according to the needs of the department for that month. **Physicians** shall cover each other's call during vacation/sick times. Participation as part of the severe weather/emergency crew is a requirement in accordance with **ABC CHC** severe weather /emergency preparedness policies.

C. **Physician** shall participate in **ABC CHC** Quality Improvement activities as assigned by the Chief Medical Officer of **ABC CHC** and will attend trainings specified by the Chief Medical Officer including Professional Development Day and periodic cultural competence related training.

D. **Physician** shall cooperate with **ABC CHC** efforts to evaluate **Physician's** performance through chart audits and other means and shall incorporate feedback into **Physician's** practice. An annual performance evaluation shall be scheduled with the Chief Medical Officer in the month of June, or such other time as may be agreed to by **ABC CHC** and **Physician**. Additional evaluations, if necessary, shall be scheduled with the **Physician** during the rest of the year. Performance evaluations may include discussions of standards with respect to completion of medical records, documentation of notes, interaction with personnel, tardiness, any other factors affecting **Physician's** performance, effectiveness, and/or the ability to meet organizational needs. Collective actions may include proctoring, temporary suspension of privileges, or termination of employment in accordance with existing **ABC CHC** policies and procedures.

E. **Physician** agrees that, in the performance of services hereunder, **Physician** shall conform with all recognized rules prescribed by the ethics of the medical profession, and all federal, state and local statutes and ordinances, and all rules, regulations, and by-laws promulgated by **ABC CHC** and such other hospitals at which **Physician** has clinical privileges .

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Physician shall avoid all acts, habits, and conduct that might injure or disrupt in any way, directly or indirectly, the professional reputation and standing of **ABC CHC** or of any of its Physicians.

F. **Physician** shall maintain privileges at a hospital within a reasonable vicinity of ABCCHC throughout the duration of this **Agreement**, including ABC GH.

G. During the term of this **Agreement**, **Physician** agrees not to undertake any private practice or “moonlighting” services that would interfere with care at **ABC CHC** or for **ABC CHC** patients. **Physician** will file and update conflict of interest statements. Any decision to work/moonlight at another practice or organization shall be made only after discussion with the Chief Medical Officer and/or Chief Executive Officer. The **Physician** shall not undertake any such additional activity which interferes with, or adversely affects, the provision of professional services under this **Agreement**, as determined by the Chief Medical Officer and/or Chief Executive Officer. The provider will submit proof of malpractice coverage for all “moonlighting” activities.

H. **Physician** agrees to cooperate, in good faith, with **ABC CHC** in all relationships or arrangements with any HMO, PPO, or PHO and to comply with all rules and regulations of **ABC CHC**, as determined by the Chief Executive Officer.

2 TERM

Physician's employment hereunder shall be deemed to have commenced on the 17th day of January, 2023 and shall continue for twenty four (24) months provided however, that it may be terminated earlier by either party pursuant to Section 5 hereunder.

This **Agreement** will renew at the end of its term unless a new agreement is in place or terminated by either party pursuant to Section 5 hereunder.

3 COMPENSATION

A. Base Salary

Physician's base annual salary shall be \$200,000 paid at \$3,846.15 per week less all applicable taxes and withholdings.

B. Bonus

A total sum of \$7,500.00 will be paid to the **Physician** in three installments as follows: the first payment of \$2,500.00 will be paid two (2) weeks after the start date with **ABC CHC**; the second payment of \$2,500.00 will be paid four (4) weeks after the start date with **ABC CHC**; the third payment of \$2,500 will be paid eight (8) weeks after the start date. This bonus is towards relocation and expenses.

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C. Extra Coverage Incentive

Occasionally the **Physician** may be asked to provide additional coverage for out-patient hours and/or call. The compensation for this additional coverage will be provided according to the prevailing **ABC CHC** Provider Additional Hour Coverage Policy.

4 FRINGE BENEFITS

In addition to the compensation to be paid to **Physician** under Section 3 of this **Agreement**, **Employer** shall, at its sole cost and expense, provide **Physician** with such fringe benefits as **Employer** may deem advisable and as provided in **ABC CHC** Personnel Policies applying to Physicians and other employees; provided, however, that such fringe benefits shall include:

A. Four (4) weeks paid vacation per year as measured from the date of hire, and ten (10) paid holidays per calendar year as defined by **ABC CHC**.

B. Up to Two Thousand Dollars (\$2,000.00) per year, defined as twelve (12) months commencing on July 1st for books, journals, or professional conferences, which offer CME credits or for other educational expenses, subject to submission of receipts and evidence of CME award. Five (5) paid CME days may be used during the year.

C. Dues for up to two (2) professional associations per year, defined as twelve (12) months commencing on July 1st and medical license, Federal and State DEA registration fees, and hospital staff application fees.

D. 100% of the cost of Worker's Compensation Insurance. Workers Compensation is contingent upon the filing for such claims in accordance with **ABC CHC** policies.

E. Ten (10) paid sick days per year.

F. Two (2) paid Personal Days, which must be used within the calendar year.

G. **ABC CHC** will provide full malpractice coverage through the Federal Tort Claims Act for time spent with health center patient care responsibilities. **Physician** is responsible for obtaining and maintaining adequate malpractice coverage and providing proof of same to **ABC CHC** before beginning any private practice or –“moonlighting” activities such as referred to in Section 1.

H. A long-range beeper during the time this **Agreement** is in effect.

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5 TERMINATION

Physician shall be employed to render services from the Commencement Date and continuing until the expiration of ONE (1) year after the Commencement Date, unless this **Agreement** is terminated earlier upon the occurrence of any of the below:

A. Either **Employer** or **Physician** may terminate this **Agreement** by providing one- hundred twenty (120) days written notice of intent to terminate. **ABC CHC** may give pay in lieu of notice.

B. Upon the death of **Physician**;

C. Upon the permanent disability of **Physician**. Permanent Disability under this section shall mean the inability of the **Physician** to perform all of **Physician's** duties and responsibilities hereunder as a result of physical or mental impairment, which inability continues for a period of more than sixty (60) days in any one hundred twenty (120) day period, provided, however, that if any law related to disability or leave requires a longer period of leave for **Physician's** disability, then the time period herein shall be modified to comply with such law;

D. Upon the loss or restriction of **Physician's** license to practice medicine in Virginia, **Physician's** board certification or board eligibility, or the revocation or restriction of **Physician's** Drug Enforcement Administration registration ;

E. Upon the permanent loss or restriction of **Physician's** clinical privileges at ABC GH or such other institution at which **Physician** has significant clinical activity; or

F. By the **Employer** for Cause. Cause under this **Agreement** shall be defined as (i) conviction of the **Physician** for a fraudulent act or felony, (ii) willful misfeasance, illegal, dishonest, or intentional conduct which constitutes a breach of the **Physician's** covenants and obligations under this **Agreement** or under any applicable legal principle, (iii) any conduct, including negligent conduct, which is likely to have an adverse effect, directly or indirectly, on the professional reputation and standing of **Employer** or any of its Physicians, (iv) the **Physician's** failure or inability to satisfactorily perform **Physician's** duties and obligations under this **Agreement**, or (v) any act, event or circumstance constituting cause under the laws of the Commonwealth of Virginia.

Before terminating the **Physician** for Cause (other than pursuant to F(i) or (ii)), the **Employer** shall first provide **Physician** written notice of any alleged basis for a Termination for Cause and **Physician** shall have a period of at least thirty (30) days from receipt of said notice to rectify or cure the conduct in question.

In the event this **Agreement** is terminated, privileges provided by **ABC CHC** to **Physician** shall terminate contemporaneously with termination of employment.

6 MISCELLANEOUS PROVISIONS

A. Governing Law: This **Agreement** shall be governed by and construed in accordance with the laws of the Commonwealth of Virginia.

B. Severability: If any provision of this **Agreement** is held to be illegal, invalid, or unenforceable under present or future laws effective during the term hereof, such provision shall be fully severable and this **Agreement** shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof; and the remaining provisions hereof shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance here from. Furthermore, in lieu of such illegal, invalid, or unenforceable provision, there shall be added automatically as a part of this **Agreement** a provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and still be legal, valid, or enforceable.

C. Entire Agreement: This **Agreement** sets forth the entire understanding of the parties and supersedes all prior agreements or understandings, whether written or oral, with respect to the subject matter hereof. No terms, conditions, warranties, other than those contained herein, and no amendments or modifications hereto shall be binding unless made in writing and signed by the parties.

D. Interpretation: The parties hereto acknowledge and agree that: (i) each party has had the opportunity to consult with counsel, has reviewed and negotiated the terms and provisions of this **Agreement** and has contributed to its revision; (ii) the rule of construction to the effect that any ambiguities are resolved against the drafting party shall not be employed in the interpretation of this **Agreement**; and (iii) the terms and provisions of this **Agreement** shall be construed fairly as to all parties hereto and not in favor of or against any party, regardless of which party was generally responsible for the preparation of this **Agreement**.

E. Counterparts: This **Agreement** may be executed in two or more counterparts, each of which shall be deemed an original, but which together shall constitute one and the same instrument.

F. Waiver: A waiver of any of the terms and conditions herewith shall not be construed as a general waiver by **Employer**.

G. Notices: Any notice required hereunder shall be deemed served if delivered personally or mailed by certified mail, postage prepaid, and properly addressed to the respective party to whom such notice relates at the addresses set forth in the records of **Employer** or at such different address as shall be specified by notice in the manner herein provided .

H. Examination of Books and Records: Until the expiration of this **Agreement** and up to seven (7) years after this **Agreement** terminates **Physician** shall, upon request, make available to the Secretary, U.S. Department of Health and Human Services, the U.S. Comptroller General, the Commissioner of the Virginia Department of Transitional Assistance, audit firms or their representatives this **Agreement** and all other books, documents, and records as are necessary to certify the nature and extent of the costs incurred by **ABC CHC**. In the event that

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there are subsequent changes of classifications or statutes, regulations or rules relating to record keeping, third party reimbursement, physician compensation, or any other matter, which **ABC CHC** determines, must be complied with to insure proper reimbursement from third parties for payments, **ABC CHC** shall notify the **Physician** of the responsibilities of the **Physician**. If the **Physician** provides such services under the **Agreement** through a subcontract worth ten thousand dollars (\$10,000) or more over a twelve (12)-month period with a related organization, the subcontract shall also contain a clause permitting access by the Secretary, Comptroller General, Commissioner and their representatives to the books and records of the related organization. **ABC CHC** mutually agrees to the above requirements in the event **Physician** is audited by parties referenced herein.

I. Non-solicitation: **Physician** agrees that, during **Physician's** employment at **ABC CHC** and for a period of one (1) year after the termination of the **Physician's** employment, regardless of the reason for such termination, the **Physician** will not actively induce, influence, or solicit any employee, agent, or independent contractor of **ABC CHC** to terminate his or her employment or other business relationship with **ABC CHC**, or otherwise interfere with any such employment or relationship, unless otherwise authorized in writing by the Chief Executive Officer, or designee. Nothing in this section is intended or shall be construed to violate G.L. c.112, 12X, or to deprive a patient of the right to see a physician of his /her own choosing.

J. Confidentiality: **Physician** agrees that, during the term of this **Agreement** or at any time thereafter, **Physician** will not use or disclose any Confidential Information which the **Physician** creates or to which the **Physician** has access as a result of the **Physician's** employment by **ABC CHC** and that such information is and shall remain the sole and exclusive property of **ABC CHC**. Confidential Information shall include all documents or electronically stored information containing clinical and other information related to **ABC CHC's** patients, providers, services, business strategy, financial and operating information. The parties acknowledge their ongoing obligations to comply with all HIPAA confidentiality regulations. Nothing in this section is intended or shall be construed to violate G.L. c.112, 12X, or to deprive a patient of the right to see a physician of his /her own choosing.

K. Board Certification: **Employer** will attempt in good faith to allocate cases to **Physician** that are required for Board Certification .

L. Intellectual Property: Any intellectual property created by or in which **Physician** participates in creating (including, but not limited to, inventions, designs, trade secrets, software, and copyrightable works) shall belong to and remain with the **Physician**, provided no **ABC CHC** resources, including time has been utilized by the provider in creating or participating in creating the said intellectual property.

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IN WITNESS WHERE OF, the parties have executed this **Agreement** under seal the day and year herein above written.


EMPLOYER:

**ABC COMMUNITY
HEALTH CENTER**

Meredith Buble
MEREDITH BUBLE
Chief Executive Officer

PHYSICIAN

DR. R. MD.


R. MD
TOP PHYSICIAN

CASE SCENARIO A1

Deemed ABC Community Health Center (“ABC CHC”) contracts with Dr. X, a pediatrician, who works part-time (24 hours a week) at the ABC CHC and is required to provide on-call services at the local hospital to maintain hospital privileges. Dr. X is a pediatrician, who receives direct payment from the ABC CHC to Dr. X, individually. On Monday morning, Mrs. Doe brings in ten-year-old Jane Doe for an annual check-up. Before seeing Dr. X, Nurse Z takes Jane’s vitals and asks Jane to step on the scale, and as Jane is stepping down from the scale she slips and falls. Jane starts to scream and cry. Jane is placed on the examination table by Mrs. Doe, who sits in a chair next to the examining table. Jane is screaming at the top of her lungs and banging at the wall. As Dr. X enters the room, the clock on the wall falls and hits Mrs. Doe on the head. Dr. X with the assistance of Nurses Y and Z checks on Mrs. Doe and Jane. Mrs. Doe insists that she fine and not injured. Jane complains that her right foot is hurting. Dr. X orders an x-ray, which shows Jane’s right ankle has a very slight fracture; Dr. X wraps Jane’s ankle and fits her in a boot. Dr. X instructs Jane to limit use of the right foot for the next four weeks. Dr. X then completes the physical examination on Jane, which is normal.

Mrs. Doe and Jane exit the building to go outside to the parking lot. As Mrs. Doe approaches her car, she steps in a small puddle of water and slips and falls to the ground. Nurses Y and Z witness Mrs. Doe’s fall and rush outside to assist Mrs. Doe, who insists that she is completely fine. A few months later, ABC CHC receives a Notice of Intent to Litigate from the attorney for Mrs. Doe and Jane Doe.

CASE SCENARIO A2

Later that evening, per his schedule, Dr. X was on-call at the local hospital. Patient P (a 16-year-old girl, who is not a patient of ABC CHC) arrived at the emergency room complaining of severe abdominal pain and discomfort. Shortly after Patient P was admitted, Dr. X diagnosed and discharged Patient P with a urinary tract infection. Dr. X made the diagnosis without an x-ray and without consulting a general surgeon. Less than 12 hours from Patient P’s original emergency room visit, she suffered a ruptured appendix, which resulted in an infection of the abdomen. Consequently, Patient P became septic and remained in the hospital for 20 days after the rupture. Patient P filed an administrative tort claim with HHS alleging that Dr. X committed medical malpractice because Dr. X failed to diagnose Patient P’s appendicitis.

CASE SCENARIO B1

ABC Community Health Center (“ABC CHC”), a deemed health center, contracts with chiropractors and orthopedists to provide chiropractic and orthopedic care to its patients. Dr. Q is in his fifth year as a full-time chiropractor. Patient W is a patient of ABC CHC and was seen by Dr. Q to relieve some neck pain. On her second visit, after her visit with Dr. Q, Patient W claims that Dr. Q fondled her breast during the examination and negligently manipulated her neck, which caused her “world to go into a dizzy spin” with nausea and loss of speech. Patient W claims that the neck manipulation Patient W received from Dr. Q permanently paralyzed one of her vocal cords and left her unable to swallow food. Patient W also claims that the sexual assault has caused her to suffer severe insomnia and emotional distress. Patient Q filed an administrative tort claim with HHS requesting damages for her pain and suffering.

CASE SCENARIO B2

Dr. R is a new part-time orthopedist at the ABC CHC; he works 35 hours per week. Dr. R recently signed an employment agreement with ABC CHC (See Employment Contract – ABC Community Health Center). Dr. R is on-call at the local hospital one afternoon, when the ER received non-ABC CHC Patient T, a large man who was ill-appearing, combative, kicking, and unable to be restrained or follow any commands. The ER was understaffed that afternoon, so it requested Dr. R’s assistance with Patient T, who had a critically low blood glucose of 29mg/dL, but due to his combativeness hospital staff was unable to obtain an IV access. Dr. R was finally able to give Patient T an intramuscular injection of Glucagon and an intraosseous (IO) line was placed into his right tibia. Subsequently, Patient T developed compartment syndrome in the anterior compartment, which required multiple surgeries. Patient T filed a Notice of Intent to Litigate against Dr. R for causing Patient T to suffer drop-foot nerve injury and permanent disability.



Using Risk Assessments to Implement Positive Change



Learning Objectives

1. Explain the purpose of risk assessments
2. Review risk assessment requirements
3. Learn how to choose risk assessment focus areas
4. Identify risk assessment tools
5. Understand the risk assessment process



Learning Objective 1: Explain the purpose of risk assessments



Polling Question #1

- At my current organization:
 - Risk assessments are done with a focus on improving patient safety
 - Risk assessments are done because they are required
 - I have heard about risk assessments being done, but I don't know much about the process
 - I don't know if risk assessments are done
 - What exactly is a risk assessment?

Risk Assessments: What

- “A risk assessment is a structured process used to identify potential hazards within the organization's operations, departments, and services.”



FTCA Application Procedural Demonstration of Compliance Tool: Risk Management—Annual Report to Board Edition. High Risk and Quarterly Risk Assessments. (pp. 3-4)

<https://bphc.hrsa.gov/sites/default/files/bphc/initiatives/ftca-compliance-tool-risk-management-annual-report.pdf>

Risk Assessments: Why

- “The Health Center Program Compliance Manual requires quarterly risk assessments **focused on patient safety**... Collecting data on practices, policies, and safety cultures in various areas generates information that can be used to **proactively target patient safety activities and prioritize risk prevention and reduction strategies.**”

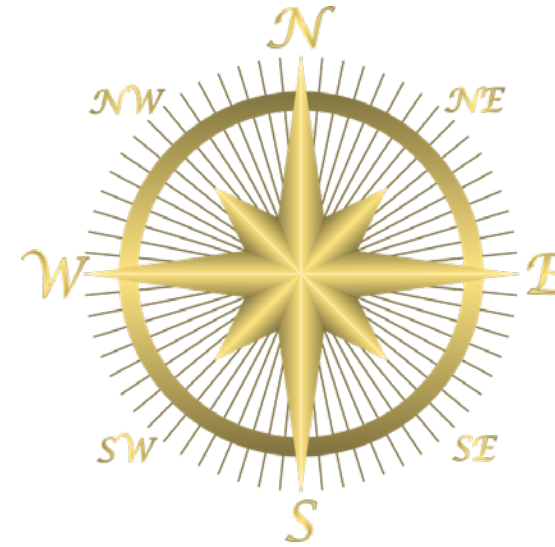


FTCA Application Procedural Demonstration of Compliance Tool: Risk Management—Annual Report to Board Edition. High Risk and Quarterly Risk Assessments. (pp. 3-4)

<https://bphc.hrsa.gov/sites/default/files/bphc/initiatives/ftca-compliance-tool-risk-management-annual-report.pdf>

Risk Assessments: Ultimate Goal

- The true north for healthcare risk assessments is identifying best practices to support patient safety
- The ultimate goal is to successfully implement these practices



Risk Assessments: One Piece of an Ongoing Process

Figure. The Risk Management Decision-Making Process



Overview of the Risk Management Process:

<https://www.ecri.org/components/HRSA/Pages/PSRM9.aspx>



Learning Objective 2: Review risk assessment requirements



Disclaimer

- ECRI provides guidance and resources on risk management and patient safety best practices. For questions about compliance with FTCA requirements, please refer directly to information from HRSA (see slides 14 and 15).

Polling Question #2

- Describe your level of knowledge about risk assessment requirements:
 - I know what is required
 - I have a partial understanding of the requirements
 - I'm uncertain about what is required
 - I have no idea what is required

FAQ: “What are the FTCA requirements for risk assessments?”

- Health Center Program Compliance Manual, Chapter 21: Federal Tort Claims Act (FTCA) Deeming Requirements > Demonstrating Compliance > Risk Management

<https://bphc.hrsa.gov/compliance/compliance-manual/chapter21#demonstrating-compliance-21>

- Health Center Program Site Visit Protocol > Federal Tort Claims Act (FTCA) Deeming Requirements (See “Document Checklist for Health Center Staff” and “Demonstrating Compliance—Risk Management”)

<https://bphc.hrsa.gov/compliance/site-visits/site-visit-protocol/federal-tort-claims-act-ftca-deeming-requirements>

FAQ: “What are the FTCA requirements for risk assessments?” (2)

➤ Program Assistance Letters (PALs)

<https://bphc.hrsa.gov/compliance/policy-information-notices-pins-program-assistance-letters-pals>

- **Refer to the most recent PAL for up-to-date information.** For example: *Calendar Year 2023 Requirements for Federal Tort Claims Act (FTCA) Coverage for Health Centers and Their Covered Individuals (see p. 11 of 24)* <https://bphc.hrsa.gov/sites/default/files/bphc/compliance/pal-2022-01.pdf>

➤ Bureau of Primary Health Care Contact Form

- <https://hrsa.force.com/support/s/>

FAQ: “What are the FTCA requirements for...?”

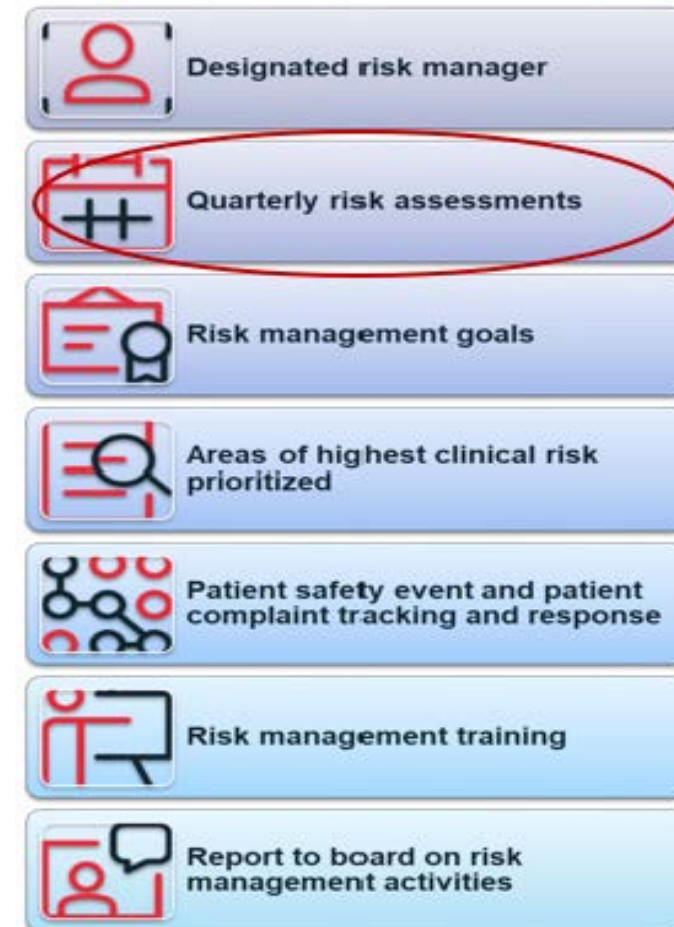
- Health Center Program Compliance Manual, Chapter 21: FTCA Deeming Requirements
 - <https://bphc.hrsa.gov/compliance/compliance-manual/chapter21>
- FTCA homepage
 - <https://bphc.hrsa.gov/initiatives/ftca>
- FTCA Policies and Program Guidance
 - <https://bphc.hrsa.gov/initiatives/ftca/policies-program-guidance>
- BPHC Contact Form
 - <https://hrsa.force.com/support/s/>
- FTCA Technical Assistance Resources
 - <https://bphc.hrsa.gov/initiatives/ftca/technical-assistance-resources>

Risk Assessments: Key Element of a Comprehensive Risk Management Program

- Risk assessments are part of “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.”

Health Center Program Compliance Manual,
Chapter 21: FTCA Deeming Requirements

<https://bphc.hrsa.gov/compliance/compliance-manual/chapter21#demonstrating-compliance-21>



Health Center Compliance Manual, Chapter 21: FTCA Deeming Requirements—Demonstrating Compliance

The screenshot shows the HRSA Health Center Compliance Manual website. The main heading is "Chapter 21: Federal Tort Claims Act (FTCA) Deeming Requirements". Below the heading, there are sections for "Authority" and "Requirements". The "Authority" section cites Section 224(g)-(n), 224(q) of the PHS Act and 42 CFR Part 6. The "Requirements" section states that health centers must submit for approval by HRSA an annual deeming application that...

Chapter 16: Billing and Collections

Chapter 17: Budget

Chapter 18: Program Monitoring and Data Reporting Systems

Chapter 19: Board Authority

Chapter 20: Board Composition

Chapter 21: Federal Tort Claims Act (FTCA) Deeming Requirements

Authority

Requirements

Demonstrating Compliance

Related Considerations

Appendix A: Health Center Program Non-Regulatory Policy Issuances That Remain in Effect

Glossary

Health Center Program Compliance Manual Resources

Demonstrating Compliance

A health center would demonstrate compliance with the FTCA requirements by providing documentation in its annual deeming application, in the form and manner prescribed by HRSA, and consistent with (but not necessarily limited to) the following:

Credentialing and Privileging / Quality Improvement and Quality Assurance

- The health center is currently compliant with all of the [credentialing](#) and [privileging](#) requirements of Chapter 5: [Clinical Staffing](#) and all requirements within Chapter 10: [Quality Improvement/Assurance](#) prior to the deeming determination.

Risk Management

- 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.
- 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

Demonstrating Compliance—Risk Management

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HRSA
Health Center Program

Home | About Health Centers | Compliance

Home » Compliance » Health Center Program Compliance Manual

Download the Health Center Compliance Manual (Last Updated August 2018) (PDF - 2 MB)

Keywords

Health Center Program Compliance Manual

- Introduction
- Chapter 1: Health Center Program Eligibility
- Chapter 2: Health Center Program Oversight
- Chapter 3: Needs Assessment
- Chapter 4: Required and Additional Health Services
- Chapter 5: Clinical Staffing
- Chapter 6: Accessible Locations and Hours of Operation
- Chapter 7: Coverage for Medical Emergencies During and After Hours

Chapter 16: Risk Management

Risk Management

a. 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.

b. 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” that address the following areas for health center services and operations:

Chapter 16: Billing and Collections

Chapter 17: Budget

Chapter 18: Program Monitoring and Data

Demonstrating Compliance

A health center would demonstrate compliance with the FTCA requirements by providing documentation in its annual deeming application, in the form and manner prescribed by the following:

Quality Improvement and Patient Safety

of the credentialing and privileging requirements within Chapter 10: Quality Improvement and Patient Safety.

an ongoing health care risk management program that could result in medical malpractice or other health or health-related litigation and that requires the following:

Health center health care activities;

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.

es 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” that address the following areas for health center services and operations:

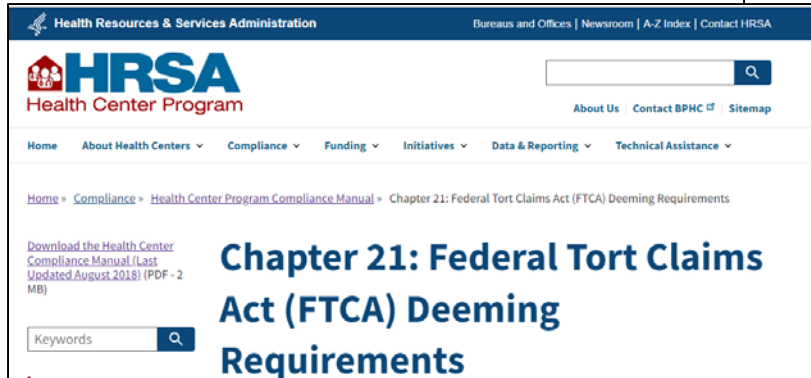
Demonstrating Compliance—Risk Assessments

<p>Health Resources & Services Administration Bureaus and Offices Newsroom A-Z Index Contact HRSA</p> <p>HRSA Health Center Program</p> <p>About Us Contact BPHC Sitemap</p>	<p>Chapter 16: Billing and Collections</p> <p>Chapter 17: Budget</p> <p>Chapter 18: Program</p> <p>Demonstrating Compliance A health center would demonstrate compliance with the FTCA requirements by providing, in the form and manner prescribed by (cited to) the following:</p>	
<p>Home » Compliance » Health Center Program Com</p> <p>Download the Health Center Compliance Manual (Last Updated August 2018) (PDF - 2 MB)</p> <p>Keywords</p> <p>Health Center Program Compliance Manual</p> <p>Introduction</p> <p>Chapter 1: Health Center Program Eligibility</p> <p>Chapter 2: Health Center Program Oversight</p> <p>Chapter 3: Needs Assessment</p> <p>Chapter 4: Required and Additional Health Services</p> <p>Chapter 5: Clinical Staffing</p> <p>Chapter 6: Accessible Locations and Hours of Operation</p> <p>Chapter 7: Coverage for Medical Emergencies During and After Hours</p>	<p>Risk Management</p> <p>a. 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:</p> <ul style="list-style-type: none"> ○ 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. <p>b. The health center has risk management procedures that address the following areas for health center services and operations:</p> <ul style="list-style-type: none"> ○ Identifying and mitigating the health care areas/activities of highest risk within the 	<p>Quality Improvement and</p> <p>of the credentialing and privileging all requirements within Chapter 10: Quality termination.</p> <p>an ongoing health care risk management ; that could result in medical malpractice or t requires the following:</p> <p>health center health care activities;</p> <p>health center staff;</p> <p>ssessments by the health center; and</p> <p>which includes: completed risk center's performance relative to established management activities that relate and/or tional risk.</p> <p>ures that address the following areas for</p> <p>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>Documenting, analyzing, and addressing clinically-related complaints and "near</p>
<p>In order to obtain deemed Public Health Service employment status under sections 224(g)-(n) of the PHS Act⁴ for themselves and for their "covered individuals,"² Health Center Program awardees and subrecipients (including those defined as subrecipients under the Health Center FTCA Medical Malpractice Program regulations),³ hereafter referred to as a "health center" in this chapter, must submit for approval by HRSA an annual deeming application that</p>	<p>Compliance Manual Resources</p>	

Demonstrating Compliance—Risk Assessments (Text Version)

- Health Center Program Compliance Manual, Chapter 21: Federal Tort Claims Act (FTCA) Deeming Requirements...
 - Risk Management: 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...

Health Center Compliance Manual, Chapter 21: FTCA Deeming Requirements—Related Considerations

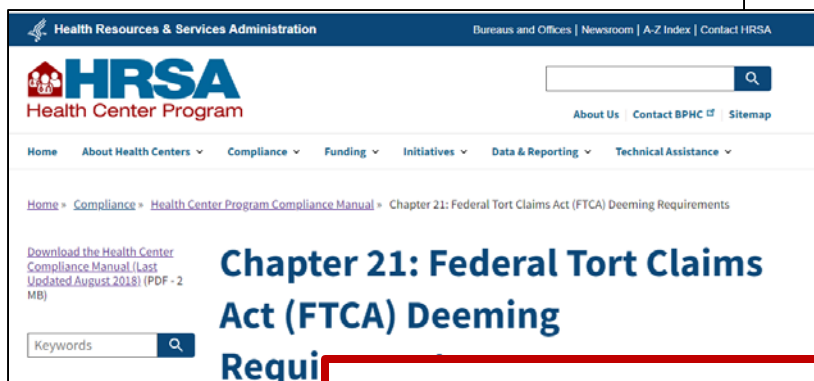


Related Considerations

The following points describe areas where health centers have discretion with respect to decision-making or that may be useful for health centers to consider when implementing these requirements:

- The health center determines how to obtain its health care risk management training (for example, through one of HRSA’s national cooperative agreements or technical assistance contracts) and which trainings to require for covered individuals and the individual(s) designated with risk management responsibilities (for example, risk manager).
- The health center determines what other types of liability coverage to obtain, such as private “gap” or “tail” insurance, directors and officer insurance, and general liability insurance, for activities that may not be eligible for FTCA coverage.
- The health center determines how to conduct and document the completion of quarterly risk management assessments.
- With the exception of health centers that use volunteer health professionals, as to which requirements are prescribed by law,⁶ the health center determines how to inform patients that it is a deemed Federal Public Health Service employee.

Related Considerations—How to Conduct and Document Risk Assessments



Related Considerations

The following points describe areas where health centers have discretion with respect to decision-making or that may be useful for health centers to consider when implementing these requirements:

- The health center determines how to obtain its health care risk management training (for example, through one of HRSA’s national cooperative agreements or technical assistance contracts) and which trainings to require for covered individuals and the individual(s) designated with risk management responsibilities (for example, risk manager).
 - The health center determines what other types of liability coverage to obtain, such as
- The health center determines how to conduct and document the completion of quarterly risk management assessments.
 - With the exception of health centers that use volunteer health professionals, as to which requirements are prescribed by law,⁶ the health center determines how to inform patients that it is a deemed Federal Public Health Service employee.

Polling Question #3

- Which of the following is a required element of risk assessments?
 - Complete one risk assessment per year
 - Use a specific checklist for risk assessments
 - Ensure that each risk assessment covers the same content
 - All of the above
 - None of the above

Polling Question #3 Answer Key (1)

- Which of the following is a required element of risk assessments?
 - *Complete one risk assessment per year is incorrect.* Health centers must complete quarterly risk assessments. (Health centers must also complete an annual risk management report for the board and key management staff.)

Polling Question #3 Answer Key (2)

- Which of the following is a required element of risk assessments?
 - *Use a specific checklist for risk assessments is incorrect.* Health centers determine how to conduct and document risk assessments. While checklists can be a helpful tool for conducting risk assessments, there are no specific risk assessment checklists that must be used.

Polling Question #3 Answer Key (3)

- Which of the following is a required element of risk assessments?
 - *Ensure that each risk assessment covers the same content is incorrect.* Repeating the same risk assessment content may be beneficial in some circumstances; however, the focus and content of each risk assessment should be based on identified areas of high risk, which may change over time.

Polling Question #3 Answer Key (4)

- Which of the following is a required element of risk assessments?
 - *All of the above is incorrect* because the previous choices were all incorrect.
 - *None of the above is the correct answer.*



Learning Objective 3: Learn how to choose risk assessment focus areas



Polling Question #4

- How should we determine what to include in a risk assessment?
 - Follow whatever the checklist says
 - Focus only on OSHA requirements
 - Choose focus areas that can be assessed as efficiently as possible to avoid interrupting daily operations
 - None of the above

Polling Question #4 Answer Key

- How should we determine what to include in a risk assessment?
 - *Follow whatever the checklist says* **is not** the best answer.
 - *Focus only on OSHA requirements* **is not** the best answer.
 - *Choose focus areas that can be assessed as efficiently as possible to avoid interrupting daily operations* **is not** the best answer.
 - *None of the above* **is the best answer**. The other choices do not ensure that patient safety is prioritized or that areas of clinical high risk are assessed.

Risk Assessment Focus Areas

- Risk assessments should be used to evaluate “health care areas/activities of highest risk within the health center’s HRSA-approved scope of project”



Health Center Program Compliance Manual, Chapter 21: FTCA Deeming Requirements

<https://bphc.hrsa.gov/compliance/compliance-manual/chapter21#demonstrating-compliance-21>

Possible Risk Assessment Focus Areas: “Risk Management Procedures”

- Consider focusing some risk assessments on required elements of risk management procedures:
 - “Risk management procedures should address high risk health center services and operations including but not limited to:
 - Tracking referrals, diagnostics, and hospital admissions
 - Clinically-related complaints and ‘near misses’”

Possible Risk Assessment Focus Areas: “Risk Management Training”

- Consider focusing some risk assessments on required elements of risk management training:
 - “Risk management training should address high risk areas/activities including but not limited to:
 - Obstetrical procedures
 - Infection control
 - HIPAA medical record confidentiality requirements”

Words to Remember



“including but not limited to”



Sources for Risk Assessment Focus Areas (1)

- Patient safety events
- Patient complaints and grievances
- Survey results
 - Patient satisfaction
 - Culture of safety
 - Employee satisfaction/burnout
- Areas requiring risk management training (e.g., obstetrics, infection control, HIPAA)
- Disruptive external events (e.g., COVID, weather disaster, negative publicity)

Sources for Risk Assessment Focus Areas (2)

- QI/QA data
- Uniform Data System (UDS) measures
- Closed claims
- Root cause analyses (RCAs) or sentinel events
- External review findings (e.g., HRSA operational site visits, FTCA deeming application and site visit findings, accreditation)
- Electronic health record trouble areas
- Feedback from staff meetings
- Ask staff and providers for their ideas!



Learning Objective 4: Identify risk assessment tools



Risk Assessment Tools

- “A risk assessment is a structured process used to identify potential hazards within the organization's operations, departments, and services.”
- “Risk assessment tools include* self-assessment questionnaires, FMEA [Failure Modes and Effect Analysis], and safety walkrounds.”

**but are not limited to!*



<https://bphc.hrsa.gov/sites/default/files/bphc/initiatives/ftca-compliance-tool-risk-management-annual-report.pdf>

Risk Assessment Tools: FMEA and Safety Walkrounds

➤ FMEA

- A proactive, systematic method of identifying ways a process can go wrong and actions to prevent them
- Focuses on identifying and addressing vulnerabilities *before* harm occurs

➤ Safety Walkrounds

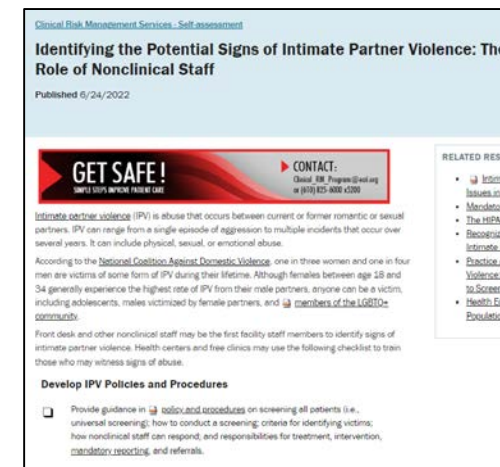
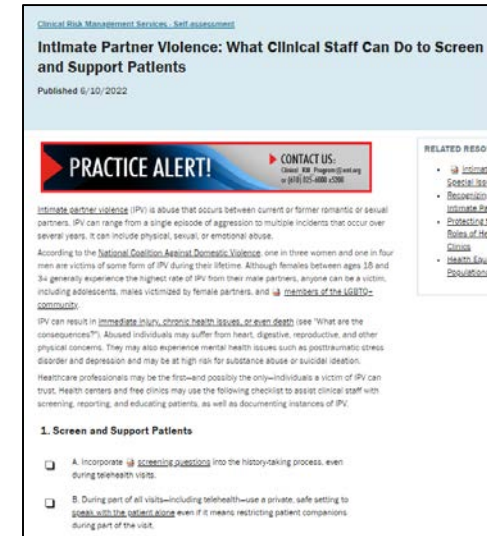
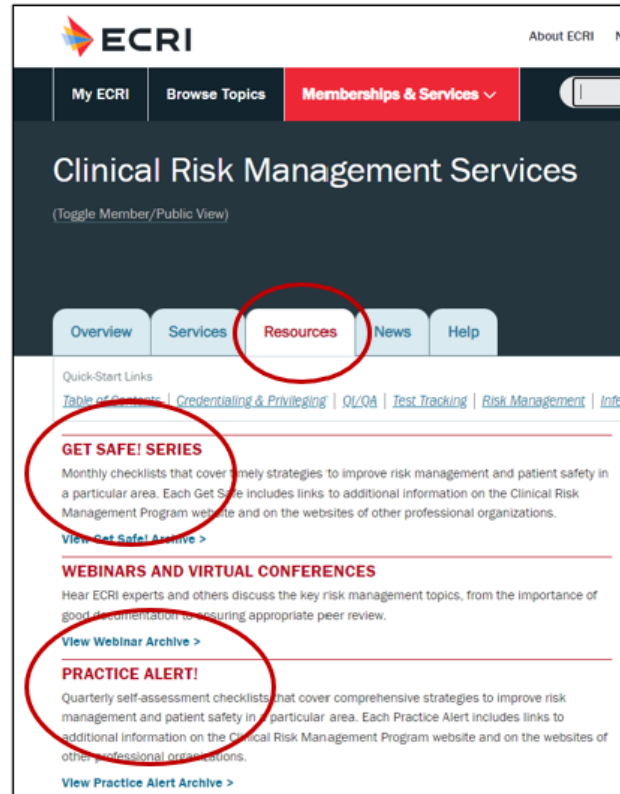
- An interactive way to connect senior leaders with front line staff to educate leadership about safety issues and convey commitment to a culture of safety
- See “Additional Resource” slides at the end of the presentation for more information on these tools

Risk Assessment Tools: Self-Assessment Questionnaires (SAQs) and Checklists

- “Risk assessment” is not synonymous with “checklist”
- A checklist is one of several tools you can use to conduct a risk assessment
- Adapt and edit self-assessment questionnaires/checklists to meet your organizational needs, based on identified areas of risk
- Be sure to include assessment of clinical risks that impact patient safety
- Consider breaking up comprehensive checklists into more manageable pieces

ECRI Get Safe! and Practice Alert! Self-Assessments

- Get Safe! and Practice Alert! checklists can be used as risk assessments
- See the “Resources” tab on the Clinical Risk Management homepage
 - Get Safe — focused
 - Practice Alert — comprehensive



Health Center Stories and Resources—Thank You!

- Thank you to these health center risk managers and their teams who shared risk assessment stories for this program (alphabetical order):
 - Margaret Calero, Cornerstone Family Healthcare (Middletown, NY)
 - Kathy Davenport, Northwest Health Services (St. Joseph, MO)
 - Nishie Perez, North Hudson Community Action Health Center (West New York, NJ)
 - Beth Royal, MedNorth Health Center (Wilmington, NC)

Risk Assessment Story: Telehealth Workflow

Clinical Risk Management Services - Self-assessment

Managing Clinical Risks Associated with Telehealth Programs

Published 5/22/2020

PRACTICE ALERT!

The Health Resources and Services Administration (HRSA) provides information on electronic information and telecommunications technology in clinical healthcare, patient and professional health administration.

Telehealth uses different technologies to deliver care:

- Live videoconferencing, which allows two-way communication between the patient and physician, or between synchronous telehealth.
- "Store and forward," in which patient information from the originating facility's computer system is secured and transmitted to a distant site for review. Store and forward allow for asynchronous telehealth.
- Remote patient monitoring, in which vital signs and other data (e.g., blood glucose levels, indicators of heart rate) are collected by devices, usually at home, and transferred to the healthcare provider, often in the care of patients with chronic conditions.
- Mobile health (mHealth), in which healthcare and public health information are communicated through mobile devices. The information may include general educational information, targeted texts, and notifications about disease outbreaks.

1. Telehealth Program Development

- A. Create a multidisciplinary team to evaluate the feasibility of implementing a telehealth program. Include providers and representatives from senior leadership, information technology, risk management, finance, human resources, and quality improvement.
- B. Collaborate with your regional [telehealth resource center](#) for assistance, education, and information about providing telehealth services, including resources for [telehealth program development](#).
- C. Evaluate telehealth needs of your [specific patient populations](#) and define the telehealth services your program will deliver based on those needs.
- D. Assess your health center's [readiness for telehealth](#) and create an action plan to address any identified gaps.
- E. Incorporate appropriate [evaluation measures](#) to assess the quality of your telehealth program and identify potential opportunities for improvement. Include patient and provider satisfaction measures.
- F. Monitor [national policy](#) and [current state laws](#) related to telehealth and determine whether any changes affect the organization's telehealth program. Extraordinary circumstances may accelerate changes in policy. For example, the COVID-19 pandemic led to [interim telehealth policy changes](#) at both the federal and state level in order to facilitate the rapid adoption of telehealth services across the country.

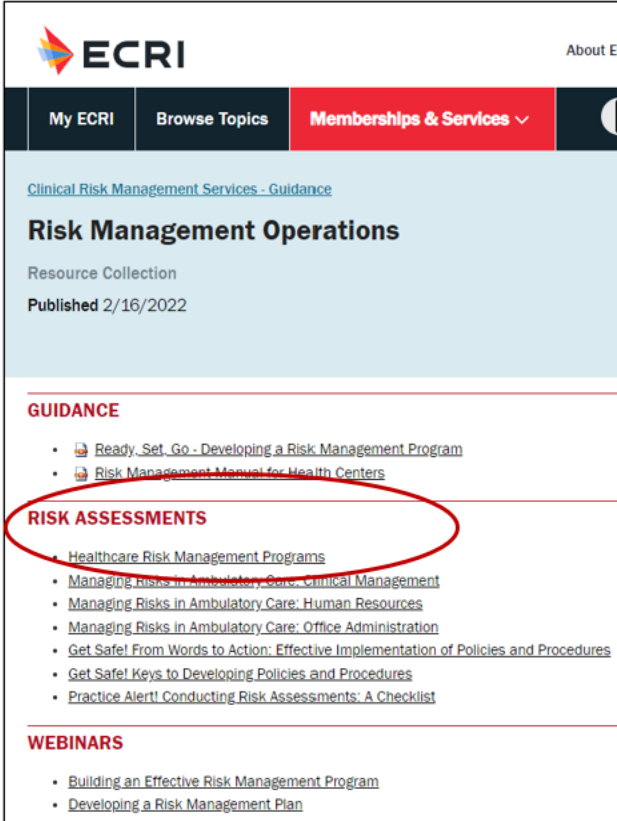
Notes:

- Rapid changes due to pandemic
- One health center piloted new web-based telehealth risk assessment
- Designated time for the assessment increased participation
- Findings/improvements
 - Determining appropriate patients and types of visits
 - Privacy measures
 - Consent processes
 - Need for repeat evaluation

Risk Assessment Checklists: *Managing Risks in Ambulatory Care*

- Found in the Risk Management Operations Resource Collection, under “Risk Assessments”
- More traditional “checklist” style templates include:
 - Managing Risks in Ambulatory Care: Clinical Management
 - Managing Risks in Ambulatory Care: Human Resources
 - Managing Risks in Ambulatory Care: Office Administration

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



The screenshot shows the ECRI website interface. At the top, there is a navigation bar with 'My ECRI', 'Browse Topics', and 'Memberships & Services'. Below this, the page is titled 'Clinical Risk Management Services - Guidance' and 'Risk Management Operations'. Underneath, it says 'Resource Collection' and 'Published 2/16/2022'. The main content area is divided into sections: 'GUIDANCE' with links like 'Ready, Set, Go - Developing a Risk Management Program' and 'Risk Management Manual for Health Centers'; 'RISK ASSESSMENTS' (circled in red) with links like 'Healthcare Risk Management Programs', 'Managing Risks in Ambulatory Care: Clinical Management', 'Managing Risks in Ambulatory Care: Human Resources', 'Managing Risks in Ambulatory Care: Office Administration', 'Get Safe! From Words to Action: Effective Implementation of Policies and Procedures', 'Get Safe! Keys to Developing Policies and Procedures', and 'Practice Alert! Conducting Risk Assessments: A Checklist'; and 'WEBINARS' with links like 'Building an Effective Risk Management Program' and 'Developing a Risk Management Plan'.

Risk Assessment Checklist: Ambulatory Medical and Dental Risk Management Assessment Tool

- Found in the Risk Management Operations Resource Collection, under “Sample Policies and Tools”
- Example sections include:
 - Communication
 - Consent
 - Dental
 - Tracking labs, imaging, and referrals

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



Risk Management Operations

Resource Collection
Published 2/16/2022

GUIDANCE

- [Ready, Set, Go - Developing a Risk Management Program](#)
- [Risk Management Manual for Health Centers](#)

RISK ASSESSMENTS

- [Healthcare Risk Management Programs](#)
- [Managing Risks in Ambulatory Care: Clinical Management](#)
- [Managing Risks in Ambulatory Care: Human Resources](#)
- [Managing Risks in Ambulatory Care: Office Administration](#)
- [Get Safe! From Words to Action: Effective Implementation of Policies and Procedures](#)
- [Get Safe! Keys to Developing Policies and Procedures](#)
- [Practice Alert! Conducting Risk Assessments: A Checklist](#)

WEBINARS

- [Building an Effective Risk Management Program](#)
- [Developing a Risk Management Plan](#)
- [Development and Implementation of Well-Designed Policies and Procedures](#)
- [Getting Back to Basics: Building Blocks for a Strong Risk Management Program](#)
- [How to Implement Effective Policies and Procedures](#)
- [Risk Management Manual for Health Centers: A Guided Tour](#)
- [Writing and Implementing Effective Policies and Procedures](#)

SAMPLE POLICIES AND TOOLS

- [Ambulatory Medical and Dental Risk Management Assessment Tool](#)
- [FTCA Application Procedure Manual/Resource Compliance Tool: Risk Management-Annual Report to Board Edition](#)
- [Patient Safety and Risk Management Plan Informational Flowchart](#)
- [Patient Safety and Risk Management Plan Operational Checklist](#)
- [A Division Office Manual Sample Table of Contents](#)

Ambulatory Medical and Dental Risk Management Assessment Tool				
Site location:		Reviewer:		
Date of annual review:				
Quarterly follow-up review				
<input type="checkbox"/> Q1				
<input type="checkbox"/> Q2				
<input type="checkbox"/> Q3				
<input type="checkbox"/> Q4				
OPERATIONAL RISK MANAGEMENT				
TOPIC	YES	NO	NA	FINDINGS/COMMENTS
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
FACILITY ACCESS				
1. Facility is adequately signed and the entrance is easily identified.				
2. Office hours are posted and easily identified.				
3. The building and facilities are handicapped accessible.				

COMMUNICATION				
1. There is an effective way for patients to reach the providers in the practice after hours.				
2. The after-hours messaging clearly states what the patient should do in an emergency.				
3. Staff use active listening techniques.				
4. There are established protocols of communication between the front desk and the treatment area.				
TOPIC				
	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
5. Front office employees and medical assistants only provide information that is in compliance with written protocols or processes approved by the provider.				
6. Staff members are instructed to consult a provider whenever they are in doubt about the correct answer.				
7. Interpreters for limited English proficiency or hard of hearing patients are available on demand.				
8. Email is done via a secure portal or other secure means.				
9. Emails from the patient and responses thereto are kept in the chart.				
10.				
11.				
12.				

Risk Assessment Story: Dental Safety

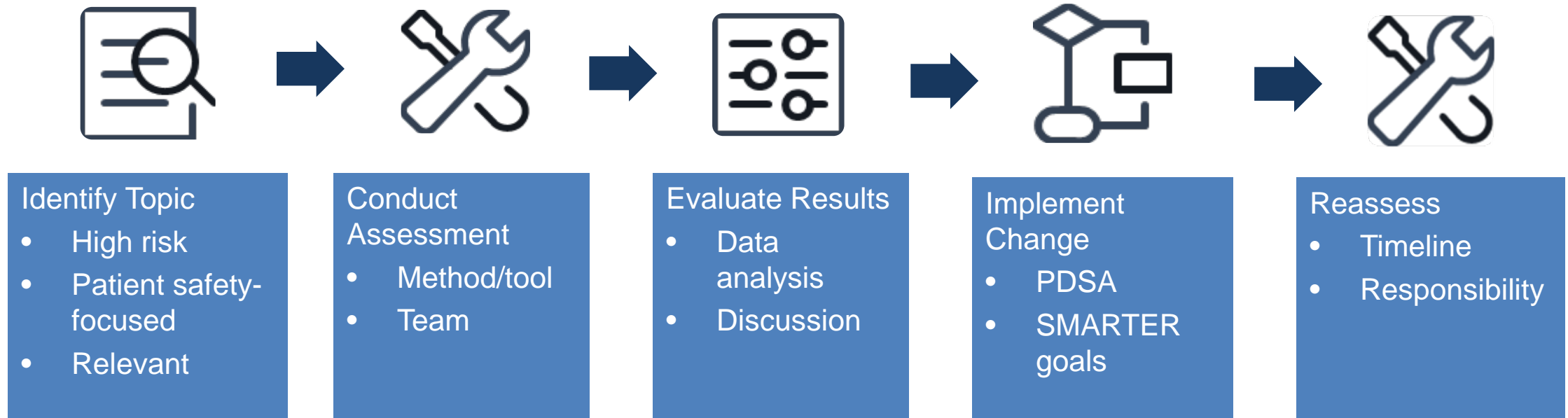
- Adapted Ambulatory Medical and Dental Risk Management Assessment Tool
- Identified need for dental dams



Learning Objective 5: Understand the risk assessment process



Anatomy of the Risk Assessment Process



- Include in:
- Risk management plan
- Annual risk management report to board of directors

Example: Risk Assessment Process (1)

- At a staff meeting, the office manager reports an increase in appointment “no-shows,” late arrivals, and last-minute cancellations
- The risk manager and office manager discuss concerns related to this increase (e.g., medically fragile patients not receiving follow-up care)
- Due to the potential impact on patient safety, they decide to do a risk assessment focusing on this issue
- The risk manager, office manager, scheduling assistant, lead social worker, and IT manager form a team and design an audit tool
- They analyze results and find that most patients with disrupted appointments over the past three months live in one geographic area

Example: Risk Assessment Process (2)

- The lead social worker investigates further and determines that a bus route had changed, eliminating two stops in that area
- Designated staff contact patients who have had disrupted appointments and who live in the impacted area to discuss transportation
- The lead social worker and other social services staff work with local transportation services on a collaborative action plan
- The team creates a specific monitoring process and timeline and assigns responsibility for follow-up on the action plan

Risk Assessment Story: Environment of Care—Restroom Locks

- Combined safety walkrounds and self-assessment checklist approach
- Discovered and immediately addressed patient safety issue with restroom locks

Risk Assessment Story: Procedural Safety—Consents and Time Outs

- Used medical record audit to assess and address obstetric procedural consents and time outs

Guidance on Conducting a Risk Assessment

- Practice Alert! Conducting Risk Assessments: A Checklist
 - <https://www.ecri.org/components/HRSA/Pages/PracticeAlerts033018.aspx>

[Clinical Risk Management Services - Self-assessment](#)

Conducting Risk Assessments: A Checklist

Published 3/30/2018

PRACTICE ALERT!

CONTACT US:
Clinical_RM_Program@ecri.org
or (610) 825-6000 x5200

Risk assessments involve collecting and analyzing information about the health center or free clinic's practices, policies, and culture. This process arms the risk manager with data that can be used to proactively design patient and worker safety and prioritize risk prevention and reduction strategies.

Risk assessments can include a variety of strategies, including surveys to evaluate overall safety culture, as well as targeted questionnaires to assess specific areas of concern such as test tracking, obstetrics, or medication safety. Health centers and free clinics can also use leadership walk-arounds to give executive staff an opportunity to hear from employees about potential risks and concerns.

No matter what strategy an organization chooses, the organization should document results and use the results for improvement. Health centers and free clinics can use the following checklist to guide risk assessments. In addition, see [Case Study: What Does a Risk Assessment Look Like?](#) which highlights the steps of a risk assessment process.

Conducting Risk Assessments: A Checklist			
Preparing for the Assessment	Yes	No	N/A
Are processes for risk assessments included in the health center or free clinic's ongoing risk management program and plan ?			
Does the health center or free clinic's culture support ongoing assessment, learning, and improvement?			
Has the health center or free clinic ensured leadership			

Tool for Documenting Quarterly Risk Assessments

- FTCA Application Procedural Demonstration of Compliance Tool: Risk Management—Annual Report to Board Edition. High Risk and Quarterly Risk Assessments. (pp. 3-4)
 - <https://bphc.hrsa.gov/sites/default/files/bphc/initiatives/ftca-compliance-tool-risk-management-annual-report.pdf>



HRSA
Health Center Program

areas generates information that can be used to proactively target patient safety activities and prioritize risk prevention and reduction strategies.

Risk Activity Focus Area/Measure	Summary Description of Assessment/Methodology/Indicators

Data Summary

See the dashboard below for completed risk management activities and status of the health center's performance relative to established risk management goals.

Person responsible	Measure/Key Performance Indicator	Threshold/Goal	Q1	Q2	Q3	Q4	Annual Total

SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats

Follow-up Actions

[QUARTER, YEAR]:

[QUARTER, YEAR]:

[QUARTER, YEAR]:

[QUARTER, YEAR]:

Conclusion

Proposed Future Activities

Take Home Action Plan for Frontline Staff (1)

- Write down a risk assessment priority that could benefit your organization
 - *“Several incident reports involving medication administration errors were reported in the past few weeks. I think we should look more closely at this trend by doing a risk assessment.”*
- Specify how or why this risk assessment would be beneficial
 - *“A structured approach to identifying factors contributing to these incidents can help us find solutions to prevent additional errors. We can use this as one of our required quarterly risk assessments.”*

Take Home Action Plan for Frontline Staff (2)

- Identify a possible tool to utilize for this risk assessment
 - ECRI Medication Safety Resource Collection
https://www.ecri.org/components/HRSA/Pages/ResourceCollection_MedicationSafety.aspx
 - ECRI Risk Management Operations Resource Collection
https://www.ecri.org/components/HRSA/Pages/ResourceCollection_RiskManagementOperations.aspx
 - “Medication Management” section of *Ambulatory Medical and Dental Risk Management Assessment Tool* and “Medication Safety” section of *Managing Risks in Ambulatory Care: Clinical Management*
- Share this information with the leadership team
- Follow up to see if action is being taken

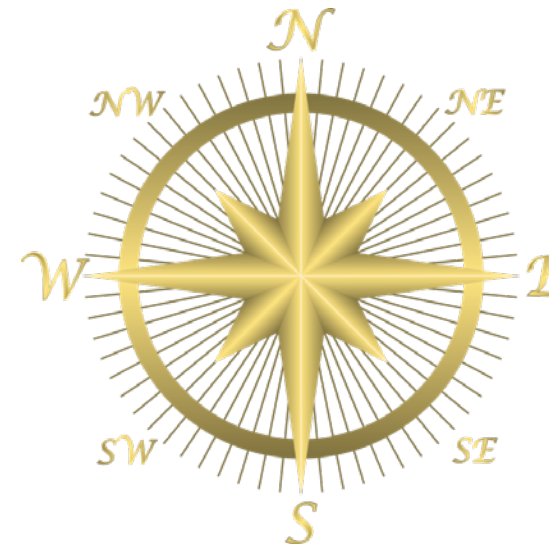
Take Home Checklist for Leadership

Do we:

1. **Prioritize** patient safety by assessing areas of high clinical risk?
2. **Tailor** risk assessments to our organization?
3. **Use tools** to structure risk assessments?
4. **Evaluate** assessment findings to identify gaps and implement process changes?
5. **Document** risk assessment procedures and related process changes?
6. **Revisit** process changes to ensure they are having the intended outcome?
7. **Incorporate** risk assessment procedures into the overall risk management plan?
8. **Include** quarterly risk assessment topics, findings, and related process changes in the annual risk management report to the Board of Directors?

Risk Assessments: Ultimate Goal (Revisited)

- The true north for healthcare risk assessments is identifying best practices to support patient safety
- The ultimate goal is to successfully implement these practices





Additional Resources



Risk Assessment Tools: FMEA

- Ready, Set, Go: Failure Mode and Effects Analysis
 - <https://www.ecri.org/components/HRSA/Documents/Csuites/Ready%20Set%20Go%20-%20Failure%20Modes%20and%20Effects%20Analysis.pdf>
- Healthcare Failure Mode and Effect Analysis (HFMEA) (U.S. Department of Veterans Affairs)
 - <https://www.patientsafety.va.gov/professionals/onthejob/hfmea.asp>
- FMEA Tool (Institute for Healthcare Improvement)
 - <https://bit.ly/3AirtDG>
- Guidance for Performing FMEA with Performance Improvement Projects (CMS)
 - <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/QAPI/downloads/GuidanceForFMEA.pdf>

Risk Assessment Tools: Safety Walk Rounds

- Patient Safety Leadership WalkRounds™ (Institute for Healthcare Improvement)
 - <https://www.ihl.org/resources/Pages/Tools/PatientSafetyLeadershipWalkRounds.aspx>
- Patient Safety Walkrounds™ Toolkit (London Health Sciences Centre)
 - https://www.lhsc.on.ca/doc/orientation/falls/presentation_content/external_files/Patient%20Safety%20WalkRounds%20Toolkit.pdf
- Executive Rounds for Safety (Washington State Hospital Association)
 - <http://www.wsha.org/wp-content/uploads/ExecLeadershipRounding.pdf>
- The evolving literature on safety WalkRounds: emerging themes and practical messages (BMJ Quality & Safety)
 - <https://qualitysafety.bmj.com/content/23/10/789.long>

Safety Culture Risk Assessments

- Measuring Safety Culture
 - <https://www.ecri.org/components/HRSA/Pages/PSRM12.aspx>
- Safety Attitudes Questionnaire (Ambulatory Version)
 - <https://www.ecri.org/components/HRSA/Documents/SPT/PSRM/PSRMPol1.pdf>
 - Also see *Safety Attitudes and Safety Climate Questionnaire* (UTHealth Houston) <https://www.uth.edu/chqs/safety-survey>
- Medical Office Survey on Patient Safety Culture (Agency for Healthcare Research and Quality)
 - <https://www.ahrq.gov/sops/surveys/medical-office/index.html>

Safety Culture Risk Assessments (2)

- Culture of Safety Organizational Self-Assessment (American College of Health Executives)
 - Electronic version: <http://safety.ache.org/quiz/culture-of-safety-organizational-self-assessment/>
 - Printable version (starts on p. 40 of 48):
https://www.osha.gov/sites/default/files/Leading_a_Culture_of_Safety-A_Blueprint_for_Success.pdf

Additional Risk Assessment Templates and Tools

- Safety Risk Assessment Toolkit (The Center for Health Design) (free with registration)
 - <https://www.healthdesign.org/sra>
- Infection Prevention and Control Assessment Tool for Outpatient Settings (CDC)
 - <https://www.cdc.gov/infectioncontrol/pdf/icar/outpatient.pdf> (English)
 - <https://www.cdc.gov/infectionControl/pdf/icar/Outpatient-es-P.pdf> (Spanish)

Additional Risk Assessment Templates and Tools (2)

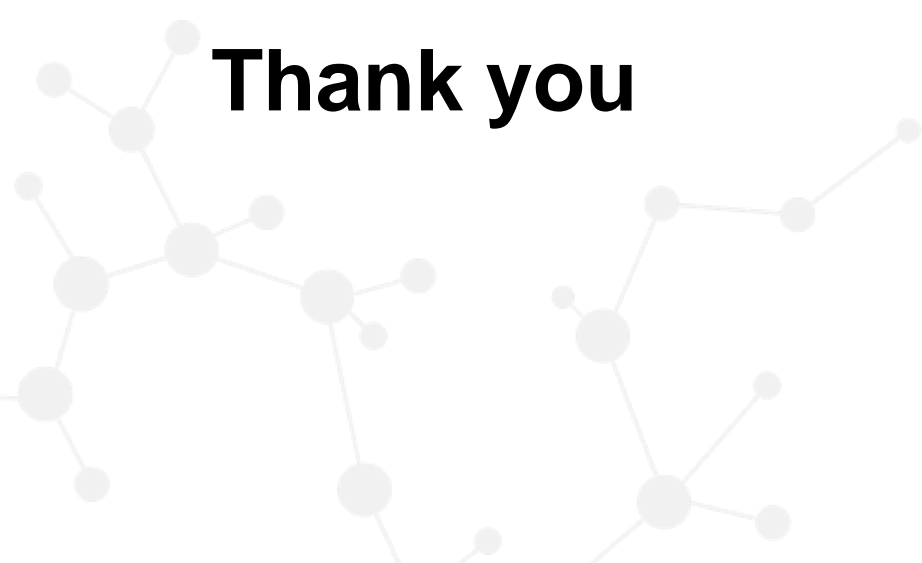
- Sample risk assessment template (Health and Safety Executive)
 - <https://www.hse.gov.uk/simple-health-safety/risk/risk-assessment-template-and-examples.htm#article>
- Implementation of Quarterly Risk Assessments
 - Webinar recording: https://hrsa.gov.zoomgov.com/rec/share/vJkCAGTSndI3mgz_j0Ak9N-5FSE7-KtKsJbK8Y0o7kZoVN3VJSJtjttPAYUcxaqg.STDMedUc6SuPrvsp?startTime=1636048722000
 - Slides: <https://bphc.hrsa.gov/sites/default/files/bphc/initiatives/ftca-quarterly-risk-assessments.pdf>



Questions?

Please email us at Clinical_RM_Program@ecri.org.

Thank you





Sample Quarterly Risk Assessment for Ambulatory Care

Ambulatory care facilities are exposed to many risks associated with clinical activities. This sample quarterly risk-assessment is designed to identify and address some of the high-risk clinical situations encountered in the ambulatory care setting. This risk assessment is not intended to be comprehensive. After completing this short assessment, an action plan should be established for addressing the shortcomings that the assessment reveals. This risk assessment can be completed routinely to periodically assess progress in various areas.

Yes	No	N/I ¹	N/A	Comments
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Diagnostic Test Tracking

1. Is there a process in place that ensures laboratory and x-ray results are tracked, received, acknowledged by the practitioner, and reported to the patient in a timely manner?
2. Is there a policy that differentiates between normal, abnormal, and critical test results and includes resources that specify laboratory test reference ranges?
3. Is there a process for reporting critical results to the practitioner immediately?
4. Is there a policy that requires patient notification of lab results and other tests, even if results are within normal limits?

Referral Tracking

5. Is there a process in place that ensures referrals and associated consultation reports are tracked, received, acknowledged by the practitioner, and reported to the patient in a timely manner?
6. Is there a mechanism in place to ensure the consulted provider's

¹ N/I stands for "Needs Improvement"



findings have been incorporated into the patient's plan of care?

7. Is there a policy to follow-up with patients who do not complete a referral within the timeframe specified by the ordering physician?

Yes	No	N/I ¹	N/A	Comments

Hospitalization Tracking

8. Is there a tracking system in place for receiving information regarding hospital or emergency department (ED) admissions?
9. Is there a mechanism in place 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?

Infection Control and Sterilization

10. Do written infection control policies and procedures address: identifying infection risks, preventing infection, reporting results to health authorities, and providing a plan to implement measures to reduce infection risks?
11. Is there a control plan to identify and manage suspected transmittable diseases (e.g., tuberculosis, COVID-19)?
12. Do cleaning procedures adhere to manufacturers' guidelines, state and federal guidelines, and acceptable standards of practice regarding the cleaning, disinfection, and sterilization of instruments, equipment, and supplies?

Confidentiality (HIPAA)

13. Are there systems in place (for example, certified electronic health records and corresponding standard

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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?

14. Is there a designated individual, such as a privacy officer, to oversee HIPAA-related training, policies and procedures, self-assessments, and other HIPAA compliance measures?

Yes	No	N/I ¹	N/A	Comments

Obstetrics

15. Does the organization include obstetrical training as part of the health center risk management training plan?
16. Is there a policy allowing collaborative relationships between providers and obstetricians and practitioners other than obstetricians (e.g., certified nurse-midwives, family practitioners, physician assistants) to provide obstetric care with written supervision, practice agreements, and protocols?
17. Are pregnant patients assessed for high-risk factors, common medical complications, and mental health status, including screening for depression or history of depression?
18. Is there a written escalation protocol identifying when and what type of abnormal findings require prompt reporting to a provider and the thresholds for patient transfer to a higher level of care?
19. Is a tracking process in place to ensure that pregnant patients attend their scheduled appointments, and that complete testing and referral results are communicated to them?
20. Are clinicians and staff trained on postpartum complications such as cardiovascular disease, venous thromboembolism, postpartum preeclampsia, postpartum



- hemorrhage, postpartum infection and sepsis, and postpartum depression?
21. Are comprehensive postpartum visits scheduled and conducted no later than 12 weeks after birth on all eligible patients?

Yes	No	N/I ¹	N/A	Comments

Preventing Sexual Misconduct

22. Does the organization have policies and procedures addressing suspected or confirmed sexual misconduct involving providers or staff and patients, either as a stand-alone policy or part of other organization policies around topics such as hiring and firing, credentialing, or romantic or sexual relationships between providers or staff and patients?
23. Does the organization have policies and procedures regarding providing chaperones as part of sensitive patient exams?

Cybersecurity

24. Does the organization have policies and procedures in place to prevent, detect, and respond to security incidents?
25. Is there a designated individual, such as a security officer, to oversee IT security related training, policies and procedures, self-assessments, and other related processes?
26. Are staff routinely trained on the risk of IT security breaches from: computer viruses, malware attacks (e.g., phishing, spam ware), equipment theft, and intentional or unintentional HIPAA violations?



Action Plan

Assessment Completed

Date:

By:

Question No.	Action Required	Responsibility	Target Date	Action Completed	
				Date	Initials



Recommended Resources

Tracking (Diagnostic Test, Referral, and Hospitalization)

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

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

FTCA Deeming Application Tracking Policies:

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

Improving Your Laboratory Testing Process: <https://www.ahrq.gov/hai/tools/ambulatory-care/lab-testing-toolkit.html>

Closing the Loop: A Guide to Safer Ambulatory Referrals in the EHR Era:

<https://www.ihl.org/resources/Pages/Publications/Closing-the-Loop-A-Guide-to-Safer-Ambulatory-Referrals.aspx>

Infection Control and Sterilization

Infection Control Resource Collection:

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

Guide to Infection Prevention for Outpatient Settings:

<https://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html>

Confidentiality (HIPAA)

Laws, Regulations, and Compliance Resource Collection:

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

HIPAA Training and Resources: <https://www.hhs.gov/hipaa/for-professionals/training/index.html>

Obstetrics

Maternal and Perinatal Health and Safety Resource Collection:

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

Optimizing Postpartum Care: <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/05/optimizing-postpartum-care>

ACOG Redefines the Postpartum Visit – The ‘Fourth Trimester’:

<https://www.obgproject.com/2022/04/25/acog-revises-redefines-postpartum-visit/>

Preventing Sexual Misconduct

Human Resources Resource Collection:

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



Privacy, Security, and HIPAA: <https://www.healthit.gov/topic/privacy-security-and-hipaa>

Sexual Harassment and Prevention Training: <https://www.ncbi.nlm.nih.gov/books/NBK587339/>

Cybersecurity

Health Information Technology Resource Collection:

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

Privacy, Security, and HIPAA: <https://www.healthit.gov/topic/privacy-security-and-hipaa>

Topic Collection: Cybersecurity: <https://asprtracie.hhs.gov/technical-resources/86/Cybersecurity/86>



Risk Management Report to Board: Sample Report and Dashboard

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

How to use this tool. Health centers can work within the format of this report to input their own data and information. The dashboards and SWOT (Strengths, Weaknesses, Opportunities, Threats) analyses referenced in this tool are examples of ways to present the information; however, health centers may choose other formats (e.g., graphs, charts, narrative) depending on their needs and preferences. The sample information provided within this tool is not all-inclusive; health centers should provide specific information that is both accurate and sufficient to inform the board and key management staff on all health care risk management activities and progress related to follow-up actions that have been implemented as well as next steps.

DISCLAIMER

Information provided by ECRI is not intended to be viewed as required by ECRI or the Health Resources and Services Administration, nor should these materials be viewed as reflecting the legal standard of care. Further, these materials should not be construed as dictating an exclusive course of treatment or procedure. Practice by providers varies, including based on the needs of the individual patient and limitations unique to the institution or type of practice. All organizations should consult with their clinical staff and other experts for specific guidance and with their legal counsel, as circumstances warrant.

This model plan is intended as guidance to be adapted consistent with the internal needs of your organization. This plan is not to be viewed as required by ECRI or the Health Resources and Services Administration. All policies, procedures, and forms reprinted are intended not as models, but rather as samples submitted by ECRI member and nonmember institutions for illustration purposes only. ECRI is not responsible for the content of any reprinted materials. Healthcare laws, standards, and requirements change at a rapid pace, and thus, the sample policies may not meet current requirements. ECRI urges all members to consult with their legal counsel regarding the adequacy of policies, procedures, and forms.



Title: [YEAR] Annual Risk Management Report to the [Name of Health Center] Governance Board

Date: January 1, [YEAR] to December 31, [YEAR]

Submitted by: Jim Roads, Risk Manager

Reviewed/approved by: Matt Vega, MD, Medical Director

Date submitted to the board: January 09, [YEAR]

Date recorded in the board minutes: February 12, [YEAR]

Introduction

The purpose of this report is to provide an account of [Name of Health Center's] annual performance relative to the risk management plan and evaluate the effectiveness of risk management activities aimed to mitigate risks and respond to identified areas of high risk. Topics presented include high-risk and quarterly risk assessments, adverse event reporting, risk management training, risk and patient safety activities, and claims management. Each topic includes:

- An introduction to explain the relevance of the topic
- A data summary to highlight performance relative to established goals
- A SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis to identify additional factors related to performance
- Follow-up actions to note activities aimed to maintain or improve performance throughout the year
- A conclusion to summarize findings at year-end
- Proposed future activities to respond to identified areas of high organizational risk

See the attached Risk Management Dashboard for a complete data summary of all topics presented.

High-Risk and Quarterly Risk Assessments

Introduction

The [Health Center Program Compliance Manual](#) requires quarterly risk assessments focused on patient safety. A risk assessment is a structured process used to identify potential hazards within the organization's operations, departments, and services. Risk assessment tools include self-assessment questionnaires, FMEA, and safety walkrounds—in which members of leadership walk around the building and ask employees about potential risks and concerns while observing processes in action. Collecting data on practices, policies, and safety cultures in various areas generates information that can be used to proactively target patient safety activities and prioritize risk prevention and reduction strategies.



Risk Activity Focus Area/Measure	Summary Description of Assessment/Methodology/Indicators
# High-risk assessments	<p>The health center has determined that the following areas are at high clinical risk: dental, obstetrics, pharmacy, and tracking (tests, referrals, hospital admissions).</p> <p>The health center's goal is to conduct a comprehensive risk assessment on two high-risk areas annually. For [YEAR], pharmacy and obstetrics were selected for comprehensive risk assessment. The health center conducted the assessment using A Brief Case For Safety: Addressing Pharmacy-Related Medication Errors checklist addressing three targets: promoting a culture of safety, taking proactive systems approach to medication errors, and engaging patients and families as partners. The health center planned to conduct a second high-risk assessment on obstetrics to meet the goal; however, this assessment was not conducted.</p>
# Quarterly risk assessments	<p>The health center at minimum conducts one risk assessment quarterly. Each department manager or designee completes one of the following checklists as appropriate to their respective department: Managing Risks in Ambulatory Care: Clinical Management Managing Risks in Ambulatory Care: Office Administration Managing Risks in Ambulatory Care: Human Resources</p> <p>The checklist is forwarded to the risk management committee for review no later than seven days after the end of the quarter. The checklists are reviewed for opportunities for improvement by the RM committee. Concerns may be elevated to the CMO, senior leadership, and/or the board as appropriate. Additional quarterly risk assessments are conducted as new risks are identified.</p>
% Open action plans	<p>Action plans are created in response to high-risk assessments, quarterly risk assessments, and other risk activities. Each action plan is assigned a deadline upon creation. Action plans contain meaningful risk reduction strategies to improve overall patient safety and should be implemented in a timely manner.</p> <p>The health center's goal is to have no more than 75% of action plans open past their initial deadline. Any action plan open past the deadline is elevated to the CMO, senior leadership, and/or the board as appropriate for further discussion and intervention.</p>

Data Summary

See the dashboard below for completed risk management activities and status of the health center's performance relative to established risk management goals.

Person responsible	Measure/Key Performance Indicator	Threshold/ Goal	Q1	Q2	Q3	Q4	Annual Total
RM	# Completed annual high-risk assessments	≥ 2/yr		1: Pharmacy			1***
RM	# Completed quarterly assessments	Min 1/qtr	1	1	1	1	4*
RM	% Open action plans	<75%	80%	80%	80%	80%	80%**

SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
Managers have been collaborating with the risk manager to complete quarterly risk assessments in their respective areas.	<p>One high-risk assessment was not conducted this year. Barriers to completion include unexpected changes in key leadership.</p> <p>Pharmacy high-risk assessment revealed gaps in labeling/packaging processes, need for medication safety leader, and need for separate physical space between pharmacy drop-off and pick-up areas.</p>	N/A	N/A



Follow-up Actions

Q1 [YEAR]: High-risk pharmacy assessment completed; an audit identified packaging and labeling issues that may lead to medication errors. Pharmacy staff were trained during the second quarter. An annual threshold for <5% medication error rate was achieved. Please see information under the Risk and Patient Safety Activities section of this report for additional details.

Q2 [YEAR]: CMO nominated [Name] as potential medication safety leader on [DATE] in response to the pharmacy high-risk assessment. Nomination approved by Board on [DATE]. [Name] accepted role on [DATE].

Q3 [YEAR]: Met with chief medical officer (CMO) to draft new high-risk assessment procedure.

Q4 [YEAR]: Construction started for separate pharmacy drop-off and pick-up areas. Construction to be finished by [DATE].

Conclusion

Although the number of quarterly risk assessments exceeded the threshold, the plan was to complete two high-risk assessments per year. One high-risk assessment was not conducted this year and is discussed in detail under proposed future activities. The high-risk assessment on pharmacy-related medication errors revealed a need for a medication safety champion which has been finalized as of [DATE] as well as an additional construction project to separate prescription drop-off and pick-up. The construction is expected to end on [DATE].

Proposed Future Activities

The number of quarterly risk assessments that were completed exceeded the threshold. Due to the demonstrated success identifying risks, the threshold will be increased to a minimum of two risk assessments per quarter.

Only one high-risk assessment (pharmacy) was completed this year. High-risk assessments are one of the most proactive activities in managing risk. The plan for 2020 is to revise the risk assessment process to ensure completion. Key changes to the procedure include the following:

- Formation of high-risk assessment team to include champion from senior leadership
- High-risk assessment progress to be reported at monthly risk management meeting and to the board quarterly

Adverse Event Reporting

Introduction



Event reporting is an essential component of the risk management program and is considered part of the performance and quality improvement process. Each provider, employee, or volunteer is responsible to report all adverse events, including sentinel events, incidents, and near misses at the time they are discovered to his or her immediate supervisor and/or the risk manager. The risk manager, in conjunction with the manager of the service (as applicable), is responsible for conducting follow-up investigations. The manager's investigation is a form of self-critical analysis to determine the cause of the incident, analyze the process, and make improvements.

Risk Activity Focus Area/Measure	Summary Description of Assessment/Methodology/Indicators
# Adverse events	<p>An adverse event or incident is defined as an undesired outcome or occurrence, not expected within the normal course of care or treatment, disease process, condition of the patient, or delivery of services.</p> <p>The health center monitors the number of events reported per quarter. Low volumes of reports may indicate barriers to reporting, such as fear of personal blame for events. The goal is to report all events so no minimum nor maximum threshold is set.</p>
# Near misses	<p>A near miss is defined as an event or situation that could have resulted in an accident, injury, or illness but did not, either by chance or through timely intervention (e.g., a procedure almost performed on the wrong patient due to lapse in verification of patient identification but caught at the last minute by chance).</p> <p>The health center monitors the number of near misses reported per quarter. Near misses are viewed as opportunities for learning and for developing preventive strategies and actions. No minimum nor maximum threshold is set.</p>
# Unsafe conditions	<p>Unsafe conditions are potentially hazardous conditions, circumstances, or events that have the capacity to cause injury, accident, or healthcare error. The health center monitors the number of unsafe reported per quarter. Reporting unsafe conditions can prevent an event from occurring. No minimum nor maximum threshold is set.</p>
# Serious reportable events/Sentinel events	<p>Serious reportable events (SREs) are serious, largely preventable, and harmful clinical events. The National Quality Forum has defined a set of SREs by event type. SREs may also be known as "never events".</p> <p>A sentinel event is a patient safety event (not primarily related to the natural course of the patient's illness or underlying condition) that reaches a patient and results in death, permanent harm, or severe temporary harm. Sentinel events may also be known as "serious events".</p> <p>Both serious reportable and sentinel event types are serious and result in severe harm to the patient, warranting thorough investigation. The health center monitors the number of serious reportable/sentinel events reported per quarter. No minimum nor maximum threshold is set.</p>
# RCAs completed per qtr	<p>Root-cause analysis is a process for identifying the basic or causal factor(s) that underlie the occurrence or possible occurrence of an adverse event or error. A root-cause analysis is conducted for all events or errors with a harm severity category of "E" or above, or near misses with the potential for an event or error with a harm severity category of "E" or above per the health center's event reporting and investigation policy.</p> <p>The health center monitors the number of RCAs conducted per quarter. No minimum nor maximum threshold is set.</p>
# Peer review audits completed (5/provider/qtr)	<p>The health center's quality improvement program includes a peer review audit process to monitor and manage the quality of care and documentation to comply with health center standards, state and federal regulations, and accreditation standards.</p> <p>The health center's goal is to conduct a minimum of 5 peer review audits per provider per calendar quarter.</p>



Data Summary

See the dashboard below for completed risk management activities and status of the health center's performance relative to established risk management goals.

Person responsible	Measure/Key Performance Indicator	Threshold/Goal	Q1	Q2	Q3	Q4	Annual Total
Center staff	# Adverse events	Total #/qtr	12	14	10	16	52
Center staff	# Near misses	Total #/qtr	0	0	2	5	7
Center staff	# Unsafe conditions	Total #/qtr	4	0	3	7	14
Center staff	# Serious reportable events/Sentinel events	Total #/qtr	2	1	3	1	7
RM	# RCAs completed per qtr	Total #/qtr	2	0	2	0	4
CMO	# Peer review audits completed (5/provider/qtr)	80%	65%	75%	80%	80%	75%**

SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
Increased near miss and unsafe conditions reporting after staff training completed.	Event reporting could decrease if staff does not see systematic improvements as a result of reporting. Peer review audit completion has been below goal through first half of year; many assigned providers state they do not have time to complete peer audits.	N/A	N/A

Follow-up Actions

- Q2 [YEAR]: Met with new CMO and implemented new process for completing peer review audits.

Conclusion

Adverse event reporting has been stable during the year. There was an increase in the number of near misses and unsafe conditions reported following the culture-of-safety and responding-to-events trainings. New process for completing peer review audits has increased rate of completion.

Proposed Future Activities

In addition to continuing culture-of-safety and responding to events trainings for new staff, a refresher course will be created and added to the annual training course bundle in the learning management system. A "good catch" program will also be initiated to encourage and reward staff for identifying near-miss events and unsafe conditions through event reporting.



Risk Management Training

Introduction

The [Health Center Program Compliance Manual](#) requires risk management training for all staff members and documentation that all appropriate staff complete training at least annually. Risk management education and training are critical for clinical and nonclinical staff to improve safety and mitigate risk related to patient care. The risk manager identifies areas of highest risk within the context of the health center's risk management plan and selects risk management training topics.

Risk Activity Focus Area/Measure	Summary Description of Assessment/Methodology/Indicators
# RM education sessions/all staff trainings (in-person)	<p>The health center provides annual mandatory training to all health center staff on the following topics: event reporting, basic infection control and prevention issues, medical record confidentiality requirements, and the Health Insurance Portability and Accountability Act (HIPAA).</p> <p>This training is offered at minimum once a year as instructor-led training. The training is also offered online through the year for those who cannot attend in person.</p>
# RM education sessions/clinical staff trainings (in-person)	<p>The health center provides annual mandatory training to all clinical staff on equipment sterilization and advanced infection control and prevention issues.</p> <p>This training is offered at minimum once a year on an administrative day as instructor-led training. The training is also offered online throughout the year for those who cannot attend in person.</p>
# Other specialty clinical training (in-person)	<p>The health center identified that Obstetrics, Dental, and Pharmacy should be trained on the following specialty topics: responding to events, managing visitors, and culture of safety.</p> <p>The health center's goal was to provide one in-person session training per quarter. This training is in addition to all other required training. The training is also offered online through the year for those who cannot attend in person.</p>
Annual training completion rate	<p>The annual training completion rate is reported as a cumulative total quarterly. Each staff member must complete all mandatory training (all staff training, clinical staff training, and other specialty clinical staff training) as assigned based on role.</p> <p>The goal is to have 95% of all staff complete annual training by the end of the calendar year. Training is offered in-person and online.</p>
Obstetrics EFM training completion rate	<p>The health center identified that clinical staff working in Obstetrics should complete three introductory and three case study courses on electronic fetal monitoring (EFM). This training is in addition to all other required training. This training is available online.</p> <p>This measure is new for [YEAR] and is reported as a cumulative total quarterly. The goal is to have 60% of all obstetrics staff complete this training by the end of the calendar year.</p>

Data Summary

See the dashboard below for completed risk management activities and status of the health center's performance relative to established risk management goals.



Person Responsible	Measure/ Key Performance Indicator	Threshold/ Goal	Q1	Q2	Q3	Q4	Annual Total
RM	# RM education sessions/all staff trainings (in-person)	1x/year	completed				1 completed*
RM	# RM education sessions/clinical staff trainings (in-person)	1x/year		completed			1 completed*
RM	# Other specialty clinical training (in-person)	Min 1/qtr	completed	completed	completed	completed	4 completed*
RM	Annual training completion rate	≥95% by year-end	10%	35%	60%	77.5%	77.5%***
RM	Obstetrics EFM training completion rate	≥60% by year-end	10%	20%	30%	60%	60%*

SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
In-person and online risk management training sessions were highly rated for content and ease of implementation. Staff appreciated having both options for training.	Some staff and providers not completing training. Cannot hold staff and providers accountable to complete training currently.	Vendor can upgrade online e-learning to manage staff/provider reminders as well as provide more online content.	Vendor e-learning upgrade may be cost prohibitive.

Follow-up Actions

- Q3 [YEAR]: The risk management training survey revealed that the most significant barrier to completion was staff and providers not having dedicated work time available for training. A majority of survey respondents agreed that automated e-learning reminders would be helpful and that more content should be presented via e-learning. Clinical staff (including providers) did not realize that they needed to complete both the mandatory training for all staff as well as training for clinical staff.
- Q4 [YEAR]: Met with human resources and the CMO to discuss annual training completion rate and full results of staff training survey.

Conclusion

Specialty clinical training was completed for the three health center-specific risk areas identified: responding to events, managing visitors, and culture of safety.

Obstetrical providers and staff completed required training and met the threshold. However, because obstetrics continues to be a high-risk area, the threshold for training will be increased to 95% participation for next year.

Risk management training sessions were highly rated for content and ease of implementation for both in-person and online modalities.



We completed annual risk management training with a staff and provider attendance rate of 77.5%, which is below threshold. The risk management training survey identified that dedicated training hours are needed to complete training, as well as improved electronic reminders that highlight what specific training bundle(s) are due and when they are due for each individual staff member. Attendance rates are discussed in proposed future activities below.

Proposed Future Activities

The training plan for next year will include policy changes from human resources and allocation of training hours into the staffing plan. The e-learning vendor will provide a cost estimate for a system upgrade to address reminders and expansion of online content.

Risk and Patient Safety Activities

Introduction

The objective of the health center’s patient safety and risk management program is to continuously improve patient safety and minimize and/or prevent the occurrence of errors, events, and system breakdowns leading to harm to patients, staff, volunteers, visitors, and others through proactive risk management and patient safety activities.

Risk Activity Focus Area/Measure	Summary Description of Assessment/Methodology/Indicators
Patient satisfaction top score rate	<p>The health center routinely analyzes patient satisfaction surveys as part of its quality assurance/quality improvement (QA/QI) program.</p> <p>The health center’s goal is to receive an overall top score of 5 out of 5 on at least 90% of all returned patient satisfaction surveys during the calendar year.</p>
# Grievances – open	<p>A patient grievance is a formal written or verbal complaint filed by a patient that cannot be resolved promptly by staff present. All grievances are investigated and reviewed for opportunities for improvement.</p> <p>The health center monitors the number of grievances opened per quarter. No minimum nor maximum threshold is set.</p>
Grievances – resolved rate	<p>The health center responds to and resolves grievances in a timely manner. In order to resolve the grievance, the health center provides the patient with written notice of the health center contact person writing the letter, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion as described in the health center’s complaint and grievance policy.</p> <p>The health center’s goal is to resolve a grievance within 10 business days from initial receipt of notification.</p>
Dental device sterilization competency rate	<p>The health center has determined that dental infection control processes, including dental device sterilization are high-risk. The health center has implemented dental sterilization procedures, staff training, and a competency checklist based on best practices from the Centers for Disease Control and Prevention (CDC), the American Dental Association (ADA), the Joint Commission, and manufacturers for dental instrument sterilization in order to reduce risks associated with inadequate infection control.</p> <p>The health center’s goal is to conduct at minimum two random staff competency checks per month in order to validate training effectiveness.</p>



Risk Activity Focus Area/Measure	Summary Description of Assessment/Methodology/Indicators
Pharmacy packaging and labeling error rate	<p>During the first quarter of [YEAR], the high-risk pharmacy assessment identified packaging and labeling issues that may lead to medication errors. Pharmacy staff were trained during Q2 in response to identified issues.</p> <p>The health center investigates all medication errors, including near misses, as part of event reporting and investigation processes. Additionally, a pharmacy medication error rate is calculated every quarter as the # pharmacy medication errors divided by the # total prescriptions filled during the reporting period. No minimum nor maximum threshold was set at the beginning of the year; however, at the end of Q2, after pharmacy training, an annual pharmacy medication error rate threshold of <5% was established.</p>
HIPAA breaches – wrong visit handouts	<p>The health center encourages all staff to report suspected HIPAA breaches. After visit summary handouts, which contain protected health information, have been unintentionally be given to the wrong patient historically. This year the health center continues to work on process improvements as identified from last year's RCA associated with these types of breaches.</p> <p>The health center monitors the number of HIPAA breaches involving visit handouts per quarter. No minimum nor maximum threshold is set.</p>
Referral completion rate	<p>Routine specialty referrals are tracked by the health center for timely completion in order to reduce the risk of missed or delayed diagnosis.</p> <p>The health center's goal is to complete at minimum 90% of all routine referrals ordered within 90 days.</p>
Timely prenatal record submission rate	<p>Prenatal record forwarding to the patient's delivery site is tracking by the health center for timely submission in order to facilitate obstetric care coordination.</p> <p>The health center's goal is to forward the patient's prenatal record by 36 weeks gestation 100% of the time.</p>
Timely annual RM goal and plan submission	<p>The annual risk management goal and plan report is submitted timely to the board for comprehensive review and approval.</p> <p>The health center's goal is to have the report submitted during Q4 of the year (with additional finalization of any Q4 data completed no later than 10 business after the end of the CY).</p>
Credentialing and privileging file review rate	<p>The health center maintains files for all clinical staff that contain documentation of licensure, credentialing verification, and applicable privileges, consistent with the health center's operating procedures as required by the Health Center Program Compliance Manual.</p> <p>The health center monitors for timely renewal of privileges. The goal is to complete all renewals within the month they are due 100% of the time.</p>

Data Summary

See the dashboard below for completed risk management activities and status of the health center's performance relative to established risk management goals.



Person responsible	Measure/ Key Performance Indicator	Threshold/ Goal	Q1	Q2	Q3	Q4	Annual Total
QI	Patient satisfaction top score rate	90%	70%	70%	70%	70%	70%***
RM	# Grievances – open	Avg/qtr	3	4	4	5	4 avg.
RM	Grievances – resolved rate	100%	70%	90%	100%	100%	90%**
IC designee	Dental device sterilization competency rate	≥2/mo	6	6	6	7	25*
QI	Pharmacy packaging and labeling error rate	<5%	0%	7%	4%	0%	< 5%*
Compliance	HIPAA breaches – wrong visit handouts	Avg/qtr	3	1	2	0	1.5 avg.
RM	Referral completion rate	>90%	50%	34%	40%	50%	43.5%***
RM	Timely prenatal record submission rate	100%	100%	100%	100%	100%	100%*
RM	Timely RM goal and plan submission	Q4				submitted	Completed*
RM	# Credentialing and privileging files reviewed	100%	100%	100%	100%	100%	100%*

SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
<p>Infection control competency checks were completed on all dental staff.</p> <p>Medical records continue to use an automated prenatal record report to identify and send records.</p>	<p>Patient satisfaction continues to be below threshold – small number of surveys are being returned, which makes it hard to track and trend themes.</p> <p>Provider referral completion has significantly decreased when compared to 2018 (historically, majority of provider referrals were completed within 45 days or less).</p>	<p>Implementing a patient advisory group may be helpful in determining patient satisfaction needs.</p> <p>Vendor suggested increasing number of online satisfaction surveys.</p> <p>EHR add-on available for provider referral tracking.</p>	<p>Some external specialty providers have been refusing to reschedule referred patients if they cancel a new patient appointment within 48 hours.</p>

Follow-up Actions

Q2 [YEAR]: New grievance resolution process initiated with significant increase in timely resolution.

Q2 [YEAR]: The high-risk assessment regarding pharmacy services identified labeling and packaging issues, which resulted in medication errors. Prompt training led to a decrease in errors and impacted the attainment of the threshold error rate of <5%.

Conclusions

Risk and patient safety activities described in last year's risk management plan were implemented as written.

High-risk activities (dental infection control, pharmacy, and HIPAA) were assessed and actions were taken. During the first quarter, a pharmacy audit identified packaging and labeling issues that may lead to



medication errors. Pharmacy staff were trained during the second quarter. An annual threshold for <5% medication error rate was achieved.

The patient satisfaction survey results did not meet the threshold and are discussed in detail under proposed future activities.

The completion of patient referrals within 90 days has significantly decreased and is discussed in detail under proposed future activities.

Proposed Future Activities

Prenatal records achieved 100% compliance for the third year in a row. We plan to drop this focus from the next year's plan.

The patient satisfaction survey results were 70% for the set goal of 5 out of 5, which did not meet the 90% threshold. There is a strong relationship between patient satisfaction and medical malpractice. We will revise the action plan for next year to include a failure mode and effects analysis process to identify gaps and ways to improve satisfaction. Considerations will be given to opportunities such as increasing online survey volumes for higher return rates and the possibility of starting a patient advisory group.

Tracking referrals is a growing problem and an identified area of high risk for missed and delayed diagnoses. We will convene a multidisciplinary team, including external providers and telehealth users, to address this risk area. The possibility of using an EHR tracking module will be considered only after a comprehensive gap analysis is completed. External providers refusing to reschedule patients will also be discussed by the multidisciplinary team.

An annual threshold for <5% medication error rate involving pharmacy packing and labeling was achieved this year, however we propose that we continue to monitor this measure throughout next year.

Claims Management

Introduction

The [Health Center Program Compliance Manual](#) requires health centers to have a claims management process for addressing any potential or actual health or health-related claims. The health center identifies risk areas most likely to lead to claims based on previous claims activity, claims prevention guidance from professional organizations, and published research.



Claims Management Focus Area/ Measure	Summary Description of Assessment/Methodology/Indicators
# Claims submitted to HHS	The health center immediately sends court complaints or notices of intent to the HHS Office of the General Counsel. The health center monitors the number claims sent per quarter. No minimum nor maximum threshold is set.
# Claims settled or closed	The health center monitors the number of claims settled or closed per quarter. No minimum nor maximum threshold is set.
# Claims open	The health center monitors the number of claims opened per quarter. No minimum nor maximum threshold is set.
# Lawsuits filed	The health center monitors the number of lawsuits resulting from a claim are filed per quarter. No minimum nor maximum threshold is set.
# Lawsuits settled	The health center monitors the number of lawsuits settled per quarter. No minimum nor maximum threshold is set.
# Lawsuits litigated	The health center monitors the number of lawsuits litigated per quarter. No minimum nor maximum threshold is set.

Data Summary

See the dashboard below for completed risk management activities and status of the health center's performance relative to established risk management goals.

Person responsible	Measure, Key Performance Indicator	Threshold	Q1	Q2	Q3	Q4	Annual Total
CM	# Claims submitted to HHS	NA	4	0	0	3	7
CM	# Claims settled or closed	NA	3	0	1	0	4
CM	# Claims open	NA	1	0	0	0	1
CM	# Lawsuits filed	NA	2	0	0	0	2
CM	# Lawsuits settled	NA	2	0	0	0	2
CM	# Lawsuits litigated	NA	0	0	0	0	0

SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
N/A	Two dental claims (both settled this year) alleged failure to use rubber dam resulting in ingestion of endodontic instruments (screws).	N/A	N/A

Follow-up Actions

- N/A

Conclusion

All new claims were investigated, and there were no emerging concerns or unexpected claims noted in [YEAR]

Two settled dental claims, which were initially identified through event reporting and investigated by the health center last year, alleged failure to use a rubber dam resulting in ingestion of endodontic instruments. In both cases, the patient was emergently transferred to a higher level of care to rule out instrument aspiration. The health center requires the use of dental dams for all endodontic procedures



and provides training on the use of rubber dams to all dental providers annually. The risk manager continues to audit dental dam use through a combination of direct observation, staff interview, and chart review as part of the health center's QA/QI and peer review processes. Last year's RCA on these events identified additional process improvement opportunities involving emergency event response and mandatory annual training on this topic continues for dental staff.

Proposed Future Activities

Continue current claims management processes that include monitoring for emerging concerns, preserving claims-related documentation, and promptly communicating with HHS Office of the General Counsel, General Law Division regarding any actual or potential claim or complaint.

Report Submission

The [YEAR] Annual Risk Management Report to the [Name of Health Center's] Governance Board is respectfully submitted to demonstrate the ongoing risk management program to reduce the risk of adverse outcomes and provide safe, efficient, and effective care and services.



Risk Management Dashboard

Person responsible	Measure/ Key Performance Indicator	Threshold	Q1	Q2	Q3	Q4	Annual Total
Risk Assessments							
RM	# Completed annual high-risk assessments	≥ 2/yr		1: Pharmacy			1***
RM	# Completed quarterly assessments	Min 1/qtr	1	1	1	1	4*
RM	% Open action plans	<75%	80%	80%	80%	80%	80%**
Adverse Events/ Incident Reports							
Center staff	# Adverse events	Total #/qtr	12	14	10	16	52
Center staff	# Near misses	Total #/qtr	0	0	2	5	7
Center staff	# Unsafe conditions	Total #/qtr	4	0	3	7	14
Center staff	# Serious reportable events/Sentinel events	Total #/qtr	2	1	3	1	7
RM	# RCAs completed per qtr	Total #/qtr	2	0	2	0	4
CMO	# Peer review audits completed (5/provider/qtr)	80%	65%	75%	80%	80%	75%**
Training and Education							
RM	# RM education sessions/all staff trainings (in-person)	1x/year	completed				1 completed*
RM	# RM education sessions/clinical staff trainings (in-person)	1x/year		completed			1 completed*
RM	# Other specialty clinical training (in-person)	Min 1/qtr	completed	completed	completed	completed	4 completed*
RM	Annual training completion rate	≥95% by year-end	10%	35%	60%	77.5%	77.5%***
RM	Obstetrics EFM training completion rate	≥60% by year-end	10%	20%	30%	60%	60%*
Risk and Patient Safety Activities							
QI	Patient satisfaction top score rate	90%	70%	70%	70%	70%	70%***
RM	# Grievances – open	Avg/qtr	3	4	4	5	4 avg.
RM	Grievances – resolved rate	100%	70%	90%	100%	100%	90%**
IC designee	Dental device sterilization competency rate	≥2/mo	6	6	6	7	25*
QI	Pharmacy packaging and labeling error rate	<5%	0%	7%	4%	0%	< 5%*
Compliance	HIPAA breaches – wrong visit handouts	Avg/qtr	3	1	2	0	1.5 avg.
RM	Referral completion rate	>90%	50%	34%	40%	50%	43.5%***
RM	Timely prenatal record submission rate	100%	100%	100%	100%	100%	100%*
RM	Timely annual RM goal and plan submission	Q4				submitted	Completed*
RM	Credentialing and privileging file review rate	100%	100%	100%	100%	100%	100%*



Risk Management Dashboard (continued)

Person responsible	Measure/ Key Performance Indicator	Threshold	Q1	Q2	Q3	Q4	Annual Total
Claims Management							
CM	# Claims submitted to HHS	NA	4	0	0	3	7
CM	# Claims settled or closed	NA	3	0	1	0	4
CM	# Claims open	NA	1	0	0	0	1
CM	# Lawsuits filed	NA	2	0	0	0	2
CM	# Lawsuits settled	NA	2	0	0	0	2
CM	# Lawsuits litigated	NA	0	0	0	0	0
Dashboard Key – Performance Threshold							
	<i>Improved/exceeded expectations (green shading or *)</i>						
	<i>Acceptable/needs improvement (yellow shading or **)</i>						
	<i>Not meeting target, action needed (red shading or ***)</i>						

DISCLAIMER

Information provided by ECRI is not intended to be viewed as required by ECRI or the Health Resources and Services Administration, nor should these materials be viewed as reflecting the legal standard of care. Further, these materials should not be construed as dictating an exclusive course of treatment or procedure. Practice by providers varies, including based on the needs of the individual patient and limitations unique to the institution or type of practice. All organizations should consult with their clinical staff and other experts for specific guidance and with their legal counsel, as circumstances warrant.

This model plan is intended as guidance to be adapted consistent with the internal needs of your organization. This plan is not to be viewed as required by ECRI or the Health Resources and Services Administration. All policies, procedures, and forms reprinted are intended not as models, but rather as samples submitted by ECRI member and nonmember institutions for illustration purposes only. ECRI is not responsible for the content of any reprinted materials. Healthcare laws, standards, and requirements change at a rapid pace, and thus, the sample policies may not meet current requirements. ECRI urges all members to consult with their legal counsel regarding the adequacy of policies, procedures, and forms.



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

Purpose

Use this document to record the risk management data, information, and activities that must be reported to the health center board on an annual basis. This tool allows for the documentation and analysis of risk management program activities that have occurred over the year. This document can be submitted with other required documents that appear on the annual FTCA deeming and redeeming applications for this programmatic area. The Health Resources and Services Administration (HRSA) does not require health centers to use this document when submitting their FTCA application. However, health centers are encouraged to complete this user-friendly tool to make documentation and demonstration of requirements related to reporting to the board clear and easy to understand.

Health centers can work within the format of this report to input their own data and information. The dashboards and SWOT (Strengths, Weaknesses, Opportunities, Threats) analyses referenced in this tool are examples of ways to present the information; however, health centers may choose other formats (e.g., graphs, charts, narrative) depending on their needs and preferences. The information provided within this tool is not all-inclusive; health centers should provide specific information that is both accurate and sufficient to inform the board and key management staff on all health care risk management activities and progress related to follow-up actions that have been implemented as well as next steps.

For specific examples of content for the report to the board, see [Risk Management Report to the Board: Sample Report and Dashboard](#). Health centers should refer to [Chapter 21: Federal Tort Claims Act \(FTCA\) Deeming Requirements](#) and [Chapter 10: Quality Improvement/Assurance](#) in the [Health Center Program Compliance Manual](#) for standards that must be met in order to meet FTCA deeming requirements related to risk management.

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Title: [YEAR] Annual Risk Management Report to the [Name of Health Center] Governance Board

Date: January 1, [YEAR] to December 31, [YEAR]

Submitted by:

Reviewed/approved by:

Date submitted to the board:

Date recorded in the board minutes:

Introduction

The purpose of this report is to provide an account of [Name of Health Center's] annual performance relative to the risk management plan and evaluate the effectiveness of risk management activities aimed to mitigate risks and respond to identified areas of high risk. Topics presented include high-risk and quarterly risk assessments, adverse event reporting, risk management training, risk and patient safety activities, and claims management. Each topic includes:

- An introduction to explain the relevance of the topic
- A data summary to highlight performance relative to established goals
- A SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis to identify additional factors related to performance
- Follow-up actions to note activities aimed to maintain or improve performance throughout the year
- A conclusion to summarize findings at year-end
- Proposed future activities to respond to identified areas of high organizational risk

See the attached Risk Management Dashboard for a complete data summary of all topics presented.

High-Risk and Quarterly Risk Assessments

Introduction

[Introduce the topic here, or use the following text] The [Health Center Program Compliance Manual](#) requires quarterly risk assessments focused on patient safety. A risk assessment is a structured process used to identify potential hazards within the organization's operations, departments, and services. Risk assessment tools include self-assessment questionnaires, FMEA, and safety walkrounds—in which members of leadership walk around the building and ask employees about potential risks and concerns while observing processes in action. Collecting data on practices, policies, and safety cultures in various



areas generates information that can be used to proactively target patient safety activities and prioritize risk prevention and reduction strategies.

Risk Activity Focus Area/Measure	Summary Description of Assessment/Methodology/Indicators
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]

Data Summary

See the dashboard below for completed risk management activities and status of the health center's performance relative to established risk management goals.

Person responsible	Measure/Key Performance Indicator	Threshold/Goal	Q1	Q2	Q3	Q4	Annual Total
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]

SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
[Enter tasks and activities that your health center is doing well on in relation to the data presented]	[Enter tasks and activities that your health center could improve on in relation to the data presented]	[Enter external situations that could benefit the health center in relation to the data presented]	[Enter external situations that could negatively impact the health center in relation to the data presented]

Follow-up Actions

[QUARTER, YEAR]: [List any follow-up actions taken to secure identified strengths and opportunities or to mitigate weaknesses and threats throughout the year.]

[QUARTER, YEAR]:

[QUARTER, YEAR]:

[QUARTER, YEAR]:

Conclusion

[Summarize your findings for the board in a short narrative here]

Proposed Future Activities

[Enter what tasks and activities should be continued, started, or stopped in order to address this topic next year.]



Adverse Event Reporting

Introduction

[Introduce the topic here, or use the following text] Event reporting is an essential component of the risk management program and is considered part of the performance and quality improvement process. Each provider, employee, or volunteer is responsible to report all adverse events, including sentinel events, incidents, and near misses at the time they are discovered to his or her immediate supervisor and/or the risk manager. The risk manager, in conjunction with the manager of the service (as applicable), is responsible for conducting follow-up investigations. The manager's investigation is a form of self-critical analysis to determine the cause of the incident, analyze the process, and make improvements.

Risk Activity Focus Area/Measure	Summary Description of Assessment/Methodology/Indicators
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]

Data Summary

See the dashboard below for completed risk management activities and status of the health center's performance relative to established risk management goals.

Person responsible	Measure/Key Performance Indicator	Threshold/Goal	Q1	Q2	Q3	Q4	Annual Total
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]

SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
[Enter tasks and activities that your health center is doing well on in relation to the data presented]	[Enter tasks and activities that your health center could improve on in relation to the data presented]	[Enter external situations that could benefit the health center in relation to the data presented]	[Enter external situations that could negatively impact the health center in relation to the data presented]

Follow-up Actions

[QUARTER, YEAR]: [List any follow-up actions taken to secure identified strengths and opportunities or to mitigate weaknesses and threats throughout the year.]

[QUARTER, YEAR]:

[QUARTER, YEAR]:

[QUARTER, YEAR]:



Conclusion

[Summarize your findings for the board in a short narrative here]

Proposed Future Activities

[Enter what tasks and activities should be continued, started, or stopped in order to address this topic next year.]

Risk Management Training

Introduction

[Introduce the topic here, or use the following text] The [Health Center Program Compliance Manual](#) requires risk management training for all staff members and documentation that all appropriate staff complete training at least annually. Risk management education and training are critical for clinical and nonclinical staff to improve safety and mitigate risk related to patient care. The risk manager identifies areas of highest risk within the context of the health center's risk management plan and selects risk management training topics.

Risk Activity Focus Area/Measure	Summary Description of Assessment/Methodology/Indicators
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]

Data Summary

See the dashboard below for completed risk management activities and status of the health center's performance relative to established risk management goals.

Person responsible	Measure/Key Performance Indicator	Threshold/Goal	Q1	Q2	Q3	Q4	Annual Total
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]

SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
[Enter tasks and activities that your health center is doing well on in relation to the data presented]	[Enter tasks and activities that your health center could improve on in relation to the data presented]	[Enter external situations that could benefit the health center in relation to the data presented]	[Enter external situations that could negatively impact the health center in relation to the data presented]



Follow-up Actions

[QUARTER, YEAR]: [List any follow-up actions taken to secure identified strengths and opportunities or to mitigate weaknesses and threats throughout the year.]

[QUARTER, YEAR]:

[QUARTER, YEAR]:

[QUARTER, YEAR]:

Conclusion

[Summarize your findings for the board in a short narrative here]

Proposed Future Activities

[Enter what tasks and activities should be continued, started, or stopped in order to address this topic next year.]

Risk and Patient Safety Activities

Introduction

[Introduce the topic here, or use the following text] The objective of the health center's patient safety and risk management program is to continuously improve patient safety and minimize and/or prevent the occurrence of errors, events, and system breakdowns leading to harm to patients, staff, volunteers, visitors, and others through proactive risk management and patient safety activities.

Risk Activity Focus Area/Measure	Summary Description of Assessment/Methodology/Indicators
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]

Data Summary

See the dashboard below for completed risk management activities and status of the health center's performance relative to established risk management goals.

Person responsible	Measure/Key Performance Indicator	Threshold/Goal	Q1	Q2	Q3	Q4	Annual Total
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]



SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
[Enter tasks and activities that your health center is doing well on in relation to the data presented]	[Enter tasks and activities that your health center could improve on in relation to the data presented]	[Enter external situations that could benefit the health center in relation to the data presented]	[Enter external situations that could negatively impact the health center in relation to the data presented]

Follow-up Actions

[QUARTER, YEAR]: [List any follow-up actions taken to secure identified strengths and opportunities or to mitigate weaknesses and threats throughout the year.]

[QUARTER, YEAR]:

[QUARTER, YEAR]:

[QUARTER, YEAR]:

Conclusion

[Summarize your findings for the board in a short narrative here]

Proposed Future Activities

[Enter what tasks and activities should be continued, started, or stopped in order to address this topic next year.]

Claims Management

Introduction

[Introduce the topic here, or use the following text] The [Health Center Program Compliance Manual](#) requires health centers to have a claims management process for addressing any potential or actual health or health-related claims. The health center identifies risk areas most likely to lead to claims based on previous claims activity, claims prevention guidance from professional organizations, and published research.

Risk Activity Focus Area/Measure	Summary Description of Assessment/Methodology/Indicators
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]
[Insert the focus area or measure name]	[Include details such as inclusion/exclusion criteria and rationale for the health center's threshold/goal.]

Data Summary

See the dashboard below for completed risk management activities and status of the health center's performance relative to established risk management goals.



Person responsible	Measure/Key Performance Indicator	Threshold/Goal	Q1	Q2	Q3	Q4	Annual Total
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from table above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]

SWOT Analysis

Strengths	Weaknesses	Opportunities	Threats
[Enter tasks and activities that your health center is doing well on in relation to the data presented]	[Enter tasks and activities that your health center could improve on in relation to the data presented]	[Enter external situations that could benefit the health center in relation to the data presented]	[Enter external situations that could negatively impact the health center in relation to the data presented]

Follow-up Actions

[QUARTER, YEAR]: [List any follow-up actions taken to secure identified strengths and opportunities or to mitigate weaknesses and threats throughout the year.]

[QUARTER, YEAR]:

[QUARTER, YEAR]:

[QUARTER, YEAR]:

Conclusion

[Summarize your findings for the board in a short narrative here]

Proposed Future Activities

[Enter what tasks and activities should be continued, started, or stopped in order to address this topic next year.]

Report Submission

The [YEAR] Annual Risk Management Report to the [Name of Health Center's] Governance Board is respectfully submitted to demonstrate the ongoing risk management program to reduce the risk of adverse outcomes and provide safe, efficient, and effective care and services.



Risk Management Dashboard

[Use the following dashboard to summarize the measures presented in the report above.]

Person responsible	Measure/ Key Performance Indicator	Threshold	Q1	Q2	Q3	Q4	Annual Total
Risk Assessments							
[Insert department or role]	[Match entry to Risk Activity Focus Area/Measure from report above]	[Use N/A if no threshold or goal]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here]	[Enter data here and fill background color according to threshold/goal – see key below]
Adverse Events/ Incident Reports							
Training and Education							
Risk and Patient Safety Activities							
Claims Management							
Dashboard Key – Performance Threshold							
	<i>Improved/exceeded expectations (green shading or *)</i>						
	<i>Acceptable/needs improvement (yellow shading or **)</i>						
	<i>Not meeting target, action needed (red shading or ***)</i>						