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Risk Management Strategies for the Outpatient Setting



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Enterprise Risk Management

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Introduction to Enterprise Risk Management

Healthcare continues to evolve, creating predictable and unpredictable risks that are most effectively addressed on an enterprise-wide basis. By taking a global view of liability, healthcare leaders are better positioned to fulfill organizational mandates and attain strategic objectives, while promoting patient safety, minimizing loss and protecting organizational reputation.

The Enterprise Risk Management (ERM) model provides a process to identify complex and interconnected activities across the outpatient setting that affect one another positively or negatively. The ERM framework can be adopted and designed to fit any size and type healthcare organization and modified to address the unique characteristics and needs within outpatient settings.

A critical step toward implementing the ERM model is to adopt a clear and concise definition of ERM. This definition will communicate to the organization the purpose and commitment of leadership to the ERM process.

ERM represents a continuous process applied across the outpatient setting and is influenced by staff conduct at every level. In a solo practice, the provider is responsible for developing and facilitating a risk-conscious culture among staff. In an outpatient setting, the medical director and practice manager collaborate to educate staff members on the ERM process and implement an integrated risk management program. For the ERM process to be effective, all staff members in the outpatient setting must be aware of what ERM encompasses and demonstrate a commitment to its implementation.

The ERM process includes the following major components:

- **Risk identification**, i.e., detecting exposures within each of the risk domains, a process that typically includes staff interviews.
- **Prioritization and scoring of risks**, i.e., analyzing the likelihood, causes and consequences of specific exposures. The potential severity of each risk is multiplied by its probability to determine the “risk score.”
- **Risk response**, i.e., developing and implementing an action plan to avoid, accept, reduce, segregate, and/or risk transfer, as defined below:
 - **Risk avoidance** denotes actions that prevent the risk from occurring such as eliminating a service or procedure.
 - **Risk acceptance** means assuming responsibility for any loss associated with an identified risk. Risks with minimal effect are customarily accepted.
 - **Risk reduction** involves activities to reduce the likelihood of a risk from occurring such as universal protocols, infection control practices, or equipment maintenance programs. Other risk reduction activities involve reducing the probability or severity, through process and system design, without eliminating the service or activity.
 - **Risk segregation** involves moving assets across multiple locations, offices, or units to reduce the likelihood of a loss of supplies, equipment, or records stored in one location.
 - **Risk transfer** refers to covering potential losses by transferring risk to a commercial insurance policy or by retaining risk through alternative mechanisms such as high deductibles, self-insured retentions, surety bonds or trust fund accounts.
- **Control and monitoring**, i.e., measuring the effectiveness of selected risk responses.

The ERM process is dynamic, involving several steps that may occur simultaneously. It serves as a useful framework for organizing risk management activities.

Mapping Risks

The first step in creating a risk management program is to classify and assess organizational risks. The following chart lists risk categories common to many healthcare settings. Risks in these categories reflect absent, inadequate or failed internal processes or systems to control the risk. There is flexibility in the specific activities assigned to each category and should be modified to complement your organizational structure. Examples of specific functions, issues, requirements and risks that fall within the various categories are provided below.

Common Risk Categories and Descriptions

Operational	Operational risks are derived from an organization's core activities: provider credentialing, research activities, professional medical services, performance improvement, risk management, appointment tracking, environment of care, emergency preparedness, policy and procedure development process.
Legal/regulatory	Legal and regulatory risks emanate from federal and state requirements, licensure/certification, reimbursement rules, fraud/abuse, compliance, contracts, patient rights, informed consent, HIPAA privacy and confidentiality provisions, Clinical Laboratory Improvements Act (CLIA) regulations, patient termination, contract management, closing or leaving a practice.
Clinical	Clinical risks involve the delivery of care to patients such as adverse events, evidence based standards of care, safety protocols, universal precautions, preventive care/screening, medication/pain management, referrals/consultations, drug/device recalls, patient education.
Strategic	Strategic planning involves an organization's ability to grow and evolve its brand and reputation. Examples include joint ventures, marketing activities, clinical service expansion, mergers and acquisitions, capital needs, and enterprise risk management.
Financial	Financial risks reflect an organization's ability to earn, raise and access capital. These risks include insurance denial of care, billing and collections, Medicare/Medicaid reimbursement, credit rating, assets and liabilities.
Human Capital	Human capital risks relate to workforce management, hiring practices, recruitment, retention, employment practices, scope of practice, background checks, competency assessments, in-service education.
Technology	Technology risks are associated with computer hardware/software, storage/retrieval of information, digital health, wearable technology/sensors, cyber exposures, electronic health records, data privacy and security, email, social media, facsimile, texting, telephone and other remote consultation.
Hazards/business interruption	Hazard risks relate to predictable risks associated within and outside the building. These include construction/renovation, earthquake, fires, tornado, hurricane/floods, facility management, plant age, parking (e.g., lot lighting, condition, security), securing valuables.

Adapted from [American Society for Health Care Risk Management, Enterprise Risk Management: Implementing ERM, 2020](#)

Prioritization and Scoring Risks

Risk-taking is inherent to healthcare organizations. Using an objective process to evaluate the scope and magnitude of risk will enhance the organization’s ability to prioritize efforts and allocation of resources involving risk mitigation. Risks can be ranked by assigning numerical scores to the “likelihood” and “impact” the risk has on the organization. An optional third measurement is “velocity”.

Likelihood is the frequency or probability the event or risk will occur.

Impact is the severity or patient injury value, often expressed in financial terms or dollar value, of the outcome should the risk occur.

$$\text{Likelihood} \times \text{Impact} = \text{Risk Score}$$

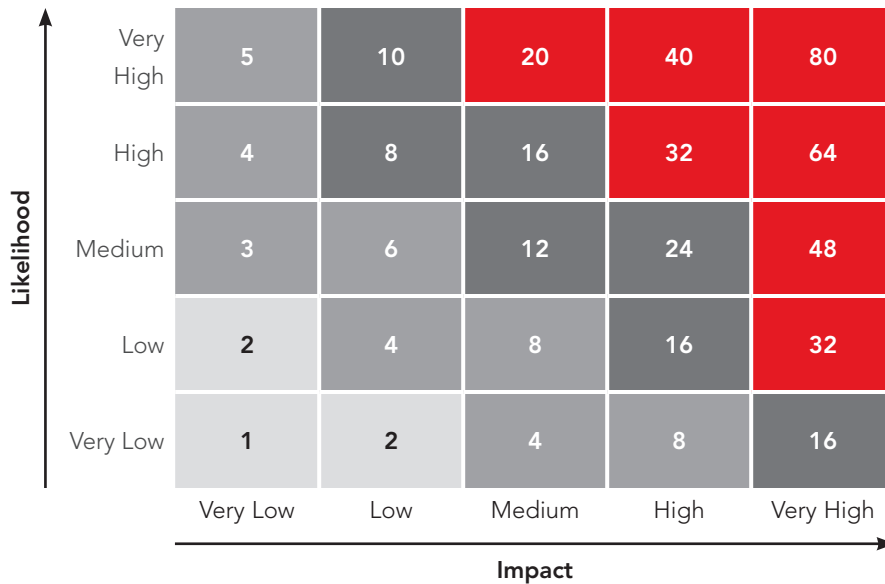
Velocity refers to the speed in which you have time to take action or “time to impact” before the outcome is realized. This is an optional measurement to enhance the risk score.

$$\text{Likelihood} + \text{Velocity} \times \text{Impact} = \text{Risk Score}$$

Ranking risks using a numeric system has flexibility to evaluate an organization’s tolerance, or appetite, for risk. Risks that are highly likely to occur with an outcome of minimal consequence to a patient or the organization, such as lost patient clothing, would have a low score (Likelihood of 5 x Impact of 1 = 5). In contrast, a risk with potential likelihood of occurring with major consequences to patient(s) and/or facility, a facility in the path of a tornado, would have a higher score (Likelihood of 3 x Impact of 5 = 15). In these examples, the facility would be guided by the risk scores and focus risk management efforts toward the more catastrophic event. Including the velocity, or time the organization has to the point of impact, will further enhance this risk scoring process.

Once the risk has been scored and prioritized, decisions around how to treat the risk must be determined: risk avoidance, risk acceptance, risk reduction, risk transfer.

Risk Heat Map



Reference: [Enterprise Risk Management: Implementing ERM](#), ASHRM 2020

Responding to Risk

Managing risk involves using the information provided through adverse event reports, survey findings and other feedback mechanisms to support these four basic initiatives:

Prevention encompasses proactive risk awareness and safety programs for patients, staff, providers, family members and visitors. The goal is to ensure that all parties are aware of the risks and know how to protect themselves and others.

Correction requires implementation of post-incident remedial actions to minimize the impact of the event and prevent future similar occurrences. The corrective measures must be documented, monitored and audited to assess their effectiveness.

Documentation is critical to effective legal defense in the event of a professional liability claim. Healthcare information records must be accurate and comprehensive. In addition, all institutional policies and procedures – including those that no longer apply or have been modified – should be carefully archived.

Education involves engaging staff through relevant, practical and meaningful in-service seminars given at orientation at least annually thereafter, and following any significant adverse event that requires an immediate change in systems or processes to prevent recurrence. Education should include both an overview of the risk management process and a detailed description of other key topics. The educational sessions should clearly explain what constitutes an adverse event, how they should be reported, and why thorough and objective incident documentation is of critical importance.

Evaluating the ERM Program

All ERM programs must be routinely evaluated and updated. As healthcare reform and other legislative and regulatory initiatives continue to transform the industry, new and unpredictable risks will emerge. Healthcare leaders responsible for risk management must remain attentive to their own unique risk situation, as well as the broader political, economic and social developments affecting the healthcare field. Any changes in the program should be promptly communicated to staff members.

Sample Risk Management Plan

Organization Name: _____

Business Address: _____ **City, St, Zip:** _____

Telephone Number: _____ **Facsimile Number:** _____

Website Address: _____ **Email Address:** _____

Mission Statement

Enter organization's mission: _____

Purpose

The purpose of the risk management program is to provide the organization with a comprehensive framework designed to strategically identify, manage and mitigate risk in order to enhance patient safety and maximize value protection.

The risk management plan is a primary tool for implementing the organization's overall risk management program. It represents a foundation for implementation of the organization's risk management program through dissemination of detailed information regarding purpose, scope and objectives to all clinical providers and staff.

The focus of the risk management plan is to provide an ongoing, comprehensive, and systematic approach to reducing risk exposures. Enterprise-wide risks encompass issues that may be categorized as operational, clinical, strategic, financial, human capital, legal/regulatory, technology, and hazards. Risk management activities include identifying, investigating, analyzing, and evaluating risks. Follow-up activities may include taking action to address the identified risks through the development and implementation of appropriate risk reduction initiatives. These initiatives and responses can include risk avoidance, risk prevention, risk reduction, segregation of risk, and/or risk transfer.

Authority and Role of the Risk Manager

The risk manager is empowered by the governing body to implement the functions and activities of the risk management program in collaboration with administrative and clinical leadership. The governing body has overall responsibility for the effectiveness of the program and for providing the necessary resources. Routine written and verbal communications regarding risk management activities that may affect the organization's finances should be provided to the governing body.

The risk manager is responsible for creating, implementing, and evaluating the outcome of the risk management plan. These activities should be coordinated with quality/performance improvement, infection prevention, organizational/patient safety and environment of care management. A job description delineating the risk manager's role should be approved by the governing body.

The risk management program is formally addressed through designated committees, such as the risk management committee, safety committee, and quality/performance improvement committee.

Scope

Under the direction of the risk manager, the risk management program provides for collaboration among all departments, services, and patient care professionals within the organization. The risk management program focuses on policies, procedures and protocols to address events that may create business-related liability, professional liability, general liability, workers' compensation and motor vehicle liability exposures. The identification, investigation and management of accidents, injuries and other potentially compensable events are a primary organizational responsibility under the risk management plan. The risk manager and others who are delegated to participate in the various components of managing adverse events occurring with patients, staff, visitors and organizational assets direct this process.

Risk management will collaborate with and educate leaders within the following departments in order to promote quality care in a safe environment and protect the organization's resources:

- Administration
- Allied Health and Adjunct Professional Services
- Billing Services
- Business Development and Marketing
- Clinical and Ancillary Services
- Data/Health Information and Privacy Management
- Employee Health
- Human Resources
- Infection Prevention
- Legal Services
- Biomedical Engineering
- Medical Staff, if applicable
- Medical Staff Credentialing, if applicable
- Patient Relations
- Quality Improvement
- Patient Safety
- Safety Management/Environment of Care
- Security Management
- Utilization Management

Objectives of the Risk Management Program

The objectives of the risk management program include, but are not limited to the following:

- **Promoting the quality of patient care** and establishing key performance measures in collaboration with quality/performance improvement activities.
- **Identifying opportunities for improving patient safety** through analysis and trending of incidents and near misses.
- **Utilizing the results of timely incident investigation** to guide open communication and disclosure discussions with patients/families.
- **Evaluating systems and processes** that can adversely affect administrative and clinical operations leading to adverse events.
- **Protection of the organization's assets** by minimizing the frequency and severity of untoward events and legal claims.
- **Reducing the impact of losses** through insurance or other risk transfer mechanisms.
- **Enhancing patient satisfaction** and responsiveness to complaints.
- **Supporting a culture of safety** that promotes awareness and empowers staff to identify risk-related issues.
- **Enhancing environmental safety** for patients, visitors and staff.
- **Educating stakeholders on emerging and known risk exposures** and risk reduction initiatives.
- **Meeting accreditation requirements** of relevant organizations.
- **Complying with state-specific scope of practice**, applicable state and federal laws, regulations and standards.

Specific Components

The risk management program will include the following components:

Event/Incident/Occurrence reporting. Event reporting provides a systematic, organization-wide program of reporting risk exposures to identify report, track, and trend patterns of actual, potential and near miss events with the potential for causing adverse patient outcomes or other injuries to people, property or other assets of the organization. The goal of the program should be to reduce or ameliorate preventable injuries and property damage, while also minimizing the financial severity of claims.

The risk manager reports analysis of event data and recommends actions to the quality/performance improvement department and the department(s) involved in the events for follow-up action.

Sentinel events, as well as other significant incidents as specified by state or federal regulations, must be reported to governmental and/or accrediting agencies through delineated methods in compliance with the requirements of these regulatory entities. The reporting responsibility should be delegated to the risk manager or compliance department/officer, noting the established guidelines and required time frames for reporting.

Reporting risk management activities as part of the quality/performance improvement process. Recognizing that the effectiveness of risk management activities is contingent upon collaboration and integration with the quality/performance improvement activities, the risk manager will work with quality/performance improvement staff to coordinate activities between the two disciplines. This collaboration will enhance the identification and resolution of risk and quality issues.

Educational activities. The risk manager will provide or facilitate orientation programs for all new employees, volunteers and contracted staff and annually to all employees. The educational programs will focus on promoting awareness of risk exposures and current risk prevention activities. In-service and training programs should be provided as identified through the ongoing monitoring, tracking and trending of events, and/or as requested by a staff member within the organization. Ongoing education should be provided on a routine basis in order to inform staff about proactive preventative measures for common risk exposures, as well as strategies to enhance defensibility in the event of a claim in the areas of documentation and communication techniques.

Management of patient and family complaints/grievances. The organization will have a formal written process for managing patient and family complaints/grievances in compliance with federal regulations and accreditation requirements. This process should delineate response to and resolution of patient and family complaints. It also should include time frames for responding, the chain-of-command used for problem-resolution, and documentation of the activities involved.

Patient satisfaction. The organization will measure patient satisfaction and respond to issues identified in patient satisfaction surveys. The risk manager will monitor complaints and report findings related to quality/performance improvement. Of equal importance is risk management's direct participation in resolution of complaints, as appropriate.

Claim Management

In some organizations, claims management is a function outside of the risk management program and may have a separate staff with unique policies, procedures and protocols.

If the claim management function is included in the risk management plan, it should be comprised of the following elements, among others that may be adapted to your organization:

- **Reporting potentially compensable events, unexpected outcomes or patient complaints** to the involved department manager, the insurer, as appropriate, in conformity with the policy provisions, and the organization's risk manager.
- **Conducting investigation and interviews** following potentially compensable events.
- **Documenting activities and correspondence** related to the investigation of the event.
- **Protecting and preserving the patient healthcare information record** and/or other documents and evidence for potential future litigation.
- **Organizing, managing and maintaining claim files.**
- **Limiting access to claim files** to individuals as authorized under the direct supervision of the risk manager.
- **Coordinating interactions with the defense team** and providing input regarding the strategy for each claim.
- **Reporting claim management activity** to the quality/performance improvement committee and appropriate organizational leaders.
- **Participating in establishing the defense/settlement posture.**
- **Resolving claims** within established limits of authority.
- **Maintaining confidentiality and security** of protected documents.
- **Reviewing, evaluating and accepting legal services** as appropriate.
- **Timely forwarding of subpoenas, summons and complaints** to legal counsel.

Reports to the Governing Body

The risk manager will provide reports to the governing body periodically, and, at a minimum, on an annual basis. The report should summarize activities, achievements, and on-going risk management issues that have occurred since the prior report.

Ad hoc communications should be initiated with the governing body pertaining to sentinel events, significant changes in claim reserves, claims that are scheduled for trial, events that may result in adverse publicity or media attention, and severe patient injuries deemed highly probable to result in litigation.

The final annual risk management report should include all of the above parameters along with recommendations for risk control activities and identified resource needs for the upcoming fiscal year.

Protection of Risk Management Information Included in the Quality/Performance Improvement Program

Risk management data and information collected should be maintained as a component of the organization's quality/performance improvement program and reported to the quality/performance improvement committee and/or designated subcommittees. This structure may result in findings being considered privileged and confidential and should be distributed outside of the quality/performance improvement process solely at the direction of and with the written consent of legal counsel.

Review of the Risk Management Plan

The risk management plan will be reviewed, updated, and approved annually, or as needed. Dated signatures and titles from designated and authorized parties should be obtained at the time of the approval.

Annual Evaluation of the Risk Management Program

The risk management program will be evaluated by the governing body annually. Recommendations for enhancements are incorporated into the program prior to final approval.

Signature and Title: _____ Date: _____

Signature and Title: _____ Date: _____

Signature and Title: _____ Date: _____

This sample form is for illustrative purposes only. As each practice presents unique situations, we recommend that you consult with your attorney prior to use of this or similar forms. This document is not intended to represent a comprehensive study of risk management practices or potential liabilities and is not to be considered legal advice. CNA Healthcare strongly recommends consultation with a competent attorney regarding specific issues related to your organization's legal obligations and applicable state laws. It is further acknowledged that CNA accepts no liability from any use or reliance on this information or any of its contents.

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Self-assessment Checklist: Enterprise Risk Management

This resource is designed to help evaluate customary risk control policies and procedures. For additional risk control tools and information on a wide and evolving range of topics, visit www.cna.com.

Risk Control Measures	Present? Yes/No	Comments
Strategic Risk		
Promotional/marketing materials (e.g. advertisements, brochures, websites, telephone directory listings) are reviewed to ensure that they do not include contain inappropriate language or inaccurate descriptions, and convey no unreasonable expectations.		
The organization has a formal risk management plan that:		
• Declares the organization’s risk control goals.		
• Describes the scope, components and methods of the risk control program.		
• Delegates responsibilities for implementation and enforcement.		
• Demonstrates leadership commitment.		
• Mandates confidentiality and immunity from retaliation for staff members who report sensitive information.		
Human Capital Risk		
A pre-employment screening process is created and implemented that includes the following documented elements:		
• Drug screen.		
• Background investigation, which includes criminal record, Office of Inspector General (OIG) and sex abuse registries for all states where the applicant has lived or worked, as well as credit history, if relevant and legally permissible.		
• Reference verification and documentation.		
Every position has a written job description delineating specific responsibilities and required competencies.		
All staff members undergo a formal office orientation program, which covers the following topics, among others:		
• The practice’s mission and vision.		
• Performance expectations and evaluation process.		
• Equipment use and other basic operations.		
• Appropriate professional appearance and behavior.		
Employees read their job description and sign an acknowledgment.		
Human resources policies and procedures are in writing, and are reviewed on a routine basis to ensure compliance with applicable federal, state and local legal requirements, such as:		
• Americans with Disabilities Act (ADA) requirements.		
• HIPAA privacy regulations.		
• Equal Employment Opportunity Commission (EEOC) and other anti-discrimination laws.		

Present?
Yes/No Comments

Risk Control Measures

Clinical Risk

Formal written policies and procedures exist , addressing the following clinical issues, among others:		
• Medication management.		
• Hand-off communication.		
• Patient identification.		
• Time-out procedures.		
• Infection prevention.		
• Disclosure of unanticipated outcomes.		
• Medical device safety.		
• Fall prevention and mitigation.		
• Informed consent and refusal.		
• Patient scheduling and after-hours care.		
• Proper professional boundaries.		
• Test result management.		
• Referral processes for patients requiring a specialist.		
• Drug and medical device recall.		
A written, individualized plan of care is developed for each patient and updated as necessary.		
Staff members participate in annual programs on patient safety , as well as risk management, customer and community relations, confidentiality and compliance.		

Operational Risk

There is a designated risk manager on staff , with well-delineated responsibilities.		
A system is in place for identifying and tracking medication errors and other untoward incidents.		
A system has been implemented for identifying and tracking quality issues and patient complaints.		
Administrative, operational and disaster preparedness practices are governed by written policies and procedures , which are approved by leadership and shared with all physicians and staff.		
Staff are trained in telephone etiquette , which includes dealing with angry or dissatisfied patients in a tactful, respectful and non-confrontational manner.		
A designated staff member responds to complaints from patients, family members and visitors.		
The risk manager is promptly notified of all complaints from patients, family members or visitors.		
All communication regarding patient complaints is reviewed by the risk manager and documented in case of later legal or regulatory action.		

Present?

Yes/No

Comments

Risk Control Measures

Technology Risk

Formal written policies and procedures exist and implemented regarding the following areas, among others:		
• Healthcare record management.		
• Confidentiality and release of medical information.		
• Maintenance of the healthcare record, including release authorization, retention time and storage security measures.		
• Social media.		
• Faxing of confidential information.		
• Electronic health records.		
• Use of electronic media.		
• Administration of cybersecurity.		
• Use of telehealth.		

Legal/Regulatory Risk

Written, regularly reviewed policies and procedures address the following areas, among others:		
• Process for handling and taking action on legal and regulatory notices.		
• Process for notification of insurance carrier.		
• Process for mandatory and voluntary external reporting of adverse events and near misses.		
• HIPAA-related patient confidentiality practices and notifications.		
• Billing regulations, both federal and state.		
• Clinical Laboratory Improvements Act (CLIA) regulations.		
• Contractual agreements containing hold harmless and/or indemnification clauses.		
• Termination of the patient-provider relationship.		

Present?

Yes/No

Comments

Risk Control Measures

Financial Risk

Legal contracts are reviewed by legal counsel and other authorized parties prior to execution, then reviewed and renewed annually.		
The following contractual and financial areas, among others, are governed by written policies:		
• Insurance denials.		
• Patient billing and collections.		
• Medicare/Medicaid billing.		
• Managing payments and accounts.		

Hazards

A hazard vulnerability assessment has been conducted.		
Disaster planning includes identification of back-up resources in the event of a major service disruption.		
An emergency response plan has been developed that outlines the necessary steps to be taken and the responsibilities of the individuals involved.		

This tool serves as a reference for organizations seeking to evaluate enterprise-wide risk exposures. The content is not intended to represent a comprehensive listing of all actions needed to address the subject matter, but rather is a means of initiating internal discussion and self-examination. Your organization and risks may be different from those addressed herein, and you may wish to modify the activities and questions noted herein to suit your individual organizational practice and patient needs. The information contained herein is not intended to establish any standard of care, or address the circumstances of any specific healthcare organization. It is not intended to serve as legal advice appropriate for any particular factual situations, or to provide an acknowledgement that any given factual situation is covered under any CNA insurance policy. The material presented is not intended to constitute a binding contract. These statements do not constitute a risk management directive from CNA. No organization or individual should act upon this information without appropriate professional advice, including advice of legal counsel, given after a thorough examination of the individual situation, encompassing a review of relevant facts, laws and regulations. CNA assumes no responsibility for the consequences of the use or nonuse of this information.

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