

## **Sample Risk Management Plan for a Community Health Center Patient Safety and Risk Management Program\***

*This Plan can serve as a model to develop a patient safety and risk management program to meet the needs of your organization. It is recommended that the Plan be approved by your organization's board of directors and disseminated to staff. ECRI Institute, on behalf of HRSA, provides tools and resources via the Clinical Risk Management Services Web site, as well as educational programs, to assist community health center organizations in developing and implementing such a plan.*

### **1. PURPOSE**

The Risk Management Plan is designed to support the mission and vision of (organization name) as it pertains to clinical risk and patient safety as well as visitor, third party, volunteer, and employee safety and potential business, operational, and property risks.

### **2. GUIDING PRINCIPLES**

The Risk Management Plan is an overarching, conceptual framework that guides the development of a program for risk management and patient safety initiatives and activities. The plan is operationalized through a formal, written risk management and patient safety program.

The Patient Safety and Risk Management Program supports the (organization name) philosophy that patient safety and risk management is everyone's responsibility. Teamwork and participation among management, providers, volunteers, and staff are essential for an efficient and effective patient safety and risk management program. The program will be implemented through the coordination of multiple organizational functions and the activities of multiple departments.

(Organization name) supports the establishment of a just culture that emphasizes implementing evidence-based best practices, learning from error analysis, and providing constructive feedback, rather than blame and punishment. In a just culture, unsafe conditions and hazards are readily and proactively identified, medical or patient care errors are reported and analyzed, mistakes are openly discussed, and

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*\*This sample 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 Institute, KePRO, or the Health Resources and Services Administration.*

suggestions for systemic improvements are welcomed. Individuals are still held accountable for compliance with patient safety and risk management practices. As such, if evaluation and investigation of an error or event reveal reckless behavior or willful violation of policies, disciplinary actions can be taken.

The (organization name) Risk Management Plan stimulates the development, review, and revision of the organization's practices and protocols in light of identified risks and chosen loss prevention and reduction strategies. Principles of the Plan provide the foundation for developing key policies and procedures for day-to-day risk management activities, including:

- Claims management
- Complaint resolution
- Confidentiality and release of information
- Event investigation, root-cause analysis, and follow-up
- Failure mode and effects analysis
- Provider and staff education, competency validation, and credentialing requirements
- Reporting and management of adverse events and near misses
- Trend analysis of events, near misses, and claims

## 2.1 Governing Body Leadership

The success of the (organization name) Patient Safety and Risk Management Program requires top-level commitment and support. The governing board authorizes the formal program and adoption of this Plan through a resolution documented in board meeting minutes.

The governing board is committed to promoting the safety of all patients, visitors, employees, volunteers, and other individuals involved in organization operations. The Patient Safety and Risk Management Program is designed to reduce system-related errors and potentially unsafe conditions by implementing continuous improvement strategies to support an organizational culture of safety. The governing body empowers the organization leadership and management teams with the responsibility for implementing performance improvement and risk management strategies.

## 3. DEFINITIONS

- **Adverse event or incident:** 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.
- **Claims management:** Activities undertaken by the risk manager to exert control over potential or filed claims against the organization and/or its providers. These activities include identifying potential claims early, notifying the organization's liability insurance carrier and/or defense counsel of potential claims and lawsuits, evaluating liability and associated costs, identifying and mitigating potential damages, assisting with the defense of claims by scheduling individuals for

deposition, providing documents or answers to written interrogatories, implementing alternate dispute-resolution tactics, and investigating adverse events or incidents.

- **Failure mode and effects analysis:** A proactive method for evaluating a process to identify where and how it might fail and for assessing the relative impact of different failures in order to identify the parts of the process that are most in need of improvement.
- **Loss control/loss reduction:** The minimization of the severity of losses through methods such as claims investigation and administration, early identification and management of events, and minimization of potential loss of reputation.
- **Loss prevention:** The minimization of the likelihood (probability) of a loss through proactive methods such as risk assessment and identification; staff and volunteer education, credentialing, and development; policy and procedure implementation, review, and revision; preventive maintenance; quality/performance review and improvement; root-cause analysis; and others.
- **Near miss:** 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). Near misses are opportunities for learning and afford the chance to develop preventive strategies and actions. Near misses receive the same level of scrutiny as adverse events that result in actual injury.
- **Patient Safety Goals:** National Patient Safety Goals (NPSGs) for ambulatory care, established by the Joint Commission. The purpose of NPSGs is to improve patient safety by focusing on problems in healthcare safety and how to solve them. 2010 goals include:
  - Identify patients correctly.
  - Use medicines safely by labeling them appropriately and taking precautions with anticoagulants.
  - Review patient medications; communicate and educate about current medication regimens.
  - Prevent infections.
- **Potentially compensable event (PCE):** An unusual occurrence or serious injury for which there is neither an active claim nor institution of formal legal action but that, in the organization's judgment, is reportable to the party (or parties) providing the medical malpractice insurance. Examples include a fall with injuries, delay or failure in diagnosing a patient's condition, an adverse reaction to treatment, significant complaints from a patient or family regarding care or treatment, and an attorney request for medical records.
- **Risk analysis:** Determination of the causes, potential probability, and potential harm of an identified risk and alternatives for dealing with the risk. Examples of risk analysis techniques include failure mode and effects analysis, systems analysis, root-cause analysis, and tracking and trending of adverse events and near misses, among others.
- **Risk assessment:** Activities undertaken in order to identify potential risks and unsafe conditions inherent in the organization or within targeted systems or processes.
- **Risk avoidance:** Avoidance of engaging in practices or of hazards that expose the organization to liability.
- **Risk control:** Treatment of risk using methods aimed at eliminating or lowering the probability of an adverse event (i.e., loss prevention) and eliminating, reducing, or minimizing harm to individuals and the financial severity of losses when they occur (i.e., loss reduction).
- **Risk financing:** Analysis of the cost associated with quantifying risk and funding for it.

- **Risk identification:** The process used to identify situations, policies, or practices that could result in the risk of patient harm and/or financial loss. Sources of information include proactive risk assessments, closed claims data, adverse event reports, past accreditation or licensing surveys, medical records, clinical and risk management research, walk-through inspections, safety and quality improvement committee reports, insurance company claim reports, risk analysis methods such as failure mode and effects analysis and systems analysis, and informal communication with healthcare providers.
- **Risk management:** Clinical and administrative activities undertaken to identify, evaluate, prevent, and control the risk of injury to patients, staff, visitors, volunteers, and others and to reduce the risk of loss to the organization itself. Activities include the process of making and carrying out decisions that will prevent or minimize clinical, business, and operational risks.
- **Risk Management Information System (RMIS):** A computerized system used for data collection and processing, information analysis, and generation of statistical trend reports for the identification and monitoring of events, claims, finances, and more.
- **Risk retention:** Internally driven financing mechanisms (e.g., self-insured retentions) intended to pay for accidental and uninsurable losses.
- **Risk transfer:** Techniques involving the process of shifting the financial burden of losses to an external party or parties (e.g., insurance, contracts).
- **Root-cause analysis:** A process for identifying the basic or causal factor(s) that underlie the occurrence or possible occurrence of an adverse event.
- **Sentinel event:** Defined by the Joint Commission as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse event.
- **Trigger methodology:** A method of measuring harm related to the occurrence of adverse events. The method utilizes a clearly defined list of patient events (also known as a “trigger tool”) against which patient medical records are screened. Screening criteria are based on high-risk areas, or those areas identified as “red flags” through event reporting or as a result of a severe adverse event (e.g., new diagnosis of cancer, nursing home placement, use of more than five medications, high-risk pregnancy).
- **Unsafe and/or hazardous condition:** Any set of circumstances (exclusive of a patient’s own disease process or condition) that significantly increases the likelihood of a serious adverse outcome for a patient or of a loss due to an accident or injury to a visitor, employee, volunteer, or other individual.

#### 4. PROGRAM GOALS AND OBJECTIVES

The Patient Safety and Risk Management Program goals and objectives are 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.
- Minimize adverse effects of errors, events, and system breakdowns when they do occur.
- Minimize losses to the organization overall by proactively identifying, analyzing, preventing, and controlling potential clinical, business, and operational risks.

- Facilitate compliance with regulatory, legal, and accrediting agency requirements (e.g., Joint Commission, Accreditation Association of Ambulatory Health Care).
- Protect human and intangible resources (e.g., reputation).

## 5. SCOPE AND FUNCTIONS OF THE PROGRAM

The (organization name) Patient Safety and Risk Management Program interfaces with many operational departments and services throughout the organization.

### 5.1 Functional Interfaces

Functional interfaces with the patient safety and risk management program include the following:

- Buildings and grounds
- Claims management
- Corporate/regulatory compliance
- Credentialing of providers
- Disaster preparation and management
- Employee health
- Event/incident/accident reporting and investigation
- Finance/billing
- Human resources
- Infection control
- Information technology
- Legal and contracts
- Marketing/advertising/public relations
- Nutritional services
- Patient and family education
- Patient satisfaction
- Pharmaceuticals and therapeutics
- Product/materials management
- Quality/performance assessment and improvement
- Safety and security
- Social service programs
- Staff education
- Volunteers

### 5.2 Risk Management Program Functions

Risk management functional responsibilities include:

a) Developing systems for and overseeing the reporting of adverse events, near misses, and potentially unsafe conditions. Reporting responsibilities may include internal reporting as well as external reporting

to regulatory, governmental, or voluntary agencies. This includes the development and implementation of event-reporting policies and procedures.

b) Ensuring the collection and analysis of data to monitor the performance of processes that involve risk or that may result in serious adverse events (e.g., preventive screening, diagnostic testing, medication use processes, perinatal care). Proactive risk assessment can include the use of failure mode and effects analysis, system analysis, and other tools.

c) Overseeing the organizational RMIS for data collection and processing, information analysis, and generation of statistical trend reports for the identification and monitoring of adverse events, claims, finances, and effectiveness of the risk management program.

This system may utilize and include, but is not limited to, the following:

- Attorney requests for medical records, x-rays, laboratory reports
- Committee reports and minutes
- Criteria-based outcome studies
- Event, incident, or near miss reports
- Medical record reviews
- Monitoring systems based on objective criteria
- Notice letters, lawsuits
- Nursing reports
- Patient complaints
- Physician and other medical professionals' input
- Results of failure mode and effects analysis of high risk processes
- Root-cause analyses of sentinel events

d) Analyzing data collected on adverse events, near misses, and potentially unsafe conditions; providing feedback to providers and staff; and using this data to facilitate systems improvements to reduce the probability of occurrence of future related events. Root-cause analysis and systems analysis can be used to identify causes and contributing factors in the occurrence of such events.

e) Ensuring compliance with data collection and reporting requirements of governmental, regulatory, and accrediting agencies.

f) Facilitating and ensuring the implementation of patient safety initiatives such as improved tracking systems for preventive screenings and diagnostic tests, medication safety systems, and falls prevention programs.

g) Facilitating and ensuring provider and staff participation in educational programs on patient safety and risk management.

- h) Facilitating a culture of safety in the organization that embodies an atmosphere of mutual trust in which all providers and staff members can talk freely about safety problems and potential solutions without fear of retribution. This ordinarily involves performing safety culture surveys and assessments.
- i) Proactively advising the organization on strategies to reduce unsafe situations and improve the overall environmental safety of patients, visitors, staff, and volunteers.
- j) Reducing the probability of events that may result in losses to the physical plant and equipment (e.g., biomedical equipment maintenance, fire prevention).
- k) Preventing and minimizing the risk of liability to the organization, and protecting the financial, human, and other tangible and intangible assets of the organization.
- l) Decreasing the likelihood of claims and lawsuits by developing a patient and family communication and education plan. This includes communicating and disclosing errors and events that occur in the course of patient care with a plan to manage any adverse effects or complications.
- m) Decreasing the likelihood of lawsuits through effective claims management, and investigating and assisting in claim resolution to minimize financial exposure in coordination with the liability insurer and its representatives.
- n) Reporting claims and PCEs to medical malpractice insurance providers and other insurers in accordance with the requirements of the insurance policy/contract.
- o) Supporting quality assessment and improvement programs throughout the organization.
- p) Implementing programs that fulfill regulatory, legal, and accreditation requirements.
- q) Establishing an ongoing patient safety/risk management committee composed of representatives from key clinical and administrative departments and services.
- r) Monitoring the effectiveness and performance of risk management and patient safety actions. Performance monitoring data may include:
- Claims and claim trends
  - Culture of safety surveys
  - Event trending data
  - Ongoing risk assessment information
  - Patient's and/or family's perceptions of how well the organization meets their needs and expectations
  - Quality performance data
  - Research data

s) Completing insurance, and deeming applications.

t) Developing and monitoring effective handoff processes for continuity of patient care.

## **6. ADMINISTRATIVE AND COMMITTEE STRUCTURE AND MECHANISMS FOR COORDINATION**

The Patient Safety and Risk Management Program is administered through the risk manager and/or designee, who reports to the administrator/chief executive officer (CEO)/executive director. The risk manager interfaces with administration, staff, medical providers, and other professionals and has the authority to cross operational lines in order to meet the goals of the program. The risk manager (or alternate as designated by the administrator/CEO) chairs the activities of the Patient Safety/Risk Management Committee. The committee meets regularly and includes representatives from key clinical and services. The composition of the Patient Safety/Risk Management Committee is designed to facilitate the sharing of risk management knowledge and practices across multiple disciplines and to optimize the use of key findings from risk management activities in making recommendations to reduce the overall likelihood of adverse events and improve patient safety. The Committee's activities are an integral part of a patient safety and quality improvement and evaluation system.

Documentation of the designation of the risk manager is contained in the Patient Safety Risk Management Plan. The risk manager is responsible for overseeing day-to-day monitoring of patient safety and risk management activities and for investigating and reporting to the insurance carrier actual or potential clinical, operational, or business claims or lawsuits arising out of the organization, according to requirements specified in the insurance policy and/or contract. The risk manager serves as the primary contact between the organization and other external parties on all matters relative to risk identification, prevention, and control, as well as risk retention and risk transfer. The risk manager oversees the reporting of events to external organizations, per regulations and contracts, and communicates analysis and feedback of reported risk management and patient safety information to the organization for action.

## **7. MONITORING AND CONTINUOUS IMPROVEMENT**

The Patient Safety/Risk Management Committee reviews risk management activities regularly. The risk manager reports activities and outcomes (e.g., claims activity, risk and safety assessment results, event report summaries and trends) regularly to the governing board. This report informs the governing board of efforts made to identify and reduce risks and the success of these activities and communicates outstanding issues that need input and/or support for action or resolution. Data reporting may include event trends, claims analysis, frequency and severity data, credentialing activity, relevant provider and staff education, and risk management/patient safety activities. In accordance with the organization's bylaws, recommendations from the Patient Safety/Risk Management Committee are submitted as

needed to the board for action or non-action. Performance improvement goals are developed to remain consistent with the stated risk management and patient safety goals and objectives.

Documentation is in the form of quarterly risk management reports to the administrator/CEO and governing board on risk management activities and outcomes.

## 8. CONFIDENTIALITY

Any and all documents and records that are part of the patient safety and risk management process shall be privileged and confidential to the extent provided by state and federal law. Confidentiality protections can include attorney client privilege, attorney work product, and peer review protections.

Medical providers may be able to apply the federal privilege and confidentiality protections granted by the Patient Safety and Quality Improvement Act of 2005 to its patient safety events, data, and reports—referred to in the law as patient safety work product—by creating a patient safety evaluation system, through which the organization collects patient safety work product with the intent of providing it to one or more patient safety organizations for analysis and feedback. Care must be taken to ensure that the patient safety evaluation system is developed within the context of the provider’s state laws for legal privilege and peer review as well as the new federal law.

The signatures below represent an acceptance of the Patient Safety and Risk Management Program.

Date: \_\_\_\_\_

Administrator/CEO Approval: \_\_\_\_\_

Date: \_\_\_\_\_

Medical Director/CMO Approval (if applicable): \_\_\_\_\_

Date: \_\_\_\_\_

Governing Board Approval: \_\_\_\_\_