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Risk Management Plan

Patient Safety and Risk Management Program*

1. PURPOSE

The Risk Management Plan is designed to support the mission and vision of Central Ozarks Medical Center (COMC) as it pertains to clinical risk and patient safety. It addresses visitor, third party, volunteer, and employee safety as well as 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. This document serves as a formal, written plan for the risk management and patient safety program.

The Quality/Risk Management Program supports COMCs' 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 quality and risk management program. All staff are key to successful implementation of the quality and risk management program and are expected to be knowledgeable about and participate in risk management activities; to assist with the implementation of recommended improvements; and to identify risk events and opportunities for improvement. The program will be implemented through the coordination of multiple organizational functions and the activities of multiple staff members.

Central Ozarks Medical Center 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 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.

Central Ozarks Medical Center's 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 risk management activities, including the following:

- Claims and insurance management
- Complaint resolution
- Confidentiality and release of information
- Compliance efforts
- Safe and secure use of technology
- Event investigation, root-cause analysis, and follow-up
- Proactive analyses (e.g., failure mode and effects analysis, proactive risk assessments)
- Provider and staff education (including such items as documentation practices and effective tracking)
- Competency validation, credentialing and privileging requirements, and background checks
- Systems for monitoring and tracking referrals (speciality care, hospital and or emergency department admissions) and diagnostic laboratory values and other tests
- Reporting and management of adverse events and near misses
- Trend analysis of events, near misses, and claims
- Implementing performance improvement strategies to mitigate risk

2.1 Leadership

The success of Central Ozarks Medical Center Quality and Risk Management Program requires top-level commitment and support. The governing board or designee authorizes the formal program and adoption of this Plan as noted by their signature.

The governing board and senior executives are committed to promoting the safety of all patients, visitors, employees, volunteers, and other individuals involved in operations of the organization. The Quality 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.

3. PROGRAM GOALS AND OBJECTIVES

The Risk Management Program goals and objectives include the following:

- Continuously improve patient safety and minimize or prevent the occurrence of errors, events, and system breakdowns leading to harm of 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, financial, and operational risks

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

4. SCOPE AND FUNCTIONS OF THE PROGRAM

COMC's Risk Management Program interfaces with many operational departments and services throughout the health center, as well as HRSA.

4.1 Functional Interfaces

Functional interfaces with the quality and risk management program include areas such as credentialing and privileging, information technology, event reporting and investigation, performance assessment and improvement, volunteers, infection control, and administration. All areas work together on risk reduction strategies and methods as defined in this plan (Attachment 1).

4.2 Risk Management Program Functions

Risk management functional responsibilities include the following:

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, 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 (e.g., preventive screening, diagnostic testing, medication use processes, perinatal care). Risk assessment tools include the use of system analysis, root-cause analysis, and other tools.
c) Overseeing the organizational risk informational management system (RIMS) 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.
d) Ensuring compliance with data collection and reporting requirements of governmental, regulatory, and accrediting agencies.
e) 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.
f) Ensuring provider and staff participation in educational programs on patient safety and risk management.

g) 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.
h) Proactively advising the organization on strategies to reduce unsafe situations and improve the overall environmental safety of patients, visitors, staff, and volunteers.
i) Preventing and minimizing the risk of liability to the health center, and protecting the financial, human, and other tangible and intangible assets of the health center.
j) Investigating and assisting in claim resolution to minimize financial exposure in coordination with the liability insurer and its representatives.
k) Reporting claims and potentially compensable events (PCEs) to the appropriate entity, including medical malpractice insurance providers or U.S. Department of Health and Human Services Federal Tort Claims Act (FTCA) claims (as appropriate) and other insurers in accordance with the requirements of the insurance policy/contract and FTCA requirements.
l) Supporting quality assessment and improvement programs throughout the organization.
m) Implementing programs that fulfill regulatory, legal, and accreditation requirements.
n) Monitoring the effectiveness and performance of risk management and patient safety actions. Performance monitoring data may include the following:

- Claims and claim trends
- Culture of safety surveys
- Event trending data
- Ongoing risk assessment information
- Patient's or family's perceptions of how well the organization meets their needs and expectations
- Quality performance data
- Research data

o) Create, track and evaluate organizational risk management goals for the organization based off the regular analysis of trending data.
p) Completing deeming applications.
q) Developing and monitoring effective handoff processes for continuity of patient care.

5. ADMINISTRATIVE AND COMMITTEE STRUCTURE AND MECHANISMS FOR COORDINATION

The Quality and Risk Management Program is administered through the Chief Quality and Risk Officer (CQRO). The CQRO reports to the Chief Executive Officer (CEO). The CQRO 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 CQRO chairs the activities of the Quality and Risk Management Committee. The committee meets regularly and includes representatives

from key clinical and support services. The composition of the Quality and Risk Management Committee is designed to facilitate the sharing of risk management knowledge and practices across multiple disciplines; to optimize the use of key findings from risk management activities in making recommendations; and 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 CQRO is contained in the Risk Management Plan. The CQRO 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 or contract. The CQRO 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 CQRO 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.

6. REPORTING REQUIREMENTS, MONITORING, AND CONTINUOUS IMPROVEMENT

The Quality and Risk Management Committee reviews risk management activities regularly. The CQRO reports activities and outcomes (e.g., claims activity, risk and safety assessment results, event report summaries, and trends) regularly to leadership and the governing board. This report informs them of efforts made to identify and reduce risks, reports on the success of these activities, and communicates outstanding issues that need input 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 Quality and Risk Management Committee are submitted as needed to the board for approval. 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 qulity and risk management meeting minutes.

7. Identification of Central Ozarks Medical Center's Chief Quality and Risk Officer

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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 may include attorney/client privilege, attorney work product, Patient Safety Organization, and peer review protections.

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

CEO Approval: _____

Date: 6/23/2020

Governing Board Approval: _____

Date: 6/23/20

Reference: ECRI Institute

ATTACHMENT 1

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 or its providers. These activities include identifying potential claims early, notifying the organization's liability insurance carrier 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.
- **Enterprise risk management (ERM):** "Enterprise risk management in healthcare promotes a comprehensive framework for making risk management decisions which maximize value protection and creation by managing risk and uncertainty and their connections to total value." (ASHRM, 2012) ERM is further defined by RIMS (the risk management society™) as a strategic business discipline that supports the achievement of an organization's objectives by addressing the full spectrum of its risks and managing the combined impact of those risks as an interrelated risk portfolio. ERM represents a significant evolution beyond previous approaches to risk management. ERM does the following:
    - Encompasses all areas of organizational exposure to risk (e.g., financial, operational, reporting, compliance, governance, strategic, reputational)
    - Prioritizes and manages those exposures as an interrelated risk portfolio rather than as individual "silos"
    - Evaluates the risk portfolio in the context of all significant internal and external environments, systems, circumstances, and stakeholders
    - Recognizes that individual risks across the organization are interrelated and can create a combined exposure that differs from the sum of the individual risks
    - Provides a structured process for the management of all risks, whether those risks are primarily quantitative or qualitative in nature
    - Views the effective management of risk as a competitive advantage
    - Seeks to embed risk management as a component in all critical decisions throughout the organization
- **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.
- **Hazards:** Situations with the potential to cause harm.
- **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 owing to a 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. For 2016 goals, see Attachment 2.
- **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 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 (actual or perceived), and an attorney request for medical records, among others.
- **Risks:** The probability that a specific adverse event will occur in a specific time period or as a result of a specific situation.
- **Risk analysis:** Determination of the causes, potential probability, and potential harm associated with an identified risk and alternatives for addressing 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.
- **Risk assessment:** Activities undertaken in order to identify potential risks and unsafe conditions inherent in the organization or within targeted systems or processes. By conducting a risk assessment, organizations capture feedback on issues that may affect quality of care, efficiency, or costs. Examples of tools utilized include risk matrices, structured surveys, quality measures, and review of patient complaints to identify issues.
- **Risk avoidance:** The risk assessment technique that entails eliminating hazards, activities, and exposures that place an organization's valuable assets (patients) at risk. Examples include protective safeguards (through policy, training, or technology), the informed consent process, and compliance with regulations.
- **Risk control:** Treatment of risk using methods aimed at eliminating or lowering the probability of an adverse event (e.g., loss prevention through a falls prevention program, procuring bariatric chairs [for waiting rooms and exam areas] to accommodate obese or overweight patients); eliminating, reducing, or minimizing harm to individuals; and minimizing the financial severity of losses when they occur (e.g., loss reduction through patient follow-up regarding abnormal lab results).
- **Risk financing:** Financing strategies including all the ways of generating funds to pay for losses that risk control techniques do not entirely prevent. These treatment techniques include risk retention and risk transfer. They involve analysis of the costs associated with quantifying risk and funding for it, such as through general liability insurance.
- **Risk identification:** The process used to identify situations, policies, or practices that could result in the risk of patient harm 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 information management system (RIMS):** 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 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 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. This problem solving method is used for identifying the root causes of faults or problems. A factor is considered a root cause if its removal from the problem-fault-sequence prevents the final undesirable event from recurring; whereas a causal factor is one that affects an event's outcome, but is not a root cause.
- **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 areas identified as "red flags" through event reporting or as a result of a severe adverse event (e.g., new diagnosis of cancer, use of more than five medications, high-risk pregnancy).
- **Unsafe 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 likelihood of a loss due to an accident or injury to a visitor, employee, volunteer, or other individual.