Risk Management and Patient Safety Plan – SAMPLE

(Subsection of Quality Management Plan)

I. Governing Body and Administrative Endorsement and Oversight

[Insert facility name] is committed to providing the highest level of safe patient services in an environment that presents minimal risk to its patients, visitors, volunteers, and employees. This goal is supported through a formal, organization-wide risk management and patient safety program that is part of the facility’s operations and its quality management plan.

The governing body, administration, leadership staff members, and medical staff members work together to establish, maintain, and support this comprehensive, integrated program. Each seeks to establish effective mechanisms for assessing and appropriately responding to risk-related findings.

The [insert name of governing body quality committee] will provide oversight of activities and outcomes of the risk management and patient safety program and perform the following tasks:

• Monitor progress toward program goals and address significant barriers;
• Receive and review periodic summary reports on risk outcomes, any trends of events and claims, and improved patient safety; and
• Consider recommendations from the [insert name of medical staff credentialing committee] and review any significant individual physician data on liability-related adverse events and actual claims received.

II. Program Mission, Vision, and Values

Consistent with the established mission and vision of the organization, the program goals and the purposes for the risk management and patient safety program are as follows:

• Encourage a culture of patient safety throughout the organization;
• Facilitate prompt identification and response to patient safety and risk issues;
• Seek to understand the full scope of any internal patient safety problems;
• Decrease the frequency and severity of any untoward events and reduce financial losses associated with claims;
• Assist in continually improving the timely, accurate, coordinated, and safe delivery of healthcare services and thus strengthen the organization;
• Ensure the safeguarding and confidentiality of all documents that are part of risk management proceedings, reports, and records; and
• Facilitate proactive identification of clinical, financial, business, and insurable risks prior to starting a new service line or a new high-risk procedure, medication, or equipment.

Components of a Culture of Patient Safety:

• Commitment to safety is articulated at the highest levels of the organization and translated into shared values, beliefs, and behavioral norms at all levels.

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- Necessary resources, incentives, and rewards provided by the organization allow this commitment to occur.
- Safety is valued as the primary priority, even at the expense of “production” or “efficiency,” and personnel are comfortable “stopping the line” for patient safety concerns.
- Communication between workers and across the organization’s levels is frequent and candid.
- Unsafe acts are rare, despite high levels of production.
- There is openness about errors and problems; they are reported when they occur.
- Learning is valued across the organization; the response to a problem focuses on improving system performance rather than blaming an individual.1

III. Structure and Scope of Program

A. Oversight, Accountability, and Authority

The authority and accountability for support and evaluation of the risk management and patient safety program is vested in the governing body, which in turn delegates the responsibility for the implementation of risk management functions to the chief executive officer and vice president of medical affairs/chief of staff. The coordination of all risk management and patient safety activities is assigned to the risk management professional/patient safety director who reports directly to the CEO or designate. The risk management and patient safety office is responsible for coordinating the activities identified within the plan. (The risk and patient safety functions may be combined with the overall quality management role; the risk management professional/patient safety director may also be the director of quality management and report directly to an executive.)

B. Program Management and Patient Safety Officer

1. Quality and Patient Safety Council

The Quality and Patient Safety Council consists of members of the governing body, the medical staff, and administration. The council agenda supports ongoing direction, coordination, and evaluation of the risk management, quality, and patient safety program. The agenda includes physician and non-physician activities related to the reducing morbidity and mortality and improving patient safety. The council will:

- Receive reports and act on recommendations from the risk management, quality, and patient safety department(s) regarding at least the following: infection prevention and control, environmental safety, patient relations, utilization review/case management, and quality improvement;
- Coordinate all quality, risk, and patient safety programs in the organization;
- Oversee event reporting and patient complaint reporting on an aggregate basis and review all high-alert events and claims;
- Cooperate with the [insert name of medical staff credentialing committee] in resolving multidisciplinary problems in patient care delivery; and
- Report on all activities to the [insert name of governing body quality committee].
2. Risk Management/Patient Safety Officer and Department Staff
   The risk management professional/patient safety officer coordinates implementation of the risk management and patient safety plan under the ultimate supervision of the governing body. The risk management and patient safety department is responsible for the following:
   • Risk identification, assessment, and analysis;
   • Risk intervention, treatment, and control;
   • Risk reduction and prevention; and
   • Risk monitoring, evaluation, and reporting.

   The risk management/patient safety department coordinates solutions for high-risk situations and develops long-term risk treatment strategies, using tools of quality and performance improvement in collaboration with the quality management program. The department also develops an annual strategic risk and patient safety plan that supports internal and external patient safety initiatives, protects facility assets against loss, and ensures regulatory compliance.

3. Medical Staff Administration and Professional Peer Review Committees
   The governing body, through this plan, authorizes the medical director, the quality director, and the designated quality review staff member(s) to coordinate, initiate, and conduct peer/professional review. The peer/professional review process is conducted in such a way as to ensure confidential and secure handling of materials and outcomes, according to established policies and state statutes. All quality management data are kept secure in the quality management office and will not be released except under court order or as deemed appropriate by the administration.

   The medical staff is responsible for the continuous review and evaluation of medical staff functions and clinical activities. Medical staff leaders will review ongoing professional practice evaluations (OPPEs) for each provider at least every six months. Providers will receive feedback on their performance at least every six months. Actions will be taken to address any quality of care concerns.

   The medical staff actively participates in risk management and patient safety activities directly associated with clinical aspects of patient care, including the identification of areas of risk through its various quality committees. Appropriate medical peers evaluate data concerning individual events or adverse patterns of care involving physician practice.

   The [insert name of medical executive committee] reviews issues that are identified by the risk management, quality, and patient safety office and evaluated by peer review committees. The [insert name of medical executive committee] will also complete the following:
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- Evaluate credentials and performance of all applicants for appointment and reappointment to the medical staff and provide recommendations to the governing body
- Review ongoing professional practice evaluation reports submitted by the quality management office
- Review data on physician practice patterns or trends and medical professional liability case findings submitted by the risk management office
- Prepare reports for the [insert name of governing body quality committee]

IV. Mechanisms for Program Coordination
The risk management and patient safety program focuses on using initiatives aimed at patient safety, risk reduction, risk prevention, and quality improvement to help realize the general corporate mission of achieving high quality and cost-effective operations and outcomes. The risk management and patient safety program will be integrated with the organization-wide quality program through periodic strategic planning and the ongoing risk-related activities of the risk management professional/director of patient safety and other leaders. Partnerships in risk control and patient safety are formed and maintained with the following personnel:
- Chief executive officer (CEO)
- Chief financial officer (CFO)
- Patient safety officer
- Patient relations representatives
- Nursing leaders and clinical department managers
- Medical department chairs and leaders
- Physicians and advanced practice professionals
- Nurses and other patient care providers
- Case managers, discharge planners and utilization review staff members
- Quality review staff members
- Credentialing coordinators/medical staff services professionals
- Performance improvement director
- Environmental engineers/safety officer
- Dietary and housekeeping staff members
- Clinical educators
- Infection prevention and control practitioners
- Admitting and billing clerks/patient account representatives
- Compliance officers and legal counsel
- Employee health nurse
- Human resource director
- Health information manager (or medical records director)
- Other staff members providing direct or indirect patient services, including volunteers

V. Communicating with Patients about Safety
One goal of the risk management and patient safety program is to foster effective patient and family communication, including the following:
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- Patient involvement in treatment/care planning
- Informed consent and/or informed refusal
- Discussion of any unanticipated outcomes and disclosure
- Discharge planning

It is the policy of [insert name of facility] to maintain honesty and integrity in all of the organization’s functions. Consistent with this policy, it is appropriate to disclose adverse events, errors, and/or unanticipated outcomes that could affect a patient’s emotional or physical health. In such cases, the risk management professional, lead physician, and the provider team members will debrief each other and agree on an effective response that openly informs the patient, safeguards her/his well-being, and provides a coordinated care plan and communication.

In order to ensure that a general environment of open communication exists and to strengthen consumer confidence, patient and family member perceptions about the provided care are elicited and suggestions for improving care are welcomed. Appropriate complaint and grievance procedures are followed. Significant clinical information is successfully conveyed to patients with limited English proficiency and/or a hearing impairment by providing the necessary and appropriate resources.

VI. Staff Member Education: Safety-Related Knowledge and Practice

The active involvement of all patient care providers and leaders is needed to prevent and control events and to collaboratively improve processes that may cause a patient to suffer an injury due to an error, accident, omission, delay, and/or poor communication. The purpose of a risk and patient safety educational program is to ensure active involvement and instill understanding of basic principles and practices of risk prevention and control.

Education on select topics of patient safety and risk management is provided to physicians, patient care staff members, and managers at the time of orientation and regularly thereafter. Educational topics may include the following:
- Patient relations and complaint management
- Patient rights
- Structured and team-based communication
- Etiology and effects of medical errors, accidents, omissions, and delays
- Medical record documentation, confidentiality, and informed consent
- Chain of command policy and delegation of duties
- Event reporting
- Medical equipment management, environmental safety, and security
- Value of evidence-based practice guidelines and standardized procedures
- Principles of performance improvement

During orientation, new employees are provided with clear and written job expectations, are assigned to a preceptor or mentor for a defined period of time, meet all entry criteria of clinical job competency, and collaborate with their supervisor to set educational goals for their first year of employment. Various educational methods are implemented, including not
VII. Risk Identification, Assessment, and Analysis

A. Data Sources

Data sources to identify risks may include the following:

- Events, incidents, adverse events, complications, and claims
- Global trigger tools
- High-risk clinical presentation assessment
- Patient complaints
- Patient satisfaction surveys
- Event investigation and root cause analyses
- External survey deficiencies
- Internal risk surveys and assessments of high-risk areas, including:
  - Clinical service lines such as obstetrics, emergency, perioperative, long-term care
  - Medical staff credentialing and privileging
  - Physician office management
  - Environmental safety assessment
- New service-line risk evaluation
- New equipment risk evaluation
- Drug utilization and new drug review
- Infection prevention and control and environmental surveillance
- Walking risk and patient safety rounds
- Educational clinical case conferences
- Concurrent, criteria-based clinical case reviews
- Risk and quality indicator monitoring and audits
- Event screens, near miss events, failure mode and effects analysis (FMEA)
- Employee and physician surveys and informal feedback
- Benchmarking information, such as The Joint Commission’s Sentinel Event Alerts and core measures
- Non-payment for hospital-acquired conditions
- State reportable events
- Data submitted to a patient safety organization (PSO)

B. Event Reporting

The risk management program will encourage risk identification through a systematic event reporting process, along with other proactive and collaborative procedures. Staff members are required to complete an event report when an event or situation occurs that is not consistent with the routine operation and procedure of the facility, the routine care of a patient or visitor, or the routine activities of an employee or volunteer. Reporting expectations also include situations that do not result in injury and may instead become an averted error (“near miss”).

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The risk management and patient safety department conducts an initial review of all events, assigns a severity level, responds immediately as needed, and completes follow-up action plans with managers and directors, as appropriate. Events are trended, analyzed, and reported at least quarterly to appropriate committees in order to improve the safety and quality of care and reduce morbidity and mortality. Strategies for loss prevention and loss reduction are integrated into the organization’s performance improvement processes in a manner that is consistent with the corporate vision, mission, and strategic objectives.

Unanticipated outcomes should be disclosed to the patient and/or family members in any healthcare environment. If the patient and/or a family member is not made aware immediately, then once the unanticipated nature of the outcome is reported to the risk management department, a plan should be developed to discover all the facts necessary to share the information with the patient and/or a family member. At this point all involved parties should follow the organization’s disclosure policy.

C. Potentially Compensable Events (PCEs)
Within the organization, and in conjunction with patient care providers and facility leaders, the risk management and patient safety program will identify unexpected or unanticipated risk exposures or events that have loss potential and/or involve unsafe conditions which have caused injury or have the potential to cause injury. Various data sources may be reviewed to identify PCEs (e.g., complaints, staff member feedback, event reports, and the results of screens). In responding to a PCE, the risk management professional/patient safety director may gather information about the event, including information about any processes and/or providers involved, obtain and sequester physical evidence related to the event, obtain and sequester documentary evidence (e.g., medical records or event reports), and secure the site.

The risk management professional/patient safety director, in coordination with involved key directors, managers and medical staff members, reviews PCEs, addresses them immediately as necessary for patient and caregiver support, implements a short-term action plan, and refers the PCEs to the quality/performance improvement process and to the professional liability carrier, as appropriate.

Risk reduction strategies are identified and may include referring to peer review, initiating a root cause analysis, and the appropriate manager(s) or director(s) developing an action plan. The risk management professional/patient safety director will be apprised of action plan(s) that are developed and implemented and will ensure that tracking, trending, and reporting will be performed and considered in future strategic planning. All potentially compensable events will be reported to the appropriate risk management, quality, medical staff, and governing body committees.

D. Identification, Reporting, and Management of Adverse Health/Never/Sentinel Events
The Agency for Healthcare Research and Quality (AHRQ) has identified the following 29 never events.
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Surgical Events
- Surgery or other invasive procedure performed on the wrong body part
- Surgery or other invasive procedure performed on the wrong patient
- Wrong surgical or other invasive procedure performed on a patient
- Unintended retention of a foreign object in a patient after surgery or other procedure
- Intraoperative or immediately postoperative/postprocedure death in an American Society of Anesthesiologists Class I patient

Product or Device Events
- Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the health care setting
- Patient death or serious injury associated with the use or function of a device in patient care, in which the device is used for functions other than as intended
- Patient death or serious injury associated with intravascular air embolism that occurs while being cared for in a health care setting

Patient Protection Events
- Discharge or release of a patient/resident of any age, who is unable to make decisions, to other than an authorized person
- Patient death or serious disability associated with patient elopement (disappearance)
- Patient suicide, attempted suicide, or self-harm resulting in serious disability, while being cared for in a health care facility

Care Management Events
- Patient death or serious injury associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation, or wrong route of administration)
- Patient death or serious injury associated with unsafe administration of blood products
- Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy while being cared for in a health care setting
- Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy
- Artificial insemination with the wrong donor sperm or wrong egg
- Patient death or serious injury associated with a fall while being cared for in a health care setting
- Any stage 3, stage 4, or unstageable pressure ulcers acquired after admission/presentation to a health care facility
- Patient death or serious disability resulting from the irretrievable loss of an irreplaceable biological specimen
- Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results

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Environmental Events
- Patient or staff death or serious disability associated with an electric shock in the course of a patient care process in a health care setting
- Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or is contaminated by toxic substances
- Patient or staff death or serious injury associated with a burn incurred from any source in the course of a patient care process in a health care setting
- Patient death or serious injury associated with the use of restraints or bedrails while being cared for in a health care setting

Radiologic Events
- Death or serious injury of a patient or staff associated with introduction of a metallic object into the MRI area

Criminal Events
- Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed health care provider
- Abduction of a patient/resident of any age
- Sexual abuse/assault on a patient within or on the grounds of a health care setting
- Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of a health care setting

The Joint Commission defines a sentinel event as follows:
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 any of the following:
- Death
- Permanent harm
- Severe temporary harm

An event is also considered sentinel if it is one of the following:
- Suicide of any patient receiving care, treatment, and services in a staffed around-the-clock care setting or within 72 hours of discharge, including from the hospital’s emergency department (ED)
- Unanticipated death of a full-term infant
- Discharge of an infant to the wrong family
- Abduction of any patient receiving care, treatment, and services
- Any elopement (that is, unauthorized departure) of a patient from a staffed around-the-clock care setting (including the ED), leading to death, permanent harm, or severe temporary harm to the patient
• Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
• Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of any patient receiving care, treatment, and services while on-site at the hospital.
• Rape, assault (leading to death, permanent harm, or severe temporary harm), or homicide of a staff member, licensed independent practitioner, visitor, or vendor while on site at the hospital
• Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure
• Unintended retention of a foreign object in a patient after an invasive procedure, including surgery
• Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)
• Prolonged fluoroscopy with cumulative dose >1,500 rads to a single field or any delivery of radiotherapy to the wrong body region or >25% above the planned radiotherapy dose
• Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care
• Any intrapartum (related to the birth process) maternal death
• Severe maternal morbidity (not primarily related to the natural course of the patient’s illness or underlying condition) when it reaches a patient and results in permanent harm or severe temporary harm

[Footnotes]
i. **Severe temporary harm** is critical, potentially life-threatening harm lasting for a limited time with no permanent residual, but requires transfer to a higher level of care/monitoring for a prolonged period of time, transfer to a higher level of care for a life-threatening condition, or additional major surgery, procedure, or treatment to resolve the condition. Adapted from: Throop C, Stockmeier C. *The HPI SEC & SSER Patient Safety Measurement System for Healthcare*. 2011 May.

ii. Sexual abuse/assault (including rape) as a sentinel event is defined as nonconsensual sexual contact involving a patient and another patient, staff member, or other perpetrator while being treated or on the premises of the hospital, including oral, vaginal, or anal penetration or fondling of the patient’s sex organ(s) by another individual’s hand, sex organ, or object. One or more of the following must be present to determine that it is a sentinel event:
- Any staff-witnessed sexual contact as described above
- Admission by the perpetrator that sexual contact, as described above, occurred on the premises
- Sufficient clinical evidence obtained by the hospital to support allegations of unconsented sexual contact
iii. Invasive procedures, including surgery, on the wrong patient, or at the wrong site, or that is the wrong procedure are reviewable under the policy, regardless of the type of the procedure or the magnitude of the outcome.

iv. If a foreign object (for example, a needle tip or screw) is left in the patient because of a clinical determination that the relative risk to the patient of searching for and removing the object exceeds the benefit of removal, this would not be considered a sentinel event to be reviewed. However, in such cases, the organization shall (1) disclose to the patient the unintended retention, and (2) keep a record of the retentions to identify trends and patterns (for example, by type of procedure, by type of retained item, by manufacturer, by practitioner) that may identify opportunities for improvement.

v. Fire is defined as a rapid oxidation process, which is a chemical reaction resulting in the evolution of light and heat in varying intensities. A combustion process that results in smoldering condition (no flame) is still classified as fire. Source: National Fire Protection Association. NFPA 901: Standard Classifications for Incident Reporting and Fire Protection Data. Quincy, MA: NFPA, 2011.

vi. Severe maternal morbidity is defined, by the American College of Obstetrics and Gynecology, the US Centers for Disease Control and Prevention, and the Society of Maternal and Fetal Medicine, as patient safety event that occurs intrapartum through the immediate postpartum period (24 hrs), that requires the transfusion of 4 or more units of blood products (fresh frozen plasma, packed red blood cells, whole blood, platelets) and/or admission to the intensive care unit (ICU). Admission to the ICU is defined as admission to a unit that provides 24-hour medical supervision and is able to provide mechanical ventilation or continuous vasoactive drug support. Ongoing vigilance to better identify patients at risk—and timely implementation of clinical interventions consistent with evidence-based guidelines—are important steps in the ongoing provision of safe and reliable care. Appropriate systems improvements can be informed by identifying occurrences of maternal morbidity, reviewing the cases, and analyzing the findings. For additional details, please see “Update: Revised Definition of Severe Maternal Morbidity in Sentinel Event Policy,” June 2015 Perspectives.

Mandatory state reporting requirements will be observed pursuant to the applicable regulatory mandates. Voluntary reporting to the Patient Safety Organization (PSO) will be performed by following the PSO reporting guidelines.
E. **Root Cause Analysis**

After each serious adverse or sentinel event or a significant near miss, a thorough investigation is performed. The Agency for Healthcare Research and Quality (AHRQ) defines a near miss as follows:

An event or situation that did not produce patient injury, but only because of chance. This good fortune might reflect the robustness of the patient (e.g., a patient with penicillin allergy receives penicillin but has no reaction) or a fortuitous, timely intervention (e.g., a nurse happens to realize that a physician wrote an order in the wrong chart). This definition is identical to that for close call.21

A root cause analysis (RCA) is conducted for all sentinel events to identify the core contributing factors. Please see [name of organization’s sentinel event policy] for more information. An RCA may be performed for significant near-miss events.

The National Patient Safety Foundation released Root Cause Analysis 2, a new RCA methodology in summer of 2015. Since that time, the Joint Commission has mandated this new methodology be used for RCAs in accredited hospitals. The title refers to an emphasis not only on defining the root cause of sentinel events, but also on developing strong, sustainable actions to prevent further errors; hence the RCA2 title refers to root cause analysis AND action.22

VIII. **Risk Treatment and Control (Risk Reduction and Prevention)**

Strategies in the phases of risk intervention, risk treatment, and risk control (reactive and proactive) may include the following:

A. **Reactive Risk Intervention and Treatment**

- Critical event response, including complaints
- Event investigation
- Debriefing and disclosure
- Root cause analysis (RCA, RCA2)
- Reporting events to external agencies as required, for example:
  - Reporting adverse event to the state, as required
  - Reporting medical device-related events to the manufacturer or FDA
  - Reporting restraint-related deaths to CMS
  - Reporting to the medical examiner, as required
  - Reporting abuse or violence to the proper authorities, as required
- Internal claims management and litigation support
- Claims management

The risk management office maintains records of professional liability claims, general liability claims, and property claims. Aggregate and claim-specific data are analyzed by the risk management professional/patient safety director to identify trends and patterns and to implement risk reduction strategies to improve the quality of patient care and reduce...
morbidity and mortality. Information pertinent to risk trends and recurring high-risk processes and outcomes is communicated to appropriate managers, directors, performance improvement coordinators, administrators, and members of the medical staff and the governing body.

B. Sample Proactive Risk Interventions and Treatment by the Risk Management Professional
   - Obtaining insurance coverage and risk financing, as assigned
   - Contract review, as assigned
   - Management of risk and patient safety data
   - Providing education to staff members on the early identification and control of patient safety issues
   - Facilitating risk surveys and assessments of various clinical service units
   - Referring complex patient safety issues to the performance improvement coordinator and directly participating in improvement projects
   - Ensuring that providers comply with redesigned procedures and clinical protocols
   - Facilitating regulatory compliance, including reviewing policies and procedures and implementing National Patient Safety Goals, HIPAA, other safety standards, laws, and regulations
   - Providing risk consultation to all levels and committees in the organization
   - Serving as liaison to federal and state agencies and regulatory bodies

C. Sample Proactive Risk Interventions and Treatment in Collaboration with Other Leaders and Providers in the Organization
   - Identification of clinical, financial, business, and insurable risks prior to starting a new clinical procedure, new service line, new high-risk medication, or new equipment
   - Implementation of a culture of patient safety
   - Participation FMEA
   - Provider-to-provider communication protocols (e.g., SBAR)
   - Chain of command policy development, implementation, and monitoring
   - Accurate and complete medical record documentation and monitoring
   - Physician involvement in performance improvement projects
   - Procedures for infection prevention and control
   - Medication error reduction procedures
   - Evidence-based clinical protocol development
   - Adequate staffing levels and mix

D. Performance Improvement Tools
   For successful implementation of risk prevention and patient safety solutions, quality tools, and methods are utilized, for example:
   - Cause and effect diagrams
   - Pareto diagrams
   - Run charts
   - Flow charts
   - Affinity grouping

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- Multi-voting
- Interviews
- Brainstorming
- Huddles
- Scatter diagrams
- Histogram
- Plan-Do-Study-Act Worksheets
- Storyboards
- Sampling
- Walk-throughs
- Surveys

E. **Failure Mode, Effects and Criticality Analysis**

Failure mode and effects analysis (FMEA) is performed as a proactive, preventive method of evaluating a potentially high-risk process in order to identify where and how it might fail. It is also useful in evaluating a new process before implementation. Facilities accredited by The Joint Commission are required to conduct one FMEA annually.

Conducting a FMEA includes reviewing the following:
- What could go wrong?
- Why would the failure happen?
- What would be the consequences of each failure?23

IX. **Risk and Patient Safety Monitoring, Evaluation and Reporting**

The risk management department engages in the continuous monitoring and evaluation of risk issues and outcomes. Toward this end, measurable indicators are strategically defined, efficient and reliable data collection is accomplished, basic statistical principles in data analysis and reporting are utilized, the involvement of appropriate providers in monitoring events is encouraged, hazardous situations are recognized, and improvements are made.

Activities in the phases of risk monitoring and evaluation include the following:
- Aggregate event analysis and claims analysis and trending
- Patient satisfaction surveys and trending of complaint type and severity
- Practitioner performance trending
- Compliance audits of redesigned safety procedures and clinical practice protocols
- Regulatory compliance monitoring regarding patient safety
- Summary patient safety reports to the governing body, managers and providers
- Required reporting to external agencies

At least quarterly, the effectiveness of the risk management and patient safety program is formally evaluated by the risk management and patient safety department and the findings are reported to executive leaders and the governing body. Such evaluation includes the effects of risk interventions and any changes and trends in risk-related outcomes and their probable causes. The report includes recommendations for further risk prevention and control activities. Quarterly reports, which include objective data of any progress made, are

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also prepared for department managers, their staff members, and the medical staff. A summary review is presented at least annually to the governing body.

Signatures of Acceptance and Approval

Chair, [inset name of governing body] ___________________________ Date ___________________________

VP of Operations ___________________________ Date ___________________________

Medical Director ___________________________ Date ___________________________

References:
3. Ibid.
4. Ibid.
5. Ibid. p. 100.
7. Ibid. p. 100.
8. Ibid. p. 99.
9. Ibid. p. 100.
10. Ibid. p. 99.
13. Ibid. p. 100.
16. Ibid. p. 100.
18. Ibid. p. 100.

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