PENINSULA REGIONAL MEDICAL CENTER
PATIENT SAFETY PLAN

A. MISSION

The leaders of Peninsula Regional Medical Center (hereinafter referred to as "Medical Center") ensure the implementation of the Patient Safety Plan (Plan) throughout the organization. The Plan is designed to promote the highest degree of patient safety by identifying and managing the potential risks to patient safety. The mission of this plan is to proactively encourage organizational learning about medical care/health care errors and supports the sharing of that knowledge to effect behavioral changes at the Medical Center to improve patient safety. Leadership of the Medical Center also strive to foster an environment of recognition and acknowledgment of risks to patient safety and medical/health care errors and supports the initiation of actions to reduce these risks; the internal reporting of what has been found; and the actions taken. Leadership, within current Medical Center policy and procedures, avoids the placement of blame for involvement in a medical/health care error. This Plan also establishes mechanisms for effective responses to actual occurrences, an ongoing proactive reduction in medical/health care errors, and integration of patient safety into all relevant organizational processes, functions, and services.

The plan includes process for:

1. Designating an individual as the Patient Safety Officer who is responsible for certain duties which are addressed within this Plan,
2. Defining the scope of the Plan and the types of occurrences that are to be addressed by the Plan,
3. Describing mechanisms to insure that all components of the health care organization participate in the Plan and that their functions and activities are integrated into the organization-wide program,
4. Detailing procedures for immediate response to medical/health care errors including care of the patient(s), containment of risk to others, and preservation of factual information and evidence for subsequent analysis,
5. Detailing clear expectations for external and internal reporting of information relating to medical/health care errors,
6. Defining mechanisms for responding to and investigating various types of adverse/sentinel events, such as using a root cause analysis in response to certain types of events as described herein; for developing an action plan based upon the root cause analysis; and for conducting proactive risk reduction activities,
7. Providing support of staff who have been involved in adverse or sentinel events,
8. Providing an orientation and ongoing educational programs for all staff that includes the presentation of the key elements of this Plan to promote a constant awareness of promoting patient safety,
9. Describing ongoing monitoring of performance based upon:
    a. Actual medical/health care errors
    b. Assessment of risk from surveys or other sources of information
    c. Level of staff knowledge and skills
    d. Adverse Events, Near Misses, and Sentinel events
    e. Industry experience
10. Providing performance improvement initiatives and follow-up-monitoring to promote organizational learning and behavioral change,

11. Detailing how an annual evaluation of the effectiveness of the plan will be performed and presented to the Quality Oversight Committee of the Board of Trustees and then to the Board of Trustees.

B. DEFINITIONS

- ACTION PLAN: a written document that includes:
  a. Specific measures to correct problems or areas of concern;
  b. Specific measures to address areas of organization-wide improvement;
  c. Time frames for implementation of any specific measures; and
  d. Title of responsible individual to monitor implementation and effectiveness.

- ADVERSE EVENT: an unexpected occurrence related to a patients medical treatment and not related to the natural course of the patient's illness or underlying disease condition.

- LEVEL 1 ADVERSE EVENT: an adverse event that results in death or serious disability.

- LEVEL 2 ADVERSE EVENT: an adverse event that requires a medical intervention to prevent death or serious disability.

- LEVEL 3 ADVERSE EVENT: an adverse event that does not result in death or serious disability and does not require any medical intervention to prevent death or serious disability.

- MEDICAL REVIEW COMMITTEE: has the meaning as stated in Health Occupations Article Section 1-401 et seq., Annotated Code of Maryland.

- NEAR-MISS: a situation that could have resulted in an adverse/sentinel event but did not, either by chance or through timely intervention.

- PATIENT SAFETY Program: an ongoing, proactive program for identifying risks to patient safety and reducing medical errors which is one component of the organization-wide Risk Management program.

- ROOT CAUSE ANALYSIS: a medical review committee process as defined under Health Occupations Article, Section 1-401, Annotated Code of Maryland, for identifying the basic or contributing causal factors that underlie variations in performance associated with adverse/sentinel events or near-misses.

- SENTINEL EVENT: 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

- 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

- SERIOUS DISABILITY: a physical or mental impairment that substantially limits one or more of the major life activities of an individual lasting more than seven (7) days or still is present at the time of discharge.

C. OVERSIGHT AND RESPONSIBILITY

The **Vice President of Patient Safety and Chief Compliance Officer** (serving as the Patient Safety Officer) shall:

1. Coordinate patient safety activities
2. Facilitate assessment and determination of the appropriate response to reported adverse events, near-misses and sentinel events related to patient care;
3. Monitor root cause analyses and any actions resulting from a root cause analysis; and
4. Provide for the flow of information among process improvement, credentialing, peer review; and any other committees related to patient safety.

The following Medical Review Committees shall be structured in accordance with Health Occupations Article, Section 1-401, Annotated Code of Maryland to conduct reviews and evaluations of patient safety activities:

1. Performance Improvement Council:
   Membership on the Performance Improvement Council includes but is not be limited to:
   a. President of the Medical Center
   b. President of the Medical Staff
   c. Vice President of the Medical Staff
   d. Vice Chairman of the Board of Trustees
   e. Chief Operating Officer
   f. Vice President of the Patient Safety and Chief Compliance Office
   g. Vice President of Patient Care Services
   h. Vice President of Medical Affairs
   i. Chief Information Officer
   j. Two (2) physicians at large
   k. Chair of Nursing Process Improvement Council

   Responsibilities include but are not limited to:

a. Recipient of reported patient safety related occurrences;
b. Monitors patient safety related occurrences and medical/health care errors including the tracking of the current status of all adverse/sentinel event activities;
c. Performs various monitoring and measuring activities;
d. Sponsors focus group activities;
e. Initiates performance improvement initiatives from any follow-up monitoring activities.
f. Determine improvement and safety priorities and assign accountabilities;
g. Review appropriate clinical and service data;
h. Determine improvement priorities and assign accountability
i. Charter teams;
j. Receive reports on the outcomes or results of priority decisions; and
k. Assure compliance with the Joint Commission and other accreditation requirements.

2. . Root Cause Analysis Committee

Membership on the Root Cause Analysis Committee includes but is not limited to:

a. Vice President of Patient Safety and Chief Compliance Officer
b. Vice President Of Operations, Optimizations and Innovations
c. President of the Medical Staff
d. Vice President of Patient Care Services
e. Vice President of Medical Staff Affairs
f. The Joint Commission Coordinator
g. Chief Operating Officer
h. Director of Risk Management (serves as Chair) & associated staff
i. Medical Staff Liaison for Risk Management
j. Chief Medical Information Officer
k. Individuals who have knowledge of the event include employees and medical staff.

Responsibilities include but are not limited to:

a. Conduct a Root Cause Analysis for all Sentinel Events
b. Conduct a Root Cause Analysis for all Level 1 Adverse Events
c. Conduct a Root Cause Analysis for all Level 2 Adverse Events
d. Conduct a Root Cause Analysis for Near-Miss if warranted after review by the Patient Safety Officer or the Director of Risk Management.
e. Develop action plan related to the root cause analysis of all events
f. Develop plans for implementation and evaluation of action plans

Other Medical Review Committees related to Patient Safety issues include but are not limited to Physician Excellence Committee, Environment of Care, Credentialing Committee, Utilization Review Committee, Pharmacy, Nutrition and Therapeutics Committee, Clinical Practice and Standards Committee, Nursing Excellence Committee, Fall Subcommittee, Radiation Safety Committee and Infection Control Committee.

D. SCOPE OF PATIENT SAFETY PLAN

The Patient Safety Plan provides for processes by which the Performance Improvement Council is designed to be the receptacle for all reported patient safety related events. Specifically when such an event has the potential to cause harm to a patient, is an unusual occurrence, or deviates from the routine shall be reported. The following list is intended to be demonstrative of the types of events that shall be reported, including but not limited to the following:

1. Patient injuries or potential injuries; i.e., falls, burns, cuts, bruises, etc.
2. Untoward events regardless of location (x-ray, lab, etc.) whether patient is injured or not (including near misses)
3. Equipment malfunction, failure or problems regardless of patient injury, including operator errors.
4. Complications of therapy that extend stay beyond expected time frame.
5. Medication occurrences.
6. Allergic or unusual reactions to medications or therapies.
7. Events causing serious patient dissatisfaction.
8. Procedural deviations where there is a potential or actual risk of patient injury.
9. Departures of routines or policies of the Medical Center that result in harm or potential harm of a patient.
10. Loss, damage or theft of the patient's or Medical Center property.
11. Visitor Injuries or potential injuries.

Sentinel Events 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:

1. 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)

2. Unanticipated death of a full-term infant

3. Discharge of an infant to the wrong family

4. Abduction of any patient receiving care, treatment, and services

5. 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

6. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)

7. 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[1]

8. 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

9. Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure[2]

10. Unintended retention of a foreign object in a patient after an invasive procedure, including surgery[3]

---

[1] ***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

[2] 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.

[3] 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

11. Severe neonatal hyperbilirubinemia (bilirubin >30 milligrams/deciliter)

12. 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.

13. Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care[4]

14. Any intrapartum (related to the birth process) maternal death

15. 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 any of the following: Permanent harm or severe temporary harm[5]

Level 1 Adverse Event is an adverse event that results in death or serious disability which is an unexpected occurrence related to an individual's medical treatment and not related to the natural course of the patient's illness or underlying disease condition.

Level 2 Adverse Event is an adverse event that requires a medical intervention to prevent death or serious disability which is an unexpected occurrence related to an individual's medical treatment and not related to the natural course of the patient's illness or underlying disease condition.

Level 3 Adverse Event is an adverse event that does not result in death or serious disability and does not require any medical intervention to prevent death or serious disability that is not related to the natural course of the patient's illness or underlying disease condition.

Near-Miss a situation that could have resulted in an adverse event but did not, either by chance or through timely intervention. The Patient Safety Officer and/or the Director or Risk Management will review a Near-Miss to determine if a Root Cause Analysis is warranted and if determined to be, the Root Cause Analysis process will be initiated. The following factors will be considered in making this determination:

a. Potential severity of outcome to the patient;

---

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.

[4] ***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.

[5] ***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-Fetal Medicine, as a patient safety event that occurs intrapartum through the immediate postpartum period (24 hrs), that requires the transfusion of 4 or more units of packed red blood cells and/or admission to the intensive care unit (ICU). Facilities are strongly encouraged to review all cases of severe maternal morbidity for learning and improvement. *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.

b. Frequency of occurrence of same or similar near misses; and
c. Likeliness of discovering the Near Miss prior to causing potential severe adverse outcome to the patient

(PLEASE NOTE THAT A SENTINEL EVENT MAY ALSO MEET THE DEFINITION OF A LEVEL 1 OR LEVEL 2 ADVERSE EVENT)

Hazardous Condition is any condition or set of circumstances within the Environment of Care that may affect the safety of patients, visitors or staff.

E. MECHANISMS OF INTEGRATION FOR ORGANIZATION WIDE PARTICIPATION

All components of the Medical Center are integrated into the Patient Safety Plan process. Information relative to patient safety is provided to all staff upon hire, annually, and as needed. In addition it is provided to the Medical Staff during orientation and through the various Medical Review Committee processes. Patient safety is promoted through participation on committees and teams such as Performance Improvement Council, Fall Subcommittee,, Root Cause Analysis Committee, Infection Control, Radiation Safety Committee, Nursing Excellence Committee and other patient safety related committees as deemed appropriate.

Teams and committees share information, guidance and recommendations with all areas of the Medical Center, as necessary, to promote patient safety. All areas of the Medical Center are governed by the same policies and procedures relative to patient safety.

Daily safety huddles are conducted on each clinical unit and within select departments across the organization as a method of proactively identifying patient safety issues. Information shared and gained through this process is used to mitigate risk of an adverse event and to promote the culture of patient safety

F. RESPONSE TO MEDICAL/HEALTH CARE ERRORS/ UNEXPECTED OUTCOMES

Medical/health care errors or events that present potential danger to the patient as defined in Section B, should be responded to with the following priority:

1. Assess the patient immediately and thoroughly for injury, potential injury or potential complication of therapy secondary to the actual or potential medical/health care error.
2. Identify and implement any immediate corrective actions to prevent further injury or complication or additional reoccurrences.
3. Provide immediate physiologic and/or pyschologic care which is within the healthcare provider's scope of practice in order to stabilize or support the patient.
4. Notify the primary physician or licensed independent practitioner (LIP) immediately of the event. Orders from the physician or LIP will dictate further medical action. Nursing orders may also be implemented to include measures which would mitigate further risk of harm or injury to the patient and to other susceptible patients.
5. Preserve any information related to the event (including physical information). Examples of physical information include but are not limited to removal and preservation of blood unit for a suspected transfusion reaction; preservation of IV tubing, fluids and pumps for drug reaction or medication occurrences; preserve medication labels and bottles, etc.
6. Document the event on an Occurrence Report or Memorandum for the Record as provided in Sections G and J and forward to the Risk Management Department. Careful

documentation of the facts and evidence surrounding the event are essential for timely communication to and tracking by the Risk Management Department.

7. Review the event with staff involved in the error and within the department to examine how/why it occurred and to develop an action plan for process improvement/error prevention.
8. Provide notification to the patient and when appropriate, their families about the event and the outcomes of care, including unanticipated outcomes in accordance with the Medical Center's policy "Disclosure of Unanticipated Events".
9. Explain the outcome of any treatments or procedures to the patient, and when appropriate the family, whenever those outcomes differ significantly from the anticipated outcomes
10. Conduct a Root Cause Analysis if warranted by criteria defining an occurrence as a sentinel event, Level 1 Adverse Event, Level 2 Adverse Event, Near-Miss (as determined by the Patient Safety Officer or the Director of Risk Management) within sixty (60) days of the time that the Risk Management Department has knowledge of the occurrence. **Sentinel Event and Adverse Event Reporting Policy in the Administrative Policy Manual** Develop an action plan and implement throughout the organization as necessary to reduce the risk of reoccurrence. Education of staff is an integral part of the action plan.
11. If an event meets the criteria defining an occurrence as a Level 3 Adverse Event or a Near Miss that does not require a Root Cause Analysis, The Risk Management Department will return the **Occurrence Report to the Clinical Manager or Department Director for further re**medial action if required and initiation of proactive occurrence reduction activities including but not limited to individual and staff education.
12. Risk Management Department will aggregate data to determine patterns and trends.
13. Risk Management Department provide monthly reports to Clinical Managers and Department Directors summarizing all reported occurrences. along with the analysis of data The Risk Management Department provides trends and analysis of occurrence data to department Directors and various Medical Review Committees as requested. .
14. Provide summary reports at least annually to Performance Improvement Council and then the Quality Oversight Committee of the Board of Trustees and the Board of Trustees.

G. EXPECTATIONS FOR INTRAHOSPITAL REPORTING (See Occurrence Reporting Policy)

Any event which has potential danger to the patient is an unusual occurrence, or deviates from the routine including but not limited to Level 1 Adverse Events, Level 2 Adverse Events, Level 3 Adverse Events, Near Misses and Sentinel Events shall be reported to The Risk Management Department. This reporting can come from internal as well as external sources. Any employee or individual including but not limited to members of the Medical Staff, who has information or who first discovers the occurrence should prepare and submit an Occurrence Report or Memorandum for the Record to the Risk Management Department within seventy two (72) hours of event.

All events involving medication errors should be reported using the Medication Occurrence Report. Events related to patient falls should be reported using the Fall Occurrence Report. All other events should be reported on the Occurrence Report or a Memorandum of Record. The purpose of this reporting is to:

1. Promote the highest degree of patient safety by identifying and managing the potential risks to patient safety.
2. Provide an early detection system for issues related to patient safety
3. Provide a foundation for early investigation of all potentially adverse occurrences.
4. Identify preventable occurrence patterns or trends.

5. Monitor compliance with Medical Center policies and procedures.
6. Provide a data base for performing a risk assessment to determine areas where we need to improve our level of patient safety
7. Contribute to the development of a sound risk assessment prevention and problem resolution program.
8. Identify opportunities for educational initiatives to impact organization wide behavioral changes that promote patient safety.

Support a just culture to encourage occurrence reporting The Medical Center procedure "Occurrence Reporting" and "Sentinel Event Reporting" provides further details relating to the process of intrahospital reporting and is incorporated herein in its entirety into the Patient Safety Plan.

H. REPORTS TO THE MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

All Level 1 Adverse Events shall be reported to the Maryland Department of Health and Mental Hygiene by the Director of Risk Management with in five (5) days of the Medical Center's knowledge that the event occurred. A Root Cause Analysis and action plan for the Level 1 Adverse Event shall be submitted to the Maryland Department of Health and Mental Hygiene within sixty (60) days of the Medical Center's knowledge of the occurrence.

Any Root Cause Analysis and any other Medical Review Committee information submitted to the Department and the identity of individuals appointed to the Root Cause Analysis Committee are confidential under Health Occupations Article, Section 1-401, Annotated Code of Maryland and are not discoverable, disclosable, or admissible as evidence in any civil action or available under the Maryland Public Information Act.

I. INTER-HOSPITAL NOTIFICATION OF LEVEL 1 OR LEVEL 2 ADVERSE EVENTS

If a patient is admitted to the Medical Center with a condition resulting from an adverse event that the Medical Center perceives may be related to care that was provided at another Maryland hospital and that appears to be unknown to the other hospital at the time of discharge, the Risk Management Department shall notify and provide any necessary information to the appropriate medical review committee at the hospital where the adverse event allegedly occurred.

The hospital where the event allegedly occurred has the statutory responsibility to conduct a root cause analysis and provide notice to the Maryland Department of Health and Mental Hygiene. The hospital where the alleged event occurred has the statutory responsibility to notify the patient or the patient's family.

J. MECHANISMS FOR FOLLOW-UP

All occurrences including but not limited to Level 1 Adverse Events, Level 2 Adverse Events, Level 3 Adverse Events, Near Misses and Sentinel Events are reviewed by the Risk Management Department to determine what follow-up or intervention is required. After the initial review by the Risk Management Department, occurrence reports requiring continued investigation are returned to the originating Department or area.

The Risk Management Department review of the Occurrence Report is based upon the following guidelines and expectations:

1. Ensure that all necessary information has been included in the report:

a. Patient identification if appropriate;
b. Identification of employees, physicians, or others who were present at time of occurrence;
c. Date, time, location, shift, sex, age, diagnosis.;
d. Classification based upon type of occurrence;
e. Identification of causal or contributing factors/parameters
f. Pre-occurrence facts (ambulating/with permission, improper footwear, call light not used, bed rails down/restrained, bed sensor, etc.)
g. Description of occurrence
    i. Factual, concise description of occurrence
    ii. Statements made by the patient
    iii. Description of what was observed
    iv. Outcome/injury
    v. Care provided at the time of occurrence
    vi. Notification of physician
    vii. If a patient fall, documentation of the fall in the medical record and notification of family if authorized by the patient
    viii. Signature, printed name and title of the person preparing the report
    ix. 24 hour follow-up if appropriate; and
    x. Signature of Clinical Manager or Department Director.

2. Further investigation and documentation may be required to provide adequate detailed information.
3. Assess Occurrence Report to identify preventable occurrence patterns or trends.
4. Referral as appropriate, i.e., track and trend, peer review, refer to Vice President of Medical Staff, Physician Process, etc.
5. Determination and categorization of the event as a Level 1 Adverse Event, Level 2 Adverse Event, Level 3 Adverse Event, Near Miss or Sentinel Event.
6. If it is determined that an occurrence could have been prevented by following appropriate processes or policies, the Occurrence Report is returned to the Clinical Manager/Department Director for staff and/or individual education.

K. ROOT CAUSE ANALYSIS

In the event that an occurrence is deemed to be a Sentinel Event, Level 1 Adverse Event, Level 2 Adverse Event, or Near-Miss that warrants a Root Cause Analysis, the Root Cause Analysis process will be initiated by the Director of Risk Management. A number of tools are used in not only conducting this analysis but also in monitoring the progress of the analysis as well as monitoring the outcomes of the recommendations.

The root cause analysis investigation shall be initiated by the Risk Management Department and the investigation includes but is not limited to a review of the patient's current and prior medical records, review of Occurrence Report/Memorandum of Record, interviews with staff and physicians who were present or have information related to the occurrence, review of organizational policies and procedures and review of relevant literature and industry best practices.

The root cause analysis shall examine the cause and effect of the event through an impartial process by:

1. Analysis of human and other factors
2. Analysis of related processes and systems;
3. Analysis of underlying cause and effect systems through a series of "why" questions;

4. Identification of risks and possible contributing factors; and
5. Determination of improvement in process or systems.
6. The root cause analysis shall be consistent organization-wide
7. Survey of relevant literature and best practice shall be part of the root cause analysis.

A sample of the root cause analysis form and a flow diagram of the root cause analysis process is attached hereto as Appendix A.

L. NON-PUNITIVE MEASURES AND SUPPORT OF STAFF

An effective Patient Safety Program cannot exist without optimal reporting of medical/healthcare errors and occurrences. Therefore it is the intent of the Medical Center to adopt a non-punitive approach in its management of errors and occurrences. The Medical Center develops and encourages a supportive environment that permits spontaneous identification, open discussion, and timely and accurate reporting of Adverse/Sentinel Events and Near-Misses.

Staff members that are involved in an adverse event, or for that matter, any occurrence that has an outcome that is severe and serious in nature, may require assistance in dealing with the personal trauma associated with the occurrence. Following an adverse/sentinel event staff may need psychological intervention and/or counseling to deal with post traumatic stress. Further involvement with staff after the Root Cause Analysis has been performed may be indicated to again re-assure staff and in some instances to re-educate staff about the behavioral changes that are needed to prevent re-occurrence.

The Medical Center's Employee Health Service will provide the initial intervention following an adverse event. Referrals to other allied health care practitioners can be made as deemed necessary by the Employee Health Department . During hours when the Employee Health Office is not open, the same level of service can be accessed by staff through the Medical Center's Emergency Department, as is the case with all other employee health related issues.

The Medical Center's Employee Assistance Program is available as a resource to assist employees as needed. .

M. ORIENTATION AND EDUCATION

The orientation and education program dealing with patient safety at the Medical Center is multi-faceted. The basis for promoting patient safety is staff knowledge, orientation, initial competency, on-going education and annual evaluation of demonstrated competency. Secondarily, but equally important are the educational systems that are brought into play to educate patients and families themselves to participate in issues related to patient safety.

Staff orientation and education

The hiring process at the Medical Center is the foundation of the Orientation and Education process. The interview process, combined with reference checks and criminal background checks, helps to insure that we hire staff with proper credentials, experience, and backgrounds that will not detract from our Patient Safety Plan. Once hired, all staff participate in the following elements of the orientation process:

1. An intensive orientation that includes generic information relating to the Medical Center's operations including a session dedicated to a review of the Patient Safety Plan.
2. An orientation process that provides initial on the job training and information and assesses the staff member's ability and competency to perform their duties as detailed in their job description. Where appropriate and needed, specific training on equipment needed to provide care or used as part of performing all aspects of the job description is also provided.
3. On going in-service education and other training and education to maintain and improve staff competence and support an interdisciplinary approach to patient care.
4. Annual review and competence assessment of the key elements of the Patient Safety Plan.
5. Annual review of the competence assessment of all staff.

N. ONGOING PERFORMANCE MONITORING

Performance monitoring and subsequent improvement are data driven. The degree of stability of important processes can provide the organization with good information about its performance. Leadership at the Medical Center prioritizes data collection based upon our mission, care and services provided, and populations served. Data that is considered for collection to monitor performance may include the following:

- Performance measures related to accreditation and regulatory issues;
- Risk Management tracking and trending data related to Occurrence Reporting;
- Utilization management;
- Quality control;
- Patient, family, and staff opinions, needs, perceptions of risks to patients, and suggestions for improving patient safety;
- Employee's Patient Safety Culture Perception Survey data
- Outcomes of processes or services;
- Autopsy results when performed;
- Performance measures from acceptable data bases;
- Customer demographics and diagnoses;
- Infection control surveillance and reporting;
- Community and national data;
- Research data;
- Medication use;
- Operative and other procedures that place patients at risk;
- Use of blood and blood components;
- Restraint use;
- Seclusion when it is part of the care or services provided; and
- Care or services provided to high risk populations.

The Performance Improvement Council will establish on an ongoing basis a number of performance measures to be monitored from the previous list that will act effectively as a dashboard for the organization. Results of performance measuring and monitoring will then be used to initiate performance improvement opportunities.

Another significant area of performance monitoring is accomplished through the Patient Satisfaction Survey Process. By surveying patients that utilize our services we are able to obtain information about the needs, expectations and satisfaction of the individuals and

organizations served by the Medical Center. The Patient Satisfaction Survey Process asks patients and families about:

- Their specific needs and expectations;
- Their perception of how well the organization meets these needs and expectations; and
- How the organization can improve performance.

The Medical Center also utilizes the data and the written comments to promote and improve patient safety. Data from the surveys is tabulated and reported monthly throughout the organization. Patient Satisfaction Analysis Teams reviews this data on a regular basis, at least every other month, and identifies opportunities for performance and process improvement.

O. PATIENT COMPLAINTS

Patient complaints will be processed in accordance with the Medical Center's policy, "Patient Complaint and Grievance Procedure". Patient rights and responsibilities, including but not limited to the complaint resolution process, are described in the "Patient & Family Information" brochure which is provided to each patient at the time of admission.

Any employee of the Medical Center may receive a complaint/grievance from a patient, family member or friend. The person receiving the complaint/grievance shall immediately notify his/her Department Manager, immediate supervisor, or the Clinical Manager of the nursing unit where the patient is located. All patient complaints/grievances shall be investigated in a timely fashion and the patient as well as the individual filing the complaint/grievance will be treated with dignity and courtesy. The complaint and any actions taken will be documented for use in performance improvement.

The Department Manager, Clinical Manager or Nursing Supervisor shall provide the patient or individual filing the complaint/grievance with the following information at the onset of the investigation:

1. The name and telephone number of the Department Manager or Clinical Manager who should be contacted for information regarding the complaint/grievance;
2. The procedure involved in investigating the complaint/grievance; and
3. The period of time that should be expect to resolve the complaint/grievance.
4. Notice that the patient may contact the Maryland Department of Health and the manner in which to contact is provided in the "Patient & Family Information" brochure which is provided to each patient at the time of admission.

The "Patient Complaint and Grievance Procedure" sets forth Medical Center's process for handling patient complaints in its entirety and is incorporated in the Plan . (See Patient Complaint and Grievance Procedure)

P. DISCLOSURE OF UNANTICIPATED EVENTS

The disclosure of unanticipated events will be made in accordance with the Medical Center's policy. "Disclosure of an Unanticipated Outcome/Adverse Event". This procedure is set forth in detail in the Medical Center's Policy Manual and is incorporated in its entirety into the Patient Safety Plan.

Q. PERFORMANCE IMPROVEMENT (*See PRMC Performance Improvement System Policy – Admin Policy Manual*)

At least annually the Performance Improvement Council will select at least one high risk process for proactive risk assessment and risk reduction. High risk process selection shall in part be based on information periodically published by the Joint Commission or other nationally recognized sources of information on patient safety and medical errors. The processes selected for proactive risk assessment and risk reduction should include those processes known to be associated with sentinel events, Level 1 Adverse Events, Level 2 Adverse Events, Level 3 Adverse Events, and Near-Misses. The Medical Center adheres to a Performance Improvement philosophy, principles and methods described in the PRMC Performance Improvement System Policy. Once an opportunity is identified, the Patient Safety Officer in conjunction with others on the Medical Center leadership team will make a determination if this will be a departmentally based or mulit-disciplinary organizational wide approach. Through either vehicle, all performance improvement initiatives follow the same format throughout the process.

Once the recommendations have been put in place, re-measuring of the data, or re-evaluation of the process should occur in order to determine if improvement has occurred. Reporting of all process initiatives will be reported through the Performance Improvement Council e, and then annually to the Quality Oversight Committee of the Board of Trustees and then to the full Board of Trustees.

R. ANNUAL EVALUATION AND REPORT TO PERFORMANCE IMPROVEMENT COUNCIL & QUALITY OVERSIGHT COMMITTEE OF THE BOARD OF DIRECTORS

The Patient Safety Officer has the responsibility for coordinating the annual evaluation and reporting of the effectiveness of the Patient Safety Plan. The Patient Safety Plan shall be evaluated on an annual basis to assess its:

- Objectives
- Scope
- Performance
- Effectiveness

In performing the annual evaluation, the Patient Safety Officer may use a variety of source documents such as Occurrence Reports, Committee reports, dashboard reports, and statistical summaries. Information from focus teams and process improvement initiatives will also be integrated into the report. All Sentinel Events, Level 1 Adverse Events and Level 2 Adverse Events will also be reported within this document. Other information such as risk assessment activities, accrediting agency reports, industry statistics and studies may also be included in this comprehensive document. The annual evaluation of the Patient Safety Plan is used as an opportunity to further develop or revise organizational-wide learning and effect organizational behavior to improve patient safety and proactively reduce medical/health errors. The findings of the annual evaluation are documented in a written narrative report. Included within the report are recommendations for improvements to the Patient Safety Plan that have been developed by the Performance Improvement Council .

The annual report is presented to the Performance Improvement Council. Receipt of the annual report is documented in the Performance Improvement Council minutes. Review by the

Performance Improvement Council includes discussion of findings and recommendations. After discussion of the findings and recommendations, the annual report and evaluation is approved by the Performance Improvement Council.

The annual report and evaluation is then presented to the Quality Oversight Committee of the Board of Trustees and then to the Board of Trustees. Any recommendations of the annual report and evaluation will then be returned to the Performance Improvement Council for implementation.

S. MAINTENANCE OF RECORDS

The Medical Center shall maintain records that document the operation of the Patient Safety Plan. Actions taken by Medical Review Committees operating under this Plan shall be documented in Committee Minutes.

T. CONFIDENTIALITY

Any report or document relating to the Patient Safety Plan is considered confidential. All reports and committee functioning in support of the Patient Safety Plan will meet the requirements of Maryland Health Occupations Article 14-501 et. seq. Annotated Code of Maryland.

U. NOTIFICATION OF CHANGES IN PATIENT SAFETY PLAN

The Medical Center shall notify the Secretary of the Maryland Department of Health and Mental Hygiene of any change in its Patient Safety Plan within thirty (30) days of the effective date.

SEE PRMC POLICIES/PROCEDURES/ PLANS:

1. PRMC: Occurrence Reporting Policy
2. PRMC: Sentinel Event Reporting and Adverse Event Reporting Policy
3. PRMC: Patient Complaint and Grievance Procedure
4. PRMC: Disclosure of Unanticipated Outcomes and Adverse Events PRMC Annual Performance Improvement Plan
5. PRMC Performance Improvement System

ADDITIONAL RESOURCES:
Maryland Patient Safety Program
http://dhmh.maryland.gov/ohcq/Pages/PatientSafety.aspx

1. Patient Event Decision Tree
2. Initial Report of an Adverse Event
3. Short Form For Reviewing Patient Falls
4. Short RCA for HA Pressure Ulcers

3/2001
Revised: 5/2001
7/2002
5/2004
5/2016

Signature Date

Board Approval: