I. PURPOSE

The purpose of the organizational Patient Safety Plan at the hospital is to improve patient safety and reduce risk to patients through an environment that encourages:

- Integration of safety priorities into all relevant organization processes, functions, services, departments and programs
- Recognition and acknowledgment of risks to patient safety and medical/health care errors
- The initiation of actions to reduce these risks
- The internal and external reporting of what has been found and the actions taken
- A focus on processes and systems, and the reduction of process and system failures through use of failure mode effect analysis
- Minimization of individual blame or retribution for involvement in a medical/health care error
- Organizational learning about medical/health care errors
- Support of the sharing of that knowledge to effect behavioral changes in itself and other healthcare organizations

- The Patient Safety Plan provides a systematic, coordinated and continuous approach to the maintenance and improvement of patient safety through the establishment of mechanisms that support effective responses to potential or actual occurrences; ongoing proactive reduction in medical/health care errors; and integration of patient safety priorities into the new design and redesign of all relevant organization processes, functions and services.

- As patient care, and therefore the maintenance and improvement of patient safety, is a coordinated and collaborative effort, the approach to optimal patient safety involves multiple departments and disciplines in establishing the plans, processes and mechanisms that comprise the patient safety activities at the hospital. The Patient Safety Plan, developed by the interdisciplinary Safety/Environment of Care Committee and approved by the medical staff, Governing Body and administration, outlines the components of the organizational Patient Safety Program.

II. PATIENT SAFETY PLAN

- Scope of Activities:
  - The scope of the Patient Safety Plan includes ongoing proactive risk assessments, using internal and external knowledge and experience, to prevent error occurrence, maintain and improve patient safety.
  - Patient safety occurrence information from aggregated data reports and individual incident occurrence reports will be reviewed by the Safety/Environment of Care Committee to prioritize organizational patient safety activity efforts. Types of patient safety or medical/health care errors included in data analysis, maybe, but not limited to:
    - No Harm Errors - those unintended acts, either of omission or commission, or acts that do not achieve their intend outcome - that do not result in a physical or psychological negative outcome, or the potential for a negative outcome, for the patient.
    - Mild-Moderate Adverse Outcome Errors - those unintended acts, either of omission or commission, or acts that do not achieve their intend outcome, that result in an identified mild to moderate physical or psychological adverse outcome for the patient.
    - Any Medication Variance
    - Any Adverse Drug Reaction
    - Hazardous Condition - any set of circumstances, exclusive of the disease or condition for which the patient is being treated, which significantly increases the likelihood of a serious physical or psychological adverse patient outcome.
    - Sentinel Event: The following events as outlined on NQF Serious Reportable Events in Healthcare:
    - Surgical Invasive Procedure Events
    - Product or Device Events

- Patient Protection Events
- Radiologic Events
- Care Management Events
- Environmental Events
- Potential Criminal Events

- Near Miss - any process variation which did not affect the outcome, but for which a recurrence carries a significant chance of a serious adverse outcome.
- Hospital Acquired Conditions (HACs):

  a. Falls and trauma (fracture, dislocation, intracranial injury, crushing injury, burn, other injuries)

- The scope of the Patient Safety Plan encompasses the patient population, visitors, volunteers and staff (including medical staff). The plan addresses maintenance and improvement in patient safety issues in every department throughout the facility. There will be an emphasis on important hospital and patient care functions of:

  - Environment of Care
  - Emergency Management
  - Human Resources
  - Infection Prevention and Control
  - Information Management
  - Leadership
  - Life Safety
  - Medication Management

- Medical Staff
- Nursing
- Provision of Care, Treatment and Services
- Performance Improvement
- Record of Care, Treatment and Services
- Rights and Responsibilities of the Individual
- Waived Testing

Methodology:

- The Interdisciplinary Safety/Environment of Care Committee is responsible for the oversight of the Patient Safety Plan. The Safety/Environment of Care Committee Chairperson will have administrative responsibility for the plan, or the Safety/Environment of Care Committee may assign this responsibility to another member of the committee.

- All departments within the organization (patient care and non-patient care departments) are responsible to report patient safety occurrences and potential occurrences to the Director PI/Risk Management, who will aggregate occurrence information and present a report to the Safety/Environment of Care Committee. The report will contain aggregated information related to type of occurrence, severity of occurrence, number/type of occurrences per department, occurrence impact on the patient, remedial actions taken, and patient outcome. The Safety/Environment of Care Committee will analyze the report information and determine further patient safety activities as appropriate.

- Through review of internal data reports and reports from external sources (including, but not limited to, sentinel event report information, ORYX and Core Measure performance data, occurrence reporting information from state and federal sources and current literature), and through the performance improvement priority criteria grid, the Safety/Environment of Care Committee will select at least one high-risk safety process for proactive risk assessment annually. All elements of the high-risk safety related process will be described using work tools as necessary (i.e., flowcharts, cause and effect diagrams). The proactive risk assessment will include:

- Identification of the ways in which the process could break down or fail to perform. This will be done through assessment of the intended and actual implementation of the process to identify the steps in the process where there is, or may be, undesirable variation. Identify the possible effects of the undesirable variation on patients, and how serious the possible effect on the patient could be

- Prioritizing the potential processes breakdowns or failures

  - For the most critical effects, conduct a root cause analysis to determine why the undesirable variation leading to that effect may occur

  - Redesign the process and/or underlying systems to minimize the risk of that undesirable variation or to protect patients from the effects of that undesirable variation

  - Test and implement the redesigned process

  - Identify and implement measures of the effectiveness of the redesigned process

  - Implement a strategy for maintaining the effectiveness of the redesigned process over time

- Description of mechanisms to ensure that all components of the healthcare organization are integrated into and participate in the organizationwide program.

- Upon identification of a process or system failure and/or medical/health care error, the patient care provider will immediately:

  - Perform necessary healthcare interventions to protect and support the patient's clinical condition.

  - As appropriate to the occurrence, perform necessary healthcare interventions to contain the risk to others.

  - Contact the patient's attending physician and other physicians, as appropriate, to report the error, carrying out any physician orders as necessary.

Preserve any information related to the error (including physical information). Examples of preservation of medication label for medications administered to the incorrect patient.

Preservation of information includes documenting the facts regarding the error on an occurrence report, and in the medical record as appropriate to organizational policy and procedure.

- Report the process/system failure or medical/health care error to the staff member's immediate supervisor.

- Submit the occurrence report to the Performance Improvement Department per organizational policy.

- Any individual in any department identifying a process/system failure and/or potential patient safety issue will immediately notify his/her supervisor and document the findings on an incident report. The report will be submitted to the Director PI/Risk Management per organizational policy.

- Staff response to process/system failures and/or medical/health care errors is dependent upon the type of error identified:

  - No Harm Failures or Errors (including "no harm" medication errors) - staff will document appropriately in the medical record according to organizational policy, document the circumstances regarding the no harm error on an occurrence report form, submit the form to the Performance Improvement Department and notify their immediate supervisor.

  - Mild-Moderate Adverse Outcome Failures or Errors (including medication errors/variances) - staff will perform any necessary clinical interventions to support and protect the patient and notify the physician staff responsible for the patient, carrying out any necessary physician orders. Staff will then preserve any physical evidence as appropriate, notify his/her immediate supervisor, document facts appropriately in the medical record and on an occurrence report - submitting the report to the PI/Risk Management Department per organizational policy.

    - Medication Variances/errors - the staff member identifying a medication variance/error (no harm and mild-moderate harm) will notify the Pharmacy Department of the event.

    - Adverse Drug Reaction (ADR) - staff will perform any necessary clinical interventions to support and protect the patient and notify the physician staff responsible for the patient, carrying out any necessary physician orders. Staff

will then preserve any physical evidence as appropriate, notify his/her immediate supervisor, document facts appropriately in the medical record and on an occurrence report, submitting the report to the PI/Risk Management Department. Staff will complete ADR report and forward to Pharmacy.

- Hazardous Condition/Patient Safety Issue - as appropriate, and if possible, staff will contain the hazardous condition or patient safety issue. Staff identifying a hazardous condition or potential patient safety issue will immediately notify his/her supervisor and document the findings on an incident report. The report will be submitted to the PI/Risk Management Department per organizational policy.

- Sentinel Event - staff will perform any necessary clinical interventions to support and protect the patient and notify the physician staff responsible for the patient, carrying out any necessary physician orders. Staff will then follow the organizational Sentinel Event Policy and Procedure.

- Near Miss - staff will report the near miss event to his/her immediate supervisor, describe the facts of the near miss on an incident report and submit the report to the PI/Risk Department.

- Hospital Acquired Conditions - staff will follow all established protocols, guidelines and policies and procedures. Staff shall complete incident reports for any breaks in technique or policy not followed.

Established organizational policy (such as the Sentinel Event Policy) and/or the Safety/Environment of Care Committee will determine the organizational response to process/system failures and/or medical/health care errors and occurrences. All sentinel events and near miss occurrences will have a root cause analysis conducted. The determination of the Safety/Environment of Care Committee members, based on internal and external data analysis and prioritizing of patient safety criticality, will determine:

- Further remedial action activities necessary for identified occurrences

- Proactive occurrence reduction activities

- Necessity and benefit of root cause analysis performance for identified occurrences or proactive reduction activities

- An effective Patient Safety Plan cannot exist without optimal reporting of process/system failures and medical/health care errors and occurrences. Therefore, it is the intent of this institution to adopt a non-punitive approach in its management of failures, errors and occurrences. All staff is required to report suspected and identified medical/health care errors, and should do so without the fear of reprisal in relationship to their employment. This organization supports the concept that errors occur due to a breakdown in systems and processes, and will focus on improving systems and processes, rather than disciplining those responsible for errors and occurrences. A focus will be placed on remedial actions to assist rather than punish staff members, with the Safety/Environment of Care Committee and the individual staff member's department supervisor determining the appropriate course of action to prevent error recurrence.

- Sentinel Events - staff members involved in a sentinel event occurrence will receive support from the Safety/Environment of Care Committee regarding the staff member's professional and emotional reconciliation of the sentinel event. The Safety/Environment of Care Committee encourages the staff member's involvement in the root cause analysis and action plan processes, to allow the staff member an active role in process resolution. Additionally, any staff member involved in a sentinel event or other medical/health care error may request and receive supportive personal counseling from the Social Service Department, Human Resources Department and/or his/her department supervisor.

As part of this organization's culture of safety and quality, any staff member who has concerns about the safety or quality of care provided by the organization may report these concerns to their accrediting organization. The organization supports the staff member's right to report these concerns and will take no disciplinary or retaliatory action against the staff member for reporting the safety or quality of care concern to their accrediting organization.

- On at least an annual basis, staff will be queried regarding their willingness to report medical/health care errors.

- The Patient Safety Plan includes implementation of the recommendations set forth by the accrediting organization, or identified alternative recommendations defined by this institution, to achieve compliance with established safety standards. The selected recommendations will be monitored on a routine basis to evaluate the organization's effectiveness in the implementation of the recommendations in achieving compliance with the identified safety standards.

- The Patient Safety Plan includes an annual survey of staff (including medical staff) opinions, needs and perceptions of risks to patients and requests suggestions for improving patient safety.

- Patients, and when appropriate, their families are informed about the outcomes of care, including unanticipated outcomes, or when the outcomes differ significantly from the anticipated outcomes. The Safety/Environment of Care Committee will analyze error reporting data submitted through the PI/Risk Management Department for evidence of this information.

  Staff will educate patients and their families about their role in helping to facilitate the safe delivery of care.

The Patient Safety Plan includes consideration, at least annually, of data obtained from the organizational Information Management Needs Assessment, which includes information regarding barriers to effective communication among caregivers.

- Staff will receive education and training during their initial orientation process and on an ongoing basis regarding job-related aspects of patient safety, including the need and method to report medical/health care errors. Education includes the staff member's right to report any safety or quality of care concerns to the organization's accrediting organization. And, because the optimal provision of healthcare is provided in an interdisciplinary manner, staff will be educated and trained on the provision of an interdisciplinary approach to patient care.

- Medical/health care errors and occurrences, including sentinel events, will be reported internally and externally, per hospital policy and through the channels established by this plan. External reporting will be performed in accordance with all state, federal and regulatory body rules, laws and requirements.

- Lessons learned from a root cause analysis shall be communicated to staff who provide services or are affected by a patient safety incident

- Patient safety reports from the Safety/Environment of Care Committee will be submitted to the organizational Quality, which exists as the oversight committee for the Safety/Environment of Care Committee. A data report and recordings of meeting minutes will be forwarded to the Quality Committee.

A written Patient Safety Report shall be forwarded to the Governing Body, at a minimum, once per year. Information in the report shall include:

- All system or process failures
- Number and type of sentinel events
- If patients and families were informed of the adverse events
- All actions taken to improve safety, both proactively and in response to actual occurrences
- All results of the analyses related to the adequacy of staffing and actions taken to resolve the identified problem(s)