I. **Purpose:**

To improve the health and safety of hospital patients through the establishment and implementation of a comprehensive Patient Safety Program and a Just Culture environment where reporting and learning from events is valued. UPMC Hamot uses process management, technology and system controls to reduce variance and error while improving clinical outcomes. The acquisition of data, the aggregation and analysis of that data to create information and the sharing of that information to create organizational intelligence, which permits leadership and clinicians to develop and implement changes to continuously improve the way care is delivered.

II. **Definitions:**

A. **Just Culture:** from Agency for Healthcare Research and Quality (AHRQ)
   - Supports a culture where frontline personnel feel comfortable disclosing errors (including their own) while maintaining professional accountability.
   - Recognizes that individual practitioners should not be held accountable for system failings over which they have no control.
   - Does not tolerate reckless behavior, conscious disregard of clear risks to patients, or gross misconduct (e.g., falsifying a record, performing professional duties while intoxicated).
   - Realizes that competent professionals make errors and acknowledges development of unhealthy norms (shortcuts, “routine rule violations”).
   - Focuses on fair, consistent and predictable organizational responses to errors.

B. **Corrective Action:** Any action recommended or taken to promote patient safety as a result of retrospective investigations and/or analyses or Reportable Patient Events or prospective analyses of existing practices, procedures, policies or systems.

C. **Healthcare-Associated Infection:** A localized or systemic condition that results from an adverse reaction to the presence of an infectious agent or its toxins that:
   - Occurs in a patient in a health care setting;
   - Was not present or incubating at the time of admission, unless the infection was related to a previous admission to the same setting; and
   - If occurring in a hospital setting, meets the criteria for a specific infection site as defined by the Centers for Disease Control and Prevention and its National Health Care Safety Network.

D. **Incident:** An event, occurrence or situation involving the clinical care of a patient which could have injured the patient but did not either cause an unanticipated injury or require
the delivery of additional health care services to the patient. This term does not include a serious event. (See Section V.B.3 for criteria used to determine if an event is an “Incident”).

E. **Infrastructure:** Structures related to the physical plan and service delivery systems necessary for the provision of health care services in a medical facility.

F. **Infrastructure Failure:** An undesirable or unintended event, occurrence or situation involving the Infrastructure of a medical facility or the discontinuation or significant disruption of a service which could seriously compromise patient safety.

G. **Mcare:** Pennsylvania’s Medical Care Availability and Reduction of Error Act.

H. **Medication Event:** Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice, health care products, procedures and systems, including prescribing; order communication; product labeling, packaging and nomenclature; compounding, dispensing, distribution, administration, education, monitoring or use. A medication event may be either an incident or serious.

I. **National Healthcare Safety Network (NHSN):** A secure internet based data collection system managed by the Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention.

J. **Peer Review Organization:** A committee or organization consisting of health care providers and/or hospital administrators who evaluate the quality and efficiency of services ordered or performed by a hospital or other health care provider and/or the compliance of a hospital or other health care facility with standards set by an association of health care providers and with applicable laws, rules and regulations.

K. **Reportable Patient Event:** Any Incident, Medication Event, Sentinel Event or Serious Event.

L. **Sentinel Event:** A sentinel event is defined by the Joint Commission as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or the risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

M. **Serious Event:** An event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an Incident. (See Section V.B.2 for criteria used to determine if an event is a “Serious Event”).

N. **TJC:** The Joint Commission.

O. **Preventable Serious Adverse Events (PSAE):** A preventable serious adverse event is defined as an event that occurs in a health care facility that is within the health care provider’s control to avoid, but that occurs because of an error or other system failure and results in a patient’s death, loss of body part, disfigurement, disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility.

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III. **Scope of Patient Safety Program:**
Patient safety is a priority for the leadership of UPMC Hamot and supports a systematic, coordinated and continuous approach to the improvement and management of patient safety. UPMC Hamot established and will continue to establish and implement through this Patient Safety Program and through supporting policies and procedures:

... clearly defined roles of the Governing Body, administrators and clinicians who will create, manage and implement the Patient Safety Program;

... an effective and timely system for the internal report of Reportable Patient Events and Infrastructure Failures;

... protocols for the immediate clinical and non-clinical responses to Serious Events;

... a timely system for the reporting of appropriate information to external governmental agencies, regulatory bodies and other patient safety organizations;

... protocols and tools for investigating and analyzing Reportable Patient Events and Infrastructure Failures;

... proactive risk reduction activities;

... through ongoing review of incidents and events, identify opportunities to improve patient safety and implement/revise processes and procedures;

... design and implementation of processes to meet TJC’s National Patient Safety Goals;

... protocols and tools for the creation and implementation of corrective actions designed to reduce Serious Events and Incidents;

... protocols to encourage and support staff to participate in all aspects of the Patient Safety Program through education and a Just Culture climate for reporting of Reportable Patient Events;

... periodic reports to the Governing Body concerning patient safety;

... mechanisms for receiving and considering the input of employees, patients and patient families concerning patient safety issues;

... protocols for the communication to patients and/or guardians and family members of the significant aspects of patient care, including disclosure and notification of Serious Events in compliance with Mcare and TJC standards.

... procedures to ensure compliance to Act 52 of 2007; health-associated infections and amendments to the Mcare Act.

The results of these efforts will:

... Demonstrate UPMC Hamot’s commitment and accountability to the community it serves.

... Hardwire UPMC Hamot and individuals who work and practice at UPMC Hamot to respond appropriately to adverse events, proactively identify risk-reduction strategies, and participate in process and system redesigns to reduce the risk of patient harm.

... Allow UPMC Hamot to implement processes, technology or systems that will reduce the risk of errors reaching patients and causing harm.

... Promote increased medical staff, nursing management and employee involvement in improving clinical care, which will result in improved employee, medical staff and patient satisfaction.

... Create a more efficient and cost-effective model of care at UPMC Hamot.
The objectives of the UPMC Hamot Patient Safety Plan are to:

... Improve the health and safety of patients by reducing real and potential incidents and serious events.

... Promote a non-retaliatory environment for health care workers who report events or incidents.

... Establish a Patient Safety and Quality Committee where issues that affect patient safety are prioritized; determinations are made to effectively implement solutions; and data provided to assist the leadership team, medical staff, and all employees in supporting the plan.

... Provide a comprehensive dataset from the incident report system and other clinical data sources for the analysis and assessment of the safety, reliability and effectiveness of the patient care system at UPMC Hamot.

... Evaluate and assist with patient safety issues identified at the unit level.

... Report Patient Safety and Quality Committee activities, issues and solutions to UPMC Hamot leadership, the Board and medical staff.

IV. Authority and Responsibility:

A. Board of Directors: The overall authority for creation and implementation of the Patient Safety Program rests with Hamot’s Governing Body, which shall follow applicable policies and procedures set by UPMC. The Governing Body has delegated its authority to implement and maintain the various components of the Patient Safety Program to the Hospital’s Chief Executive Officer.

B. Chief Executive Officer:

Hamot’s Chief Executive Officer, in collaboration with the Patient Safety Officer and administrators and medical staff leaders, is charged with the creation and implementation of the Patient Safety Program. This Program will be integrated with other Hospital and UPMC activities such as performance improvement, environmental safety and risk management.

C. Patient Safety Officer:

The Patient Safety Officer shall be that individual designated by each Hospital’s Chief Executive Office to be responsible to coordinate the Patient Safety Program and to carry out specific aspects of the Program. The Patient Safety Officer will be accountable to the Chief Executive Officer, and Hospital Governing Body. The Patient Safety Officer for UPMC will provide direction to each hospital’s Patient Safety Officer. The duties of the hospital’s Patient Safety Officer, either alone or in cooperation with the Patient Safety and Quality Committee shall include:

... overseeing the creation of, and reviewing, evaluating and refining the Patient Safety Program on an ongoing basis;

... serving as a member of and coordinating and prioritizing the activities of the Patient Safety and Quality Committee;

... overseeing the Hospital’s system for internal reporting of Reportable Patient Events and Infrastructure Failures;

... overseeing and ensuring the reasonable investigations of Reportable Patient Events;

... fostering a culture of proactive risk assessment and analysis;
... fostering the development/revision of processes to enhance patient safety;

... coordinating communications with patients and families about significant aspects of patient care, including the disclosure of Serious Events in accordance with Hospital Policy, Mcare and TJC standards;

... analyzing investigations of Reportable Patient Events and taking such action as is immediately necessary to ensure patient safety;

... reviewing and monitoring Corrective Actions;

... creating and presenting to the Patient Safety and Quality Committee reports of investigations of Serious Events and Incidents and Corrective Actions taken as a result of such investigations; and

... serving as a link to the Governing Body, and Chief Executive Officer, and various Hospital and UPMC peer review organizations on matters related to patient safety.

D. Patient Safety and Quality Committee:

The Patient Safety and Quality Committee shall meet at least monthly to oversee the Patient Safety Program and carry out the duties described in Sections 307(b)(2) and 310 (a) of Mcare.

1. The Patient Safety and Quality Committee shall be composed of:
   The Hamot Executive Vice Presidents and key leadership roles of the Chief Executive Officer, Chief Operations Officer, Chief Medical Officer, Chief Quality Officer, Patient Safety Officer, Risk Manager, Director of Pharmacy and Chief Nursing Officer. In addition Clinical Directors, Director of Infection Control & Quality, Director of Nursing Informatics and Medical staff leads for Neonatology, Cardiology, Trauma, Emergency, Anesthesiology, and Ob/Gyn are included. The Director of Patient Advocacy, Quality Assurance Manager, Director of Strategic Planning, Executive Director of Hospital-based Outpatient Services, Patient Safety and Quality Coordinator, and Patient Safety Specialist complete the Committee membership.

   The Patient Safety Officer is designated to chair the Patient Safety and Quality Committee.

   The UPMC Hamot Patient Safety and Quality Committee includes three community members which adhere to the following conditions:
   a) The community members shall not be agents, employees or contractors of Hospital.
   b) No more than one (1) member shall be a member of the Governing Body.
   c) Members from the clinical staff must include at least one (1) nurse and one (1) physician.

2. The Patient Safety and Quality Committee shall:
   a) Receive, review and evaluate:
      i. Serious Event, Incident reports, PSAEs, and Sentinel Events;
      ii. Reports from the Patient Safety Officer/designee, including reports regarding investigations and Corrective Actions;
      iii. Reports from any Data Collection Agency appointed by the Pennsylvania Patient Safety Authority advising of immediate changes that can be instituted to reduce Serious Events and Incidents.
   b) Receive and act upon notices and reports received from the Pennsylvania Patient Safety Authority concerning the investigations of Serious Events

reported anonymously to the Authority.

i. The Patient Safety and Quality Committee shall delegate to the Patient Safety Officer the obligation to send the results of investigations to the Patient Safety Authority and to do all things necessary to cooperate with the Authority and comply with care.

c) Make recommendations to eliminate future Serious Events, Incidents and Sentinel Events.

d) Report on a quarterly basis to each Hospital’s Chief Executive Office and the Governing Body regarding the number of Serious Events and Incidents and its recommendations to eliminate future Serious Events and Incidents.

i. This obligation may be carried out on behalf of the Patient Safety and Quality Committee by the Patient Safety Officer or Vice President, Patient Care Services.

V. Summaries of Key Elements of Patient Safety Program:

A. Internal Reporting System:

1. UPMC Hamot has in place a system for reporting Reportable Patient Events and Infrastructure Failures 24 hours a day, 7 days a week.

2. The basic elements of the reporting system are:
   a) An Initial Incident/Event Report will be generated by the individual discovering any Reportable Patient Event.
   b) The staff will immediately communicate any significant event that could be a Serious Event, Sentinel Event and/or Infrastructure Failure to the appropriate vice president and/or administrator on-call.
   c) The staff may communicate any potentially Reportable Patient Event to their manager or directly to the Patient Safety Officer.

3. In accordance with the Pennsylvania Whistleblower Law, 43 P.S. 1421, et. Seq., no adverse action, including discharge discrimination or retaliation regarding compensation, terms, conditions, location or privileges of employment or staff membership, shall be taken against any staff member or employee for the sole reason that the staff member or employee has or is about to report a Reportable Patient Event.
   a) Staff members or employees may be subject to disciplinary action if they knowingly make false statements in a report, knowingly cause a false report to be filed or fail to report a Serious Event with knowledge of the event and the obligation to report.

4. Employees and staff shall be educated about and encouraged to actively participate in the reporting process as outlined by the established policy. However, any health care worker, including physicians who have concerns about the safety or quality of care provided by the hospital may report these concerns to The Joint Commission without fear of retaliatory disciplinary action because of such reporting.

B. Determination of Serious Events and Incidents

The Patient Safety Officer, the Patient Safety and Quality Committee and others involved in implementing this Safety Plan shall identify “Serious Events” and “Incidents” reportable to the Patient Safety Authority in accordance with the following criteria:
1. **The event occurs in a Medical Facility of UPMC.**
   A Medical Facility is defined by MCARE as a Hospital or hospital-based ambulatory surgical facility (ASF).
   a) An event is not considered to occur in a Medical Facility just because it occurs in a facility owned by or affiliated with UPMC. For example, an event that occurs in a physician’s private office, even if located on property owned by UPMC, does not occur in a Medical Facility as defined by Mcare.

2. A Reportable Patient Event shall be considered a **Serious Event** if all of the following exist:
   a) **The event involves the clinical care of a patient.**
      An event is not considered to involve clinical care merely because the patient is in a Medical Facility of UPMC. The event must be related to some aspect of medical care, treatment, observation, diagnosis or examination.
   b) **The event results in death or compromises patient safety.**
   c) **The event results in unanticipated injury.**
      An injury is NOT unanticipated if it is a recognized and accepted risk of the clinical care that can occur without any deviation from the standard of care and either occurs on a not infrequent basis to patients in general or is well understood to be a likely outcome for a particular patient.
   d) **The event required the delivery of additional health care services.**
      The following are NOT considered additional health care services:
      i. Steps taken to determine if there are any injuries, such as x-rays or other diagnostic tests,
      ii. Minor acts of first aid that do not need to be performed by a professional health care provider, such as cleansing of a cut or abrasion, application of a topical antibiotic, application of a bandage, etc.

3. A Reportable Patient Event shall be considered an **Incident** if the following exist:
   a) **The event involves the clinical care of the patient: and**
   b) **If one or more of the following criteria are NOT met:**
      i. results in death or compromises patient safety;
      ii. results in unanticipated injury
      iii. Required delivery of additional health care services.

C. **Determination of Sentinel Events**

The Patient Safety Officer, the Patient Safety Peer Review Committee will identify sentinel events using TJC definition of a sentinel event and TJC Sentinel Event Policy as references.

D. **Determination of Preventable Serious Adverse Events (PSAE)**

The Patient Safety Officer, the Patient Safety Peer Review Committee will identify “Preventable Serious Adverse Events: using the process outlined in Policy “HS-PT1204” Preventable Serious Adverse Events.

1. The following principles will be used in making this determination:
   a) **The error or event must be within the control of the facility.** Errors that may have occurred in the manufacture of drugs, devices, or
equipment, well before the materials reached a facility’s doors, are examples of 
events that would be outside of the UPMC’s control.
b) **The error or event must be the result of a mistake made by UPMC.**
These include errors in which UPMC failed to successfully carry out a 
practice that would have, in all probability, prevented harm to the patient.
c) **The error or event must result in significant harm.** The list of events 
should be limited to those that yield very serious results.
d) **The error or event must be clearly and precisely defined.** A great 
level of specificity is required to identify events that could result in a 
facility foregoing payment.

2. PSAE’s will be coded as such in Riskmaster to facilitate communication with 
fiscal services and Health Information Management.

E. **Identification, Reporting and Disclosure of Healthcare-Associated Infections (HAI)**

1. **Identification of HAI**
Infections identified during hospitalization or after a procedure will be reviewed 
by an infection control practitioner (ICP) to determine whether or not the 
infection is healthcare associated (HA) as defined by CDC criteria. If criteria are 
met, the infection is confirmed to be HA. Should the ICP be unable to determine 
whether the infection is HA, the case will be referred to an infectious disease 
physician specialist for confirmation.

2. **Reporting of HAI**
   a) Each identified case of HAI will be entered into CDC’s National Health 
   Care Safety Network (NHSN) within 24 hours of confirmation.
   b) The Patient Safety Authority (PSA) and the Department of Health (DOH) 
   have been given the right to access NHSN to meet serious event reporting 
   requirements under MCARE.
   c) HAI identified at any Surgery Center will be directly entered into the PA-
   PSRS as serious events within 24 hours of determination.
   d) Where denominator data is required for surgical site infections, such data 
   will be entered into NHSN 30 days after the monthly plan date (i.e.
   February data will be entered no later than March 30.)

3. **Disclosure of HAI**
   a) HAI will be considered serious events under Mcare.
   b) Letters of disclosure will be sent to the patient/significant other within 7 
   days of confirmation of the infection.

F. **Peer Review Investigations:**

1. Reportable Patient Events will be reviewed and categorized by or on behalf of the 
   Patient Safety and Quality Peer Review Committee.

2. Serious Events, Incidents and sentinel events will be appropriately investigated 
   by or on behalf of the Patient Safety and Quality Peer Review Committee or 
   another designated Peer Review body.

G. **Peer Review Analyses:**

1. Retrospective Analyses:
   a) Based upon information gathered during investigations and any other 
   relevant information, the Patient Safety and Quality Peer Review 
   Committee and/or other Peer Review body shall determine the need for
and conduct appropriate root cause, intensive or other analyses to identify the
cause or causes of Serious Events, Sentinel Events and selected Incidents.

2. Prospective Risk Assessments:
   a) The Patient Safety and Quality Peer Review Committee and/or other Peer
      Review body shall, either individually or collaboratively:
      i. carry out ongoing prospective risk assessments of Hospital/ASF
         practices, policies, procedures, systems and organizations utilizing
         failure mode analyses or other methodologies to identify need for
         improvement;
      ii. conduct a focused prospective assessment of at least one (1) high-
          risk process within the hospital every 18 months;
      iii. Serve as resources and consultants concerning patient safety for
           administrators and clinicians who are creating new practices,
           policies, procedures and systems.
   b) The Patient Safety Officer or delegated individual shall individually or
      collectively compare current policies, procedures and processes to
      published risk reduction activities and revise internal processes
      accordingly.

H. Process Improvements:

1. Based upon ongoing peer review investigations and analyses, the Patient Safety
   and Quality Peer Review Committee and other Peer Review bodies shall strive to
   develop recommended Process Improvements which shall be forwarded to the
   Patient Safety Officer.

2. Based upon its review of reports from the Patient Safety Officer, reports from the
   Pennsylvania Patient Safety Authority and reports of Serious Events, Incidents
   and Sentinel Events, the Patient Safety and Quality Committee shall make
   recommendations for Corrective Actions/Process Improvements and
   communicate such recommendations to the UPMC Hamot staff through the
   Patient Safety Officer.

3. The Patient Safety Officer in collaboration with other members of one or more
   Peer Review bodies shall analyze recommended Process Improvements and
   determine the scope and timing of any Corrective Actions to be implemented by
   UPMC Hamot.

4. The Patient Safety and Quality Committee or other designated Peer Review body
   shall monitor and evaluate implemented Corrective Actions on an ongoing basis
   to determine their effectiveness.

I. Patient Safety Education:

1. UPMC Hamot has focused on patient safety education to the Board, Hospital
   leaders, medical leadership, Hospital staff and patients.

2. UPMC Hamot routinely participates in local, regional and national coalitions to
   improve patient safety. Several examples include the Patient Safety Authority,
   Hospital and Health System Association of Pennsylvania, Agency for Healthcare
   Research and Quality, Institute for Safe Medication Practices, American Hospital
   Association, and TJC.
3. UPMC Hamot has built quality improvement and patient safety policies into staff orientation and continuing education materials and patient and family educational materials.

4. Patient safety has been incorporated in the annual education requirements of all staff members.

J. Communications with Patients and Patient Families:

1. UPMC Hamot will work collaboratively with its clinical staff to inform patients, and when appropriate, their families, about the patient’s plan of care and outcome of care, including unanticipated results.
   a) Communications should be made in language appropriate to the patient’s educational level and cultural status.

2. UPMC Hamot will coordinate the process by which patients, family members and/or designees are provided written notices within 7 days of the discovery of a Serious Event.
   a) All written notices to patients shall be created and communicated in the manner and form approved by the Patient Safety and Quality Peer Review Committee and or its designee(s) as coordinated by the Patient Safety Officer.
      i. Notices shall go to the patient and any family member(s) and/or designee(s) authorized by the patient.
      ii. If the patient is unable to give consent, notification will be given to an adult member of the patient’s immediate family, or if none known, to the closest adult family member.
      iii. For a minor patient, notification will be given to a parent or guardian.
      iv. If there is no family or designated representative a copy of the letter will be placed on file.

K. External Reporting:

1. The Patient Safety Officer, in collaboration with the Patient Safety and Quality Peer Review Committee, shall oversee all reporting to external organizations. The Patient Safety Officer may delegate the actual creation and forwarding of such reports to one (1) or more Peer Review bodies or individual members of such Peer Review bodies.
   a) Serious Events shall be reported to the Pennsylvania Department of Health and Patient Safety Authority within 24 hours of confirmation using the Pennsylvania – Patient Safety Reporting System (PA-PSRS).
   b) Incidents shall be reported to the Patient Safety Authority using the PA-PSRS.
   c) Infrastructure Failures shall be reported to the Department of Health within 24 hours of confirmation using the PA-PSRS.
   d) Reports to the Food and Drug Administration, the Center for Disease Control, Pennsylvania Department of Health and other organizations shall be made in accordance with applicable laws and Hospital policy.
   e) HAI will be reported to the National Healthcare Safety Network as required by Act 52 of 2007.

L. Anonymous Reporting to the Patient Safety Authority

1. A healthcare worker who believes that a serious event has occurred and has
reported the event through the hospitals/ASF’s internal reporting system may file an anonymous report with the Patient Safety Authority.

2. The healthcare worker must submit the event on the form designated for this purpose by the Patient Safety Authority.
   a) This form is available to staff on the Patient Safety Authority website (www.patientsafetyauthority.org) and within the facility.

VI. PERFORMANCE MEASUREMENTS:

The following are measurements monitored to gauge the impact of the Patient Safety Plan:
1. The number of sentinel events and Department of Health reportable events
2. Medication error rates
3. Incident reporting trends
4. Number of pending cases in litigation trends by frequency and type
5. Accreditation scores and recommendations
6. Other appropriate metrics identified by our constituents.

VII. ADDENDUMS:

1. A Just Culture Decision Tree
2. Event Disclosure Letter (attached)
3. UPMC Hamot Management Protocol for Serious or “Near Miss” Events (attached)

VIII. REFERENCES:

Medical Care Availability and Reduction of Error Act 13 (2002)

IX. RELATED POLICIES AND PROCEDURES:

1. Performance Improvement Plan
2. Initial Incident/Event Reporting (IIER) (HS-RI1305 *)
3. Preventable Serious Adverse Events (HS-PT1204 *)
4. Disclosures of Serious Events/Outcomes of Care (HS-PT1202 *)
5. Patient Safety/Quality Peer Review of Reportable Patient Events (HS-PT1200)
6. Patients’ Notice and Bill of Rights and Responsibilities (HS-HD-PR-01 *)