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GA-006-200 Patient Safety Plan

I. **Purpose**

To improve patient safety and reduce risk through an environment that encourages:

A. Recognition and acknowledgment of risks to patient safety and medical/health errors

B. The initiation of actions to reduce these risks

C. The internal reporting of what has been found and the actions taken

D. A focus on process and systems rather than individual actions

E. A non-punitive culture through minimization of individual blame or retribution for involvement in a medical/health care error

F. Organizational learning about cause and prevention of medical/health care errors

G. Support of the sharing of that knowledge to effect behavioral changes in all Broward Health facilities

II. **Definitions**

A. **Adverse Event:** an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention, rather than the condition for which such intervention occurred.

B. **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.

C. **Error:** an unintended act, either of omission or commission or an act that does not achieve its intended outcome.

D. **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 adverse outcome.

E. **Occurrence/Variance:** any event which is not, or may not be, consistent with normal routine and/or established policies, guidelines, procedures as referenced in Policy RA- 008-040, Occurrence/Variance Reporting.

F. **Sentinel Event:** an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function. The phrase "of risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. These events include any occurrence that meets any of the following criteria:

1. The event has resulted in an unanticipated death, permanent harm or severe temporary harm or major permanent loss of function, not related to the natural course of the patient's illness or underlying condition, or
2. The event is one of the following (even if the outcome was not death or major permanent loss of function unrelated to the natural course of the patient's illness or underlying condition):
    a. 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)
    b. Unanticipated death of a full-term infant
    c. Discharge of an infant to the wrong family
    d. Abduction of any patient receiving care, treatment and services
    e. 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
    f. Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities (ABO, Rh, other blood groups)
    g. 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

    h. .
        i. Sexual abuse/assault (including rape) – 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:
            i. Any staff-witnessed sexual contact as described above
            ii. Sufficient clinical evidence obtained by the hospital to support allegations of unconsented sexual contact
            iii. Admission by the perpetrator that sexual contact, as described above, occurred on the premises

    i. Invasive procedure, including surgery, on the wrong patient, at the wrong site, or that is the wrong (unintended) procedure
        i. 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.

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

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

k. Prolonged fluoroscopy with cumulative dose >1500 rads to a single field or any delivery of radiotherapy to the wrong body region or greater than 25% above the planned radiotherapy dose

l. Fire, flame, or unanticipated smoke, heat, or flashes occurring during an episode of patient care

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

n. Severe maternal morbidity (not primarily related to the natural course of the patient's illness or underlying condition) when it reaches a patient and results in permanent harm or severe temporary harm

o. Fall resulting in any of the following: any fracture; surgery, casting, or traction; required consult/management or comfort care for a neurological (e.g., skull fracture, subdural or intracranial hemorrhage) or internal (e.g. rib fracture, small liver laceration) injury; a patient with coagulopathy who receives blood products as a result of the fall; or death or permanent harm as a result of injuries sustained from the fall (not from physiologic events causing the fall).

G. **High-Risk Patient Care Process:** Any activity that:

1. Has a history of adverse patient outcome
2. Is identified in the literature as high-risk
3. Has several characteristics of a high-risk process:
    a. Constant modification to accommodate input variation
    b. Complex process with many interdependent steps
    c. Inconsistency from lack of standardization
    d. Tightly coupled steps, which follow one another so closely that a variation in the output of one step cannot be recognized and responded to before the next step is underway.
    e. Heavy reliance on human intellectual and/or physical actions
    f. Tight time constraints between process steps
    g. Hierarchical culture
4. Is a new or redesigned process

a. Common high-risk patient care processes include but are not limited to:
    i. Use of medication
    ii. Pain management
    iii. Operative and other invasive procedures
    iv. Use of blood and blood components
    v. Opportunities identified when appropriate to reduce restraint or seclusion use
    vi. Cardiopulmonary resuscitation
    vii. Interpretation of diagnostic results
    viii. Security of infants and other patients at high risk for abduction
    ix. Use of medical equipment that has been shown to be at risk for human error

5. All medication and Adverse Drug Reactions.
Severity of Events

Level 1	An event occurred but the patient was not harmed
Level 2	An event occurred that resulted in the need for increased patient assessments but no change in vital signs and no patient harm
Level 3	An event occurred that resulted in the need for treatment and/or intervention and caused temporary patient harm
Level 4	An event occurred that resulted in initial or prolonged hospitalization and caused temporary patient harm
Level 5	An event occurred that resulted in permanent patient harm or near death event, such as anaphylaxis
Level 6	An event occurred that resulted in patient death

III. Policy

A. Broward Health is active in promoting initiatives to improve patient safety in health care. The Patient Safety Plan is designated to promote such a function among the services of all Broward Health facilities. A further intent of the Patient Safety Plan is to assure compliance with patient safety related regulatory directives.

B. An effective Patient Safety Plan cannot exist without optimal reporting of medical errors and occurrences. Therefore, it is the intent of Broward Health to adopt a just approach in its management of errors and occurrences. All personnel are required to report suspected and identified medical errors and should do so without the fear of reprisal. Broward Health supports the concept that errors occur due to breakdown in systems and processes and will focus on improving those, rather than disciplining those, responsible for errors and occurrences. A focus will be placed on remedial actions to assist rather than punish staff members. (See policy, Non- Punitive Reporting of Medical/Clinical Errors.)

C. 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 actual occurrences; ongoing proactive reduction in medical errors; and integration of patient safety priorities into the new design and redesign of all relevant organization processes, functions, and services.

D. Leaders implement a system-wide patient safety program and provide direction and resources to conduct proactive activities to reduce risk to patients.
    1. At least every 18 months, one high-risk process is selected for proactive risk assessment (Failure Mode Effects Analysis)
    2. Accountability is promoted for all employees, including assuming proactive and reactive responsibility for personal actions and for patients
    3. New goals for the organization are identified on a regular basis
    4. The Patient Safety Plan is reviewed and revised as appropriate

E. 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 plans, processes and mechanisms that comprise the patient safety activities of Broward Health. The Patient Safety Plan is developed by an interdisciplinary committee and approved by the Medical Staff, Board of Commissioners and Administration.

F. The Patient Safety Plan encompasses the patient population, visitors, volunteers and staff, including medical staff. The program addresses maintenance and improvement in patient safety issues in every department throughout all Broward Health facilities. Important patient care functions are emphasized, such as:
    1. Environment of Care
    2. Emergency Management
    3. Human Resources
    4. Infection Prevention and Control
    5. Information Management
    6. Leadership
    7. Life Safety
    8. Medication Management
    9. Medical Staff
    10. Nursing
    11. Provision of Care, Treatment and Services
    12. Rights and Responsibilities of the Individual
    13. Transplant Safety
    14. Waived Testing
    15. Performance Improvement
    16. Record of Care, Treatment and Services
    17. Risk Management
    18. National Patient Safety \Goals

G. The scope of the Patient Safety Plan includes an ongoing assessment, using internal and external knowledge and experience, to prevent error occurrence, maintain and improve patient safety. Patient safety occurrence information from aggregate data reports will be reviewed by the Regional Patient Safety Committee(s) to prioritize organizational patient safety efforts.

IV. **Procedure**

A. The Regional Patient Safety Officers in conjunction with the Regional Patient Safety Committees are responsible for the oversight of the Patient Safety Program. These Regional Committees operate as subcommittees of the Risk Management Practice Council. The Regional Patient Safety Committees are co-chaired by key leadership. The Patient Safety co-chairpersons have administrative responsibility for the program and report to the oversight committee. Membership of the committee is multidisciplinary and establishes the linkages to the other committees such as Patient Care Key Group (PCKG), Pharmacy and Therapeutics, Regional Quality Council, Medical Staff, Nursing Leadership, and Environment of Care Committee. The Safety Officer or his/her designee may be included in membership.

B. The Patient Safety Officer at each Region will be determined by the Chief Executive Officer (CEO). All departments within the organization (patient care and non-patient care departments) are responsible to report patient safety occurrences and potential occurrences to Risk Management, where the information will be aggregated and presented in a report to the Regional Patient Safety Committee, Risk Management Practice Council, Quality Assessment and Oversight Committee, Regional Quality Council, and Medical Staff Leadership committee(s).

C. The Patient Safety Committee and/or Regional Quality Council will select at least one high-risk safety process for proactive risk assessment every 18 months. The proactive risk assessment – Failure Mode Effects Analysis (FMEA) – will include:

1. 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. Identification of the possible effects of the undesirable variation on patients, and how serious the possible effect on the patient could be;
2. An intense analysis or root cause analysis of the most critical effects to determine why the undesirable variation leading to that effect may occur;
3. Redesign of the process and/or underlying systems to determine why the undesirable variation leading to that effect may occur;
4. Testing and implementation of the redesigned process;
5. Identification and implementation measures of the effectiveness of the redesigned process;
6. Implementation of a strategy for maintaining the effectiveness of the redesigned process over time.

D. When a medical error is identified, the patient care provider will immediately:

a. Perform necessary health care interventions to protect and support the patient's clinical condition;

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

c. Preserve any information related to the error (including physical evidence). This includes documenting the facts on an occurrence variance report via HAS program , and in the medical record, in accordance with current policy;

d. Report the medical error to the staff member's immediate supervisor;

e. Notify the Quality Management Department of the facility when quality of care is compromised;

f. Submit the occurrence/variance report to the Risk Manager in accordance with the current Occurrence/Variance Policy of the Broward Health.

E. If the staff members involved in an event suspect that the event may be either a Code 15 or a Sentinel Event, then the occurrence/variance will be managed by the pre-established Broward Health Policy, RA-008-015, Reporting, Disclosure and Management of Adverse Events, Code 15's, Sentinel Events, Near Misses and Hazardous Conditions.

1. Immediate action/intervention may be required to prevent a re-occurrence and risk of injury to other patients. However, if warranted, further and more in-depth analysis is to be initiated promptly.
2. The Regional Risk Manager will notify the respective Chief Executive Officer, Corporate Director of Risk and Insurance Services, and Chief of Staff of each potential Code 15/ Sentinel Event. The Regional Risk Manager will initiate an investigation of the facts and determine if the occurrence/variance meets the criteria for a Code 15 or a Sentinel Event and report as appropriate.
3. The Regional Risk Managers of Risk and/or Quality will determine promptly whether a Root Cause Analysis (RCA) or Intense Analysis is needed and will provide oversight of the RCA on the identified Code 15/Sentinel Event.
4. The scope of the RCA will minimally include the evaluation of the systems and components of care identified on the RCA matrix. Attachment A
5. Action plans related to the analysis will be implemented as appropriate and monitored for effectiveness by the identified department directors/managers and reported to the Regional Patient Safety Committee, Regional Quality Council and Risk Management Practice Council.

F. Although certain occurrences/variances not specifically referenced in this policy may necessitate a further evaluation, a RCA will be conducted on the following Code 15/Sentinel Events that actually occur and/or those near misses that, if not corrected, could result in:

1. Surgical or other invasive procedures on the wrong patient
2. Wrong site (side or organ) surgery
3. Any error or deviation in policy or procedure, such as a medication error, delay in treatment, or failure to follow an order, that resulted in:
    a. Death of a patient
    b. Brain/spinal injury
    c. Loss of limb, permanent disfigurement, neurological, physical, or sensory limitations
    d. A condition requiring a more acute level of care or the need for specialized medical or surgical intervention

4. Attempted or successful suicide of a patient
5. Assault, homicide, rape and/or other crime resulting in a patient's death or major permanent loss of function
6. Abduction of any patient receiving care, treatment or services
7. Infant discharged to the wrong family
8. Death or serious injury while the patient was restrained
9. Elopements where the patient subsequently died, committed suicide, or suffered a major loss in function
10. Falls that directly caused death or permanent loss of function

G. Support Services will be provided for staff members involved in sentinel events, and Code 15's through the Employee Assistance Program

H. **COMMUNICATING WITH PATIENTS ABOUT SAFETY**

1. Staff will educate patients and their families regarding their role in helping to facilitate the safe delivery of care. This could include, but not be limited to, information regarding safe and effective use of medications or equipment, food/drug interactions, adverse drug reactions, diet and/or exercise.
    a. An educational brochure describing Patient Safety Tips will be made available to patients.
2. Patients and, when appropriate, their families will be informed about outcomes of care including unanticipated outcomes (unusual occurrences), or when outcomes differ significantly from the anticipated outcomes.

I. **STAFF EDUCATION**

1. Staff will receive education and training during the orientation process and on an ongoing basis regarding job-related aspects of patient safety, including the need and method to report medical errors.
    a. The patient safety orientation and education program focuses on reducing the risk of illness and injury to patients.
    b. The orientation and education program addresses:
        i. assessment of each staff member's ability to fulfill specific responsibilities
        ii. familiarizes staff members with their jobs and work environment before the staff begin to administer patient care or other activities specific job-related aspects of patient safety
        iii. provision of safety-related information through new employee orientation and continuing education including basic information on RCA and FMEA
        iv. a review of reporting forms and protocols
2. Staff will also be educated and trained on the provision of an interdisciplinary approach to patient care.
3. Medical errors and occurrences, including Sentinel Events and Code 15's, will be reported

internally and externally, per policy, and through the channels established by this and/or other plans. Any external reporting will be performed in accordance with all state, federal, and regulatory body rules, laws and requirements.

J. **PERFORMANCE IMPROVEMENT**

1. Consistent with the Broward Health Performance Improvement Plan, each region will aggregate and analyze clinical and administrative data to support reduction in risks to patients.
    a. Data from patient safety initiatives and quality control will be collected on an ongoing basis.
    b. High-risk patient care processes will be measured and analyzed.
    c. At least one high-risk process will be selected every 18 months for proactive risk assessment (FMEA).
    d. Quarterly reports will be provided to the Regional Quality Council.
    e. At least once a year, the leaders responsible for the hospital wide patient safety program review a written report on the results of any analysis related to the adequacy of staffing and any actions taken to resolve any identified problems.
    f. Other measures related to patient safety will be monitored:
        i. Performance improvement priorities identified by leaders
        ii. Operative or other procedures that place patients at risk of disability or death
        iii. Significant discrepancies between preoperative and postoperative diagnoses, including pathologic diagnoses
        iv. Adverse events related to using moderate or deep sedation or anesthesia
        v. Use of blood and blood components
        vi. Confirmed transfusion reactions
        vii. Results of resuscitation
        viii. Behavior management and treatment
        ix. Significant medication errors
        x. Significant adverse drug reactions
        xi. Patient perception of the safety and quality of care, treatment and services
        xii. Risk Management Activities

K. **CONFIDENTIALITY**

1. All reports, committee minutes, audits, studies and documentation of patient safety activities will be held confidential in accordance with Florida law.
    a. Review of minutes by third parties will be restricted to reviews conducted by state and federal auditors, or other parties authorized by law and accreditation survey teams.
    b. Distribution of reports, assessment results, and other patient safety specific documentation is restricted to the following:
        i. Board of Commissioners

ii. Members of the Regional Patient Safety Committees
iii. Legal Counsel or designee (as appropriate)
iv. Risk Management (as appropriate)
v. Quality Assessment and Oversight Committee

V. **Related Policies**

A. Broward Health Performance Improvement Plan
B. Reporting, Disclosure and Management of Adverse Events, Code 15's, Sentinel Events, Near Misses and Hazardous Conditions.
C. Occurrence / Variance Reporting
D. Non-Punitive Reporting of Medical / Clinical Errors

VI. **Regulation/Standards**
N/A

VII. **References**
The Joint Commission Hospital Accreditation Standards
Interpretation and Administration
Administration and Interpretation of this policy is the responsibility of the Senior Vice President / Chief Financial Officer

Approval Signatures

Step Description	Approver	Date
	Joshua Lenchus: REG CHIEF MEDICAL OFFICER	09/2021
	Barry Gallison: VP, CLINICAL QUAL & RISK MGMT	08/2021
	Donna Williamson: REG MGR, QUL/EPI/PS/PE-BHIP	08/2021
	Janet Dougherty: REG DIR, QUAL/EPI/PAT SAFE-BG	08/2021
	Christopher LaRue: REG MGR, QUAL/EPI/PAT SAFE-NB	08/2021
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Older Version Approval Signatures

	Lee Ghezzi: SVP, QUALITY & CASE MGMT [JM]	04/2021
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