SOUTH LYON MEDICAL CENTER
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PATIENT SAFETY COMMITTEE

SUBJECT: Patient Safety Plan	**POLICY NO:**
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	EFFECTIVE: 11/2002
	REVISED:1/2021
CROSS: Medical Staff	**APPROVED:**

POLICY: South Lyon Medical Center Patient Safety Plan

PROCEDURE:

1. The Medical Staff, with the approval of the Governing Board shall develop and implement a Patient Safety Plan to encompass all facets of patient care at South Lyon Medical Center. This includes Acute Care, Long Term Care and Rural Health Clinics.

2. The Medical Staff will appoint and submit to the Governing Board for approval the implementation of a Patient Safety Committee which will comprise at a minimum: a physician, a nurse, pharmacist, governing board member and risk manager. This committee shall:

    a. function under the authority of the Medical Staff
    b. meet monthly
    c. investigate, report and formulate corrective actions related to alleged sentinel events
    d. review medical equipment/devices safety and maintenance inspections
    e. review and recommend actions related to medication events
    f. review and investigate patient care related incident reports
    g. review, investigate and recommend corrective actions for near-miss events
    h. additional tasks as assigned by the Medical Staff

3. The Administrator shall appoint a Patient Safety Officer whose responsibilities are outlined in the position description.

4. The Patient Safety Plan shall include but not limited to the following items:

    I. General:

    a. Patient Safety involves a variety of clinical and administrative activities that health care organizations undertake to identify, evaluate, and reduce the potential for harm to beneficiaries and to improve the quality of health care. Effective medical/health care error reduction requires an integral approach and a supportive environment, in which patients, their families, organization staff and leaders can identify, manage and learn from actual and potential risks.
    b. A successful patient safety program facilitates non-punitive, interdisciplinary approach to decrease unanticipated adverse health care outcomes. The organizational focus is on

continued learning about risks and mitigation strategies and reengineering systems/processes to reduce the chance of human error. South Lyon Medical Center (SLMC) fosters and supports an organizational environment that recognizes and acknowledges potential risks to patient safety and the occurrence of medical/health care errors. The patient safety program encourages medical error reporting in order to identify system or process failures and to enhance improvement strategies.

II. South Lyon Medical Center (SLMC) Patient Safety Program

a. The goal of the SLMC Patient Safety Program is to reduce the chance that the adverse effects of human error will harm patients. By creating and promoting a culture in which staff willingly report actual and near-miss patient safety related events without fear of disciplinary action, SLMC is encouraging these events to be freely identified. Once events have been identified, systems and processes can be analyzed and improved in order to prevent future recurrence. Improved systems and processes result in a safer patient care environment.
b. SLMC Patient Safety Program works in conjunction with the Civil Rights Coordinator and helps to assure that SLMC is up to date with all ADA requirements.
c. SLMC Patient Safety Program focuses on system and process design rather that on the individual involved in a given patient safety related mishap. This paradigm is very different from that which prevails in the health care community at large. In the patient safety conscious culture, when an error occurs the response is not to ask "who", but rather "why". This new paradigm can exist in light of other organizational expectations associated with risk management, claims management and review of potentially compensable events (PCE) for which the facility may incur financial liability.
d. All patient safety related reports require that an investigation be conducted to determine the cause(s) of the adverse event.
e. A patient safety event that causes no patient harm requires no standard of care determination. However, any patient safety event that results in patient harm or potential patient harm, by definition, is a PCE. The patient safety officer will be notified of all PCE's and these will be managed according to the established policies and procedures outlined in the Patient Safety Committee. Given the results of the investigation of the event, a Standard of Care determination will be required. Competency related information that arises through patient safety investigations will not be released outside of the Patient Safety Program except as noted in paragraph e below. The Patient Safety Program will consider process/system issues, while the Standard of Care determination reviews the individual's performance.
f. Although not a specific focus of the Patient Safety Program, concerns about a specific provider's/professional's competence may arise. Competence relates directly to an individual and, as such, requires an evaluation of the provider's/professional's performance, not an evaluation of the health care system. Competence will be addressed through the organization's competence assessment, credentialing and privileging process. No individual competence related information will be released outside of the Patient Safety Program, except as noted in paragraph f below. If the competence assessment processes are determined to require review and improvement, such recommendations by the Patient Safety Committee and Medical Staff may be appropriate.
g. The vast majority of errors are unintentional. No disciplinary action will be initiated against the individual(s) involved in an unintentional error. However, certain events, such as noted below, do warrant administrative, disciplinary or legal action. Should any of the following be discovered in the course of a patient safety event investigation, the Administrator and

Medical Staff will be immediately informed of the circumstance and action taken beyond the scope of the Patient Safety Program:

1) Criminal activity (e.g. assault and battery, etc)
2) Intentional unsafe acts due to gross negligence or reckless behavior
3) Alleged patient abuse of any kind
4) Impairment due to medical and psychological conditions including alcohol or other drug abuse.

III. South Lyon Medical Center Patient Safety Function.

a. Integration of all patient safety related issues and processes under the auspices of a single committee/ functional team. This reduces duplication of effort and enhances program efficiency.

b. Patient Safety Committee.

1) Membership. Membership is outlined in NRS 439.875; 1) The infection control officer, 2) The patient safety officer, 3) At least three providers of health care who treat patients at the medical facility, including, without limitation, at least one member of the medical, nursing and pharmaceutical staff of the medical facility. And 4) One member of the executive or governing body of the medical facility.
2) Chairperson. The chairperson shall be a nurse or physician.
3) Committee minutes/reports. The committee minutes/reports will summarize the organizations patient safety activities to include, as a minimum:
    a. Analysis of all clinical and non-clinical reported events, trends and lessons learned.
    b. Actions necessary for organizational process/systems improvements as appropriate.
    c. Proactive patient safety error reduction activities.
    d. Progress related to risk assessments, prospective analysis and root cause analysis action plan implementation and effectiveness, according to established time-lines.
    e. Patient Safety Committee minutes/reports will be forwarded to the Medical Staff Committee and the Governing Board quarterly. Recommendations associated to patient safety will be forwarded to the Medical Staff for implementation as appropriate.

c. Management of Patient Safety Information.

a. The focus of patient safety data collection and reporting is to improve organizational systems and to provide the safest care possible. The information and data amassed through reporting, investigation and evaluation will be confidential and reported through the Medical Staff Quality Assurance process.
b. Data trend analysis will include, but not be limited to, the following:
    1) Sentinel Events or actual or alleged.
    2) Medication errors and fall.
    3) Equipment malfunctions.
    4) Preventive/corrective interventions
c. Ad hoc committees may be assigned by the Medical Staff regarding competency investigations related to a patient safety related event to insure

that peer status is maintained throughout any investigation. All information obtained will remain confidential under the auspices of Medical Staff Quality Assurance.

IV. Patient Safety Event Management.

a. Event identification. A patient safety event is any incident that occurred (actual event) or almost occurred (near miss) that caused or had the potential to cause harm to a patient. Identification and reporting of near misses and adverse events, including those that result from practitioner/professional error, should be encouraged as an expectation of everyday practice. The three types of patient safety events include near miss, adverse events and sentinel events.
b. Near Miss. A near miss is an event or situation that could have resulted in harm to a patient, but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the patient. Because near misses generally occur more frequently than actual adverse events, proactive analyses of near misses provide a tangible opportunity to improve the system without having to experience an actual adverse event. Staff should be encouraged to report near miss events for the purpose of analysis and identification of methods improvement.
c. Adverse Event. An adverse event is an occurrence associated with the provision of health care or services that may or may not result in harm to the patient. Adverse events may be due to acts of commission or omission. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no harm or permanent effect to the patient.
d. Sentinel Event. A sentinel event is an unexpected occurrence involving death, serious physical or psychological injury, or the risk thereof. **Serious injury** specifically includes loss of limb or function. The phrase "or risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and proactive response on the part of the organization.

V. Event Documentation and Reporting.

1. Prevention of harm to patients is everyone's responsibility and reporting all potential and/or actual patient safety events is a performance expectation of all organizational staff. Anyone with knowledge of a patient safety event not only may, but should, report it.

a. Immediate actions.

1) Upon identification of a actual patient safety event, the staff member will immediately perform necessary health care interventions to protect and support the patient's clinical condition. The patient's attending physician and other physicians, as appropriate, will be contacted as soon as possible to report the incident and provide an update on the patient's current clinical status.
2) As appropriate to the event, the staff will initiate all physician directed orders and take other necessary health care interventions to contain the risk to others, and to preserve event-related materials that may require further investigation. Examples of physical information preservation include: removal and preservation of a blood unit for a

suspected transfusion reaction; preservation of IV tubing, fluid bag, and/or IV pump for a patient with a severe drug reaction from a IV medication. Preservation of information also includes documenting the facts regarding the event in the patient's medical record according to organizational policy and procedure.

3) If the patient safety event involves serious physical or psychological injury, unexpected death, or qualifies as a sentinel event, the appropriate department director will be notified immediately. If such events occur after hours, the administrative on-call staff will be notified immediately. Individuals notified will ensure proper notification of senior management is accomplished in a timely fashion.

b. Documentation and Internal Reporting.

1) Any individual in any department who identifies a potential (e.g.near-miss) or actual patient safety event will immediately notify their immediate supervisor and will initiate a Incident Report. This report will contain concise, factual, objective and complete details about the event.
2) Incident Reports or in the case of medication errors, a Adverse Drug Event Report will be forwarded to the department director within 24 hours of the discovery of the event or the first duty day following a weekend or holiday. The department director will review the report, add any additional relevant information, and forward it to the Patient Safety Officer, or designee, within 24 hours of receipt.
3) The Patient Safety Officer (PSO), or designee, will review all incident reports and ADE reports. In addition, the PSO will determine what specific actions are necessary to further evaluate the event. If the event is a sentinel event, the PSO will immediately notify the Administrator and Risk Manager and activate a Root Cause Analysis Team from the Patient Safety Committee and others as deemed appropriate to investigate the event.
4) If the patient safety event is an intentional unsafe act that results from gross negligence or possible criminal activity, the event shall be reported to the appropriate authorities for investigation.
5) Some events fall within the definition of both an adverse event and an intentional unsafe act. For example, infant abduction would be both a crime and a reportable Sentinel Event that require Root Cause Analysis. In cases that appear to be both a adverse event and an intentional unsafe act, primary authority and responsibility for dealing with the event belongs to the Administrator and Risk Manager. This is beyond the scope of the Patient Safety Program. The PSO will coordinate a review of the systems and processes implicated in the actual or potential unsafe act, to include conducting a root cause analysis, if applicable, but will defer to a separate investigation with respect to the culpability of any persons involved in the event.
6) External reporting requirements. All incidents meeting the definition of a Sentinel Event must be reported to the State Health Department

and Bureau of Licensure. Reports must be completed within the time frame as outlined in policy and procedure.

VI. Patient Safety Event Analysis.

Event analysis assists in the discovery of the root causes and/or contributing factors associated with the patient safety event. Tracking and trending of data allows the Patient Safety Committee and Medical Staff to identify familiar trends or circumstances so that system or process issues can be identified and improved.

a. Aggregate review analyses. Aggregate review consists of examining data elements for common trends or patterns within the group. The use of aggregated review serves two purposes. It allows for wider applicability of the analyses (i.e., trends or patterns that were not noticeable in an individual case analysis become more obvious as the number of cases increases). In addition, it more clearly defines specific data elements in a recurring problem and encourages prudent use of the time and expertise of the organization staff associated with evaluation and corrective action.
b. Root Cause Analysis. A root cause analysis must be conducted and an action plan completed for all actual sentinel events. The Patient Safety Committee will formally designate a root cause analysis team to conduct a thorough and credible root cause analysis on all sentinel events. A Root Cause Analysis (RCA) is the process for identifying the basic and/or contributing casual factor(s) associated with patient safety events. The review is interdisciplinary and includes those who are closest to the process, but typically not those directly involved in the specific event. Those directly involved may be consulted for event-related information if appropriate. The RCA focuses on systems and processes, not individual performance. It identifies changes that could be made in the systems and processes to improve performance and to reduce the risk of adverse events, or the recurrence of near misses, with the ultimate goal of reducing and/or eliminating patient harm.
c. Root Cause Analysis Action Plan. Once the RCA has been completed, a detailed action plan must be developed to enumerate the risk reduction strategies that the organization intends to implement to prevent the recurrence of similar events. The action plan should address responsibility for implementation, oversight, pilot testing (if appropriate), timeliness, and the specific metrics to be employed in evaluating the effectiveness of the actions taken.
d. The RCA action plan will be submitted to the Medical Staff for approval.
e. Follow-up review. All RCA action plans will be reviewed at a minimum of 6 months following implementation to address the effectiveness of the improvements implemented by the organization. These findings will be reported to the Medical Staff and Governing Board.

VII. Patient Safety Event Communication.

Administration and all staff are reminded that all data compiled as part of the Patient Safety Program are QA information and protected from disclosure and must be marked as Quality Assurance Document.

a. Staff involved in a patient safety event. Any staff member reporting and/or directly involved in a patient safety event that caused patient harm will receive

support and assistance from their supervisor to facilitate the staff member's professional and emotional needs related to the patient safety event. Management efforts and activities will focus on improving the systems and processes that may have contributed to the event rather than disciplining those involved.

b. Reporting a patient safety event. Staff members and supervisors who submit patient safety event reports will receive timely feedback on the actions being taken as a result of their report.

c. Patient/family affected by a patient safety event. In cases involving an unanticipated outcome of care, a qualified health care provider will inform the patient and/or his/her family member(s) within seven (7) days of discovery of the event. This information is provided as a matter of policy and does not affect any rights or obligations in legal or administrative proceedings. Under no circumstances will QA-protected information be released or provided to the patient/family member.

d. The Patient Safety Officer, or designee, is responsible to ensure that the provider and patient/family member communication takes place. The designated primary communicator will document in the patient's medical record what was communicated to the patient/family member, the patient/family member's response, and any other pertinent information. It shall be the responsibility of the affected patient's primary care physician or Chief of the Medical Staff or Vice Chief of the Medical Staff to make the initial and subsequent notification.

e. In most cases, facts surrounding the patient safety event that affect the patient can and should be disclosed to the patient/family member by the provider.

f. Any specific questions relative to disclosure of information associated with unanticipated adverse outcomes should be referred to the organization's legal representatives.

VIII Patient safety Education and Training

a. All staff shall receive patient safety education and training during their initial new employee orientation and on an annual and as-needed basis, regarding job-related aspects of patient safety and staff specific roles and responsibilities to actively support patient safety policy.

b. Community education. Patients and potential patients/family members shall be educated concerning their role in helping to facilitate the safe delivery of care. Methods include but are not limited to; public forums, newspaper articles, addressing specific community groups and organizations.

c. Checklists have been developed and implemented in several different formats that range from facility policies, department checklists and medical record audits. These checklists and policies include but are not limited to; correct patient identification and verification, foley catheter criteria, informing patients of Healthcare Acquired Infections (HAI's) or Facility Acquired Infections (FAI's), hospital inpatient information sheets related to HAI's and hand hygiene and respiratory etiquette and patient information regarding discharge planning, medication reconciliation and request that providers indicate the use or reason for each prescription that is issued.

a. On or before July 1 of each year a report will be submitted to the Director of the Legislative Counsel Bureau which includes the development, revision and usage of patient safety checklists and policies.

IX Confidentiality of Medical Quality Assurance Information.

As with other medical QA documents, any information, records, reports, minutes, and other documents directly associated with patient safety activities are protected under 10 USC 1102. In discussing medical information with family members, staff shall also comply with other applicable restrictions on nonconsensual disclosures, including those under the Privacy Act, 5 USC 552a. As a general rule under the Privacy Act, information regarding a patient's condition shall not be provided to others without the patient's consent.