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HOSPITAL ACQUIRED ADVERSE EVENT.

SERIOUS ADVERSE EVENT (NEVER-EVENT),

AND SENTINEL EVENT

PURPOSE:

1. To provide guidelines to follow in reporting significant process variation, incidents with potential to harm, adverse events, serious adverse events, and sentinel events involving patients at John Dempsey Hospital.

2. To establish a mechanism for immediate identification, thorough investigation

and effective response to a sentinel or adverse event.

3. To outline procedures for complying with Connecticut's Adverse Event Reporting law (PA 04-164).

4. To use a standard process to review all preventable adverse events, including "never events" that result in serious patient harm in order to determine when it may be appropriate to suspend billing for charges related to the adverse event.

5. To embrace and promulgate a non-punitive culture of safety in regards to medical error reporting, and to learn about adverse events and gain new knowledge about the cause(s) of errors in order to prevent future error(s).

Definitions:

Adverse Event: an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.

<u>Serious Adverse Events</u>: an adverse event that is also known as a "Never Event" is a serious, preventable adverse event that is identifiable and measurable, and the risk of occurrence of this event is significantly influenced by the policies and procedures of the healthcare organization. (From the National Quality Forum).

<u>Preventable</u>: (see serious adverse event definition) an event is determined to be preventable if the occurrence is found not to be related to the patient's underlying illness or condition, and instead, related to the medical management or the lack of appropriate medical management. The determination is made by a multidisciplinary team with clinical expertise in the field under review.



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Sentinel Event: an adverse event that is an unexpected occurrence, not related to the patient's underlying illness or condition, that results in death or serious physical or psychological injury, or the risk thereof. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome (TJC).

Process Variation is a deviation from the normal or expected outcome of a process. This is generally a nonrandom and preventable type of variation evidenced by different outcomes that occur when a process is repeated.

Policy

- 1. Any provider or staff member who discovers, witnesses, or becomes aware of an occurrence that is a significant process variation or suspects the occurrence may be or has the potential to be, related to an adverse event, serious adverse event, or sentinel event shall immediately report this occurrence.
- 2. Any provider or staff should report process variations or adverse events through the Safety Intelligence® (SI) system. If the incident/event involves a Medical Device, a call should also be placed to Clinical Engineering. (Ext. 2964).
- 3. For serious adverse events or sentinel events, the faculty or staff member shall notify, either in person or by telephone, the manager of the unit where the occurrence took place or his/her designee. For occurrences that are suspected to be related to a serious adverse event or sentinel event, the Clinical Risk Manager, Director of Quality, or Senior Director of Regulatory Readiness and Accreditation shall be notified in person or by telephone. Alternatively, hospital senior leaders, including the Chief Nursing Officer, the Chief Medical Officer, and the Chief Quality Officer may also be contacted. During off-shift, holiday, and weekends, reporting should be to the hospital Administrator On-Call (AOC).
- 4. For serious adverse events or sentinel events, the faculty or staff member shall report this *immediately* and a SI report should be filed by the end of the shift of the person reporting the occurrence.
- 5. The Office of Regulatory Readiness and Accreditation will report to the Department of Public Health all adverse events that fall within the CT Adverse Event Reporting Law within the required time frame.



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6. The attending physician is to be notified of adverse events involving his/her patient.

- 7. The facts of the adverse event should be documented in the patient's chart.
- 8. Providers and staff should not document in the medical record that an SI report has been filed or that Risk Management has been called.
- 9. Providers and staff should not document in the Medical Record that the event has been reported to DPH or The Joint Commission.
- 10. The supervisor of a given caregiver or staff member involved in an adverse event or serious Reportable Event will advise the caregiver or staff member of the availability of the Employee Assistance Program, Chaplain Service, and/or Social Services to assist in dealing with emotional difficulties experienced by the caregiver.
- 11. At the request of the patient and/or his/her family, we will inform them of the action(s) that our hospital will take to prevent future recurrences of similar events based on the findings from an ACA or RCA conducted as part of the analysis of the event.

Procedure

1. The manager of the clinical service area involved in the adverse event will conduct a preliminary review. For serious adverse events and/or sentinel events, the Director of Quality, the Quality Department Manager, the Risk Manager, the Office of Regulatory Readiness and Accreditation and/or the Chief Quality Officer will participate in the initial review.



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- 2. Based on the preliminary review, hospital leadership or the Director of Quality will determine the need for more in-depth analysis, including the assignment of an Apparent Cause Analysis or Root Cause Analysis to be performed.
- 3. Adverse events among patients who have or had a healthcare-associated infection will be reviewed by the Infection Prevention Specialist.
- 4. The findings of the ACA or RCA team shall be reviewed by a multidisciplinary team to identify system and process improvement opportunities. A corrective action plan (CAP) to address identified issues is developed that may include mechanisms for ongoing monitoring to measure the plan's effectiveness. The results of RCA's are discussed at the Quality Assessment and Performance Improvement Committee and presented in peer review at the Clinical Affairs Subcommittee of the Board of Directors.
- 5. If the preliminary review determines that the event does not require an ACA or RCA, leadership will consider options that may include: Morbidity & Mortality review, a focused review, and/or follow-up with the involved individuals.
- 6. For serious adverse events or sentinel events, hospital leadership will review the case with the Finance Department to waive applicable charges associated with the event.

Andrew Agwunobi, MD, MBA

Chief Executive Officer John Dempsey Hospital

Richard H. Simon, MD Chief of Medical Staff

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