State of New Jersey
DEPARTMENT OF HEALTH AND SENIOR SERVICES
PO BOX 360
TRENTON, N.J. 08625-0360

JON S. CORZINE
Governor

www.nj.gov/health

HEATHER HOWARD, J.D.
Commissioner

TO: Administrators and Patient Safety Liaisons for Ambulatory Surgery Centers
Interested Parties

FROM: Mary Noble, M.D., M.P.H. Mary Noble
Clinical Director, Patient Safety Initiative

RE: Guidance on Serious Reportable Adverse Events For
Ambulatory Surgery Centers

DATE: September 9, 2009

Background Information

Mandatory reporting: The Patient Safety Act ("The Act") (N.J.P.L. 2004, c.9) was enacted in April 2004 and requires that all licensed health care facilities report serious preventable adverse events to the Department of Health and Senior Services (the Department) for the purpose of minimizing the occurrence of and level of harm from adverse events, and to incorporate mechanisms that will continually improve the performance of health care facilities in their delivery of services.

Definition: In general, the Act defines a serious preventable adverse event as an event that results in death or loss of body part, or disability or loss of bodily function lasting for more than seven days or present at discharge. However, some reportable event types do not need to meet a threshold of injury to require reporting, such as wrong site surgery or a wrong surgical procedure. These events are signs of larger systems problems, should never occur, and are always reportable.

Facility responsibilities: The Act requires that all licensed health care facilities establish a patient or resident safety committee and develop a patient or resident safety plan. The plan developed by the facility must specify the process for facility staff, representing specific disciplines and competencies within the facility, to conduct ongoing analyses and application of evidence-based patient safety practices to reduce the probability of future preventable adverse events. The plan must provide for analyses of serious preventable adverse events, and some lesser preventable adverse events and near-misses; it must also provide for ongoing patient safety training for facility staff.

Confidentiality protections: Although The Act requires disclosure by health care facilities to a patient or resident affected by the occurrence of a serious preventable adverse event, it otherwise restricts the discoverability, admissibility and disclosure of any documents, materials or information developed by the patient safety committee or reported to the Department as part of the process of self-critical analysis.

Time requirements: When a health care facility becomes aware that a serious preventable adverse event has occurred, the facility must report the details of the event to the Department within five (5) business days. An RCA must be prepared by the patient safety committee exploring the underlying causes and contributing factors to the event. This report must be submitted to the Department within forty-five (45) calendar days from the date when the initial event report was submitted to the Department.

Ambulatory Surgery Centers (ASCs): ASCs began reporting to the Department October 1, 2008. It was recognized that additional guidance was needed regarding the types of adverse events that should be reported by these centers. Some of the reportable events are self-explanatory, such as wrong site surgery. However, there is less clarity regarding the type of events that should be reported. In order to better identify and/or define the serious preventable adverse events that should be reported by ASCs, the Department convened a small Work Group to provide guidance. The Work Group met in April 2009 and by conference call in June 2009. There was representation from ASC Administrators, the New Jersey Association of Ambulatory Surgery Centers, the New Jersey Hospital Association, the New Jersey Council of Teaching Hospitals/New Jersey Council of Children's Hospitals, the Hospital Alliance of New Jersey and clinicians. Members represented the following medical specialties: Anesthesiology, Colon & Rectal/General Surgery, Gastroenterology, Obstetrics/Gynecology, Orthopedics, Ophthalmology, and Pain Management.

Recommendations for Reporting

The types of reportable serious preventable adverse events are based on the National Quality Forum's Serious Reportable Events in Healthcare ('Never Events'). They can be located in the *Mandatory Patient Safety Reporting Requirements for Licensed Health Care Facilities* manual. **Based on the types of services a facility provides, some categories may not be applicable.** For example, surgical events could only occur at facilities that perform surgical procedures. Some types of events are not likely to occur at ASCs (such as pressure ulcers or hyperbilirubinemia in a neonate).

Reportable Events

Many of the reportable types of events applicable to ASCs are self-explanatory, such as wrong site surgery and wrong surgical procedure, and should always be reported to the Department. The following guidance should be used when there is uncertainty regarding a potentially reportable event:

- In general, any patient transferred to the Emergency Department and/or hospitalized with a procedure and/or anesthesia related complication which requires treatment other than observation should be reported to the Patient Safety Initiative.
  - Complications may include, but are not limited to:
    - Aspiration
    - Pneumothorax
    - Perforation of an organ
    - Cardiac and/or respiratory related problems which require intervention
    - Moderate to severe bleeding which requires intervention
    - Serious infections which require intervention
    - Prolonged decrease in oxygenation and/or blood pressure which require intervention
  - Treatment may include, but is not limited to:
    - Fluid resuscitation
    - Unscheduled blood transfusion
    - Surgery
    - IV Antibiotics

Not Reportable Events

The following types of events do not need to be reported to the Patient Safety Initiative:

- Any patient who is transferred to the Emergency Department and/or hospitalized due to an unstable medical problem prior to the scheduled procedure and/or administration of anesthesia.

- Any patient who develops an expected or common complication of surgery, with the following qualifiers:
  - The complication should be identified on the Consent Form;
  - The patient does not require hospitalization and treatment of the complication.
  - Common complications may include:
    - Post-operative urinary retention.
    - The need for more intense post-operative pain control.
    - Post-operative bleeding following tonsillectomies that do not require transfusion.

If there is any question whether an event should be reported, the Department recommends that the Center err on the side of reporting in order to comply with the Act. Department staff will review the reported event and determine if it meets the statutory definition.

c: Cynthia Kirchner, Senior Policy Advisor
Emmanuel Noggoh, Director, Health Care Quality Assessment