Sec. 19a-127n-2. Procedures for adverse event reporting

(a) All adverse events shall be documented by the facility and submitted to the department. All documentation of adverse events shall be maintained at the facility for not less than three (3) years.

(b) All adverse events identified in the National Quality Forum's list of serious events, as amended, and those on the list compiled by the department, as amended, shall be reported by the facility on the adverse event reporting form prescribed by the Commissioner.

(c) Reports: A hospital or outpatient surgical facility shall report an adverse event to the department as follows:

(1) An adverse event deemed to be emergent by the facility shall be reported immediately by telephone and confirmed by written report not later than seven (7) days after the occurrence of said event; and

(2) An adverse event not deemed to be emergent by the facility shall be submitted in writing not later than seven (7) days after the occurrence of the event.

(d) Emergent adverse event telephone notification shall include the following:

(1) Date and time of occurrence;

(2) Name and phone number of the facility's contact person;

(3) Name and address of the hospital or outpatient surgical facility;

(4) The number assigned to the adverse event report; and

(5) A brief description of the emergent adverse event.

(e) Each written adverse event report shall contain the following information:

(1) Demographic data for all facilities

(A) Facility information: type of facility, facility name and address, license number, reporter's name, contact person's name and telephone number; and

(B) Patient information: medical record number, age, sex, date of admission, patient's billing number, date and time of event, date and time event first known, date of patient death, if applicable, and patient admission diagnosis;

(2) Demographic data for hospitals only

(A) Inpatient: hospital based, off campus satellite site-name and address; or

(B) Outpatient: hospital based, off campus satellite site-name and address; and

(C) Location of occurrence within the site;

(3) Notifications: Indicate whether notification of the event was provided to the patient or to any other entity listed in the adverse event reporting form;

(4) Description of event from list of required reportable adverse events;

(5) Facts of event and patient condition; and

(6) Immediate plan of action, which shall include the immediate care provided to the patient as well as the immediate actions taken by the facility to reduce the risk of a similar event occurring until the long-term preventive strategies can be determined and implemented.

(f) A corrective action plan shall be submitted to the department not later than thirty (30) days after the occurrence of the adverse event.

(g) Each corrective action plan shall include the following information:

(1) Facility name;

(2) Report number;

(3) Patient billing number;
(4) Date plan submitted;
(5) Event being addressed;
(6) Findings of facility investigation;
(7) Corrective action plan: Following the facility investigation, each corrective action plan shall address a prospective plan to reduce the risk of the occurrence of a similar adverse event and shall include but not be limited to the following information:
(A) How other patients having the potential to be affected by a similar event will be identified;
(B) Identification of long term strategies to be implemented to prevent subsequent occurrences;
(C) Mechanisms for monitoring the implementation of the components of the corrective action plan;
(D) Root cause analysis determination;
(E) Timeline for implementation of the corrective action plan;
(F) Completion date for the corrective action plan;
(G) Identification of the staff member, by title, who will monitor the implementation of the corrective action plan;
(H) Name of person submitting the corrective action plan; and
(I) Date the corrective action plan was signed.
(h) Numbering: Each adverse event report shall be identified on each page with a number as follows:
(1) The number appearing in the facility license;
(2) The last two digits of the year; and
(3) The sequential number assigned to the report for the calendar year.
(i) The department's list of reportable adverse events includes:
(1) Perforations during open, laparoscopic and/or endoscopic procedures resulting in death or serious disability;
(2) Obstetrical events resulting in death or serious disability to the neonate;
(3) Significant medication reactions resulting in death or serious disability;
(4) Laboratory or radiologic test results not reported to the treating practitioner or reported incorrectly which result in death or serious disability due to incorrect or missed diagnosis in the emergency department; and
(5) Nosocomial infections defined as reportable sentinel events by the Joint Commission on Accreditation of Healthcare Organizations.

(Adopted effective October 29, 2007; Amended December 4, 2009)