

Legislative Regulation Review Committee

2009-062

Department of Public Health

**ADVERSE EVENT REPORTING FOR
HOSPITALS & OUTPATIENT SURGICAL
FACILITIES**

IMPORTANT: Read instructions on bottom of Certification Page before completing this form. Failure to comply with instructions may cause disapproval of proposed Regulations.

**STATE OF CONNECTICUT
REGULATION
OF
Department of Public Health
Name of Agency**

**Concerning
Adverse Event Reporting for Hospitals and Outpatient Surgical Facilities
SUBJECT MATTER OF REGULATION**

The Regulations of Connecticut State Agencies are amended by adding section 19a-127n-1 to section 19a-127n-2, inclusive as follows:

Section 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, [patient's social security 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;

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- (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.

Statement of Purpose: (A) The purpose of this regulation is to update section 19a-127n-2 regarding hospital and outpatient surgical facilities mandatory reporting forms. (B) This update will delete the requirement for hospitals and outpatient surgical facilities to provide a patient's social security number on a form required by the Department. This information has the potential to lead to identify theft if released. (C) The proposed regulation amends section 19a-127n-2 of the Regulations of Connecticut State Agencies.

Be it known that the foregoing:

Regulations Emergency Regulations

are:

Adopted Amended as hereinabove stated Repealed

By the aforesaid agency pursuant to:

Sections 19a-127n of the General Statutes.

Section of the General Statutes, as amended by Public Act. No. of the Public Acts.

Public Act. No of the Public Acts.

After publication in the Connecticut Law Journal on July 7, 2009 the notice of the proposal to:

Adopt Amend Repeal such regulations

(If applicable): And the holding of an advertised public hearing on

WHEREFORE, the foregoing regulations are hereby:

Adopted Amended as hereinabove stated Repealed

Effective:

When filed with the Secretary of the State.

(OR)

The ____ day of ____ 20__.

Witness Whereof:	Date 2009	SIGNED (Head of Board, Agency or Commission) <i>[Signature]</i>	OFFICIAL TITLE, DULY AUTHORIZED Commissioner
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Approved by the Attorney General as to legal sufficiency in accordance with Sec. 4-169, as amended, C.G.S.:	SIGNED <i>[Signature]</i>	9/15/09	OFFICIAL TITLE, DULY AUTHORIZED ASSOC. ATTY. GENERAL
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Approved

Disapproved

Disapproved in part, (Indicate Section Numbers disapproved only)

Rejected without prejudice.

The Legislative Review Committee in accordance with Sec. 4-170, as amended, of the General Statutes	DATE	SIGNED (Clerk of the Legislative Regulation Review Committee)
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Two certified copies received and filed, and one such copy forwarded to the Commission on Official Legal Publications in accordance with Section 4-172, as amended, of the General Statutes.

DATE	SIGNED (Secretary of the State)	BY
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INSTRUCTIONS

C... copy of all regulations for adoption, amendment or repeal, except emergency regulations, must be presented to the Attorney General for his determination of legal sufficiency. Section 4-169 of the General Statutes.

Eighteen copies of all regulations for adoption, amendment or repeal, except emergency regulations, must be presented to the standing Legislative Regulation Review Committee for its approval. Section 4-170 of the General Statutes.

Each regulation must be in the form intended for publication and must include the appropriate regulation section number and section heading. Section 4-172 of the General Statutes.

Indicate by "(NEW)" in heading if new regulation. Amended regulations must contain new language in capital letters and deleted language in brackets. Section 4-170 of the General Statutes.