On and after July 1, 2004, a hospital or outpatient surgical facility shall report to the Department of Public Health (DPH) adverse events as follows:

**Monday through Friday, 8:30 AM – 4:30 PM**

Emergent reports: Should the institution deem an event to be emergent in nature the reporter should immediately contact the department at (860) 509-7400 and request to speak to a supervisor or manager indicating that they are reporting an "Emergent Adverse Event".

Emergent reports include an unexpected situation or sudden occurrence of a serious and urgent nature which requires immediate remedial action on the part of the hospital to protect the health and safety of its patient population, or an event which is unusually serious in nature and has resulted in a patient’s death or injury.

Emergent reports may include adverse events as defined in Section 19a-127-(a)(1).

**Before 8:30 AM and after 4:30 PM on weekdays and on weekends and holidays**

Emergent reports: Should the institution deem the situation to be emergent in nature, the reporter should contact the Department’s answering service at (860) 509-8000. The answering service should be advised that an “Emergent Adverse Event” has occurred, provide a brief summary of the situation and the name and phone number of the facility’s contact person. A Department staff member will immediately contact the designated facility contact person.

- **Please remember to identify the institution, address, phone number and contact person**, the involved patient(s), utilizing identification number, and specify the number assigned to the adverse event report.

1. **WRITTEN REPORTS**

A written report shall be submitted on an approved form (AE#1) to the Department, within seven (7) days after the occurrence of any adverse events.

**DIRECTIONS AND DEFINITIONS FOR USE OF FORM AE#1**

**Demographic Data-Page 1**

a) Facility Information

i) Type of facility: Check the applicable licensure level of the facility.

ii) Facility name and address – self-explanatory.

iii) License Number – The number as it appears on the current license. May also include letter designations for certain licensure levels.
b) Sequential Report Number:
   All adverse events shall be identified on each page with a number as follows:
   i) The number appearing on the facility license.
   ii) The last two digits of the year.
   iii) The sequential number assigned to the report for the calendar year.

   Example: 0085-02-01
   Breakdown: 0085-license number; 02-year; 01 – sequential number (first report)

   Example: 21CD-02-03
   Breakdown: 21CD-license number; 02-year; 03 – sequential number (third report)

c) Reporter’s Name: The name of the person reporting the adverse event to the Department of Public Health.

d) Patient Information: The majority of information reported under this designation is self-explanatory.

e) Date and Time Event First Known: That point in time when the facility first became aware of the adverse event.

Demographics: Hospitals Only Page 2

a) Hospital Based: Emergency Departments are included in the in-patient hospital based category.

b) Off Campus Satellite Sites: Health care and service delivery sites that would require a separate institutional license in accordance with Connecticut General Statutes 19a-490 but for the fact that these entities are incorporated within the hospital’s single license.

c) Location of Occurrence: Check only the specific location where the event occurred.

NOTIFICATIONS: PAGE 2

Note: Separate reports should be submitted for a patient who experiences 2 or more discrete adverse events during their stay in the facility.

2. CORRECTIVE ACTION PLAN (CAP)

a) A CAP shall be filed for each adverse events not later than thirty (30) days after said occurrence. (see form AE#2).

b) Corrective Action Plan” means a plan that implements strategies that reduce the risk of similar events occurring in the future. Said plan shall measure the effectiveness of such strategies by addressing the implementation, oversight and time lines of such strategies.

   Directions for use of form AE #2

   i. Facility: Enter name, address of institution.
ADVERSE EVENT REPORTING FORM
HOSPITALS/OUTPATIENT SURGICAL FACILITIES
DIRECTIONS FOR USE

ii. Sequential Report Number for which the plan is being submitted: Enter the number which was assigned to the original notification to the Department for the event (e.g., number utilized on Form AE #1).

iii. Date of event: Enter the date that the event happened.

iv. Date CAP submitted: Enter the date CAP sent to the Department.

v. Unique Patient Identifier: Enter the patient billing number as utilized on the original adverse event reporting form AE #1.

vi. Event being addressed: Identify the adverse event.

vii. Findings: List outcome of facility investigation.

viii. Corrective Action Plan: The CAP must identify strategies/plans to reduce the occurrence of such events in the future inclusive of, but not limited to, implementation of policies/procedures, in-servicing of appropriate staff, monitoring, remediation, supervision, oversight and measures or mechanisms that shall be utilized to monitor the ongoing effectiveness of the plan.

ix. Time line for implementation: Identify the date that the components of the CAP are to be initiated.

x. Completion date for CAP: Identify the date that all components of the plan have been completed.

xi. Identification of staff member by title who has been designated the responsibility for monitoring the CAP: It is important that the institution identify a “position/title” rather than an individual name in this area as CAPs are an ongoing responsibility.

xii. Submitted by and date: Self-explanatory.

Written reports and corrective action plans shall be faxed to (860) 509-8369 or mailed to:

Department of Public Health
Division of Health Systems Regulation
Attention: Susan Newton RN
Supervising Nurse Consultant
410 Capital Avenue – MS#12HSR
P.O. Box 340308
Hartford, CT 06134-0308

3. ADDITIONAL INFORMATION

a) Each hospital or outpatient surgical facility shall have a mechanism in place to provide the Department with the patient’s name, physician(s) name and the name of any other healthcare provider or staff member involved in or with first-hand knowledge of this event. This information must be available to Department of Public Health representatives twenty-four (24) hours a day, seven (7) days a week.

b) Healthcare provider or staff person includes, but is not limited to, the individual who performed the surgery or procedure, administered the anesthesia, delivered the substance or was directly involved in the discrete event. In all cases please include the name of the patient’s attending physician of record.