

CONNECTICUT DEPARTMENT OF  
**PUBLIC HEALTH**

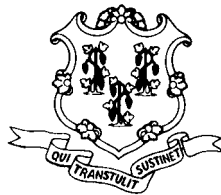
Keeping Connecticut Healthy

**ANNUAL LEGISLATIVE REPORT TO THE GENERAL ASSEMBLY  
Adverse Event Reporting**

**PUBLIC ACT 02-125  
AN ACT CREATING A PROGRAM FOR  
QUALITY IN HEALTH CARE**

**MARCH 2003**

*Joxel Garcia, M.D., M.B.A., Commissioner*



State of Connecticut  
Department of Public Health  
410 Capitol Avenue  
P.O. Box 340308  
Hartford, CT 06134-0308



**State of Connecticut  
Department of Public Health**

**Annual Legislative Report to the General Assembly  
Adverse Event Reporting**

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An Act Creating a Program for Quality in Health Care**

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## **INTRODUCTION**

### **Public Act 02-125**

Public Act 02-125 (Appendix A) requires the Department of Public Health (DPH) to establish a quality of care program for health care facilities as defined in section 19a-630 of the general statutes. DPH must develop a health care quality performance measurement and reporting system initially applicable to the state's hospitals and outpatient surgical facilities. Other health care facilities come under the quality program in later years as it develops. An advisory committee, chaired by the DPH commissioner, advises the program.

The act directs the Commissioner to report on the quality of care program on or before June 30, 2003. The act directs DPH to produce a report that compares the state's hospitals based on quality performance measures. The act requires all hospitals to implement performance improvement plans. These plans must be submitted annually to DPH as a condition of licensure, beginning June 30, 2003. On or before March first and annually thereafter the Commissioner shall report on adverse event reporting to the General Assembly. The following is the first report submitted to the General Assembly on adverse event reporting.

### **Reporting on Adverse Events**

An "adverse event" is an injury caused by or associated with medical management that results in death or measurable disability. It includes those sentinel events for which remediation plans are required by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), an independent, not-for-profit organization that evaluates and accredits health care organizations, including hospitals, in the United States. A "sentinel event," according to JCAHO, is an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof.

The following four categories are used for reporting adverse events to DPH:

Class A: An adverse event resulting in or associated with a patient's death or immediate danger of death.

Class B: An adverse event resulting in or associated with a patient's serious injury or disability or immediate danger of such.

Class C: An adverse event resulting in or associated with a patient's physical or sexual abuse.

Class D: An adverse event not reported in Class A through C above.

As of October 1, 2002, hospitals and outpatient surgical facilities were required to report adverse events classified as A through C to the Department of Public Health. These facilities must also report, on a quarterly basis, Class D adverse events along with a corrective action plan.

## **BACKGROUND/ NATIONAL TRENDS**

According to the Institute of Medicine (IOM, 2000), mandatory adverse event reporting systems, like the system recently introduced in Connecticut, serve three purposes. The first is to protect the public by assuring that serious errors are reported and will be investigated. Second, they provide an incentive to health care facilities to improve quality of care, because facilities want to avoid the negative consequences associated with adverse events. Last, they require that all health care facilities devote additional efforts to patient safety.

Several other states have mandatory adverse event reporting systems (OHCQ, 2002. NASHP, 2002). According to the Health Policy Tracking Service, National Conference of State Legislatures, as of 9/27/02, sixteen states had mandatory reporting systems, and another five had voluntary systems. Reporting formats vary by state – some states have a specific reporting form like Connecticut, others have different forms for different types of events, and some have no forms. It varies as to which events are reportable, ranging from vague, general requirements to highly specific definitions. States with well-defined reportable events approach the reporting of events in either of two ways: by outcome and by the mechanism of death or injury. P.A. 02-125 calls for an outcomes-based reporting system. Reportable events are stipulated as those injuries that result in,

are associated with, or present an immediate danger of, certain outcomes: death, serious injury, measurable disability, or are associated with physical or sexual abuse.

## **IMPLEMENTATION**

The Department of Public Health (DPH) initiated preparations for the October 1, 2002 implementation of Adverse Event reporting in July 2002.

### **Hospitals**

Currently, Connecticut licenses forty-four (44) hospitals consisting of thirty (30) general hospitals, one (1) children's hospital, six (6) chronic disease hospitals, one (1) hospice facility, five (5) psychiatric hospitals and one (1) maternity hospital.

A work group consisting of representatives from the Connecticut Hospital Association (CHA) and the DPH was convened in July 2002. This group met on a regular basis to discuss the implementation of Adverse Event reporting to the DPH. CHA was provided with the opportunity to share the views of the hospital providers, review and comment on the reporting tool, related forms and DPH's proposed processes. Three formal presentations were provided to the hospital community by DPH. All three forums were well attended by various levels of hospital personnel, such as administrators, physicians, nurses and risk managers.

### **Outpatient Surgical Facilities**

Currently, Connecticut licenses 20 outpatient surgical facilities. The outpatient surgical facilities that are affiliated with hospitals provided comments through the DPH/CHA workgroup and one other meeting was held to receive additional comments. One formal presentation was provided to outpatient surgical facilities.

### **General Information**

A reporting mechanism was established at DPH to enable Hospitals and Outpatient Surgical Facilities to report Adverse Events on a twenty-four hour basis, seven days a week. DPH staff is also accessible via the Department's after hours emergency answering service (860) 509-8000.

Hospitals and Outpatient Surgical Facilities are required to use the following standardized documents:

- **Adverse Event Reporting Form:** This form requires the reporting of demographic data in addition to discreet adverse event information. In order to ensure consistent reporting across facilities, directions for completing the form are also provided. (Appendix B)
- **Corrective Action Plans:** Forms were designed for providers to document strategies that reduce the risk of similar events. There are two corrective action plans, one for Class A, B and C events; the other for Class D events. (Appendix C)

Hospitals and Outpatient Surgical Facilities may use the following document to assist them in their reporting:

- **Decision Making Model:** A flow chart was designed to assist the providers in determining what situations were required to be reported to the Department. (Appendix D)

The Adverse Event reporting requirements were implemented on October 1, 2002, as required by Public Act 02-125.

## **Status of Adverse Event Data Reporting**

The adverse event data collection system is being developed in two phases, the first of which is complete. The first phase included development of a data repository and data entry tool, allowing Department of Public Health (DPH) staff to process paper reports submitted by facilities. To facilitate linkage with appropriate facility information, for reporting and analysis, the adverse event data is incorporated into tables within the DPH facility licensure system.

Concurrent with the development of this data storage system the Connecticut Hospital Association (CHA) created a local database system that could be deployed in a hospital environment. This allows hospitals to maintain a local database of information, if desired, for their own reporting and analysis purposes. Entry of submitted reports, into the central system, is currently being performed upon receipt at DPH with no backlog for Class A, B and C events.

Phase two of the project, underway now, addresses the desire for an automated interface between the Hospital systems and the central data store at DPH. The interface will eliminate double data entry and minimize the chance for data entry errors. Initial consideration was for a World Wide Web (Web) based data entry screen allowing direct input by hospitals into the central repository. Since, however, hospitals still would like to maintain a local copy, this solution failed to eliminate double data entry. The current design will utilize the Web as the interface but will provide a file transfer page, allowing hospitals to upload a local extract file to the central DPH repository.

Several hardware components of the solution are in place, including the mechanism for transporting data from the Web into the licensure system at DPH. Current efforts are focusing on establishing the remaining architectural components and development of the Web based file transfer page. Deployment of the new solution will likely be timed with the release of a major form revision, if one is needed. This will minimize the impact and timing of modifications to both hospital and central systems associated with file structure changes.

In January 2003, staff began work on evaluating the new database. At this point there are 188 records in the data base representing Class A, B, and C events that occurred between October 1, 2002, and January 31, 2003. This does not include the Class D events that are being reported to DPH on a quarterly basis. Over 200 Class D event reports for the first quarter were submitted in February and are still being entered into the database. Of importance, a tally of Class D events for 2002 was derived from reporting logs and is included in the Adverse Event Data Collection table for the reporting quarter ending December 31, 2002.

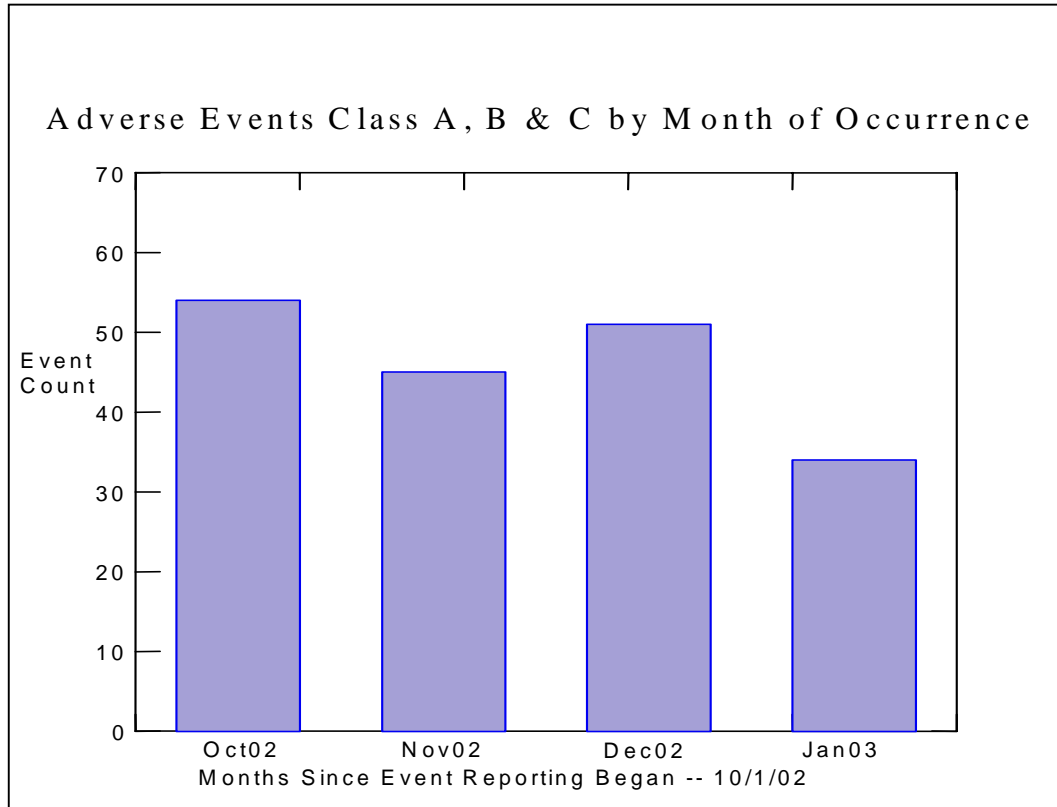
As with any new information system, there are some issues affecting the quality of the data set. We are now taking steps to improve both the reliability and accuracy of the information in this database. This process involves working with hospital staff to assure that the reporting forms are complete and responses are logical. It also involves building adequate quality control procedures to review over 100 separate fields in each form after they reach DPH. In addition, the complexity of some of the diagnostic and surgical procedure information reported makes it difficult to classify and evaluate this information consistently.

## **Results**

The reported number of adverse events that occur each month has been fairly stable over the four-month period from October, 2002, to January, 2003 (see Figure 1). The number reported in January 2003 (n=34) is somewhat lower than in the three preceding months (n=54, 45, and 51 respectively).

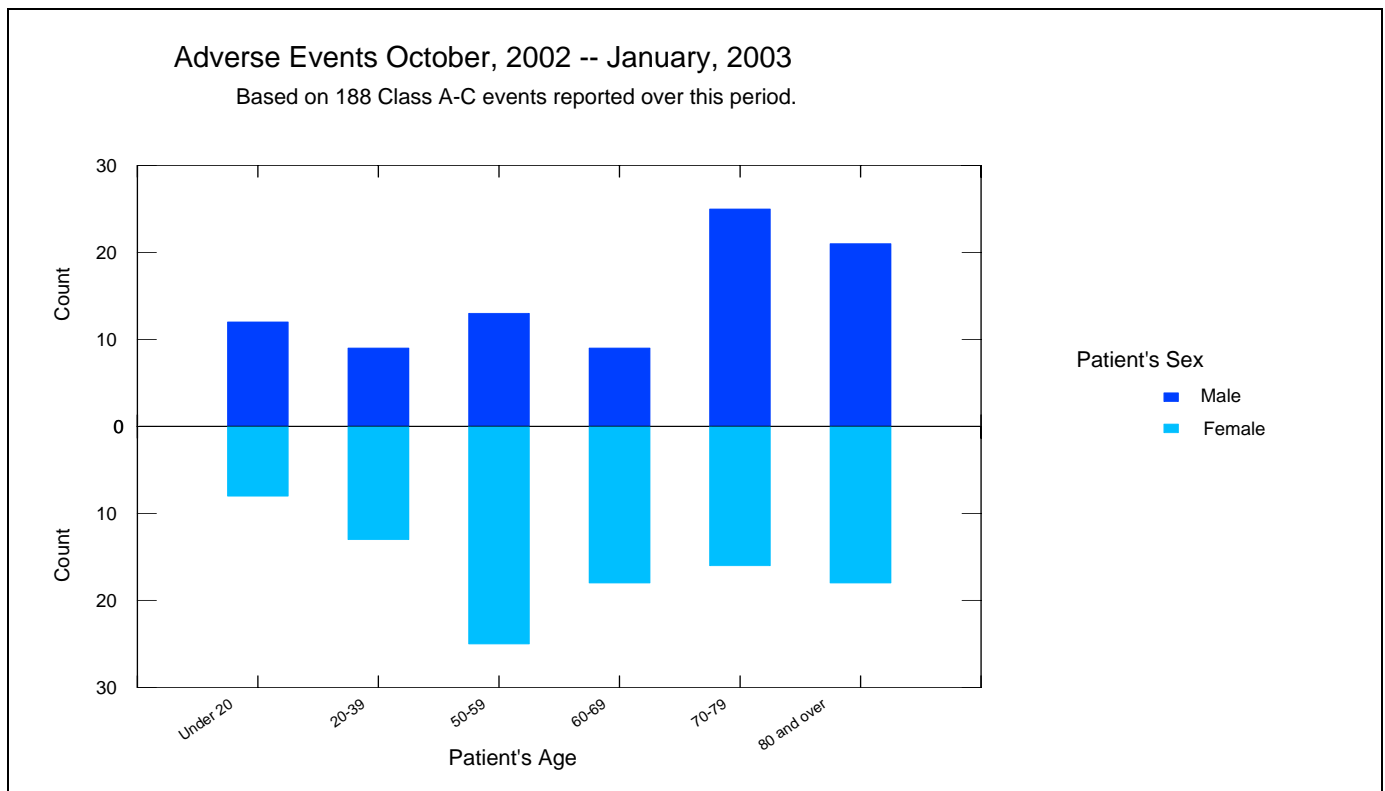
The age of patients experiencing an adverse event differs for men and women, with a greater number of events being reported for women between the ages of 20 and 69 (see Figure 2). Of the 188 events, the median age for men and women is 65 years, with about equal numbers of males (48%) and females (52%).

**Figure 1.**



Source: Connecticut Department of Public Health, OHCQ

**Figure 2.**



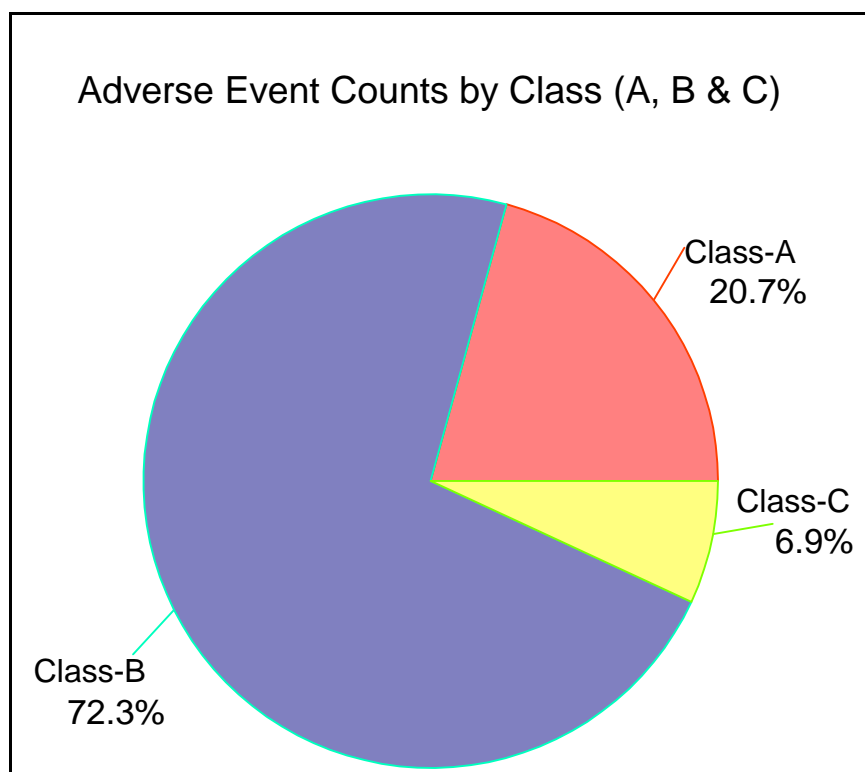
Source: Connecticut Department of Public Health, OHCQ



Most of this patient population was from inpatient (82%) compared to outpatient services (18%). Evidence of the impact of these events can be found in statements about actions that took place after the adverse event. When asked, “Was the patient’s anticipated stay extended?” about 40% said “yes.” Almost 46% of patients were either transferred to another health care facility or transferred to a more intensive level of care within the same hospital.

Class B was clearly the predominant event class among this group, accounting for 72% of all events (see Figure 3). Class B refers to “an event that has resulted in or is associated with a patient’s serious injury or disability or immediate danger of serious injury or disability.” The most serious event type is Class A. It is “an event that has resulted in or is associated with the patient’s death, or the immediate danger of death.” Class A events accounted for 20.7% of the reported events. Finally, an event that has “resulted in or is associated with the physical or sexual abuse of a patient.” is classified as Class C.

**Figure 3.**



Source: Connecticut Department of Public Health, OHCQ

### **Adverse Event Subcommittee**

An adverse events subcommittee was established by the Quality in Health Care Advisory Committee. The subcommittee has met twice to examine the adverse events reporting issues more closely. They have developed and presented recommendations for the Committee’s review and are appended to this report. These recommendations are from the minutes of their meeting on January 29, 2003 (Appendix E).

## ADVERSE EVENT DATA COLLECTION

Adverse events summary for the reporting quarter ending December 31, 2002

Hospital Type/ Out-patient Surgical Centers	Class A	Class B	Class C	Totals	Class D	Grand Totals
General and Children's	27	99	6	132	191	223
Chronic Disease	2	8	1	11	7	18
Psychiatric	1	4	4	9	13	22
Out-patient Surgical Centers	1	1	0	2	24	26
<b>Totals</b>	31	112	11	154	235	389

Adverse events summary for January 2003

Hospital Type/ Out-patient Surgical Centers	Class A	Class B	Class C	Totals
General and Children's	8	19	2	29
Chronic	0	1	0	1
Psychiatric	0	1	0	1
Out-patient Surgical Centers	0	3	0	3
<b>Totals</b>	8	24	2	34

## **ADDITIONAL REMARKS**

### **Regulations**

The department has completed an initial draft of proposed regulations in order to further clarify the implementation of this program. It is expected that extensive discussion regarding the drafted regulations will occur based on both DPH's and the providers' experiences with this reporting system (Appendix F).

### **Corrective Action Plans**

Corrective action plans are being submitted to DPH as required by the public act.

### **Future Plans**

1. Efforts to improve the quality of information reported to DPH will be maintained. Clarifying the definitions of the terms used in the form by means of discussions and educational outreach to health care facilities will continue to be important. This type of clarification is expected to have a beneficial affect on both the quality of the data being reported and the consistency of decisions made by health facilities about which events to report. The development of internal quality improvement reports will help to promote and maintain an accurate and complete database. The complexity of the diagnostic and medical procedure information now being reported should be addressed. Since this information is reported as free text, that is, without standardized terms or codes, it is difficult to use. DPH staff will need to develop strategies for processing this information. This quality improvement work has already begun. With continued effort these steps will improve the quality of the data needed for future assessments.
2. The department of public health plans to continue to work with hospitals and outpatient surgical facilities, on both a provider-wide and an individual basis, in order to improve the quality and consistency of data collection and reporting.
3. The adverse events subcommittee plans to continue its work regarding future concerns.
4. All reporting tools will be evaluated to ensure they meet the needs of both DPH and the reporting entities.



## APPENDICES

**APPENDIX A**  
**Public Act 02-125**



**Substitute House Bill No. 5715**

**Public Act No. 02-125**

**AN ACT CREATING A PROGRAM FOR QUALITY IN HEALTH CARE.**

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective October 1, 2002*) (a) There is established a quality of care program within the Department of Public Health. The department shall develop for the purposes of said program (1) a standardized data set to measure the clinical performance of health care facilities, as defined in section 19a-630 of the general statutes, and require such data to be collected and reported periodically to the department, including, but not limited to, data for the measurement of comparable patient satisfaction, and (2) methods to provide public accountability for health care delivery systems by such facilities. The department shall develop such set and methods for hospitals during the fiscal year ending June 30, 2003, and the committee established pursuant to subsection (c) of this section shall consider and may recommend to the joint standing committee of the General Assembly having cognizance of matters relating to public health the inclusion of other health care facilities in each subsequent year.

(b) In carrying out its responsibilities under subsection (a) of this section, the department shall develop the following for the quality of care program:

- (1) Comparable performance measures to be reported;
- (2) Selection of patient satisfaction survey measures and instruments;
- (3) Methods and format of standardized data collection;
- (4) Format for a public quality performance measurement report;
- (5) Human resources and quality measurements;
- (6) Medical error reduction methods;
- (7) Systems for sharing and implementing universally accepted best practices;
- (8) Systems for reporting outcome data;
- (9) Systems for continuum of care;

(10) Recommendations concerning the use of an ISO 9000 quality auditing program;

(11) Recommendations concerning the types of statutory protection needed prior to collecting any data or information under this act; and

(12) Any other issues that the department deems appropriate.

(c) There is established a Quality of Care Advisory Committee which shall advise the Department of Public Health on the issues set forth in subdivisions (1) to (12), inclusive, of subsection (b) of this section. The advisory committee shall meet at least quarterly.

(d) The advisory committee shall consist of (1) four members who represent and shall be appointed by the Connecticut Hospital Association, including three members who represent three separate hospitals that are not affiliated of which one such hospital is an academic medical center; (2) one member who represents and shall be appointed by the Connecticut Nursing Association; (3) two members who represent and shall be appointed by the Connecticut Medical Society, including one member who is an active medical care provider; (4) two members who represent and shall be appointed by the Connecticut Business and Industry Association, including one member who represents a large business and one member who represents a small business; (5) one member who represents and shall be appointed by the Home Health Care Association; (6) one member who represents and shall be appointed by the Connecticut Association of Health Care Facilities; (7) one member who represents and shall be appointed by the Connecticut Association of Not-For-Profit Providers for the Aging; (8) two members who represent and shall be appointed by the AFL-CIO; (9) one member who represents consumers of health care services and who shall be appointed by the Commissioner of Public Health; (10) one member who represents a school of public health and who shall be appointed by the Commissioner of Public Health; (11) one member who represents and shall be appointed by the Office of Health Care Access; (12) the Commissioner of Public Health or said commissioner's designee; (13) the Commissioner of Social Services or said commissioner's designee; (14) the Secretary of the Office of Policy and Management or said secretary's designee; (15) two members who represent licensed health plans and shall be appointed by the Connecticut Association of Health Care Plans; (16) one member who represents and shall be appointed by the federally designated state peer review organization; and (17) one member who represents and shall be appointed by the Connecticut Pharmaceutical Association. The chairperson of

the advisory committee shall be the Commissioner of Public Health or said commissioner's designee. The chairperson of the committee, with a vote of the majority of the members present, may appoint ex-officio nonvoting members in specialties not represented among voting members. Vacancies shall be filled by the person who makes the appointment under this subsection.

(e) The chairperson of the advisory committee may designate one or more working groups to address specific issues and shall appoint the members of each working group. Each working group shall report its findings and recommendations to the full advisory committee.

(f) The Commissioner of Public Health shall report on the quality of care program on or before June 30, 2003, and annually thereafter, in accordance with section 11a-4 of the general statutes, to the joint standing committee of the General Assembly having cognizance of matters relating to public health and to the Governor. Each report on said program shall include activities of the program during the prior year and a plan of activities for the following year.

(g) On or before April 1, 2004, the Commissioner of Public Health shall prepare a report, available to the public, that compares all licensed hospitals in the state based on the quality performance measures developed under the quality of care program.

(h) The Department of Public Health may seek out funding for the purpose of implementing the provisions of this section. Said provisions shall be implemented upon receipt of said funding.

Sec. 2. (NEW) (*Effective October 1, 2002*) All hospitals, licensed pursuant to provisions of the general statutes, shall be required to implement performance improvement plans. Such plans shall be submitted on or before June 30, 2003, and annually thereafter by each hospital to the Department of Public Health as a condition of licensure.

Sec. 3. (NEW) (*Effective July 1, 2002*) (a) For purposes of this section, an "adverse event" means an injury that was caused by or is associated with medical management and that results in death or measurable disability. Such events shall also include those sentinel events for which remediation plans are required by the Joint Commission on the Accreditation of Healthcare Organizations.

(b) Adverse events shall be classified into the following categories:

(1) "Class A adverse event" means an event that has resulted in or is associated with a patient's death or the immediate danger of death;

(2) "Class B adverse event" means an event that has resulted in or is associated with a patient's serious injury or disability or the immediate danger of serious injury or disability;

(3) "Class C adverse event" means an event that has resulted in or is associated with the physical or sexual abuse of a patient; and

(4) "Class D adverse event" means an adverse event that is not reported under subdivisions (1) to (3), inclusive, of this subdivision.

(c) On and after October 1, 2002, a hospital or outpatient surgical facility shall report to the Department of Public Health on Class A, B and C adverse events as follows: (1) A verbal report shall be made not later than twenty-four hours after the adverse event occurred; (2) a written report not later than seventy-two hours after the adverse event occurred; and (3) a corrective action plan shall be filed not later than seven days after the adverse event occurred.

(d) A hospital or outpatient surgical facility shall report to the Department of Public Health on Class D adverse events on a quarterly basis. Such reports shall include corrective action plans. For purposes of this subsection and subsection (c) of this section, "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. Failure to implement a corrective action plan may result in disciplinary action by the Commissioner of Public Health, pursuant to section 19a-494 of the general statutes.

(e) The Commissioner of Public Health shall adopt regulations, in accordance with chapter 54 of the general statutes, to carry out the provisions of this section. Such regulations shall include, but shall not be limited to, a prescribed form for the reporting of adverse events pursuant to subsections (c) and (d) of this section. The commissioner may require the use of said form prior to the adoption of said regulations.



(f) On or before March first annually, the commissioner shall report, in accordance with the provisions of section 11-4a of the general statutes, on adverse event reporting, to the joint standing committee of the General Assembly having cognizance of matters relating to public health.

(g) Information collected pursuant to this section shall not be required to be disclosed pursuant to subsection (a) of section 1-210 of the general statutes, for a period of six months from the date of submission of the written report required pursuant to subsection (c) of this section and shall not be subject to subpoena or discovery or introduced into evidence in any judicial or administrative proceeding except as otherwise specifically provided by law.

Approved June 7, 2002

## APPENDIX B

### Part I - Adverse Event Reporting Form (Directions for Use)

### Part II - Adverse Events Reporting Form

# STATE OF CONNECTICUT

## DEPARTMENT OF PUBLIC HEALTH

### ADVERSE EVENT REPORTING FORM

#### HOSPITALS/OUTPATIENT SURGICAL FACILITIES

#### DIRECTIONS FOR USE

On and after October 1, 2002, a hospital or outpatient surgical facility shall report to the Department of Public Health (DPH) on all Class A, B and C and D adverse events as follows:

#### 1. VERBAL REPORTS:

Verbal reports shall be made to DPH not later than twenty-four (24) hours after a Class A, B or C adverse event occurred. (Note: Class D reports do not require a verbal report).

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

Emergent reports: Should the institution deem the situation to be emergent in nature the reporter should 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.

Non-emergent reports: Events may be reported directly on the DPH Adverse Event Reporting line: (888) 519-2400 (toll free line). This line has voice mail capacity. Department staff will retrieve these verbal reports throughout the day.

#### 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.

Non-emergent reports: Events may be reported directly on the Department's Adverse Event Reporting line: (888) 519-2400 (toll free line). This line has voice mail capacity. Department staff will retrieve these verbal reports on a regular basis.

#### 2. CONTENT OF VERBAL REPORTS

Verbal reports recorded on the adverse event reporting line shall contain the following information:

- i) Facility name and address.
- ii) Sequential report number.
- iii) Contact person and telephone number where said person can be reached for additional information, if necessary.
- iv) Date and time verbal report is being recorded.
- v) Patient's billing number.
- vi) Date and time event occurred.
- vii) Notification of the Medical Examiner's Office, if applicable.
- viii) Brief summary of the event and patient's condition.
- ix) Class of adverse event (i.e., A, B, or C).

The contents of the verbal reports are highlighted on the adverse event reporting form.

### 3. WRITTEN REPORTS

A written report shall be submitted on an approved form to the Department, within seventy-two (72) hours after the occurrence of any adverse events classified as an A, B and C. (see form AE #1).

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

- a) "Adverse Event" means an injury that was caused by or is associated with medical management and that results in death or measurable disability. Such events include sentinel events for which remediation plans are required by the Joint Commission on the Accreditation of Healthcare Organizations.
- b) "Disabilities" means any weakening, impairment or destruction of a patient's physical, mental or cognitive status which was not a foreseeable effect of the patient's planned treatment regime or was not related to the natural course of the patient's illness or underlying condition(s).
- c) "Foreseeable effect" means an expected or anticipated outcome due to an individual patient's clinical presentation and/or underlying condition(s).
- d) "Immediate Danger" means an adverse event has the potential to directly and in the near future, place an patient at risk for death, serious injury or disability.
- e) "Medical Management" means to assess, direct, provide, control, or supervise the care and services provided to a patient, either directly or indirectly.

#### **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) Verbal Report to DPH: Date, time and name of individual that filed the verbal class A, B, or C report.
- e) Patient Information: The majority of information reported under this designation is self-explanatory.
- f) 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 and 3**

- 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.
- d) Adverse Event: Check one classification only (A, B, C, or D).

**Medical/General and Surgical/Anesthesia Events Pages 4-7**

Check all the boxes that apply to the discrete event.

Example: A patient is administered chemotherapeutics in a higher dose than that ordered by the physician due to an infusion pump malfunctioning. The form would indicate the following:

<p><b>Infusion Pump</b></p> <p><input checked="" type="checkbox"/> Equipment malfunction</p> <p><input type="checkbox"/> Programming Error</p> <p><input type="checkbox"/> Component incompatibility</p> <p><input type="checkbox"/> Other _____</p>	<p><b>Substance Administration Events</b></p> <p><b>Product</b></p> <p><input checked="" type="checkbox"/> Chemotherapeutic</p> <p><input type="checkbox"/> Dietary</p> <p><input type="checkbox"/> Electrolytes</p> <p><input type="checkbox"/> Fluids</p> <p><input type="checkbox"/> Medical Gases</p> <p><input type="checkbox"/> Medications</p> <p><input type="checkbox"/> Treatments</p> <p><input type="checkbox"/> Other _____</p>	<p><b>Event Associated with:</b></p> <p><input type="checkbox"/> Omission</p> <p><input checked="" type="checkbox"/> Dose/quantity</p> <p><input type="checkbox"/> Patient identification</p> <p><input type="checkbox"/> Preparation</p> <p><input type="checkbox"/> Product</p> <p><input type="checkbox"/> Rate of administration _____</p> <p><input type="checkbox"/> Route of administration _____</p> <p><input type="checkbox"/> Time of administration _____</p> <p><input type="checkbox"/> Other _____</p>
--	--	---

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

This report is to include all Adverse Events and is not limited to the categories noted in this reporting tool. Categories labeled "other" have been included for this purpose.

**4. CORRECTIVE ACTION PLAN (CAP)**

- a) A CAP shall be filed for each Class A, B, and C adverse event not later than seven (7) 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 timelines of such strategies.

**Directions for use of form AE #2**

- i. Facility: Enter name, address of institution.
- 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. 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.
- viii. Time line for implementation: Identify the date that the components of the CAP are to be initiated.
- ix. Completion date for CAP: Identify the date that all components of the plan have been completed.
- x. 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.
- xi. 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: Adverse Event  
 410 Capital Avenue – MS#12HSR  
 P.O. Box 340308  
 Hartford, CT 06134-0308

## 5. CLASS D EVENTS

- a) All Class D adverse events shall be forwarded to the Department on a quarterly basis, on the form approved by the Department. Each event shall be accompanied by a corrective action plan. One corrective action plan may address multiple adverse events of a similar nature (e.g. medication administration).
- b) Class D adverse reporting quarters are as follows:
  - ✓ January, February, March
  - ✓ April, May, June
  - ✓ July, August, September
  - ✓ October, November, December
- c) Reports are to be submitted 10 working days following the closure of each quarter.

## 6. 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 means, 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.

# STATE OF CONNECTICUT

## DEPARTMENT OF PUBLIC HEALTH ADVERSE EVENT REPORTING FORM

### DEMOGRAPHIC DATA

#### FACILITY INFORMATION:

Type of Facility: <input type="checkbox"/> Children's Hospital <input type="checkbox"/> Chronic Disease Hospital <input type="checkbox"/> General Hospital	<input type="checkbox"/> Hospital for Mentally Ill Persons <input type="checkbox"/> Hospital for the Care of Hospice Patients <input type="checkbox"/> Maternity Hospital <input type="checkbox"/> Outpatient Surgical Facility
Facility Name and Address:	License Number:
	Sequential Report Number:
Reporter's Name:	
Contact Person: Name: <span style="float: right;">Telephone Number:</span>	

#### PATIENT INFORMATION:

Medical Record Number:	Age	Date of Admission:
Patient's Billing Number:	Sex <input type="checkbox"/> M  <input type="checkbox"/> F	Date and Time of Event:  Date: <span style="margin-left: 100px;">Time:</span>
Social Security Number:		Date and Time Event First Known:  Date: <span style="margin-left: 100px;">Time:</span>
Date of Patient Death (if applicable):		
Admission Diagnosis:		

DEPARTMENT OF PUBLIC HEALTH  
ADVERSE EVENT REPORTING FORM  
HOSPITAL & OUTPATIENT SURGICAL FACILITIES

Sequential Report Number \_\_\_\_\_

DEMOGRAPHICS – Hospitals Only

<input type="checkbox"/> In Patient <input type="checkbox"/> Hospital Based <input type="checkbox"/> Off Campus Satellite Site Name: _____  Address _____	<input type="checkbox"/> Out Patient <input type="checkbox"/> Hospital Based <input type="checkbox"/> Off Campus Satellite Site Name: _____  Address _____
<b>LOCATION OF OCCURENCE:</b> <input type="checkbox"/> Acute Intensive Care <input type="checkbox"/> Medical Intensive Care <input type="checkbox"/> Neonatal Intensive Care <input type="checkbox"/> Surgical Intensive Care Unit <input type="checkbox"/> Other _____  <input type="checkbox"/> Adult Medical <input type="checkbox"/> Adult Surgical <input type="checkbox"/> Ambulatory Surgical <input type="checkbox"/> Cardiac Cath Lab <input type="checkbox"/> Cardiac Care <input type="checkbox"/> Dialysis <input type="checkbox"/> Emergency Department <input type="checkbox"/> Neurological Services <input type="checkbox"/> Neurosurgical <input type="checkbox"/> Nursery	<input type="checkbox"/> Obstetrical /Gynecological <input type="checkbox"/> Oncology Care <input type="checkbox"/> Operating Room <input type="checkbox"/> Orthopedics <input type="checkbox"/> Outpatient Services - Specify Type _____ <input type="checkbox"/> Palliative Care <input type="checkbox"/> Pediatrics <input type="checkbox"/> Psychiatric <input type="checkbox"/> Diagnostic Services – Specify Type: _____ <input type="checkbox"/> Rehabilitative Services – Specify Type: _____ <input type="checkbox"/> Respiratory <input type="checkbox"/> Other _____

**NOTIFICATIONS:**

<b>MEDICAL EXAMINER NOTIFIED</b> Y <input type="checkbox"/> N <input type="checkbox"/>  <b>CASE NUMBER (if applicable)</b> _____	<b>AUTOPSY PERFORMED (if applicable)</b> Y <input type="checkbox"/> N <input type="checkbox"/> Unknown <input type="checkbox"/>  <b>LOCATION:</b> _____
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At the time of this report, were any other entities known to have been notified of this event?

Check all that apply: <input type="checkbox"/> Center for Medicare/Medicaid Services <input type="checkbox"/> Department of Children and Families <input type="checkbox"/> Food and Drug Administration <input type="checkbox"/> Joint Commission on the Accreditation of Health Care Organizations	<input type="checkbox"/> Local/State Police <input type="checkbox"/> Office of Protection and Advocacy for Persons with Disabilities <input type="checkbox"/> State Fire Marshal <input type="checkbox"/> Department of Social Services, Protective Services <input type="checkbox"/> Unknown to reporter at time of report
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DEPARTMENT OF PUBLIC HEALTH  
ADVERSE EVENT REPORTING FORM  
HOSPITAL & OUTPATIENT SURGICAL FACILITIES

Sequential Report Number \_\_\_\_\_

Following the adverse event:

1. Was the patient's anticipated stay extended?                      Y       N       Not Determined

2. Was the patient transferred to another health care facility      Y       N   
for treatment?

3. Was the hospitalized patient transferred to a more                      Y       N   
intensive level of care within the hospital?

Was the patient discharged prior to identification of the event?      Y       N

If yes, did the patient return for treatment?                      Y       N       Date : \_\_\_\_\_

**Facts of Event and Status of Patient Condition:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**FOR DPH USE ONLY**

Date Report Received- Verbal	
Date Report Received- Written	
Date Corrective Action Plan Received:	



DEPARTMENT OF PUBLIC HEALTH  
ADVERSE EVENT REPORTING FORM  
HOSPITAL & OUTPATIENT SURGICAL FACILITIES

Sequential Report Number \_\_\_\_\_

**CLASSIFICATION DATA**

An Adverse Event means an injury that was caused by or is associated with medical management and that results in death or measurable disability. Such events shall also include those sentinel events for which remediation plans are required by the Joint Commission on the Accreditation of Healthcare Organizations

Please check applicable class of event:

- Class A:** An event that has resulted in or is associated with a patient's death or the immediate danger of death
- Class B:** An event that has resulted in or is associated with a patient's serious injury or disability or the immediate danger of serious injury or disability
- Class C:** An event that has resulted in or is associated with the physical or sexual abuse of a patient. Class A, B, & C events require a verbal report to DPH no later than twenty-four (24) hours after the event occurred and a written report within seventy two (72) hours after its occurred.

- Class D:** An event that is not class A, B, or C. Class D events are reported on a quarterly basis only.  
Note: Verbal reports are not required for Class D Events

**MEDICAL/GENERAL EVENT**

Event associated with:

- Diagnosis
- Lack of treatment
- Hemorrhage (over 15% of circulating blood volume loss)
- Obstetrical event
- Restraints
- Seclusion
- Nosocomial Malnutrition
- Nosocomial Dehydration
- Nosocomial Infections
- Other \_\_\_\_\_

Organism  
\_\_\_\_\_

Location of Infection  
\_\_\_\_\_

Is this a surgical site:   Y                   N

Device/Equipment Event

Equipment Type:  
\_\_\_\_\_

Patient Implant Type:  
\_\_\_\_\_

- Internal
- External

Other \_\_\_\_\_

Alarm

- Malfunction
- Disconnected
- Not audible to staff
- Other \_\_\_\_\_

Infusion Pump

- Equipment malfunction
- Programming Error
- Component incompatibility
- Other \_\_\_\_\_

DEPARTMENT OF PUBLIC HEALTH  
ADVERSE EVENT REPORTING FORM  
HOSPITAL & OUTPATIENT SURGICAL FACILITIES

Sequential Report Number \_\_\_\_\_

MEDICAL/GENERAL EVENT

<p><b>Substance Administration Events</b></p> <p>Product</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Chemotherapeutic</li> <li><input type="checkbox"/> Dietary</li> <li><input type="checkbox"/> Electrolytes</li> <li><input type="checkbox"/> Fluids</li> <li><input type="checkbox"/> Medical Gases</li> <li><input type="checkbox"/> Medications</li> <li><input type="checkbox"/> Treatments</li> <li><input type="checkbox"/> Other _____</li> </ul> <p>Event Associated with:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Omission</li> <li><input type="checkbox"/> Dose/quantity</li> <li><input type="checkbox"/> Patient identification</li> <li><input type="checkbox"/> Preparation</li> <li><input type="checkbox"/> Product</li> <li><input type="checkbox"/> Rate of administration</li> <li><input type="checkbox"/> Route of administration _____</li> <li><input type="checkbox"/> Time of administration _____</li> <li><input type="checkbox"/> Other _____</li> </ul> <p>Adverse Drug/Biological Reaction</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Anaphylactic Shock</li> <li><input type="checkbox"/> Allergic response</li> <li><input type="checkbox"/> Other _____</li> </ul> <p>Poisoning</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Drug</li> <li><input type="checkbox"/> Food</li> <li><input type="checkbox"/> Chemicals</li> <li><input type="checkbox"/> Other _____</li> </ul>	<p><b>Physical Accidents</b></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Observed by staff</li> <li><input type="checkbox"/> Unobserved by staff</li> <li><input type="checkbox"/> Other _____</li> </ul> <p>Burn</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> 1<sup>st</sup> degree; _____% of body surface area</li> <li><input type="checkbox"/> 2<sup>nd</sup> degree; _____% of body surface area</li> <li><input type="checkbox"/> 3<sup>rd</sup> degree; _____% of body surface area</li> </ul> <ul style="list-style-type: none"> <li><input type="checkbox"/> Patient neglect (circumstance not documented under another category)</li> <li><input type="checkbox"/> Suicide while in the facility</li> <li><input type="checkbox"/> Attempted Suicide while in the facility</li> </ul> <p>Use of Substances/Products:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Contaminated/Infected</li> <li><input type="checkbox"/> Related to storage or maintenance</li> <li><input type="checkbox"/> Outdated</li> <li><input type="checkbox"/> Other _____</li> </ul> <p>Types:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Blood</li> <li><input type="checkbox"/> Biologic</li> <li><input type="checkbox"/> Drugs</li> <li><input type="checkbox"/> Device</li> <li><input type="checkbox"/> Fluids</li> <li><input type="checkbox"/> Gases</li> <li><input type="checkbox"/> Other _____</li> </ul> <ul style="list-style-type: none"> <li><input type="checkbox"/> Administration of ABO-incompatible blood or blood products</li> <li><input type="checkbox"/> Electric Shock</li> </ul>
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DEPARTMENT OF PUBLIC HEALTH  
ADVERSE EVENT REPORTING FORM  
HOSPITAL & OUTPATIENT SURGICAL FACILITIES

Sequential Report Number \_\_\_\_\_

**MEDICAL/GENERAL EVENT**

<p><b>Intra-Vascular Embolism</b></p> <p><input type="checkbox"/> Air</p> <p><input type="checkbox"/> Blood</p> <p><input type="checkbox"/> Fat</p> <p><input type="checkbox"/> Foreign body</p> <p><input type="checkbox"/> Other _____</p> <p><b>Decubitus Developed after admission:</b></p> <p><input type="checkbox"/> Stage II</p> <p><input type="checkbox"/> Stage III</p> <p><input type="checkbox"/> Stage IV</p> <p><b>Laboratory test event associated with</b></p> <p><input type="checkbox"/> Omission</p> <p><input type="checkbox"/> Results</p> <p><input type="checkbox"/> Patient identification</p> <p><input type="checkbox"/> Mislabeled specimen</p> <p><input type="checkbox"/> Other _____</p> <p><input type="checkbox"/> Elopement</p>	<p><b>Patient Abuse</b></p> <p><input type="checkbox"/> Sexual molestation</p> <p><input type="checkbox"/> Rape</p> <p><input type="checkbox"/> Physical Assault</p> <p><input type="checkbox"/> Sexual relations involving two patients one of which is 15 years old or younger</p> <p><input type="checkbox"/> Other _____</p> <p><input type="checkbox"/> Abduction of a patient of any age</p> <p><input type="checkbox"/> Discharge of an infant to the wrong guardian/parent</p> <p><input type="checkbox"/> Infant given to wrong guardian/parent within hospital</p> <p><input type="checkbox"/> Other: _____</p>
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**SURGICAL/ANESTHESIA EVENT**

<p><b>Identify procedure that was performed (e.g. appendectomy):</b></p> <p>_____</p> <p><b>Length of time in Surgery</b></p> <p>_____ hours _____ minutes</p> <p><b>Surgical procedure associated with</b></p> <p><input type="checkbox"/> Patient identification</p> <p><input type="checkbox"/> Site on a patient</p> <p><input type="checkbox"/> Surgical procedure</p> <p><input type="checkbox"/> Unexpected retention of a foreign object in a patient post closure</p> <p><input type="checkbox"/> Implantation of wrong device</p> <p><input type="checkbox"/> Other _____</p>	<p><b>Open Surgical Procedures</b></p> <p><input type="checkbox"/> Perforation</p> <p><input type="checkbox"/> Trauma</p> <p><input type="checkbox"/> Hemorrhage (over 15% of circulating blood volume loss)</p> <p><input type="checkbox"/> Dehiscence</p> <p><input type="checkbox"/> Laceration</p> <p><input type="checkbox"/> Other _____</p> <p><b>Anesthesia procedure</b></p> <p><input type="checkbox"/> Endotracheal tube placement</p> <p><input type="checkbox"/> Airway obstruction</p> <p><input type="checkbox"/> Aspiration</p> <p><input type="checkbox"/> Other _____</p>
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DEPARTMENT OF PUBLIC HEALTH  
ADVERSE EVENT REPORTING FORM  
HOSPITAL & OUTPATIENT SURGICAL FACILITIES

Sequential Report Number \_\_\_\_\_

SURGICAL/ANESTHESIA EVENT

<p><input type="checkbox"/> Cardiac or respiratory arrest - Patient requiring resuscitation during a procedure or within 24 hours of a procedure</p> <p>Resuscitation Procedures</p> <p><input type="checkbox"/> Fractures</p> <p><input type="checkbox"/> Burns</p> <p><input type="checkbox"/> Trauma/Injury</p> <p><input type="checkbox"/> Other _____</p> <p>Endoscopic Procedures</p> <p><input type="checkbox"/> Perforation</p> <p><input type="checkbox"/> Trauma</p> <p><input type="checkbox"/> Hemorrhage (over 15% of circulating blood volume loss)</p> <p><input type="checkbox"/> Unplanned conversion to an open procedure</p> <p><input type="checkbox"/> Other _____</p> <p>Biopsy Procedures</p> <p><input type="checkbox"/> Perforation</p> <p><input type="checkbox"/> Trauma</p> <p><input type="checkbox"/> Hemorrhage (over 15% of circulating blood volume loss)</p> <p><input type="checkbox"/> Other _____</p>	<p>Type of Anesthesia</p> <p><input type="checkbox"/> General</p> <p><input type="checkbox"/> Spinal</p> <p><input type="checkbox"/> Regional</p> <p><input type="checkbox"/> Local</p> <p><input type="checkbox"/> Sedation</p> <p><input type="checkbox"/> Other _____</p> <p>Anesthesia Event Associated with:</p> <p><input type="checkbox"/> Dose</p> <p><input type="checkbox"/> Preparation</p> <p><input type="checkbox"/> Product</p> <p><input type="checkbox"/> Rate</p> <p><input type="checkbox"/> Route of administration</p> <p><input type="checkbox"/> Patient identification</p> <p><input type="checkbox"/> Other _____</p> <p><input type="checkbox"/> Other _____</p>
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**APPENDIX C**  
**Corrective Action Plans**

**STATE OF CONNECTICUT**

DEPARTMENT OF PUBLIC HEALTH  
 Hospital and Outpatient Surgical Facility  
**Corrective Action Plan (CAP)**  
**Adverse Event**

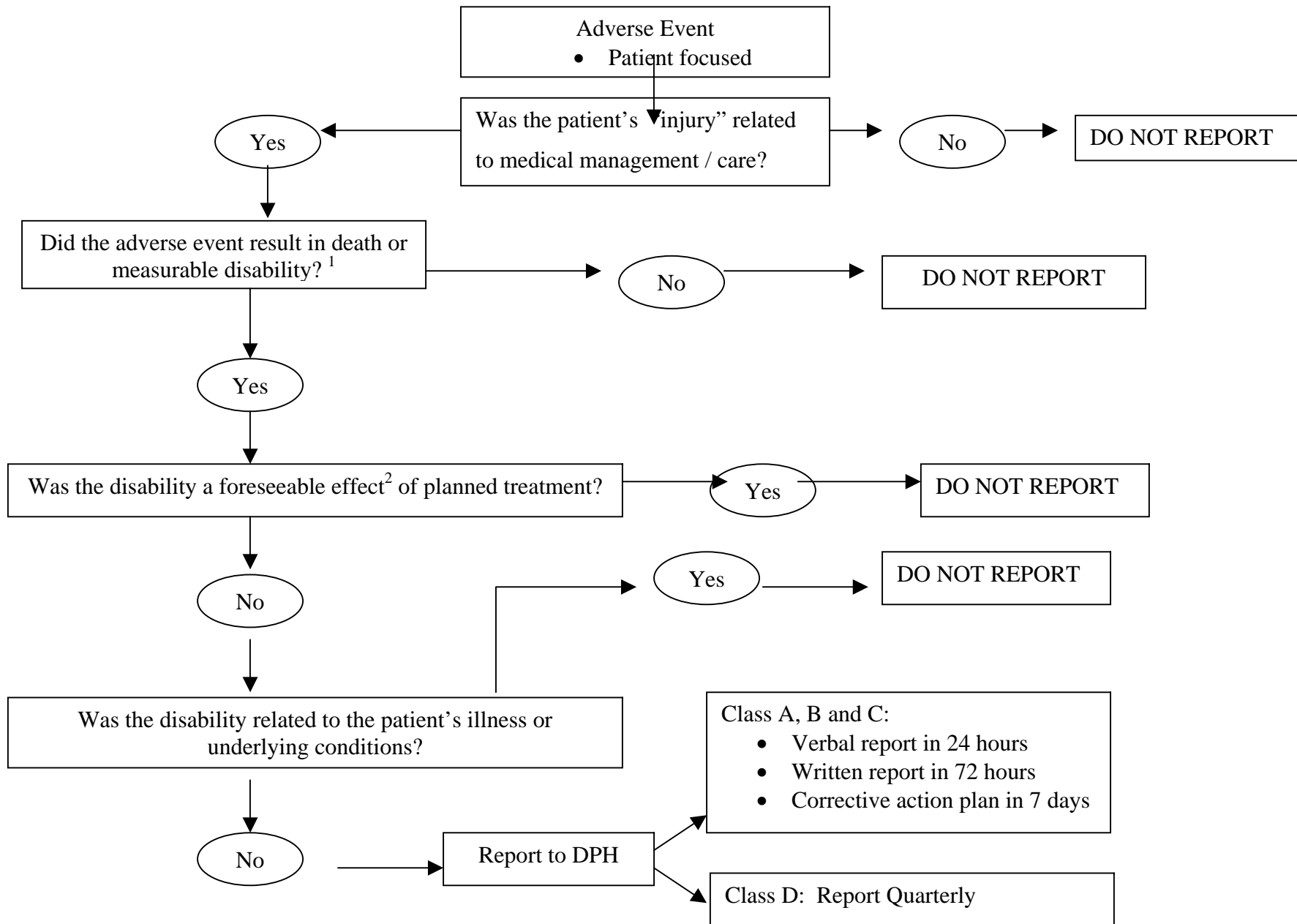
Facility:	Sequential Report Number for which this plan is being submitted:
	Date of Event
Patient Billing Number:	Date CAP Submitted
Events being addressed:	
Corrective Action Plan to prevent reoccurrence:	
Attach additional information if necessary	
Time line for implementation:	Completion date for CAP:
Identification of staff member, by title, who has been designated the responsibility for monitoring CAP implementation:	
Submitted by:	Date:

# STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH  
Hospital and Outpatient Surgical Facility  
**Corrective Action Plan (CAP)**  
**Class "D" Adverse Events**

Facility:	Sequential Report Number(s) for which this plan is being submitted:
Quarter _____ Year _____	
Date CAP Submitted	
Events being addressed:	
Corrective Action Plan to prevent reoccurrence:	
Attach additional information if necessary	
Time line for implementation:	Completion date for CAP:
Identification of staff member, by title, who has been designated the responsibility for monitoring CAP implementation:	
Submitted by:	Date:

**APPENDIX D  
Decision Making Model Chart**



<sup>1</sup> Disability means any weakening, impairment or destruction of a patient's physical, mental or cognitive status (may be brief or lengthy)

<sup>2</sup> Foreseeable effect means an expected or anticipated outcome due to an individual patient's clinical presentation and/or underlying condition(s).

## APPENDIX E

### Subcommittee Recommendations

#### *Subcommittee Recommendations*

As a result of the subcommittees January 29<sup>th</sup>, 2003 meeting the following recommendations are being presented regarding Adverse Events Reporting, for consideration by the Quality in Health Care Advisory Committee:

- Timelines of reporting law are too short:
  - Suggestion (would require change in the statute): "emergent" report should be immediate, otherwise verbal report in 48 - 72 hours or eliminate non-emergent verbal reports entirely; written report in 5 - 7 days; CAP - need more time for a complete plan.
- Need to clarify some definitions, e.g. disability, foreseeable, immediate danger, serious disability, measurable disability;
  - This may help differentiate Class B and D.
- Redefine "disability" as "any destruction, or significant weakening or impairment...."
- Develop a noncomprehensive list of examples of reportable and nonreportable events.
- Protect confidentiality of reports indefinitely (would require change in statute);
  - Attorney General's advice has been sought regarding portions of reports that may/should be redacted before release under current law. All patient identifiers will be removed and facility identifiers should be removed as well.
- All aggregate data reports should be shared with hospitals in a timely fashion, to support internal quality improvement efforts.
- When sufficient data has been collected, it should be sorted by individual data elements and/or categories, so statewide quality improvement efforts can be focused and resource - efficient.
- Utilize a proactive, preventive data analysis model to review processes of care.
- Hospitals should have a mechanism for sharing "near-miss" information which is separate from the Adverse Event Reporting System and is non-punitive, anonymous and not part of regulatory oversight. Any information shared among hospitals for patient safety and quality improvement purposes should receive protection from disclosure equivalent to the protection given to peer review information, even if the information does not fit precisely within the current requirements for peer review protection. This type of protection is reflected in recent federal legislation which proposed protecting information shared with "Patient Safety Organizations" who work with hospitals to improve patient safety and quality.
- Any "report card" developed should focus on implementation of best practices, rather than occurrence of adverse events.
- After reappraisal of the current reporting system, move to an aggregate or line-list reporting of "D" level events.



**APPENDIX F**  
**Draft 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**

**SECTION \_\_\_\_\_**

The Regulations of Connecticut State Agencies are amended by adding section 19a-XXX-1 as follows:

(NEW) Section 19a-XXX-1. Definitions. As used in section 19a-XXX-1 to section 19a-XXX-X-2, inclusive of the Regulations of the Connecticut State Agencies:

- (1) “Adverse Event” means an injury that was caused by or is associated with medical management and that results in death or measurable disability. Such events include sentinel events for which remediation plans are required by the Joint Commission on the Accreditation of Healthcare Organizations;
- (2) “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;
- (3) “Disabilities” means any weakening, impairment or destruction of a patient’s physical, mental or cognitive status which was not a foreseeable effect of the patient’s planned treatment regime or was not related to the natural course of the patient’s illness or underlying condition;
- (4) “Foreseeable effect” means an expected or anticipated outcome due to an individual patient’s clinical presentation or underlying condition;
- (5) “Healthcare provider or staff person” means, 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;
- (6) “Immediate Danger” means an adverse event has the potential to directly and in the near future, place a patient at risk for death or serious injury or disability;
- (7) “Medical Management” means to assess, direct, provide, control, or supervise the care and services provided to a patient, either directly or indirectly;
- (8) “Commissioner” means the Commissioner of Public Health;
- (9) “Department” means the department of public health;
- (10) “Health Care Facility” means any hospital or outpatient surgical facility licensed pursuant to section 19a-490 of the Connecticut General Statutes;

- (11) “Class A adverse event” means an event that has resulted in or is associated with a patient’s death or immediate danger of death;
- (12) “Class B adverse event” means an event that has resulted in or is associated with a patient’s serious injury or disability or the immediate danger of serious injury or disability;
- (13) “Class C adverse event” means an event that has resulted in or is associated with the physical or sexual abuse of a patient; and
- (14) “Class D adverse event” means an adverse event that is not reported as a class A, B or C adverse event.

(NEW) Section 19a-XXX-2. Procedures for adverse event reporting.

- (a) Adverse events and corrective action plans shall be documented and submitted in the format prescribed by the Commissioner.
- (b) All documentation of adverse events shall be maintained for not less than five (5) years and shall be made accessible to the department upon request.
- (c) Class A, B, and C adverse events shall be reported by a health care facility to the department as follows:
  - (1) A verbal report shall be made not later than twenty-four (24) hours after the adverse event has occurred or immediately if the event is discovered more than twenty-four (24) hours after its occurrence;
  - (2) A written report shall be made not later than seventy-two hours after the adverse event occurred;
  - (3) A corrective action plan shall be filed not later than seven days after the adverse event occurred.
- (d) Class D adverse events shall be reported by a health care facility to the department as follows:
  - (1) Written reports shall be submitted quarterly by the tenth (10<sup>th</sup>) working day in the months of January, April, July and October;
  - (2) Such reports shall include corrective action plans. One corrective action plan may address multiple class D adverse events of a similar nature.
- (e) Each facility shall have a mechanism in place to provide the department with the patient’s name, physician’s name, including the attending physician of record and the name of any other healthcare provider or staff member involved in or with first-hand knowledge of each event. This information shall be available to department representatives twenty-four (24) hours a day, seven (7) days a week.
- (f) Numbering. Each report shall be identified on each page with a number as follows:
  - (1) the number appearing on the facility license; and
  - (2) the last two digits of the year and the sequential number of the report during each calendar year.
- (g) Subsequent reports. Subsequent reports relevant to any adverse event shall be submitted as often as is necessary to inform the department of significant changes in the status of affected individuals or changes in material facts originally reported. Such reports shall be attached to a photocopy of the original adverse event report.

**Statement of Purpose:** To enact Section 3 (e) of Public Act 02-125 which requires the Commissioner to codify an adverse event reporting form and system in regulations.

## **APPENDIX G**

### **References**

Kohn LT, Corrigan JM, Donaldson MS. 2000. *To Err is Human: Building a Safer Health System*. Institute of Medicine.

Bower, Carol. 2002. *Mandatory Reporting of Adverse Events at Acute Care Hospitals: Programs of Other States, and Their Lessons for Connecticut*. Office of Health Care Quality, Connecticut Department of Public Health.

National Academy of State Health Policy. 2002. *State Mandatory Reporting Rules and Statutes*.