



Senate

General Assembly

File No. 457

February Session, 2004

Substitute Senate Bill No. 566

Senate, April 5, 2004

The Committee on Public Health reported through SEN. MURPHY of the 16th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING THE QUALITY OF HEALTH CARE.

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

1 Section 1. Section 19a-127n of the general statutes, as amended by
2 section 123 of public act 03-278, is repealed and the following is
3 substituted in lieu thereof (*Effective July 1, 2004*):

4 (a) (1) For purposes of this section, an "adverse event" means [an
5 injury that was caused by or is associated with medical management
6 and that results in death or measurable disability. Such events shall
7 also include those sentinel events for which remediation plans are
8 required by the Joint Commission on the Accreditation of Healthcare
9 Organizations] any event that is identified on the National Quality
10 Forum's List of Serious Reportable Events or on a list compiled by the
11 Commissioner of Public Health and adopted as regulations pursuant
12 to subsection (d) of this section; and "corrective action plan" means a
13 plan that implements strategies that reduce the risk of similar adverse
14 events occurring in the future, and measures the effectiveness of such

15 strategies by addressing the implementation, oversight and time lines
16 of such strategies.

17 (2) The commissioner shall review the list of adverse events
18 periodically, but not less than annually, to ascertain whether any
19 additions, deletions or modifications to the list are necessary.

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

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

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

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

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

30 [(c)] (b) On and after October 1, 2002, a hospital or outpatient
31 surgical facility shall report adverse events to the Department of Public
32 Health [on Class A, B and C adverse events] as follows: (1) [A verbal
33 report shall be made not later than twenty-four hours after the adverse
34 event occurred; (2) a] A written report shall be submitted not later than
35 [seventy-two hours] seven days after the adverse event occurred; and
36 [(3)] (2) a corrective action plan shall be filed not later than seven days
37 after the adverse event occurred. Emergent reports, as defined in the
38 regulations adopted pursuant to subsection (c) of this section, shall be
39 made to the department immediately. Failure to implement a
40 corrective action plan may result in disciplinary action by the
41 Commissioner of Public Health, pursuant to section 19a-494.

42 [(d) A hospital or outpatient surgical facility shall report to the
43 Department of Public Health on Class D adverse events on a quarterly
44 basis. Such reports shall include corrective action plans. For purposes

45 of this subsection and subsection (c) of this section, "corrective action
46 plan" means a plan that implements strategies that reduce the risk of
47 similar events occurring in the future. Said plan shall measure the
48 effectiveness of such strategies by addressing the implementation,
49 oversight and time lines of such strategies. Failure to implement a
50 corrective action plan may result in disciplinary action by the
51 Commissioner of Public Health, pursuant to section 19a-494.]

52 [(e)] (c) The Commissioner of Public Health shall adopt regulations,
53 in accordance with chapter 54, to carry out the provisions of this
54 section. Such regulations shall include, but shall not be limited to, a list
55 of adverse events that are in addition to those contained in the
56 National Quality Forum's List of Serious Reportable Events and a
57 prescribed form for the reporting of adverse events pursuant to
58 [subsections (c) and (d)] subsection (b) of this section. The
59 commissioner may require the use of said form prior to the adoption of
60 said regulations.

61 [(f)] (d) On or before [March] October first annually, the
62 commissioner shall report, in accordance with the provisions of section
63 11-4a, on adverse event reporting, to the joint standing committee of
64 the General Assembly having cognizance of matters relating to public
65 health.

66 [(g)] (e) Information collected pursuant to this section shall not be
67 [required to be] disclosed pursuant to subsection (a) of section 1-210, as
68 amended, [for a period of six months from the date of submission of
69 the written report required pursuant to subsection (c) of this section
70 and] at any time, and information collected pursuant to this section
71 shall not be subject to subpoena or discovery or introduced into
72 evidence in any judicial or administrative proceeding except as
73 otherwise specifically provided by law. Nothing in this section shall be
74 construed to limit access to or disclosure of investigative files,
75 including any adverse event report contained in such files, maintained
76 by the department as otherwise provided in section 19a-499.

77 (f) If the department determines that it will initiate an investigation

78 of an adverse event that has been reported, such investigation may
79 include review by one or more practitioners with clinical expertise of
80 the type involved in the reported adverse event.

81 [(h)] (g) The Quality of Care Advisory Committee established
82 pursuant to section 19a-127l shall establish methods for informing the
83 public regarding access to the department's consumer and regulatory
84 services.

85 Sec. 2. (NEW) (*Effective July 1, 2004*) (a) For purposes of this section:

86 (1) "Patient safety organization" means any public or private
87 organization, or component of any such organization, whose primary
88 activity is to improve patient safety and the quality of health care
89 delivery for patients receiving care through the collection, aggregation,
90 analysis or processing of medical or health care-related information
91 submitted to it by health care providers; and

92 (2) "Patient safety work product" means any information,
93 documentation or communication, including, but not limited to,
94 reports, records, memoranda, analyses, statements, root cause
95 analyses, protocols or policies that (A) a health care provider or health
96 care institution prepares exclusively for the purpose of disclosing to a
97 patient safety organization, (B) is created by a patient safety
98 organization, or (C) contains the deliberations or analytical process of a
99 patient safety organization or between a patient safety organization
100 and health care providers participating in the evaluation of patient
101 care.

102 (b) (1) Any private or public organization or a component of any
103 private or public organization may apply to the Department of Public
104 Health to be designated as a patient safety organization.

105 (2) The department may designate as a patient safety organization
106 each applicant that (A) has a mission statement indicating its primary
107 purpose is to conduct activities to improve patient safety, (B) has
108 qualified staff and professionals capable of reviewing and producing

109 patient safety work product, (C) is not a component of a health insurer
110 or other entity that provides health insurance to individuals or group
111 health plans, and (D) certifies that its mission does not create a conflict
112 of interest with the health care providers who will submit patient
113 safety work product to it. Each hospital or outpatient surgical facility
114 shall seek to work with one or more patient safety organizations as
115 they become available. The department shall assist hospitals and
116 outpatient surgical facilities in developing working relationships with
117 patient safety organizations.

118 (c) A health care provider or institution shall enter into a written
119 contract with each patient safety organization to which it sends patient
120 safety work product. Each contract shall require the provider or
121 institution to maintain a document log itemizing the types of
122 documents submitted to patient safety organizations without
123 indicating the content of such documents. Such document log shall be
124 accessible to the department for the sole purpose of allowing the
125 department to verify the type of information submitted to patient
126 safety organizations. The department shall not have access to patient
127 safety work product. Notwithstanding the provisions of sections 1-210,
128 as amended, 1-211 and 1-213 of the general statutes, such document
129 log shall not be subject to disclosure to, or use by, any person or entity,
130 other than the patient safety organization and the provider or
131 institution with which it has contracted, and by the department for the
132 purposes provided in this subsection.

133 (d) A patient safety organization shall, as appropriate, disseminate
134 to health care providers, the department, the Quality of Care Advisory
135 Committee, as established by 19a-127l of the general statutes, and the
136 public, information or recommendations, including suggested
137 policies, procedures or protocols, on best medical practices or
138 potential system changes designed to improve patient safety and
139 the overall quality of care.

140 (e) A patient safety organization shall have in place appropriate
141 safeguards and security measures to ensure the technical integrity and

142 physical safety of any patient safety work product. Patient safety
 143 work product shall be confidential, and shall not be subject to any
 144 discovery, access or use by any person or entity other than the patient
 145 safety organization and the provider or institution with which the
 146 patient safety organization has contracted. Patient safety work
 147 product, if submitted to a public or governmental organization, shall
 148 not be subject to the provisions of section 1-210, as amended, 1-211 or
 149 1-213 of the general statutes. Nothing in this subsection shall prohibit a
 150 patient safety organization from choosing to disclose patient safety
 151 work product, or portions of patient safety work product, in
 152 conformity with its mission and within its contractual obligations to
 153 the provider submitting the information. No patient safety
 154 organization may release protected health information or patient
 155 identifying information without meeting the requirements of state
 156 laws and the federal Health Insurance Portability and Accountability
 157 Act of 1996, as amended from time to time.

158 (f) A provider's disclosure of patient safety work product to a
 159 patient safety organization shall not modify, limit or waive any
 160 existing privilege or confidentiality protection.

This act shall take effect as follows:	
Section 1	<i>July 1, 2004</i>
Sec. 2	<i>July 1, 2004</i>

Statement of Legislative Commissioners:

Subsection (a) of section 1 was split into two subdivisions so substantive provision is not within definition. Subsection (c) of section 1 was rearranged for clarity, placing the definition of "corrective action plan" in subsection (a) and placing the sentence regarding failure to implement a corrective action plan at the end of the new subsection (b).

PH *Joint Favorable Subst.*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 05 \$	FY 06 \$
UConn Health Ctr.	Various - Cost	Potential	Potential
Public Health, Dept.	GF - Cost	None	None

Note: GF=General Fund

Municipal Impact: None

Explanation

It is anticipated that the Department of Public Health will be able to revise its regulations concerning the listing of adverse events without requiring additional resources.

Authorizing the department to utilize practitioners with relevant clinical expertise in investigations prompted by the reporting of an adverse event will result in no fiscal impact. The DPH currently has the authority to retain individuals in this capacity. Any reimbursement for their participation in cases which progress to an administrative hearing would be expected to be accommodated within the anticipated budgetary resources of the agency.

The DPH can designate patient safety organizations as required in Section 2 without requiring additional resources. It is anticipated that the number of entities seeking this designation will be few.

However, the bill specifies that hospitals shall seek to work with the patient safety organization(s). It is not clear how these new entities will derive their funding. Should the John Dempsey Hospital at the University of Connecticut Health Center (UCHC) enter into a contract with a patient safety organization that requires it to pay fees, an indeterminate cost will result for the Health Center.

Further, it is likely that the UCHC will incur additional administrative costs related to compilation and maintenance of the document log and the patient safety work product required for the patient safety organization. Any such costs are expected to be minimal.

Dempsey Hospital may experience a workload decrease to the extent that it would no longer have to provide certain verbal reports of adverse events to DPH nor would it have to submit quarterly reports on Class D adverse events.

OLR Bill Analysis

sSB 566

AN ACT CONCERNING THE QUALITY OF HEALTH CARE**SUMMARY:**

This bill revises the law requiring hospitals and outpatient surgical facilities to report adverse events to the Department of Public Health (DPH). Specifically, it:

1. replaces an existing adverse event classification reporting system with a list of reportable events identified by the National Quality Forum (NQF), or by DPH;
2. changes the time by which adverse events must be reported to DPH and requires immediate reports of events DPH defines as emergent;
3. restricts disclosure of adverse events reports; and
4. allows DPH to use practitioners with clinical expertise of the type involved in an adverse event in its investigation.

The bill also allows DPH to designate as a "patient safety organization," a public or private organization whose primary mission involves patient safety improvement activities. An organization must apply to DPH for such designation. An organization must be engaged in "patient work safety product," which means information, documentation, or communication, such as reports, records, analyses, protocols, or policies that (1) it creates, (2) contains its deliberations or analyses or those between the organization and health care providers involved in evaluating patient care, or (3) a health care provider prepares exclusively for disclosure to the organization.

The bill requires hospitals and outpatient surgical facilities to seek to work and contract with such organizations as they become available. These organizations must provide providers and others, as appropriate, with information on best practices. And they must have appropriate safeguards and safety measures in place to protect the patient safety work product.

EFFECTIVE DATE: July 1, 2004

ADVERSE EVENT REPORTING

Definition of Adverse Event; National Quality Forum List

By law, hospitals and outpatient surgical facilities must report adverse events to DPH. An “adverse event” is an injury caused by or associated with medical management that results in death or measurable disability. Under current law, it includes those sentinel events for which remediation plans are required by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). A “sentinel event” is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. The law creates four categories of adverse events (Class A: patient death or immediate danger of death, Class B: patient seriously injured or disabled, Class C: patient physical or sexual abuse, and Class D: adverse event not reported under A through C).

The bill eliminates the Class A through D adverse event reporting and substitutes reporting any event identified on the National Quality Forum’s List of Serious Reportable Events or on a list compiled by the DPH commissioner and adopted in regulations (see BACKGROUND). The bill requires the commissioner to review the list at least annually, to determine if any changes are necessary. NQF is a not-for-profit membership organization created to develop and implement a national strategy for health care quality management and reporting.

Adverse Event Reporting

Current law requires hospitals and outpatient surgical facilities to report Class A, B and C adverse events to DPH as follows: (1) a verbal report within 24 hours of the event, (2) a written report within 72 hours, and (3) a corrective action plan within seven days. They must report Class D adverse events quarterly and include corrective action plans.

The bill instead requires facilities to submit a written report to DPH on an adverse event, as identified on the NQF list or the DPH list, within seven days after the event occurs. A corrective action plan must also be filed with DPH within the same seven days. Under the bill, emergent reports, to be defined in DPH regulations, must be reported

immediately to DPH.

Reporting and Information Disclosure

The bill requires DPH to report annually to the Public Health Committee by October 1, instead of March 1, on adverse events reported to it. Under current law, information collected on adverse events does not have to be disclosed for a six-month period from the date the required report is submitted (72 hours after the event). This bill instead specifies that the information does not have to be disclosed at any time and as under existing law, is not subject to subpoena, discovery, or introduction into evidence in any judicial or administrative proceeding except as specifically provided by law.

The bill also specifies that it should not be construed as limiting access to or disclosure of investigative files maintained by DPH, including adverse event reports. Existing law provides that information DPH receives through filed reports must not be disclosed publicly in a way that identifies any patient or institution, except in limited circumstances. By law, all records DPH obtains in connection with any investigation must not be disclosed to the public for six months from the date of the petition or other event initiating the investigation, or until the investigation is terminated pursuant to a withdrawal or other informal disposition or until a hearing is convened, whichever is earlier.

The bill allows DPH, if it determines that it will investigate a reported adverse event, to include review by one or more practitioners with clinical expertise of the type involved in the event.

PATIENT SAFETY ORGANIZATIONS

Definitions

The bill defines a “patient safety organization” as any public or private organization, or part of one, whose primary activity is improving patient safety and quality of health care delivery for patients. The organization must do this through the collection, aggregation, analysis, or processing of medical or health care-related information it receives from health care providers.

The bill defines “patient work safety product” as any information,

documentation, or communication, including reports, records, memoranda, analyses, statements, root cause analyses, protocols, or policies that (1) a health care provider or institution prepares exclusively for the purpose of disclosure to a patient safety organization, (2) is created by a patient safety organization, or (3) contains the deliberations or analytical process of a patient safety organization or between an organization and health care providers participating in evaluating patient care.

DPH Designation as Patient Safety Organization

The bill allows any public or private organization or part thereof, to apply to DPH for designation as a patient safety organization. It authorizes DPH to designate as a patient safety organization an applicant that (1) has a mission statement indicating that its primary purpose concerns patient safety improvement activities, (2) has qualified staff capable of reviewing and producing patient work safety product, (3) is not part of a health insurer or other entity providing health insurance to groups or individuals, and (4) certifies that its mission does not create a conflict of interest with the health care providers who will submit patient safety work product to it.

The bill requires each hospital or outpatient surgical facility to try to work with one or more patient safety organizations as they become available. DPH must assist these facilities in developing such working relationships.

Contracts with Patient Safety Organizations

The bill requires health care providers and institutions to enter into written contracts with each patient safety organization to which it sends patient safety work product. Each contract must require the provider or institution to keep a log that itemizes the types of documents it submits to the patient safety organizations without indicating their content. This log must be available to DPH solely to allow it to verify the type of information submitted to patient safety organizations. DPH does not have access to patient safety work product under the bill. The document log cannot be disclosed to or used by any person or entity other than (1) the patient safety organization and the provider or institution with which it has contracted and (2) DPH, for purposes listed above.

Best Practices

The bill requires a patient safety organization, as appropriate, to give to providers, DPH, the Quality of Care Advisory Committee and the public information or recommendations on best medical practices or potential system changes designed to improve patient safety and overall quality of care. This can include suggested policies, procedures, or protocols.

Security Measures and Safeguards; Disclosure of Information

The bill requires a patient safety organization to have appropriate safeguards and safety measures to ensure the technical integrity and physical safety of any patient safety work product. Such work product must be confidential and not subject to any discovery, access or use by any person or entity other than the patient safety organization and the provider or institution with which it has contracted. Patient safety work product submitted to a public or governmental organization is not public information.

The bill specifies that it does not prohibit a patient safety organization from choosing to disclose patient safety work product, in conformity with its mission and within contractual obligations to the provider submitting the information. The bill prohibits a patient safety organization from releasing protected health information or patient identifying information unless requirements of state law and the federal Health Insurance Portability and Accountability Act are met.

Finally, the bill specifies that a provider's disclosure of patient safety work product to a patient safety organization does not modify, limit or waive any existing privilege or confidentiality protection.

BACKGROUND***NQF's List of Reportable Events in Healthcare***

In March 2002, NQF released a report, *Serious Reportable Events in Healthcare: A National Quality Forum Consensus Report*, designed to form the basis for a national, state-based adverse events reporting system. The report identifies 27 adverse events in six major categories: (1) surgical events, (2) product or device events, (3) patient protection events, (4) care management events, (5) environmental events, and (6) criminal events.

Table 1 presents the list of serious reportable events.

Table 1: NQF's List of Serious Reportable Events

<i>Event</i>	<i>Additional Specifications</i>
1. SURGICAL EVENTS	Defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient.
A. Surgery performed on the wrong body part	Excludes emergent situations that arise in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.
B. Surgery performed on the wrong patient	Defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. Surgery includes endoscopies and other invasive procedures.
C. Wrong surgical procedure performed on a patient	Defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excludes emergent situations that arise in the course of surgery and/or whose exigency precludes obtaining informed consent. Surgery includes endoscopies and other invasive procedures.
D. Retention of a foreign object in a patient after surgery or other procedure	Excludes objects intentional implanted as part of a planned intervention and objects present prior to surgery that were intentionally retained.
E. Intraoperative or immediately post-operative death in an American Society of Anesthesiologists (ASA) Class I patient	Includes all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. "Immediately post-operative" means within 24 hours after induction of anesthesia (if surgery not completed), surgery, or other invasive procedure was completed.
2. PRODUCT OR DEVICE EVENTS	Includes generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination and/or product.
A. Patient death or serious disability associated with the use of contaminated	

drugs, devices, or biologics provided by the healthcare facility	
B. Patient death or serious disability associated with the use of function of a device in patient care in which the device is used or functions other than as intended	Includes, but is not limited to, catheters, drains, and other specialized tubes, infusion pumps, and ventilators.
C. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility	Excludes deaths associated with neurosurgical procedures known to present a high risk of intravascular air embolism.
3. PATIENT PROTECTION EVENTS	
A. Infant discharged to the wrong person	
B. Patient death or serious disability associated with patient elopement (disappearance) for more than four hours	Excludes events involving competent adults.
C. Patient suicide, or attempted suicide resulting in serious disability, while being cared for in a healthcare facility	Defined as events that result from patient actions after admission to a healthcare facility. Excludes deaths resulting from self-inflicted injuries that were the reason for admission to the healthcare facility.
4. CARE MANAGEMENT EVENTS	
A. Patient death or serious disability associated with a medication error (<i>e.g.</i> , errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration)	Excludes reasonable differences in clinical judgment on drug selection and dose.
B. Patient death or serious disability associated with a hemolytic reaction due to the administration of incompatible blood or blood products	
C. Maternal death or serious disability with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility	Includes events that occur within 42 days after delivery. Excludes deaths from pulmonary or amniotic fluid embolism, acute fatty liver of pregnancy, or cardiomyopathy.
D. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility	
E. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates	Hyperbilirubinemia is defined as a bilirubin level >30mg/dl. "Neonates" refers to the first 28 days of life.
F. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility	Exclude progression from Stage 2 to Stage 3 if Stage 2 was recognized upon admission.
G. Patient death or serious disability due to	

spinal manipulative therapy	
5. ENVIRONMENTAL EVENTS	Excludes events involving planned treatments such as electric countershock.
A. Patient death or serious disability associated with an electric shock while being cared for in a healthcare facility	
B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances	
C. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility	
D. Patient death associated with a fall while being cared for in a healthcare facility	
E. Patient death or serious disability associated with the use of restraints or bedrails while being cared for in a healthcare facility	
6. CRIMINAL EVENTS	
A. Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider	
B. Abduction of a patient of any age	
C. Sexual assault on a patient within or on the grounds of a healthcare facility	
D. Death or significant injury of a patient or staff member resulting from a physical assault (<i>i.e.</i> , battery) that occurs within or on the grounds of a healthcare facility	

Quality of Care Advisory Committee

This committee, established by PA 02-125, the act that also established the adverse events reporting provisions, advises DPH on quality of care issues. The 24-member committee must meet at least quarterly and is chaired by the DPH commissioner, or his designee. The Department of Social Services commissioner and Office of Policy and Management secretary are also members. Other members represent health care providers and institutions, professional organizations, the business community, organized labor, health plans, and others involved in quality of care issues.

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute
Yea 22 Nay 0