



**TESTIMONY
OF
CONNECTICUT HOSPITAL ASSOCIATION
JUDICIARY COMMITTEE
Friday, April 11, 2003**

SB 1164, An Act Concerning Quality Health Care For Connecticut Citizens

The Connecticut Hospital Association (CHA) appreciates the opportunity to submit testimony on **SB 1164, An Act Concerning Quality Health Care For Connecticut Citizens**. SB 1164 would expand the definition of “adverse event” and would require physicians, in addition to hospitals and outpatient surgical facilities, to report adverse events to the Department of Public Health (DPH).

CHA is concerned about the effect that SB 1164 will have on hospitals and outpatient surgical facilities that are complying in good faith with the adverse event reporting law. The adverse event reporting requirements have been in effect for only six months, and there are still many unresolved implementation issues that are being addressed. By expanding the definition of “adverse event” and imposing independent reporting obligations on physicians before the issues with the existing system have been resolved, SB 1164 is likely to create more confusion and impede the goal of obtaining reliable data that can be used to improve patient safety.

Should the Committee decide to move forward with a bill revising the adverse event reporting system, we respectfully suggest that the bill incorporate the recommendations of the Adverse Event Reporting Working Group of the DPH Quality in Healthcare Advisory Committee. The recommendations, which include modifications to the reporting timelines and additional opportunities for hospitals to share data, are designed to refine the adverse event reporting system to ensure that it achieves its goal of improving patient safety in Connecticut. A copy of the recommendations is attached.

CHA also is concerned about Section 2 of SB 1164, which states that healthcare providers must warn individuals of the risks and possible side effects of the smallpox vaccine before administering the vaccine, and would allow any person who did not receive the warning to sue the healthcare provider for damages. This section is unnecessary. The federal Centers for Disease Control (CDC) is overseeing the smallpox vaccination program and has a standardized consent process, including mandatory screening and consent forms, and a video that explains the risks and possible side effects to vaccination candidates. Healthcare providers administering smallpox vaccines must follow the CDC screening and consent protocols, which involve clear warnings about the risks and side effects of the vaccine. If a healthcare provider failed to use the CDC warnings, the person injured by the vaccine would have a cause of action under the federal Homeland Security Act for damages, which preempts state law causes of action. Therefore, we respectfully suggest that Section 2 of the bill is unnecessary.

Thank you for your consideration of our position.

Excerpt from March 2003 Department of Public Health Annual Legislative Report to the General Assembly on Adverse Event Reporting

APPENDIX E Subcommittee Recommendations

Subcommittee Recommendations

As a result of the subcommittees January 29th, 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.