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An Act to Reduce Medical Errors and Improve Patient Health: A Case Study from Maine

Interest in Mandatory Reporting

Among recommendations to address medical errors, the Institute of Medicine (IOM) called for the creation of a nationwide mandatory reporting system for adverse events that result in death or serious injury, implemented through state collection of standardized data. However, states report financial, political, and legal barriers to developing such systems. Maine, like many states, recently considered and enacted a bill to create a mandatory reporting system. The bill, Legislative Document LD 1363, was amended by the Joint Standing Committee on Health and Human Services and passed during the 2002 legislative session. The enacted law, Public Law 2001, Chapter 678, takes effect May 1, 2003.

Summary of the Act

Health care facilities are required to report sentinel events to the state Department of Human Services Division of Licensure and Certification. The Division reviews the events and takes appropriate action. Reports are confidential and privileged. Reporters are immune from liability for reporting events. The Division will develop an annual report of summary data. Facilities that knowingly violate the act are subject to fine. Funding for two positions and information system development was provided.

Chronology of the Act

During the 2001 legislative session, LD1363, sponsored by a Senate Democrat and co-sponsored by a House Republican, was introduced in Maine in response to personal or constituent experience with error. LD1363 proposed developing a Maine Health Care Quality Improvement Center and requiring reporting of adverse events for regulatory, research, and educational purposes. The bill was developed as a response to interest from a consumer advocate and several legislators. Perceived as complicated and controversial, it received little attention and was held over for the 2002 session.

During the summer of 2001, interested parties, convened by the Legislative Office of Policy and Legal Analysis, met several times to debate aspects of the bill. Health care providers and consumers generally expressed opposing views, and no consensus could be reached.

When the health committee resumed its work in the fall, committee members voted unanimously to recommend that the bill ought not to pass. However, a bill sponsor persuaded two absent members of the committee to submit a minority report in favor of the bill.

In the process of developing the minority report, interested parties continued to meet and discuss controversial sections of the bill. The original concept of a patient safety center, and its research and educational functions, was eliminated. The bill was redrafted to eliminate confusion and some controversy. The next version of the bill presented a bare-bones mandatory reporting system. Reportable events and procedures were clarified and narrowed to mirror the JCAHO's definitions for sentinel events. Confidentiality provisions were added to protect all but aggregate data from disclosure. The hospital and medical associations claimed to be comfortable with the draft, and the state licensure agency provided an estimate of resource needs.

The minority report, with its modified version of the bill, was reviewed by the committee prior to being presented on the House floor. Stakeholders present at the meeting claimed they could support the bill. The committee was persuaded to reconsider the bill in its new form: three members voted to support the new version and two voted to support the original version.

After additional negotiations among stakeholders about confidentiality provisions, the final version was drafted. Data collected under the new system would be protected from disclosure to address provider concerns, but data that are currently available to the public, such as complaint data, would continue to be available to address regulator concerns. An annual report would include summary data only. The committee reconvened for a final vote on the bill and voted unanimously to pass it.

After the bill passed both houses, the appropriations committee voted to fund the bill, although not at the requested level. Two of four requested positions were cut. Given the tight budget environment, implementation was delayed until May 2003 to reduce expenditures.

Lessons Learned

- The most powerful momentum for improving patient safety stemmed from a knowledgeable, credible constituent who had personal experience with an error and who was committed to policy change. The constituent was focused on patient safety as a public policy and public health issue beyond being a personal experience.

- "Do not take lightly the power of tragedy and how it affects legislators." (Sponsor, Representative David Trahan.) Individual experiences of unnecessarily losing a loved one had a powerful effect on legislators at public hearings and in generating substantial sympathetic press. The human element and press interest maintained the momentum.

- The bill had a legislative champion with single-minded determination to pass the bill in some form, despite his minority party status and lack of a leadership position. The legislator's passion was based on the personal experience of someone he knew and on constituency support. He contacted committee chairs to carry the bill forward, found committee members to support compromise, and secured several committee member votes. These votes ensured full House debate on the bill and kept it alive. He called a final meeting of interested parties and stressed that he would "continue to fight for this bill until my last day in office." (Representative Trahan.) This commitment proved to be a turning point for many who had previously objected to mandatory reporting, and it led to renewed interest in finding common ground.

- The primary bill sponsor was a committed senior legislator from the majority party whose interest in the bill was based in part on family experience with an error.

- The bill received bipartisan support. Both Democratic Senate and Republican House caucuses were persuaded by sponsors to support funding for the legislation.

- Consumers contacted legislators, Congress, and the media regarding patient safety issues to bring attention to the issue.

- Compromise was necessary. "The final groundbreaking legislation was the bi-product of nearly two years of discussions and negotiations. Maine's error reporting process was developed with the assistance of all parties." (Representative David Trahan; Steven Michaud, Maine Hospital Association; and Gordon Smith, Maine Medical Association, "New Law Promotes Patient Safety, Fosters Accountability," Portland Press Herald, June 16, Opinion Editorial.)

- Confidentiality of data proved to be the most controversial aspect of the bill. Consumers who strongly supported the bill were pleased with its passage, although they were disappointed that provisions protecting data were added to itl, eliminating public access to the information. As Representative Trahan noted, "There was not enough support within the legislature to take that giant step. If improving patient safety is your goal, health care providers must be committed to reporting and sharing information and the appearance of blame or retribution must not exist."

- "Information from national resources, other states, and NASHP publications proved useful in defining reportable events, method of reporting, and other aspects of the system." (Jane Orbeton, Office of Policy and Legal Analysis, Maine State Legislature.)

For resources and information on state-based mandatory reporting, visit the National Academy for State Health Policy's website resource center, www.nashp.org

For more information on Maine's legislative experiences with mandatory reporting, contact Representative David Trahan at dptrahan@midcoast.com.

Publications of interest from the National Academy for State Health Policy

- Statewide Patient Safety Coalitions: A Status Report, May 2002
- State Responses to the Problem of Medical Errors: An Analysis of Recent State Legislative Proposals, February 2002
- How Safe Is Your Health Care? A Workbook for States Seeking to Build Accountablity and Quality Improvement Through Mandatory Reporting Systems, November 2001
- Cost Implications of State Medical Error Reporting Programs: A Briefing Paper, May 2001
- Patient Safety and Medical Errors: A Roadmap for State Action, March 2001
- State-based Mandatory Reporting of Medical Errors: An Analysis of the Legal and Policy Issues, March 2001
- Current State Programs Addressing Medical Errors: An Analysis of Mandatory Reporting and Other Initiatives, January 2001
- Improving Patient Safety: What States Can Do About Medical Errors, September 2000
- How States Are Responding to Medical Errors: An Analysis of Recent State Legislative Proposals, August 2000
- Medical Errors and Adverse Events: A Report of a 50-State Survey, April 2000

For more information about these and other NASHP publications, visit the NASHP website at www.nashp.org.