

Medicine & Health Perspectives

BEYOND STICKS AND CARROTS: WHY ERROR BILLS CAN'T DO IT ALL

This is the first in an occasional series of Perspectives on issues surrounding medical-error reporting.

State and federal legislation can help establish a climate friendlier — or more hostile — to fledgling efforts to refocus the health care system on questions of safety and quality. But what's really needed to achieve that goal is a cultural shift that may be largely beyond the influence of legislators and demand from them chiefly patience, since change can be a long time coming. That's the observation of many involved in the patient safety arena as the 107th Congress nears an end and legislative proposals on medical error reporting are left dangling.

Throughout 2001 and 2002, Republicans and Democrats in both houses of Congress have pursued compromise legislative language they hoped would encourage reporting and analysis of medical errors and near misses. Through such study, many experts say, health care providers can learn to develop good systems that will help them work more safely. Progress has been made, with the four main extant bills inching together over the months through incremental changes.

However, while there's general belief that acceptable statutory language is achievable — and before too long — it now appears that the compromise likely will wait until the 108th Congress convenes in 2003. In recent weeks, members haven't felt the same pressure to struggle with details of patient safety language as they have for some other legislation, **Jim Manley** told **M&H** Oct. 17. Manley is chief spokesperson for Sen. **Edward Kennedy** (D-MA), who is sponsor of one of the competing bills.

Four main proposals are in contention: two Senate bills, Kennedy's and another sponsored by Sens. **Bill Frist** (R-TN) and **Jim Jeffords** (I-VT), and two House bills, one Republican-initiated measure that was approved with significant bipartisan support this summer by the **Committee on Ways and Means** and a second sponsored by the bipartisan leadership of the **Committee on Energy and Commerce**.

Several areas of contention remain.

For example, unlike the other bills, the Frist-Jeffords legislation doesn't mandate establishment of a national center to collect and analyze error information but contains only mild language stating that the federal government "may" establish such a center. That fact doesn't necessarily indicate hostility toward a federal center on the part of the sponsors, however.

Most likely it's a bid to move at least some patient safety measures — federal protection of reported safety information against legal discovery and other public disclosure — in an unfavorable budget climate. The competing bills, which mandate establishment of a national center to collect and analyze error information on a very large scale, would require Congress to ante up new money and could provoke more congressional oppo-

sition — or at least foot-dragging — on that ground.

Completing the job when error information is reported will cost money, no matter where it's done or who's paying for it. And without completing the job — analyzing the information and providing feedback to those who report — reporting itself is meaningless, **Harvard School of Public Health** patient safety researcher **Lucian Leape** told Ways and Means' health subpanel Sept. 10.

"Reporting alone does not improve safety," said Leape. "Reports must be analyzed and lead to recommendations for changes in care, and those changes must be implemented. Analysis of reports is an expensive enterprise, requiring a high level of expertise. It is far more costly than the data entry component of a reporting system."

A center that collected and analyzed data on a nationwide basis would be very expensive, he said. For example, the aviation event reporting system run by the **National Aeronautics and Space Administration** "receives over 30,000 reports annually and costs approximately \$70 per case. The annual number of preventable injuries in health care is estimated to be over 1 million. A successful national reporting system for health care conducted at a similar level of expert analysis ... could cost as much as \$70 million a year."

"More feasible," said Leape, is an option that already "in fact is occurring ... development of system-wide programs, such as that being developed by NASA for [the **Department of Veterans' Affairs** health system], and specialty-based focused reporting programs, such as those developed by neonatal and adult intensivists."

Money aside, the main bone of contention between Kennedy and sponsors of competing bills is what information would be protected from disclosure and exactly what that information would be protected from. Kennedy argues that protections shouldn't be so strong that they prevent courts and others from holding providers accountable for egregious behavior or failure to maintain a safety-friendly climate. Sponsors of other bills caution that unless would-be reporters feel sure that information they provide won't open the door for legal or disciplinary actions against themselves or others, they won't report at all.

For example, to encourage reporting, Frist and Jeffords would create a privilege protecting safety data from subpoenas and discovery related to civil, administrative, or criminal proceedings. They also would protect data from use in adverse employment actions or "the evaluation of decisions made in relation to accreditation, certification, credentialing or licensing of an individual."

To promote accountability, on the other hand, Kennedy would not extend the privilege to criminal proceedings and also doesn't include protections related to adverse employment actions or credentialing.

In a related provision, Kennedy's bill would exempt several categories of safety-related information from any protections. Nonprotected information would include "records of a patient's medical diagnosis and