Medical-Error Reporting Bill Starts Up the Mountain . . . Again

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Public outrage over the widespread occurrence of medical errors has faded somewhat since the pioneering report from the Institute of Medicine (IOM) in January 2000 (To Err is Human), which set off a cascade of headline and congressional hearings. In the ensuing five-and-a-half years, Congress has tried repeatedly to pass legislation that would encourage hospitals, physicians, and pharmacists to voluntarily report errors—these reports would be kept confidential. In 2004, the House and Senate passed vaguely similar bills but were unable to hammer out a compromise version in a conference committee.

The wheels have started turning again with the Senate Health, Education, Labor, and Pensions (HELP) Committee’s passage of the Safety and Quality Improvement Act of 2005 (S. 544) in March. The bill allows the secretary of the U.S. Department of Health and Human Services (DHHS) to accredit Patient Safety Organizations (PSOs). Health care providers would send data about medical errors to these PSOs. That information would be beyond the reach of trial lawyers, who could still subpoena a physician’s or a hospital’s original records as part of any malpractice lawsuit. The PSOs would analyze the data and, presumably, make recommendations, although they would have no power to impose them on anyone.

The bill, which is very similar to the one that Congress nearly passed last year, would be an extremely modest step. Frankly, it is difficult to understand why one would want proliferating PSOs, which the bill anticipates, competing for data from health care providers.

Why not just have one federally sanctioned PSO? Moreover, the legislation says nothing about what happens to the information after these PSOs collect it. The idea is to use the data to improve health care quality, but there is no provision for doing that.

As limited as the bill is, groups such as Consumers Union (CU) and the Association of Trial Lawyers of America (ATLA) raised questions about it last year. These organizations were concerned that too much valuable personal medical data would be “locked up” under the bill’s confidentiality provisions. According to one Senate staffer, for example, CU “pulled out [its] big guns last year and even developed a Web site exclusively devoted to opposing this bill.” However, Sally Greenberg, a CU spokesperson, says her group’s concerns have been quieted by the new Senate bill and that CU is neither for nor against the bill in 2005.

Carlton Carl, spokesperson for the ATLA, calls the Senate bill “a work in progress.” He says ATLA’s final position on the bill will depend on “how it is done.”

As a result, 2005 may be the year in which Congress finally passes a patient safety bill. Certainly, even the limited authority of Congress is needed here. At the moment, no one is systematically collecting data on medical errors. DHHS’s Agency for Healthcare Research and Quality (AHRQ) is collecting hospital discharge data and what it calls “patient safety indicators.” The AHRQ is trying to tease from that very general data indications of potential patient safety problems, according to James B. Battles, senior fellow for patient safety and medical errors at the AHRQ Center for Quality Improvement and Patient Safety. But the agency’s 16 grantees do not obtain “spontaneous” data on immediate medical errors—data that are very much needed.

Again, even if a patient safety bill is eventually passed by Congress after five long years, it won’t have nearly the impact that it should, and it will not address some medical-error remedies that could be implemented with a lot less political angst. The IOM’s report suggested that the Food and Drug Administration (FDA) develop and enforce standards for the design of drug packaging and labeling to maximize safety and to require pharmaceutical testing of proposed drug names in order to avoid confusion between two drugs with similar names. The FDA could propose that now. These types of advances would certainly help pharmacists avoid errors.

Allen J. Vaida, PharmD, executive director of the Institute for Safe Medication Practices, based near Philadelphia, Pa., claims that considerable progress has been made since the IOM published its report.

“Back in 2000, we sent out self-assessments and then redid that process last year. There have been tangible changes, although maybe nothing that jumps out at a patient,” he explains.

He cites actions taken by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), such as its issuance in 2004 of a “minimum list” of dangerous abbreviations, acronyms, and symbols that hospitals must not use. JCAHO has also published goals for hospital pharmacies. Readers can find the JCAHO’s 2005 Hospitals’ National Patient Safety Goals at www.jcaho.org/ accredited+organizations/patient+safety /05+npsg/05_npcg_hap.htm.

“A lot has been done,” Dr. Vaida states, “but we have a long way to go.”