



IOM reports err

regarding peer review
confidentiality

by F. Dean Griffen, MD, FACS,
Shreveport, LA

“The granting and continuation of surgical privileges should be based upon the surgeon’s record of demonstrated performance as evaluated by an established peer review mechanism and medical audit.”

—*Statements on Principles*,
American College of Surgeons, 1994

Current federal and state laws provide confidentiality for peer review. Because of an increasing frequency of judicial opinions denying privilege, this confidentiality has become tenuous.¹ There is now a new and equally threatening attack on confidentiality that has been launched by a group of scientists in related fields who have concluded that a current presumed increase in medical errors is in part related to a failed peer review mechanism.

In 2000, these experts at the Institute of Medicine (IOM) published their conclusions regarding the problem of errors as well as their recommendations for solving the problem in a report titled *To Err Is Human: Building a Safer Health System*.² This report was followed by a second report, *Crossing the Quality Chasm: A New Health System for the 21st Century*.³

These reports espouse disclosure of serious errors and are of considerable concern because most health care organizations and providers consider both patient safety and professional liability to be favorably affected by peer review confidentiality. Although the authors have introduced many exciting possibilities for improving our health care delivery systems, they have erred in a very human way regarding their assessment of confidentiality in peer review. To be forewarned and knowledgeable will help health care providers and other concerned parties defend against initiatives that propose to advance the destructive force of disclosure.

Most observers consider peer review confidentiality essential to enhance the willingness of providers to report and objectively evaluate problems in the delivery of care. Agreeing with this premise, the federal government included confidentiality provisions for peer review in the Health Care Quality Improvement Act (HCQIA) in 1986 (42 USC § 11101). The act states that a qualified peer review body and any member of a qualified peer review body "shall not be liable in damages under any law of the United States or of any State" with respect to peer review actions that are solely for the furtherance of quality health care. Virtually every state has enacted additional statutory provisions in support of the confidentiality provided by HCQIA.

Challenges

In spite of this well intended and carefully drafted legislation, the judiciary is challenging peer review confidentiality. The courts' interpretations of HCQIA and supportive state legislation are increasingly denying privilege and allowing the disclosure of peer review materials. A recent Kentucky case (*Nazareth Literary and Benevolent Inst. v. Stephenson*, 503 SW 2d 177) provides a good paradigm. The judge denied the defendant's plea for confidentiality of peer review documents, and in his summation wrote that "although this might be regarded as an initially appealing argument, on reflection, one might well debate wherein the public interest lies. Claims of privilege are carefully scrutinized, and impediments to the discovery of truth are afforded validity in relatively few instances in the common law." Simply stated, judges have great latitude to interpret the law according to

the pleasure of the court and with total disregard for legislative intent.

This judicial attack on confidentiality is threatening enough, but now a new and equally bothersome challenge has been launched. The IOM report is on the brink of forever changing the way we conduct peer review and, as a consequence, is placing both health care providers and patients at great risk for loss of confidentiality. The problem that the report addresses is well defined by two large studies, one conducted in Colorado and Utah and the other in New York, which show that adverse events occur in 2.9 and 3.7 percent of hospitalizations, respectively. These percentages have been questioned by various medical groups, but their degree of accuracy is irrelevant; any error is one too many. According to these data, medical error is the eighth most common cause of death in the U.S. Citing that "the frequency and significance of errors in health care create an imperative to improve our understanding of the problem and devise workable solutions," the report makes numerous recommendations. Categories include: (1) building leadership and knowledge for patient safety; (2) designing error-reporting systems; (3) setting performance standards and expectations for patient safety; (4) creating safety systems in health care organizations; and (5) vis-à-vis confidentiality, establishing a new system for peer review.²

In introductory statements, the committee clarifies its intentions: "The combined goal of the recommendations is for the external environment to create sufficient pressure to make errors costly to health care organizations and providers, so they are compelled to take action to improve safety."² This statement clearly indicates a vision for a system that achieves the goal of patient safety through the intimidation and punishment of health care providers. Accordingly, in terms of peer review, the committee recommends mandatory reporting and public disclosure of adverse events that involve death or serious harm. Confidentiality is reserved for a second system of voluntary reporting to focus on less serious errors and near misses. According to the report, this voluntary system is already in place, and the committee does not suggest new statutory regulations.²

Organized medicine, including the American College of Surgeons, aggressively lobbied the IOM

regarding its stand on disclosure of adverse events and related peer review materials. These groups enumerated potential problems that could result from disclosure, including: (1) loss of confidentiality for patients; (2) less effective peer review due to the loss of confidentiality for involved health care providers; (3) increased liability by providing a list of already presumably validated errors for plaintiff attorneys; (4) creation of incentives to hide errors; (5) inappropriate damage to the patients' perceptions of their health care delivery system; and (6) inaccurate and unfair comparisons for institutions and providers who, because of rural settings or tertiary care environments, are called upon to treat more difficult patient populations.

The IOM then published what the Quality of Health Care in America Committee has characterized as its final report: *Crossing the Quality Chasm: A New Health System for the 21st Century*. In this second report, although the disclosure recommendations remain the same in spite of the revelations from organized medicine, the rhetoric is tempered: "One important route to restoring trust is through a commitment to transparency by all health care systems.... The transition to openness is a difficult one for our often-beleaguered health care organizations, but it is a journey worth making."³

Congressional activity

The recommendations for mandatory reporting and disclosure are of considerable importance because the IOM is an arm of the National Academy of Sciences, a private not-for-profit society. The academy is mandated to advise the federal government on scientific and technical matters upon the authority of a charter granted by Congress in 1863. Accordingly, the Senate's Health, Education, Labor and Pensions Committee (HELP) met three times during the 106th Congress and once again in the 107th Congress to review the IOM reports. The committee concluded that congressional action is absolutely indicated. In response, a Senate bill called the Patient Safety Improvement Act was drafted for consideration by the 106th Congress, but it was never acted upon. The bill was minimally modified for the 107th Congress and resubmitted in the Senate as S. 2590 and in the House as H.R. 4889.

These bills have suffered the same fate as their predecessors. After all, the 107th Congress became necessarily preoccupied with terrorism and other related matters. This understandable preoccupation and a lack of consensus regarding the issue of confidentiality and disclosure of peer review materials among key members of the House and Senate forestalled the act's progression through the legislative process.

Almost all informed observers agree that legislation prompted by the IOM reports will ultimately be passed. The act was changed little from the 106th to 107th Congresses, but what it will contain for the 108th Congress is a matter of conjecture. A review of this year's act is important because it will logically be used as a template for future drafts.

The authors address the regulations recommended by the IOM reports, and many of the Institute's recommendations are included. Some are noticeably missing. Assuming that the current peer review system fails to properly use its deliberations and findings toward the development of best practice standards, the legislation provides for an integrated group of patient safety organizations that are mandated to submit their material to a national data bank where it may be integrated and distributed nationwide to improve care. In contradistinction to the IOM recommendations, incentives for voluntary reporting are provided without mention of mandatory reporting. Even more encouraging, confidentiality is preserved if not enhanced: "notwithstanding any other provision of law...patient safety data shall be privileged and confidential," and such data "shall not be subject to subpoena, subject to discovery, or admitted as evidence in any civil, criminal, or administrative proceeding."

Initially, in both the House and Senate versions, disclosure of patient safety data was allowed in criminal proceedings if the data were material to the proceeding, within the public interest, and not available from any other source. Subsequently, the House Ways and Means Committee amended H.R. 4889 to allow unrestricted disclosure in criminal cases, but S. 2590 remains unchanged. Also included is the stipulation that patient safety data shall be de-identified, being presented in a form and manner that prevents the identification of patients, providers, and reporters of errors. Fi-

nally, provisions for legal action against any provider who discloses privileged material are clearly defined.

Organized medicine monitored the progress of the Patient Safety Improvement Act closely. As with most bills, there are good parts and bad. It's hard to find any enthusiasm for yet another national data bank at risk for abuse through subsequent legislative or judicial assault. Nonetheless, it is virtually impossible to envision any better confidentiality provisions.

If you would like to share your personal feelings with elected officials regarding this legislation, the ACS makes it easy. Simply log on to www.facs.org, look for the link "Legislative Action Center" in the left-hand column and click on "Federal." Then click on "Elected Officials," and follow the subsequent prompts. You will be given a blank page onto which you may draft a letter or e-mail that the College will send to the officials of your choice. The authors of the Senate bill are James Jeffords (I-VT); Bill Frist, MD, FACS (R-TN); John Breaux (D-LA); and Judd Gregg (R-NH). For the House bill, the authors are Nancy Johnson (R-CT); Bill Thomas (R-CA); Amo Houghton (NY); Ernie Fletcher (R-KY); Constance Morella (R-MD); J.D. Hayworth (R-AZ); Jerry Weller (R-IL); and Dave Camp (R-MI). Unless encouraged by concerned constituents, these authors, being frustrated by the reticence of their colleagues to embrace full confidentiality, may choose to compromise their commitment in the next rendering of the act. The College represents you well in legislative matters, but there is no substitute for personal contacts to properly mold legislative activity.

Conclusion

In summary, peer review has long been employed to enhance the safety and quality of care patients receive. Nonetheless, the system is imperfect, as evidenced by data documenting a plethora of medical errors. To address the problems defined by the recent IOM reports, new legislation has been introduced. To this point, the recommendation of the IOM for more disclosure and transparency with mandatory reporting of medical errors has not been included. Instead, legislation espousing voluntary reporting and additional protection of confidentiality for patients, providers, and report-

ers of errors has been drafted. Lack of consensus regarding the issue of confidentiality and disclosure, in addition to a very busy agenda, has blocked the passage of this legislation thus far. Nonetheless, new laws governing peer review are expected to come in time.

Because the ultimate balance between disclosure and confidentiality cannot be predicted, those individuals wishing to protect patient safety and avert increased professional liability must remain alert and proactive in the defense of confidentiality. In response to evidence indicating that medical errors are all too common, the health care industry and various government agencies are introducing many new patient safety initiatives, which reflect to some extent the recommendations of the IOM reports. For now, these efforts are proceeding under the very tenuous confidentiality afforded by HCQIA and supportive state legislation. □

References

1. Griffen FD: The challenge to confidentiality in peer review. *Bull Am Coll Surg*, 84(5):27-32, 1999.
2. Kohn LT, Corrigan JM, Donaldson MS (eds): *To Err Is Human: Building a Safer Health System*. Committee on Quality of Health Care in America, Institute of Medicine. Washington, DC: National Academy Press, 2000.
3. Committee on Quality of Health Care in America, Institute of Medicine: *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington, DC: National Academy Press, 2001.

Dr. Griffen is a private practitioner of general surgery, Highland Clinic, Shreveport, LA. He is Chair of the Regent's Committee on Patient Safety and Professional Liability.

