Risks of Reporting Sentinel Events

A system for reporting medical errors could be used for lawsuits rather than just for safety purposes.

By Bryan A. Liang

Error in health care is common and has been recognized to derive from the systems nature of health care delivery. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recently proposed its Sentinel Event Policy to “encourage the self-reporting of medical errors in order to learn about the relative frequencies and underlying causes of sentinel events, share ‘lessons learned’ with other healthcare organizations, and reduce the risk of future sentinel event occurrences.” Yet providers, while interested in safety, strongly resisted the policy. Concerns were raised that the information would be subject to disclosure in a lawsuit rather than being limited to safety use. Indeed, the American Hospital Association (AHA), which occupies seven seats on the JCAHO board, sent advisory notices to its members expressing this concern, and the American Society for Healthcare Risk Management characterized the policy as a “lawsuit kit for attorneys.” Nevertheless, the JCAHO continued with implementation, indicating information would be protected by peer-review/quality-assurance (PR/QA) privilege.

This Commentary reviews the Sentinel Event Policy and the potential for sentinel-event materials to be discovered under PR/QA privilege.

The Sentinel Event Policy

A sentinel event is defined in the policy as “an unexpected occurrence involving death or severe physical or psychological injury, or the risk thereof,” including unanticipated death or major loss of functioning unrelated to the patient’s condition; patient suicide; wrong-side surgery; infant abduction/discharge to the wrong family; rape; and hemolytic transfusion reactions. In contrast to other error-reporting systems such as in the aviation industry, the Sentinel...
Event Policy excludes “near-miss” reporting and thus may not capture important facets of error. Although they initially were required, the JCAHO now only “encourages” sentinel-event reports. However, mandated review of organizational responses to sentinel events remains a part of the standard JCAHO accreditation process, and sentinel-event activities are required if an event is discovered by the JCAHO.

Under the policy, once a sentinel event has occurred, the entity must perform a “root-cause analysis” (RCA). The RCA is a detailed systems analysis by providers and administration reviewing the entity’s alteration in performance that led to the sentinel event. As a part of the RCA, an “action plan” must be created addressing identified problems. The RCA is submitted to the JCAHO within forty-five days of the event or of the organization’s learning of the event. If, however, the organization does not report the event and the JCAHO discovers it, the entity will be contacted and must submit an RCA under the same forty-five-day schedule. If the JCAHO deems the reported or discovered event a continuous threat to patient safety with significant noncompliance with a JCAHO standard, it will immediately initiate an on-site sentinel-event review and assessment.

Provider Issues In Reporting

The critical risk for the provider is legal discovery of sentinel-event materials. The general expectation is that the entity will send a copy of the RCA to the JCAHO. But because of providers’ resistance, the JCAHO came up with four alternatives. The first allows an employee of the entity to hand-deliver the RCA to the JCAHO, where it will be reviewed and returned on the same day. The second allows a JCAHO surveyor to come to the facility and conduct an on-site RCA review. The third allows the entity to have a JCAHO surveyor conduct an on-site RCA review without viewing the RCA documents; the surveyor conducts interviews and reviews “relevant documentation,” including “any documentation relevant to the organization’s process for responding to sentinel events and the action plan resulting from the analysis of the subject sentinel event.” The fourth, which attempts to address legal discovery, allows a JCAHO surveyor to conduct an on-site review through interviews and review of relevant documentation. The surveyor does not make reference to the RCA or action plan, and the focus is on review of the entity’s analysis process. This fourth alternative is available only if the entity’s chief executive officer (CEO) affirms that disclosure would waive material confidentiality under state law; it is available only as a twelve-month pilot project. All four alternatives require at least
fifteen days’ notice to the JCAHO, and associated JCAHO costs are
the entity’s responsibility.

To induce providers to follow the policy, the JCAHO indicates
that if “the organization fails to submit or otherwise make available
an acceptable root cause analysis and action plan, or otherwise pro-
vide for Joint Commission evaluation of its response to the sentinel
event under an approved protocol…a recommendation will be made
to the Accreditation Committee to place the organization on Ac-
creditation Watch…Continued refusal to permit review could lead
to eventual loss of accreditation.”

Legal Discovery

Legal discovery is a mechanism whereby one party in a lawsuit may
force another to provide all relevant information not protected by
some legal privilege. Indeed, even information that would not be
admissible at trial is discoverable if it appears “reasonably calcu-
lated” to lead to admissible information. Further, in 1993 the Su-
preme Court approved sweeping changes to discovery rules, formu-
lating automatic disclosure requirements that require, without
formal request, the production of “all documents, data compilations,
and tangible things in the possession, custody, or control of the
party that are relevant to disputed facts” at lawsuit initiation.

Information regarding a sentinel event would seem clearly dis-
coverable in a civil suit, absent some legal privilege. Because an event
report, analysis, records, and data are directly relevant to its occur-
rence, plaintiffs will likely seek these documents, which may have to
be disclosed automatically under Supreme Court rules. Thus, absent
a privilege, by reporting a sentinel event and delivering an RCA to
the JCAHO, an entity may be compiling, and may need to deliver to
the opposition without request, very damaging materials that were
intended for safety rather than legal use.

Peer-Review/Quality-Assurance Privilege

The major protection against information discovery under the Senti-
nel Event Policy indicated by the JCAHO is PR/QA privilege, which
is based on state law and protects providers’ PR/QA assessments
from discovery. PR/QA proceedings are protected to allow candid,
critical analysis of providers’ performance. However, according to
the Supreme Court, “privileges contravene the fundamental princi-
ple that ‘the public…has the right to every man’s evidence,’ ” and
exceptions “are not lightly created nor expansively construed, for
they are in derogation of the search for the truth.” Thus, there is a
conflict between plaintiffs legitimately desiring information and de-
fendants legitimately attempting to shield it.

Whether PR/QA statutes will protect an entity's sentinel-event information from discovery will depend on how courts treat the materials. There have been no reported cases reviewing accessibility under PR/QA statutes or Sentinel Event Policy information breaches, yet relevant issues have been assessed that may indicate that PR/QA protection is tenuous.\textsuperscript{17}

Under the best of circumstances, courts would treat Sentinel Event Policy materials as PR/QA deliberations, such as minutes of a PR/QA committee meeting discussing clinical care rendered by a physician on staff or applying for privileges. Such typical PR/QA materials would generally be protected by many state statutes, although clearly not by all. Even here, the privilege is not absolute: If the trial court deems that claim success or failure would likely turn on the evidence within the PR/QA statute, the trial court can compel its production. Further, to be eligible for the privilege, the relevant body must actually perform PR/QA activities, with these activities being its primary function. An entity cannot simply deem any professional staff member with a role in quality as part of a PR/QA committee for privilege purposes.

Note that information provided to and/or reviewed by a PR/QA body does not make that information privileged; it is only the body's own deliberations and opinions that are generally protected. The policy against protecting submitted information is that if such protection were afforded, all damaging materials would be placed in the hands of such committees to avoid disclosure.

Although reporting sentinel events and formulating RCAs may be considered typical PR/QA activities, the extent of involvement and broad requirements of an RCA seem to go beyond traditional PR/QA subjecting it to discovery. This is exacerbated by courts “narrowing the scope of the [PR/QA] privilege in favor of full disclosure of relevant facts.”\textsuperscript{18}

\textbf{Exceptions.} One important area of agreement relates to administrative materials: They are usually not protected. Beyond data or reports submitted to or reviewed by a PR/QA committee, discoverable administrative information includes incident/occurrence reports and any other information compiled in the entity’s ordinary course of business, such as reports memorializing facts; information originating outside the PR process; personnel, administrative, and other hospital records; PR/QA proceeding effects; hospital administration investigation reports; PR information from other sources; and documents created for rendering legal opinions, weighing liability risk, or instituting corrective action. Since the Sentinel Event Policy involves incident/occurrence reports, is reported and com-
piled in the entity’s normal course of business, is not exclusively generated by or in the PR/QA committee’s exclusive purview, and involves the hospital’s administration and providers generating corrective-action materials, courts may assess sentinel-event documents as outside PR/QA protection.

PR/QA privilege also is limited by its state-law origins. Any cause of action involving federal law in a federal court will generally not be subject to state-law privileges under the Federal Rules of Evidence. Only if the federal court chooses to adopt state-law privileges will any privilege apply. But federal courts have refused almost universally to adopt state-law PR/QA privilege because recent Supreme Court jurisprudence disfavors PR-based discovery limitations. Indeed, because state-law claims may be pled with federal claims, the federal court may exercise jurisdiction over them. In these situations, the federal privilege approach applies to state claims. This result is reinforced by the Health Care Quality Improvement Act, which provides qualified immunity to PR participants but no privilege for PR materials.

PR/QA privilege also does not apply in the increasingly common criminal cases in health care. Further, placing sentinel-event information in the hands of an institutional review board does not appear to afford it PR/QA privilege protection, nor are non-PR/QA committees’ treatment modality documents and activities protected. In addition, sentinel-event information disclosed to an investigating state provider board also may preclude application of PR/QA privilege. Such information may be discoverable through other legal avenues such as the federal Freedom of Information Act (FOIA) and its state-law equivalents. This may be of great concern because recent federal regulations may subject all research data of a federal agency grant recipient to FOIA, potentially exposing federally funded sentinel-event study data to disclosure.

Special status of court testimony. Assuming that sentinel-event materials are considered PR/QA materials, the court’s balancing test for discovery favors the entity, the case does not involve federal law, and PR/QA privilege is successfully invoked, sentinel-event information still may be accessed through testimony. Although the participants in reports and RCA formulation may be considered a valid PR/QA committee, this status does not shield providers from subpoena and questioning regarding the sentinel event and its assessment. Even in states with strong PR/QA discovery privilege, courts have noted that plaintiffs are “free to depose those authors [of protected information] in the regular course of discovery,” and “denial of the privileged documents should have little impact on any patient’s ability to maintain a cause of ac-
tion...considering that [they] ‘can also depose all persons involved.’ ” Indeed, “a person cannot be asked what he said in a [PR/QA] committee proceeding. But he can be asked questions in discovery or on a witness stand that would elicit the same information.” The mandate may be stronger: “A physician may...be obligated to testify about the course of a patient’s case...even though a [QA] committee may...have elicited the same testimony on the same subject.”

The four alternatives offered by the JCAHO do not appear to address these risks. Opposing parties may still make sentinel-event material discovery requests under any of the alternatives. Entity materials created in response to the policy will remain discoverable regardless of where the JCAHO views the documents. Indeed, if entities engage in discussions with the JCAHO regarding the sentinel event during on-site review, such discussions could act as a waiver of PR/QA privilege and subject the discussions to the difficulties associated with subpoena and testimony.

**Conflict with liability insurance.** There also is a very practical concern: Liability insurers generally require immediate reporting of an event that may invoke the insurer’s responsibility. A standard insurance contract clause requires that the entity make no statements and/or take no actions that could compromise the insurer from defending the claim(s).26 If a sentinel event results in a lawsuit, and sentinel-event materials are prepared and discoverable, the entity may not only face suit, but also face suit without insurance coverage and with sensitive sentinel-event materials in the opposing party’s hands.

**Not Reporting**

There appear to be significant obstacles in the way of obtaining PR/QA protection for sentinel-event materials. Therefore, an entity may choose not to report a sentinel event and instead address the event internally. This avenue is attractive because, officially, the Sentinel Event Policy only encourages reporting. Further, even if discovered by the JCAHO, the entity simply enters into the standard policy process. This option allows the entity to address the sentinel event using its own analyses and resources. Also, this option has the tremendous advantage of crafting personnel, materials, and information in a state-specific manner that could minimize discovery risk.

This option appears to be the one most often taken. Voluntary reports under the Sentinel Event Policy have been low—only 60 percent of all reports since 1995 were voluntary. Even counting all report types obtained from all sources, only roughly 800 total sentinel events have come to the attention of the JCAHO over the past five years, compared with the estimated hundreds of thousands of
error-related patient deaths over this period.\textsuperscript{27}

Voluntary reporting to a neutral third party may elicit greater participation. For example, aviation incident reports originally went to the Federal Aviation Administration, an entity with punishment power, which resulted in few reports. When the reporting system was changed to go through the National Aeronautics and Space Administration, a neutral entity without such power, reports increased dramatically.\textsuperscript{28} This experience is consistent with under-reporting in states’ mandatory reporting systems.\textsuperscript{29} These results may inform policy about event reporting. The Institute of Medicine (IOM) report strongly advocates mandatory adverse-event reporting and encourages the investigation and development of voluntary systems for other events.\textsuperscript{30} However, the JCAHO’s Sentinel Event Policy and states’ experiences indicate that the IOM recommendations may not result in substantive provider participation. Instead, a focus on voluntary reporting of near-misses until legal issues are addressed may be more effective in gaining participation and making safety progress. This alternative would reflect the nonpunitive, systems-based philosophy inherent in effectively reducing error.

Clearly, the downside for nonreporting is possible loss of JCAHO accreditation. However, beyond resistance to the policy, providers have expressed dissatisfaction with JCAHO accreditation methods in the past.\textsuperscript{31} Using alternative methodologies such as International Standards Organization 9000 (ISO-9000) registration may be more desirable and may open international markets.\textsuperscript{32} Providers have in fact obtained such registration to satisfy state and federal requirements for public program reimbursement.\textsuperscript{33}

**Policy Recommendations**

The most effective solution to address the risks of reporting sentinel events would be federal legislation protecting safety program information, similar to legislation proposed previously by the JCAHO.\textsuperscript{34} Absent broader reform, the Federal Rules of Evidence, which exclude subsequent remedial measures that improve systems as proof of negligence, should exclude internal and external event reporting and analyses, allowing these efforts to be used only for safety improvement rather than as a substitute for expert assessment of clinical care in civil suits.\textsuperscript{35}

The JCAHO can play a positive role in such efforts. Implementing an accreditation standard involving entity participation in safety and error reduction research with recognized expert groups and standardizing data forms to facilitate robust error categorization and information sharing would be important steps. The JCAHO also could focus its resources on the passage of federal legislation to
further the goal of safety and advocate for a neutral error-reporting site such as a safety center within the National Institutes of Health (NIH), rather than the Agency for Healthcare Research and Quality (AHRQ), as the IOM report suggests. This would illustrate the national commitment to patient safety and avoid the political battles that at one point almost eliminated AHRQ. Importantly, the JCAHO should eliminate punitive approaches such as the threat of accreditation watch and accreditation loss, which embody “shame-and-blame” approaches that the Sentinel Event Policy was designed to eliminate. Finally, the JCAHO should address legal issues before policy implementation, to maximize providers’ participation.

The Sentinel Event Policy attempts to address medical error and the occurrence of sentinel events. However, this information may be used for purposes other than safety. The JCAHO and policymakers should take these considerations into account when assessing systems to improve patient safety.

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NOTES


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8. JCAHO, Joint Commission statement regarding the Sentinel Event Policy, online at www.jcaho.org/sentinel/se_stat.htm (accessed 3 April 2000).
17. Note that due to space constraints, case authority throughout this paper is not specifically provided except for Supreme Court cases; case citations are available from the author at baliang@alum.mit.edu.
22. 42 U.S. Code, sec. 11101 et seq.
24. 5 U.S. Code, sec. 552.
25. 64 Federal Register 5684 (4 February 1999).
29. Kohn et al., eds., To Err Is Human.