Draft Rule Shapes Patient Safety Organizations

BY DENISE NAPOLI Assistant Editor

Draft federal regulations more than 2 years in the making aim to give hospital networks, physician groups, and similar organizations the ability to help doctors reduce medical errors and improve the quality of care they provide to patients. The rule offers the government’s first pass on how to implement the Patient Safety and Quality Improvement Act of 2005 and guidance on how to create confidential patient safety organizations (PSOs). Comments on the proposed rule are being accepted until April 14.

First called for by the Institute of Medicine in its 1999 report “To Err is Human,” PSOs will be entities to which physicians and other health care providers can voluntarily report patient safety events with anonymity and without fear of tort liability. PSOs will collect, aggregate, and analyze data and provide feedback to help clinicians and health care organizations improve on those events in the future.

In an interview, Dr. Bill Munier, director of the Center for Quality Improvement and Patient Safety at the Agency for Health Care Research and Quality, said that patient safety events can be reported from health care associated infections and patient falls to adverse drug reactions and wrong-site surgery.

According to the proposed rule, a “patient safety event” may include an error of omission or commission, mistake, or malfunction in a patient care process; it may also involve an input to such a process (such as a drug or device) or the environment in which such process occurs.

The term is intentionally more flexible than the more commonly used “medical errors” to account for not only traditional health care settings, but also for patients who are participating in clinical trials, school based clinics, and even locations where a provider is not present, such as a patient’s home, according to the rule.

Until now, there has been no clear guidance on how an organization can become a PSO. But according to the proposed rule, public and private entities, both for-profit and not-for-profit, can seek listing as a PSO. This includes individual hospitals, hospital networks, professional associations, and almost any group related to providers with a solid network through which safety information can be aggregated and analyzed, said Dr. Munier.

Insurance companies, accreditation boards, and licensing agencies cannot be PSOs because of potential conflicts of interest.

“We know that clinicians and health care organizations want to participate in efforts to improve patient care, but they often are inhibited by fears of liability and sanctions,” said Dr. Munier, director of the Center for Quality Improvement and Patient Safety at the Agency for Health Care Research and Quality. “Therefore, the proposed rule provides a framework for (PSOs) to facilitate a shared learning approach that supports effective interventions that reduce risk of harm to patients.”

Dr. Munier said that the rule took a long time to issue partly because its authors had to be sure it didn’t conflict with state reporting requirements and the Health Insurance Portability and Accountability Act (HIPAA).

In a statement, Rich Umbdenstock, president and CEO of the American Hospital Association, said that his group was in strong support of the creation of PSOs. “Hospitals have already waited 2 years for this rule and this is only a first step in the process toward establishing PSOs. We will continue to work with HHS to ensure the timely creation of PSOs,” he said.

Dr. James Rohack, a board member of the American Medical Association, agreed. In a statement, he said, “Since the passage of patient safety legislation in 2005, the American Medical Association and other patient safety advocates have eagerly awaited guidance for implementation from the administration. The proposed rule ... will allow health care professionals to report errors voluntarily without fear of legal prosecution and transform the current culture of blame and punishment into one of open communication and prevention.”

To view the proposed rule and learn how to comment, go to http://www.regulations.gov/ftpublic/components/main/main-AHRQ-2008-0001.html. Comments will be accepted until April 14.

Hospitals Tackle Joint Commission’s 2008 Patient Safety Goal

BY MARY ELLEN SCHNEIDER New York Bureau

The Joint Commission’s new 2008 patient safety goal of requiring a process to respond quickly to a deteriorating patient is being mistakenly interpreted by some hospitals as a mandate for “rapid response teams” or “medical emergency teams.”

Further, at some organizations that already have rapid response teams, staff have expressed concerns they will need to redo their established systems.

Dr. Peter Angood, vice president and chief patient safety officer for the Joint Commission, said such presumptions are incorrect.

Hospitals are simply being asked to select a “suitable method” that allows staff members to directly request assistance from a specially trained individual or individuals when a patient’s condition appears to be worsening, he said. The key is to focus on early recognition and response to a deteriorating patient’s condition.

According to the rule, hospitals are likely to play a significant role in accomplishing it, said Dr. Franklin Michota, director of academic affairs for the department of hospital medicine at the Cleveland Clinic.

Organizations that already have hospitalist programs in place are leaning toward the use of rapid response teams or medical emergency teams, because hospitalists can function as members of the team. Some hospitals without an adequate number of staff to have a team in place around the clock are considering starting hospitalist programs. Another strategy would be to form teams that do not include physicians, he said.

The Joint Commission requirement will not be without cost, Dr. Michota said, especially for those organizations that need to add staff. If no professional staff was there at 2 a.m., before the hospital now needs to take on the cost of salary and benefits for more employees, he said.

When hospitalists aren’t a part of a response team, they are likely to be crucial to developing the response plan, said Dr. Robert Wachter, chief of the division of hospital medicine at the University of California, San Francisco. And perhaps the biggest rule for the hospitalist is in providing the around-the-clock coverage that could negate the need to call the formal response team as often, he said.

While the Joint Commission requirement might seem like a greater challenge for small hospitals, Brock Slabach, senior vice president for member services at the American Health Association, disagrees. In many cases, smaller organizations can meet the Joint Commission’s requirement in an easier fashion than large, urban facilities can, because they are more nimble and can work faster with less bureaucracy.

Rapid response teams, for example, can be tailored to a hospital’s resources by using staff from the emergency department to respond to a call, he said.

A number of hospitals have already made a commitment to establishing some type of rapid response teams. Establishing these teams is one of the strategies advocated as part of the Institute for Healthcare Improvement’s 5 Million Lives Campaign, a national patient safety campaign designed to reduce harm in U.S. hospitals.

Of the 3,800 hospitals enrolled in the 5 Million Lives Campaign as of January, about 2,700 have committed to using rapid response teams, according to IHI.

This idea is catching on, said Kathy Duncan, R.N., faculty for the 5 Million Lives Campaign. The cost of implementing these types of teams varies, she said. About 75% of hospitals in the campaign have done this with zero increase in full-time employees. For most staff involved, this is just an additional task. Investment is required for training team members, which can be costly at the outset, she said. Hospitals also need to invest time to educate the rest of the staff on when and how to call for assistance.

Ms. Duncan’s advice for implementing whatever process a hospital chooses is to start by assessing what resources are available. She advises figuring out how people will request assistance, when to make that call, and who should respond. “Start small with a pilot process,” Ms. Duncan said.