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 72-page proposed rule offers the government's first pass on how to implement the Patient Safety and Quality Improvement Act of 2005 and gives 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, according to the law and proposed rule.

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 anything 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 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 participating in clinical trials, and for ambulances, school 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 licensure 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. Carolyn M. Clancy, AHRQ director. "The proposed regulation 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. J. 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 www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=AHRQ-2008-0001. 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 at 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 of a deteriorating patient and mobilization of resources and to document the success or failure of the system that is in place.

"This is not a goal that states there needs to be a rapid response team," Dr. Angood said.

Many institutions in the United States have implemented rapid response teams, and the data on their efficiency is generally good, but not every study has been positive, Dr. Angood said. As a result, officials at the Joint Commission wanted to move forward with a more basic approach with the goal of avoiding variation in response from day to day and shift to shift.

Regardless of how hospitals choose to implement the Joint Commission goal, hospitalists 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 central 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 role 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 National Rural Health Association, disagrees. In many cases, smaller organizations can meet the Joint Commission's requirements in 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. ■

Deadlines for Meeting Joint Commission Goal

Because of the complexity of implementing a process to respond quickly to a deteriorating patient, officials at the Joint Commission are giving hospitals a year to develop and phase in their program.

By April 1, the first deadline, hospital leaders are required to assign responsibility for the oversight, coordination, and development of the goals and requirements. By July 1, there needs to be an implementation work plan in place that identifies the resources needed. By Oct. 1, pilot testing in one clinical area should be underway.

The Joint Commission is serious about organizations meeting these implementation milestones, Dr. Angood said. Hospitals that don't meet the quarterly deadlines will be docked points on their evaluation.

For 2009, hospitals will need to comply with the following six "implementation expectations" set out by the Joint Commission:

- ► Select an early recognition and response method suitable to the hospital's needs and resources.
- ► Develop criteria for how and when to request additional assistance to respond to a change in a patient's condition.
- ► Empower staff, patients, and/or families to request additional assistance if they have a concern.
- ► Provide formal education about response policies and practices for both those who might respond and those who might request assistance.
- ► Measure the utility and effectiveness of the interventions.
- ► Measure cardiopulmonary arrest rates, respiratory arrest rates, and mortality rates before and after implementation of the program.