Rule Proposed for Patient Safety Organizations

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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.

Dr. Dan Solomon, chair of the American College of Rheumatology's Quality of Care committee, said that although the ACR does not have a specific position on this Act, the College is in support of any effort to increase patient safety. "PSOs may be a method for improving patient safety by improving the reporting of potential safety issues, but I think the devil is in the details with how this information flows from providers and patients to these organizations and then how it flows to the health care providers," he said.

Patient safety organizations will collect, aggregate, and analyze data and provide feedback to help clinicians and health care organizations improve.

"I think it is too early to know [whether they will be effective]." 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 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 Healthcare 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, Dr. Munier said.

Insurance companies, accreditation boards, and licensure agencies cannot function as 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. Clancy said.

Dr. Munier said 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). ■

To view the proposed rule and learn how to comment, go to www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=AHRQ-2008-0001.