

failure to properly act on abnormal test results);

- Equipment failures (for example, a defibrillator without working batteries, or inadvertent dosing of medications in a short time frame due to intravenous pumps with valves that are easily dislodged);
- Infections (for example, nosocomial and post-surgical wound infections);
- Blood transfusion-related injuries (for example, hemolytic blood transfusion reactions); and
- Deaths due to seclusion or restraint use.

Harm experienced while receiving healthcare services is a growing concern for the American public. While both the public and the private sectors have made notable contributions to reducing preventable medical errors, additional and aggressive efforts are needed to further reduce these types of incidents. Therefore, we are publishing this final rule, with some modification in response to comments, to guide improved patient safety in the hospital setting.

Medical errors can be difficult to recognize in healthcare due to the variations in individuals' responses to treatment. In addition, medical professionals may not recognize that a particular product or procedure may have contributed to or caused a problem since the patient is already ill or the event appears unrelated to the product or procedure. Because medical errors usually affect only a single patient at a time, they are treated as isolated incidents and little attention, if any, is drawn to these problems. Finally, the healthcare community acknowledges that errors are most likely under reported due to malpractice threats and practitioner confidentiality concerns. All of these factors explain the ongoing invisibility of medical errors despite the existence of research that documents their high prevalence. The IOM report recommended the following:

- Action to reduce preventable medical errors;
- Implementation of a system of public accountability;
- The development of a knowledge base system regarding medical errors; and
- A culture change in healthcare organizations in order to promote the recognition of errors and improve patient safety.

### *C. Balancing Collegial and Regulatory Modes of Oversight*

The proposed revision of the hospital CoPs is part of a larger effort to bring about improvement in the quality of care furnished to beneficiaries through a

patient-centered approach to healthcare delivery, quality improvement, and integration of care, as well as our quality of care oversight responsibilities.

The fundamental purpose of the QAPI CoP is to set a clear expectation that hospitals must take a proactive approach to improve their performance and focus on improved patient care. We stress improvement in systems in order to improve processes and patient outcomes. This is not meant to suggest that we plan to abandon our regulatory role. In fact, this approach reinforces our primary responsibility for assuring patient safety and protection through our delegated regulatory authority.

We must note that accreditation surveys for deemed status performed by JCAHO, AOA, and any other national accrediting organization recognized by us in the future, are performed under an extension of our authority. Onsite accreditation surveys may serve as the basis for enforcement activity since accreditation organizations' standards are determined by us to meet or exceed our own CoPs. SAs acting as our regulatory agents perform validation, recertification, and complaint surveys in hospitals to determine compliance with the CoPs.

During surveys the QAPI program will be evaluated for its hospital-wide effectiveness on the quality of care provided. The impact of the program will be assessed during a survey, as surveyors are looking at data gathered at different points in time, compared, and actions taken based on that comparison. The hospitals will be analyzing data and evaluating the effectiveness of their own program continually.

Whenever the state agency surveyors enter the hospital to conduct a survey they will evaluate the hospital's program and its own internal evaluation process along with an evaluation of all hospital services. When there is an onsite review of the hospital's QAPI program, the surveyors determine whether or not the hospital is meeting the QAPI CoP requirements. Following the existing survey process and procedures, if the SA determines that the hospital is significantly out of compliance with the QAPI CoP requirements, the hospital will be scheduled for termination from the Medicare and Medicaid programs. The hospital is then given the opportunity to submit a plan of correction. The SA would conduct a follow-up survey to assess whether the hospital is now in compliance with all of the requirements, prior to the actual termination taking place.

Three to five years after the implementation of this final rule, we

will assess Online Survey Certification and Reporting System (OSCAR) data and evaluate how well hospitals have implemented the QAPI process. During this time, we will also assess the state of the art for quality improvement practices.

Similarly, we view the Quality Improvement Organizations (QIOs) (formally known as Peer Review Organizations (PROs)) operating in a largely "penalty-free" environment, as our quality improvement agents. Each State has a QIO that contracts with Medicare to monitor and improve the care delivered to beneficiaries. Each QIO operates under a contract known as a "statement of work" governed by extensive portions of Titles 11 and 18 of the Act, as amended by the Peer Review Improvement Act of 1982. Specific QIO tasks fall under three areas of responsibility, as provided in the Act and reiterated in the statement of work:

- Improve quality of care for beneficiaries by ensuring that beneficiary care meets professionally recognized standards of health care;
- Protect the integrity of the Medicare trust fund by ensuring that Medicare only pays for services and items that are reasonable and medically necessary and that are provided in the most appropriate (for example, economical setting);
- Protect beneficiaries by expeditiously addressing individual cases, such as beneficiary complaints, provider-issued notices of noncoverage, Emergency Medical Treatment and Active Labor Act (EMTALA) violations and other statutory responsibilities.

We look to the QIOs to advance quality of care in the hospital environment. We view accreditation deeming activities as part of our overall responsibility to certify providers for program participation.

## **II. Legislation**

Section 1861(e)(1) through (9) of the Act: (1) Defines the term "hospital"; (2) lists the statutory requirements that a hospital must meet to be eligible for Medicare participation; and (3) specifies that a hospital must also meet other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Under this authority, the Secretary has established in the regulations 42 CFR part 482, the requirements that a hospital must meet to participate in the Medicare program. Under section 1865 of the Act and 42 CFR 488.5 of the regulations, hospitals that are accredited by the JCAHO or the AOA are not routinely surveyed by SAs for compliance with the CoPs but are