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[FR Doc. 03-1631 Filed 1-23-03; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

[CMS-3050-F]

RIN 0938-AK40

Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule requires hospitals to develop and maintain a quality assessment and performance improvement (QAPI) program. In the December 19, 1997 **Federal Register**, we published a proposed rule to revise the hospitals conditions of participation (CoPs). The QAPI CoP was one of the conditions included in the proposed rule. We separated the QAPI CoP from the larger set of hospital CoPs so that it could be published in advance of the remaining CoPs to implement the Administration's initiatives regarding medical errors. QAPI focuses provider efforts on the actual care delivered to patients, the performance of the hospital as an organization, and the impact of treatment furnished by the hospital on the health status of its patients. Specifically, it is important to note that a QAPI is not designed to measure a hospital's quality, but rather a minimum requirement that the hospital systematically examine its quality and implement specific improvement projects on an ongoing basis. State agencies (SAs) during their surveys, review all aspects of a hospital's operations and this review provides a framework in which the SA can assess a hospital's QAPI program. In addition, the QAPI entails all activities required for measuring quality of care and maintaining it at acceptable levels. This typically includes—

- Identifying and verifying quality-related problems and their underlying cause;
- Designing and implementing corrective action activities to address deficiencies; and

- Following up to determine the degree of success of an intervention and to detect new problems and opportunities for improvement.

Performance improvement activities aim to improve overall performance assuming that there is no permanent threshold for good performance. Under performance improvement framework, hospitals will continuously study and improve the processes of healthcare and delivery of service.

EFFECTIVE DATE: These regulations are effective on March 25, 2003.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

A. General

In the December 19, 1997 **Federal Register** (62 FR 66726), we published a proposed rule entitled "Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval" to revise the entire set of Conditions of Participation (CoPs) for hospitals. The CoPs are the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The CoPs are intended to protect patient health and safety and to ensure that high quality care is provided to all patients. The State survey agencies (SAs), in accordance with section 1864 of the Social Security Act (the Act), survey hospitals to assess compliance with the CoPs. The SAs conduct surveys using the instructions in the State Operations Manual (SOM), (Health Care Financing Administration (HCFA) Publication No. 7). The SOM contains the regulatory language of the CoPs as well as interpretive guidelines and survey procedures and probes that elaborate on regulatory intent and give guidance on how to assess provider compliance. Under § 489.10(d), the SAs determine whether hospitals have met the CoPs and report their recommendations to us.

Under the authority of section 1865 of the Act and the regulations at § 488.5, hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) are deemed to meet the requirements in the CoPs, and therefore, are not routinely surveyed for compliance by the SAs. However, all Medicare and Medicaid participating hospitals are required to be in compliance with our CoPs regardless of their accreditation status.

B. Patient Safety and Medical Errors

In 1999, the Institute of Medicine (IOM) published a report entitled "To Err is Human: Building a Safer Health System," which highlighted patient injuries associated with medical errors. In this report, the IOM defined an error as the following: "An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim." The IOM report also indicated that an estimated 44,000 to 98,000 Americans die annually as a result of preventable medical errors. The results of the report have generated substantial media, public, Congressional, and Departmental concerns regarding patients health and safety.

As recommended by the IOM, the Quality Interagency Coordination Task Force (QuIC), evaluated and responded to the recommendations in the IOM report with a strategy to identify patient safety issues and to reduce the number of errors by 50 percent over the next 5 years. In an effort to thoroughly consider all of the relevant issues related to medical errors, the QuIC expanded the IOM's definition to read as follows: "An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems." We have adopted the QuIC revised definition of an error.

Accordingly, the QAPI CoP has been separated from the larger set of CoPs and published in an accelerated timeframe because it provides the framework to implement the Administration's initiatives designed to help distinguish and avoid mistakes in the healthcare delivery system. In addition, we are requiring that a hospital's QAPI program be an ongoing program that shows measurable improvement in indicators for which there is evidence that they will improve health outcomes and identify and reduce medical errors. The remaining provisions of the hospital CoPs will be published at a later date.

Many people believe that medical errors involve medication (for example, an incorrect or improper dosage of medicine) or surgical errors (for example, incorrect site amputation). However, there are many other types of medical errors including—

- Diagnostic errors (for example, misdiagnoses leading to an incorrect choice of therapy or treatment, failure to use an indicated diagnostic test, misinterpretation of test results, and