

deemed to meet most of the requirements based on their accreditation.

Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. The regulations at § 440.10(a)(3)(iii) require hospitals to meet the Medicare CoPs to qualify for participation in Medicaid.

III. Provisions of the Proposed QAPI CoP

We proposed revisions of the CoPs that emphasized lessening Federal regulation: (1) To eliminate unnecessary structural and process requirements; (2) focus on outcomes of care; (3) allow greater flexibility to hospitals and practitioners to meet quality standards; and (4) place a strong emphasis on quality assessment and performance improvement.

The proposed provisions of the QAPI CoPs included three standards that addressed the scope and direction of the performance improvement program, discussed the hospital entity that is responsible and accountable for the QAPI activities, and retained the current requirement on autopsies (existing § 482.22(d)). In addition, we proposed 12 critical areas in which hospitals must, at a minimum, objectively evaluate their performance.

We solicited comments on the feasibility of national outcome-based performance measures for hospitals and the minimum level requirements for performance improvement activities. We did not include in the hospital CoPs any requirement for hospitals to collect and report certain standard data items that could produce quality of care predictors in the future. However, we did invite public comment on the following seven key questions regarding the development and implementation of hospital-based performance measures.

(1) Should CMS assume a leadership role in developing the measures?

(2) How should CMS proceed to develop and implement the measures?

(3) If CMS does not assume a leadership role in this area and hospitals invest in the development of multiple systems, would the overall burden be greater than if a single system had been imposed at the outset?

(4) If CMS does not assume a leadership role in this area and individual hospitals adopt multiple systems that produce nonstandardized data, to what extent would it be difficult to make comparisons between hospitals?

(5) Should CMS require or encourage hospitals to use the standardized measures that some accredited hospitals are using?

(6) Would it be appropriate for CMS to include "placeholder" language in the revised CoPs concerning the eventual need for hospitals to report relevant data, or is this premature?

(7) If CMS includes "placeholder" language, what changes should we make to these proposed requirements to set the stage for the development and implementation of such a system?

IV. Analysis of and Responses to Public Comments

We received over 1,200 comments in response to the QAPI requirements presented in the December 19, 1997 proposed rule. These comments were from hospitals, professional organizations, accrediting bodies, practitioners, and other individuals. Summaries of the public comments received and our responses to those comments are set forth below.

A. Regulatory Approach

We asked for comments on the fundamental shift in our regulatory focus for quality from the current approach that identifies and corrects problems in patient care delivery to an approach that emphasizes improving patient outcomes and satisfaction using a data-driven QAPI program.

Comment: The majority of commenters expressed support for our change in philosophy and the introduction of the new QAPI CoP, stating this approach will create more consistency between accrediting and regulatory bodies' standards.

Response: We appreciate the support. One of our initiatives is to revise many of the provider CoPs, including hospitals, so that they focus on outcomes of care and eliminate unnecessary procedural requirements.

Comment: A commenter requested clarification regarding whether this requirement applies to all patients or only Medicare patients.

Response: This requirement as well as all of the other hospital CoPs applies to all Medicare- and Medicaid-participating hospitals; therefore, all patients receiving services provided by these hospitals are protected by this requirement. Moreover, these standards govern quality of care issues for the hospital and its practitioners and contractors.

Comment: Many commenters were against promulgating a final regulation that is too prescriptive. They emphasized that what is needed, above all, is flexibility to design a program that meets the needs of hospitals of varying sizes and specialties, rather than a "one-size-fits-all" regulation.

Response: We agree and believe that the proposed QAPI condition was designed to incorporate flexibility with the appropriate amount of accountability. We have made several revisions to the QAPI condition, to increase its flexibility and accountability, and minimize burden.

Comment: Some commenters stated that the proposed QAPI condition is process-oriented and conflicts with our intent of reducing process-oriented requirements. In addition, the commenters stated that we should allow hospitals to pursue quality improvement in whatever manner they choose.

Response: We recognize that by permitting hospitals to evaluate themselves in the 12 specific areas we believe are critical to hospital performance, the proposed QAPI appeared prescriptive in nature. Based on public comments, we have deleted the proposed requirement for hospitals to assess their performance in 12 specific areas. We agree that hospitals should be able to pursue quality improvement in a manner of their choosing. We encourage hospitals to identify and resolve performance problems specific to their situations in the most effective and efficient manner possible. The provisions also require collaboration between all hospital departments and services, to ensure that all entities are included, to the greatest extent possible, in the QAPI program. After monitoring, tracking, and assessing performance in all areas of hospital service and operations, the hospital has the flexibility to design a program to address its specific needs. We also believe giving the hospital flexibility to design its own program provides the hospital with the flexibility to adopt its own best practices in specific areas, (for example, hospital staff education, record reviews, and information technology). We believe that it is critically important that hospitals examine the adequacy of their information technology and identify opportunities to improve and expand the use of such technologies to prevent medical errors and improve quality of care. This Administration is committed to working with other public and private stakeholders to develop means for improving and expanding the use of information technologies (for example, bar coding and computerized physician order entry systems) in health care settings.

Comment: Some commenters were concerned that our proposal to have an outcome-oriented and patient-centered regulatory approach would eliminate structure and standardized practice