

purposes; however, sufficient work in this area has not been performed. Therefore, we have not included a requirement for hospitals to report certain data elements in this final rule. As standardized measures are developed and implemented, they will complement, not replace the QAPI process.

Comment: Commenters cited the importance of the provision requiring hospitals to share collected information with patients and consumers, and supported information sharing to facilitate decisions based on quality. Many of these commenters felt as though it was not only prudent, but the Federal government's responsibility to ensure the availability of this information.

Response: We agree. We have the responsibility to increase awareness of patient safety issues and the role beneficiaries can play in enhancing patient safety in general. We would like to enable patients and family members to become more involved in their care and to be active participants in the decision-making that impacts their care. We support the development of patient safety messages and themes that can be used by healthcare purchasers, and consumers to guide their choices in the selection of quality healthcare.

V. Provisions of the Final Rule

Since this final rule sets forth the requirements for the QAPI CoP only, we are placing the QAPI CoP with the existing hospital CoPs under Subpart C—Basic Hospital Functions at § 482.21 that will replace the existing Quality Assurance requirements. The five standards in this CoP will set forth the requirements for the development of an effective ongoing hospital-wide QAPI program that will focus on indicators related to improve health outcomes and prevention, and reduction of medical errors. As with the existing CoPs, the enforceability of the CoPs will be rooted in the evidence found during the onsite survey. The requirements of the QAPI CoP are as follows:

Section 482.21

This condition requires that hospitals must develop, implement, maintain, and evaluate their own QAPI programs. We have retained the provision requiring the hospital's QAPI program to reflect the complexity of the hospital's services and operations. We state that the QAPI program must be hospital-wide, ongoing and focus on indicators related to improved health outcomes. We also added language to—(1) stress the importance of the inclusion of measures that foster the

prevention and reduction of medical errors; and (2) require hospitals to maintain and demonstrate evidence of its QAPI program for review by CMS.

Section 482.21(a)

The first standard, Program Scope, requires that a hospital's QAPI program include an ongoing program that shows measurable improvements in indicators for which there is evidence that they will improve health outcomes, and identify and reduce medical errors. There is also a provision that the hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations. We have deleted the proposed requirement for the mandated assessment of 12 minimum areas.

Section 482.21(b)

The second standard, Program Data, provides the framework and clearly defines the expectations for hospitals regarding data the hospital must use as part of its QAPI program. It contains the provisions presented in the proposed rule, that described the type of data to be used including patient care and other data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.

Section 482.21(c)

The third standard, Program Activities, has been added to clarify the hospital's responsibilities. This section contains a requirement on setting priorities for performance improvement, previously found in the proposed rule at § 482.25(a)(5), with some modifications based on comments. The first requirement under the program activities standard requires hospitals to set priorities for improvement, considering prevalence and severity or incidence, or both, of high-risk, high volume or problem prone areas, and giving priority to improvement activities that affect health outcomes, patient safety, and quality of care. A hospital's performance improvement activities should track adverse patient events, analyze their causes, and implement preventive actions and mechanisms of feedback and learning throughout the hospital. This must include incidents of medical errors and adverse patient events. Finally, hospitals are required to take actions that result in performance improvements. After implementing actions, the hospital must measure its success and track its performance to assure that improvements are sustained.

Section 482.21(d)

The fourth standard, Performance Improvement Projects, has been added to distinguish the requirements for improvement projects from program activities as requested by the commenters. We require that the number of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations. Demonstration of minimum effort will be achieved by requiring hospitals to document what projects they are conducting, the reason for conducting these projects, and measurable progress achieved. The standard does not require hospitals to participate in a QIO cooperative project but its own projects are required to be of comparable effort.

Section 482.21(e)

The fifth standard, Executive Responsibilities, clarifies our intent to hold the hospital's leadership responsible and accountable for QAPI activities. We have maintained the requirement ensuring that a hospital-wide QAPI program addresses priorities and implements, maintains, and evaluates all improvement actions. This standard is further strengthened by requiring the hospital's governing body to provide strong, clear, and visible attention to setting expectations for safety and for allocating adequate resources for measuring, assessing, improving, and sustaining the hospital's performance and for reducing risks to patients.

VI. Regulatory Impact Analysis

A. Introduction

We have examined the impact of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, distributive impacts, and equity.

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless we certify that a final rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. We consider most hospitals small entities, either by nonprofit status or by