

commenters' concerns regarding burden and the misunderstanding of the self-assessment in the 12 areas and have eliminated this requirement. In this final rule, although we have not specifically prescribed areas to be assessed, the CoP requirement is for the hospital's QAPI program to be, but not be limited to, 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. Section 482.21(c) requires that hospitals set priorities for performance improvement based on the prevalence and severity of identified problems. Hospitals are expected to assess all areas of hospital services and operations, and based on that information prioritize the improvement activities that most directly affect patient safety and clinical outcomes. The most important aspect of a QAPI program is the implementation of actions based on the hospital's assessment of its improvement needs. The hospital must use the data collected and make changes in its processes or programs to improve patient outcomes. When adverse outcomes are identified, hospitals must, when applicable, perform system and process analyses and take action to achieve and sustain long-term corrections. These actions could include changes in protocols and systems and staff education and training.

We recognize the special needs and circumstances of rural hospitals. We also recognize that the collection and analysis of clinical outcome data could represent some increase in burden on some hospitals, particularly on the nonaccredited hospitals that are subject to our survey process. Nonaccredited hospitals typically are smaller than most accredited hospitals, are located in sparsely populated areas, and may not have the resources for extensive data gathering and reporting. For these reasons, the framework established by the QAPI CoP is flexible enough to recognize the unique circumstances and characteristics of hospitals. The QAPI CoP affords the hospital the flexibility to identify processes targeted for improvement based on its unique needs, priorities and patients. Hospitals that have more resources may be able to produce more sophisticated measures that involve more complex issues, but the focus for all hospitals is that they make an aggressive and continuous effort to improve performance and address patient safety issues. Moreover, we would expect the processes targeted for improvement to change over time as

the hospital succeeds in its initial efforts.

Comment: Some commenters agreed with our rationale for the inclusion of these areas stating these can point to opportunities for improvement in both hospital and practitioner performance.

Response: Although we agree that our rationale for listing these 12 areas represent identifiable opportunities around which a hospital could develop a QAPI program, we determined that a far more valuable approach, at this time, would be to allow hospitals the flexibility to identify their own areas to address. Characteristics of healthcare delivery are too diverse and hospitals strengths and weaknesses are too varied to take such a narrow approach.

Comment: We were asked to clarify how a hospital would show sustained improvement in all 12 areas, anticipating it would be too difficult to select measures to guarantee and improve patient outcomes.

Response: As stated above, we have eliminated the 12 areas presented in the proposed rule. One of the benefits of operationalizing a QAPI program is that, because it is a continuous process, it affords the hospital a mechanism for evaluating its own improvement efforts. Specifically, the process of improvement includes—

- Identification of an organization's critical patient care and services components;
- Application of performance measures that are predictive of quality outcomes that would result from delivery of the patient care and services; and
- Continuous use of a method of data collection and evaluation that identifies or triggers further opportunities for improvement.

Comment: Commenters requested that we clarify and define the list of 12 areas, but the overwhelming majority of commenters strongly encouraged the deletion of the list. These commenters argued it would be more effective to allow hospitals to assess, measure and analyze themselves, but concurred with the identification of hospital processes and functions that could produce valuable information. Alternatives were given such as the adaptation of JCAHO's standards, or us merely providing the components of the QAPI program and giving the hospital the flexibility to create a program of its own design.

Response: As stated previously, we have eliminated the list of 12 areas for self-assessment. The regulations provide the components of a QAPI program and allow for individual hospital flexibility in implementation.

Comment: Some commenters suggested that nonaccredited hospitals be exempt from QAPI requirements until we provide scientific evidence that participation in external measurement systems by nonaccredited hospitals improves patient care.

Response: We cannot relinquish our responsibility for assuring quality healthcare to all patients. We believe that we have provided hospitals with enough flexibility and have identified enough resources for improving the process of patient care to facilitate the development of an effective QAPI program by a hospital of any size. Therefore, we do not believe there is a need to differentiate our expectations for accredited and nonaccredited hospitals.

D. Data

We proposed that hospitals use hospital-specific data (for example, medical record and committee information), including QIO, and other relevant data as an integral part of its QAPI program. In this final rule under § 482.21(b), program data, we use the phrase "quality indicator data including patient care data, and other relevant data," since hospital-specific data, is covered under "other relevant data." The infrastructure of performance improvement activities is based on the collection of data. Analysis of this data allows hospitals to identify trends, identify process variations, and assess performance patterns. We recognize there may be some costs associated with data collection, and realize it is not feasible nor desirable to collect data on everything. Therefore, we have given the hospital the flexibility to establish, through its priorities and needs, the areas on which to focus. Data collection should focus on areas of prevalence and the severity of identified problems, giving consideration to patient safety and quality of care. The governing body must determine priorities regarding which processes to monitor with data collection and the subsequent development of planned improvement efforts, as needed.

E. Improvement Projects and QIO Projects

In the preamble to the proposed rule, we asked whether we should require a hospital to engage in a minimum number of improvement projects that are based upon their own performance assessments. In the proposed regulation text, we stated that hospitals must track performance to assure that improvements are sustained. We asked for comment on the advisability and necessity of such a requirement, and