

patterns and ultimately jeopardize patient safety.

Response: We did not intend to suggest that hospitals eliminate the standardization of care when appropriate and effective. We believe that one of the most effective means of reducing errors is by standardizing processes wherever possible. For example, by standardizing drug doses and times of administration, the advantages in efficiency as well as in error reduction are obvious. By mandating a QAPI CoP that focuses on performance improvement activities, we expect hospitals to conduct systematic internal QAPI activities including the application of standards of care and best practices throughout the institution. For example, if standardizing insulin coverage sliding scales in the intensive care unit decreased the incidence of hypoglycemia by 25 percent, we would expect the hospital to determine other areas that would benefit from the standardized approach. After making this determination, hospitals should implement and track actions and determine a mechanism to assure achievement of goals and sustained improvement.

Comment: A commenter suggested strengthening the regulation text by adding the phrase "hospital-wide" as used in the preamble.

Response: We agree with the commenter and have made the appropriate changes to § 482.21. The change in language recognizes the importance of assuring that the QAPI program reflects the complexity of the hospital's organization and services.

Comment: Some commenters believed that medical staff provisions should not be deleted as they are not entirely captured in this QAPI provision.

Response: In the December 19, 1997 proposed rule, we proposed to eliminate several process-oriented requirements, currently set forth in §§ 482.12 and 482.22, relating to the composition, organization, and conduct of a hospital's medical staff. We have decided to defer any decision regarding the proposal to delete these requirements until the remaining hospital CoPs are published in their entirety.

B. Other QAPI Approaches

We solicited comments on other possible approaches to the QAPI condition to ensure that hospitals invest substantial effort in QAPI. In addition, we solicited comments on how we might offer a more precise explanation of our expectations.

Comment: Several commenters made recommendations for more precise ways to measure performance. One

commenter suggested that we use historical billing data to establish minimum benchmarks or standards of performance as a basis for the performance-based reimbursement system, stating that financial incentives are the best way to motivate change and improve performance. Other commenters stated that a combination of outcome data and the assessment of structured quality improvement processes would be more effective. However, most commenters overwhelmingly expressed concerns that we should develop a final requirement that would allow for flexibility.

Response: We appreciate the commenters' suggestions for more precise ways to measure performance but we believe that these suggestions are more prescriptive than the proposed strategy. In addition, we currently do not have a basis or statutory authority for a performance-based reimbursement system based on benchmarks developed from historical billing data. We agree that using outcome data in combination with assessing the structure of the QAPI program and processes of the hospital would be very effective. However, standardized outcome measures that can be used nationwide have not been established to date so this is not feasible at this time. We believe that the QAPI requirements presented in this final rule address the flexibility concerns of the majority of commenters.

Comment: Several commenters suggested creating a transition period in order to ease the burden of creating a QAPI program.

Response: Since hospitals are currently required to have an "effective, hospital-wide quality assurance program" in accordance with § 482.21, we do not believe a transition period is necessary.

Comment: Many commenters stated the proposed QAPI requirements will substitute high-level hospital-wide QI processes for more effective, focused, department-level performance improvement. These commenters suggested strengthening the language by adding sentinel events to the minimum performance elements.

Response: We agree that hospitals should consider adverse events in the development of its QAPI strategy. We expect hospitals to implement an internal error reduction system. Adverse event tracking and analysis of underlying causes are an effective way to determine issues involving medical errors. We emphasize the need for hospitals to assess processes and systems that affect patient care and quality. Section 482.21(c) requires the

hospital(s) to establish priorities, and identify areas of risk that affect patient safety. We believe that the identification of adverse events and analyses of events must be an integral part of the hospital's QAPI program, as the analyses will lead to better protections for patients.

JCAHO's performance improvement strategy is consistent with our approach. Their standards require hospitals to collect data to monitor performance of processes that involve risks or may result in sentinel events. Similarly, § 482.21(c) requires hospitals to consider prevalence and severity of identified problems and to give priority to improvement activities that affect clinical outcomes, patient safety, and quality of care. In order to meet the requirements, a hospital should consider information from its own risk-management data or from external sources of information (for example, hospital industry data on problem-prone processes, JCAHO's list of frequently occurring sentinel events; data from the National Patient Safety Foundation) and quality indicators from the Healthcare Cost and Utilization Project (HCUP QIs), as possible data measures to assist hospitals in designing their QAPI programs pertinent data and information from our "science partner" the Agency for Healthcare Research and Quality (AHRQ) (<http://www.arhq.gov/data/hcup/qiact.htm>).

C. Minimum Elements for a QAPI Program

We proposed that the hospital's QAPI program consist of assessment activities in a minimum of 12 areas. We also asked for comments on the minimum content of the QAPI program.

Comment: We received many comments citing concerns in the medical community about the broad language of the proposed rule regarding minimum performance areas and associated projects, and the possibility that it could be interpreted to mean that hospitals must perform 12 simultaneous projects. Commenters stated that projects in all areas would be too prescriptive and burdensome, and suggested allowing hospitals to prioritize and implement improvement activities based upon self-assessment. It was stressed that small hospitals would have difficulty identifying measures predictive of outcomes in all 12 areas and low patient volumes in rural hospitals would produce data of little value.

Response: We proposed 12 specific areas of self-assessment, which we believe are critical to a hospital's evaluation of its performance. However, we gave serious consideration to