

that are currently available. In response to the unique needs of rural hospitals, we want to assure these hospitals that our goal for the utilization of performance measures considers the hospital's size and available resources. We will take into account the special circumstances faced by rural hospitals and ensure their needs are considered when developing performance standards in the future.

Meaningful performance programs are often derived from simple designs that use direct and uncomplicated measures. One of the factors that has impeded this progress is the lack of standardization where possible. These comments reinforce the importance of our adoption of a national performance measurement strategy.

*Comment:* Commenters stated that we should defer to the private sector until the field of clinical outcome measures has matured, stating there is a lack of consensus in this area. Commenters suggested that we clarify our intent by addressing such issues as data element definition, risk-adjustment methodologies, audit criteria, and modification of existing commercial monitoring systems before mandating a Federal requirement.

*Response:* We agree that these issues must be addressed before proceeding to mandate utilization of a core set of performance measures. We plan to work with all of our partners, stakeholders, and other interested parties in developing these outcome measures and believe this will provide scientific evidence needed for our national performance measurement strategy.

*Comment:* A commenter stated we must develop an outcomes survey process independent of JCAHO, noting current significant inconsistencies between JCAHO and State survey agency findings.

*Response:* We intend, through our survey process, to assess the hospital's success in using performance measures principally in terms of whether the hospital can demonstrate with objective data that sustained improvements have taken place. We recognize the need for surveyor training and education in the area of quality improvement. We do not intend and would not be in a position to judge the measures ourselves. Instead, we would assess the hospital's use of these measures to improve its performance. Whenever the state agency surveyors enter the hospital to conduct a survey they will evaluate the hospital's program and its own internal evaluation process. When there is an onsite review of the hospital's QAPI program, the surveyors determine whether or not the hospital is meeting

the QAPI CoP requirements. Following the existing survey process and procedures, if the SA determines that the hospital is significantly out of compliance with the QAPI CoP requirements, the hospital will be scheduled for termination from the Medicare and Medicaid programs. The hospital is then given the opportunity to submit a plan of correction. The SA would conduct a follow-up survey to assess whether the hospital is now in compliance with all of the requirements, prior to the actual termination taking place.

Regarding the survey process, our survey process is developed independent of JCAHO's. In addition, we have an ongoing effort with JCAHO to address inconsistency in survey findings.

c. *Question 3:* If CMS does 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?

*Comment:* The majority of commenters focused on the burden that this requirement would impose on hospitals and the healthcare industry. These commenters argued that the increased burden is due to the lack of standardization among technology companies and programs, not due to lack of interest and willingness of providers. These commenters offered the suggestion that we develop and require a single set of performance measures, but allow hospitals to develop their own system as long as it meets established criteria. In like spirit, commenters suggested requiring companies that develop approved systems to include specific attributes of the prescribed measurement system that will be evaluated. The overall tone of the comments genuinely stressed the need for adequate time for any system implementation once decided. Commenters also requested an exemption for rural hospitals stating the needs of these facilities are unique and would not be best served by such a standardized system.

*Response:* We will consider all possibilities that will reduce burden and enhance a hospital's ability to successfully transition to a single system. We continue to consider the geographical and financial needs of individual hospitals, but we strive to offer the same basic protections and safeguards to all patients regardless of the hospital in which they receive services.

*Comment:* A commenter stated that we should use available resources, such as Medicare-contracted utilization and

quality assurance organizations, QIOs, and other resources. This commenter requested that we outline the current resources that are available to hospitals via these organizations.

*Response:* It is our intention to avail ourselves of quality assessment resources. We have considered integrating standardized measurement data sets into a system that could provide access, by an institution, to data reported to a QIO.

d. *Question 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?

*Comment:* Several commenters strongly disagreed with our proposal to allow multiple systems to be used in making comparisons between hospitals. They believe that inherent differences in systems and lack of uniformity provide too many variables to accurately compare hospitals.

*Response:* We understand the commenters' concerns. Many hospitals will need more experience with data collection methods and in the design, implementation, and monitoring of improvement projects. We realize the difficulty in assessing comparability of hospital performance without the requirement of hospitals to utilize like systems. As stated in the December 19, 1997 preamble of the proposed rule, we sought comment on establishing evaluation criteria that must be a part of the system or systems the hospital may choose.

Currently, hospitals across the country use a wide variety of measurement systems and performance indicators to assess the quality of care delivered. The number of these performance measures has increased in recent years. Hospitals are committing substantial and increasing resources for data collection and measurement, as both consumers and purchasers demand greater accountability from their healthcare providers. Since the various measures are not standardized, the data cannot be used to make accurate comparisons about the quality of care among hospitals.

In December 2002, the American Hospital Association (AHA), the Federation of American Hospitals (FAH), and the Association of American Medical Colleges launched a national voluntary initiative to collect and report hospital quality performance information. This effort is intended to make critical information about hospital performance accessible to the public and to inform and invigorate efforts to