

proposing that a hospital be required to participate in a system of performance measurement at this time * * * however, we intend to develop such a requirement for inclusion in our final rule and welcome public comments addressing the appropriateness of such a requirement or how it could best be structured.

In this final rule, we are not setting a requirement for using and reporting on a core set of evidence-based performance measures. Once the evidence and methodologies to support a set of performance measures that can be used nationwide are available, we will assess issues such as commonality of data elements, standardization, and reporting systems. We will inform hospitals and the public of the specifics of and the methods for reporting these performance measures via future rulemaking. This will give the public the opportunity to comment on the core measures before implementation.

4. Core Set of Standardized Performance Measures

In the December 19, 1997 preamble to the proposed QAPI Condition, we also asked for responses and comments to seven questions we posed to the public regarding the development of standardized performance measures for hospitals.

a. *Question 1:* Should CMS assume a leadership role in developing the measures?

Comment: Several commenters stated that we should assume a leadership role in developing a national database of clinical outcomes accessible to all healthcare provider organizations. We received comments from providers as well as practitioners stating that it was the Federal Government's responsibility to set quality standards for the nation with its parallel roles of protecting consumers and supporting healthcare professionals.

Response: We remain committed to our leadership role of protecting consumers and supporting healthcare professionals. We are exploring the concept of requiring Medicare- and Medicaid-participating hospitals to report on a standardized set of performance measures that can be used nationwide. Currently, we are negotiating the terms of a pilot project. The pilot project will be conducted through a collaborative effort among several States, accrediting bodies, and QIOs. These organizations will evaluate a set of standardized performance measures that can be used nationwide. We believe the outcome of this project will yield valuable information regarding the efficacy of data, as well as

the effectiveness of requiring Medicare- and Medicaid-participating hospitals to report on a standardized set of performance measures that can be used for national comparative studies.

Comment: Many commenters stated our role should be limited to convening a group of experts and stakeholders to develop performance measures, while others argued that we should not be involved in this process or limit its role to nonaccredited hospitals. Some commenters believed that we should not enter into public/private partnerships to develop measures, stating high accreditation costs would be passed on to consumers. While others stated an outcome measure database should be developed with input from CMS regional office and State agency staff.

Response: We have established a performance measurement leadership agenda to pursue standardization of hospital performance measurement. We plan to work with organizations like the NQF, hospital associations, and accrediting organizations to standardize a core set of hospital performance measures. Through the QIO Program 6th Scope of Work, we currently have performance measures for pneumonia, heart failure, stroke, acute myocardial infarction, diabetes, and breast cancer to offer as a starting point. As stated earlier, we are exploring conducting a pilot program to test these and other standardized measures. One goal of the QIO program is to improve the quality of care to Medicare and Medicaid beneficiaries, which is parallel with our oversight responsibilities.

Before proposing new provider requirements, we routinely network with healthcare providers, regional and State agency staff, and other interested stakeholders so that what is proposed reflects optimal provider practices, to yield optimal results. Finally, although the majority of commenters favored a standardized approach, opinions varied with respect to whom should take the leadership role in the development of these standards.

Comment: Many commenters disagreed with our goal of creating standardized performance measures. These commenters stated this approach should not be required and strongly felt that a national quality assessment database should not be established because comparisons between hospitals will not be meaningful or reliable. Additionally, other commenters expressed concern that there is no basis for recommending one indicator over another, and that reliable and valid measures do not currently exist. It was further argued, that the infrastructure and data elements for performance

standards are not available, stating that clear data definitions are needed before a core data set may be implemented to increase the hospital's understanding of what is being measured and how it is being measured.

Response: As we stated previously, we believe that standardization of these measures is key to assuring comparability of performance and to making these measures appropriate for accountability purposes. Further refinement and testing of select measures that are suitable for public reporting of comparisons of performance among like-providers is part of our long-range plan. Ultimately, a continuous process of refinement and flexibility in the selection of a core set of standardized measures will benefit both hospitals and beneficiaries as individual hospital performance on standardized measures will invoke appropriate improvement activities to improve overall patient care.

b. *Question 2:* How should CMS proceed to develop and implement the measures?

Comment: Several commenters stated that QIOs should formalize a national database.

Response: We plan to utilize all available resources, including QIOs and organizations like the NQF, to formalize and finalize a source for comparable data to be used nationwide. We currently have some data entry software systems that we offer to providers. The systems have tutorial help for users to gain an overall understanding of the applications, with emphasis on designing data entry systems, explaining how to create an analysis, and evaluating the quality of the abstracted data.

Comment: Some commenters were concerned with the impact that the requirements would have on rural hospitals and suggested that we defer to JCAHO's ORYX. The commenters believe that ORYX recognizes these needs.

Response: We do not agree with deferring to the JCAHO to establish a set of standardized performance measures for Medicare- and Medicaid-participating hospitals. However, we recognize the JCAHO's efforts with regard to performance measures and we acknowledge the need to collaborate with accrediting bodies to facilitate the most appropriate principles for standardizing performance measures. While we are aware that there is no single system available for the measurement of a hospital's performance, we are also aware of efforts by the hospital industry to find ways to increase the use of the systems