

due to the requirement for accrediting bodies to report data.

*Response:* We remain committed to developing a core set of standardized performance measures but we have decided not to include “placeholder” language in this final rule. A core set of standardized performance measures, as well as the method of reporting these measures, will be defined in a future rulemaking document.

g. *Question 7:* If CMS should include “placeholder” language, what changes should we make to these proposed requirements to set the stage for the development and implementation of such a system?

*Comment:* Several commenters wanted to know our projected timeframes for implementation. Others requested that we clarify whether standardized reporting and performance measures will be based solely on standardized clinical data and not on individual programs or projects at the hospital level.

*Response:* We realize that hospitals will need more experience with data collection methods for standardized measurement. Implementation timeframes for the standardized performance measures and the data to be reported will be presented to the public for comment in a separate rulemaking document.

*Comment:* Many commenters stated that the primary purpose for establishing a core set of measures is not quality improvement, but rather public accountability and data comparison. These commenters stated that meaningful improvement is best achieved by allowing caregivers the flexibility to identify opportunities for improvement. Commenters added that our focus should be on the hospital’s mission and patient quality of care needs.

*Response:* We agree that a major reason for reporting on standardized data and core measures is public accountability and data comparison. However, we do not believe this QAPI regulation prohibits the hospital from exploring its own methods and implementing actions that are specific to its institution. Furthermore, we are committed to increasing consumer and patient awareness and facilitating the use of healthcare quality information in making key healthcare decisions.

*Comment:* A commenter suggested that we develop a preliminary set of measures from data on adverse patient events while a complete set of measures is being developed.

*Response:* After the release of the IOM report, “To Err is Human,” as well as the response by the QulC, the NQF was

given the task of identifying a list of adverse events that should never occur, however, the task has not been completed. We expect, as a part of the hospital’s error reduction program, that each hospital will assess institutional adverse events and incorporate this information into its QAPI. For example, if the hospital has had patients that experience adverse reactions, serious harm, or death due to the incorrect administration of intravenous potassium, the hospital should perform an analysis of these events to determine the process that allowed these mistakes and initiate a plan to correct the problem.

*Comment:* Several commenters stated that we should defer to JCAHO and not create a separate system of performance measures for hospitals, stating the proposed requirement is not consistent with JCAHO’s agenda for change.

*Response:* Although we value JCAHO’s role in hospital oversight and quality improvement initiatives, we have responsibility and accountability for quality of care in Medicare- and Medicaid-participating hospitals. We believe that we must directly establish a system of performance measurement for hospitals and maintain a leadership role in hospital oversight. In addition, we are aware of JCAHO’s agenda for change. Our representatives sit on key measurement committees and on the various JCAHO clinical advisory panels charged with selection of the initial set of measures. CMS and JCAHO will strive to minimize burden on hospitals through the selection of a single set of core measures. Finally, we are incorporating criteria that will create a minimum amount of burden on hospitals, especially those hospitals that are subject to more than one method of surveillance.

#### 5. Nonaccredited Hospital Participation in Performance Measurement

We also invited comment on whether we should require nonaccredited hospitals to participate in one or more performance measurement systems as part of their overall QAPI program (both internally and externally). We received a number of comments on this provision.

*Comment:* Many commenters supported the requirement that these hospitals participate in a facility-specific or internal QAPI program. They also stated that for external participation (that is, comparison against national benchmarks) it is premature to propose a specific set of quality indicators or performance measures for nonaccredited hospitals.

*Response:* We do not expect the same utilization of performance measures for small hospitals as we would for large hospitals. We recognize that collection and analysis of clinical outcome data may represent an increased burden on some hospitals, particularly on the nonaccredited hospitals that are routinely subject to our survey process. These nonaccredited hospitals typically are smaller than accredited hospitals, located in more sparsely populated areas, and may not have the resources for extensive data gathering and reporting. Given the uncertain readiness of some individual hospitals to comply with performance expectations under this final rule, quantitative analysis of the effects of these proposed changes is not possible. Hospitals with QAPI programs already in place that meet these requirements, at a minimum level if not in whole, may see little increased burden. However, nonaccredited hospitals are still required to follow this CoP as participants in the Medicare and Medicaid programs. Rather than mandating specific areas of assessment and data collection, this final rule gives hospitals flexibility to identify their own measures of performance for the activities they identify as priorities.

*Comment:* Some commenters offered suggestions that hospitals be allowed the option of using measures developed by QIOs because these measures will have wider application.

*Response:* Although hospitals are not required to participate with QIOs on their projects, we recommend that the QIO be used as a resource. By working with its QIO, a hospital will reap the benefits of a more standardized, streamlined, and cost-effective approach to quality improvement.

#### J. Reporting

As stated earlier, since the standardized measures project would involve the Federal government, as well as accrediting bodies and other organizations like the NQF, its development would not only lessen the burden on hospitals but would also support our goal of developing a regulation that would be universally endorsed by all. In that process, we would determine how data can be collected, validated, and presented to the general public, and determine the impact of providing this type of information. In the proposed rule, we considered requiring hospitals to report certain data elements (for example, patient falls, injuries, and medication errors) to us to serve as the basis of a performance database, which could then be used for provider improvement, consumer information, and other