

priorities. We also believe the implementation of the QAPI CoP will lead to an increase in quality care, optimal patient outcomes and a reduction in the number of medical errors.

3. Effect on the Medicare and Medicaid Programs

We do not expect the implementation of the new QAPI CoP to generate any significant cost to the Medicare or Medicaid programs. As our budget pays for survey and certification activities by the States and States already survey hospitals for compliance with the existing hospital quality assurance CoP, surveyors will only change their focus when surveying from a quality assurance approach to a QAPI approach. Surveyors will be trained on the QAPI approach during their normally scheduled training on the hospital CoPs. Therefore, we believe that there will be no additional costs associated with this training. However, as the QAPI program progresses in individual hospitals, surveyors may have to spend more time evaluating an increasingly robust quality program. These efforts are difficult to quantify.

C. Alternatives Considered

We considered adding requirements that were more prescriptive in nature. However, in response to public comments, and in recognition that this requirement will apply to hospitals of varying size, operating in wide ranges of localities, serving diverse populations, we opted not to utilize this approach. Development of more detailed strategies and policies to comply with the requirement will be left to the discretion of each hospital.

We originally proposed that hospitals use 12 minimum performance areas as the foundation for the QAPI program. However, after analysis of public comments and literature, we agreed with commenters that specifying 12 minimum areas for analysis as part of a hospital's QAPI program was too prescriptive. 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 by us merely providing the components of the QAPI program and giving the hospital the flexibility to create a program of its own design. Some commenters suggested that nonaccredited hospital be exempt from QAPI requirements until we provide scientific evidence that

participation in such programs improves patient care.

Based on public comments, we have deleted the proposed requirement for hospitals to assess their performance in 12 specific areas. We agree that hospitals should be able to pursue quality improvement in a manner of their choosing. Regarding the exemption of nonaccredited hospitals, we cannot relinquish our responsibility for assuring quality healthcare for 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.

In the proposed rule, we also solicited comment on standards regarding the development and implementation of a set of evidence-based standardized performance measures. At that time, we did not propose a requirement for hospitals to participate in a system of performance measurements with other hospitals, but we stated that we intend to do so in the future. Many commenters supported our approach to include placeholder language, because commenters believe it will take a minimum of 2 years for us to develop standardized measures. Some commenters stated placeholder language is premature pending extensive research to insure the accuracy of standardized data, concluding that the QAPI condition be modified at a later date as necessary. In this final rule, we have considered public comments and are not setting a requirement for using and reporting on a core set of performance measures. Once the evidence and methodologies to support a set of performance measures that can be used nationwide are available, we will inform hospitals and the public of the specifics of and the methods for reporting these performance measures for future rulemaking. This will give the public the opportunity to comment on the core measures before implementation.

Our goal is to foster and stimulate a culture of shared learning that will help to identify processes, systems, and even events that potentially or actually lead to error or poor quality care and less than optimal patient outcomes. We believe that this final rule will enable hospitals to identify and resolve performance problems specific to their situations in the most effective and efficient manner possible.

Although we view the anticipated results of this regulation as beneficial to the Medicare and Medicaid programs, as well as to Medicare beneficiaries and Medicaid recipients and State governments, it is impossible to quantify meaningfully a projection of the future effects of this standard in the event of noncompliance issues.

We believe that the foregoing analysis concludes that this regulation would not have any significant impact on the aforementioned providers. Also, the burden associated with this requirement will vary, in some instances be greater, depending on the sophistication of the hospital current QA program.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved, section 43506(c)(2)(a) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information collection burden; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements summarized and discussed below.

The title and description of the individual information collection requirements are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate, is the time for searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the QAPI process, including education and feedback.