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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Part 482

[CMS-3050-F]

RIN 0938-AK40

### Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule requires hospitals to develop and maintain a quality assessment and performance improvement (QAPI) program. In the December 19, 1997 **Federal Register**, we published a proposed rule to revise the hospitals conditions of participation (CoPs). The QAPI CoP was one of the conditions included in the proposed rule. We separated the QAPI CoP from the larger set of hospital CoPs so that it could be published in advance of the remaining CoPs to implement the Administration's initiatives regarding medical errors. QAPI focuses provider efforts on the actual care delivered to patients, the performance of the hospital as an organization, and the impact of treatment furnished by the hospital on the health status of its patients. Specifically, it is important to note that a QAPI is not designed to measure a hospital's quality, but rather a minimum requirement that the hospital systematically examine its quality and implement specific improvement projects on an ongoing basis. State agencies (SAs) during their surveys, review all aspects of a hospital's operations and this review provides a framework in which the SA can assess a hospital's QAPI program. In addition, the QAPI entails all activities required for measuring quality of care and maintaining it at acceptable levels. This typically includes—

- Identifying and verifying quality-related problems and their underlying cause;
- Designing and implementing corrective action activities to address deficiencies; and

- Following up to determine the degree of success of an intervention and to detect new problems and opportunities for improvement.

Performance improvement activities aim to improve overall performance assuming that there is no permanent threshold for good performance. Under performance improvement framework, hospitals will continuously study and improve the processes of healthcare and delivery of service.

**EFFECTIVE DATE:** These regulations are effective on March 25, 2003.

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**SUPPLEMENTARY INFORMATION:**

#### I. Background

##### A. General

In the December 19, 1997 **Federal Register** (62 FR 66726), we published a proposed rule entitled "Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval" to revise the entire set of Conditions of Participation (CoPs) for hospitals. The CoPs are the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. The CoPs are intended to protect patient health and safety and to ensure that high quality care is provided to all patients. The State survey agencies (SAs), in accordance with section 1864 of the Social Security Act (the Act), survey hospitals to assess compliance with the CoPs. The SAs conduct surveys using the instructions in the State Operations Manual (SOM), (Health Care Financing Administration (HCFA) Publication No. 7). The SOM contains the regulatory language of the CoPs as well as interpretive guidelines and survey procedures and probes that elaborate on regulatory intent and give guidance on how to assess provider compliance. Under § 489.10(d), the SAs determine whether hospitals have met the CoPs and report their recommendations to us.

Under the authority of section 1865 of the Act and the regulations at § 488.5, hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) are deemed to meet the requirements in the CoPs, and therefore, are not routinely surveyed for compliance by the SAs. However, all Medicare and Medicaid participating hospitals are required to be in compliance with our CoPs regardless of their accreditation status.

#### B. Patient Safety and Medical Errors

In 1999, the Institute of Medicine (IOM) published a report entitled "To Err is Human: Building a Safer Health System," which highlighted patient injuries associated with medical errors. In this report, the IOM defined an error as the following: "An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim." The IOM report also indicated that an estimated 44,000 to 98,000 Americans die annually as a result of preventable medical errors. The results of the report have generated substantial media, public, Congressional, and Departmental concerns regarding patients health and safety.

As recommended by the IOM, the Quality Interagency Coordination Task Force (QuIC), evaluated and responded to the recommendations in the IOM report with a strategy to identify patient safety issues and to reduce the number of errors by 50 percent over the next 5 years. In an effort to thoroughly consider all of the relevant issues related to medical errors, the QuIC expanded the IOM's definition to read as follows: "An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems." We have adopted the QuIC revised definition of an error.

Accordingly, the QAPI CoP has been separated from the larger set of CoPs and published in an accelerated timeframe because it provides the framework to implement the Administration's initiatives designed to help distinguish and avoid mistakes in the healthcare delivery system. In addition, we are requiring that a hospital's QAPI program be an ongoing program that shows measurable improvement in indicators for which there is evidence that they will improve health outcomes and identify and reduce medical errors. The remaining provisions of the hospital CoPs will be published at a later date.

Many people believe that medical errors involve medication (for example, an incorrect or improper dosage of medicine) or surgical errors (for example, incorrect site amputation). However, there are many other types of medical errors including—

- Diagnostic errors (for example, misdiagnoses leading to an incorrect choice of therapy or treatment, failure to use an indicated diagnostic test, misinterpretation of test results, and

failure to properly act on abnormal test results);

- Equipment failures (for example, a defibrillator without working batteries, or inadvertent dosing of medications in a short time frame due to intravenous pumps with valves that are easily dislodged);
- Infections (for example, nosocomial and post-surgical wound infections);
- Blood transfusion-related injuries (for example, hemolytic blood transfusion reactions); and
- Deaths due to seclusion or restraint use.

Harm experienced while receiving healthcare services is a growing concern for the American public. While both the public and the private sectors have made notable contributions to reducing preventable medical errors, additional and aggressive efforts are needed to further reduce these types of incidents. Therefore, we are publishing this final rule, with some modification in response to comments, to guide improved patient safety in the hospital setting.

Medical errors can be difficult to recognize in healthcare due to the variations in individuals' responses to treatment. In addition, medical professionals may not recognize that a particular product or procedure may have contributed to or caused a problem since the patient is already ill or the event appears unrelated to the product or procedure. Because medical errors usually affect only a single patient at a time, they are treated as isolated incidents and little attention, if any, is drawn to these problems. Finally, the healthcare community acknowledges that errors are most likely under reported due to malpractice threats and practitioner confidentiality concerns. All of these factors explain the ongoing invisibility of medical errors despite the existence of research that documents their high prevalence. The IOM report recommended the following:

- Action to reduce preventable medical errors;
- Implementation of a system of public accountability;
- The development of a knowledge base system regarding medical errors; and
- A culture change in healthcare organizations in order to promote the recognition of errors and improve patient safety.

### *C. Balancing Collegial and Regulatory Modes of Oversight*

The proposed revision of the hospital CoPs is part of a larger effort to bring about improvement in the quality of care furnished to beneficiaries through a

patient-centered approach to healthcare delivery, quality improvement, and integration of care, as well as our quality of care oversight responsibilities.

The fundamental purpose of the QAPI CoP is to set a clear expectation that hospitals must take a proactive approach to improve their performance and focus on improved patient care. We stress improvement in systems in order to improve processes and patient outcomes. This is not meant to suggest that we plan to abandon our regulatory role. In fact, this approach reinforces our primary responsibility for assuring patient safety and protection through our delegated regulatory authority.

We must note that accreditation surveys for deemed status performed by JCAHO, AOA, and any other national accrediting organization recognized by us in the future, are performed under an extension of our authority. Onsite accreditation surveys may serve as the basis for enforcement activity since accreditation organizations' standards are determined by us to meet or exceed our own CoPs. SAs acting as our regulatory agents perform validation, recertification, and complaint surveys in hospitals to determine compliance with the CoPs.

During surveys the QAPI program will be evaluated for its hospital-wide effectiveness on the quality of care provided. The impact of the program will be assessed during a survey, as surveyors are looking at data gathered at different points in time, compared, and actions taken based on that comparison. The hospitals will be analyzing data and evaluating the effectiveness of their own program continually.

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 along with an evaluation of all hospital services. 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.

Three to five years after the implementation of this final rule, we

will assess Online Survey Certification and Reporting System (OSCAR) data and evaluate how well hospitals have implemented the QAPI process. During this time, we will also assess the state of the art for quality improvement practices.

Similarly, we view the Quality Improvement Organizations (QIOs) (formally known as Peer Review Organizations (PROs)) operating in a largely "penalty-free" environment, as our quality improvement agents. Each State has a QIO that contracts with Medicare to monitor and improve the care delivered to beneficiaries. Each QIO operates under a contract known as a "statement of work" governed by extensive portions of Titles 11 and 18 of the Act, as amended by the Peer Review Improvement Act of 1982. Specific QIO tasks fall under three areas of responsibility, as provided in the Act and reiterated in the statement of work:

- Improve quality of care for beneficiaries by ensuring that beneficiary care meets professionally recognized standards of health care;
- Protect the integrity of the Medicare trust fund by ensuring that Medicare only pays for services and items that are reasonable and medically necessary and that are provided in the most appropriate (for example, economical setting);
- Protect beneficiaries by expeditiously addressing individual cases, such as beneficiary complaints, provider-issued notices of noncoverage, Emergency Medical Treatment and Active Labor Act (EMTALA) violations and other statutory responsibilities.

We look to the QIOs to advance quality of care in the hospital environment. We view accreditation deeming activities as part of our overall responsibility to certify providers for program participation.

## **II. Legislation**

Section 1861(e)(1) through (9) of the Act: (1) Defines the term "hospital"; (2) lists the statutory requirements that a hospital must meet to be eligible for Medicare participation; and (3) specifies that a hospital must also meet other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Under this authority, the Secretary has established in the regulations 42 CFR part 482, the requirements that a hospital must meet to participate in the Medicare program. Under section 1865 of the Act and 42 CFR 488.5 of the regulations, hospitals that are accredited by the JCAHO or the AOA are not routinely surveyed by SAs for compliance with the CoPs but are

deemed to meet most of the requirements based on their accreditation.

Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. The regulations at § 440.10(a)(3)(iii) require hospitals to meet the Medicare CoPs to qualify for participation in Medicaid.

### III. Provisions of the Proposed QAPI CoP

We proposed revisions of the CoPs that emphasized lessening Federal regulation: (1) To eliminate unnecessary structural and process requirements; (2) focus on outcomes of care; (3) allow greater flexibility to hospitals and practitioners to meet quality standards; and (4) place a strong emphasis on quality assessment and performance improvement.

The proposed provisions of the QAPI CoPs included three standards that addressed the scope and direction of the performance improvement program, discussed the hospital entity that is responsible and accountable for the QAPI activities, and retained the current requirement on autopsies (existing § 482.22(d)). In addition, we proposed 12 critical areas in which hospitals must, at a minimum, objectively evaluate their performance.

We solicited comments on the feasibility of national outcome-based performance measures for hospitals and the minimum level requirements for performance improvement activities. We did not include in the hospital CoPs any requirement for hospitals to collect and report certain standard data items that could produce quality of care predictors in the future. However, we did invite public comment on the following seven key questions regarding the development and implementation of hospital-based performance measures.

(1) Should CMS assume a leadership role in developing the measures?

(2) How should CMS proceed to develop and implement the measures?

(3) If CMS does not 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?

(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?

(5) Should CMS require or encourage hospitals to use the standardized measures that some accredited hospitals are using?

(6) Would it be appropriate for CMS to include "placeholder" language in the revised CoPs concerning the eventual need for hospitals to report relevant data, or is this premature?

(7) If CMS includes "placeholder" language, what changes should we make to these proposed requirements to set the stage for the development and implementation of such a system?

### IV. Analysis of and Responses to Public Comments

We received over 1,200 comments in response to the QAPI requirements presented in the December 19, 1997 proposed rule. These comments were from hospitals, professional organizations, accrediting bodies, practitioners, and other individuals. Summaries of the public comments received and our responses to those comments are set forth below.

#### A. Regulatory Approach

We asked for comments on the fundamental shift in our regulatory focus for quality from the current approach that identifies and corrects problems in patient care delivery to an approach that emphasizes improving patient outcomes and satisfaction using a data-driven QAPI program.

*Comment:* The majority of commenters expressed support for our change in philosophy and the introduction of the new QAPI CoP, stating this approach will create more consistency between accrediting and regulatory bodies' standards.

*Response:* We appreciate the support. One of our initiatives is to revise many of the provider CoPs, including hospitals, so that they focus on outcomes of care and eliminate unnecessary procedural requirements.

*Comment:* A commenter requested clarification regarding whether this requirement applies to all patients or only Medicare patients.

*Response:* This requirement as well as all of the other hospital CoPs applies to all Medicare- and Medicaid-participating hospitals; therefore, all patients receiving services provided by these hospitals are protected by this requirement. Moreover, these standards govern quality of care issues for the hospital and its practitioners and contractors.

*Comment:* Many commenters were against promulgating a final regulation that is too prescriptive. They emphasized that what is needed, above all, is flexibility to design a program that meets the needs of hospitals of varying sizes and specialties, rather than a "one-size-fits-all" regulation.

*Response:* We agree and believe that the proposed QAPI condition was designed to incorporate flexibility with the appropriate amount of accountability. We have made several revisions to the QAPI condition, to increase its flexibility and accountability, and minimize burden.

*Comment:* Some commenters stated that the proposed QAPI condition is process-oriented and conflicts with our intent of reducing process-oriented requirements. In addition, the commenters stated that we should allow hospitals to pursue quality improvement in whatever manner they choose.

*Response:* We recognize that by permitting hospitals to evaluate themselves in the 12 specific areas we believe are critical to hospital performance, the proposed QAPI appeared prescriptive in nature. 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. We encourage hospitals to identify and resolve performance problems specific to their situations in the most effective and efficient manner possible. The provisions also require collaboration between all hospital departments and services, to ensure that all entities are included, to the greatest extent possible, in the QAPI program. After monitoring, tracking, and assessing performance in all areas of hospital service and operations, the hospital has the flexibility to design a program to address its specific needs. We also believe giving the hospital flexibility to design its own program provides the hospital with the flexibility to adopt its own best practices in specific areas, (for example, hospital staff education, record reviews, and information technology). We believe that it is critically important that hospitals examine the adequacy of their information technology and identify opportunities to improve and expand the use of such technologies to prevent medical errors and improve quality of care. This Administration is committed to working with other public and private stakeholders to develop means for improving and expanding the use of information technologies (for example, bar coding and computerized physician order entry systems) in health care settings.

*Comment:* Some commenters were concerned that our proposal to have an outcome-oriented and patient-centered regulatory approach would eliminate structure and standardized practice

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

commenters' concerns regarding burden and the misunderstanding of the self-assessment in the 12 areas and have eliminated this requirement. In this final rule, although we have not specifically prescribed areas to be assessed, the CoP requirement is for the hospital's QAPI program to be, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that they will improve health outcomes and identify and reduce medical errors. Section 482.21(c) requires that hospitals set priorities for performance improvement based on the prevalence and severity of identified problems. Hospitals are expected to assess all areas of hospital services and operations, and based on that information prioritize the improvement activities that most directly affect patient safety and clinical outcomes. The most important aspect of a QAPI program is the implementation of actions based on the hospital's assessment of its improvement needs. The hospital must use the data collected and make changes in its processes or programs to improve patient outcomes. When adverse outcomes are identified, hospitals must, when applicable, perform system and process analyses and take action to achieve and sustain long-term corrections. These actions could include changes in protocols and systems and staff education and training.

We recognize the special needs and circumstances of rural hospitals. We also recognize that the collection and analysis of clinical outcome data could represent some increase in burden on some hospitals, particularly on the nonaccredited hospitals that are subject to our survey process. Nonaccredited hospitals typically are smaller than most accredited hospitals, are located in sparsely populated areas, and may not have the resources for extensive data gathering and reporting. For these reasons, the framework established by the QAPI CoP is flexible enough to recognize the unique circumstances and characteristics of hospitals. The QAPI CoP affords the hospital the flexibility to identify processes targeted for improvement based on its unique needs, priorities and patients. Hospitals that have more resources may be able to produce more sophisticated measures that involve more complex issues, but the focus for all hospitals is that they make an aggressive and continuous effort to improve performance and address patient safety issues. Moreover, we would expect the processes targeted for improvement to change over time as

the hospital succeeds in its initial efforts.

*Comment:* Some commenters agreed with our rationale for the inclusion of these areas stating these can point to opportunities for improvement in both hospital and practitioner performance.

*Response:* Although we agree that our rationale for listing these 12 areas represent identifiable opportunities around which a hospital could develop a QAPI program, we determined that a far more valuable approach, at this time, would be to allow hospitals the flexibility to identify their own areas to address. Characteristics of healthcare delivery are too diverse and hospitals strengths and weaknesses are too varied to take such a narrow approach.

*Comment:* We were asked to clarify how a hospital would show sustained improvement in all 12 areas, anticipating it would be too difficult to select measures to guarantee and improve patient outcomes.

*Response:* As stated above, we have eliminated the 12 areas presented in the proposed rule. One of the benefits of operationalizing a QAPI program is that, because it is a continuous process, it affords the hospital a mechanism for evaluating its own improvement efforts. Specifically, the process of improvement includes—

- Identification of an organization's critical patient care and services components;
- Application of performance measures that are predictive of quality outcomes that would result from delivery of the patient care and services; and
- Continuous use of a method of data collection and evaluation that identifies or triggers further opportunities for improvement.

*Comment:* Commenters requested that we clarify and define the list of 12 areas, but the overwhelming majority of commenters strongly encouraged the deletion of the list. 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 us merely providing the components of the QAPI program and giving the hospital the flexibility to create a program of its own design.

*Response:* As stated previously, we have eliminated the list of 12 areas for self-assessment. The regulations provide the components of a QAPI program and allow for individual hospital flexibility in implementation.

*Comment:* Some commenters suggested that nonaccredited hospitals be exempt from QAPI requirements until we provide scientific evidence that participation in external measurement systems by nonaccredited hospitals improves patient care.

*Response:* We cannot relinquish our responsibility for assuring quality healthcare to 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.

#### D. Data

We proposed that hospitals use hospital-specific data (for example, medical record and committee information), including QIO, and other relevant data as an integral part of its QAPI program. In this final rule under § 482.21(b), program data, we use the phrase “quality indicator data including patient care data, and other relevant data,” since hospital-specific data, is covered under “other relevant data.” The infrastructure of performance improvement activities is based on the collection of data. Analysis of this data allows hospitals to identify trends, identify process variations, and assess performance patterns. We recognize there may be some costs associated with data collection, and realize it is not feasible nor desirable to collect data on everything. Therefore, we have given the hospital the flexibility to establish, through its priorities and needs, the areas on which to focus. Data collection should focus on areas of prevalence and the severity of identified problems, giving consideration to patient safety and quality of care. The governing body must determine priorities regarding which processes to monitor with data collection and the subsequent development of planned improvement efforts, as needed.

#### E. Improvement Projects and QIO Projects

In the preamble to the proposed rule, we asked whether we should require a hospital to engage in a minimum number of improvement projects that are based upon their own performance assessments. In the proposed regulation text, we stated that hospitals must track performance to assure that improvements are sustained. We asked for comment on the advisability and necessity of such a requirement, and

also on the best approaches to achieve this minimum level of effort. We also proposed that if a hospital chooses not to participate in a QIO project, it must be able to demonstrate, to the SA, a level of achievement through its own QAPI strategy comparable to or better than expected from QIO participation.

*Comment:* A commenter stated QAPI should not be required without the supporting scientific evidence showing QAPI improves patient care.

*Response:* The current quality assurance CoP (§ 482.21) has been in effect since 1986. At that time the healthcare industry as a whole embraced a quality assurance approach to measuring and improving the care delivered to patients. The 1986 CoP reflected state-of-the-art practices. Since that time, the healthcare industry has moved toward a QAPI approach in the delivery and measurement of patient care. The proposed rule was intended to update the existing quality assurance CoP to reflect current practice in quality improvement. We proposed to change the focus of a hospital's quality assurance activities from one that relies on a problem-focused approach of quality assurance to one that focuses on systemic quality improvements, that parallels the JCAHO's overhaul of its accreditation standards.

We specifically requested public comment on the approach as well as the advisability and necessity of the proposed requirements. Commenters were in favor of and supported the continuance of the existing quality assurance CoP. However, they were overwhelmingly opposed to the proposed QAPI requirement that mandated assessment in 12 predetermined areas, stating that this was too rigid and prescriptive.

As stated earlier, we restructured the final rule based on public comments and have eliminated the proposed provision requiring assessment in 12 predetermined areas. We believe that this final rule gives the hospital the flexibility to establish a QAPI program that meets our requirements by conducting systems or process analysis and taking actions to afford long-term correction and improvement of identified or potential problems.

*Comment:* Several commenters stated that the final regulation should specify both a minimum level of scope, as well as a minimum number of improvement projects. One commenter added the number of improvement projects required should be based on the percentage of all patients receiving services at the hospital. Conversely, the overwhelming majority of commenters were strongly against any such

requirement, favoring an approach where the hospital would be required to demonstrate to the SA what projects they are doing and what progress is being achieved.

*Response:* We considered specific requirements regarding the number, scope, and complexity of projects to be performed by each hospital. In the preamble of the proposed rule, we specifically stated that at a minimum, we were considering requiring that the number of distinct successful improvement activities to be conducted annually be proportional to the scope and complexity of the hospital's programs and we also presented other alternatives for consideration. We decided not to base the number of projects on discharges, number of beds, or operational areas as proposed. Based on public comments, we have decided to require hospitals to document what quality projects are being conducted, the reasons for conducting these projects, and measurable progress achieved on these projects. In fulfilling the QAPI regulatory requirements for collection and use of clinical data, we anticipate that hospitals will make use of information technologies. Indeed, we believe that the effective use of information technology (IT) systems (for example computerized physician order entry systems (CPOE) or barcoding) could over time prove invaluable to the improvement of quality and safety of patient care. As an alternative to a performance improvement project, we added a provision, § 482.21(d)(2), that allows hospitals to invest in information technology; that is, we will allow hospitals to undertake a program of investment and development of IT system that are geared to improvements in patient safety and quality, in place of a QAPI project. In recognition of the time required to develop and implement this type of system, we will not require that such activities have a demonstrable benefit in their initial stages, but we would expect that quality improvement goals and their achievement would be incorporated in the plan for the program. Initial stages of development, include activities such as installation of hardware and software, testing of an installed system, training of staff, piloting the system, and hospital-wide implementation of the system. Upon implementation of the system, monitoring will begin and data will be collected over time as part of the process to evaluate the impact of the new system on patient safety and quality. We believe that this modification demonstrates this Administration's deep commitment to

patients, high quality care, and flexibility to our partners. This approach will allow hospitals the flexibility to invest appropriate efforts in their quality program and the freedom to make decisions about the best way to improve the quality of care.

*Comment:* A commenter stated that we have failed to identify the specific outcomes hospitals should achieve, measure, and report. The commenter advocated uniform, standardized measures.

*Response:* Our long-term goal is the identification of a standardized measure set for hospitals. However, since these measures have not yet been identified, we expect hospitals to engage in activities based on analyses of their own data, initiatives that promote patient safety, improve quality of care, and increase patient satisfaction. One goal of this rule is to stimulate providers to develop and pursue a wide variety of information and data, from internal and external sources, to guide their improvement efforts. External sources of information and data can include organizations like the National Quality Forum (NQF), QIOs, and accrediting bodies.

*Comment:* Commenters agreed with the concept of performance improvement, but stated most aspects of quality depend on judgments and subjective assessments. These commenters questioned if quality improvement would be quantified into numerical values, and if so, what numerical value would demonstrate optimum performance, and what should be done if that level is not achieved.

*Response:* Through our survey process, we intend to assess the hospitals' success in using its own objective data, assessing performance, prioritizing improvement efforts, and demonstrating that sustained improvements have taken place. In the future, based on a set of standardized performance measures that can be used nationwide, some improvement efforts might be quantified into numeric values. However, as stated in the 1999 IOM report, continuous improvement assumes there is no threshold for good performance. The central premise is that healthcare systems should never be content with present performance. Rather, providers of healthcare services should continuously study and improve the process of healthcare and service delivery.

*Comment:* One commenter proposed a revision to the following requirement: The hospital must take actions that result in performance improvements and must track performance to assure that improvements are sustained. The

commenter proposed the requirement should read: "The hospital must take quality assessment and improvement actions that result in improved performance outcomes for identified problems." Several other commenters wrote seeking clarification regarding the meaning of the phrase, "improvements that are sustained."

*Response:* We did not accept the commenter's proposed language verbatim, but we did modify the language. The evaluation should enable a facility to judge where resources need to be focused for priority improvement efforts, while assuring sustained improvement in areas where improvement goals have been achieved. For example, if project(s) to improve reduction in antimicrobial resistance have produced successful improvements in the physician's antibiotic prescribing patterns and in the facility's anti-microbial resistance rate, a hospital might defer funding for this effort to focus on another priority topic. At the same time, success with the first project must be sustained, and where possible, improved further over time. Lessons learned from past projects should be incorporated into staff training and evaluations, where appropriate. The evaluation "loop" of setting priorities for improvement, tracking results and determining continued use of resources based on priorities must include continued evaluation of outcomes in "past" improvement projects and staff education in a manner determined by the facility. These activities should lead to long-term correction and improvement of identified focus areas.

*Comment:* A commenter stated that not all hospital departments and services, for example marketing and maintenance, should be included in QAPI programs. The commenter also recommended that the language of the requirement be changed to delete the word "all."

*Response:* We did not accept the commenter's suggestion to delete the word "all." We believe that all hospital departments and services furnished under contract or arrangement, must be involved in the hospital-wide QAPI program. The hospital's marketing program may be instrumental in increasing patient satisfaction and performing post-hospital surveys. The hospital's maintenance program may be instrumental in decreasing the potential for infections. There are many ways to involve all areas of the hospital. This final rule, although flexible, requires hospitals to consider the entire scope of its services and operations. However, we reiterate that although a hospital is

required to monitor and track performance in all areas of its operations, it must use this surveillance activity to help set priorities for the remainder of its QAPI program including data collection, development of performance measures, and the selection of specific quality improvement projects.

*Comment:* The overwhelming majority of commenters wrote that not all QIO data is relevant and timely and sought clarification regarding how a hospital choosing not to participate in a QIO project would demonstrate that its own QAPI strategy is comparable to or better than that expected from QIO participation. Some commenters requested clarification regarding demonstrating "value," as well as the determination of a "sufficient" project.

*Response:* We share the commenters' concern and as a result, we are revising the proposed regulation text, now § 482.21(d)(4) of this final rule, to require projects of comparable effort. Through our QIOs, we are working to reduce errors of omission for 39 million Medicare beneficiaries. Under their current performance-based contracts, QIOs are working to prevent failures and delays in delivering services for breast cancer, diabetes, heart attack, heart failure, pneumonia, and stroke. These efforts have already decreased mortality for heart attack victims. In assessing projects, hospitals should consider the number of patients affected, range of services covered, the projected magnitude of the benefit to individual patients, as well as the actual changes achieved by the project versus the actual changes achieved by participants in the QIO project. Any improvements in care made by hospitals working with the QIOs on their projects would transfer to better care and services to all patients served by these hospitals. Although hospitals are not required to participate in QIO projects, the hospital must document what quality projects are being conducted, the reason for conducting these projects, and that the measurable progress achieved on these projects demonstrate that the projects are of comparable effort. A hospital can compare its own projects to QIO cooperative projects if the following techniques are used as guidance:

- **Improvement Projects**—These projects are based upon the hospital's own assessments of its performance and show measured, sustained results that actually benefit patients. Because most organizations identify more improvement opportunities than they can initiate, improvement project priorities have to be set. These priorities

must be endorsed by the hospital's governing body. Although we do not require a specific number of projects, we do expect the number of distinct improvement projects conducted annually to be proportional to the scope and complexity of the hospital's program. JCAHO states in its Comprehensive Accreditation Manual for Hospitals that certain criteria—the expected impact on performance; and the selection of a high-risk, high-volume, or problem-prone process to monitor—are helpful in setting project improvement priorities. We are adopting a parallel philosophy by specifying at § 482.21(c) that a hospital must prioritize its performance activities, which must focus on high-risk, high volume, or problem-prone areas; consider the incidence, prevalence, and severity of the problem in those areas; and affect clinical outcomes, patient safety, and quality of care. Therefore, we are giving the hospital the flexibility to determine the areas that require performance projects.

- **Quality Improvement Organization Projects**—There are two basic areas of consideration used when establishing criteria for selection of QIO projects: identifying clinical topics and prioritizing clinical topics. These criteria were designed to ensure that a project has the greatest likelihood of significantly impacting the health outcomes of Medicare beneficiaries. Hospitals should utilize these same criteria in determining which projects best encompass the needs of their particular hospital, and in determining if projects identified by the hospital would be comparable to the expected outcomes of those identified by their QIO.

*Comment:* Many commenters understood that the proposed requirement would mean that hospitals would have to demonstrate they are doing as "good of a job" as a QIO if they chose not to participate in QIO projects. These commenters, however, stated that this process would be burdensome for hospitals, and would be counterproductive to the goal of establishing positive cooperative relationships.

*Response:* We disagree. The requirement is to demonstrate a comparable effort. Since the requirement is to invest equal effort, the following material is included as guidance only as how to better make these decisions.

There are four criteria that QIOs use to assess when identifying clinical topics: prevalence, science, measurability and the opportunity to improve care. These criteria address the



issues central to identifying appropriate clinical topics and quality indicators. The remaining criteria are relevant in establishing priorities among those clinical topics that meet the first four criteria (essentially, determining how you can best allocate limited resources to obtain the greatest improvement for the most beneficiaries). We are providing additional guidance regarding the use of criteria for identifying clinical topics as follows:

- **Prevalence, Incidence and Disease Impact**—The burden (morbidity, mortality) of the clinical condition or medical procedure under consideration is great for the population affected. The burden within a subpopulation (for example, minority, disabled, at-risk) may be another consideration that is taken into account.

- **Science**—There should be scientific consensus through multiple independent observations or clinical trials that changing a process or procedure of care will measurably improve patient outcomes. Note that we are adopting the operational definition of the term “scientific consensus” by the Office of Medical Applications of Research in the Office of the Director of the National Institutes of Health as follows:

\* \* \* (T)he (consensus) statement reflects the unified view of a panel of thoughtful people who understand the issues before them and have carefully examined and discussed the scientific data available on these issues. The creative work of the panel is to synthesize this information, along with sometimes conflicting interpretations of the data, into clear and accurate answers to the questions posed to the panel.

- **Measurability**—The process(es) or outcome(s) of care for the topic can be stated in clearly defined, discrete, and quantifiable data elements from data sources which are valid and reliable; accessible in a timely manner; from appropriate care settings; and when necessary, span the continuum of care. In addition to the final measures of outcome, interim measures of progress toward achieving the quality improvement goal are desirable.

- **Opportunity to Improve Care**—Not only should the process or outcome be measurable, there should be a gap between current performance and what can reasonably be achieved. The wider the gap between the present situation and what is feasibly achievable, the greater the opportunity is for improvement. Additionally, there must be a feasible means of narrowing that gap. Merely measuring the problem is not sufficient; you must also be

reasonably certain your actions can improve the situation.

Clinical topics meeting the above criteria should be further prioritized. The following criteria should be helpful in that process. Although it is likely that no topic will consistently meet all of the criteria, proposed topics can be compared on the basis of the number and degree to which the criteria are met.

- **Previous Projects or Pilot Studies**—Demonstrate or provide a citation that demonstrate previous experience with the proposed project methodology or demonstrate that a project of similar design can reasonably be expected to improve healthcare outcomes. Potential priority topics may have been the subject of previous successful projects by QIOs or other organizations. Here, the focus is on selecting topics for which quality improvement has previously been demonstrated or on replicating successful project methodologies.

- **Adequate Program Resources**—Consider whether you have adequate resources (time, personnel, and funding) to implement the quality improvement project. Alternative potential projects with similar costs should be compared for their relative potential benefit. Whenever feasible, topics that make use of existing data sets should be selected.

- **Availability of Partnerships**—Select topics that allow you to collaborate with other providers and national, regional, and local organizations with similar goals. Collaboration with other organizations is encouraged for several reasons: planning, implementation, and analytic costs can be shared; planned, coordinated differences in project methods can be compared for efficacy and cost; local lessons learned can be shared and compared; and ideas for second and subsequent improvement cycles can be gathered.

- **Ability to Enable or Facilitate Ongoing Quality Improvement**—Select topics and interventions that are likely to foster or enhance the development of quality improvement efforts which extend to care processes and conditions beyond those targeted by the improvement project. Some topics may be selected, in part, because of the learning value to the intended user (for example, demonstrating principles and methods that can be applied by the user to other topics) and the ability to sustain the improvements that they trigger.

- **Likelihood of Success (Readiness)**—Identify topics that are of interest to the relevant stakeholders who will be asked to make improvements. This criterion recognizes the fact that significant improvement is not likely to occur if some pivotal individuals (for example,

chiefs of Medicine, department heads, and clinical leaders) do not welcome or are not capable of participating in the project.

*Comment:* Several commenters stated that the regulation should eliminate the requirement to use QIO data. Others suggested that hospitals, especially rural hospitals, should be required to only use QIO data that is relevant to its own QAPI programs.

*Response:* A hospital is not required to use QIO data. The QAPI program must incorporate quality indicator data that may include data, for example, QIO data or other relevant data.

*Comment:* Several commenters stated that the quality of care and patient outcomes should be the focus of the QAPI program, not the usage of specific data. Some commenters stated the proposed data requirement was too prescriptive and unclear. Others stated that many providers are unaware of what “QIO data” is, how to access it, and the associated costs, if any. Several commenters requested this provision be removed.

*Response:* As stated previously, there is no requirement to use QIO data. QIO data is generally relevant information submitted to (or received) from the hospital’s QIO. It can be a good source of quality indicator data to inform the hospital of areas where improvements are necessary. It is important that each quality improvement project have valid and representative baseline data; however, that baseline data may be from QIO data or from another source.

*Comment:* A commenter stated QIO cooperative projects, rules, and policies are already established and stated referring to them in regulatory text is unnecessary.

*Response:* As stated before, the QIOs are making great strides in national quality projects; however, hospitals are free to work on projects of their own design as long as the effort is comparable to QIO projects. Our intent is to allow hospitals the greatest flexibility, by offering options and examples.

#### F. Assessment of Compliance and Enforcement

Through our survey process, we intend to assess whether hospitals have all of the components of a QAPI program in place. The SAs will expect hospitals to demonstrate, with objective data, that improvements have taken place in actual care outcomes, processes of care, patient satisfaction levels, hospital operations, or other performance indicators.

*Comment:* Many commenters strongly supported our proposal to require,



through the survey process, an assessment of the hospital's success in using performance measures and objective data to demonstrate improvements have occurred.

*Response:* We are encouraged by the comments that support the proposed survey focus for the QAPI requirements. Further, we recognize the need for appropriate training of our surveyors. We do not intend for surveyors to judge the measures used by a hospital. Instead, we will train the SAs to assess the hospital's success in its own efforts to improve its performance. The surveyors will ensure that the number of distinct successful improvement activities conducted annually are proportional to the scope and complexity of the hospital services, operations and patient acuity, and that improvement activities demonstrate sustained improvement over time.

*Comment:* A commenter stated JCAHO should be involved in enforcement, emphasizing the hospital's familiarity with the current JCAHO requirements regarding QAPI.

*Response:* We disagree. JCAHO is an accreditation organization that sets healthcare standards but it does not have the direct authority to enforce our regulatory requirements. We also note that compliance with our quality standards is assessed either through an accreditation process that we have determined meets or exceeds our requirements or through the survey and certification process conducted by SAs under contractual agreements with us. Ultimately, we are responsible for enforcing our own requirements; and therefore have the following hospital quality oversight responsibilities: (1) Being a prudent purchaser of quality hospital services; (2) establishing minimum standards to ensure the health and safety of our beneficiaries through the CoPs; (3) ensuring that hospitals are in compliance with the CoPs; and (4) promoting quality improvement in hospitals.

*Comment:* Many commenters expressed concern over the lack of clarity regarding the specific documentation hospitals are required to provide to surveyors to indicate compliance on surveys and the correlation of this information in determining how these regulations improve and protect the quality of care and increase patient satisfaction. Commenters also questioned the hospital's ability to deny access to information collected for quality activities, citing confidentiality and fear of disclosure.

*Response:* As previously stated, surveyors will not judge the various

measures used by a hospital in its QAPI program. In general, a hospital should maintain materials and documentation that it deems necessary to objectively demonstrate its QAPI goals and outcomes to a surveyor. The surveyor should, at a minimum, expect a hospital to have documentation that describes the program; assessment information (data); the rationale for prioritized improvement projects; and the progress that has been achieved. The SAs and we have the legal authority to review records pertaining to the operation of the provider, including patient medical records (including, medical error reports, and peer review information), when these documents are necessary to determine whether the provider is in compliance with the statutory and regulatory requirements for Medicare and Medicaid participation. Section 1864 of the Act authorizes SAs to determine whether an entity meets hospital qualification under section 1861 of the Act. Included in these qualifications are requirements concerning patient records, hospital administration, and medical and nursing services. The surveyor must have access to the hospital and patient records as necessary to determine compliance for participation in the Medicare program. Also, the facility denial of access to our surveyors or us may prevent us from determining that facility's compliance with program requirements. Therefore, under the statute and regulations, we may need to pursue termination proceedings.

This information is protected by the provision of section 1106 of the Act, 42 CFR 401, as well as, the survey agency's responsibilities for protecting the confidentiality of documents, as set out in sections 3300–3316 and 3318 of the State Operations Manual.

#### *G. Responsibilities of the Hospital's Governing Body*

We proposed that the hospital's governing body, medical staff, and administrative officials are responsible for ensuring that the hospital-wide QAPI efforts address identified priorities in the hospital and for implementing and evaluating improvement actions.

*Comment:* A commenter stated that all of proposed § 482.25(b) should be deleted because it is included in the opening paragraph for the QAPI CoP.

*Response:* Accountability and leadership are vital to any QAPI program, and the hospital's leadership (for example, administration and governing body) must provide the foundation for its establishment. There must be an explicit organizational goal

that is demonstrated by clear leadership and support. With this, the hospital and its staff would be more likely to consider the quality program as a high priority and initiative. We have expanded the proposed standard entitled "Program Responsibilities" and renamed it "Executive Responsibilities" to more appropriately reflect the scope and intent of this standard. The organization's governing body must have an ongoing commitment to creating safe systems of care. The IOM report, "To Err is Human," states, "Senior level leadership should define program objectives, plans, personnel and budget, and should monitor QAPI activities by requiring reports to the executive committee and board of directors." The executive responsibilities standard clarifies that it is the responsibility of the hospital's governing body to establish a culture of safety and quality and to define the importance of QAPI activities throughout the institution. The culture of a hospital plays a critical role in how well patient safety and quality of care are viewed throughout the institution. The standard also requires the governing body to ensure that the hospital-wide QAPI efforts address priorities for improved quality of care and patient safety and that all improvement actions are evaluated.

*Comment:* A commenter stated that the governing body should not be held accountable for the performance of independent contractors in the medical staff because the governing body lacks the scientific knowledge to judge physicians.

*Response:* We are not asking, nor do we expect, the governing body to "judge" physicians or any member of the multidisciplinary team. The governing body is responsible for assuring that there is an ongoing, effective, internal QAPI program and that this program methodically identifies and addresses priorities in the hospital and initiates efforts to evaluate and address improvement actions. The analysis of these projects and events identified by the quality initiative is an integral part of the program. It is not a separate function performed by the governing body. We expect hospitals to learn from these efforts and initiate plans and actions to improve patient care outcomes, safety, and satisfaction.

#### *H. Autopsies*

We proposed that hospitals must attempt to secure autopsies in all cases of unusual deaths and in the interest of medical, legal, and educational endeavors. The mechanism for documenting permission to perform an

autopsy must be defined. There must be a system for notifying the medical staff, specifically the attending practitioner, when performing an autopsy.

*Comment:* A few commenters asked why we would give hospitals (instead of the medical staff) the responsibility for securing autopsies and then notifying the medical staff and attending practitioner. These commenters suggested that this authority be maintained under the auspices of the physician. Conversely, other commenters supported this shift of authority, but strongly opposed the elimination of the medical staff CoP, stating this group is essential for quality oversight of any hospital. There were other commenters that requested that we delete the autopsy requirements and administrative assessments. These commenters believe that these requirements were particularly burdensome and may have an adverse effect on patient care or are too difficult to measure.

*Response:* We have removed the proposed standard for autopsies under the QAPI condition. However, we will retain the current autopsy requirements at § 482.22. This requirement states that the medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical, legal and educational interests.

#### *I. Future Development of a Core Set of Evidenced-Based Standardized Measures for Hospitals*

We have a national strategy for standardizing performance measurement and data collection that is, in part, an outgrowth of the creation of a National Forum for Health Care Quality Measurement and Reporting (National Quality Forum (NQF)). In May 1999, the NQF was organized in the private sector and brought together private and public purchasers and stakeholders to reach a consensus on standardizing a national approach to performance measurement in healthcare. The NQF adopted the concepts of our guiding principles and incorporated them into its own national strategy to standardize performance.

The three principles that guide our national performance measurement strategy are as follows:

- *Performance measures should be consumer- and purchaser-driven.* A major challenge for us is to determine value through quality measurement and to use the information to purchase better healthcare services for beneficiaries. This should be done through collaboration with other purchasers.
- *Performance measures and the collection tools needed to collect them*

*should be in the public domain with a publicly held copyright.* This means that the public good is served through a broader access to the measures and data collection tools. Further, the government and the public need unrestricted access to the measures and measurement systems to be able to adopt, collect, revise and report results to the public.

- *The content and collection of data and performance measures derived from that data should be standardized.* Standardization leads to more useful information for consumers and purchasers and reduces the burden for providers and plans.

Our performance measurement strategy is designed to achieve our mission of: (1) Providing consumer information that assists beneficiaries in making choices in healthcare; (2) setting process and outcome criteria to which plans/providers are held accountable; and (3) facilitating quality improvement activities at the program level focusing on national Medicare and Medicaid key clinical priorities at the plan and provider level.

#### *1. Why Standardized Measures?*

Quality improvement is difficult to measure and accountability for quality improvement may be a new concept for some providers of care. A quality improvement program is developed from the collection of data within a facility that are analyzed and used internally to develop and measure the impact of standards of practice, processes, and systems. The organization learns to compare its measured performance results, using appropriate risk-adjustment techniques, with standardized benchmarks used nationally to evaluate how well it is doing compared to similar institutions across the nation. In order to develop these standardized benchmarks, we participate in pilot projects with our QIOs and accrediting bodies. We are committed to partnering with consumers, health plans, providers, purchasers, States, industry and professional representatives, and accrediting organizations over time, to identify key performance measures of quality that guide what institutions can measure internally for comparisons of standardized measures. Standardization of these measures is key to assure comparability of performance and to make 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 the long-range plan for the use

of standardized measures. Ultimately, a continuous process of refinement and flexibility in the selection of a core set of standardized measures is our long-term goal. The requirement for hospitals to conduct ongoing monitoring and evaluation of their internal processes and systems through the QAPI program will continue to be a part of the effort for improving the quality of care provided. Standardized measurements will complement QAPI, not replace it.

#### *2. How Will This Program Be Implemented in Hospitals?*

We are engaged in multiple initiatives that address the development of a core set of evidence-based standardized performance measures, which will be universally applied to hospitals. One initiative is a pilot project where we intend to work with multiple partners, including the JCAHO and the QIOs, in the development of a core set of evidence-based standardized performance measures, which are expected to be presented to the NQF for endorsement. Additionally, we are working with other organizations, like the NQF, on an initiative that will further the national private/public effort to standardize a core set of hospital performance measures that include patient safety measures. Until a core set of measures is developed, we expect hospitals to conduct their QAPI programs using pertinent objective measures of performance. Hospitals also have the opportunity to pursue measurement of clinical practices in focus areas of national high priority. One example of this could be a hospital's assessment of physician prescribing patterns in comparison to evidence-based clinical guidelines, in an effort to reduce the prevalence of antimicrobial resistant organisms.

#### *3. Reporting*

Since the standardized measures project would involve the Federal government, as well as accrediting bodies and other organizations, 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. In this process, we will determine how data could be collected, validated, and presented to the general public, and determine the impact of providing this type of information. In the December 19, 1997 proposed rule we stated the following:

Under this proposed rule, we would require a hospital to engage in a quality assessment and performance improvement program that uses objective measures, but we are not

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

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

improve quality. Voluntary reporting is an essential first step to realize this goal. An important component of this coordinated effort is the identification and development of tools for standardizing data collection and making these tools readily available to the industry. We have tools available for utilization that are refined as needed, to include relevant data elements that capture the information needed or the clinical area under assessment. For example, data elements used for collecting information about a patient's experience with acute myocardial infarction would include portions that differ from data elements needed to collect information about a patient's experience with pneumonia. We recognize that not only are the tools important, but even more important are clear definitions to allow consistent categorization and counting of events or values for measurement. Future priorities and measures will be informed by a forthcoming report from the IOM that will identify 15 to 20 priority areas for quality improvement. Measures will be drawn from those endorsed by NQF; measures will be sought that respond to the six aims set forth in IOM's "Crossing the Quality Chasm," and where possible will include cross-cutting measures. The entire spectrum of stakeholders will be engaged to work toward focusing national public reporting of hospital performance on agreed-upon priorities and NQF-endorsed measures.

*Comment:* Some commenters stated that JCAHO and NCQA have standardized indicator systems; and therefore, we should not proceed unless it can consolidate and remove existing systems. Numerous commenters stated that the burden should not be placed on the hospitals to invest resources in the development of individual hospital systems, in lieu of the increased resources needed for the collection and analysis of outcome data.

*Response:* We are aware that there may be costs assumed by hospitals in choosing different systems. The methods and processes for collection of data vary widely. Our interest lies within the ability of hospitals to be measured against one another when different systems are used. We did not specifically propose that hospitals be required to participate with other hospitals in a system of performance measurement. Although we stated this was our intention for inclusion in the final rule, standardized outcome measures that can be used nationwide have not been established; therefore, we have not set forth this requirement in the final rule. Regarding the existence of

proprietary indicator systems, we have no authority to "remove" these systems.

e. *Question 5:* Should CMS require or encourage hospitals to use standardized measures that some accredited hospitals are using?

*Comment:* Some commenters supported using standardized measures used by accredited hospitals. In contrast, many commenters believed that the measures used by accredited hospitals are outdated.

*Response:* We intend to require that hospitals use standardized measures. We are committed to advancing the scientific effort already underway nationally to standardize the specifications of measures (that is, the data dictionaries and other elements that define quality indicators). We are working in partnership with the QIO program, State initiatives, the NQF or similar organizations, and accrediting bodies in national efforts being conducted to identify and develop standardized specifications. These specifications would then be presented to the NQF or similar organizations for endorsement and subsequently published in future rulemaking. Our position is that any system of measures that incorporates these specifications would be acceptable for use by hospitals. Our concern focuses on how a measure of quality can be standardized for longitudinal comparative purposes among similar hospitals and includes public reporting. Purchasers and consumers benefit from the establishment of measures that could be used to publicly report hospital-specific performance across the full spectrum of hospitals in the United States. Hospitals benefit from a reduction in burden in data collection and measurement, and an ability to obtain comparative data to evaluate and improve their performance. A collaborative effort to develop standardized measures will provide the basis for an initial measurement set for assessment and reporting of hospital performance. Having purchasers and consumers provide the leadership in defining key content areas for the first set of measures and obtaining consensus around these validated measures as a standardized reporting set would be a major achievement in improving the quality of care in the nation. For example, standardized measures of medical errors could be used widely as part of a hospital's medical error reduction program and ultimately for accountability. We believe that requiring standardized data collection and reporting on consensus-developed, scientifically based measures, is an opportunity for hospitals, purchaser and

consumers to work jointly to improve the quality of hospital care. The precise measures to be required will be determined by the Secretary and communicated to the public for comment before they are initiated.

*Comment:* Some commenters stated that the area of performance improvement needs further development before we require specific measures.

*Response:* We agree that there is not a wide menu of available performance measures that have proven to be reliable and valid that could be offered to a hospital to use. Currently, we have not set forth requirements; therefore, hospitals will be able to evaluate themselves on their own data.

f. *Question 6:* Would it be appropriate for CMS to include "placeholder" language in the revised CoPs concerning the eventual need for hospitals to report relevant data, or is this premature?

*Comment:* The majority of commenters agreed with our plan and supported the goals and objectives of a core set of standardized measures. Some commenters believed that these measures should not replace organization-specific projects. They stated that the technical issues surrounding data definitions, uniform systems, and burden, specifically regarding the ability of hospitals to utilize existing information systems, would have to be addressed.

*Response:* In the preamble of the proposed rule, we solicited public comment on standards regarding the development and implementation of a standardized set of performance measures to be used nationwide. At that time, we did not propose a requirement for hospitals to participate in a system of performance measurement with other hospitals but we stated that we intend to in the future. We recognize the specific issues that need to be addressed (for example, technical issues surrounding data definitions, uniform systems, and costs) before implementation of a set of standardized performance measures that can be used nationwide. Hopefully, these measures will help hospitals to identify organizational-specific projects.

*Comment:* 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. Others felt this unnecessary

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

purposes; however, sufficient work in this area has not been performed. Therefore, we have not included a requirement for hospitals to report certain data elements in this final rule. As standardized measures are developed and implemented, they will complement, not replace the QAPI process.

*Comment:* Commenters cited the importance of the provision requiring hospitals to share collected information with patients and consumers, and supported information sharing to facilitate decisions based on quality. Many of these commenters felt as though it was not only prudent, but the Federal government's responsibility to ensure the availability of this information.

*Response:* We agree. We have the responsibility to increase awareness of patient safety issues and the role beneficiaries can play in enhancing patient safety in general. We would like to enable patients and family members to become more involved in their care and to be active participants in the decision-making that impacts their care. We support the development of patient safety messages and themes that can be used by healthcare purchasers, and consumers to guide their choices in the selection of quality healthcare.

## V. Provisions of the Final Rule

Since this final rule sets forth the requirements for the QAPI CoP only, we are placing the QAPI CoP with the existing hospital CoPs under Subpart C—Basic Hospital Functions at § 482.21 that will replace the existing Quality Assurance requirements. The five standards in this CoP will set forth the requirements for the development of an effective ongoing hospital-wide QAPI program that will focus on indicators related to improve health outcomes and prevention, and reduction of medical errors. As with the existing CoPs, the enforceability of the CoPs will be rooted in the evidence found during the onsite survey. The requirements of the QAPI CoP are as follows:

### Section 482.21

This condition requires that hospitals must develop, implement, maintain, and evaluate their own QAPI programs. We have retained the provision requiring the hospital's QAPI program to reflect the complexity of the hospital's services and operations. We state that the QAPI program must be hospital-wide, ongoing and focus on indicators related to improved health outcomes. We also added language to—(1) stress the importance of the inclusion of measures that foster the

prevention and reduction of medical errors; and (2) require hospitals to maintain and demonstrate evidence of its QAPI program for review by CMS.

### Section 482.21(a)

The first standard, Program Scope, requires that a hospital's QAPI program include an ongoing program that shows measurable improvements in indicators for which there is evidence that they will improve health outcomes, and identify and reduce medical errors. There is also a provision that the hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations. We have deleted the proposed requirement for the mandated assessment of 12 minimum areas.

### Section 482.21(b)

The second standard, Program Data, provides the framework and clearly defines the expectations for hospitals regarding data the hospital must use as part of its QAPI program. It contains the provisions presented in the proposed rule, that described the type of data to be used including patient care and other data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.

### Section 482.21(c)

The third standard, Program Activities, has been added to clarify the hospital's responsibilities. This section contains a requirement on setting priorities for performance improvement, previously found in the proposed rule at § 482.25(a)(5), with some modifications based on comments. The first requirement under the program activities standard requires hospitals to set priorities for improvement, considering prevalence and severity or incidence, or both, of high-risk, high volume or problem prone areas, and giving priority to improvement activities that affect health outcomes, patient safety, and quality of care. A hospital's performance improvement activities should track adverse patient events, analyze their causes, and implement preventive actions and mechanisms of feedback and learning throughout the hospital. This must include incidents of medical errors and adverse patient events. Finally, hospitals are required to take actions that result in performance improvements. After implementing actions, the hospital must measure its success and track its performance to assure that improvements are sustained.

### Section 482.21(d)

The fourth standard, Performance Improvement Projects, has been added to distinguish the requirements for improvement projects from program activities as requested by the commenters. We require that the number of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations. Demonstration of minimum effort will be achieved by requiring hospitals to document what projects they are conducting, the reason for conducting these projects, and measurable progress achieved. The standard does not require hospitals to participate in a QIO cooperative project but its own projects are required to be of comparable effort.

### Section 482.21(e)

The fifth standard, Executive Responsibilities, clarifies our intent to hold the hospital's leadership responsible and accountable for QAPI activities. We have maintained the requirement ensuring that a hospital-wide QAPI program addresses priorities and implements, maintains, and evaluates all improvement actions. This standard is further strengthened by requiring the hospital's governing body to provide strong, clear, and visible attention to setting expectations for safety and for allocating adequate resources for measuring, assessing, improving, and sustaining the hospital's performance and for reducing risks to patients.

## VI. Regulatory Impact Analysis

### A. Introduction

We have examined the impact of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits, including potential economic, environmental, public health and safety effects, distributive impacts, and equity.

We generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless we certify that a final rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. We consider most hospitals small entities, either by nonprofit status or by



having revenues between \$6 million and \$29 million. Individuals and States are not considered small entities. We certify that this final rule will not have a significant impact on small entities.

Also, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. That analysis must conform to the revision of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We certify that this final rule will not have a significant impact on a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandate Reform Act of 1995 also requires that agencies assess anticipated costs and benefits for any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This final rule has no mandated effect on State, local, tribal governments, or on the private sector that reach the threshold of section 202.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications.

In 1994, we invited all interested parties to a town hall meeting to discuss our plans to set forth regulations to establish a new approach to improving the quality of healthcare provided in hospitals. Parties from the Association of Health Facility Survey Agencies, hospital associations, and other stakeholders were in attendance. These agencies were given the opportunity to provide input and were generally in favor of our plans.

We welcomed comments on our December 1997 proposed rule. We received a number of comments on our QAPI CoP but we did not receive any comments indicating that States would be adversely affected by this rulemaking.

Thus, we have examined this final rule and have determined that this final rule will not have a negative impact on the rights, rules and responsibilities of State, local or tribal governments.

#### *B. Anticipated Effects*

In December 1997, we proposed to revise all of the hospital CoPs that emphasized lessening Federal regulations to eliminate unnecessary

structural and process requirements, to focus on outcomes of care, to allow greater flexibility to hospitals and practitioners to meet quality standards, and to place a stronger emphasis on QAPI.

Within this newly revised CoP we proposed to establish a QAPI program that encompasses all hospital services and operations. We solicited comments on the QAPI provisions and received overwhelming support for its establishment. There was consensus among, provider, public, professional organizations, accrediting organizations, and the Congress that supported its establishment. The need again arose for a program due to serious concern regarding patient safety and medical errors after publication of the 1999 IOM's report along with the response to the report. These factors led us to set forth this final rule to ensure high quality of care in a safe environment in our nation's hospitals.

#### *1. Effect on Hospitals*

Given the shift to regulatory flexibility, for the most part, we are not prescribing the exact process hospitals must follow to meet the regulatory requirements of the QAPI CoP. However, the following components must be established and maintained in the development of a QAPI program: hospitals will be required to have a QAPI program encompassing all services and operations that focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

Some hospitals may need to revise their existing programs to conform to this regulation; however, we do not believe this CoP will impose a significant economic burden above what hospitals are already doing to meet the current quality assurance CoP.

Currently under § 482.21, hospitals must ensure that there is an effective, hospital-wide quality assurance program to evaluate the provisions of patient care. Under the existing requirement hospitals must have a written plan of implementation, this plan must include all organized services and contractors. The hospital is also required to document appropriate remedial actions to address deficiencies found through the quality assurance program, as well as the outcome of the remedial actions. However, as a hospital's QAPI program matures, we expect that hospitals will be engaging in quality improvement activities in an expanding number of areas as resources are redirected from areas of program success to new areas, but existing improvements are sustained.

This QAPI CoP focuses provider efforts on the actual care delivered to the patient, the performance of the hospital as an organization, and the impact of the treatment furnished by the hospital on the health status of its patients. In developing this CoP, we have included structure and process-oriented requirements only where we believe they are essential to achieving desired patient outcomes or preventing harmful outcomes. This approach is intended to incorporate into our regulations current best practices in well-managed hospitals, relying on each hospital to identify and resolve its performance problems in the most effective and efficient manner possible.

This QAPI CoP is in fact an extension and modification of the existing quality assurance CoP found at § 482.21. We anticipate that hospitals, both large and small, rural and urban, will or already use a variety of data to inform their internal QAPI programs. Some of these data may be measures designed by the hospital itself, while others will be developed through research or by consensus groups or other sources outside the hospital. Thus, the impact will vary according to each hospital's current quality improvement activities and programs. The impact will also vary and is subject in large part to their decision-making, current policies and procedures, and level of compliance with existing quality assurance regulations. It is important to note that due to the flexibility of these provisions, the extent of the economic impact of most of these requirements is dependent upon decisions made by the hospital. We believe that this CoP will minimize the administrative burden on hospital's to comply with detailed Federal requirements. Instead, this QAPI CoP will provide hospitals with more flexibility to determine how best to pursue our shared quality of care objectives in the most cost-effective manner.

We expect hospitals to develop different approaches to compliance based on their varying resources, patient populations and other factors. There are several provisions that will impact the hospital's processes to a greater or lesser degree. Specifically, this CoP does introduce a new concept that the hospital will have to develop an internal error prevention and reduction program to ensure optimum outcomes for its patients.

The requirements of the rule effect current industry practice. Therefore, hospitals with QAPI programs already in place that meet these requirements, at a minimum level if not in whole, may see little increased burden. Hospitals

that do not meet the current QA CoP, may encounter an increased burden in the short-term because resources would have to be devoted to the development of a QAPI program that covers the complexity and scope of the particular hospital's services. Based upon information that we do possess, small and rural hospitals may be the least prepared and may experience an increased burden in implementation of a QAPI program. However, even in the situations where the proposed requirements could result in some immediate costs to an individual hospital (that is, the development and utilization of performance measures to be used in their QAPI program), we believe the changes the hospital would

make would produce real but difficult to estimate long-term economic benefits to the hospital, such as cost-effective performance practices or higher patient satisfaction that could lead to increased business for the hospital. Additionally, as hospitals are encouraged to choose projects that reflect the scope of their services, it will become increasingly difficult to quantify the burden of data collection. As QAPI projects vary within each hospital and amongst all hospitals, so will the quantity of and the time required for data collection. Overall, we believe that the benefits of complying with the QAPI CoP will outweigh any associated burden.

For the sake of quantitative analysis, we have based our figures on all

hospitals having to develop or update their QAPI program. The projected training time for staff is expected to cost an average hospital allocating a group of 10 clinicians with various duties and responsibilities, approximately \$840 based on a average hourly rate of \$28 per hour (3 hours x \$28 per hour x 10 clinicians = \$840). We have proposed 12 hours of training for the QAPI coordinator, which is projected to cost \$360, based on a average salary of \$30 per hour (12 hours x \$30 per hour x 1 coordinator). The total hourly burden for each hospital is projected to be 42 hours (3 hours x 10 staff) and (12 hours x 1 coordinator).

Hours/ Estimated salary/Number of hospitals	Annual burden hours	Annual cost estimate
10 clinicians x 6,069 hospitals x 3 hours x \$28 per hour .....	182,070 .....	\$5,097,960
1 coordinator x 6,069 hospitals x 12 hours x \$30 per hour .....	72,828 .....	2,184,840
Subtotal .....	254,898 .....	7.3 million

We estimate that the burden associated with updating and in some instances, writing the internal policies would be an average of 8 hours annually. If the updating or writing of the internal policies is done by the nurse coordinator, we estimate the cost at \$240 a year (8 hours X 30 per hour). However, we believe that this figure may be much lower, since many hospitals have existing internal quality improvement programs.

Hours/ Estimated salary/ Number of hospitals	Annual cost estimate
1 coordinator x \$30 per hour x 8 hours x 6,069 hos- pitals .....	\$1,456,560

We also note that the following factors may also affect the costs of updating and writing of the internal policies:

- *Additional Staff Costs.* Examples of these costs include— (1) physician or other professional staff reviewing the internal policies; and (2) clerical staff providing typing, printing, or copying support.

- *Staff Training Costs.* Staff may need additional training to write, update or review the hospital's internal policies.

- *Printing and Copying Costs.* These costs are dependent upon the magnitude of the hospital's changes to its internal policies and the number of copies of the policy that are made available to staff.

Policy development is necessary to patient health and safety because the by-laws provide the framework within which all patient care services are furnished. The initial development of the by-laws will take approximately 2.5 hours. Not more than 2 hospitals a year become certified under Medicare and Medicaid.

Requirement	Number of hospitals	Annual hours per hospital	Annual burden hours
Policy Development .....	6,069	8	48,552

  

Hours/Estimated salary/Number of hospitals	Annual burden hours	Annual cost estimate
2.5 hours x 2 hospitals .....	5 .....	.....
5 physicians x .40 hours each x \$65 per hour x 2 hospitals .....	.....	\$260.00
1 clerical x .50 hours x \$6 per hour x 2 hospitals .....	.....	6.00
Subtotals .....	5	266.00

## 2. Effect on Beneficiaries

The Federal Government plays many important roles that affect the quality of healthcare Americans receive. In fact, the Federal Government is the largest purchaser and provider of healthcare services in the United States. Our goal is to improve the care delivered by

providers and purchased on behalf of Federal beneficiaries, and to facilitate hospitals in developing the infrastructure needed to improve their hospital services. The implementation of the QAPI CoP will benefit and protect not only Medicare and Medicaid beneficiaries, but all patients receiving

care in any of the approximately 6,100 Medicare-participating hospitals (that is, short-term, psychiatric, rehabilitation, long-term, children's, and alcohol-drug), including small rural hospitals. We believe the patient will benefit from the hospital establishing a QAPI program, making quality of care and patient safety

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.

*Section 482.21 Condition of Participation: Quality Assessment and Performance Improvement*

This revised section requires the hospital to develop, implement, and maintain an ongoing effective hospital-wide, data driven, QAPI program. The current requirements provided for the operation of an internal quality assurance program to evaluate the provision of patient care. The revised condition further requires hospitals to examine its methods and practices of providing care, identify opportunities to improve its performance, and then take actions that result in higher quality of care and improved safety for hospital patients. We have not prescribed the structures and methods for implementing this requirement and have focused the condition toward the

expected results of the program. This provides flexibility to the hospital, as it is free to develop a creative program that meets the needs of the hospital and reflects the scope of its services. We believe that developing the data systems necessary to implement a QAPI program and internal policies governing the hospitals approach to the development, implementation, maintenance, and evaluation of the QAPI program will impose minimal burden, depending somewhat on the level of compliance with the existing quality assurance requirements. Flexibility is provided to the hospitals to ensure that each program reflects the scope of its services and operations. We believe this requirement provides a performance expectation of hospital's setting their own goals and using information to continuously strive to improve their

performance over time. Given the variability across the hospitals in size and experience and the flexibility provided by the regulation, we believe the burden associated with these requirements governing the approach to the development, implementation, and evaluation of the QAPI program will reflect that diversity. We want to provide flexibility and do not want to be prescriptive in defining hourly parameters; however, we need to quantify the burden § 482.21 associated with this requirement.

We estimate that the burden associated with updating and in some instances, developing a QAPI program would be an average of 80 hours annually (although this figure may be much lower, since many hospitals have existing internal quality improvement programs).

Requirement	Number of hospitals	Annual hours per hospital	Annual burden hours
QAPI Program Development .....	6,069	80	485,520

*Section 482.21(b) Standard: Program Data*

This regulation would require data collection and necessitates staff training

on data collection. Again, we estimate the burden associated with this requirement would vary, depending on the sophistication of the hospital's

quality assurance programs currently in place.

Requirement	Number of personnel per hospital	Annual hours	Number of hospitals	Annual burden
Training .....	10 clinicians .....	3 hours .....	6,069	182,070
	1 coordinator .....	12 hours .....	6,069	72,828
Data Collection and Analysis .....	.....	80 hours .....	6,069	485,520
Subtotal .....	.....	.....		740,418

*Section 482.21(c) Standard: Program Activities*

The current QA CoP requires hospitals to document appropriate remedial actions, and address deficiencies found through its QA program. The new QAPI CoP replaces the existing QA CoP by focusing on the continuous improvement of the hospital as an organization requiring hospitals to track incidents, analyze their causes, and share and implement preventive actions and mechanisms of feedback and learning throughout the facility. We realize it is neither practical nor economically feasible to collect data and analyze all areas, processes, and systems of the hospital. Therefore, we are requiring the hospital's governing body to ensure the priorities set by the QAPI

program are reflective of the hospitals services, ensure quality of care, and protect the safety of the patients. The burden associated with these requirements are captured above in sections 482.21 (a) and (b).

*Section 482.21(d) Standard: Performance Improvement Projects*

This new requirement reflects an interdisciplinary, coordinated approach to performance improvement. The proposed new performance improvement projects requirement sets forth the requirement that each hospital must establish a mechanism that further explores the specific needs identified in the organization's assessment. This mechanism of action is a performance improvement project. These projects demonstrate the hospital's ability to:

identify problems; evaluate and track quality indicators, or other aspects of performance; and implement actions or adopt changes that reflect processes of care and hospital operations. The hospital must be able to document and demonstrate to the SA what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

We believe, that in order to comply with this QA CoP, hospitals, for the most part, are already documenting their efforts as remedial actions. Nevertheless, we are estimating the QAPI coordinators document the projects being conducted, the reason for the projects, and the measurable progress on these projects.

Requirement	Number of personnel per hospital	Annual hours per hospital	Number of hospitals	Annual hours
PIP Documentation .....	Coordinator .....	32 hours .....	6,069	194,208
Subtotal .....	.....	.....		194,208

*Section 482.21(e) Standard: Executive Responsibilities*

The participating hospitals must have in writing by-laws governing the medical staff and the governing body. This incorporation of executive responsibilities pertaining to QAPI would be a one-time development by an administrative team consisting of medical staff or an appointed committee of 5 physicians and one clerical personnel. We are not associating burden with this requirement, as by-laws should be updated regularly as a normal function of the hospital. This requirement is necessary to patient health and safety because the by-laws provide the framework within which all patient care services are furnished. The initial development of the by-laws will take approximately 2.5 hours. Not more than 2 hospitals a year become certified under Medicare and Medicaid. Therefore, since this requirement impacts less than 10 hospitals on an annual basis this requirement is exempt from the PRA.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements in § 482.21.

If you have any comments on any of the information collection and record keeping requirements, please mail the original and three copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Information Services, Standards and Security Group Division of CMS Enterprise, Standards Room N2-14-26, 7500 Security Blvd., Baltimore, Maryland 21244-1850, *Attention:* John Burke CMS-3050-F; and

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, *Attention:* Brenda Aguilar, CMS Desk Officer CMS-3050-F.

**List of Subjects in 42 CFR Part 482**

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons stated in the preamble of this final rule, 42 CFR chapter IV is amended as set forth below:

**PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS**

1. The authority citation for part 482 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

**Subpart C—Basic Hospital Functions**

2. In § 482.21 the heading and text are revised to read as follows:

**§ 482.21 Condition of participation: Quality assessment and performance improvement program.**

The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

(2) The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.

(b) *Standard: Program data.* (1) The program must incorporate quality indicator data including patient care data, and other relevant data, for example, information submitted to, or received from, the hospital's Quality Improvement Organization.

(2) The hospital must use the data collected to—

(i) Monitor the effectiveness and safety of services and quality of care; and

(ii) Identify opportunities for improvement and changes that will lead to improvement.

(3) The frequency and detail of data collection must be specified by the hospital's governing body.

(c) *Standard: Program activities.* (1) The hospital must set priorities for its performance improvement activities that—

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital.

(3) The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital must measure its success, and track performance to ensure that improvements are sustained.

(d) *Standard: Performance improvement projects.* As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.

(1) The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.

(2) A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of development, does not need to demonstrate measurable improvement in indicators related to health outcomes.

(3) The hospital must document what quality improvement projects are being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(4) A hospital is not required to participate in a QIO cooperative project, but its own projects are required to be of comparable effort.

(e) *Standard: Executive responsibilities.* The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for

operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.

(2) That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.

(5) That the determination of the number of distinct improvement projects is conducted annually.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93778, Medical Assistance)

Dated: March 28, 2002.

**Thomas A. Scully,**

*Administrator, Centers for Medicare & Medicaid Services.*

Dated: September 23, 2002.

**Tommy G. Thompson,**

*Secretary.*

[FR Doc. 03-1293 Filed 1-23-03; 8:45 am]

**BILLING CODE 4120-01-P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 2, 21 and 101

[ET Docket No. 00-258; FCC 02-304]

#### Advanced Wireless Services

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This document allocates spectrum for advanced services in the 1710-1755 MHz, 2110-2150-MHz, and 2150-2155 MHz bands. The goal of this document is to promote the provision of advanced wireless services to the public, which supports the Commission's obligations under section 706 of the 1996 Telecommunication Act.

**DATES:** Effective February 24, 2003.

**FOR FURTHER INFORMATION CONTACT:** Jamison Prime, Office of Engineering and Technology, (202) 418-7474.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's *Second*

*Report and Order*, ET Docket No. 00-258, FCC 02-304, adopted November 7, 2002, and released November 15, 2002. The full text of this document is available for inspection and copying during regular business hours in the FCC Reference Center (Room CY-A257), 445 12th Street, SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Qualex International, 445 12th Street, SW., Room, CY-B402, Washington, DC 20554. The full text may also be downloaded at: <http://www.fcc.gov>. Alternative formats are available to persons with disabilities by contacting Brian Millin at (202) 418-7426 or TTY (202) 418-7365.

#### Summary of the Second Report and Order

1. This *Second Report and Order* allocated 90 MHz of spectrum in the 1710-1755 MHz and 2110-2155 MHz bands that can be used for Advanced Wireless Service (AWS). This spectrum comes from bands that the Commission previously identified as candidate bands for the provision of AWS, and includes spectrum used by Federal government entities that is slated for transfer to non-Federal government use, spectrum currently used by fixed microwave services and designated for emerging technologies, and spectrum currently used by the Multipoint Distribution Service (MDS).

#### Spectrum for AWS

2. 1710-1755 MHz—The 1710-1755 MHz band was initially identified in 1995 for transfer from Federal government use to mixed Federal government/non-Federal government use. At that time, National Telecommunications Information Administration (NTIA) determined that this band could be made available to non-Federal government users in 2004. NTIA also identified certain incumbent Federal government facilities that may continue to operate in the band and must be protected from interference. In its *2002 Viability Assessment*, NTIA outlined additional steps for reaccommodating existing Federal government users in the band segment, including some that have a right to remain in the band indefinitely. The NTIA plan offered a mechanism that could largely clear the band of Federal government users no later than December 31, 2008.

3. Commenters note that the 1710-1755 MHz band enjoys many characteristics that make it suitable for AWS. They note it is already being used in many countries for 2G-style wireless

services so it is likely to promote global spectrum harmonization in the long term, which in turn will foster roaming, and economies of scale that can translate into lower development costs and manufacturing efficiencies. They further state that this band can also help ensure that United States residents enjoy the same level of advanced services as in other countries. The parties observe that the 1710-1755 MHz band is slated to be made available for non-Federal Government commercial use, and that the *2002 Viability Assessment* offers a plan that can make the band even more useful for AWS. Catholic Television Network also states that the band "offers better propagation characteristics," than other bands under consideration. We also note that the band size—45 megahertz would provide flexibility to accommodate a variety of channelization plans.

4. We find that it serves the public interest to allocate the 1710-1755 MHz band segment for mobile and fixed services on a co-primary basis contingent on its becoming available for non-Federal government mixed use January 1, 2004. In addition, we are removing the fixed and mobile allocations from the Federal government Table in the 1710-1755 MHz band, except as specified in the new United States footnote US378, which codifies Federal government residual rights. We also retain and modify footnote US311 in the Table of Frequency Allocations. This footnote identifies certain pre-existing radio astronomy activities that exist between 1718.8 MHz and 1722.2 MHz at observatories set forth in Appendix F of the *Notice of Proposed Rule Making* (NPRM) 66 FR 7438, January 23, 2001. Because radio astronomy facilities in this band operate on an unprotected basis, we conclude that it is not necessary to add rules setting forth coordination procedures and exclusion zones, as the National Academies of Science (NAS) suggests. The footnote, modified to update the list of radio astronomy facilities, will serve to apprise parties of these operations.

5. 2110-2150/2150-2155 MHz—Currently, the 2110-2150 band is used in the United States primarily for non-Federal Government fixed and mobile services licensed under the Fixed Microwave Service in part 101 of the rules, the Public Mobile Services under part 22 of the rules, and the Domestic Public Fixed Radio Services under part 21 of the rules. Federal government use of this band is generally on a secondary basis and is limited to space research earth stations for earth-to-space transmissions in the 2110-2120 MHz portion of the band. The Commission