

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