

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