

improvement programs. One commenter stated support for our interpretation of congressional intent to implement quality assessment and performance improvement (QAPI) programs in RHCs. Another commenter was in favor of replacing the current "annual evaluation" process, stating that the current process is of little value.

*Response:* We appreciate the supportive comments. Our revised quality requirements in § 491.11 are directed at improving outcomes of care and satisfaction for patients while eliminating unnecessary procedural requirements. A QAPI program must be based on a continuous, proactive approach to both managing the RHC and improving outcomes of care and patient satisfaction. As stated in section II. E of this preamble discussion, the BBA requirement, the new QAPI standard will replace the current program evaluation condition for certification at § 491.11.

*Comment:* Many commenters stated that the requirement, as proposed, is too burdensome and would be counterproductive for clinics with limited staff and resources. They stated the clinics do not have the resources to carry out the volume of evaluation proposed. Further, some commenters stated that a QAPI program would increase the cost to deliver care at a rural health clinic. One commenter suggested a pilot program in provider-based facilities that can be later expanded to independent clinics with a cost allowance. Also, two commenters suggested a phase-in period be considered.

*Response:* There are two distinct steps to a QAPI program. The first step is to compare care delivered against an identified standard for a particular type of health care provider or delivery system. The second step is to correct or improve processes of care and clinic operations that are predictive of improved outcomes of care or actual care outcomes. Currently, RHCs are required to carry out or arrange for an annual evaluation or assessment of their total program, take necessary actions to correct remedial problems, review policies and guidelines for medical management of health problems, and review the utilization of clinic services. Currently, resources that are allocated to the annual program evaluation can be used to comply with the new QAPI requirement.

We anticipate that both large and small RHCs will use a variety of performance measures in their QAPI program. These measures may be designed by the clinic itself or by other sources outside the clinic. We are

clarifying proposed § 491.11(b)(3) to state that the RHC will determine the number and frequency of distinct improvement projects it will conduct. The QAPI program could result in some immediate costs to an individual clinic. However, we believe that the QAPI program will result in real, but difficult to estimate, long-term economic benefits to the clinics (such as cost-effective performance practices or higher patient satisfaction that could lead to increased business for the clinic).

We disagree with a phase-in or pilot approach for the QAPI program. Clinics are currently performing, at a minimum, the evaluation or assessment portion of the new standard. The final rule will change the focus in performing the evaluations. Instead of focusing on the processes, we want clinics to focus on improving outcomes and patient satisfaction. Rather than making remedial changes (fixing problems once they occur), we prefer clinics to continuously improve the quality of care they provide. We expect a clinic's assessments to be based on objective data or information that will enable them to assess if changes are needed and to subsequently evaluate the effectiveness of the changes or interventions. Striving to improve care that is given must be the number one priority in delivering care for any provider. As currently permitted in existing § 491.11 for annual evaluation, clinics will be free to arrange for or to solicit outside assistance with their QAPI efforts.

*Comment:* A few commenters stated many RHCs already have quality assurance programs in place and those current programs should be considered for content and value. To eliminate duplication for provider-based clinics, several commenters recommended that we should accept QAPI programs designed to meet the requirement of an accrediting agency (that is, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)) as meeting the minimum level of effort required by the proposed rule.

*Response:* There are no accrediting organizations that have been approved and granted deemed status for RHCs. Any assertion that RHC meet the QAPI requirements of any accrediting body does not substitute for onsite inspection by State survey agencies to ensure compliance with the Medicare requirements. We believe that the standards in § 491.11 are very basic to any QAPI program. For example, JCAHO's accreditation process for ambulatory care providers requires measurement in areas of clinical effectiveness, access to care, and patient

satisfaction. All of these areas are under the umbrella of "organizational processes, functions and services" areas in which we require clinics to perform a self-assessment and improve performances. If a clinic currently has a QAPI program that addresses the requirements of this final rule, we do not see a need to require a clinic to duplicate its quality activities. To the extent that clinics are currently evaluating their processes, functions and services, they will be better prepared to comply with our QAPI rule. We expect RHCs that have no experience with QAPI programs to take advantage of the resources that are available. RHCs are encouraged to explore a variety of resources so that they can become familiar with the variety of approaches that exist to develop a QAPI program. An RHC that chooses to implement the QAPI resources (that is, model QAPI programs) provided by the Department and other on-line resources mentioned elsewhere in this regulation will be considered to meet the QAPI CfC provided that the model program chosen is one that is relevant to the RHC and its patient population.

*Comment:* One commenter stated that because of the physician credentialing process, board oversight process, State sentinel event laws, and malpractice suits, there is very little need for more quality assessment regulations from us. A few commenters stated that the introduction of the issue of specific attention to medical errors is troublesome in that there appears to be no legislative requirement for this specific area. These commenters believe that medical errors should not be addressed or required in the QAPI requirement. Another commenter stated that the responsibility for medical errors should be left to each State's licensing authority.

*Response:* While we agree that credentialing, oversight, and the reporting of sentinel events are fundamental activities that occur and are required on a State level, we disagree that these activities, or malpractice suits, negate the requirement for RHCs to have a QAPI program. The focus of any QAPI is to improve outcomes and patient care without being prompted by negative activities such as sentinel events or lawsuits. In fact, the prevention of the occurrences must be considered by the clinic when developing its QAPI strategy.

In the 1999 report entitled "To Err is Human: Building a Safer Health System," the Institute of Medicine (IOM) of the National Academy of