

Sciences discussed medical errors as one of the nation's leading causes of death and injury. The report estimated that more people die from medical errors each year than from highway accidents, breast cancer, or autoimmune deficiency syndrome. The Administration called for increased awareness and accountability in America's health care system. Further, the Secretary may impose requirements on providers if they are found necessary in the interest of the health and safety of the individuals who receive services from the providers. We believe it is appropriate to include a discussion on medical errors in the preamble language for the QAPI standards. In lieu of proposing a specific standard requiring RHCs to track and analyze medical errors, we believe that errors and the potential for errors will be detected and resolved through the clinic's QAPI activities.

*Comment:* Several commenters expressed caution about the elimination of structure and process criteria in favor of outcome measures. They stated that quality of care is a function, as well as a result of all three of the domains (clinical effectiveness, access to care, and patient satisfaction) in the proposed rule. One commenter further stated that there is insufficient evidence and experience to support a comprehensive shift solely to outcome standards. They also stated that care involving low-volume and high-risk procedures should also be a focus of assessment and improvement as needed.

Also, several commenters stated that the QAPI requirement provides very little flexibility and seems to require that improvement projects be done in all clinical and nonclinical areas annually on the basis of performance criteria that have yet to be determined.

*Response:* The fundamental purpose of the QAPI requirement is to set a clear expectation that RHCs must take a proactive approach to improve their performance and focus on outcomes of care. This does not eliminate the need for improving structures and processes that are indicative of improving outcomes.

However, after further consideration, in response to the commenters' concerns, we have removed, in this final rule, reference to the specific domains: access to care, patient satisfaction, and clinical effectiveness. While the domains are critical areas in which a clinic must evaluate its performance, the final rule allows clinics the flexibility to identify their own areas to address. RHCs are required to use objective measures to analyze organizational processes, functions, and

services annually. RHCs are required to develop, implement, maintain, and evaluate an on-going self-assessment of the quality and appropriateness of care provided through their data-driven QAPI program. We do not intend and are not in a position to judge the measures themselves; instead, we will assess their utility for the clinic in its own efforts to improve its performance.

We also believe that it is critically important that RHCs identify opportunities to improve and expand the use of information technology (IT) 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 (such as, computerized patient records). We encourage RHCs, as they assess their organizational processes, functions, and services, to identify opportunities and make use of information technologies. We believe that the effective use of IT systems could prove invaluable to improving the quality and safety of patient care over time. We will allow RHCs to undertake programs of investment and development of IT systems that are designed to result in improvements in patient safety and quality of care as an alternative to performance improvement projects (see § 491.11(b)(5)). In recognition of the time and resources required to develop and implement these IT programs, we would not require that associated activities have a demonstrable benefit in their initial stages, but would expect that quality improvement goals and their achievement would be incorporated in the plans for these programs. We believe that this modification demonstrates this Administration's deep commitment to patients, high quality care, and flexibility to our partners.

*Comment:* Several commenters stated that quality assurance programs should be applied to all clinics that provide care to Medicare and Medicaid beneficiaries, not just those in underserved areas.

*Response:* We agree that all providers must have an effective quality assurance program. The purpose of this final rule is to implement requirements for RHCs as required by the BBA. We plan to systematically update regulations for all Medicare and Medicaid providers to require quality assessment and performance programs. We have already required quality assessment and performance programs for certain Medicare providers.

*Comment:* Several commenters stated that the proposed rule grossly

underestimated the time required to implement the data requirements mandated by the QAPI program. Commenters further stated that it would take approximately 70 to 80 hours per year for an RHC to maintain this program. Commenters requested we minimize the data requirement in light of limited staff time.

*Response:* Under the Paperwork Reduction Act of 1995, we are required to provide notice and solicit comment before a collection of information requirement is submitted to OMB. In that proposed rule, under section III of that preamble, Collection of Information Requirements, we estimated that it would take each clinic a total of 1 hour per year to maintain the data required by the QAPI requirement. This estimation does not include the time it will take to collect and analyze data or perform the activities for the program. The hour is an estimation of the time it will take a member of the clinic's staff to store or file the documentation of the QAPI program activities. RHC resources that are currently used to comply with existing annual program evaluation can be used to comply with the new QAPI requirement. We have not established a specific amount of data to be collected. The minimum data, or information, required is that which will enable a clinic, with its available staff and resources, to assess change or improvement.

This QAPI CoP will replace the existing program evaluation CoP found at § 491.11. RHCs are currently required to perform an annual program evaluation and the burden reported for the annual evaluation will be used in the new QAPI requirement. We agree that the PRA collection (0938-0334) should be updated to increase burden for RHCs to develop a QAPI program and train staff. The estimation of 70 to 80 hours to maintain a QAPI program may be realistic for the clinic that commented. However, it is difficult to accurately state the impact of the QAPI requirement on RHCs without knowing the size and scope of the clinics and how complex the QAPI program will be for each clinic. We have developed this requirement with the flexibility that allows both large and small clinics to develop a program that reflects the resources and complexity of each clinic's organization and services.

We estimate that on average it will take a clinic approximately 40 hours to develop a QAPI program. For those clinics that are provider based and have experience with the QAPI process, this time will be reduced. This time will also vary based on the simplicity or complexity of the program that a clinic