

develops. The QAPI CfC will replace the existing annual program evaluation CfC (42 CFR 491.11). The activities that are currently covered by the existing PRA on file with OMB are found in § 491.9—“Provisions of Services.” These activities include—Patient care policies; guidelines for medical management of health care problems; and procedures to review and evaluate services furnished by the RHC. In the existing PRA for the current regulations, the burden hours for provisions of services include 10 hours (one time) for initial development, and 2 hours annually for review and revision. The next time we update its PRA submission for Part 491, we will add the 10 hours and 2 hours with the 40-hour initial burden for the QAPI program. We used the previous burden estimate for the annual

evaluation, in part, to estimate the new QAPI requirement. 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. In developing the requirement, we wanted to assure flexibility for RHCs so that both large and small clinics can develop a program that reflects the resources and complexity of each clinic's organization and services. We estimate it will take a clinic approximately 40 hours to develop a QAPI program from a variety of assumptions. First, the hospital QAPI condition of participation estimates 80 hours for a hospital to develop the program. We expect that at the level-of-effort for a RHC would be less than that for a hospital QAPI program as hospitals

provide more services than RHCs. For hospital provider-based clinics, we expect that they would already have experience with the QAPI process. Therefore, their level-of-effort would be reduced. The 40-hour time estimate also recognizes that the time will vary based on the simplicity or complexity of the program that a clinic develops. We also estimate that the RHC will spend an additional 4 hours a year collecting and analyzing data. In addition, we estimate that clinics will spend 3 hours a year training and or updating staff on their QAPI program. Since the QAPI program will replace the current annual evaluation requirement, the administrative burden and annual review of policies and procedures are currently covered by 0938–0334.

Requirement	Annual burden hours	One-time burden hours
Program Development	40 hrs × 3,300 = 132,000
Data Collection and Analysis	13,200	
Training		3 hrs × 3,300 = 9,000
Total	13,200	141,000

These are preliminary projections that may change slightly as we update the PRA submission.

Comment: Most of the commenters recommended that, rather than requiring a minimum number of QAPI projects, we require RHCs to demonstrate to the survey agency what projects they are doing and what progress is being achieved. Some commenters suggested requiring two projects annually, while others suggested only one project annually. Another commenter stated that the minimum level should be defined as requiring the RHCs to choose a single domain in which to undertake an evaluation and to perform a single performance improvement project within that selected domain on an annual basis. Still, other commenters stated that the rule should include specific and limited definition of minimal expectations of the QAPI program, particularly for the smaller clinics. Several commenters wanted clarification on how our expectation that the use of performance measures will be commensurate with the size and resources available to the clinic.

Response: We appreciate the comments regarding what must be the minimum expectation for the quality standard. We believe it is important to allow RHCs the flexibility to fulfill this requirement in a variety of ways. As

evidenced by the variance in the comments received, clinics have different views regarding the manner in which a clinic must comply with the standard. Each clinic will approach this requirement differently based on its resources and orientation to performance improvement.

The final rule does not require a specific number of improvement projects to be conducted annually. However, we will require that an RHC conduct distinct improvement projects. The number and frequency of distinct improvement projects to be conducted by the clinic as a result of its self-assessment must reflect the level and complexity of the clinic's organization and services. While large provider-based clinics might be involved in a complex QAPI program with its host facility, small independent clinics might develop very simple straightforward mechanisms to evaluate and improve their performance. The QAPI standard is the same for both large and small clinics but it can be fulfilled in a number of ways. We do not expect or insist that very small independent clinics develop a complex program. In both instances, we expect clinics to be proactive in assessing and improving outcomes and patient satisfaction.

Comment: One commenter stated that proposed § 491.11(a)(2) and (a)(3) are misplaced and inappropriate as

regulation. They recommended that these instructions be included in the interpretive guidance for surveyors. They further suggested that we replace “and” with “or” and remove the “at a minimum” statement.

Response: We agree with replacing “and” with “or” and removing the “at a minimum” statement and have done so in the final rule.

We disagree that proposed § 491.11(a)(2) and (a)(3) are misplaced and inappropriate for regulation. However, we have made minor clarifying changes to these provisions. Since we allow flexibility in areas of performance measures and the number and frequency of improvement projects, we maintain that it is important to state in the QAPI standards that RHCs are expected to prioritize their improvement activities that most directly affect patient safety and clinical outcomes. Therefore, we have combined the provisions of proposed § 491.11(a)(2) and (a)(3) and included them at § 491.11(b)(2) under the program activities standard.

In section II of the preamble, page 10459, of the February 28, 2000 proposed rule, we included a discussion clarifying how we would apply the term “measure” as it pertains to the QAPI requirement for RHCs. We defined the word “measure” to mean that the RHC would have to use objective means of