

organizational processes, functions and services, while still being held accountable for results. This decision allows clinics the flexibility to fulfill this requirement based on their resources.

Conclusion

We do not expect a significant change in the operations of RHCs generally, nor do we believe a substantial number of small entities in the community, including RHCs and a substantial number of small rural hospitals, will be adversely affected by these changes. The commingling provision of this regulation adds little savings. One reason for this conclusion is that the outpatient visit rate for HCPCS code 99214 was about \$59.00 and the RHC visit was also about \$59.00. If an adjustment is made for lower physician overhead than that of the RHC, the savings will probably be marginal.

Therefore, we are not preparing analyses for either the regulatory impact analysis or section 1102(b) of the Act since we believe that this rule will not result in a significant economic impact on a substantial number of small entities and will not have a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the OMB.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment when a collection of information requirement is submitted to the OMB for review and approval. In order to fairly evaluate whether OMB should approve an information collection, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements discussed below.

Section 491.3 Rural Health Clinic (RHC) Procedures

Section 491.3(c)(2) states that an existing RHC located in an area no longer considered a shortage area may apply for an exception from disqualification by submitting a written request to our regional offices within 180 days from the date we notify it that it is no longer located in a shortage area. We believe that this information collection requirement is exempt in accordance with 5 CFR 1320.4(a)(2) since this activity is in accordance with the conduct of an investigation or audit against specific individuals or entities.

Section 491.3(c)(4) states that clinics can renew their essential provider status by submitting written assurances to our regional office that they continue to meet the conditions at § 491.5.

The burden associated with this requirement is the time and effort for the clinic to prepare and submit written assurances that they continue to meet the conditions. It is estimated that this requirement will take each clinic 30 minutes. There are approximately 400 clinics that may be affected by this requirement for a total of 200 burden hours.

Section 491.8 Staffing and Staff Responsibilities

Section 491.8(d)(1) states that we may grant a temporary waiver if the RHC requests a waiver and demonstrates that it has been unable, despite reasonable efforts in the previous 90-day period, to hire a nurse midwife, nurse practitioner, or physician assistant to furnish services at least 50 percent of the time the RHC operates.

The burden associated with this requirement is the time and effort for the RHC to request a waiver and demonstrate that it has been unable to hire a nurse midwife, nurse practitioner, or physician assistant to furnish services at least 50 percent of the time the RHC operates. It is estimated that this requirement will take each RHC 3 hours. There are approximately 45 RHCs that will be affected by this requirement for a total of 135 burden hours.

Section 491.11 Quality Assessment and Performance Improvement

Section 491.11 states that the RHC must develop, implement, evaluate, and maintain an effective, ongoing, data-driven quality assessment and performance improvement program. The self-assessment and performance improvement program must be appropriate for the complexity of the RHC's organization and services and focus on maximizing outcomes by

improving patient safety, quality of care, and patient satisfaction.

Most of the burden of this section is covered by the paperwork requirements of § 491.9(b)(3), patient care policies, which requires the RHCs to have in place a description of services the clinic furnishes, guidelines for management of health problems, and procedures for periodic review and evaluation of clinic services. This burden is approved under 0938–0334 and expires in April, 2003.

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 how simplicity or complexity of the program that a clinic 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 updates its PRA submission for Part 491, we will add the 10 hours and 2 hours with the 40 hr 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