

Comment: One commenter noted that we did not emphasize the importance of pharmacists to quality care. As medication experts, pharmacists can play a significant role in ensuring that appropriate medications are given to patients in RHCs.

Response: We agree that pharmacists play a significant role in ensuring that appropriate medications are given to patients. The focus of the QAPI requirement is for RHCs to have a program to assess its processes, functions and services. If a clinic identifies a medication administration or dispensing problem, or is interested in assessing other quality of care issues, that involves pharmaceutical services, it would be appropriate for the RHC to solicit a pharmacist input into the QAPI activity.

Comment: One commenter stated the current requirements regarding protocols for the mid-level practitioners are restrictive and, in many cases, conflict with scopes of practices permitted in States' law. The commenter believes that midlevels should be allowed to practice to the highest level of scope of practice permitted by State law. This will ensure appropriate care to patients and enhance patient care and satisfaction.

Response: While we appreciate the commenter's concern, this issue is beyond the scope of this final rule.

Comment: Two commenters stated that since § 405.243(a) provides that a Federally Qualified Health Center (FQHC) must agree in its provider agreement with us to maintain compliance with requirements set forth in part 491, it could be read to apply to FQHCs. The commenter requested that we revise the February 2002 proposed rule to specifically state that § 491.11 does not apply to FQHCs stating that it would be duplicative to require FQHCs to meet this QAPI requirement because they are currently required to meet extensive performance standards established by the PHS. Section 330 of the Public Health Service Act requires grantees to undergo a rigorous PHS grant application process and the grantees are answerable to PHS in carrying out their grant activities; it is unnecessary to apply the RHC certification compliance process to FQHCs.

Response: We agree with the commenters that FQHCs currently have a QAPI program, as required under the PHS grant, that is more comprehensive than the requirements for RHCs. FQHCs and other health centers are required to have quality improvement systems to examine topics such as patient satisfaction and access, quality of

clinical care, work force, work environment, and health status outcomes. In addition, FQHCs' quality improvement systems must have the capacity to measure performance using standard performance measures and accepted scientific approaches. In analyzing performance data, FQHCs must compare their results with other comparable providers at the State and national level and set realistic goals for improvement.

Since the BBA language did not specifically include FQHCs, and FQHCs are currently required under the section 330 grantees' program to have a continuous quality improvement and performance measurement program, we agree that it would be redundant to require health centers to comply with this condition. Even though FQHCs are required to comply with part 491 of the regulations, there are instances in part 491, based on statutory requirements, where the RHC requirements are different from the FQHC requirements. For example, FQHCs are allowed to contract for midlevels but as specified in § 491.8(a)(3), RHCs are not. Therefore, FQHCs must continue to comply with part 491 of the regulations except where noted.

IV. Provisions of the Final Rule

For the most part, this final rule incorporates the provisions of the February 28, 2002 proposed rule. However, we are making the following changes to the regulations:

We are revising, in § 405.2401(b), the definition of rural health clinic as follows:

- The definition of RHC only applies to physicians and nonphysician practitioners working for the entity to furnish RHC services.
- Those physicians and nonphysician practitioners may not operate a private Medicare or Medicaid practice during RHC hours of operation, using clinic resources.

We are revising § 405.2462 to eliminate a standard used to qualify RHCs that are based in small rural hospitals for an exception to the national RHC payment limit.

We are revising § 491.3(b)(1) to clarify that both participating RHCs as well as applicants must be located in a current shortage area.

We are revising § 491.3(b)(2) to specify that RHCs with outdated shortage area designations will have 120 days to submit an application to update their medically underserved designation with protection from disqualification while the application is under review.

We are revising § 491.3(c)(2) to increase the period that RHCs may

apply for an exception from disqualification.

We are revising § 491.5(b) to clarify the test used to determine if an RHC is essential to the delivery of primary care.

We are revising § 491.5(b) to establish rural patient utilization thresholds for RHCs located in nonurbanized areas that demonstrate they are essential to the delivery of primary care.

We are revising § 491.5(b) to combine the traditional community provider test with the major community provider test.

We are revising § 491.5(b) to establish a minimum national utilization patient threshold for RHCs applying for an exception as a major community provider.

We are removing the graduate medical education test at proposed § 491.5(b)(5). This test is no longer needed due to the refinements and clarifications we have made to the other essential community provider tests.

We are revising § 491.11 to clarify the requirements of the quality assessment performance improvement program the RHCs must develop, implement, evaluate, and maintain.

V. Regulatory Impact Analysis

Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review) and the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year).

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 to \$25 million or less annually (see 65 FR 69432). For purposes of the RFA, all RHCs are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory