

tracking performance that enables a clinic (and a surveyor) to identify the difference in performance between two points in time. Not all objective measures would have to be shown to be valid and reliable based on scientific methodology in order to be usable in improvement projects. These measures may be designed by the clinic itself or by other sources outside the clinic. We anticipate that both large and small RHCs will use a variety of performance measures in their QAPI program. The proposed standard at § 491.11(b) is now stated in paragraphs (b)(1)(i) and (b)(1)(ii).

In order to promote consistency in the language to describe quality activities, we have replaced the term "performance criteria" in the first sentence of the proposed provision at § 491.11(b) with "performance measures" in § 491(b)(1)(i). We also replaced the word "criteria" in the second sentence of § 491(b) with the word "measures" in § 491(b)(1)(ii).

*Comment:* One commenter recommended that there be requirements for providing preventive health care services. However, a few commenters stated that the issue of prevention should be withdrawn from the rule, unless we would agree to reimburse for preventive services provided.

*Response:* Section 1861(aa)(1)(A) of the Act describes rural health clinic services as physicians' services and those services and supplies covered under section 1861(s)(2)(A) of the Act if they are furnished as an incident to a physician's professional service and items and services described in section 1861(s)(10) of the Act. We agree that there are no requirements for the provision of preventive primary health services for an RHC and stated so in the February 28, 2000 proposed rule. However, since section 1861(s)(10) of the Act allows RHCs to provide pneumococcal, influenza, and hepatitis B vaccines, the topic of prevention was included under clinical effectiveness as an example of an area to evaluate if clinics were involved in these activities.

*Comment:* One commenter stated that availability of personnel to communicate with the patients they serve should be included under cultural competency.

*Response:* We agree that the ability to communicate with the patient population is an important part of cultural competency. However, the list in the February 2000 proposed rule under the "access to care" domain was given as an example and was not meant to be all-inclusive. Clinics will be free

to identify and concentrate on areas that are priorities for them.

*Comment:* One commenter asked if emergency intervention meant that the clinic should have staff trained and competent in the delivery of cardiopulmonary resuscitation (CPR) and other services that might be necessary to maintain a very ill patient until care could be transferred to the emergency medical services system.

*Response:* A clinic is required to provide medical emergency procedures as a first response to common life threatening injuries and acute illnesses. The Emergency Medical Services (EMS) Systems Act defines first response services as a preliminary level of prehospital emergency care that includes CPR, monitoring vital signs and control of bleeding. Therefore, the clinic's staff should be competent in the delivery of first response emergency services.

*Comment:* One commenter stated that the surveyor should not be the only one to determine what constitutes an "identifiable unit of measure."

*Response:* As stated in section II of the preamble of the February 2000 proposed rule, we will not judge the measures themselves. Instead, we will assess how useful the measures are to the clinic in its overall program.

*Comment:* One commenter stated that surveyors should not have the authority to require an RHC to demonstrate what projects they are doing and the progress of the projects. Surveyors should only review and offer suggestions.

*Response:* The authority for surveyors to conduct onsite reviews of RHCs is contained in section 1864(a) of the Act. Surveyors acting on our behalf are expected to interview staff and probe on significant issues to determine if an entity meets RHC qualifications under section 1861(aa) of the Act.

We will develop interpretive guidelines and survey procedures to train surveyors on how to review QAPI program requirements, in addition to all other RHC requirements. As stated above, surveyors will not judge the performance measures but will look at elements that comprise each RHC's QAPI program, such as assessment data, rationale for prioritizing improvement activities, and progress on achieving improvement goals. As part of oversight, we would expect an RHC to make information on its QAPI program available to surveyors during initial certification, routine recertification, and complaint surveys to demonstrate how they meet the requirement.

We have stressed improvement in systems in order to improve processes and patient outcomes. The RHC's QAPI

program will be evaluated for its effectiveness on the quality of care provided. Surveyors will not criticize the performance measures that RHCs choose to use in their QAPI program. Rather, surveyors will look at how well the RHC was able to mount an effective QAPI program. The surveyors will look at what the RHC has identified as an area for improvement, what the clinic did to address those areas of concern and what they are doing to maintain their improvement efforts. We will train surveyors on how to survey for an effective QAPI program. QAPI standards are designed to ensure that the providers have an effective process for continually measuring and improving care. The RHC QAPI supports the flexibility to establish, implement, maintain, and evaluate its individual QAPI program. Each RHC can custom-design a program that analyzes its own organizational processes, functions, and services, while maintaining the appropriate accountability. Performance improvement, as the basis for QAPI, fosters a "blame-free" environment and encourages providers to be proactive instead of being reactive.

*Comment:* One commenter suggested that the rule explicitly state that RHCs include the medical director of the clinic, a health care professional with experience in the delivery of services, or other "reasonable" individuals in determining appropriate measures.

*Response:* In § 491.11(c), we state that the RHC's professional staff, administrative officials, and governing body (if applicable) are responsible for the development, implementation, and evaluation of improvement actions. In addition, the clinic may develop a QAPI program using staff and resources it deems appropriate in accordance with its policies and procedures.

*Comment:* One commenter expressed concern regarding the reporting requirements, especially on small clinics. The commenter stated that small clinics should either be exempt from the proposed requirements or we should develop different standards for large and small clinics.

*Response:* The Congress has mandated that RHCs have a QAPI program as specified by the Secretary of the Department of Health and Human Services. We have not proposed that RHCs report the results of their evaluation and subsequent improvement activities to us. As a result, there is no need for any exemptions. However, as stated in § 491.11(b)(4), we will require a clinic to maintain records on its program and have them available for review by a surveyor.