

managed care final rule, as appropriate. However, in other instances the QISMC standards, which we previously offered to States as guidelines and not requirements, were not appropriate as requirements in the regulations text. Further, the QISMC standards in a number of ways have become outdated. For example, the QISMC document does not sufficiently address individuals with special health care needs. Individuals looking for a cohesive vision of a quality improvement system for Medicaid managed care should look to three documents: (1) The Medicaid managed care final rule, (2) this EQR final rule, and (3) the EQR protocols developed in response to the BBA statutory requirement. The QISMC document has been superseded by these three documents for the purposes of Medicaid. Each of these documents is accompanied by text describing how they should be integrated into State quality improvement systems.

*Comment:* One commenter contended that the proposed rule significantly reduced State flexibility in defining the content and cycle of EQR, exacerbated what the commenter considered a double standard for quality oversight between Medicaid FFS and Medicaid managed care, and placed new requirements on States not previously required of managed care programs. The commenter was concerned that this rule would create another reason to discourage MCOs and potentially PIHPs (especially those that provide behavioral health services) from participating in Medicaid resulting in fewer managed care options for Medicaid agencies and beneficiaries.

*Response:* We do not agree that this regulation significantly reduces State flexibility. EQR is not a new requirement on States. EQR has been a requirement for States contracting with MCOs since section 1902(a)(30)(C) of the Act was enacted in OBRA 1986. The BBA introduced new requirements for EQR and provided parameters we are obligated to follow in developing this regulation. The new requirement in section 1932(c)(2)(A)(iii) of the Act that protocols be developed which must be followed by States necessarily limits State flexibility to some extent. However, we believe that we have provided appropriate flexibility in implementing this statutory requirement. To do this, in collaboration with an expert panel that included State participants, we defined what activities we considered to be essential for an EQR. The statute also requires that EQR be conducted annually. While flexibility as the nature of review under EQR may have been limited somewhat by the

requirement in section 1932(c)(2)(a)(iii) of the Act that protocols be followed, the new rule provides States with substantial new flexibility by allowing an expansion of the types of entities with which States can contract to conduct EQR activities, and extends the 75 percent match rate to these types of entities. In addition, this final rule allows a State to conduct EQR-related activities itself or through other State contractors. Thus, we do not believe that this rule will discourage managed care contracting.

*Comment:* One commenter expressed concern that the rule will limit a State's ability to maintain and improve distinct State quality initiatives due to more extensive Federal quality improvement initiatives. Specifically, the commenter believes the rule would require States to either externalize or duplicate ongoing State quality improvement activities.

*Response:* We do not believe that these EQR requirements will result in a duplication of any ongoing State quality improvement activities. A State may conduct any of the EQR-related activities internally or through other State contractors. The State will need to conduct the activities using our protocols or protocols consistent with ours if the information is to be used as part of the EQR. Therefore, at a minimum, our protocols or protocols consistent with ours must be used for the mandatory activities. As stated earlier, the protocols are generic instructions to ensure that the activities are conducted in a methodologically sound manner. If a State chooses to conduct EQR activities internally or have a State contractor other than the EQRO conduct the activities, the State expenses will be matched at 50 percent. States must contract with an EQRO for only one function, that is for the analysis and evaluation of the aggregated information provided from the EQR activities and the development of the EQR results. States can also continue to conduct other quality initiatives outside of the scope of EQR and claim the 50 percent administrative match.

*Comment:* One commenter contended that the proposed rule exceeded our statutory authority. Specifically, the commenter argued that with this rule, we effectively assumed control of a State's quality assessment and performance improvement strategy by specifying (1) the details of QI activities through detailed protocols developed without input from individual States, and (2) which activities can be performed by a State government entity, and which must be delegated to the EQRO. The commenter recommended

that the proposed rule be withdrawn and redrafted to: (1) Allow for public review and comment of the protocols, and (2) permit States to carry out their statutory responsibilities as reflected in section 1932 (c)(1)(A) of the Act. The commenter also doubted that uniformity of EQR results could be accomplished in light of State programs that demand custom-tailored management and oversight models.

*Response:* We do not agree that we have exceeded our statutory authority in developing this regulation. The statute clearly required us to develop protocols to be used in the external review. We developed the protocols, as mandated, through an independent quality review organization with the guidance of an expert panel that included State representation, as required by the statute. A **Federal Register** notice announcing the completion of the protocols was published on November 23, 2001 (66 FR 58741). In that notice, we asked for comment on the extent to which burdens were imposed by the protocols, or on any other aspect of the protocols. Comments received from that solicitation, and our responses, are included in the preamble to this final rule.

We also believe we have provided significant flexibility to States as to which activities must be performed by an EQRO, as the only activity that must be conducted by the EQRO is the analysis and evaluation of the aggregated information produced from the EQR activities, and production of the results of that review as defined in § 438.364. The State can conduct the mandatory EQR-related activities, or have another State contractor conduct these activities, as long as the State uses our protocols or protocols consistent with ours.

*Comment:* One commenter believed that the EQR activities in the proposed rule were duplicative of the scope of work required in Independent External Evaluations of waivers under section 1915(b) of the Act, and recommended that the proposed rule be withdrawn until we develop a unified, coordinated approach to waiver oversight.

*Response:* The EQR activities in this rule are not duplicative of activities conducted as a part of independent assessments under section 1915(b) of the Act. The independent assessment requirement is a review of a State's mandatory managed care program under the authority of section 1915(b) of the Act. It reviews how adequately a State ensures access to quality services in the mandatory managed care waiver program, and the costs of the waiver program. The unit of analysis of the