

We believe that the EQR mandatory activities can easily be incorporated into existing State quality assessment systems and will not duplicate existing oversight activities. The conduct of EQR and the conduct of EQR-related activities is required as part of the quality strategy under § 438.204 of the Medicaid managed care final rule and MCO quality assessment and performance improvement program requirements under § 438.240 of the Medicaid managed care final rule. Furthermore, we believe that there will not be additional costs incurred by the State to administer and oversee the EQRO contracts since this is already an existing requirement on States and MCOs under OBRA 1986. Because the commenters did not provide us with an alternative methodology to use or evidence to support their statement, we retain the approach taken in the November 23, 2001 **Federal Register** notice on the information collection requirements and in the impact statement in the December 1, 1999 proposed rule.

Comment: One commenter disagreed with our assumption that the implementation of EQR would not have an increased cost to the Federal government. The commenter did not agree that the costs incurred with current EQR activities are representative of costs that would be incurred under the new requirement. The commenter argued that States currently contract with EQROs for a more limited scope of activities.

Response: Our December 1, 1999 proposed rule acknowledged that there is likely to be an increase in Federal expenditures but that we did not anticipate this to be a significant increase. We agree with the commenter that the scope of work may be different under the BBA EQR requirements than it was under the OBRA 1986 requirements. However, we do not believe that the cost difference will be significant and it is likely that there could be a decrease. By expanding the pool of organizations available to conduct EQR, State agencies may be able to negotiate savings. We also hope that additional savings will be realized through opportunities afforded by this rule to coordinate EQR activities with other quality and oversight activities.

As stated in our December 1, 1999 proposed rule, we expect some increase in expenditures since we are applying the EQR requirement to PIHPs. We do not expect this to be a significant increase in expenditures because States already conduct quality review activities on PIHPs and receive a 50 percent FFP. Now States will be able to

qualify for the enhanced 75 percent FFP.

Section 438.352 EQR Protocols—General Comments

Comment: One commenter believes the scope of the protocols could result in excessive burdens and they should be revised.

Response: For several reasons, we do not agree that the scope of the protocols will result in excessive burdens. First, all protocols are based on procedures already in use in the private sector. These protocols, therefore, are consistent with common industry practice in widespread use today. Second, many States and MCOs and PIHPs are already conducting these activities, using methods consistent with or more intensive than the activities and steps found in these protocols. For example, many State agencies are using the CAHPS surveys. The protocols for administering these surveys are consistent with our survey protocol, but much more prescriptive. Similarly, many States are also requiring validation of performance measures or encounter data using approaches consistent with these protocols. Third, the States have the option to use the protocols we developed or protocols consistent with ours. The protocols also include sample worksheets that can be used or modified at the State's discretion. Fourth, we note that States are only required to use three of the nine protocols that we have developed; the other six protocols are developed for optional activities that States can choose to undertake or not, at their discretion. For these reasons, we believe the protocols will not be excessively burdensome, and we retain the scope of the protocols as introduced through the November 23, 2001 **Federal Register** notice.

Comment: One commenter recommended that there be a better explanation of the use and purpose of the protocols.

Response: Section 1932 (c)(2)(iii) of the Act required us, in coordination with NGA, to contract with an independent quality review organization to develop protocols to be used as part of EQR. The purpose of the protocols is to provide EQROs with a set of generic instructions that ensure that EQR activities are conducted using sound methodological principles. To provide ongoing explanation about the use of the protocols, we have created a Web site at <http://www.cms.hhs.gov/medicaid/managedcare/mceqrhmp.asp> that presents the protocols and an explanation of their intended use.

Comment: One commenter recommended that we not base the protocols on Federal or industry guidelines and standards, but that we incorporate these standards by reference.

Response: We disagree with the commenter. We purposefully directed our contractor to develop the protocols following protocols and quality review activities currently used in the managed care and quality oversight industries. We believe it is important to take advantage of the knowledge and experience that exists in the Medicare program and the private sector. Consistency with these approaches will also minimize the burden of complying with the protocols.

Comment: One commenter believes that the activities in this protocol will result in the State agency becoming the accrediting agency for Medicaid managed care, increasing the scope of prescribing and monitoring necessary by the State.

Response: We disagree with the commenter. The purpose of the three mandatory EQR-related activities is to ensure that MCOs and PIHPs are in compliance with §§ 438.204(g) and 438.240 of the Medicaid managed care final rule. However, many States currently conduct these activities. States that do not currently monitor for compliance with quality standards, monitor MCO and PIHP quality improvement projects or require the calculation of performance measures will need to initiate these activities. We believe that monitoring for these activities is consistent with the intent of the BBA EQR statutory provision to ensure that MCOs and PIHPs are providing access to timely and quality services.

Comment: One commenter believes the protocols are very clear in describing what information needs to be collected.

Response: We agree with the commenter and retain the activities and steps in the protocols introduced through the November 23, 2001 **Federal Register** notice.

Comment: One commenter believes that the protocols lack an evidenced-based approach to quality improvement. Another commenter believes that measuring MCO performance should be oriented to empirical performance outcomes and applied against quantifiable baselines and benchmarks rather than determining compliance through document reviews and interviews.

Response: We disagree with the first commenter. As we explained above, these protocols were developed