

Comment: One commenter felt that the EQR-related activities were not clearly defined, and were limited in scope. The proposed language did not appear to the commenter to require the State to provide actual data to the EQRO, only information on the validation of the data. The commenter was concerned that the State could report to the EQRO that the data are valid, without actually providing the data itself.

Response: We do not agree with the commenter that the EQR-related activities are limited in scope. The activities reflect those that States have used existing EQR contractors to conduct in the past. These activities are more fully explained in the protocols that we reference in this final rule. On November 23, 2001, we published a notice in the **Federal Register** announcing the completion of these protocols noting their availability on our website and asking for comment on the extent to which they impose a burden, as well as any other issues the commenters wished to raise. Our protocols clearly define EQR activities, and the steps needed to conduct these activities in a valid and reliable manner. As noted in the preamble of our proposed rule, the full content of the protocols themselves was not included in the proposed rule, and is not included in this final rule because the protocols are more detailed than appropriate for Federal regulations, will need to be revised as the state-of-the-art of quality improvement changes, and States may use other protocols as long as they are consistent with those we developed. The need for the EQRO to have raw data will depend on the activities a State chooses to have its EQRO perform. For the actual conduct of EQR as defined in § 438.320, as well as the mandatory activities, access to raw data will not be needed. If the EQRO conducts all of the mandatory activities, it will be responsible for validating the methodological approach used by the MCO and PIHP for the conduct of performance improvement projects, and the calculation of performance measures. Regardless of who conducts the EQR-related activities, the CMS protocols, or a method consistent with the CMS protocols, must be used, and the information derived from the activity, as specified in § 438.364(a)(1)(i) through paragraph (iv), must then be provided to the EQRO.

Comment: One commenter did not support our decision to make performance improvement projects a mandatory activity, while focused studies are an optional activity. The

commenter expressed concern that performance measures tend to focus on things that are easy to fix, and do not always provide a reliable picture of quality across a broad range of concerns.

Response: As the state-of-the-art of quality assessment and improvement has changed, we have found it more suitable to implement performance improvement projects than focused studies. Focused studies aim to assess the quality of care provided at a point in time, whereas performance improvement projects, in addition to assessing a focused area of care at a point in time, aim to initiate an intervention to improve care over time. In our proposed rule, we discussed the limitations of solely using focused studies, without information from other quality activities, to assess the care provided to all enrollees of a State Medicaid managed care program. It is for these reasons that improvement projects are mandatory while focused studies are optional. We note, however, that States may employ focused studies and use an EQRO to conduct this activity, thus accessing the enhanced 75 percent Federal match under section 1903(a)(3)(C)(ii) of the Act.

In this rule, we provide for a multipronged approach to quality improvement that uses information from three sources: (1) Determination of compliance with standards, (2) validation of performance improvement projects, and (3) validation of performance measures. We believe that this approach will provide for a reliable assessment of the quality, timeliness, and access to care provided to Medicaid beneficiaries by an MCO/PIHP.

Comment: One commenter interpreted the proposed rule to prohibit States and EQROs from conducting focused studies, and to instead require States to perform comprehensive reviews of all areas of the MCO contracts every year. This commenter recommended that we reconsider the scope of annual review, suggesting that a 1 year cycle does not allow sufficient time to procure an EQR contract, conduct and complete EQR activities, and report results on the EQR as specified in this rule. The commenter also recommended that we allow for a multiyear rotational approach to quality measurement and improvement (for example, rotate specified performance measures, focused clinical topic reviews). One commenter similarly believed that 1 year was too short a period of time in which to conduct the activities under § 438.358 (a)(1)(i) and (ii) of the proposed rule. This commenter suggested that this time period instead be left up to the State

agency. Another commenter recommended that we require only that the information used by the EQRO for validation of performance improvement projects be from the most recent review performed within the previous 3 years, rather than requiring a yearly review.

Response: Section 1932(c)(2) of the Act requires an annual external review. In the final rule, we require that there be three sources of information used in this review. First, for performance improvement projects, this final rule requires that there be performance improvement projects underway during the previous 12 months. We understand that an MCO or PIHP may have multiple projects underway at a given time, and these projects may be at various stages of implementation. In response to this comment, we have revised the language under proposed § 438.358(a)(1)(i) (now § 438.358(b)(1)) to clarify that performance improvement projects need to be underway during the preceding 12 months, instead of having been completely performed during the preceding 12 months. Consistent with private sector practices, we therefore would allow States to use a multiyear rotational approach when conducting performance improvement projects and calculating performance measures. Second, for performance measures, the rule requires that one or more measures be reported annually. Finally, as was indicated in our proposed rule, EQR also needs to employ information from a review of structural and operational standards, conducted within the previous 3-year period.

Comment: Many commenters suggested that the list of mandatory activities include an examination of reasons for disenrollment and termination.

Response: Under § 438.358(b)(3) of this final rule, we require a review of MCO and PIHP compliance with State standards, in accordance with the Medicaid managed care final rule. This includes standards for enrollment and disenrollment. The Medicaid managed care final rule includes standards for disenrollments requested by the beneficiary, as well as those requested by the MCO or PIHP. In addition, the Medicaid managed care final rule requires MCO and PIHP compliance with State standards for health information systems. As part of the health system provisions, we require that the State ensure that the MCO or PIHP information system provides information including, but not limited to, utilization rates, grievances, and numbers of appeals and disenrollments. We believe these provisions adequately address the commenter's concern, and