

Comment: One commenter concurred with our requirement that EQR be a multipronged approach which recognizes that none of the activities alone can ensure quality in the complex Medicaid population. One commenter supported the definitions as proposed.

Response: We appreciate that the commenters agreed with our approach to EQR and the proposed definitions. We have retained the multipronged approach to EQR as proposed in the proposed rule.

Comment: One commenter asked that the definition of quality include assessments of structure and process as well as measurements of health and functional outcomes. Several commenters recommended that the definition of quality include both clinical and nonclinical measures of consumer satisfaction and define quality in a way that would be meaningful to people with disabilities. One commenter stated that this definition should address the multifaceted needs of people who have chronic and disabling conditions, for whom there is little likelihood of demonstrable improvement. The commenter recommended that we convene focus groups of consumers, including people with disabilities and families of children with disabilities, to identify how quality should be defined from the consumer's perspective and that the definition should not focus solely on health outcomes. One commenter concurred with the definition of quality as proposed.

Response: We agree with the commenter that the proposed definition of quality did not address situations when beneficiaries have conditions where maintenance or improvement of health outcomes is not likely. We have, therefore, revised the definition to mean the degree to which an MCO or PIHP increases the likelihood of desired health outcomes through the provision of health services that are consistent with current professional knowledge. The revision is consistent with the Institute of Medicine's definition of quality. We do not agree with the remaining recommendations by commenters on how to revise the definition of quality because we think that the commenters' concerns are addressed by other provisions of the regulation. Under § 438.358, we identify three activities that must be conducted to provide information for the EQR. These activities also are required in the Medicaid managed care final rule. They include: (1) The review of compliance with structural and operation standards; (2) the validation of performance

measures;¹ and (3) the validation of performance improvement projects. The optional EQR-related activities are activities that some States currently conduct as part of EQR and we believe are also appropriate to an assessment of quality (such as consumer surveys). We are providing States with the flexibility to determine which, if any, of these optional activities will be included in the EQR and what types of performance measures and performance improvement projects to require of their contracting MCOs and PIHPs. We suggest in the performance improvement project protocol that projects be conducted to address both clinical and nonclinical areas that cover the various categories of beneficiaries and services provided. We also note, as stated in the Medicaid managed care final rule, that EQR is a part of the State's quality strategy, and therefore, States are to provide for the input of Medicaid beneficiaries and other stakeholders in this component of the strategy.

Comment: One commenter suggested amending the definition of EQR to read “* * * quality of health care services furnished or contracted for by each MCO * * *”

Response: We agree with this comment and, as stated previously, have revised the final rule to clarify our intent that the EQR provisions apply to all services received by Medicaid beneficiaries regardless of whether those services are provided by the MCO or PIHP directly or through a subcontract (§ 438.320).

Comment: Several commenters stated that the definition of EQR too narrowly limits the scope of EQR because the definition implies that EQR is primarily concerned with analysis and evaluation of data rather than with collection of data. One of the commenters expressed concern that this would limit the EQRO's ability to identify and bring to the State's attention individual quality of care concerns revealed during data abstraction, or to provide provider-specific feedback on performance measures. The commenter recommended that the rule avoid any reference to “aggregate” information in the definition of EQR. One commenter

recommended that the definition of EQR include the development of aggregated data. Another commenter stated that external review should not be limited to the review of information. The commenter believes the external review of plans should include an on-site review of provider practices and procedures and that data alone are insufficient to evaluate performance.

Response: We do not agree that the definition of EQR limits the scope of EQR. We define EQR as the analysis and evaluation of aggregated information. That aggregated information, according to this rule, must be obtained from activities that are consistent with protocols, as defined in this rule, to ensure that data to be analyzed are collected using sound methods widely used in the industry. For each activity, as specified in § 438.364, the entity conducting the activity must report on the objectives, technical methods of data collection and analysis, a description of the data obtained, and conclusions drawn from each activity. Therefore, as part of these activities, the entity conducting them will need to identify and assess quality of care concerns revealed by the activities. The EQR analysis will incorporate findings from all activities, including the evaluation of MCO or PIHP structure and operations. The findings of the overall analysis will need to include an assessment of the strengths and weakness with respect to quality, timeliness, and access of care, and make recommendations for MCO or PIHP improvement in the EQR results as required under § 438.364. Further, we note that under the BBA statutory provisions, EQR is a review of a Medicaid MCO under contract to the State. EQR of individual providers or provider practices is not provided for in the BBA. We believe that the appropriate unit of analysis of EQR is the MCO and PIHP, not individual practitioners.

C. State Responsibilities (§ 438.350)

This section of the proposed rule set forth the State's responsibilities related to EQR. We proposed that each State agency that contracts with MCOs, PHPs, or other entities that have comprehensive risk contracts must, except as provided in § 438.362, ensure that (1) An annual EQR is performed for these contracting entities by a qualified EQRO; (2) the EQRO has sufficient information to use in performing the review; (3) the information that the State agency provides to the EQRO is obtained through methods consistent with protocols specified by CMS; and (4) the results of the EQR are made

¹ In the Medicaid managed care final rule under § 438.240(c)(2) we permit States to calculate performance measures on the MCO's/PIHP's behalf in place of the MCO/PIHP calculating and reporting performance measures to the State. Under this circumstance, the validation of MCO/PIHP performance measures is not required as a mandatory activity but the State must submit the State-calculated performance measures to the EQRO for the EQR function as specified under § 438.358(b)(2). This issue is addressed later in the preamble in response to a comment.