

available, upon request, to specified groups and to the general public.

Section 1932(c)(2)(A) of the Act requires that each contract with an MCO “provide for an annual (as appropriate) external independent review, conducted by a qualified independent entity

\* \* \*” In this section we interpreted the parenthetical statement (for which there is no explanation in the legislative history) to be a reference to those MCOs that may be exempted from EQR under section 1932(c)(2)(C) of the Act on the basis of “deemed compliance.” We invited comment on other possible interpretations, which are discussed at the end of this section.

*Comment:* One commenter noted they concurred with this section of the rule.

*Response:* We appreciate the commenter’s support for the provisions in this section of the proposed rule and retain the provision that requires the State to ensure that the EQRO has information obtained from EQR-related activities and that the information provided is obtained through methods consistent with the EQR protocols established under § 438.352 in this final rule.

*Comment:* Several commenters asked us for a definition, or the criteria that we will use to determine if State-established protocols are consistent with those developed by us. One of the commenters noted that it would be difficult for all States to follow a single set of protocols because State Medicaid programs vary as to structure, capacity, funding, and governing laws. One commenter asked that we also establish criteria for denominators, numerators, and units of measurement for performance measures. Other commenters concurred with the requirement to use protocols that are “consistent with” rather than “identical to” those developed by us to accommodate the rapidly changing field of quality assessment and improvement.

*Response:* Section 1932(c)(2)(A)(iii) of the Act required the Secretary in coordination with the National Governors Association, to contract with an independent quality review organization to develop protocols to be used in EQR. In planning for the development of the protocols, we had to determine the level of detail to be specified in each of the protocols. Because States have flexibility to choose what aspects of quality to measure and in order to accommodate different methodological approaches to studying quality, we contracted for the development of protocols that specified activities and steps of data collection and analysis that would produce valid and reliable information. These apply

regardless of the data collected or the topics that States choose. Protocols will be considered “consistent” with ours to the extent that they affirmatively address each element specified in § 438.352, including the activities and steps for collecting data. We have revised the regulations under § 438.352(c) to clarify that instead of following “detailed procedures,” the EQR-related activities follow “activities and steps” specified for accurate, valid, and reliable data collection.

*Comment:* One commenter recommended that external review be required every 3 years rather than on an annual basis. The commenter noted that the National Committee for Quality Assurance (NCQA) requires a standard external review every 3 years and believes that this rule and the protocols should not set a standard more stringent than the industry standard.

*Response:* Section 1932(c)(2)(A)(i) of the Act clearly states that contracts “shall provide for an annual (as appropriate) external independent review.” We discuss later in this preamble why the parenthetical was not intended to modify what is otherwise an explicit requirement that EQR be conducted annually. An annual EQR has been a statutory requirement since 1986 under section 1902(a)(30)(C) of the Act. Pub. L. 106–113 made it clear that the provision was being replaced by 1932(c)(2) of the Act. We further note that the EQR described in this rule is very different from the accreditation review performed by NCQA. However, in the monitoring for compliance with the standards protocol that provides accreditation-like data, we only provide that information from a review of compliance with standards be generated every 3 years. This is consistent with the industry standard.

*Comment:* One commenter asked for confirmation that § 438.356(a) allows for EQR for a single MCO or PIHP to be performed by more than one EQRO.

*Response:* We are revising proposed § 438.356(a) to clarify that while we allow a State to contract with different EQROs to conduct EQR and EQR-related activities for a single MCO or PIHP, we believe and continue to require that the final analysis of all the information, as distinguished from the EQR-related activities, be performed by a single EQRO. This provides State flexibility to use different contractors to conduct different activities. Section 438.350 addresses the analysis and evaluation of information derived from mandatory and any optional activities. We believe that a single EQRO should perform this function to ensure that one entity receives all the available information

and draws the overall conclusions about a particular MCO or PIHP. To clarify our intent to require that one EQRO perform the overall analysis (that is, conduct EQR) but that multiple EQROs may conduct EQR-related activities, we revised the language from the proposed rule to (1) remove the reference to “other related activities” in the definition of EQR, (2) add the reference to EQR-related activities to the definition of EQRO at § 438.320, and (3) add the reference to EQR-related activities to § 438.370 which provides for the 75 percent enhanced match. We also revised § 438.356(a) to clarify that States may only contract with one entity for EQR but may contract with multiple entities to conduct EQR-related activities.

*Comment:* One commenter recommended the addition of language allowing States the option to employ alternative quality assessment and improvement methods approved by CMS to substitute for the EQR requirements. The revised language should emphasize the State’s responsibility under section 1932(c)(1)(A) of the Act to develop and implement a quality assessment and performance improvement (QAPI) strategy that includes, but is not restricted to, EQR-related activities. If CMS seeks to define minimum specifications for a State’s QAPI strategy, those specifications should be set out in a proposed rule and subject to public review and comment.

*Response:* Our Medicaid managed care final rule outlined the elements of a State quality strategy, of which EQR is one element. States have the flexibility to determine how to ensure the quality strategy elements are designed and implemented. The public had the opportunity to review and comment on the proposed elements in the Medicaid managed care proposed rule published August 20, 2001 in the **Federal Register** (66 FR 43614). The EQR proposed rule addresses EQR in greater detail than does the managed care final rule, including what activities can be funded under the EQR enhanced matching rate. In this final rule, we describe optional EQR-related activities for which a State can obtain the enhanced Federal match under § 438.370. We believe we have provided States with the flexibility to design their EQR to best meet State needs while at the same time ensuring, through the three mandatory activities, that essential quality activities are conducted.

*Comment:* Several commenters recommended that we require that States coordinate their EQR with the State’s quality strategy established