

under § 438.200 through § 438.204 of the Medicaid managed care rule and that EQR evaluate compliance with standards for quality, timeliness, and access in § 438.206 through § 438.242 of the Medicaid managed care proposed rule.

Response: We agree with the commenter. The Medicaid managed care final rule provides that an annual EQR be one element of a State's quality strategy. The EQR rule provides that information from a review of compliance with structural standards (including quality, timeliness, and access) be used in the EQR. Because of this we believe that the two rules together will require each State to coordinate its EQR with all other components of its State strategy.

Comment: One commenter agreed with our interpretation of the statutory provision requiring an external review annually "as appropriate" as being a reference to the deemed compliance provision. The commenter also suggested that reasons for not conducting a review be expanded to include (1) when the MCO is new and there are no historical records and (2) when the population of the MCO is too small to conduct a particular study.

Response: We disagree that newly contracting MCOs and PIHPs should not be subject to EQR. New MCOs and PIHPs will be required to meet structural standards, and we believe that information about MCO and PIHP compliance with these standards should be subject to EQR. We understand that the calculation of performance measures and the implementation of performance improvement projects require time to complete and may not be available at the time of the EQR. Therefore, while we acknowledge there are mandatory activities for EQR that may not be possible the first year of an MCO's or PIHP's operations, we do not agree that the MCO or PIHP should be entirely exempt from EQR. We also do not agree that small population size should be a reason to exempt an MCO or PIHP from EQR. Rather, the State, or MCO or PIHP if the State permits, should choose a performance improvement topic for which the entity has a sufficient number of enrollees to conduct a valid study.

Comment: Several commenters believe that the "as appropriate" parenthetical allows CMS the discretion to interpret EQR time frames more broadly and to give States discretion to require EQRs less frequently than annually. One commenter suggested that "as appropriate" modifies the word "annual," not "review."

Response: We do not believe that the Congress intended for us or the States to

have discretion to provide for reviews less frequently than annually. As discussed above, section 1932(c)(2) of the Act replaces a statutory requirement for annual review that has applied since 1986. There is no indication in the legislative history that the Congress intended to change this. To the contrary, there is a persuasive alternative explanation for the Congress having inserted the parenthetical language. Section 1932(c) of the Act, unlike section 1902(a)(30)(C) of the Act has exemptions from the EQR requirement. Annual reviews for exempt entities are not appropriate.

Comment: One commenter interpreted the parenthetical to allow States to conduct reviews more frequently, not less frequently. If the EQR identified problems, the EQRO could be authorized to conduct follow-up evaluations, as appropriate, to ensure progress toward compliance.

Response: We do not agree with the commenter's interpretation because we believe that if problems are identified in the reports that the EQRO provides the States, the States can follow-up on any corrective action. Because we were not persuaded by any of the comments received for a different or additional interpretation of the parenthetical "as appropriate," we are retaining in the final rule the interpretation that it refers to "deemed compliance" under section 1932(c)(2)(C) of the Act.

D. External Quality Review Protocols (§ 438.352)

In this section, we proposed that EQR protocols must specify: (1) The data to be gathered, that is, the substantive areas to be covered by the protocol; (2) the sources of the data; (3) detailed procedures to be followed in collecting the data to promote its accuracy, validity, and reliability; (4) the proposed methods for valid analysis and interpretation of the data; and (5) all instructions, guidelines, worksheets and any other documents or tools necessary for implementing the protocol. At the time the proposed rule was published, the protocols were under development. The strategy and timeline for protocol development were undertaken in response to BBA language that directed the Secretary to "contract with an independent quality review organization" to develop the protocols. The contract procurement process and scope of work necessitated that the protocols be completed after publication of the proposed rule. On November 23, 2001, we published a notice in the **Federal Register** (66 FR 58741) announcing the completion of the protocols and asking for comment on

their burden or any other aspect of the protocols. Comments received on the November 23, 2001 **Federal Register** notice are addressed later in this preamble.

In developing the protocols, we instructed our contractor to draw from existing protocols that have been tested for reliability and validity and that have been used in the public and private sectors to conduct reviews of the quality of MCO and PHP services, consistent with current industry practice. We also expressed a preference for protocols that are in the public domain. The principle reason for not including the protocols in our regulation is because quality measurement is a rapidly changing field. The protocols must be revised regularly to reflect the changing state-of-the-art in quality improvement. Protocols developed in the private sector for validation of performance measures and administration of consumer surveys are usually revised annually. The delays inherent in revising regulations would make it difficult to make frequent changes. In addition, the protocols are detailed and lengthy, as they provide optional worksheets and recording documents in addition to the required activities and steps.

We proposed that all activities that provide information for EQR must be undertaken consistent with the protocols. Use of the CMS protocols or others consistent with ours will ensure that the conduct of the activities is methodologically sound, thereby maintaining a standard of quality for the review. However, by requiring protocols that are "consistent," rather than "identical," with those that we specify, we leave the States free to improve their protocols continuously, as the art and science of quality measurement improves.

Comment: One commenter asked that the protocols not pose an undue burden on physicians, clinical, or nonclinical personnel, noting that many physicians contract with more than one MCO and that duplicative information gathering should be avoided.

Response: EQR focuses on the MCO's and PIHP's structure and processes, and their ability to manage access to and provide quality services to Medicaid beneficiaries. The review process is not directed to individual physicians or other clinical or nonclinical personnel. However, it will be necessary for MCOs and PIHPs to request information from providers in order to conduct some of the activities required in this regulation. In recognition of the potential for burden, our request for proposal (RFP) to procure the development of the