

various means, and that mandating this be done through EQR would mean an increase in Federal and State funding for the EQR contract. One commenter believed that the proposed requirement for review of structural and operational standards went beyond the statute's reference to "quality outcomes, and timeliness of, and access to items and services for which the organization is responsible under contract." This commenter recommended that we reevaluate the extent of this review to ensure that it is consistent with the intent of the statute. The commenter further noted that this review was so broad that it would encompass most of the areas currently reviewed by States under their general contract responsibilities.

Response: States are not required to contract with an EQRO to conduct a review of the MCO's or PIHP's compliance with State structural and operational standards. A State can conduct this activity using the CMS protocols or protocols consistent with ours and provide the results of the review to the EQRO. The regular 50 percent administrative FFP match would be available to the State for this activity if it is not conducted by the EQRO. The EQRO will use this information in conjunction with information derived from the other two mandatory activities and any optional EQR-related activities conducted to determine quality of, timeliness of, and access to the quality of care provided by the MCO or PIHP. This final rule provides States with the flexibility to determine which activities it wants to have its EQRO conduct. Although we prescribe mandatory activities, which are consistent with the requirements set forth in the Medicaid managed care final rule, the State does not have to have its EQRO conduct these activities. A State is only required to have an EQRO conduct the analysis and evaluation of the information derived from the activities to determine if an MCO or PIHP is providing access to quality services. We do not believe that the scope of the mandatory activities goes beyond the statutory provisions under section 1932(c) of the Act which require States to have a quality assessment and improvement strategy which includes access standards, and measures to assess care, including grievance procedures and marketing and information standards. Furthermore, the statute requires that States implement monitoring strategies that address the quality and appropriateness of care. We, therefore, retain the review of MCO and

PIHP compliance with State standards as a mandatory activity in our final rule.

Comment: One commenter believed that the intent and usefulness of the proposed language in § 438.358 requiring the EQR to "use information" obtained from the mandatory and optional EQR-related activities was unclear. The commenter recommended changing the language to read "The State or the EQRO shall/must conduct" the EQR-related activities.

Response: Sections 1932(c)(2)(A)(ii) and (iii) of the Act required us to (1) in consultation with States, develop a method to identify qualified entities for the conduct of EQR, and (2) in coordination with the NGA, develop protocols to be used in EQR. In order for us to determine who was qualified to conduct EQR and for us to develop protocols to be used in an EQR we first needed to define EQR. Based on the advice of an expert panel convened under the auspices of the NASHP, the proposed rule, and this final rule, define EQR as the analysis and evaluation by an EQRO of aggregated information. Based on this definition, the expert panel confirmed the types of activities that would produce information as it relates to the quality, timeliness of, and access to care provided to our beneficiaries. These are the mandatory and optional activities found in this section of our rule. To provide consistency with the definition of EQR, and because we do not require that States contract with an EQRO to conduct these activities, we retain the language that an EQR must use information derived from the EQR-related activities in the final rule.

Comment: Many commenters did not agree with our proposal to require that information be used from a review of structural standards every 3 years, and cited the statutory language requiring "an annual * * *" review. Many commenters recommended that all activities be done annually, citing reasons such as the changing status of provider networks, and pressures to control utilization. One commenter claimed that we did not adequately explain our rationale for permitting the use of data and information that may be up to 3 years old. The commenter argued that given the volatility of both the managed care market place and State Medicaid programs, the problems identified in Medicaid managed care systems throughout the country, and the fact that the majority of beneficiaries are children, allowing the use of 3-year-old data was inadequate. The commenter suggested that an evaluation of quality, timeliness, and access to services must

be timely to allow for effective interventions to correct the problems.

Response: Reviews of MCO and PIHP compliance with structural and operational standards are very time consuming and costly. To be consistent with private industry standards, we proposed that information from the review of MCO and PIHP compliance with standards be from the most recent review conducted within the previous 3 years. Both NCQA and JCAHO perform their accreditation reviews once every 3 years. As stated earlier, our rule takes a multipronged approach to quality assessment and improvement. This is one reason why we require the EQR to use information from a minimum of the three mandatory activities to render a decision regarding the quality and timeliness of and beneficiary access to health care services. We believe that this comprehensive approach addresses the commenters' concerns, and that annual reviews for compliance with structural standards is not justified.

H. Nonduplication of Mandatory Activities (§ 438.360)

Proposed § 438.360 provided State agencies, under certain circumstances, the option not to require a review of MCO or PHP compliance with certain structural and operational standards specified in proposed § 438.358(a)(2) if the MCO or PHP is a certified M+C organization with a current Medicare contract, and has been evaluated and approved by us, our contractor, or certain approved accrediting organizations as a part of accreditation for compliance with these standards. The December 1, 1999 proposed rule also provided that a State agency under certain circumstances may similarly avoid duplicate reviews of all mandatory activities (listed in paragraphs (a)(1) and (a)(2) of proposed § 438.358) for any MCO or PHP that serves only individuals who are eligible for both Medicare and Medicaid. Under the December 1, 1999 proposed rule, if the State agency exercises this option, each MCO and PHP must make available to the State agency all reports, findings, and other results of the Medicare quality review or the accreditation survey that is to substitute for the Medicaid review.

Comment: Several commenters supported provisions designed to avoid duplication in the EQR process.

Response: We retain the nonduplication provisions in the final rule while providing clarifying language on their applicability, as discussed in responses to comments below, in order to better explain our intent.