

consistent with protocols and quality review activities currently used in the managed care and quality oversight industries. Further, the protocols addressing performance improvement projects explicitly incorporate provisions addressing the use of clinical and nonclinical evidence in the selection of quality indicators. We agree with the second commenter that MCO and PIHP performance should be oriented towards performance outcomes that are measured against baselines and benchmarks. This is one reason why the information obtained from the validation of performance measures and the validation of performance projects is to be included as part of the EQR function. We also believe however, that a review of the MCO's and PIHP's compliance with State standards is essential for determining whether access to quality and timely services is provided. We believe this information used in conjunction with the information obtained from the validation of performance measures and performance improvement projects provides for both a qualitative and quantitative approach to assessing MCO and PIHP performance.

Comment: One commenter recommended that specific clinical areas (for example, early and periodic screening, diagnosis, and treatment (EPSDT) reporting) be addressed in multiple protocols.

Response: We believe that a variety of both clinical and nonclinical areas of care need to be assessed by the State and MCO or PIHP over time. However, we do not specify in regulation or in our protocols what those specific clinical and nonclinical areas should be because we believe that States should have the discretion to identify priority topics based on their knowledge of the public health priorities in the State, the health care needs of their beneficiaries, and based on discussions with beneficiaries and other stakeholders in the State. If we do decide that it is necessary to identify national priority topics, § 438.240(a)(2) of the Medicaid managed care final rule provides us with the authority to do so in consultation with States and other stakeholders.

Comment: One commenter asked that the protocols reflect our review criteria for children with special needs.

Response: When States require children with special health care needs to enroll in a capitated Medicaid managed care program, they must follow the review criteria provided in the January 19, 2001 State Medicaid Directors' letter. The Medicaid managed care final rule includes standards States must comply with when contracting

with MCOs and PIHPs that enroll Medicaid beneficiaries, including children with special health care needs. These standards address the principles on which the review criteria are based. This protocol does not put forth any new standards, but identifies methods to determine compliance with current standards.

Comment: One commenter suggested that the protocols require the validation of performance measures submitted by MCOs, unless the measures were validated by a reliable entity using comparable standards.

Response: If performance measures are validated by an entity using an approach consistent with our protocol, only the information obtained from that review needs to be provided to the EQRO to be used as part of the EQR function. The review activity itself need not be duplicated. In addition, if the entity qualifies as an EQRO, the State can capture the enhanced 75 percent Federal match.

Comment: One commenter recommended that assessments of quality should include multiple sources of information including audits, certifications of sufficient networks and systems, and other submissions the MCO has provided to the State outside of the review process.

Response: We agree with the commenter that information from multiple sources should be included as part of the EQR. We believe we have accomplished this through the multipronged approach we have provided for in this final rule. The EQR will include information from the validation of performance improvement projects, the validation of performance measures, and a review for compliance with standards that may include plan network adequacy information, service authorization procedures, and other documentation that attests to the structural and operational components of the MCO or PIHP.

B. Protocol for Determining Compliance With Structural and Operational Standards

1. General Comments

Comment: The commenter believes that because we used a combination of private sector protocols in the development of the protocol for compliance with structural and operational standards, our protocol is likely to be more burdensome than that of any one private sector protocol.

Response: We reviewed a number of private sector protocols in the development of the protocol for compliance with structural and

operational standards. We identified those elements common to all and used those as a basis for the protocol. Our protocol is not an additive combination of private sector protocols. Conversely, it is a synthesis or a streamlining of common elements found in multiple private sector protocols. Consequently, we do not believe our protocol is more burdensome than any one private sector protocol.

Comment: One commenter argued that CMS, for Medicare, is changing its onsite review process so this will be less frequent and more targeted. Medicare is also streamlining its review guide and will be reviewing less documentation and including more self-auditing by MCOs. The commenter recommended that we adopt a similar approach.

Response: The process for how this protocol will be used is set forth in this final rule, which contains provision for less frequent monitoring, and under certain circumstances, for the nonduplication of activities conducted under the Medicare program reviews or independent accreditation surveys. Through these regulatory provisions, we believe we have adopted a streamlined approach to quality review, similar to that used by Medicare.

Comment: One commenter is concerned that this protocol requires intensive onsite reviews to determine compliance with the structural and operational standards required in the Medicaid managed care final rule. The commenter believes that to meet the goals of EQR, it is not necessary to include all the areas identified in the monitoring protocol and that States should not be required to use this approach. One commenter believes that the guidance on the onsite review process is prescriptive and it is unlikely that the EQRO will need or use this detailed level of guidance. In general, the commenter believes the protocol is overly detailed and should be simplified to examine major structural and process requirements.

Response: The degree to which the protocol relies upon onsite reviews is consistent with the degree to which onsite review is used by private accrediting bodies. Therefore, we do not believe the onsite review specified in our protocol is too intensive. In the private sector, when an accrediting body has a standard, they monitor for compliance with it through a combination of interview activities and document review. We have followed this private sector approach and intend that all Federal requirements be monitored for compliance. Because the protocol contains only "potential" interview questions and documents for