

“potential” review, States, in using the protocol, will be able to target the reviews as they determine appropriate. We believe the protocol provides an appropriate amount of detail needed to reflect the scope and depth of the quality review activities to be conducted. We note in the protocol that, although the EQR activities must be consistent with the protocol, they need not be identical, thus providing the option for the States to prescribe a less detailed level of activity to the EQRO.

*Comment:* One commenter recommended that documents be obtained in advance and that multiple fact-finding efforts occur over time before conducting the onsite reviews. This allows State staff to be better prepared and is less disruptive for MCO staff.

*Response:* The EQR protocols are designed for use by EQROs which in many circumstances are not likely to be staffed by State personnel. However, State staff conducting compliance reviews may also use the protocols at their discretion. The protocols specify that documents may be obtained in advance, and reviewers, though not directed to do so, are not precluded from performing these activities over time.

*Comment:* One commenter recommended that the protocol include the review of previous monitoring reports and that the MCO's efforts and progress in correcting past problems be noted.

*Response:* We agree with the commenter. Therefore, in the final protocol, we have added that, before the onsite visit, reports on previous reviews and subsequent MCO and PIHP corrective actions be reviewed to identify areas on which the EQRO might need to focus the current monitoring activities.

*Comment:* One commenter recommended that the protocol include a mechanism for the State to prepare and submit oversight findings to the MCO and approaches to follow-up to ensure that corrective action has occurred. The commenter also recommended that every onsite review end with an exit interview to focus the MCO's attention on those areas the State is concerned about and intends to address in the findings and recommendations report.

*Response:* We agree with the commenter that evaluation results need to be reported to the MCO or PIHP. This reporting is common practice upon completion of a performance evaluation and a number of strategies are available for this reporting. We describe four possible alternatives for reporting in the

protocol, but States are not precluded from selecting other alternatives that might include exit interviews with the MCO or PIHP at the conclusion of the onsite review.

*Comment:* One commenter recommended simplifying the compliance scoring system and placing greater emphasis on objective indicators of organizational performance such as performance improvement projects and survey results.

*Response:* We agree that other sources of information may provide information pertaining to MCO/PIHP compliance with the regulatory provisions, and we list some of these sources in the protocol under Activity 5, “Collecting Accessory Information.” In defining regulatory compliance, we have indicated that the State Medicaid agency will need to identify the level of compliance it requires and what rating or scoring system is to be used. In the protocol, we offer examples of common approaches, but because there is no evidence that one scoring system is better than all others, we allow States the discretion to select the scoring system to be used.

*Comment:* One commenter believes that of the four alternatives listed in the protocol for reporting evaluation results to the State Medicaid agency, neither the first nor the fourth alternative is acceptable. The commenter claims the first alternative makes information vital to the review; that is, the reviewers' analysis, unavailable to the State, while the fourth alternative represents a complete delegation of the State's monitoring responsibility to the EQRO.

*Response:* We do not agree with the commenter. In the first alternative, analysis is guaranteed based upon the definition of EQR in this final rule. According to that definition, EQR requires “the analysis and evaluation of aggregated information.” In the fourth alternative, reporting is accomplished based on pre-established State thresholds and guidelines, and therefore does not represent a complete delegation of the State's monitoring responsibility to the EQRO. The four alternatives listed in the protocol are possible scoring strategies; we state in the protocol that other options are available for use by States.

*Comment:* One commenter recommended that States require EQROs to use a standard written reporting tool.

*Response:* We agree with the commenter and have included a sample document and reporting tool (Appendix C, Attachment C of the final protocol) for this purpose. However, we allow States to modify this sample tool or

develop another standard reporting tool, at their discretion.

*Comment:* One commenter noted that many questions are broad and not well written so the nature of the response being sought is unclear. The commenter recommended that the entire section for interviews should be reviewed in the context of whether the EQR rule is being exceeded by the data required during the interviews. Several commenters recommended that the interview section be dramatically shortened by eliminating duplicate questions and by deleting questions whose answers cannot be evaluated against the State's MCO contract specifications or a specific provision in the rule.

*Response:* We do not agree that we should more narrowly construct or abbreviate the interview questions. We have included a range of potential interview questions related to the subject matter of the regulatory provisions for reviewer use in prompting discussion. We expect, in practice, the reviewers will customize the interviews as necessary to clarify issues and confirm document findings. In the protocol, we compiled questions related to the regulatory provisions for each group of interview participants; for example, MCO or PIHP leadership, enrollee services staff. While this format creates some redundancy among the interview groups, we believe it facilitates the interviews by enabling each interview group's questions to stand alone. We also note that it is common practice in private accreditation reviews to ask the same or similar questions of different MCO or PIHP staff and also to review documents to support information obtained from interviews to determine if the information obtained from multiple sources converges and reaffirms the EQROs conclusions.

*Comment:* One commenter believes the protocols are bureaucratic and administratively burdensome and that there is a lack of evidence of the success of this type of process-oriented oversight. The commenter further stated that the level of detail is excessive to ensure conformance with MCO contracts and the BBA rule, and that the purpose is not for an accreditation.

*Response:* The protocols are based upon the common elements found in compliance protocols used by private sector accrediting bodies and the Medicare program. Consequently, we do not believe they are overly bureaucratic, administratively burdensome, or without a sound evidentiary basis. We also have followed the private sector approach in specifying that all standards, in this case the Federal