

this protocol, survey validation is limited to a review of the survey procedures. The validation process does not include collecting survey data anew from respondents to verify their responses.

*Comment:* One commenter believes that beta testing all surveys and the additional questions to members and providers would be time consuming and cost prohibitive.

*Response:* The protocols do not suggest beta testing of all surveys. Instead, they acknowledge the commitment of time and resources and the demands on survey respondents that make such an activity infeasible. The protocol suggests that survey validation be limited to a review of survey procedures.

#### *H. Other Appendices (Attachments to Final Protocols)*

*Comment:* One commenter recommended that we explain the obligations of the State or the EQRO with regard to the documents included in the appendices (for example, what is the role of the documents and how the documents are to be used).

*Response:* With the exception of Appendix Z, ISCA for MCOs and PIHPs, the appendices (Attachments to the final protocols) provide additional guidance to States and EQROs on how to implement the EQR-related activities. The information contained in the appendices (Attachments to the final protocols) are to be used at the discretion of the State or EQRO based on the particular circumstances of the activity being conducted and other means of obtaining needed information.

#### *I. Section 438.360 (Nonduplication of Mandatory Activities)*

*Comment:* One commenter believes the estimates of the time necessary to collect the information under this provision are too low. In addition, the commenter believes that this function needs to be performed by both professional staff and clerical staff and that a blend of the hourly costs should be used to determine the estimated costs.

*Response:* As we stated earlier, because we received several comments indicating that this estimate is low but commenters did not provide us with what they believe the correct estimate to be, we have increased the burden hours by 100 percent to 8 hours. We have taken the commenters recommendation and blended the hourly costs to reflect that both professional and clerical staff will partake in this effort.

#### *J. Section 438.362 (Exemption From EQR)*

No comments were received on this section.

#### *K. Section 438.364 (EQR Results)*

No comments were received on this section.

### **IV. Provisions of the Final Regulation**

For the most part, this final rule adopts the provisions of the December 1, 1999 proposed rule. In response to public comments, we have made clarifying wording changes. Those provisions of this final rule that differ from the provisions of the December 1, 1999 proposed rule follow.

#### *Section 438.310—Basis, Scope, and Applicability*

We have revised this section to reference the applicability of this rule to PIHPs. We have added the reference to PIHPs throughout the rule as appropriate.

#### *Section 438.320—Definitions*

We have revised this section by adding clarifying language to the definitions for the terms “EQR” and “EQRO” and adding a definition for the term “financial relationship.” The definition of EQR has been revised to clarify that this rule applies to the care provided to Medicaid beneficiaries that receive health care services furnished by MCO and PIHP subcontractors as well as MCOs and PIHPs. This definition has also been revised to clarify that EQR-related activities are not considered part of the EQR function. We have revised the definition of EQRO to mean an organization that conducts the EQR function as well as EQR-related activities. EQR-related activities had not previously been included in the EQRO definition. As a result of this clarifying language, how we use the terms EQR, EQR-related activities, and EQRO needed to be changed in several sections of this rule.

#### *Section 438.350—State Responsibilities*

We have revised this section to add clarifying language that the information provided to the EQRO is consistent with the information we require as part the EQR results; for each EQR-related activity that provides information for the EQR, the EQRO must have the objectives of the activity, the methods of data collection and analysis, a description of the data obtained, and the conclusions drawn.

#### *Section 438.352—External Quality Review Protocols*

We have revised this section to add clarifying language at paragraph (c) of this section to explain what we meant by each protocol must specify the “detailed procedures” to be followed in collecting the data to promote its accuracy, validity, and reliability. We have changed the wording of “detailed procedures” to “activities and steps” to be consistent with how the EQR protocols have been designed.

#### *Section 438.354—Qualifications of External Quality Review Organizations*

We have revised this section to add at paragraph (b)(1) that the EQRO must have “demonstrated experience” as well as knowledge of the Medicaid recipients, policies, data systems, and processes; managed care delivery systems, organizations, and financing; quality assessment and improvement methods, and research design and methodology.

We have revised paragraph (c) of this section to require that all EQROs, as opposed to only State entities that qualify as EQROs, may not deliver any health care services to Medicaid beneficiaries, or conduct on the State’s behalf ongoing Medicaid managed care program operations related to the oversight of MCO or PIHP quality of services. This later provision has been revised to apply only to Medicaid managed care operations as opposed to all Medicaid program operations. This provides States the opportunity to contract with a broader group of entities than was provided for in the December 1, 1999 proposed rule.

We have also revised paragraph (c) of this section to add clarifying language to explain how “control” is defined in 48 CFR 19.101. In addition, we have added a provision that prohibits an entity from qualifying as an EQRO if it has a financial relationship with an MCO or PIHP that it will review as an EQRO.

#### *Section 438.356—State Contract Options*

We have revised paragraph (a) of this section to clarify that States may only contract with one entity for EQR alone or EQR and other EQR-related activities, but may contract with multiple entities to conduct additional EQR-related activities.

#### *Section 438.358—Activities Related to External Review*

We have revised this section by adding cross-references to the Medicaid managed care final rule. We have made these cross-references throughout this rule where appropriate. We had not