

alternative forms to accommodate individuals with sight impairments.

Response: We note that we have provided guidance on this issue in the August 2001 proposed Medicaid managed care rule. In the preamble to the August 2001 proposed rule, we indicated that materials should be understandable to enrollees at a fourth to fifth grade reading level, or at another level established by the State agency that adequately reflects the potential population to be enrolled. Materials should use an easily readable typeface, frequent headings, and should provide short, simple explanations of key concepts. Technical or legal language should be avoided whenever possible. We proposed further that enrollment notices as well as informational and instructional materials relating to enrollment take into account the specific needs of enrollees and potential enrollees, including furnishing information in alternative formats for the visually impaired and for individuals with limited reading proficiency. Also, in 1999, we developed and distributed to the State Medicaid agencies and made available to others a guide entitled, "Writing and Designing Print Materials for Beneficiaries: A Guide for State Medicaid Agencies." The guide was produced to assist States and MCOs/PIHPs in the creation of materials appropriate for their Medicaid populations. We believe the guidance that we have provided in the August 2001 proposed rule and through this guide is appropriate and reflects the current state-of-the-art. Because there is no state-of-the-art standard to apply in measuring the adequacy of the MCO's/PIHP's efforts to inform enrollees, we decline to do so in this protocol.

Comment: One commenter recommended that we monitor the States' definition of what constitutes a "significant change" in certain MCO structural and operational features to ensure the State's definition of "significant change" is reasonable and fair to enrollees, and that we provide guidance on what parameters a State can use in setting the definitional standards.

Response: The protocol addresses the extent to which an MCO/PIHP, as opposed to the State, complies with the requirements in the Medicaid managed care final rule. Section 438.10(f)(4) of the Medicaid managed care final rule specifies that the definition of "significant change" is the State's responsibility. It, therefore, would not be appropriate to include in the protocol the monitoring of the State's definition. Monitoring of States occurs through

separate activities conducted by our regional offices. Further, as we stated previously, the protocol is not intended as a mechanism to impose additional quality standards on MCOs/PIHPs or States. Therefore, we do not believe it appropriate to provide guidance in the protocol on what parameters a State can use in setting the definitional standards.

Comment: One commenter noted that the interview questions are good initial probes, but suggested the protocol include additional guidance to more fully probe the MCO's dissemination of enrollee information, and require interviews of providers and enrollees regarding the quality of the informational materials.

Response: We specify in the protocol that reviewers should tailor the interviews as necessary to clarify and confirm document findings. We believe this direction affords the reviewers sufficient flexibility to more fully probe areas as appropriate. Further, we do not believe it is possible, given the diversity among States and MCOs/PIHPs and the scope of the review itself, to include in the list of potential interview questions probes to explore every possible problem or issue that might arise. Provider interviews are time and resource intensive, but because they offer an opportunity to secure additional information regarding MCO/PIHP performance, we have included them as an optional activity if informational needs warrant them and resources permit. We provide for the consideration of enrollee input by including the review of the results of Medicaid beneficiary surveys as accessory information under Activity 5.

Comment: One commenter believes the protocol does not adequately address linguistic issues. The commenter recommended that the review confirm that MCOs collect required language information on enrollees and recognize non-English speakers in all transactions. The commenter suggested further that the protocol include the review of documentation regarding professional translations of written materials, and interviews to assess the quality of the written translations and the MCO's oral interpretation practices and resources.

Response: We believe the protocol does adequately address linguistic issues. In Appendix B (page 79, Attachment B of the final protocol), among the materials to be obtained from the State, we include information on the language(s) that the State Medicaid agency has determined are prevalent in the MCO's/PIHP's geographic service area. On page 85, we direct the reviewer to look at marketing, enrollment and

other informational and instructional materials relating to enrollment, enrollee handbooks, new enrollee materials, statements of enrollee rights, and other written materials routinely prepared for Medicaid enrollees and potential enrollees to determine whether these materials are available in the language(s) that have been identified as prevalent within the MCO/PIHP's particular service area. Further, the Medicaid managed care final rule at § 438.204(b)(2) requires States to identify the primary language spoken by each Medicaid enrollee and provide this information to the MCO/PIHP at the time of enrollment. Finally, we believe requiring EQRO re-review of translated materials is more burdensome than appropriate and therefore have not included it in the protocol.

6. Enrollee-Provider Communication

Comment: One commenter objected to the implication that by contract MCOs may place limits on providers' communication with enrollees about reproductive health services. The commenter recommended that the protocol include document review and interview questions to address whether reproductive health services are provided and whether restrictions are placed on provider communication. The commenter suggested further that for MCOs that exclude any reproductive health services the State monitor enrollee access to the full scope of services. The commenter noted a potential correlation between restricted access to reproductive health care services and poor outcomes in other women's health areas, and recommended the State monitor related health outcomes and comparison of rates to those of MCOs without restrictions.

Response: Appendix B of the protocol (Attachment B of the final protocol) specifies documents for review and interview questions to address whether the MCO/PIHP has any moral or religious objection to providing, reimbursing for, or providing coverage of, a counseling or referral service for a particular Medicaid service or services. This would include reproductive health services. For counseling and referral services the MCO/PIHP does not cover because of moral or religious objections, the Medicaid managed care final rule at § 438.10(f)(6)(xii) specifies that it is the State's responsibility to provide enrollees with information on where and how to obtain the service(s). The protocol is designed to address MCO/PIHP compliance with the BBA regulatory standards. Consequently, State monitoring of enrollee access to