

Medicaid beneficiaries, and that States must regularly monitor and evaluate MCO and PIHP compliance with operational standards.

As noted in earlier responses, we believe the Congress clearly intended States to have the option of avoiding duplicate reviews of MCOs that have been accredited by a national accrediting organization, and we accordingly allow for this in the final rule.

Comment: One commenter recommended that we clarify that States may only eliminate elements of the EQR process, whether mandatory or optional, if components of the M+C evaluation process or private accreditation review are the same as or similar to those of the Medicaid review process. Several commenters felt that this provision should address two concepts: whether the standard or requirement is duplicative, and whether the methodology of the review is duplicative. One commenter asked that we clarify what we mean when we say, under § 438.360(b)(2), that the “* * * methodologies must be * * * established by the State, not CMS.” The commenter noted that it is the State, not CMS, that establishes the standards for the mandatory activity under § 438.358(a)(2) and therefore it is not clear what benchmark we intend to use to determine comparability.

Response: This section of the regulation applies only to mandatory activities as specified in § 438.358(b). Because the optional activities are not required, we do not address optional activities in the nonduplication provisions. As stated earlier, we have clarified the regulations text to better explain that Medicare or accreditation standards must be comparable to those established by the State. We have removed the reference to standards and review procedures needing to be as stringent as those established by CMS because we agree with the commenter, that it is the State, not CMS, that will establish standards to comply with § 438.204 of the Medicaid managed care final rule. As for review methodology, the statute required that we establish protocols to be used in EQR. The protocols we developed include generic activities and steps to be followed to ensure that the EQR activities are conducted in a reliable and valid manner.

Comment: One commenter asked that, because implementation of proposed § 438.360(b)(2)(ii) would depend upon our approval and recognition of private accrediting organizations under § 422.158 as having standards and review procedures as stringent as those

established by Medicare, we move forward to make these later determinations so this provision can be implemented in a timely fashion when these regulations become final.

Response: We have already received and approved applications for M+C deeming from several accrediting organizations: (1) NCQA, (2) JCAHO, and (3) the Accreditation Association for Ambulatory Health Care (AAAHC).

Comment: One commenter was confused about the distinction between proposed § 438.360 and proposed § 438.362, and felt they were redundant. The commenter also objected to our provisions applying to dual eligibles, specifically the State's option of permitting information obtained from performance improvement projects and performance measures specific to dual eligibles to substitute for Medicaid specific information.

Response: We do not agree that § 438.360 and § 438.362, which permit States to exempt an MCO or PIHP from EQR in its entirety, are redundant. However, we agree that proposed § 438.360 was potentially confusing in its use of the word “exempt.” We have revised the language in § 438.360 to clarify that § 438.360 allows States to use the findings of Medicare or accreditation reviews in place of a Medicaid review in order to avoid duplication, but does not exempt MCOs or PIHPs from EQR, as does § 438.362 where it applies. We think that there is a clear distinction between § 438.360 under which analysis and evaluation of information must still be conducted, and § 438.362 under which the MCO or PIHP is exempted from the EQR function. We disagree with the commenter concerning the appropriateness of the dual eligible provision. In the case of dual eligibles, Medicare review necessarily is targeted to the population involved. We therefore believe that Medicaid review could be particularly duplicative in this case.

Comment: One commenter requested that if accreditation is to be used as the basis for exemption, regulations require that the MCO be specifically accredited with respect its Medicaid line of business, and that information from this Medicaid enrollee review be provided to the State.

Response: We do not agree that we should limit the applicability of the nonduplication provisions in § 438.360 to MCOs or PIHPs accredited specifically for their Medicaid product. Most accrediting organizations do not conduct separate reviews for an MCO's or PIHP's Medicaid product. With respect to the commenter's second

point, we do require that the findings of the accreditation be provided to the State and then, in turn, to the EQRO to be used as part of the EQR.

Comment: One commenter urged that we allow for the use of review findings of related “focus studies” of groups that Medicaid serves (for example, the elderly or disabled) which are conducted by other types of certified Medicare organizations.

Response: As long as a focused study is conducted using a methodology consistent with our protocols, and the study population is composed of Medicaid beneficiaries, a State can have its EQRO use the review findings. In addition, if the organization that conducts the focused study is the State's EQRO, the State can obtain the 75 percent enhanced match for its review of these findings.

Comment: One commenter believed that the activities under proposed § 438.358(a)(2) are not the same regardless of the populations served, and specifically that there is a difference when serving individuals with disabilities. To address this concern, the commenter felt that the EQRO must be knowledgeable and sensitive to people with disabilities in order to effectively assess an MCO's compliance with standards.

Response: As specified in § 438.354, an EQRO must meet certain competency requirements, including having staff with knowledge of Medicaid beneficiaries. In addition, our Medicaid managed care final rule requires, under the State's quality strategy, that the State have procedures in place for assessing the quality and appropriateness of care and services furnished to enrollees with special health care needs. This includes individuals with disabilities.

Comment: One commenter recommended that audits conducted by the State licensing organization be coordinated with the EQRO, and that the audit of components conducted by the State licensing organization be “deemed” to have been performed by the contracted EQRO.

Response: States can use their State licensing organization to assess MCO or PIHP compliance with State standards, or perform any of the mandatory or optional EQR-related activities identified in § 438.358. If a State wants to use this information for the EQR, the review must, at a minimum, use our protocols or protocols that are consistent with ours. Thus, there would be no reason to “deem” these reviews to have been performed by the EQRO, other than to claim the 75 percent match that would apply if the EQRO performed these functions. As noted