

Response: We understand that accrediting organizations use different terms to describe the extent to which MCOs or PIHPs meet their standards. However, in this provision of the regulation, we are not requiring that the MCO or PIHP achieve a certain level of accreditation. Rather, we are allowing States to use information gathered in the private accreditation process that is shared with the State to assess compliance. To make this more clear, in response to this comment, we have removed the term “fully accredited” from the regulations text. We also have revised the language of this section in order to make our intent more clear. We now specify that accrediting organizations that have been approved by us for M+C deeming under § 422.158 meet the requirements of this provision.

Comment: Several commenters did not agree with permitting States to avoid mandatory activities by relying upon information gathered from a Medicare or private accreditation review in order to assess MCO compliance with structural and operational standards. Some of these commenters specifically strongly opposed the exemption from mandatory activities when an MCO has a Medicare contract. They believed that activities such as review for the availability of services, establishment of provider networks, enrollee information, confidentiality, and use of practice guidelines all have Medicaid and pediatric components that would not be examined under a Medicare review. If an exemption is allowed, the commenters suggested that additional activities be required to ensure compliance in problem-prone or sensitive areas that reviews by Medicare or private accrediting organizations may not adequately address. One of the commenters recommended that if an MCO is being considered for the exemption, that there must be substantial overlap between the Medicare and Medicaid products in (1) geographic service area, (2) network composition and management, (3) quality management structures and processes, and (4) levels of accreditation. Many commenters suggested that unless our quality review or accreditation has established the quality of the Medicaid provider network and administrative structures, these activities should not be exempted under nonduplication.

Response: The Congress clearly intended that we provide States the option to avoid duplicating review activities conducted for Medicare or by accrediting organizations. We limit the applicability of this provision to the mandatory activity designed to help

States assess structural and operational standards for all MCOs and PIHPs other than those serving only dual eligibles. For the latter, under § 438.360, we also permit States to use this option with respect to the validation of performance measures or the validation of performance improvement projects. We believe proposed § 438.360 generally places sufficient parameters on States that choose to exercise this option.

We retain the provision that permits States to use this option to assess compliance with standards. We note that § 438.207 of the Medicaid managed care final rule requires that MCOs and PIHPs submit documentation to the State of compliance with requirements in the Medicaid managed care final rule that requires MCOs and PIHPs to maintain a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the enrollees in the MCO or PIHP. In addition, § 438.207 requires that any time there has been a significant change in MCO or PIHP operations that would affect adequate capacity, additional documentation must be submitted. We believe this information adequately complements any review of availability of services that would be conducted by Medicare or an accrediting organization that provides information for the EQR.

We are concerned, however, that the wording of proposed § 438.360 has caused some confusion about the intent of this provision. Specifically, our words “A State may exempt an MCO from mandatory activities * * *” may be interpreted by some as exempting an MCO or PIHP from oversight, rather than an exemption from State Medicaid reviews that duplicate Medicare and private accreditation reviews. To clarify this, we have removed the word “exempt” from this provision in the final rule (noting also that the Congress did not use this word in the corresponding statutory provision) and replaced it with language reflecting the fact that these provisions do not exempt MCOs from review for compliance with structural and operational standards, but instead permit States to use information generated through Medicare or private accreditation review to assess compliance with these standards, in lieu of engaging in their own otherwise “mandatory” review activity.

In addition, in response to the commenters’ concerns about permitting States to substitute Medicare or private accreditation review for direct State review, we are adding a new paragraph (4) to § 438.360(b) and (c) requiring that States identify in their qualities strategies those standards and activities

they plan to monitor through the use of Medicare or private accreditation review data, and explain why direct State review would “be duplicative.” This will help ensure that this approach is only taken when State review would truly be needlessly duplicative of review already performed.

Comment: One commenter was concerned that proposed § 438.360 appeared to allow the nonduplication exemptions to last indefinitely, and believed that it was not unusual for plan performance to vary significantly from year to year due to organizational changes. The commenter recommended that States be required to develop mechanisms to periodically re-evaluate MCO compliance with standards during the course of a 3-year period, and to re-institute a direct Medicaid agency review if accreditation, Medicare, or State oversight indicate potential quality problems.

One of the commenters cited recent OIG studies that identified significant issues with accrediting bodies, and did not think that States should relinquish their direct MCO oversight responsibilities to the accreditation industry.

Response: Neither the statutory nor conference committee language discussed any time limit on a State using Medicare or accreditation review data in its assessment of an MCO or PIHP in lieu of a direct Medicaid review. We believe it appropriate to allow States to make the determination as to whether this remains appropriate. We note that the new paragraph (4) that we have added to § 438.360(b) and (c) requires that States explain and justify their use of this approach, and believe that it is appropriate to permit the approach to be used for so long as this justification remains valid. Therefore, we do not specify a time limit in the final rule.

With respect to the commenter’s recommendation for periodic re-evaluation every 3 years, § 438.360 requires that information obtained from a Medicare review or a review by an accrediting organization be provided to the State, which must then provide the information to the EQRO for use in the EQR. Because this information must be obtained from a review of compliance with standards conducted within the past 3 years, this requirement should address the changes in plan performance that the commenter is concerned about. Moreover, the Medicaid managed care final rule requires that States have a quality strategy that has procedures for assessing the quality and appropriateness of care provided to