

*Response:* In the preamble of the proposed rule, we explained that we did not solely rely upon the recommendation that an EQRO should not share management or corporate board membership with the MCO it reviews, because we do not think this criterion is stringent enough to ensure against conflict of interest. Therefore, we incorporated in § 438.354(c)(3)(i), the concepts of “control” in 48 CFR 19.101, which effectively preclude affiliation between the EQRO and the MCO/PIHP under review. Specifically, this means that there can be no control through common management (which includes interlocking management, common facilities, and newly organized concerns) as well as through stock ownership, stock options and convertible debentures, voting trusts, and contractual relationships (which includes joint ventures, that is, procurement and property sale assistance and franchise and license agreements). We retain this provision in our final rule. In order to provide further clarification in § 438.354(c)(3)(i) of the final rule (§ 438.354(c)(3) of the proposed rule), we now specify the different types of control addressed in § 19.101. In determining whether this type of control exists, the details in § 19.101 under each category would apply.

*Comment:* Several commenters recommended strengthening the requirements for EQRO independence from MCOs by revising § 438.354(c)(3) to read as follows: “A private entity may not (1) have managed care licensing authority, including the authority to certify managed care plans in compliance with standards that serve as the basis for deemed certification with Federal or State regulatory standards; (2) deliver any health care or related services to Medicaid recipients for which it is paid by the Medicaid State agency or by a managed care plan. Related services include enrollment services, grievance resolution, external review of health care coverage decisions, or other similar activities; (3) conduct, on the State’s behalf, any other ongoing Medicaid program operations related to oversight of the quality of MCO services; and (4) have financial interest that would prevent it from exercising independent judgement when engaging in EQRO activities.” The commenters also suggested adding a new § 438.354(c)(4) providing that “a private entity must be governed by a board or similar body, the majority of whose members are not MCO employees.” Another commenter did not agree with the provision that

prohibits an organization from performing EQR if it also conducts ongoing Medicaid program operations related to quality, arguing it could be less expensive to use a single contractor to perform multiple functions. One of the commenters found the definition of control in 48 CFR 19.101 a useful concept, but felt that it has little relevance to the potential organizational relationships between EQROs and MCOs in the Medicaid program.

*Response:* The independence criteria set forth in the proposed rule did not address those private organizations that provide health care services to Medicaid beneficiaries or that conduct ongoing Medicaid program operations related to quality. We agree with the commenters that organizations performing these functions have a conflict of interest. Therefore, in response to this comment, we are revising § 438.354(c)(3)(ii) in this final rule to preclude private organizations, as well as State entities, that provide health care services to Medicaid beneficiaries from qualifying as EQROs. We also are revising § 438.354(c)(3)(iii) to preclude private organizations as well as State entities, that conduct ongoing Medicaid managed care operations related to quality from qualifying as EQROs. We narrow the scope of this provision from entities that conduct program operations to entities that conduct managed care related operations in order to allow States to contract with entities that conduct quality activities for the States such as FFS medical and utilization review activities. We agree with the last commenter who agrees that it will be more efficient for States to use a single contractor to perform multiple functions; therefore, we intend to allow entities that conduct limited quality activities such as providing technical assistance to States in the collection of encounter data or who assist the State in other quality improvement areas to qualify as an EQRO. These activities would not be considered ongoing operations conducted on behalf of the State.

We do not permit an entity to qualify as an EQRO if that entity conducts activities that State staff would otherwise conduct in Medicaid managed care program operations related to quality oversight. As an example, a State university or consulting firm that designs and implements or has significant responsibility for the State’s Medicaid managed care program operations would not qualify as independent.

We do not agree with the commenter who recommended that the independence provisions should

preclude any organization from being an EQRO that has the authority to certify managed care plans in compliance with standards that serve as the basis for deemed certification with Federal or State regulatory standards. These organizations, while they may provide services under contract to a State, follow their own independently set standards and procedures. We believe that States should be permitted to contract with these organizations to consolidate review processes. This is consistent with congressional intent as indicated by the nonduplication and deemed compliance provisions in sections 1932(c)(2)(B) and (C) of the Act.

As stated above, we agree with the commenters’ suggestions to revise the independence criteria as it applies to private organizations that deliver health care services to Medicaid beneficiaries or who, on behalf of the State, conduct Medicaid managed care program operations related to quality. However, we do not agree with the commenters’ suggestions to add to this provision health care-related services such as enrollment services, grievance resolution, and review of health care coverage decisions. We leave it to the States to determine if health care-related services are Medicaid managed care program operations related to quality, in which case the organizations would be precluded from qualifying as an EQRO. In addition, States have the flexibility to adopt a more strict standard for “independence” if they wish and to deny entities that provide any health care-related services from contracting as an EQRO.

We agree with the commenters’ suggestions that the final regulation include a provision to prohibit an EQRO from having a financial interest that would prevent it from exercising independent judgement when engaging in EQRO activities. The types of “control” addressed in 48 CFR 19.101 address financial relationships involving such things as stock options and convertible debentures. To be consistent with other CMS regulations, however, and in order to respond to this comment, we believe the financial relationship between organizations must be addressed in the conflict of interest requirements. Therefore, we revised § 438.354(c)(3)(iv) to address direct and indirect financial relationships. We also have added a definition for financial relationships under § 438.320.

We believe the language in proposed § 438.354(c)(2) addresses the suggestion by one commenter that we add a provision requiring a private entity to be governed by a board or similar body, the majority of whose members are not