

MCO employees. By referencing 48 CFR 19.101, specifically § 19.101(f)(1), a concern is considered controlling through interlocking management if officers, directors, employees, or principal stockholders serve as a working majority of the board of directors or officers of another concern. As noted above, to provide clarification, the final rule under § 438.354(c)(3)(i) (§ 438.354(c)(3) of the proposed rule) specifies the elements that constitute control of one entity over another as those in 48 CFR 19.101.

Comment: Several commenters expressed support for our independence requirements. One commenter supported our proposal to allow States to contract with entities that possess the necessary skill and expertise to conduct the mandatory and optional EQR activities, but suggested that we query State agencies for specific citations or contract language that they have used to define independence, or for concrete examples of situations that may create conflicts of interest. The commenter also suggested that we consider delineating specific competence standards for each of the mandatory activities. One commenter agreed that it is critical for CMS to establish a set of criteria to which States must adhere when selecting EQROs.

Response: At the expert panel meeting convened under the auspices of the NASHP, we asked the panel for recommendations on how to define conflict of interest. This panel included State representatives as well as representatives from advocacy organizations and other stakeholders. The expert panel recommended that independence be established by requiring the disclosure of any ownership interest of greater than 5 percent of the entity seeking to become an EQRO. As was discussed in the proposed rule, we believe this “disclosure of ownership” requirement is inadequate to ensure independence, first, because it does not preclude an entity from being an EQRO but only requires disclosure of the financial interest, and second, because there may be other types of conflicts such as interlocking management, common facilities, and so forth. Moreover, in the proposed rule, we requested comments on how better to identify situations that create conflict of interest. As noted above, we made some changes based on comments we received.

We do not believe that it is necessary for us to revise the competency requirements to address each EQR activity. The criteria outlined in the proposed rule were intentionally broad to provide States with the flexibility to

contract with one or multiple entities that have the skills necessary to conduct the particular activity/activities under contract. For example, if a State wants to have one of its EQROs conduct only encounter data validation, to meet the requirement under § 438.354(b)(3), the EQRO would not need to possess the clinical skills but would need the “nonclinical skills” in its organization (or through a subcontract) to conduct encounter validation.

Comment: A commenter believed that the proposed rule did not make clear who, specifically, would be responsible for designating an entity as an EQRO. The commenter recommended that this responsibility rest in our Office of Clinical Standards and Quality, as it already has oversight responsibility for Medicare’s Health Care Quality Program.

Response: Under this rule, States are required to select and thereby designate EQROs through an open, competitive procurement process. CMS will not be designating EQROs, as it currently does in the case of QIOs and entities claiming that they meet the standards to contract as a QIO. When monitoring State Medicaid managed care programs, CMS regional office staff have the opportunity to review RFPs, contracts, and EQR results to ensure compliance with the EQR provisions.

F. State Contract Options (§ 438.356)

This section set forth proposed requirements State agencies would be required to follow, and options that they would have selecting EQROs. We proposed that State agencies may contract with more than one EQRO. The final rule in § 438.356 (a)(1) and (a)(2) reflects clarifications made to the provisions based on comments discussed in an earlier section of the preamble.

We also proposed that each EQRO be permitted to use subcontractors. EQROs that use subcontractors are accountable for, and required to oversee, all EQR activities performed by the subcontractors. In addition, we proposed that each EQRO be required to meet the competency requirements, and each EQRO and EQRO subcontractor be required to meet the independence requirement. We also proposed that State agencies follow an open competitive procurement process that is in accordance with State law and regulation and consistent with 45 CFR part 74, as it applies to State procurement of Medicaid services.

Comment: Several commenters supported the language in § 438.356 as proposed. One commenter specifically agreed that all subcontractors should be

required to meet the test of independence, and that the contract must be procured through a competitive bid process.

Response: We appreciate the commenter’s support for the provisions, and have retained them in the final rule.

Comment: One commenter believed that a competitive bidding process was the most appropriate way for States to secure efficient cost-effective reviews.

Response: We agree that competitive bidding provides the best means to select a qualified contractor at the best price, and we retain the requirement for competitive procurement of EQROs in the final rule.

Comment: One commenter asked us to clarify whether the State Medicaid agency could contract directly with a State organization without using a competitive procurement process if the State organization otherwise meets the standard of being “independent,” and meets the requirements of a qualified EQR.

Response: The Department of Health and Human Services has regulations governing the extent to which States are required to competitively procure contracts. Those regulations apply to EQRO contract as cited under § 438.356(e).

G. Activities Related to External Quality Review (§ 438.358)

Section 438.358 proposed a requirement that EQR utilize information obtained from specified mandatory activities that must be performed by the State agency, a State agent, or the EQRO. Proposed § 438.358 also identified optional activities that the State agency or its agent may perform, or have the EQRO perform, to produce additional information for use in EQR. The mandatory activities are consistent with the requirements set forth in the Medicaid managed care final rule. The optional activities were not included in that rule. They are, however, activities that States have had their EQR contractors perform in the past.

We proposed that each year, the EQRO must use information obtained from the validation of performance improvement projects performed that year, and the validation of performance measures reported that year, by the MCO. To be consistent with the private sector, however, we proposed that information used by the EQRO from a review of MCO and PHP compliance with State structural and operational standards be from the most recent review performed within the previous 3 years.