

that no additional requirements are necessary.

*Comment:* One commenter noted that there was no cross-reference in the proposed EQR rule to the requirements in the then proposed Medicaid managed care rule that required MCOs to measure performance and conduct performance projects, and to comply with State-mandated standards. The commenter suggested that we make this cross-reference to the applicable sections in the Medicaid managed care rule.

*Response:* We have in this final rule added cross-references to the appropriate citations in the Medicaid managed care final rule.

*Comment:* One commenter recommended that we establish a core set of State standards for MCOs and evaluate these during the EQR process. The commenter was concerned that allowing States to determine the measures to be collected would provide little or no comparable plan or State level data.

*Response:* We do not agree that this rule should specify standardized performance measures for States or their contracting MCOs and PIHPs. The Medicaid managed care final rule specifies that States, through their contracts, must require their MCOs and PIHPs to calculate performance measures or submit data to the State that enables the State to measure MCO's or PIHP's performance. Many States currently require that standard performance measures be collected across MCOs. In addition, we believe that States will require that specified measures be calculated over time to enable the State to evaluate MCO and PIHP performance. In § 438.364(a)(4), we require that the EQR results include comparative information, as determined appropriate by the State. Furthermore, § 438.10(i)(2)(ii) of the Medicaid managed care final rule requires, for those States that provide for mandatory managed care under section 1932(a)(1)(A) of the Act, that the State provide comparative information annually. This must include, to the extent available, quality and performance indicators as required under § 438.10(i)(3)(iv). In addition, the Medicaid managed care final rule provides that CMS may, in collaboration with States and other stakeholders, prescribe standard performance measures.

*Comment:* One commenter asked us to clarify how proposed § 438.358(a)(1) fulfills the statutory requirement of EQR, and specifically how this information relates to a review of "the quality outcomes and timeliness of, and access to, the items and services for

which the managed care organization is responsible under the contract."

*Response:* In order to make an assessment about the quality, timeliness, and access to services provided by MCOs and PIHPs, there must be information from which an assessment can be made. Section 1932(c)(A)(iii) of the Act required us, in coordination with the NGA, to contract with an independent quality review organization to develop protocols to be used in EQR. In order to develop protocols, we first needed to define EQR, as it was not defined under section 1902(a)(30)(C) of the Act. We also needed to determine what activities we consider necessary or appropriate to provide information for a quality review. The EQR activities in § 438.358(b) and (c) are activities that (1) the expert panel convened under the auspices of the NASHP recommended be included as part of EQR; (2) a survey of States by the Department of Health and Human Services' Office of Inspector General identified as quality review activities used by States; and (3) a survey of States by NASHP confirmed as activities most frequently used by States for EQR. The EQRO must develop a report, based on the information provided, as specified in § 438.364, that includes a detailed assessment of each MCO's and PIHP's strength and weaknesses with respect to the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

*Comment:* A commenter noted that the rule does not clearly identify which entities are qualified and competent to undertake the validation of performance measures and performance improvement projects. In the commenter's view, as drafted, the rule could be interpreted as allowing entities other than EQROs, including the State or the MCO itself, to undertake these tasks. The commenter recommended that we clarify what types of entities can engage in validation activities and at a minimum require those entities to be competent and independent.

*Response:* The State, an EQRO, or other State contractor can undertake any of the EQR-related activities. However, it is only when an EQRO, that meets the competency and independence criteria, conducts any of these activities that a State can obtain the enhanced 75 percent Federal match under section 1903(a)(3)(C)(ii) of the Act. Regardless of who conducts the activity, the CMS protocols (or other protocols consistent with ours) must be used to gather information for the mandatory and optional activities used in EQR. We did not intend to allow the MCO or PIHP

itself to be able to conduct any EQR-related activities and in response to this comment we have revised § 438.358 so that it is clear that "the agent" must be an entity other than an MCO or PIHP.

*Comment:* One commenter recommended that we modify the regulation to grant State agencies the discretion to adapt these requirements to more appropriately address the circumstances of small or new MCOs and PIHPs. The commenter suggested that enrollment in some MCOs and PIHPs may be too small for an EQRO to validate the data for performance improvement projects or performance measures. Similarly, for an MCO that is not yet operational or which has only been operating for a short amount of time, there may be insufficient experience to use to evaluate for compliance with standards.

*Response:* We do not agree that we should modify the regulation to allow States to adapt the requirements to address small or new MCOs and PIHPs. If enrollment in an MCO or PIHP is small, the entire applicable population, as opposed to a sample, can be used when conducting performance improvement projects, calculating performance measures, or validating these activities. Regarding compliance with State standards, all MCOs and PIHPs that contract with a State to provide Medicaid services must be in compliance with the contracting requirements in the Medicaid managed care final rule. Regardless of when the EQR is conducted, MCOs and PIHPs should have procedures in place to be compliant with these provisions. Therefore, an assessment of compliance with these standards must be conducted and the findings provided to the EQRO to make its assessment regarding quality, timeliness, and access to services provided by the MCO or PIHP to Medicaid beneficiaries.

*Comment:* One commenter felt that State Medicaid agency staff should conduct the review of MCO compliance with structural and operational standards, as the review requires extensive knowledge of the State Medicaid program, its regulations, and the MCO contract. This commenter believed that this requirement was duplicative of current practice and unnecessarily burdensome, and did not provide States needed flexibility to choose which activities it wants to have its EQRO conduct. The commenter suggested deleting this provision. Another commenter urged that the review of compliance with standards be an optional instead of mandatory activity. The commenter noted that States conduct this activity through