

(b) The EQRO has sufficient information to use in performing the review;

(c) The information used to carry out the review must be obtained from the EQR-related activities described in § 438.358.

(d) For each EQR-related activity, the information must include the elements described in § 438.364(a)(1)(i) through (a)(1)(iv);

(e) The information provided to the EQRO in accordance with paragraph (c) of this section is obtained through methods consistent with the protocols established under § 438.352; and

(f) The results of the reviews are made available as specified in § 438.364.

#### **§ 438.352 External quality review protocols.**

Each protocol must specify—

(a) The data to be gathered;

(b) The sources of the data;

(c) The activities and steps to be followed in collecting the data to promote its accuracy, validity, and reliability;

(d) The proposed method or methods for validly analyzing and interpreting the data once obtained; and

(e) Instructions, guidelines, worksheets, and other documents or tools necessary for implementing the protocol.

#### **§ 438.354 Qualifications of external quality review organizations.**

(a) *General rule.* The State must ensure that an EQRO meets the requirements of this section.

(b) *Competence.* The EQRO must have at a minimum the following:

(1) Staff with demonstrated experience and knowledge of—

(i) Medicaid recipients, policies, data systems, and processes;

(ii) Managed care delivery systems, organizations, and financing;

(iii) Quality assessment and improvement methods; and

(iv) Research design and methodology, including statistical analysis.

(2) Sufficient physical, technological, and financial resources to conduct EQR or EQR-related activities.

(3) Other clinical and nonclinical skills necessary to carry out EQR or EQR-related activities and to oversee the work of any subcontractors.

(c) *Independence.* The EQRO and its subcontractors are independent from the State Medicaid agency and from the MCOs or PIHPs that they review. To qualify as “independent”—

(1) A State agency, department, university, or other State entity may not have Medicaid purchasing or managed care licensing authority; and

(2) A State agency, department, university, or other State entity must be governed by a Board or similar body the majority of whose members are not government employees.

(3) An EQRO may not—

(i) Review a particular MCO or PIHP if either the EQRO or the MCO or PIHP exerts control over the other (as used in this paragraph, “control” has the meaning given the term in 48 CFR 19.101) through—

(A) Stock ownership;

(B) Stock options and convertible debentures;

(C) Voting trusts;

(D) Common management, including interlocking management; and

(E) Contractual relationships.

(ii) Deliver any health care services to Medicaid recipients;

(iii) Conduct, on the State’s behalf, ongoing Medicaid managed care program operations related to oversight of the quality of MCO or PIHP services, except for the related activities specified in § 438.358; or

(iv) Have a present, or known future, direct or indirect financial relationship with an MCO or PIHP that it will review as an EQRO.

#### **§ 438.356 State contract options.**

(a) The State—

(1) Must contract with one EQRO to conduct either EQR alone or EQR and other EQR-related activities; and

(2) May contract with additional EQROs to conduct EQR-related activities as set forth in § 438.358.

(b) Each EQRO must meet the competence requirements as specified in § 438.354(b).

(c) Each EQRO is permitted to use subcontractors. The EQRO is accountable for, and must oversee, all subcontractor functions.

(d) Each EQRO and its subcontractors performing EQR or EQR-related activities must meet the requirements for independence, as specified in § 438.354(c).

(e) For each contract, the State must follow an open, competitive procurement process that is in accordance with State law and regulations and consistent with 45 CFR part 74 as it applies to State procurement of Medicaid services.

#### **§ 438.358 Activities related to external quality review.**

(a) *General rule.* The State, its agent that is not an MCO or PIHP, or an EQRO may perform the mandatory and optional EQR-related activities in this section.

(b) *Mandatory activities.* For each MCO and PIHP, the EQR must use

information from the following activities:

(1) Validation of performance improvement projects required by the State to comply with requirements set forth in § 438.240(b)(1) and that were underway during the preceding 12 months.

(2) Validation of MCO or PIHP performance measures reported (as required by the State) or MCO or PIHP performance measure calculated by the State during the preceding 12 months to comply with requirements set forth in § 438.240(b)(2).

(3) A review, conducted within the previous 3-year period, to determine the MCO’s or PIHP’s compliance with standards (except with respect to standards under §§ 438.240(b)(1) and (2), for the conduct of performance improvement projects and calculation of performance measures respectively) established by the State to comply with the requirements of § 438.204(g).

(c) *Optional activities.* The EQR may also use information derived during the preceding 12 months from the following optional activities:

(1) Validation of encounter data reported by an MCO or PIHP.

(2) Administration or validation of consumer or provider surveys of quality of care.

(3) Calculation of performance measures in addition to those reported by an MCO or PIHP and validated by an EQRO.

(4) Conduct of performance improvement projects in addition to those conducted by an MCO or PIHP and validated by an EQRO.

(5) Conduct of studies on quality that focus on a particular aspect of clinical or nonclinical services at a point in time.

(d) *Technical assistance.* The EQRO may, at the State’s direction, provide technical guidance to groups of MCOs or PIHPs to assist them in conducting activities related to the mandatory and optional activities that provide information for the EQR.

#### **§ 438.360 Nonduplication of mandatory activities.**

(a) *General rule.* To avoid duplication, the State may use, in place of a Medicaid review by the State, its agent, or EQRO, information about the MCO or PIHP obtained from a Medicare or private accreditation review to provide information otherwise obtained from the mandatory activities specified in § 438.358 if the conditions of paragraph (b) or paragraph (c) of this section are met.

(b) *MCOs or PIHPs reviewed by Medicare or private accrediting*