

**§ 438.354**

- (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;

**42 CFR Ch. IV (10–1–03 Edition)**

- (B) Stock options and convertible debentures;
- (C) Voting trusts;
- (D) Common management, including interlocking management; and
- (E) Contractual relationships.
  - (i) Deliver any health care services to Medicaid recipients;
  - (ii) 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: