Centers for Medicare & Medicaid Services, HHS § 438.354

(c) Applicability. The provisions of this subpart apply to MCOs, PIHPs, and to health insuring organizations (HIOs) that began on or after January 1, 1986 that the statute does not explicitly exempt from requirements in section 1903(m) of the Act.

§ 438.320 Definitions.

As used in this subpart—

EQR stands for external quality review.

EQRO stands for external quality review organization.

External quality review means the analysis and evaluation by an EQRO, of aggregated information on quality, timeliness, and access to the health care services that an MCO or PIHP, or their contractors furnish to Medicaid beneficiaries.

External quality review organization means an organization that meets the competence and independence requirements set forth in § 438.354, and performs external quality review, other EQR-related activities as set forth in § 438.358, or both.

Financial relationship means—

(1) A direct or indirect ownership or investment interest (including an option or nonvested interest) in any entity. This direct or indirect interest may be in the form of equity, debt, or other means and includes any indirect ownership or investment interest no matter how many levels removed from a direct interest; or

(2) A compensation arrangement with an entity.

Quality, as it pertains to external quality review, means the degree to which an MCO or PIHP increases the likelihood of desired health outcomes of its enrollees through its structural and operational characteristics and through the provision of health services that are consistent with current professional knowledge.

Validation means the review of information, data, and procedures to determine the extent to which they are accurate, reliable, free from bias, and in accord with standards for data collection and analysis.

§ 438.350 State responsibilities.

Each State that contracts with MCOs or PIHPs must ensure that—

(a) Except as provided in § 438.362, a qualified EQRO performs an annual EQR for each contracting MCO or PIHP;

(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 beneficiaries, 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.
§ 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.