

§ 438.240

42 CFR Ch. IV (10–1–07 Edition)

apply are consistent with the guidelines.

§ 438.240 Quality assessment and performance improvement program.

(a) *General rules.* (1) The State must require, through its contracts, that each MCO and PIHP have an ongoing quality assessment and performance improvement program for the services it furnishes to its enrollees.

(2) CMS, in consultation with States and other stakeholders, may specify performance measures and topics for performance improvement projects to be required by States in their contracts with MCOs and PIHPs.

(b) *Basic elements of MCO and PIHP quality assessment and performance improvement programs.* At a minimum, the State must require that each MCO and PIHP comply with the following requirements:

(1) Conduct performance improvement projects as described in paragraph (d) of this section. These projects must be designed to achieve, through ongoing measurements and intervention, significant improvement, sustained over time, in clinical care and nonclinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction.

(2) Submit performance measurement data as described in paragraph (c) of this section.

(3) Have in effect mechanisms to detect both underutilization and overutilization of services.

(4) Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

(c) *Performance measurement.* Annually each MCO and PIHP must—

(1) Measure and report to the State its performance, using standard measures required by the State including those that incorporate the requirements of § 438.204(c) and § 438.240(a)(2);

(2) Submit to the State, data specified by the State, that enables the State to measure the MCO's or PIHP's performance; or

(3) Perform a combination of the activities described in paragraphs (c)(1) and (c)(2) of this section.

(d) *Performance improvement projects.*

(1) MCOs and PIHPs must have an ongoing program of performance improvement projects that focus on clinical and nonclinical areas, and that involve the following:

(i) Measurement of performance using objective quality indicators.

(ii) Implementation of system interventions to achieve improvement in quality.

(iii) Evaluation of the effectiveness of the interventions.

(iv) Planning and initiation of activities for increasing or sustaining improvement.

(2) Each MCO and PIHP must report the status and results of each project to the State as requested, including those that incorporate the requirements of § 438.240(a)(2). Each performance improvement project must be completed in a reasonable time period so as to generally allow information on the success of performance improvement projects in the aggregate to produce new information on quality of care every year.

(e) *Program review by the State.* (1) The State must review, at least annually, the impact and effectiveness of each MCO's and PIHP's quality assessment and performance improvement program. The review must include—

(i) The MCO's and PIHP's performance on the standard measures on which it is required to report; and

(ii) The results of each MCO's and PIHP's performance improvement projects.

(2) The State may require that an MCO or PIHP have in effect a process for its own evaluation of the impact and effectiveness of its quality assessment and performance improvement program.

§ 438.242 Health information systems.

(a) *General rule.* The State must ensure, through its contracts, that each MCO and PIHP maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this subpart. The system must provide information on areas including, but not limited to, utilization, grievances and appeals, and disenrollments for other than loss of Medicaid eligibility.

(b) *Basic elements of a health information system.* The State must require, at a minimum, that each MCO and PIHP comply with the following:

(1) Collect data on enrollee and provider characteristics as specified by the State, and on services furnished to enrollees through an encounter data system or other methods as may be specified by the State.

(2) Ensure that data received from providers is accurate and complete by—

(i) Verifying the accuracy and timeliness of reported data;

(ii) Screening the data for completeness, logic, and consistency; and

(iii) Collecting service information in standardized formats to the extent feasible and appropriate.

(3) Make all collected data available to the State and upon request to CMS, as required in this subpart.

Subpart E—External Quality Review

SOURCE: 68 FR 3635, Jan. 24, 2003, unless otherwise noted.

§ 438.310 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart is based on sections 1932(c)(2), 1903(a)(3)(C)(ii), and 1902(a)(4) of the Act.

(b) *Scope.* This subpart sets forth requirements for annual external quality reviews of each contracting managed care organization (MCO) and prepaid inpatient health plan (PIHP), including—

(1) Criteria that States must use in selecting entities to perform the reviews;

(2) Specifications for the activities related to external quality review;

(3) Circumstances under which external quality review may use the results of Medicare quality reviews or private accreditation reviews; and

(4) Standards for making available the results of the reviews.

(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 ex-

empt 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 recipients.

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;