

not expect this to significantly increase Medicaid expenditures. PIHP costs account for approximately 5 percent of the payments we make to capitated arrangements. Furthermore, State agencies currently conduct quality review activities on PIHPs at a 50 percent Federal matching rate. Additional costs may arise for States' quality review activities that would now qualify for 75 percent and for new quality review activities undertaken as a result of the activities required in this rule.

Although we cannot quantify these various cost and savings effects, we believe that their net impact would be well below the \$100 million threshold for a major rule, and therefore that a regulatory impact analysis is not required. We do not believe that this final rule will cause MCOs to devote significantly more time to collect, organize and prepare for EQR than is already required by States. While the scope of work for EQR may be different under this final rule, we do not believe that the cost difference will be significant and States may actually be able to achieve savings since we are expanding the pool of organizations available to conduct EQR. Further, additional savings may also be realized through opportunities afforded by this rule to coordinate EQR activities with other quality and oversight activities. We acknowledge with the increased opportunity to contract with other qualified entities to conduct EQR, more States may avail themselves the 75 percent match for EQR activities. However, we do not believe this would represent a significant cost impact.

C. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs—health, Medicaid, Reporting and record keeping requirements.

42 CFR Part 438

Grant Programs—health, Managed care entities, Medicaid, Quality

assurance, Reporting and record keeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below.

PART 433—STATE FISCAL ADMINISTRATION

A. Amend part 433 as set forth below.

1. The authority citation for part 433 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 433.15, add a new paragraph (b)(10) to read as follows:

§ 433.15 Rates of FFP for administration.

* * * * *

(b) * * *

(10) Funds expended for the performance of external quality review or the related activities described in § 438.358 of this chapter when they are performed by an external quality review organization as defined in § 438.320 of this chapter: 75 percent.

B. Add a new subpart E to part 438 to read as set forth below.

PART 438—MANAGED CARE

Subpart E—External Quality Review

Sec.

- 438.310 Basis, scope, and applicability.
- 438.320 Definitions.
- 438.350 State responsibilities.
- 438.352 External quality review protocols.
- 438.354 Qualifications of external quality review organizations.
- 438.356 State contract options.
- 438.358 Activities related to external quality review.
- 438.360 Nonduplication of mandatory activities.
- 438.362 Exemption from external quality review.
- 438.364 External quality review results.
- 438.370 Federal financial participation.

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

Subpart E—External Quality Review

§ 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 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 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;