APPENDIX B
42 CFR §438 SUBPART E

Subpart E—Quality Measurement and Improvement; External Quality Review

SOURCE: 81 FR 27853, May 6, 2016, unless otherwise noted.

§438.310 Basis, scope, and applicability.

(a) *Statutory basis.* This subpart is based on sections 1932(c), 1903(a)(3)(C)(ii), 1902(a)(4), and 1902(a)(19) of the Act.

(b) *Scope.* This subpart sets forth:

(1) Specifications for a quality assessment and performance improvement program that States must require each contracting MCO, PIHP, and PAHP to implement and maintain.

(2) Requirements for the State review of the accreditation status of all contracting MCOs, PIHPs, and PAHPs.

(3) Specifications for a Medicaid managed care quality rating system for all States contracting with MCOs, PIHPs, and PAHPs.

(4) Specifications for a Medicaid managed care quality strategy that States contracting with MCOs, PIHPs, PAHPs, and PCCM entities (described in paragraph (c)(2) of this section) must implement to ensure the delivery of quality health care.

(5) Requirements for annual external quality reviews of each contracting MCO, PIHP, PAHP and PCCM entity (described in paragraph (c)(2) of this section) including—

(i) Criteria that States must use in selecting entities to perform the reviews.

(ii) Specifications for the activities related to external quality review.

(iii) Circumstances under which external quality review may use the results of Medicare quality reviews or private accreditation reviews.

(iv) Requirements for making the results of the reviews publicly available.

(c) *Applicability.* (1) The provisions of this subpart apply to States contracting with MCOs, PIHPs, and PAHPs for the delivery of services covered under Medicaid.

(2) The provisions of §438.330(b)(2), (b)(3), (c), and (e), §438.340, and §438.350 apply to States contracting with PCCM entities whose contracts with the State provide for shared savings, incentive payments or other financial reward for the PCCM entity for improved quality outcomes.

(d) *Applicability dates.* States will not be held out of compliance with the following requirements of this subpart prior to the dates noted below so long as they comply with the corresponding standard(s) in

42 CFR part 438 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015:

(1) States must comply with §438.330 and §438.332 no later than the rating period for contracts beginning on or after July 1, 2017.

(2) States must comply with §§438.340, 438.350, 438.354, 438.356, 438.358, 438.360, 438.362, and 438.364 no later than July 1, 2018.

§438.320 Definitions.

As used in this subpart—

Access, as it pertains to external quality review, means the timely use of services to achieve optimal outcomes, as evidenced by managed care plans successfully demonstrating and reporting on outcome information for the availability and timeliness elements defined under §438.68 (Network adequacy standards) and §438.206 (Availability of services).

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, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)), 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 non-vested 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.

Health care services means all Medicaid services provided by an MCO, PIHP, or PAHP under contract with the State Medicaid agency in any setting, including but not limited to medical care, behavioral health care, and long-term services and supports.

Outcomes means changes in patient health, functional status, satisfaction or goal achievement that result from health care or supportive services.

Quality, as it pertains to external quality review, means the degree to which an MCO, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)) increases the likelihood of desired outcomes of its enrollees through:

(1) Its structural and operational characteristics.

(2) The provision of services that are consistent with current professional, evidenced-based-knowledge.

(3) Interventions for performance improvement.

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.

§438.330 Quality assessment and performance improvement program.

(a) *General rules.* (1) The State must require, through its contracts, that each MCO, PIHP, and PAHP establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees that includes the elements identified in paragraph (b) of this section.

(2) After consulting with States and other stakeholders and providing public notice and opportunity to comment, CMS may specify performance measures and PIPs, which must be included in the standard measures identified and PIPs required by the State in accordance with paragraphs (c) and (d) of this section. A State may request an exemption from including the performance measures or PIPs established under paragraph (a)(2) of this section, by submitting a written request to CMS explaining the basis for such request.

(3) The State must require, through its contracts, that each PCCM entity described in §438.310(c)(2) establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees which incorporates, at a minimum, paragraphs (b)(2) and (3) of this section and the performance measures identified by the State per paragraph (c) of this section.

(b) *Basic elements of quality assessment and performance improvement programs.* The comprehensive quality assessment and performance improvement program described in paragraph (a) of this section must include at least the following elements:

(1) Performance improvement projects in accordance with paragraph (d) of this section.

(2) Collection and submission of performance measurement data in accordance with paragraph (c) of this section.

(3) Mechanisms to detect both underutilization and overutilization of services.

(4) Mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs, as defined by the State in the quality strategy under §438.340.

(5) For MCOs, PIHPs, or PAHPs providing long-term services and supports:

(i) Mechanisms to assess the quality and appropriateness of care furnished to enrollees using long-term services and supports, including assessment of care between care settings and a comparison of

services and supports received with those set forth in the enrollee's treatment/service plan, if applicable; and

(ii) Participate in efforts by the State to prevent, detect, and remediate critical incidents (consistent with assuring beneficiary health and welfare per §§441.302 and 441.730(a) of this chapter) that are based, at a minimum, on the requirements on the State for home and community-based waiver programs per §441.302(h) of this chapter.

(c) *Performance measurement.* The State must—

(1)(i) Identify standard performance measures, including those performance measures that may be specified by CMS under paragraph (a)(2) of this section, relating to the performance of MCOs, PIHPs, and PAHPs; and

(ii) In addition to the measures specified in paragraph (c)(1)(i) of this section, in the case of an MCO, PIHP, or PAHP providing long-term services and supports, identify standard performance measures relating to quality of life, rebalancing, and community integration activities for individuals receiving long-term services and supports.

(2) Require that each MCO, PIHP, and PAHP annually—

(i) Measure and report to the State on its performance, using the standard measures required by the State in paragraph (c)(1) of this section;

(ii) Submit to the State data, specified by the State, which enables the State to calculate the MCO's, PIHP's, or PAHP's performance using the standard measures identified by the State under paragraph (c)(1) of this section; or

(iii) Perform a combination of the activities described in paragraphs (c)(2)(i) and (ii) of this section.

(d) *Performance improvement projects.* (1) The State must require that MCOs, PIHPs, and PAHPs conduct performance improvement projects, including any performance improvement projects required by CMS in accordance with paragraph (a)(2) of this section, that focus on both clinical and nonclinical areas.

(2) Each performance improvement project must be designed to achieve significant improvement, sustained over time, in health outcomes and enrollee satisfaction, and must include the following elements:

(i) Measurement of performance using objective quality indicators.

(ii) Implementation of interventions to achieve improvement in the access to and quality of care.

(iii) Evaluation of the effectiveness of the interventions based on the performance measures in paragraph (d)(2)(i) of this section.

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

(3) The State must require each MCO, PIHP, and PAHP to report the status and results of each project conducted per paragraph (d)(1) of this section to the State as requested, but not less than once per year.

(4) The State may permit an MCO, PIHP, or PAHP exclusively serving dual eligibles to substitute an MA Organization quality improvement project conducted under §422.152(d) of this chapter for one or more of the performance improvement projects otherwise required under this section.

(e) *Program review by the State.* (1) The State must review, at least annually, the impact and effectiveness of the quality assessment and performance improvement program of each MCO, PIHP, PAHP, and PCCM entity described in §438.310(c)(2). The review must include—

(i) The MCO's, PIHP's, PAHP's, and PCCM entity's performance on the measures on which it is required to report.

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

(iii) The results of any efforts by the MCO, PIHP, or PAHP to support community integration for enrollees using long-term services and supports.

(2) The State may require that an MCO, PIHP, PAHP, or PCCM entity described in §438.310(c)(2) develop a process to evaluate the impact and effectiveness of its own quality assessment and performance improvement program.

§438.332 State review of the accreditation status of MCOs, PIHPs, and PAHPs.

(a) The State must require, through its contracts, that each MCO, PIHP, and PAHP inform the State whether it has been accredited by a private independent accrediting entity.

(b) The State must require, through its contracts, that each MCO, PIHP, and PAHP that has received accreditation by a private independent accrediting entity must authorize the private independent accrediting entity to provide the State a copy of its most recent accreditation review, including:

(1) Accreditation status, survey type, and level (as applicable);

(2) Accreditation results, including recommended actions or improvements, corrective action plans, and summaries of findings; and

(3) Expiration date of the accreditation.

(c) The State must—

(1) Make the accreditation status for each contracted MCO, PIHP, and PAHP available on the Web site required under §438.10(c)(3), including whether each MCO, PIHP, and PAHP has been accredited and, if applicable, the name of the accrediting entity, accreditation program, and accreditation level; and

(2) Update this information at least annually.

§438.334 Medicaid managed care quality rating system.

(a) *General rule.* Each State contracting with an MCO, PIHP or PAHP to furnish services to Medicaid beneficiaries must—

(1) Adopt the Medicaid managed care quality rating system developed by CMS in accordance with paragraph (b) of this section; or

(2) Adopt an alternative Medicaid managed care quality rating system in accordance with paragraph (c) of this section.

(3) Implement such Medicaid managed care quality rating system within 3 years of the date of a final notice published in the FEDERAL REGISTER.

(b) *Quality rating system.* CMS, in consultation with States and other stakeholders and after providing public notice and opportunity to comment, will identify performance measures and a methodology for a Medicaid managed care quality rating system that aligns with the summary indicators of the qualified health plan quality rating system developed per 45 CFR 156.1120.

(c) *Alternative quality rating system.* (1) A State may submit a request to CMS for approval to use an alternative Medicaid managed care quality rating system that utilizes different performance measures or applies a different methodology from that described in paragraph (b) of this section provided that—

(i) The ratings generated by the alternative Medicaid managed care quality rating system yield information regarding MCO, PIHP, and PAHP performance which is substantially comparable to that yielded by the Medicaid managed care quality rating system described in paragraph (b) of this section; and,

(ii) The state receive CMS approval prior to implementing an alternative quality rating system or modifications to an approved alternative Medicaid managed care quality rating system.

(2) Prior to submitting a request for, or modification of, an alternative Medicaid managed care quality rating system to CMS, the State must—

(i) Obtain input from the State's Medical Care Advisory Committee established under §431.12 of this chapter; and

(ii) Provide an opportunity for public comment of at least 30 days on the proposed alternative Medicaid managed care quality rating system or modification.

(3) The State must document in the request to CMS the public comment process utilized by the State including discussion of the issues raised by the Medical Care Advisory Committee and the public. The request must document any policy revisions or modifications made in response to the comments and rationale for comments not accepted.

(d) *Quality ratings.* Each year, the State must collect data from each MCO, PIHP, and PAHP with which it contracts and issue an annual quality rating for each MCO, PIHP, and PAHP based on the data collected, using the Medicaid managed care quality rating system adopted under this section.

(e) *Availability of information.* The State must prominently display the quality rating given by the State to each MCO, PIHP, or PAHP under paragraph (d) of this section on the Web site required under §438.10(c)(3) in a manner that complies with the standards in §438.10(d).

§438.340 Managed care State quality strategy.

(a) *General rule.* Each State contracting with an MCO, PIHP, or PAHP as defined in §438.2 or with a PCCM entity as described in §438.310(c)(2) must draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished by the MCO, PIHP, PAHP or PCCM entity.

(b) *Elements of the State quality strategy.* At a minimum, the State's quality strategy must include the following:

(1) The State-defined network adequacy and availability of services standards for MCOs, PIHPs, and PAHPs required by §§438.68 and 438.206 and examples of evidence-based clinical practice guidelines the State requires in accordance with §438.236.

(2) The State's goals and objectives for continuous quality improvement which must be measurable and take into consideration the health status of all populations in the State served by the MCO, PIHP, and PAHP.

(3) A description of—

(i) The quality metrics and performance targets to be used in measuring the performance and improvement of each MCO, PIHP, and PAHP with which the State contracts, including but not limited to, the performance measures reported in accordance with §438.330(c). The State must identify which quality measures and performance outcomes the State will publish at least annually on the Web site required under §438.10(c)(3); and

(ii) The performance improvement projects to be implemented in accordance with §438.330(d), including a description of any interventions the State proposes to improve access, quality, or timeliness of care for members enrolled in an MCO, PIHP, or PAHP.

(4) Arrangements for annual, external independent reviews, in accordance with §438.350, of the quality outcomes and timeliness of, and access to, the services covered under each MCO, PIHP, PAHP, and PCCM entity (described in §438.310(c)(2)) contract.

(5) A description of the State's transition of care policy required under §438.62(b)(3).

(6) The State's plan to identify, evaluate, and reduce, to the extent practicable, health disparities based on age, race, ethnicity, sex, primary language, and disability status. States must identify this demographic information for each Medicaid enrollee and provide it to the MCO, PIHP or PAHP at the time of enrollment. For purposes of this paragraph (b)(6), “disability status” means whether the individual qualified for Medicaid on the basis of a disability.

(7) For MCOs, appropriate use of intermediate sanctions that, at a minimum, meet the requirements of subpart I of this part.

(8) A description of how the State will assess the performance and quality outcomes achieved by each PCCM entity described in §438.310(c)(2).

(9) The mechanisms implemented by the State to comply with §438.208(c)(1) (relating to the identification of persons who need long-term services and supports or persons with special health care needs).

(10) The information required under §438.360(c) (relating to nonduplication of EQR activities); and

(11) The State's definition of a “significant change” for the purposes of paragraph (c)(3)(ii) of this section.

(c) *Development, evaluation, and revision.* In drafting or revising its quality strategy, the State must:

(1) Make the strategy available for public comment before submitting the strategy to CMS for review, including:

(i) Obtaining input from the Medical Care Advisory Committee (established by §431.12 of this chapter), beneficiaries, and other stakeholders.

(ii) If the State enrolls Indians in the MCO, PIHP, or PAHP, consulting with Tribes in accordance with the State's Tribal consultation policy.

(2) Review and update the quality strategy as needed, but no less than once every 3 years.

(i) This review must include an evaluation of the effectiveness of the quality strategy conducted within the previous 3 years.

(ii) The State must make the results of the review available on the Web site required under §438.10(c)(3).

(iii) Updates to the quality strategy must take into consideration the recommendations provided pursuant to §438.364(a)(4).

(3) Submit to CMS the following:

(i) A copy of the initial strategy for CMS comment and feedback prior to adopting it in final.

(ii) A copy of the revised strategy whenever significant changes, as defined in the state's quality strategy per paragraph (b)(11) of this section, are made to the document, or whenever significant changes occur within the State's Medicaid program.

(d) *Availability.* The State must make the final quality strategy available on the Web site required under §438.10(c)(3).

§438.350 External quality review.

Each State that contracts with MCOs, PIHPs, or PAHPs, or with PCCM entities (described in §438.310(c)(2)) must ensure that—

(a) Except as provided in §438.362, a qualified EQRO performs an annual EQR for each such contracting MCO, PIHP, PAHP or PCCM entity (described in §438.310(c)(2)).

(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 or, if applicable, from a Medicare or private accreditation review as described in §438.360.

(d) For each EQR-related activity, the information gathered for use in the EQR must include the elements described in §438.364(a)(2)(i) through (iv).

(e) The information provided to the EQRO in accordance with paragraph (b) of this section is obtained through methods consistent with the protocols established by the Secretary in accordance with §438.352.

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

[81 FR 27853, May 6, 2016, as amended at 82 FR 39, Jan. 3, 2017]

§438.352 External quality review protocols.

The Secretary, in coordination with the National Governor's Association, must develop protocols for the external quality reviews required under this subpart. Each protocol issued by the Secretary 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.

(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 must be independent from the State Medicaid agency and from the MCOs, PIHPs, PAHPs, or PCCM entities (described in §438.310(c)(2)) that they review. To qualify as "independent"—

(1) If a State agency, department, university, or other State entity:

(i) May not have Medicaid purchasing or managed care licensing authority; and

(ii) Must be governed by a Board or similar body the majority of whose members are not government employees.

(2) An EQRO may not:

(i) Review any MCO, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)), or a competitor operating in the State, over which the EQRO exerts control or which exerts control over the EQRO (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 beneficiaries;

(iii) Conduct, on the State's behalf, ongoing Medicaid managed care program operations related to oversight of the quality of MCO, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)) services, except for the related activities specified in §438.358;

(iv) Review any MCO, PIHP, PAHP or PCCM entity (described in §438.310(c)(2)) for which it is conducting or has conducted an accreditation review within the previous 3 years; or

(v) Have a present, or known future, direct or indirect financial relationship with an MCO, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)) that it will review as an EQRO.

§438.356 State contract options for external quality review.

(a) The State—

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

(2) May contract with additional EQROs or other entities 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 with an EQRO described in paragraph (a) of this section, the State must follow an open, competitive procurement process that is in accordance with State law and regulations. In addition, the State must comply with 45 CFR part 75 as it applies to State procurement of Medicaid services.

§438.358 Activities related to external quality review.

(a) *General rule.* (1) The State, its agent that is not an MCO, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)), or an EQRO may perform the mandatory and optional EQR-related activities in this section.

(2) The data obtained from the mandatory and optional EQR-related activities in this section must be used for the annual EQR in §438.350 and must include, at a minimum, the elements in §438.364(a)(2)(i) through (iv).

(b) *Mandatory activities.* (1) For each MCO, PIHP, or PAHP the following EQR-related activities must be performed:

(i) Validation of performance improvement projects required in accordance with §438.330(b)(1) that were underway during the preceding 12 months.

(ii) Validation of MCO, PIHP, or PAHP performance measures required in accordance with

§438.330(b)(2) or MCO, PIHP, or PAHP performance measures calculated by the State during the preceding 12 months.

(iii) A review, conducted within the previous 3-year period, to determine the MCO's, PIHP's, or PAHP's compliance with the standards set forth in subpart D of this part and the quality assessment and performance improvement requirements described in §438.330.

(iv) Validation of MCO, PIHP, or PAHP network adequacy during the preceding 12 months to comply with requirements set forth in §438.68 and, if the State enrolls Indians in the MCO, PIHP, or PAHP, §438.14(b)(1).

(2) For each PCCM entity (described in §438.310(c)(2)), the EQR-related activities in paragraphs (b)(1)(ii) and (iii) of this section must be performed.

(c) *Optional activities.* For each MCO, PIHP, PAHP, and PCCM entity (described in §438.310(c)(2)), the following activities may be performed by using information derived during the preceding 12 months:

(1) Validation of encounter data reported by an MCO, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)).

(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, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)) and validated by an EQRO in accordance with paragraph (b)(1)(ii) of this section.

(4) Conduct of performance improvement projects in addition to those conducted by an MCO, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)) and validated by an EQRO in accordance with paragraph (b)(1)(i) of this section.

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

(6) Assist with the quality rating of MCOs, PIHPs, and PAHPs consistent with §438.334.

(d) *Technical assistance.* The EQRO may, at the State's direction, provide technical guidance to groups of MCOs, PIHPs, PAHPs, or PCCM entities (described in §438.310(c)(2)) to assist them in conducting activities related to the mandatory and optional activities described in this section that provide information for the EQR and the resulting EQR technical report.

[81 FR 27853, May 6, 2016, as amended at 82 FR 39, Jan. 3, 2017; 82 FR 12510, Mar. 6, 2017]

§438.360 Nonduplication of mandatory activities with Medicare or accreditation review.

(a) *General rule.* Consistent with guidance issued by the Secretary under §438.352, to avoid duplication the State may use information from a Medicare or private accreditation review of an MCO, PIHP, or PAHP to provide information for the annual EQR (described in §438.350) instead of conducting one or more of the EQR activities described in §438.358(b)(1)(i) through (iii) (relating to the validation of

performance improvement projects, validation of performance measures, and compliance review) if the following conditions are met:

(1) The MCO, PIHP, or PAHP is in compliance with the applicable Medicare Advantage standards established by CMS, as determined by CMS or its contractor for Medicare, or has obtained accreditation from a private accrediting organization recognized by CMS as applying standards at least as stringent as Medicare under the procedures in §422.158 of this chapter;

(2) The Medicare or private accreditation review standards are comparable to standards established through the EQR protocols (§438.352) for the EQR activities described in §438.358(b)(1)(i) through (iii); and

(3) The MCO, PIHP, or PAHP provides to the State all the reports, findings, and other results of the Medicare or private accreditation review activities applicable to the standards for the EQR activities.

(b) *External quality review report.* If the State uses information from a Medicare or private accreditation review in accordance with paragraph (a) of this section, the State must ensure that all such information is furnished to the EQRO for analysis and inclusion in the report described in §438.364(a).

(c) *Quality strategy.* The State must identify in its quality strategy under §438.340 the EQR activities for which it has exercised the option described in this section, and explain the rationale for the State's determination that the Medicare review or private accreditation activity is comparable to such EQR activities, consistent with paragraph (a)(2) of this section.

§438.362 Exemption from external quality review.

(a) *Basis for exemption.* The State may exempt an MCO from EQR if the following conditions are met:

(1) The MCO has a current Medicare contract under part C of Title XVIII or under section 1876 of the Act, and a current Medicaid contract under section 1903(m) of the Act.

(2) The two contracts cover all or part of the same geographic area within the State.

(3) The Medicaid contract has been in effect for at least 2 consecutive years before the effective date of the exemption and during those 2 years the MCO has been subject to EQR under this part, and found to be performing acceptably for the quality, timeliness, and access to health care services it provides to Medicaid beneficiaries.

(b) *Information on exempted MCOs.* When the State exercises this option, the State must obtain either of the following:

(1) *Information on Medicare review findings.* Each year, the State must obtain from each MCO that it exempts from EQR the most recent Medicare review findings reported on the MCO including—

(i) All data, correspondence, information, and findings pertaining to the MCO's compliance with Medicare standards for access, quality assessment and performance improvement, health services, or delegation of these activities.

(ii) All measures of the MCO's performance.

(iii) The findings and results of all performance improvement projects pertaining to Medicare enrollees.

(2) *Medicare information from a private, national accrediting organization that CMS approves and recognizes for Medicare Advantage Organization deeming.* (i) If an exempted MCO has been reviewed by a private accrediting organization, the State must require the MCO to provide the State with a copy of all findings pertaining to its most recent accreditation review if that review has been used for either of the following purposes:

(A) To fulfill certain requirements for Medicare external review under subpart D of part 422 of this chapter.

(B) To deem compliance with Medicare requirements, as provided in §422.156 of this chapter.

(ii) These findings must include, but need not be limited to, accreditation review results of evaluation of compliance with individual accreditation standards, noted deficiencies, corrective action plans, and summaries of unmet accreditation requirements.

§438.364 External quality review results.

(a) *Information that must be produced.* The State must ensure that the EQR results in an annual detailed technical report that summarizes findings on access and quality of care, including:

(1) A description of the manner in which the data from all activities conducted in accordance with §438.358 were aggregated and analyzed, and conclusions were drawn as to the quality, timeliness, and access to the care furnished by the MCO, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)).

(2) For each EQR-related activity conducted in accordance with §438.358:

(i) Objectives;

(ii) Technical methods of data collection and analysis;

(iii) Description of data obtained, including validated performance measurement data for each activity conducted in accordance with §438.358(b)(1)(i) and (ii); and

(iv) Conclusions drawn from the data.

(3) An assessment of each MCO's, PIHP's, PAHP's, or PCCM entity's (described in §438.310(c)(2)) strengths and weaknesses for the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(4) Recommendations for improving the quality of health care services furnished by each MCO, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)) including how the State can target goals and objectives in the quality strategy, under §438.340, to better support improvement in the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(5) Methodologically appropriate, comparative information about all MCOs, PIHPs, PAHPs, and PCCM entities (described in §438.310(c)(2)), consistent with guidance included in the EQR protocols issued in accordance with §438.352(e).

(6) An assessment of the degree to which each MCO, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)) has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

(b) *Revision.* States may not substantively revise the content of the final EQR technical report without evidence of error or omission.

(c) *Availability of information.* (1) The State must contract with a qualified EQRO to produce and submit to the State an annual EQR technical report in accordance with paragraph (a) of this section. The State must finalize the annual technical report by April 30th of each year.

(2) The State must—

(i) Post the most recent copy of the annual EQR technical report on the Web site required under §438.10(c)(3) by April 30th of each year.

(ii) Provide printed or electronic copies of the information specified in paragraph (a) of this section, upon request, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO, PIHP, PAHP, or PCCM entity (described in §438.310(c)(2)), beneficiary advocacy groups, and members of the general public.

(3) The State must make the information specified in paragraph (a) of this section available in alternative formats for persons with disabilities, when requested.

(d) *Safeguarding patient identity.* The information released under paragraph (b) of this section may not disclose the identity or other protected health information of any patient.

§438.370 Federal financial participation (FFP).

(a) FFP at the 75 percent rate is available in expenditures for EQR (including the production of EQR results) and the EQR-related activities set forth in §438.358 performed on MCOs and conducted by EQROs and their subcontractors.

(b) FFP at the 50 percent rate is available in expenditures for EQR-related activities conducted by any entity that does not qualify as an EQRO, and for EQR (including the production of EQR results) and EQR-related activities performed by an EQRO on entities other than MCOs.

(c) Prior to claiming FFP at the 75 percent rate in accordance with paragraph (a) of this section, the State must submit each EQRO contract to CMS for review and approval.