

Fact Sheet: Subpart D and E of 438–Quality of Care

Each state must ensure that all services covered under the state plan are available and accessible to enrollees of *Managed Care Organizations (MCOs)*, *Pre-paid Inpatient Health Plans (PIHP)*, *Pre-paid Ambulatory Health Plans (PAHP)* in a timely manner. The state must also ensure that MCO, PIHP, PAHP provider networks for services covered under the contract meet standards developed by the state.

- **An MCO** is defined as being an entity that has or is seeking to qualify for a comprehensive risk contract that is a federally qualified health maintenance organization (HMO) or meets the qualifications set out by the secretary to make health services it provides to Medicaid enrollees.
- **A PAHP** is an entity that is responsible for **primarily ambulatory services** for enrollees under a contract with the state, and on the basis of a capitation payment, or other payment arrangements that do not use state plan payment rates.
- **A PIHP** is an entity that is responsible for the provision of **inpatient hospital or other types of institutional services** under contract with the state, and on the basis of a capitation payment, or other payment arrangements that do not use state plan payment rates.
- PAHPs and PIHPs do not enter into comprehensive risk contracts.

Subpart D—MCO, PIHP and PAHP Standards

§438.206–Availability of services.

Delivery network. Each MCO, PIHP, and PAHP under contract with a state must meet the following requirements:

- Maintains and monitors a network of providers under a written agreement that **provides sufficient access** to all services covered under the state’s contract for all Medicaid enrollees, including those with limited English proficiency or physical or mental disabilities.
- Provides female enrollees with direct **access to women’s health specialist**.
- Provides for a **second opinion from a network provider**, or arranges for one outside of the network, at no cost to the enrollee.
- If the provider network is **unable to provide necessary services** covered under the contract, the contracted managed care entity must adequately and timely cover these services out-of-network as long as the provider network is unable to provide the necessary services.
- Requires **out-of-network providers** to coordinate with the contracted managed care entity for payment and ensures the cost to the enrollee is not greater than it would be if the services were furnished within the network.
- Demonstrates that its network **providers are credentialed**.
- Demonstrates that its network includes **sufficient family planning providers** to ensure timely access to covered services.

Furnishing of services. Each contract with a managed care entity must comply with the following:

- **Timely access**—Each managed care entity must do the following:
 - Require network providers to meet state standards for timely access to care and services.
 - Ensure that network providers offer hours of operation that are not less than those offered in commercial or comparable to Medicaid fee-for-service (FFS) products.
 - Make services included in the contract available 24 hours a day, 7 days a week, when medically necessary.
 - Establish mechanisms to ensure compliance by network providers.
 - Monitor provider compliance regularly.
 - Take corrective action if noncompliance exists on the part of a network provider.
- **Access and cultural consideration**—Participates in the state’s efforts to promote the delivery of services in a culturally competent manner, including to those enrollees with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of gender, sexual orientation or gender identity.
- **Accessibility considerations**—Ensure that network providers provide physical access, reasonable accommodations, and accessible equipment for Medicaid enrollees with physical or mental disabilities.

Applicability date. *This section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2018. Until the applicability date, states are required to continue to comply with these provisions as edited as of Oct. 1, 2015.*

§438.207 Assurances of adequate capacity and services.

Required supporting documentation—Each contracted managed care entity must give assurances to the state and provide supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area, in accordance with state standards for access to care. The documentation must be submitted to the state at the time of initiating the contract, annually, and any time there is a significant change in operation affecting capacity.

States must review all documentation and submit an assurance of compliance to the Center for Medicare and Medicaid Services (CMS). The state must make available to CMS, upon request, all documentation collected by the state from the managed care entities.

Applicability—*This requirement applies to the rating period for contracts with managed care entities beginning on or after July 1, 2018.*

§438.208 Coordination and continuity of care.

General rule—Contracted managed care entities must comply with the coordination and continuity of care requirements.

PIHP and PAHP exception.—The state will determine whether a particular PIHP or PAHP is required to implement mechanisms for identifying, assessing, and producing a treatment plan for an individual with special health care needs.

Exception for MCOs that serve dually eligible enrollees.—For each MCO that serve enrollees who are also enrolled in and receive Medicare benefits from a Medicare Advantage Organization, the state determines to what extent the MCO must meet the identification, assessment, and treatment planning provisions for dually eligible individuals. The state bases its determination on the needs of the population it requires the MCO to serve.

Care and coordination of services for all MCO, PIHP, and PAHP enrollees. Each contracted managed care entity must implement procedures to deliver care to and coordinate services for all of their enrollees. These procedures must meet state requirements and do the following:

- Centralize coordination of access to appropriate care.
- Coordinate services between settings of care and sources of coverage
- **Initial enrollee screening**—within 90 days of the effective date of enrollment for all new enrollees.
- **Collaboration with state and other managed care entities involved in providing services**—This process is to prevent duplication of those activities.
- **Enrollee health records**—Each provider furnishing services to enrollees will maintain and share an enrollee health record in accordance with professional standards.
- **Privacy requirements**—Each enrollee’s privacy is protected in accordance with the privacy requirements to the extent that they are applicable.

Additional services for enrollees with special health care needs or who need LTSS.

Managed care entities under contracts must do the following:

- **Identification**—Implement mechanisms to identify persons who need long-term services and supports (LTSS) or persons with *special health care needs* to managed care entities, as those persons are **defined by the state**.
- **Assessment**—Assess each Medicaid enrollee identified by the state as needing LTSS or having *special health care needs* to identify any ongoing special conditions of the enrollee that require a course of treatment or regular care monitoring.
- **Treatment/service plans**—produce a treatment or service plan meeting the criteria specified in the state QS for enrollees who require LTSS and, if the state requires, produce a treatment or service plan meeting the criteria for enrollees with special health care needs. The treatment or service plan should be:

- Developed by an individual meeting LTSS service coordination requirements with enrollee participation, and in consultation with any provider caring for the enrollee,
- Developed by a person trained in person-centered planning using person process and plan,
- In compliance with any applicable state quality assurance and utilization review standards, and
- Reviewed and revised upon reassessment of functional need, at least **every 12 months**, or when the enrollee’s circumstances or needs change significantly, or at the request of the enrollee.
- **Direct access to specialist**—There should be in place a mechanism to allow enrollees with special health care needs to directly access a specialist as appropriate for the enrollee’s condition and identified needs.

Applicability date—*This section applies to the rating period for contracts with managed care entities beginning on or after July 1, 2017.*

§438.210 Coverage and authorization of services.

Coverage. Each contract between a state and an MCO, PIHP, or PAHP must do the following:

- **Identifies scope of covered services**—Identify, define, and specify the amount, duration, and scope of each service that the managed care entity is required to offer, and require that the services identified be no less than those furnished to beneficiaries under FFS Medicaid under a subcontractual arrangement, or for enrollees under the age of 21.
- **Ensures network adequacy:**
 - Ensure that the services are sufficient in amount, duration, or scope to reasonably achieve the care objectives,
 - May not arbitrarily deny or reduce the amount, duration, or scope of a required service solely because of diagnosis, type of illness, or condition of the beneficiary,
- **Utilization control parameters**—Permit a managed care entity to place appropriate limits on a service:
 - On the basis of criteria applied under the state plan, such as medical necessity, or
 - For the purposes of utilization control, provided that:
 - i. The services furnished can reasonably achieve their purpose,
 - ii. The service supporting individuals with ongoing or chronic conditions or who require LTSS are authorized in a manner that reflects the enrollee’s ongoing need, and
 - iii. Family planning services are provided in a manner that protects and enables the enrollee’s freedom to choose the method of family planning.
- **Medically necessary services**—Specify what constitutes “*medically necessary services*” in a manner that:
 - Is no more restrictive than that used in the state Medicaid program, including quantitative, and non-quantitative treatment limits, as indicated in state statutes and regulations, the state plan, and other state policy and procedures, and
 - Addresses the extent to which the managed care entity is responsible for covering services that address:
 - i. The prevention, diagnosis, and treatment of an enrollee’s disease, condition, and/or disorder that results in impairments and/or disability.
 - ii. The ability for an enrollee to achieve age-appropriate growth and development.
 - iii. The ability for an enrollee to attain, maintain, or regain functional capacity.
 - iv. The opportunity for an enrollee receiving LTSS to have access to the benefits of community living, to achieve person-centered goals, and live and work in the setting of their choice.

Authorization of Services. Each managed care contract should require:

- Written policies and procedures,
- Mechanisms to ensure consistent application of review criteria for authorization decisions,
- Consult with the requesting provider for medical services when appropriate,
- Authorization of LTSS based on an enrollee’s current needs assessment and consistent with the person-centered service plan, and
- That any decision to deny a service authorization request or to authorize a service in an amount, duration, or scope that is less than requested, be made by an individual who has appropriate expertise in addressing the enrollee’s medical, behavioral health, or LTSS needs.

Notice of adverse benefit determination. Managed care entities should notify the requesting provider, and give the enrollee written notice of any decision to deny a service in an amount, duration, or scope that is less than requested.

Timeframe for decisions. Each managed care contract must provide for the following decisions and notices:

- **Standard authorization decisions**—Notice will be provided as expeditiously as the enrollee’s condition requires and within state-established timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, if—
 - The enrollee, or the provider requests the extension, or
 - The managed care entity justifies a need for additional information and how the extension is in the enrollee’s interest.
- **Expedited authorization decisions.**
 - In the case that a provider indicates, or the managed care entity determines, that following the standard timeframe could seriously jeopardize the enrollee’s life or health or function, the managed care entity will make an expedited authorization decision and provide notice as expeditiously as the enrollee’s health condition requires and no later than 72 hours after receipt of the request for service.
 - The managed care entity may extend the 72 hour time period to up to 14 calendar days if the enrollee requests the extension, or if the managed care entity justifies (to the state agency upon request) that the extension is in the enrollee’s interest.
- **Covered outpatient drug decisions.** For all covered outpatient drug authorization decisions, notice of a determination must be given within 24 hours of a request for prior authorization.

Compensation for utilization management activities. Contracts for compensation provided to utilization review agents to conduct utilization review activities should not be structured in such a way as to provide an incentive to deny, limit, or discontinue medically necessary services to any enrollee.

Applicability date. *This section applies to the rating period for contracts with managed care entities beginning on or after July 1, 2017.*

§438.214 Provider selection.

General rules. Each managed care entity must implement written policies and procedures for selection and retention of network providers and that meet the requirements of this final rule.

Credentialing and re-credentialing requirements.

- **Credentialing policy**—Each state must establish a uniform credentialing and re-credentialing policy that address acute, primary, behavioral, substance use disorders, and LTSS providers, as appropriate, and requires each managed care entity to follow those policies.
- **Documented process**—Each managed care entity must follow a documented process for credentialing and re-credentialing of provider networks.

Nondiscrimination. Managed care network provider selection policies and procedures must not discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment.

Excluded providers. Managed care entities may not employ or contract with providers who are excluded from participation in federal health care programs.

State requirements. Each managed care entity must comply with any additional requirement established by the state.

§438.224 Confidentiality.

All managed care entity should adhere to privacy requirements relative to individually identifiable health information.

§438.228 Grievance and appeal systems.

Each managed care entity must have in effect a grievance and appeal system that meets the requirements of the final rule. If the state delegates to the managed care entity responsibility for notice of action, the state must conduct random reviews of each delegated managed care entity and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

§438.230 Subcontractual relationships and delegation.

Applicability. These provisions apply to any contracts or written arrangements where a managed care entity has established with a subcontractor.

General rules on managed care entity subcontractual relationships:

- Maintains ultimate responsibility for adhering to and fully complying with all terms and conditions of its contract with the state,
- Contracts or written arrangements should specify that if any of the managed care entity's activities or obligations under contract with the state are delegated to a subcontractor:
 - The activity and related reporting is specified in the contract or written agreement,
 - The subcontractor agrees to perform the delegated activities and reporting responsibilities in compliance with the managed care entities contract obligation,
 - The contract or written arrangement should either provide for revocation of the delegation of activities, or specify other remedies in instances where the state or the managed care entity determine the subcontractor has not performed satisfactorily.
- The subcontractor agrees to comply with all Medicaid laws, regulations, including applicable sub-regulatory guidance and contract provisions.
- The subcontractor agrees that–
 - The state, the Center for Medicare and Medicaid Services (CMS), the Department of Health and Human Services (HHS) Inspector General, the Comptroller General, or their designees have the right to audit or inspect any documents or records in any format of the subcontractor, or the subcontractor's contractor, that pertain to any aspect of services and activities performed, or determination of amounts payable under the managed care entities contract with the state.
 - The subcontractor will make available its premises, physical facilities, equipment, books, records, contracts, computer or other records, contracts, computer or other electronic systems relating to its Medicaid enrollees.
 - The right to audit will exist through 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.
 - If there is a reasonable possibility of fraud or similar risk, an inspection, evaluation or audit of the subcontractor may occur at any time.

Applicability date. *This section applies to the rating period for contracts with managed care entities beginning on or after July 1, 2017.*

§438.236 Practice guidelines.

Basic rule. Managed care entities must meet the requirements of the final rule pertaining to practice guidelines.

Adoption of practice guidelines. Each managed care entity, when applicable, adopts practice guidelines that:

- Are based on valid and reliable clinical evidence or a consensus of providers in the particular field,
- Are adopted in consultation with contracting health care professionals, and
- Are review periodically reviewed and updated.

§438.242 Health information systems.

General rule. Each managed care entity must maintain a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives.

Basic elements of a health information system. The state must require, at a minimum, that each managed care entity:

- Comply with the provisions of the Affordable Care Act (ACA) which require a state claims processing and retrieval system to be able to collect certain data elements.
- Collect data on enrollee and provider characteristics as specified by the state, and on all services furnished to the enrollee through the encounter data system.
- Ensure that data received from providers is accurate and complete, and
- Make all collected data available to the state upon request.

State review and validation of encounter data. The state must review and validate that the encounter data collected, maintained, and submitted to the state by the managed care entity meets the requirements of the final rule. The state must have procedures and protocols to ensure that encounter data is a complete and accurate representation of the services provided to the enrollees under the contract between the state and the managed care entity.

Applicability data. *This section applies to the rating period for contracts with managed care entities beginning on or after July 1, 2017.*

Subpart E—Quality Measurement and Improvement; External Quality Review

§438.310 Basis, scope, and applicability.

Applicability. These provisions apply to states contracting with managed care entities for the delivery of services covered under Medicaid.

§438.320 Definitions.

Provides for the following definition of terms:

- *Access*—As it pertains to external review, means the timely use of services to achieve optimal outcomes.
- *EQR*—Stands for external quality review.
- *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 a managed care entity or their contractors furnished a Medicaid beneficiary.
- *External quality review organization*—Means an organization that meets the competence and independence requirements and performs external quality review and other EQR related activities.
- *Financial relationship*—A direct or indirect ownership or investment interest in any entity.
- *Health care services*—All Medicaid services provided by an entity under contract with the State Medicaid agency.
- *Outcomes*—As it pertains to EQR, means the degree to which a managed care entity increases the likelihood of desired outcomes of its enrollees.
- *Validation*—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 (QAPI) program.

Extends the existing requirements on MCOs and PIHPs related to Managed Care Quality Strategy (QS), QAPI Program, and External Quality Review (EQR) to PAHPs, and Primary Care Case Manager (PCCM) entities whose contracts provide for shared savings, incentive payments or other financial reward for improved quality outcomes. These changes apply 60 days after publication of the final rule.

General rules. Requires managed care entities to establish and implement an ongoing comprehensive QAPI program for the services it furnishes to its Medicaid enrollees.

Basic elements.

- Performance improvement projects,
- Collection and submission of performance measurement data,
- Mechanisms to detect both underutilization and overutilization of services,
- Mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs, and
- For managed care entity's providing LTSS:
 - Mechanisms to assess the quality and appropriateness of care furnished to enrollees using LTSS, including assessment of care between care settings and a comparison of services and supports received, and
 - Participate in efforts by the state to prevent, detect, and remediate critical incidents that are based, at a minimum, on the requirements on the state for home and community-based waiver programs—

Performance measurement. The state must:

- Identify standard performance measures, including those that may be specified by CMS, relating to the performance of managed care entity's, and
- Identify standard performance measures relating to quality of life rebalancing, and community integration activities for individuals receiving LTSS.

Managed care entity's must **annually measure and report to the state** on its performance, using the standard measure required by the state.

Performance improvement projects. Managed care entities must conduct performance improvement projects including any performance improvement projects required by CMS, which focus on both clinical and nonclinical areas and to report the status and results of each project they conducted to the state as requested, but not less than once per year.

Application to PCCM entities—PCCM entities with financial incentives must at a minimum collect and submit performance data and implement mechanisms to detect inappropriate utilization of services.

Program review by state. The state must review, at least annually, the impact and effectiveness of the QAPI program of each managed care entity. The review must include:

- The managed care entity's performance on the measures on which it is required to report.
- The outcomes and trended results of each managed care entity performance improvement projects.
- The results of any efforts by the managed care entity to support community integration for enrollees using LTSS.
- The state may require that a managed care entity develop a process to evaluate the impact and effectiveness of its own QAPI program.

National performance measures—If CMS chooses to identify national performance measures and performance improvement project (PIP) topics, the final rule provides that:

- CMS will use a public notice and comment process to obtain input from beneficiaries and stakeholders, and
- States can request an exemption from any nationally identified performance measures and/or PIP topics.

This provision applies no later than the rating period for contracts starting on or after July 1, 2017.

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

Each managed care entity must inform the state whether it has been accredited by a private independent accrediting entity, and authorize that accrediting entity to provide the state a copy of its most recent accreditation review, including:

- Accreditation status, survey type, and level,
- Accreditation results, including recommended actions or improvements, corrective action plans, and summaries of findings, and
- Expiration date of the accreditation.

The accreditation status must be made available on the state website, including whether each managed care entity has been accredited and, if applicable, the name of the accrediting entity, accreditation program, and accreditation level. The information should be updated at least annually.

States should post on their website the accreditation status of each managed care plan or if that plan is not accredited. *Posting of accreditation status applies no later than the rating period for contracts starting on or after July 1, 2017.*

§438.334 Medicaid managed care quality rating system.

General rule. States should choose one of the following quality rating options:

- **Adopt the Medicaid managed care quality rating system developed by CMS.**
- **Adopt an alternative Medicaid managed care quality rating system.**
 - 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.
 - Prior to requesting approval for an alternative system, a state must obtain input from the State’s Medical Care Advisory Committee, and provide an opportunity for public comment of at least 30 days on the proposed alternative rating system or modification.
 - Additional guidance will be provided through CMS public engagement and notice and comment processes.
- **Implement a Medicaid managed care quality rating system by May 2019.**

Quality ratings. Each year the state must collect data from each managed care entity under contract and issue an annual quality rating for each one based on the data collected using the Medicaid managed care quality rating system adopted.

CMS plans to establish a common framework for all states contracting with MCOs, PIHPs, and PAHPs to use in implementing a quality rating system (QRS);

- Alignment with the summary indicators modeled after and adopted by Marketplace QRS,
- Specific measures within each summary indicator may differ and will vary based on the population served.

Public engagement process—States should plan to use a public engagement process to develop a proposed QRS framework and methodology:

- Similar to the process used for Marketplace QRS systems including multiple state and stakeholder listening sessions and technical expert panel, and
- Publication of a proposed QRS in the *Federal Register*, with opportunity to comment, followed by notice of the final Medicaid and CHIP expected in 2018.

States will have three-years to implement a QRS system following final notice in the Federal Register.

§438.340 Managed care state quality strategy (QS).

General rule. Each state must draft and implement a written QS for assessing and improving the quality of health care and services furnished by managed care.

Elements of the state QS. At a minimum, the state’s QS will include the following:

- Network-adequacy and service availability standards.
- Goals and objectives for quality improvement.
- A description of:
 - The quality metrics and performance targets used to measure the performance targets and improvement of each contracted managed care entity. The state will identify and publish quality measures and performance outcomes at least annually on the web site.
 - The performance improvement projects to be implemented, including a description of interventions to improve access, quality, or timeliness of care.
- An annual, external independent review of the quality outcomes and timeliness of, and access to, the services covered under each managed care entity contract.

- A description of the state’s transition of care policy.
- The state’s plan to identify, evaluate, and reduce health disparities based on age, race, ethnicity, sex, primary language, and disability status. States should identify this demographic information for each Medicaid enrollee and provide it to the managed care entity at the time of enrollment. For the purposes of this section “*disability status*” means whether the individual qualified for Medicaid on the basis of a disability.
- A description of how the state will assess the performance and quality outcomes achieved by each primary care case manager (PCCM) entity.
- The mechanisms implemented by the state to comply with provisions in the rule pertaining to the identification of persons who need LTSS and persons with special health care needs.
- Information relating to non-duplication of external quality review (EQR) activities.
- The state’s definition of a “*significant change*” as it pertains to the state Medicaid program.

Developmental, evaluation, and revision. In drafting and revising it QS, the state must:

- Make the strategy available for public comment before submitting the strategy to CMS for review along with input from the Medical Care Advisory Committee, beneficiaries, and other stakeholders. If the state enrolls Indians in their managed care entities they must consult with the Tribes in accordance with the state’s Tribal consultation policy.
- **Review and update the QS as needed, but no less than once every 3 years** which should include an evaluation of the effectiveness of the strategy. All results must be available on the program Web site.
- Submit to CMS the following:
 - A copy of the initial strategy for CMS comment and feedback prior to adopting the final.
 - A copy of the revised strategy whenever significant changes have been made, as defined by the state’s QS.

Availability. The state must make the final QS available on the program Web site.

Effective Date–*This provision applies no later than July 1, 2018.*

***States are not required to include PAHPs that provide only NEMT services in their managed care QS.*

§438.350 External quality review (EQR).

An external quality review should be performed annually on each contracting entity and the review results published on the program web site by April 30th of each year.

§438.352 External quality review protocols.

HHS, in coordination with the National Governor’s Association (NGA), must develop protocols for the EQRs.

§438.354 Qualifications of external quality review organizations(EQRO).

General rule. The state must ensure that an EQRO meets the requirements set forth in the final rule pertaining to the EQRO qualifications.

Competence. The EQRO must have at a minimum the following:

- Staff with demonstrated experience and knowledge of Medicaid.
- Sufficient physical, technological, and financial resources to conduct EQR or EQR-related activities.

Independent status–The EQRO must be independent from the state Medicaid agency and from managed care entities that they review. To qualify as “*independent*”:

- If a state agency, department, university, or other state entity:
 - May not have Medicaid purchasing or managed care licensing authority, and
 - Must be governed by a board or similar body the majority of whose members are not government employees.
- An EQRO may not:

- Review any managed care entity, or competitor operating in the state over which the EQRO exerts control or which exerts control over the EQRO through:
 - i. Stock ownership,
 - ii. Stock options and convertible debentures,
 - iii. Voting trusts,
 - iv. Common management, and
 - v. Contractual relationship.
- Deliver any health care services to Medicaid beneficiaries,
- Conduct, on the state’s behalf, ongoing Medicaid managed care program operations related to oversight of the quality of managed care entity services, except for the related activities.
- Review any managed care entity for which it is conducting or has conducted an accreditation review within the previous 3 years.
- Have a present, or known future, direct or indirect financial relationship with the managed care entity that it will review as an EQRO.

§438.356 State contract options for external quality review.

The state must contract with at least one EQRO to conduct EQR alone and or other EQR related activities. The state may contract with additional EQROs, but all organizations must meet the competence requirements. The organizations are permitted to use subcontractors, but are accountable for, and must oversee all subcontractor functions. All EQROs and their subcontractors must meet the requirements for independence.

For each contract the state must follow an open, competitive procurement process that is in accordance with state law and regulations, and federal rules governing state procurement of Medicaid services.

§438.360 Activities related to external quality review (EQR).

General rule. The data obtained from the mandatory and optional EQR-related activities must be used for annual EQR and must include, at a minimum, the objectives, technical methods of data collection and analysis, description of data collected, and conclusions drawn.

Mandatory activities. For each managed care entity the following EQR-related activities must be performed:

- Validation of performance improvement projects during the preceding 12 months.
- Validation of the managed care entities performance measures calculated by the state during the preceding 12 months.
- A review, conducted within the previous 3-year period, to determine the managed care entities compliance with the standards.
- Validation of network adequacy during the preceding 12 months; *applies no later than one year from the issuance of the EQR protocol.*
- The EQR-related activities for PAHPs and to PCCM entities who receive financial incentives. PCCMs are required to undergo only 2 mandatory activities: validation of performance measures and compliance review.

Optional activities. The following activities may be performed by using information derived during the preceding 12 months:

- Validation of encounter data reported.
- Administration or validation of consumer or provider surveys of quality of care.
- Calculation of performance measures and validated by an EQRO.
- Conduct of performance improvement projects.
- Conduct of studies on quality that focus on a particular aspect of clinical or nonclinical services.
- Assist with the quality rating of the managed care entity.

Quality strategy (QS). The state must identify in its QS activities for which it has exercised the option and explain the rationale for the state’s determination that the Medicare review or private accreditation activity is comparable to such EQR activities.

All EQR provisions apply no later than July 1, 2018, except federal financial participation (FFP), which applies May 6, 2016 with the final rule publication.

§438.362 Exemptions from external quality review (EQR).

Basis for exemption. The state may exempt an MCO from EQR if the following conditions are met:

- The MCO has a current contract with the Medicare + Choice Program and a Medicaid contract that covers all or part of the same geographic region and the Medicaid contract has been in effect for at least two consecutive years during which the MCO was subject to EQR and found to be performing acceptably.
- To exercise this option, the state must obtain certain information on Medicare or private review findings.

§438.364 External quality review results.

Information that must be produced. The state must ensure that the EQR results in an annual report meet certain specifications outlined in the final rule.

Revisions. States may not substantively revise the content of the final EQR technical report without evidence of error or omission.

Availability of information. The state must contract with a qualified EQRO to produce and submit to the state an annual EQR technical report. **States must finalize the annual technical report by April 30th of each year.**

States must provide copies of the information upon request. The state must also make the information available in alternative formats for persons with disabilities, when requested.

Safeguarding patient identity. The information released may not disclose the identity or other protected health information of any patient.

§438.370 Federal financial participation (FFP).

FFP at the 75 percent rate will be available only for EQR expenditures (including the production of the EQR report) and the EQR-related activities performed on MCOs and conducted by EQROs and their subcontractors.

FFP at the 50 percent match rate will be available for EQR expenditures and EQR-related activities performed on entities other than MCOs (including PIHPs, PAHPs, PCCM entities, or other types of integrated care models) or performed by entities that do not meet the requirements of an EQRO.

In order to claim the FFP at the 75 percent rate **the state must submit each EQRO contract to CMS** for review and approval. The rate is no longer available for EQR activities for PIHPs.

The provision applies on May 6 2016, the publication date of the final rule.

CMCS Informational Bulletin: [Federal Financial Participation for Managed Care External Quality Review](#) (6/10/2016)

Improving the Quality of Care: CHIP

All new managed care provisions apply to CHIP managed care contracts as of the state fiscal year beginning on or after July 1, 2018.

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