(b) *Reporting of Medicaid and CHIP beneficiaries.* In States that have implemented a separate child health program (''separate CHIP'') under part 457 of this chapter:

(1) The agency must report, in accordance with attribution rules established by the Secretary pursuant to §437.10(b)(6), on measures included in the Child Core Set for—

(i) The Medicaid beneficiaries (including those for whom the State claims Federal financial participation under both Title XIX and Title XXI) in the age range to which the measure applies, as per reporting guidance described in paragraph §437.10(b)(2); and

(ii) The beneficiaries in the State's separate CHIP in the age range to which the measure applies, as per reporting guidance described in paragraph §437.10(b)(2).

(2) If the separate CHIP elects to report on Adult Core Set measures for individuals enrolled in their separate CHIP, the agency must report on individuals described in paragraphs (b)(1)(i) and (ii) of this section.

§437.20 State plan requirements.

(a) The State plan must specify that:

(1) The agency will report on the Child and Adult Core Sets in accordance with §437.15.

(2) If health home services are covered under the State plan pursuant to section 1945 or 1945A of the Act, the agency will report on the applicable Health Home Core Set or Sets in accordance with §437.15 of this subpart.

(3) If health home services are covered under the State plan pursuant to section 1945 or 1945A of the Act, the agency requires health home services providers to report to the agency on all populations served by the health home providers and on the measures in the applicable Health Home Core Set or Sets that are identified by the Secretary pursuant to §437.10(b)(1)(iii), as a condition for receiving payment for health home services.

(b) [Reserved]

PART 438—MANAGED CARE

Subpart A—General Provisions

Subpart B—State Responsibilities

Subpart C—Enrollee Rights and Protections

Subpart D—MCO, PIHP and PAHP Standards

Subpart E—Quality Measurement and Improvement; External Quality Review

Subpart F—Grievance and Appeal System

Subpart G—Medicaid Managed Care Quality Rating System

Subpart H—Additional Program Integrity Safeguards

Subpart I—Sanctions

Subpart J—Conditions for Federal Financial Participation (FFP)

Subpart K—Parity in Mental Health and Substance Use Disorder Benefits

AUTHORITY: 42 U.S.C. 1302.

SOURCE: 67 FR 41095, June 14, 2002, unless otherwise noted.

Subpart A—General Provisions

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

§ 438.1 Basis and scope.

(a) *Statutory basis.* This part is based on the following statutory sections:

(1) Section 1902(a)(4) of the Act requires that States provide for methods of administration that the Secretary finds necessary for proper and efficient operation of the State plan. The application of the requirements of this part to PIHPs and PAHPs that do not meet the statutory definition of an MCO or a PCCM is under the authority in section 1902(a)(4) of the Act.

(2) Section 1903(i)(25) of the Act prohibits payment to a State unless a State provides enrollee encounter data required by CMS.

(3) Section 1903(m) of the Act contains requirements that apply to comprehensive risk contracts.

(4) Section 1903(m)(2)(H) of the Act provides that an enrollee who loses Medicaid eligibility for not more than 2 months may be enrolled in the succeeding month in the same MCO or PCCM if that MCO or PCCM still has a contract with the State.

(5) Section 1905(t) of the Act contains requirements that apply to PCCMs.

(6) Section 1932 of the Act—

(i) Provides that, with specified exceptions, a State may require Medicaid beneficiaries to enroll in MCOs or PCCMs.

(ii) Establishes the rules that MCOs, PCCMs, the State, and the contracts between the State and those entities must meet, including compliance with requirements in sections 1903(m) and 1905(t) of the Act that are implemented in this part.

(iii) Establishes protections for enrollees of MCOs and PCCMs.

(iv) Requires States to develop a quality assessment and performance improvement strategy.

(v) Specifies certain prohibitions aimed at the prevention of fraud and abuse.

(vi) Provides that a State may not enter into contracts with MCOs unless it has established intermediate sanctions that it may impose on an MCO that fails to comply with specified requirements.

(vii) Specifies rules for Indian enrollees, Indian health care providers, and Indian managed care entities.

(viii) Makes other minor changes in the Medicaid program.

(b) *Scope.* This part sets forth requirements, prohibitions, and procedures for the provision of Medicaid services through MCOs, PIHPs, PAHPs, PCCMs and PCCM entities. Requirements vary depending on the type of entity and on the authority under which the State contracts with the entity. Provisions that apply only when the contract is under a mandatory managed care program authorized by section 1932(a)(1)(A) of the Act are identified as such.

§ 438.2 Definitions.

As used in this part—

Abuse means as the term is defined in § 455.2 of this chapter.

Actuary means an individual who meets the qualification standards established by the American Academy of Actuaries for an actuary and follows the practice standards established by the Actuarial Standards Board. In this part, Actuary refers to an individual who is acting on behalf of the State when used in reference to the development and certification of capitation rates.

Capitation payment means a payment the State makes periodically to a contractor on behalf of each beneficiary enrolled under a contract and based on the actuarially sound capitation rate for the provision of services under the State plan. The State makes the payment regardless of whether the particular beneficiary receives services during the period covered by the payment.

Choice counseling means the provision of information and services designed to assist beneficiaries in making enrollment decisions; it includes answering questions and identifying factors to

consider when choosing among managed care plans and primary care providers. Choice counseling does not include making recommendations for or against enrollment into a specific MCO, PIHP, or PAHP.

Comprehensive risk contract means a risk contract between the State and an MCO that covers comprehensive services, that is, inpatient hospital services and any of the following services, or any three or more of the following services:

(1) Outpatient hospital services.

(2) Rural health clinic services.

(3) Federally Qualified Health Center (FQHC) services.

(4) Other laboratory and X-ray services.

(5) Nursing facility (NF) services.

(6) Early and periodic screening, diagnostic, and treatment (EPSDT) services.

(7) Family planning services.

(8) Physician services.

(9) Home health services.

Enrollee means a Medicaid beneficiary who is currently enrolled in an MCO, PIHP, PAHP, PCCM, or PCCM entity in a given managed care program.

Enrollee encounter data means the information relating to the receipt of any item(s) or service(s) by an enrollee under a contract between a State and a MCO, PIHP, or PAHP that is subject to the requirements of §§ 438.242 and 438.818.

Federally qualified HMO means an HMO that CMS has determined is a qualified HMO under section 1310(d) of the PHS Act.

Fraud means as the term is defined in § 455.2 of this chapter.

Health insuring organization (HIO) means a county operated entity, that in exchange for capitation payments, covers services for beneficiaries—

(1) Through payments to, or arrangements with, providers;

(2) Under a comprehensive risk contract with the State; and

(3) Meets the following criteria—

(i) First became operational prior to January 1, 1986; or

(ii) Is described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734 of the Omnibus Budget Reconciliation Act of 1990 and section 205 of the Medicare Improvements for Patients and Providers Act of 2008).

In lieu of service or setting (ILOS) is a service or setting that is provided to an enrollee as a substitute for a covered service or setting under the State plan in accordance with § 438.3(e)(2). An ILOS can be used as an immediate or longer-term substitute for a covered service or setting under the State plan, or when the ILOS can be expected to reduce or prevent the future need to utilize the covered service or setting under the State plan.

Long-term services and supports (LTSS) means services and supports provided to beneficiaries of all ages who have functional limitations and/or chronic illnesses that have the primary purpose of supporting the ability of the beneficiary to live or work in the setting of their choice, which may include the individual's home, a worksite, a provider-owned or controlled residential setting, a nursing facility, or other institutional setting.

Managed care organization (MCO) means an entity that has, or is seeking to qualify for, a comprehensive risk contract under this part, and that is—

(1) A Federally qualified HMO that meets the advance directives requirements of subpart I of part 489 of this chapter; or

(2) Any public or private entity that meets the advance directives requirements and is determined by the Secretary to also meet the following conditions:

(i) Makes the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid beneficiaries within the area served by the entity.

(ii) Meets the solvency standards of § 438.116.

Managed care program means a managed care delivery system operated by a State as authorized under sections 1915(a), 1915(b), 1932(a), or 1115(a) of the Act.

Material adjustment means an adjustment that, using reasonable actuarial judgment, has a significant impact on the development of the capitation payment such that its omission or

misstatement could impact a determination whether the development of the capitation rate is consistent with generally accepted actuarial principles and practices.

Network provider means any provider, group of providers, or entity that has a network provider agreement with a MCO, PIHP, or PAHP, or a subcontractor, and receives Medicaid funding directly or indirectly to order, refer or render covered services as a result of the state's contract with an MCO, PIHP, or PAHP. A network provider is not a subcontractor by virtue of the network provider agreement.

Nonrisk contract means a contract between the State and a PIHP or PAHP under which the contractor—

(1) Is not at financial risk for changes in utilization or for costs incurred under the contract that do not exceed the upper payment limits specified in § 447.362 of this chapter; and

(2) May be reimbursed by the State at the end of the contract period on the basis of the incurred costs, subject to the specified limits.

Overpayment means any payment made to a network provider by a MCO, PIHP, or PAHP to which the network provider is not entitled to under Title XIX of the Act or any payment to a MCO, PIHP, or PAHP by a State to which the MCO, PIHP, or PAHP is not entitled to under Title XIX of the Act.

Potential enrollee means a Medicaid beneficiary who is subject to mandatory enrollment or may voluntarily elect to enroll in a given MCO, PIHP, PAHP, PCCM or PCCM entity, but is not yet an enrollee of a specific MCO, PIHP, PAHP, PCCM, or PCCM entity.

Prepaid ambulatory health plan (PAHP) means an entity that—

(1) Provides services to enrollees under contract with the State, and on the basis of capitation payments, or other payment arrangements that do not use State plan payment rates.

(2) Does not provide or arrange for, and is not otherwise responsible for the provision of any inpatient hospital or institutional services for its enrollees; and

(3) Does not have a comprehensive risk contract.

Prepaid inpatient health plan (PIHP) means an entity that—

(1) Provides services to enrollees under contract with the State, and on the basis of capitation payments, or other payment arrangements that do not use State plan payment rates.

(2) Provides, arranges for, or otherwise has responsibility for the provision of any inpatient hospital or institutional services for its enrollees; and

(3) Does not have a comprehensive risk contract.

Primary care means all health care services and laboratory services customarily furnished by or through a general practitioner, family physician, internal medicine physician, obstetrician/gynecologist, pediatrician, or other licensed practitioner as authorized by the State Medicaid program, to the extent the furnishing of those services is legally authorized in the State in which the practitioner furnishes them.

Primary care case management means a system under which:

(1) A primary care case manager (PCCM) contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid beneficiaries; or

(2) A PCCM entity contracts with the State to provide a defined set of functions.

Primary care case management entity (PCCM entity) means an organization that provides any of the following functions, in addition to primary care case management services, for the State:

(1) Provision of intensive telephonic or face-to-face case management, including operation of a nurse triage advice line.

(2) Development of enrollee care plans.

(3) Execution of contracts with and/or oversight responsibilities for the activities of FFS providers in the FFS program.

(4) Provision of payments to FFS providers on behalf of the State.

(5) Provision of enrollee outreach and education activities.

(6) Operation of a customer service call center.

(7) Review of provider claims, utilization and practice patterns to conduct

provider profiling and/or practice improvement.

(8) Implementation of quality improvement activities including administering enrollee satisfaction surveys or collecting data necessary for performance measurement of providers.

(9) Coordination with mental and substance use disorder health systems and providers.

(10) Coordination with long-term services and supports systems/providers.

Primary care case manager (PCCM) means a physician, a physician group practice or, at State option, any of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse-midwife.

Provider means any individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is legally authorized to do so by the State in which it delivers the services.

Rate cell means a set of mutually exclusive categories of enrollees that is defined by one or more characteristics for the purpose of determining the capitation rate and making a capitation payment; such characteristics may include age, gender, eligibility category, and region or geographic area. Each enrollee should be categorized in one of the rate cells for each unique set of mutually exclusive benefits under the contract.

Rating period means a period of 12 months selected by the State for which the actuarially sound capitation rates are developed and documented in the rate certification submitted to CMS as required by § 438.7(a).

Risk contract means a contract between the State an MCO, PIHP or PAHP under which the contractor—

(1) Assumes risk for the cost of the services covered under the contract; and

(2) Incurs loss if the cost of furnishing the services exceeds the payments under the contract.

State means the Single State agency as specified in § 431.10 of this chapter.

State directed payment (SDP) means a contract arrangement that directs an MCO's, PIHP's, or PAHP's expenditures under § 438.6(c).

Subcontractor means an individual or entity that has a contract with an MCO, PIHP, PAHP, or PCCM entity that relates directly or indirectly to the performance of the MCO's, PIHP's, PAHP's, or PCCM entity's obligations under its contract with the State. A network provider is not a subcontractor by virtue of the network provider agreement with the MCO, PIHP, or PAHP.

[81 FR 27853, May 6, 2016, as amended at 89 FR 41267, May 10, 2024]

§ 438.3 Standard contract requirements.

(a) *CMS review.* The CMS must review and approve all MCO, PIHP, and PAHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in § 438.806. Proposed final contracts must be submitted in the form and manner established by CMS. For States seeking approval of contracts prior to a specific effective date, proposed final contracts must be submitted to CMS for review no later than 90 days prior to the effective date of the contract.

(b) *Entities eligible for comprehensive risk contracts.* A State may enter into a comprehensive risk contract only with the following:

(1) An MCO.

(2) The entities identified in section 1903(m)(2)(B)(i), (ii), and (iii) of the Act.

(3) Community, Migrant, and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act. Unless they qualify for a total exemption under section 1903(m)(2)(B) of the Act, these entities are subject to the regulations governing MCOs under this part.

(4) An HIO that arranges for services and became operational before January 1986.

(5) An HIO described in section 9517(c)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) *Payment.* The following requirements apply to the final capitation rate and the receipt of capitation payments under the contract:

(1) The final capitation rate for each MCO, PIHP or PAHP must be:

(i) Specifically identified in the applicable contract submitted for CMS review and approval.

(ii) The final capitation rates must be based only upon services covered under the State plan, ILOS, and additional services deemed by the State to be necessary to comply with the requirements of subpart K of this part (applying parity standards from the Mental Health Parity and Addiction Equity Act), and represent a payment amount that is adequate to allow the MCO, PIHP or PAHP to efficiently deliver covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements.

(2) Capitation payments may only be made by the State and retained by the MCO, PIHP or PAHP for Medicaid-eligible enrollees.

(d) *Enrollment discrimination prohibited.* Contracts with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities must provide as follows:

(1) The MCO, PIHP, PAHP, PCCM or PCCM entity accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by CMS), up to the limits set under the contract.

(2) Enrollment is voluntary, except in the case of mandatory enrollment programs that meet the conditions set forth in § 438.50(a).

(3) The MCO, PIHP, PAHP, PCCM or PCCM entity will not, on the basis of health status or need for health care services, discriminate against individuals eligible to enroll.

(4) The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race; color; national origin; disability; or sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes; and will not use any policy or practice that has the effect of discriminating on the basis of race; color; national origin; disability; or sex which includes discrimination on the basis of sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes.

(e) *Services that may be covered by an MCO, PIHP, or PAHP.* (1) An MCO, PIHP, or PAHP may cover, for enrollees, services that are in addition to those covered under the State plan as follows:

(i) Any services that the MCO, PIHP or PAHP voluntarily agree to provide, although the cost of these services cannot be included when determining the payment rates under paragraph (c) of this section.

(ii) Any services necessary for compliance by the MCO, PIHP, or PAHP with the requirements of subpart K of this part and only to the extent such services are necessary for the MCO, PIHP, or PAHP to comply with § 438.910.

(2) An MCO, PIHP, or PAHP may cover, for enrollees, an ILOS as follows:

(i) The State determines that the ILOS is a medically appropriate and cost effective substitute for the covered service or setting under the State plan;

(ii) The enrollee is not required by the MCO, PIHP, or PAHP to use the ILOS, and the MCO, PIHP, or PAHP must comply with the following requirements:

(A) An enrollee who is offered or utilizes an ILOS offered as a substitute for a covered service or setting under the State plan retains all rights and protections afforded under part 438, and if an enrollee chooses not to receive an ILOS, they retain their right to receive the service or setting covered under the State plan on the same terms as would apply if an ILOS was not an option; and

(B) An ILOS may not be used to reduce, discourage, or jeopardize an enrollee's access to services and settings covered under the State plan, and an MCO, PIHP, or PAHP may not deny access to a service or setting covered under the State plan, on the basis that the enrollee has been offered an ILOS as an optional substitute for a service or setting covered under the State plan, is currently receiving an ILOS as a substitute for a service or setting covered under the State plan, or has utilized an ILOS in the past;

(iii) The approved ILOS is authorized and identified in the MCO, PIHP, or PAHP contract, and will be offered to enrollees at the option of the MCO, PIHP, or PAHP;

(iv) The utilization and actual cost of the ILOS is taken into account in developing the component of the capitation rates that represents the covered State plan services and settings, unless a statute or regulation explicitly requires otherwise; and

(v) With the exception of a short term stay as specified in § 438.6(e) in an Institution for Mental Diseases (IMD), as defined in § 435.1010 of this chapter, for inpatient mental health or substance use disorder treatment, an ILOS must also comply with the requirements in § 438.16.

(f) *Compliance with applicable laws and conflict of interest safeguards.* All contracts with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities must:

(1) Comply with all applicable Federal and State laws and regulations including Title VI of the Civil Rights Act of 1964; Title IX of the Education Amendments of 1972 (regarding education programs and activities); the Age Discrimination Act of 1975; the Rehabilitation Act of 1973; the Americans with Disabilities Act of 1990 as amended; and section 1557 of the Patient Protection and Affordable Care Act.

(2) Comply with the conflict of interest safeguards described in § 438.58 and with the prohibitions described in section 1902(a)(4)(C) of the Act applicable to contracting officers, employees, or independent contractors.

(g) *Provider-preventable condition requirements.* All contracts with MCOs, PIHPs and PAHPs must comply with the requirements mandating provider identification of provider-preventable conditions as a condition of payment, as well as the prohibition against payment for provider-preventable conditions as set forth in § 434.6(a)(12) and § 447.26 of this chapter. MCOs, PIHPs, and PAHPs, must report all identified provider-preventable conditions in a form and frequency as specified by the State.

(h) *Inspection and audit of records and access to facilities.* All contracts must provide that the State, CMS, the Office of the Inspector General, the Comptroller General, and their designees may, at any time, inspect and audit any records or documents of the MCO, PIHP, PAHP, PCCM or PCCM entity, or its subcontractors, and may, at any time, inspect the premises, physical facilities, and equipment where Medicaid-related activities or work is conducted. The right to audit under this section exists for 10 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(i) *Physician incentive plans.* (1) MCO, PIHP, and PAHP contracts must provide for compliance with the requirements set forth in §§ 422.208 and 422.210 of this chapter.

(2) In applying the provisions of §§ 422.208 and 422.210 of this chapter, references to ''MA organization,'' ''CMS,'' and ''Medicare beneficiaries'' must be read as references to ''MCO, PIHP, or PAHP,'' ''State,'' and ''Medicaid beneficiaries,'' respectively.

(3) The State, through its contracts with an MCO, PIHP, and PAHP must require that incentive payment contracts between the MCO, PIHP, and PAHP and network providers:

(i) Have a defined performance period that can be tied to the applicable MLR reporting periods.

(ii) Be signed and dated by all appropriate parties before the commencement of the applicable performance period.

(iii) Include clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that the provider must meet to receive the incentive payment.

(iv) Specify a dollar amount or a percentage of a verifiable dollar amount that can be clearly linked to successful completion of the metrics defined in the incentive payment contract, including a date of payment.

(4) The State through its contracts with an MCO, PIHP, and PAHP must:

(i) Define the documentation that must be maintained by the MCO, PIHP, and PAHP to support the provider incentive payments.

(ii) Prohibit the use of attestations as supporting documentation for data that factor into the MLR calculation.

(iii) Require the MCO, PIHP, and PAHP to make incentive payment contracts, and any documentation in paragraph (e)(4)(i) of this section, available to the State upon request and at any routine frequency established in the

State's contract with the MCO, PIHP, and PAHP.

(j) *Advance directives.* (1) All MCO and PIHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives, as if such regulation applied directly to MCOs and PIHPs.

(2) All PAHP contracts must provide for compliance with the requirements of § 422.128 of this chapter for maintaining written policies and procedures for advance directives as if such regulation applied directly to PAHPs if the PAHP includes, in its network, any of those providers listed in § 489.102(a) of this chapter.

(3) The MCO, PIHP, or PAHP subject to the requirements of this paragraph (j) must provide adult enrollees with written information on advance directives policies, and include a description of applicable State law.

(4) The information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the change.

(k) *Subcontracts.* All subcontracts must fulfill the requirements of this part for the service or activity delegated under the subcontract in accordance with § 438.230.

(l) *Choice of network provider.* The contract must allow each enrollee to choose his or her network provider to the extent possible and appropriate.

(m) *Audited financial reports.* The contract must require MCOs, PIHPs, and PAHPs to submit audited financial reports specific to the Medicaid contract on an annual basis. The audit must be conducted in accordance with generally accepted accounting principles and generally accepted auditing standards.

(n) *Parity in mental health and substance use disorder benefits.* (1) All MCO contracts, and any PIHP and PAHP contracts providing services to MCO enrollees, must provide for services to be delivered in compliance with the requirements of subpart K of this part insofar as those requirements are applicable.

(2) Any State providing any services to MCO enrollees using a delivery system other than the MCO delivery system must provide documentation of how the requirements of subpart K of this part are met with the submission of the MCO contract for review and approval under paragraph (a) of this section.

(o) *LTSS contract requirements.* Any contract with an MCO, PIHP or PAHP that includes LTSS as a covered benefit must require that any services covered under the contract that could be authorized through a waiver under section 1915(c) of the Act or a State plan amendment authorized through sections 1915(i) or 1915(k) of the Act be delivered in settings consistent with § 441.301(c)(4) of this chapter.

(p) *Special rules for certain HIOs.* Contracts with HIOs that began operating on or after January 1, 1986, and that the statute does not explicitly exempt from requirements in section 1903(m) of the Act, are subject to all the requirements of this part that apply to MCOs and contracts with MCOs. These HIOs may enter into comprehensive risk contracts only if they meet the criteria of paragraph (b) of this section.

(q) *Additional rules for contracts with PCCMs.* A PCCM contract must meet the following requirements:

(1) Provide for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment for emergency medical conditions.

(2) Restrict enrollment to beneficiaries who reside sufficiently near one of the PCCM's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation.

(3) Provide for arrangements with, or referrals to, sufficient numbers of physicians and other practitioners to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care.

(4) Prohibit discrimination in enrollment, disenrollment, and re-enrollment, based on the beneficiary's health status or need for health care services.

(5) Provide that enrollees have the right to disenroll in accordance with § 438.56(c).

(r) *Additional rules for contracts with PCCM entities.* In addition to the requirements in paragraph (q) of this section, States must submit PCCM entity

contracts to CMS for review and approval to ensure compliance with the provisions of this paragraph (r); § 438.10; and § 438.310(c)(2).

(s) *Requirements for MCOs, PCCMs, PIHPs, or PAHPs that provide covered outpatient drugs.* Contracts that obligate MCOs, PCCMs, PIHPs, or PAHPs to provide coverage of covered outpatient drugs must include the following requirements:

(1) The MCO, PIHP or PAHP provides coverage of covered outpatient drugs as defined in section 1927(k)(2) of the Act, that meets the standards for such coverage imposed by section 1927 of the Act as if such standards applied directly to the MCO, PIHP, or PAHP.

(2) The MCO, PIHP, or PAHP reports drug utilization data that is necessary for States to bill manufacturers for rebates in accordance with section 1927(b)(1)(A) of the Act no later than 45 calendar days after the end of each quarterly rebate period. Such utilization information must include, at a minimum, information on the total number of units of each dosage form, strength, and package size by National Drug Code of each covered outpatient drug dispensed or covered by the MCO, PIHP, or PAHP.

(3) The MCO, PIHP or PAHP establishes procedures to exclude utilization data for covered outpatient drugs that are subject to discounts under the 340B drug pricing program from the reports required under paragraph (s)(2) of this section when states do not require submission of managed care drug claims data from covered entities directly.

(4) The MCO, PCCM, PIHP, or PAHP must operate a drug utilization review program that complies with the requirements described in section 1927(g) of the Act and part 456, subpart K, of this chapter, as if such requirement applied to the MCO, PCCM, PIHP, or PAHP instead of the State.

(5) The MCO, PCCM, PIHP, or PAHP must provide a detailed description of its drug utilization review program activities to the State on an annual basis.

(6) The MCO, PIHP or PAHP must conduct a prior authorization program that complies with the requirements of section 1927(d)(5) of the Act, as if such requirements applied to the MCO, PIHP, or PAHP instead of the State.

(t) *Requirements for MCOs, PIHPs, or PAHPs responsible for coordinating benefits for dually eligible individuals.* In a State that enters into a Coordination of Benefits Agreement (COBA) with Medicare for Medicaid, an MCO, PIHP, or PAHP contract that includes responsibility for coordination of benefits for individuals dually eligible for Medicaid and Medicare must specify the methodology by which the State ensures that the appropriate MCO, PIHP, or PAHP receives all applicable crossover claims for which the MCO, PIHP, or PAHP is responsible. If the State elects to use a methodology other than requiring the MCO, PIHP, or PAHP to enter into a COBA with Medicare, that methodology must ensure that the submitting provider is promptly informed on the State's remittance advice that the State has not denied payment and that the claim has been sent to the MCO, PIHP, or PAHP for payment consideration.

(u) *Recordkeeping requirements.* MCOs, PIHPs, and PAHPs must retain, and require subcontractors to retain, as applicable, the following information: enrollee grievance and appeal records in § 438.416, base data in § 438.5(c), MLR reports in § 438.8(k), and the data, information, and documentation specified in §§ 438.604, 438.606, 438.608, and 438.610 for a period of no less than 10 years.

(v) *Applicability date.* Paragraphs (e)(2)(v) of this section applies to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following July 9, 2024, and paragraphs (i)(3) and (4) of this section apply to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 1 year following July 9, 2024.

[81 FR 27853, May 6, 2016, as amended at 85 FR 37243, June 19, 2020; 85 FR 72837, Nov. 13, 2020; 85 FR 87101, Dec. 31, 2020; 89 FR 37691, May 6, 2024; 89 FR 41267, May 10, 2024]

EFFECTIVE DATE NOTE: At 89 FR 79081, Sept. 26, 2024, § 438.3 was amended by adding paragraphs (s)(7) and (8) and (w), effective Nov. 19, 2024. For the convenience of the user, the added text is set forth as follows:

§ 438.3 Standard contract requirements.

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(s) * * *

(7) The MCO, PIHP, or PAHP must assign and exclusively use unique Medicaid-specific Bank Identification Number (BIN) and Processor Control Number (PCN) combination, and group number identifiers for all Medicaid managed care enrollee identification cards for pharmacy benefits.

(8) The MCO, PIHP, or PAHP that contracts with any subcontractor for the delivery or administration of the covered outpatient drug benefit must require the subcontractor to report separately to the MCO, PIHP, or PAHP the amounts related to:

(i) The incurred claims described in § 438.8(e)(2) such as reimbursement for the covered outpatient drug, payments for other patient services, and the fees paid to providers or pharmacies for dispensing or administering a covered outpatient drug; and

(ii) Administrative costs, fees and expenses of the subcontractor.

* * * * *

(w) *Applicability date.* Paragraphs (s)(7) and (8) of this section apply to the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 1 year following November 19, 2024.

§ 438.4 Actuarial soundness.

(a) *Actuarially sound capitation rates defined.* Actuarially sound capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the MCO, PIHP, or PAHP for the time period and the population covered under the terms of the contract, and such capitation rates are developed in accordance with the requirements in paragraph (b) of this section.

(b) *CMS review and approval of actuarially sound capitation rates.* Capitation rates for MCOs, PIHPs, and PAHPs must be reviewed and approved by CMS as actuarially sound. To be approved by CMS, capitation rates must:

(1) Have been developed in accordance with the standards specified in § 438.5 and generally accepted actuarial principles and practices. Any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations must be based on valid rate development standards that represent actual cost differences in providing covered services to the covered populations. Any differences in the assumptions, methodologies, or factors used to develop capitation rates must not vary with the rate of Federal financial participation (FFP) associated with the covered populations in a manner that increases Federal costs. The determination that differences in the assumptions, methodologies, or factors used to develop capitation rates for MCOs, PIHPs, and PAHPs increase Federal costs and vary with the rate of FFP associated with the covered populations must be evaluated for the entire managed care program and include all managed care contracts for all covered populations. CMS may require a State to provide written documentation and justification that any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations or contracts represent actual cost differences based on the characteristics and mix of the covered services or the covered populations.

(2) Be appropriate for the populations to be covered and the services to be furnished under the contract.

(3) Be adequate to meet the requirements on MCOs, PIHPs, and PAHPs in §§ 438.206, 438.207, and 438.208.

(4) Be specific to payments for each rate cell under the contract.

(5) Payments from any rate cell must not cross-subsidize or be cross-subsidized by payments for any other rate cell.

(6) Be certified by an actuary as meeting the applicable requirements of this part, including that the rates have been developed in accordance with the requirements specified in § 438.3(c)(1)(ii) and (e).

(7) Meet any applicable special contract provisions as specified in § 438.6.

(8) Be provided to CMS in a format and within a timeframe that meets requirements in § 438.7.

(9) Be developed in such a way that the MCO, PIHP, or PAHP would reasonably achieve a medical loss ratio standard, as calculated under § 438.8, of at least 85 percent for the rate year. The capitation rates may be developed in such a way that the MCO, PIHP, or

PAHP would reasonably achieve a medical loss ratio standard greater than 85 percent, as calculated under § 438.8, as long as the capitation rates are adequate for reasonable, appropriate, and attainable non-benefit costs.

(c) *Option to develop and certify a rate range.* (1) Notwithstanding the provision at paragraph (b)(4) of this section, the State may develop and certify a range of capitation rates per rate cell as actuarially sound, when all of the following conditions are met:

(i) The rate certification identifies and justifies the assumptions, data, and methodologies specific to both the upper and lower bounds of the rate range.

(ii) Both the upper and lower bounds of the rate range must be certified as actuarially sound consistent with the requirements of this part.

(iii) The upper bound of the rate range does not exceed the lower bound of the rate range multiplied by 1.05.

(iv) The rate certification documents the State's criteria for paying MCOs, PIHPs, and PAHPs at different points within the rate range.

(v) The State does not use as a criterion for paying MCOs, PIHPs, and PAHPs at different points within the rate range any of the following:

(A) The willingness or agreement of the MCOs, PIHPs, or PAHPs or their network providers to enter into, or adhere to, intergovernmental transfer (IGT) agreements; or

(B) The amount of funding the MCOs, PIHPs, or PAHPs or their network providers provide through IGT agreements.

(2) When a State develops and certifies a range of capitation rates per rate cell as actuarially sound consistent with the requirements of this paragraph (c), the State must:

(i) Document the capitation rates, prior to the start of the rating period, for the MCOs, PIHPs, and PAHPs at points within the rate range, consistent with the criteria in paragraph (c)(1)(iv) of this section.

(ii) Not modify the capitation rates under § 438.7(c)(3).

(iii) Not modify the capitation rates within the rate range, unless the State is increasing or decreasing the capitation rate per rate cell within the rate range up to 1 percent during the rating period. However, any changes of the capitation rate within the permissible 1 percent range must be consistent with a modification of the contract as required in § 438.3(c) and are subject to the requirements at paragraph (b)(1) of this section. Any modification to the capitation rates within the rate range greater than the permissible 1 percent range will require the State to provide a revised rate certification for CMS approval, which demonstrates that—

(A) The criteria in paragraph (c)(1)(iv) of this section, as described in the initial rate certification, were not applied accurately;

(B) There was a material error in the data, assumptions, or methodologies used to develop the initial rate certification and that the modifications are necessary to correct the error; or

(C) Other adjustments are appropriate and reasonable to account for programmatic changes.

(iv) Post on the website required in § 438.10(c)(3) the following information prior to executing a managed care contract or contract amendment that includes or modifies a rate range:

(A) The upper and lower bounds of each rate cell;

(B) A description of all assumptions that vary between the upper and lower bounds of each rate cell, including for the assumptions that vary, the specific assumptions used for the upper and lower bounds of each rate cell; and

(C) A description of the data and methodologies that vary between the upper and lower bounds of each rate cell, including for the data and methodologies that vary, the specific data and methodologies used for the upper and lower bounds of each rate cell.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72837, Nov. 13, 2020; 85 FR 72837, Nov. 13, 2020]

§ 438.5 Rate development standards.

(a) *Definitions.* As used in this section and § 438.7(b), the following terms have the indicated meanings:

Budget neutral means a standard for any risk sharing mechanism that recognizes both higher and lower expected costs among contracted MCOs, PIHPs,

or PAHPs under a managed care program and does not create a net aggregate gain or loss across all payments under that managed care program.

Prospective risk adjustment means a methodology to account for anticipated variation in risk levels among contracted MCOs, PIHPs, or PAHPs that is derived from historical experience of the contracted MCOs, PIHPs, or PAHPs and applied to rates for the rating period for which the certification is submitted.

Retrospective risk adjustment means a methodology to account for variation in risk levels among contracted MCOs, PIHPs, or PAHPs that is derived from experience concurrent with the rating period of the contracted MCOs, PIHPs, or PAHPs subject to the adjustment and calculated at the expiration of the rating period.

Risk adjustment is a methodology to account for the health status of enrollees via relative risk factors when predicting or explaining costs of services covered under the contract for defined populations or for evaluating retrospectively the experience of MCOs, PIHPs, or PAHPs contracted with the State.

(b) *Process and requirements for setting actuarially sound capitation rates.* In setting actuarially sound capitation rates, the State must follow the steps below, in an appropriate order, in accordance with this section, or explain why they are not applicable:

(1) Consistent with paragraph (c) of this section, identify and develop the base utilization and price data.

(2) Consistent with paragraph (d) of this section, develop and apply trend factors, including cost and utilization, to base data that are developed from actual experience of the Medicaid population or a similar population in accordance with generally accepted actuarial practices and principles.

(3) Consistent with paragraph (e) of this section, develop the non-benefit component of the rate to account for reasonable expenses related to MCO, PIHP, or PAHP administration; taxes; licensing and regulatory fees; contribution to reserves; risk margin; cost of capital; and other operational costs associated with the MCO's, PIHP's, or PAHP's provision of State plan services to Medicaid enrollees.

(4) Consistent with paragraph (f) of this section, make appropriate and reasonable adjustments to account for changes to the base data, programmatic changes, non-benefit components, and any other adjustment necessary to establish actuarially sound rates.

(5) Take into account the MCO's, PIHP's, or PAHP's past medical loss ratio, as calculated and reported under § 438.8, in the development of the capitation rates, and consider the projected medical loss ratio in accordance with § 438.4(b)(9).

(6) Consistent with paragraph (g) of this section, if risk adjustment is applied, select a risk adjustment methodology that uses generally accepted models and apply it in a budget neutral manner across all MCOs, PIHPs, or PAHPs in the program to calculate adjustments to the payments as necessary.

(c) *Base data.* (1) States must provide all the validated encounter data, FFS data (as appropriate), and audited financial reports (as defined in § 438.3(m)) that demonstrate experience for the populations to be served by the MCO, PIHP, or PAHP to the actuary developing the capitation rates for at least the three most recent and complete years prior to the rating period.

(2) States and their actuaries must use the most appropriate data, with the basis of the data being no older than from the 3 most recent and complete years prior to the rating period, for setting capitation rates. Such base data must be derived from the Medicaid population, or, if data on the Medicaid population is not available, derived from a similar population and adjusted to make the utilization and price data comparable to data from the Medicaid population. Data must be in accordance with actuarial standards for data quality and an explanation of why that specific data is used must be provided in the rate certification.

(3) *Exception.* (i) States that are unable to base their rates on data meeting the qualifications in paragraph (c)(2) of this section that the basis of the data be no older than from the 3 most recent and complete years prior

to the rating period may request approval for an exception; the request must describe why an exception is necessary and describe the actions the state intends to take to come into compliance with those requirements.

(ii) States that request an exception from the base data standards established in this section must set forth a corrective action plan to come into compliance with the base data standards no later than 2 years after the last day of the rating period for which the deficiency was identified.

(d) *Trend.* Each trend must be reasonable and developed in accordance with generally accepted actuarial principles and practices. Trend must be developed primarily from actual experience of the Medicaid population or from a similar population.

(e) *Non-benefit component of the rate.* The development of the non-benefit component of the rate must include reasonable, appropriate, and attainable expenses related to MCO, PIHP, or PAHP administration, taxes, licensing and regulatory fees, contribution to reserves, risk margin, cost of capital, and other operational costs associated with the provision of services identified in § 438.3(c)(1)(ii) to the populations covered under the contract.

(f) *Adjustments.* Each adjustment must reasonably support the development of an accurate base data set for purposes of rate setting, address appropriate programmatic changes, reflect the health status of the enrolled population, or reflect non-benefit costs, and be developed in accordance with generally accepted actuarial principles and practices.

(g) *Risk adjustment.* Prospective or retrospective risk adjustment methodologies must be developed in a budget neutral manner consistent with generally accepted actuarial principles and practices.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72837, Nov. 13, 2020]

§ 438.6 Special contract provisions related to payment.

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Academic medical center means a facility that includes a health professional school with an affiliated teaching hospital.

Average commercial rate means the average rate paid for services by the highest claiming third-party payers for specific services as measured by claims volume.

Base amount is the starting amount, calculated according to paragraph (d)(2) of this section, available for pass-through payments to hospitals in a given contract year subject to the schedule in paragraph (d)(3) of this section.

Condition-based payment means a prospective payment for a defined set of Medicaid covered service(s) that are tied to a specific condition and delivered to Medicaid managed care enrollees under the contract.

Final State directed payment cost percentage means the annual amount calculated, in accordance with paragraph (c)(7)(iii) of this section, for each State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section and for each managed care program.

Incentive arrangement means any payment mechanism under which a MCO, PIHP, or PAHP may receive additional funds over and above the capitation rates it was paid for meeting targets specified in the contract.

Inpatient hospital services means the same as specified at § 440.10.

Maximum fee schedule means any State directed payment where the State requires an MCO, PIHP, or PAHP to pay no more than a certain amount for a covered service(s).

Minimum fee schedule means any State directed payment where the State requires an MCO, PIHP, or PAHP to pay no less than a certain amount for a covered service(s).

Nursing facility services means the same as specified in § 440.40(a).

Outpatient hospital services means the same as specified in § 440.20(a).

Pass-through payment is any amount required by the State to be added to the contracted payment rates, and considered in calculating the actuarially sound capitation rate, between the MCO, PIHP, or PAHP and hospitals, physicians, or nursing facilities that is not for the following purposes: A specific service or benefit provided to a

specific enrollee covered under the contract; a provider payment methodology permitted under paragraphs (c)(1)(i) through (iii) of this section for services and enrollees covered under the contract; a subcapitated payment arrangement for a specific set of services and enrollees covered under the contract; GME payments; or FQHC or RHC wrap around payments.

Performance measure means, for State directed payments, a quantitative measure with a numerator and denominator that is used to monitor performance at a point in time or track performance over time, of service delivery, quality of care, or outcomes as defined in § 438.320 for enrollees.

Population-based payment means a prospective payment for a defined set of Medicaid service(s) for a population of Medicaid managed care enrollees covered under the contract attributed to a specific provider or provider group.

Qualified practitioner services at an academic medical center means professional services provided by both physicians and non-physician practitioners affiliated with or employed by an academic medical center.

Risk corridor means a risk sharing mechanism in which States and MCOs, PIHPs, or PAHPs may share in profits and losses under the contract outside of a predetermined threshold amount.

State plan approved rates means amounts calculated for specific services identifiable as having been provided to an individual beneficiary described under CMS approved rate methodologies in the Medicaid State plan. Supplemental payments contained in a State plan are not, and do not constitute, State plan approved rates.

Supplemental payments means amounts paid by the State in its FFS Medicaid delivery system to providers that are described and approved in the State plan or under a demonstration or waiver thereof and are in addition to State plan approved rates. Disproportionate share hospital (DSH) and graduate medical education (GME) payments are not, and do not constitute, supplemental payments.

Total payment rate means the aggregate for each managed care program of:

(i) The average payment rate paid by all MCOs, PIHPs, or PAHPs to all providers included in the specified provider class for each service identified in the State directed payment;

(ii) The effect of the State directed payment on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking prior approval under paragraph (c)(2)(i) of this section;

(iii) The effect of any and all other State directed payments on the average rate paid to providers included in the specified provider class for the same service for which the State is seeking prior approval under paragraph (c)(2)(i) of this section; and

(iv) The effect of any and all allowable pass-through payments, as defined in paragraph (a) of this section, to be paid to any and all providers included in the provider class specified in the State directed payment for which the State is seeking prior approval under paragraph (c)(2)(i) of this section on the average payment rate to providers in the specified provider class.

Total published Medicare payment rate means amounts calculated as payment for specific services that have been developed under Title XVIII Part A and Part B.

Uniform increase means any State directed payment that directs the MCO, PIHP, or PAHP to pay the same amount (the same dollar amount or the same percentage increase) per Medicaid covered service(s) in addition to the rates the MCO, PIHP or PAHP negotiated with the providers included in the specified provider class for the service(s) identified in the State directed payment.

Withhold arrangement means any payment mechanism under which a portion of a capitation rate is withheld from an MCO, PIHP, or PAHP and a portion of or all of the withheld amount will be paid to the MCO, PIHP, or PAHP for meeting targets specified in the contract. The targets for a withhold arrangement are distinct from general operational requirements under the contract. Arrangements that withhold a portion of a capitation rate for noncompliance with general operational requirements are a penalty and not a withhold arrangement.

(b) *Basic requirements.* (1) If used in the payment arrangement between the State and the MCO, PIHP, or PAHP, all applicable risk-sharing mechanisms, such as reinsurance, risk corridors, or stop-loss limits, must be documented in the contract and rate certification documents for the rating period prior to the start of the rating period, and must be developed in accordance with § 438.4, the rate development standards in § 438.5, and generally accepted actuarial principles and practices. Risk-sharing mechanisms may not be added or modified after the start of the rating period.

(2) Contracts with incentive arrangements may not provide for payment in excess of 105 percent of the approved capitation payments attributable to the enrollees or services covered by the incentive arrangement, since such total payments will not be considered to be actuarially sound. For all incentive arrangements, the contract must provide that the arrangement is—

(i) For a fixed period of time and performance is measured during the rating period under the contract in which the incentive arrangement is applied.

(ii) Not to be renewed automatically.

(iii) Made available to both public and private contractors under the same terms of performance.

(iv) Does not condition MCO, PIHP, or PAHP participation in the incentive arrangement on the MCO, PIHP, or PAHP entering into or adhering to intergovernmental transfer agreements.

(v) Necessary for the specified activities, targets, performance measures, or quality-based outcomes that support program initiatives as specified in the State's quality strategy at § 438.340.

(3) Contracts that provide for a withhold arrangement must ensure that the capitation payment minus any portion of the withhold that is not reasonably achievable is actuarially sound as determined by an actuary. The total amount of the withhold, achievable or not, must be reasonable and take into consideration the MCO's, PIHP's or PAHP's financial operating needs accounting for the size and characteristics of the populations covered under the contract, as well as the MCO's, PIHP's or PAHP's capital reserves as measured by the risk-based capital level, months of claims reserve, or other appropriate measure of reserves. The data, assumptions, and methodologies used to determine the portion of the withhold that is reasonably achievable must be submitted as part of the documentation required under § 438.7(b)(6). For all withhold arrangements, the contract must provide that the arrangement is—

(i) For a fixed period of time and performance is measured during the rating period under the contract in which the withhold arrangement is applied.

(ii) Not to be renewed automatically.

(iii) Made available to both public and private contractors under the same terms of performance.

(iv) Does not condition MCO, PIHP, or PAHP participation in the withhold arrangement on the MCO, PIHP, or PAHP entering into or adhering to intergovernmental transfer agreements.

(v) Necessary for the specified activities, targets, performance measures, or quality-based outcomes that support program initiatives as specified in the State's quality strategy under § 438.340.

(c) *State directed payments under MCO, PIHP, or PAHP contracts*—(1) *General rule.* Except as specified in this paragraph (c), in paragraph (d) of this section, in a specific provision of Title XIX, or in another regulation implementing a Title XIX provision related to payments to providers, that is applicable to managed care programs, the State may not in any way direct the MCO's, PIHP's or PAHP's expenditures under the contract.

(i) The State may require the MCO, PIHP or PAHP to implement value-based purchasing models for provider reimbursement, such as pay for performance arrangements, bundled payments, or other service payment models intended to recognize value or outcomes over volume of services.

(ii) The State may require MCOs, PIHPs, or PAHPs to participate in a multi-payer or Medicaid-specific delivery system reform or performance improvement initiative.

(iii) The State may require the MCO, PIHP, or PAHP to:

(A) Adopt a minimum fee schedule for providers that provide a particular

service under the contract using State plan approved rates.

(B) Adopt a minimum fee schedule for providers that provide a particular service under the contract using a total published Medicare payment rate that was in effect no more than 3 years prior to the start of the rating period and the minimum fee schedule to be used by the MCO, PIHP, or PAHP is equivalent to 100 percent of the specified total published Medicare payment rate.

(C) Adopt a minimum fee schedule for providers that provide a particular service under the contract using rates other than the State plan approved rates or one or more total published Medicare payment rates described in paragraph (c)(1)(iii)(B) of this section.

(D) Provide a uniform dollar or percentage increase for providers that provide a particular service under the contract.

(E) Adopt a maximum fee schedule for providers that provide a particular service under the contract, so long as the MCO, PIHP, or PAHP retains the ability to reasonably manage risk and has discretion in accomplishing the goals of the contract.

(2) *Standards for State directed payments.* (i) State directed payments specified in paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(C) through (E) of this section must have written prior approval that the standards and requirements in this section are met.

(ii) Each State directed payment must meet the following standards. Specifically, each State directed payment must:

(A) Be based on the utilization and delivery of services;

(B) Direct expenditures equally, and using the same terms of performance, for a class of providers providing the service under the contract;

(C) Expect to advance at least one of the goals and objectives in the quality strategy in § 438.340;

(D) Have an evaluation plan that measures the degree to which the State directed payment advances at least one of the goals and objectives in the quality strategy in § 438.340 and includes all of the elements outlined in paragraph (c)(2)(iv) of this section;

(E) Not condition provider participation in State directed payments on the provider entering into or adhering to intergovernmental transfer agreements;

(F) Result in achievement of the stated goals and objectives in alignment with the State's evaluation plan and, upon request from CMS, the State must provide an evaluation report documenting achievement of these stated goals and objectives;

(G) Comply with all Federal legal requirements for the financing of the non-Federal share, including but not limited to, 42 CFR 433, subpart B;

(H)(*1*) Ensure that providers receiving payment under a State directed payment attest that they do not participate in any hold harmless arrangement for any health care-related tax as specified in § 433.68(f)(3) of this subchapter in which the State or other unit of government imposing the tax provides for any direct or indirect payment, offset, or waiver such that the provision of the payment, offset, or waiver directly or indirectly guarantees to hold the taxpayer harmless for all or any portion of the tax amount, and

(*2*) Ensure either that, upon CMS request, such attestations are available, or that the State provides an explanation that is satisfactory to CMS about why specific providers are unable or unwilling to make such attestations;

(I) Ensure that the total payment rate for each service and provider class included in the State directed payment must be reasonable, appropriate, and attainable and, upon request from CMS, the State must provide documentation demonstrating the total payment rate for each service and provider class; and

(J) Be developed in accordance with § 438.4, and the standards specified in §§ 438.5, 438.7, and 438.8.

(iii) The total payment rate for each State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section for inpatient hospital services, outpatient hospital services, nursing facility services, or qualified practitioner services at an academic medical center must not exceed the average commercial

rate. To demonstrate compliance with this paragraph, States must submit:

(A) The average commercial rate demonstration, for which States must use payment data that:

(*1*) Is specific to the State;

(*2*) Is no older than from the three most recent and complete years prior to the rating period of the initial request following the applicability date of this section;

(*3*) Is specific to the service(s) addressed by the State directed payment;

(*4*) Includes the total reimbursement by the third-party payer and any patient liability, such as cost sharing and deductibles;

(*5*) Excludes payments to FQHCs, RHCs, and from any non-commercial payers, such as Medicare; and

(*6*) Excludes any payment data for services or codes that the applicable Medicaid MCOs, PIHPs, or PAHPs do not cover.

(B) A total payment rate comparison, for which States must provide a comparison of the total payment rate for these services included in the State directed payment to the average commercial rate that:

(*1*) Is specific to each managed care program that the State directed payment applies to;

(*2*) Is specific to each provider class to which the State directed payment applies;

(*3*) Is projected for the rating period for which the State is seeking prior approval of the State directed payment under paragraph (c)(2)(i) of this section;

(*4*) Uses payment data that are specific to each service included in the State directed payment; and

(*5*) Describes each of the components of the total payment rate as a percentage of the average commercial rate (demonstrated by the State as provided in paragraph (c)(2)(iii)(A) of this section) for each of these services included in the State directed payment.

(C) The ACR demonstration described in paragraph (c)(2)(iii)(A) of this section must be included with the initial documentation submitted for written prior approval of the State directed payment under paragraph (c)(2)(i) of this section, and then subsequently updated at least once every 3 years thereafter as long as the State continues to include the State directed payment that requires prior approval under paragraph (c)(2)(i) of this section in any MCO, PIHP, or PAHP contract. The total payment rate comparison described in paragraph (c)(2)(iii)(B) of this section must be included with the documentation submitted for written prior approval under paragraph (c)(2)(i) of this section and updated with each amendment and subsequent renewal.

(iv) For State directed payments for which written prior approval under paragraph (c)(2)(i) of this section is required, the State must include a written evaluation plan with its submission for written prior approval under paragraph (c)(2)(i) of this section and an updated written evaluation plan with each amendment and subsequent renewal. The evaluation plan must include the following elements:

(A) Identification of at least two metrics that will be used to measure the effectiveness of the State directed payment in advancing at least one of the goals and objectives in the quality strategy on an annual basis, which must:

(*1*) Be specific to the State directed payment and, when practicable and relevant, attributable to the performance by the providers for enrollees in all of the State's managed care program(s) to which the State directed payment applies; and

(*2*) Include at least one performance measure as defined in § 438.6(a) as part of the metrics used to measure the effectiveness of the State directed payment;

(B) Include baseline statistics on all metrics that will be used in the evaluation of the State directed payment for which the State is seeking written prior approval under paragraph (c)(2)(i) of this section;

(C) Include performance targets for all metrics to be used in the evaluation of the State directed payment for which the State is seeking written prior approval under paragraph (c)(2)(i) of this section that demonstrate either maintenance or improvement over the baseline statistics and not a decline relative to baseline. The target for at

least one performance measure, as defined in §438.6(a), must demonstrate improvement over baseline; and

(D) Include a commitment by the State to submit an evaluation report in accordance with §438.6(c)(2)(v) if the final State directed payment cost percentage exceeds 1.5 percent.

(v) For any State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section that has a final State directed payment cost percentage greater than 1.5 percent, the State must complete and submit an evaluation report using the evaluation plan outlined during the prior approval process under paragraph (c)(2)(iv) of this section.

(A) This evaluation report must:

(*1*) Include all of the elements in paragraph (c)(2)(iv) of this section as specified in the approved evaluation plan;

(*2*) Include three most recent and complete years of annual results for each metric as required in paragraph (c)(2)(iv)(A) of this section; and

(*3*) Be published on the public facing website as required under §438.10(c)(3).

(B) States must submit the initial evaluation report as described in paragraph (c)(2)(v)(A) of this section to CMS no later than 2 years after the conclusion of the 3-year evaluation period. Subsequent evaluation reports must be submitted to CMS every 3 years.

(vi) Any State directed payments described in paragraph (c)(1)(i) or (ii) of this section must:

(A) Make participation in the value-based purchasing, delivery system reform, or performance improvement initiative available using the same terms of performance to a class of providers providing services under the contract related to the reform or improvement initiative;

(B) If the State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section conditions payment upon performance, the payment to providers under the State directed payment:

(*1*) Cannot be conditioned upon administrative activities, such as the reporting of data nor upon the participation in learning collaboratives or similar administrative activities;

(*2*) Must use a common set of performance measures across all of the payers and providers specified in the State directed payment;

(*3*) Must define and use a performance measurement period that must not exceed the length of the rating period and must not precede the start of the rating period in which the payment is delivered by more than 12 months, and all payments must be documented in the rate certification for the rating period in which the payment is delivered;

(*4*) Must identify baseline statistics on all metrics that will be used to measure the performance that is the basis for payment to the provider from the MCO, PIHP, or PAHP; and

(*5*) Must use measurable performance targets, which are attributable to the performance by the providers in delivering services to enrollees in each of the State's managed care program(s) to which the State directed payment applies, that demonstrate maintenance or improvement over baseline data on all metrics that will be used to measure the performance that is the basis for payment to the provider from the MCO, PIHP, or PAHP.

(C) If the State directed payment is a population-based or condition-based payment, the State directed payment must:

(*1*) Be based upon the delivery by the provider of one or more specified Medicaid covered service(s) during the rating period or the attribution of a covered enrollee to a provider for treatment during the rating period;

(*2*) If basing payment on the attribution of enrollees to a provider, have an attribution methodology that uses data that are no older than the three most recent and complete years of data; seeks to preserve existing provider-enrollee relationships; accounts for enrollee preference in choice of provider; and describes when patient panels are attributed, how frequently they are updated, and how those updates are communicated to providers;

(*3*) Replace the negotiated rate between an MCO, PIHP, or PAHP and providers for the Medicaid covered service(s) included in the population or condition-based payment; no other payment may be made by an MCO, PIHP, or PAHP to the same provider

on behalf of the same enrollee for the same services included in the population or condition-based payment; and

(*4*) Include at least one metric in the evaluation plan required under paragraph (c)(2)(iv) of this section that measures performance at the provider class level; the target for this performance measure, as defined in § 438.6(a), must be set to demonstrate improvement over baseline.

(vii) Any State directed payment described in paragraph (c)(1)(iii) of this section must:

(A) Condition payment from the MCO, PIHP, or PAHP to the provider on the utilization and delivery of services under the contract for the rating period for which the State is seeking written prior approval only; and

(B) Not condition payment from the MCO, PIHP, or PAHP to the provider on utilization and delivery of services outside of the rating period for which the State is seeking written prior approval and then require that payments be reconciled to utilization during the rating period.

(viii) A State must complete and submit all required documentation for each State directed payment for which written prior approval is required under (c)(2)(i) and for each amendment to an approved State directed payment, respectively, before the start date of the State directed payment or the start date of the amendment.

(3) *Approval and renewal timeframes.* (i) Approval of a State directed payment described in paragraphs (c)(1)(i) and (ii) of this section is for one rating period unless a multi-year approval of up to three rating periods is requested and meets all of the following criteria:

(A) The State has explicitly identified and described the State directed payment in the contract as a multi-year State directed payment, including a description of the State directed payment by year and if the State directed payment varies by year.

(B) The State has developed and described its plan for implementing a multi-year State directed payment, including the State's plan for multi-year evaluation, and the impact of a multi-year State directed payment on the State's goals and objectives in the State's quality strategy in § 438.340.

(C) The State has affirmed that it will not make any changes to the State directed payment methodology, or magnitude of the payment, described in the contract for all years of the multi-year State directed payment without CMS written prior approval. If the State determines that changes to the State directed payment methodology, or magnitude of the payment, are necessary, the State must obtain written prior approval of such changes under paragraph (c)(2) of this section.

(ii) Written prior approval of a State directed payment described in paragraph (c)(1)(iii)(C) through (E) of this section is for one rating period.

(iii) State directed payments are not automatically renewed.

(4) *Reporting requirements.* The State must submit to CMS, no later than 1 year after each rating period, data to the Transformed Medicaid Statistical Information System, or in any successor format or system designated by CMS, specifying the total dollars expended by each MCO, PIHP, and PAHP for State directed payments, including amounts paid to individual providers. The initial report will be due after the first rating period that begins after the release of reporting instructions by CMS. Minimum data fields to be collected include the following, as applicable:

(i) Provider identifiers.

(ii) Enrollee identifiers.

(iii) MCO, PIHP or PAHP identifiers.

(iv) Procedure and diagnosis codes.

(v) Allowed, billed, and paid amounts. Paid amounts include the amount that represents the MCO's, PIHP's or PAHP's negotiated payment amount, the amount of the State directed payment, and any other amounts included in the total amount paid to the provider.

(5) *Requirements for Medicaid Managed Care contract terms for State directed payments.* State directed payments must be specifically described and documented in the MCO's, PIHP's, or PAHP's contracts. The MCO's, PIHP's or PAHP's contract must include, at a minimum, the following information for each State directed payment:

(i) The State directed payment start date and, if applicable, the end date within the applicable rating period;

(ii) A description of the provider class eligible for the State directed payment and all eligibility requirements;

(iii) A description of the State directed payment, which must include at a minimum:

(A) For State directed payments described in paragraphs (c)(1)(iii)(A), (B), and (C) of this section:

(*1*) The required fee schedule;

(*2*) The procedure and diagnosis codes to which the fee schedule applies;

(*3*) The applicable dates of service within the rating period for which the fee schedule applies;

(*4*) For State directed payments that specify State plan approved rates, the contract must also reference the State plan page, when it was approved, and a link to the currently approved State plan page when possible; and

(*5*) For State directed payments that specify a Medicare-referenced fee schedule, the contract must also include information about the Medicare fee schedule(s) that is necessary to implement the State directed payment, including identifying the specific Medicare fee schedule, the time period for which the Medicare fee schedule is in effect, and any material adjustments due to geography or provider type that need to be applied.

(B) For State directed payments described in paragraphs (c)(1)(iii)(D) of this section:

(*1*) Whether the uniform increase will be a specific dollar amount or a percentage increase of negotiated rates;

(*2*) The procedure and diagnosis codes to which the uniform dollar or percentage increase applies;

(*3*) The specific dollar amount or percentage increase that the MCO, PIHP or PAHP must apply or the methodology to establish the specific dollar amount or percentage increase;

(*4*) The applicable dates of service within the rating period for which the uniform increase applies; and

(*5*) The roles and responsibilities of the State and the MCO, PIHP, or PAHP, the timing of payments, and other significant relevant information.

(C) For State directed payments described in paragraph (c)(1)(iii)(E) of this section:

(*1*) The fee schedule the MCO, PIHP, or PAHP must ensure that payments are below;

(*2*) The procedure and diagnosis codes to which the fee schedule applies;

(*3*) The applicable dates of service within the rating period for which the fee schedule applies; and

(*4*) Details of the State's exemption process for MCOs, PIHPs, or PAHPs and providers to follow if they are under contractual obligations that result in the need to pay more than the maximum fee schedule.

(D) For State directed payments described in paragraphs (c)(1)(i) and (ii) of this section that condition payment based upon performance:

(*1*) The approved performance measures upon which payment will be conditioned;

(*2*) The approved measurement period for those measures;

(*3*) The approved baseline statistics for all measures against which performance will be measured;

(*4*) The performance targets that must be achieved on each measure for the provider to obtain the performance-based payment;

(*5*) The methodology to determine if the provider qualifies for the performance-based payment, as well as the amount of the payment; and

(*6*) The roles and responsibilities of the State and the MCO, PIHP, or PAHP, the timing of payments, what to do with any unearned payments, and other significant relevant information.

(E) For State directed payments described in paragraphs (c)(1)(i) and (ii) of this section using a population-based or condition-based payment as defined in paragraph (a) of this section:

(*1*) The Medicaid covered service(s) that the population or condition-based payment is for;

(*2*) The time period that the population or condition-based payment covers;

(*3*) When the population or condition-based payment is to be made and how frequently;

(*4*) A description of the attribution methodology, if one is used, which must include at a minimum the data used, when the panels will be established, how frequently those panels will be updated, and how the attribution

methodology will be communicated to providers; and

(*5*) The roles and responsibilities of the State and the MCO, PIHP, or PAHP in operationalizing the attribution methodology if an attribution methodology is used.

(iv) Any encounter reporting and separate reporting requirements necessary for auditing the State directed payment in addition to the reporting requirements in paragraph (c)(4) of this section; and

(v) All State directed payments must be specifically described and documented in the MCO's, PIHP's, and PAHP's contracts that must be submitted to CMS no later than 120 days after the start date of the State directed payment.

(6) *Payment to MCOs, PIHPs, and PAHPs for State Directed Payments.* The final capitation rate for each MCO, PIHP, or PAHP as described in § 438.3(c) must account for all State directed payments. Each State directed payment must be accounted for in the base data, as an adjustment to trend, or as an adjustment as specified in § 438.5 and § 438.7(b). The State cannot withhold a portion of the capitation rate to pay the MCO, PIHP, or PAHP separately for a State directed payment nor require an MCO, PIHP, or PAHP to retain a portion of the capitation rate separately to comply with a State directed payment.

(7) *Final State directed payment cost percentage.* For each State directed payment for which written prior approval is required under paragraph (c)(2)(i) of this section, unless the State voluntarily submits the evaluation report per paragraph (c)(2)(v) of this section, the State must calculate the final State directed payment cost percentage and if the final State directed payment cost percentage is below 1.5 percent the State must provide a final State directed payment cost percentage report to CMS as follows:

(i) *State directed payment cost percentage calculation.* The final State directed payment cost percentage must be calculated on an annual basis and recalculated annually.

(ii) *State directed payment cost percentage certification.* The final State directed payment cost percentage must be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices.

(iii) *Calculation of the final State directed payment cost percentage.* The final State directed payment cost percentage is the result of dividing the amount determined in paragraph (c)(7)(iii)(A) of this section by the amount determined in paragraph (c)(7)(iii)(B) of this section.

(A) The portion of the actual total capitation payments that is attributable to the State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section, for each managed care program.

(B) The actual total capitation payments, defined at § 438.2, for each managed care program, including all State directed payments in effect under § 438.6(c) and pass-through payments in effect under § 438.6(d).

(iv) *Annual CMS review of the final State directed payment cost percentage.* The State must submit the final State directed payment cost percentage annually to CMS for review as a separate report concurrent with the rate certification submission required in § 438.7(a) for the rating period beginning 2 years after the completion of each 12-month rating period that includes a State directed payment for which the State has obtained written prior approval under paragraph (c)(2)(i) of this section.

(8) *Applicability dates.* States must comply with:

(i) Paragraphs (a), (c)(1), (c)(1)(iii), (c)(2)(i), (c)(2)(ii)(A) through (C), (c)(2)(ii)(E), (c)(2)(ii)(G), (c)(2)(ii)(I) and (J), (c)(2)(vi)(A), (c)(3) of this section beginning on July 9, 2024.

(ii) Paragraphs (c)(2)(iii), (c)(2)(vi)(B), and (c)(2)(vi)(C)(*1*) and (*2*) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after July 9, 2024.

(iii) Paragraphs (c)(2)(vi)(C)(*3*) and (*4*), (c)(2)(viii) and (c)(5)(i) through (iv) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after July 9, 2024.

(iv) Paragraphs (c)(2)(ii)(D) and (F), (c)(2)(iv), (c)(2)(v), (c)(2)(vii), (c)(6) and (c)(7) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 3 years after July 9, 2024.

(v) Paragraph (c)(5)(v) of this section no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after July 9, 2024.

(vi) Paragraph (c)(4) of this section no later than the date specified in the T–MSIS reporting instructions released by CMS.

(vii) Paragraph (c)(2)(ii)(H) of this section no later than the first rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after January 1, 2028.

(d) *Pass-through payments under MCO, PIHP, and PAHP contracts*—(1) *General rule.* States may continue to require MCOs, PIHPs, and PAHPs to make pass-through payments (as defined in paragraph (a) of this section) to network providers that are hospitals, physicians, or nursing facilities under the contract, provided the requirements of this paragraph (d) are met. States may not require MCOs, PIHPs, and PAHPs to make pass-through payments other than those permitted under this paragraph (d).

(i) In order to use a transition period described in this paragraph (d), a State must demonstrate that it had pass-through payments for hospitals, physicians, or nursing facilities in:

(A) Managed care contract(s) and rate certification(s) for the rating period that includes July 5, 2016, and were submitted for CMS review and approval on or before July 5, 2016; or

(B) If the managed care contract(s) and rate certification(s) for the rating period that includes July 5, 2016 had not been submitted to CMS on or before July 5, 2016, the managed care contract(s) and rate certification(s) for a rating period before July 5, 2016 that had been most recently submitted for CMS review and approval as of July 5, 2016.

(ii) CMS will not approve a retroactive adjustment or amendment, notwithstanding the adjustments to the base amount permitted in paragraph (d)(2) of this section, to managed care contract(s) and rate certification(s) to add new pass-through payments or increase existing pass-through payments defined in paragraph (a) of this section.

(2) *Calculation of the base amount.* The base amount of pass-through payments is the sum of the results of paragraphs (d)(2)(i) and (ii) of this section.

(i) For inpatient and outpatient hospital services that will be provided to eligible populations through the MCO, PIHP, or PAHP contracts for the rating period that includes pass-through payments and that were provided to the eligible populations under MCO, PIHP, or PAHP contracts two years prior to the rating period, the State must determine reasonable estimates of the aggregate difference between:

(A) The amount Medicare FFS would have paid for those inpatient and outpatient hospital services utilized by the eligible populations under the MCO, PIHP, or PAHP contracts for the 12-month period immediately two years prior to the rating period that will include pass-through payments; and

(B) The amount the MCOs, PIHPs, or PAHPs paid (not including pass through payments) for those inpatient and outpatient hospital services utilized by the eligible populations under MCO, PIHP, or PAHP contracts for the 12-month period immediately 2 years prior to the rating period that will include pass-through payments.

(ii) For inpatient and outpatient hospital services that will be provided to eligible populations through the MCO, PIHP, or PAHP contracts for the rating period that includes pass-through payments and that were provided to the eligible populations under Medicaid FFS for the 12-month period immediately 2 years prior to the rating period, the State must determine reasonable estimates of the aggregate difference between:

(A) The amount Medicare FFS would have paid for those inpatient and outpatient hospital services utilized by the eligible populations under Medicaid FFS for the 12-month period immediately 2 years prior to the rating period that will include pass-through payments; and

(B) The amount the State paid under Medicaid FFS (not including pass through payments) for those inpatient

and outpatient hospital services utilized by the eligible populations for the 12-month period immediately 2 years prior to the rating period that will include pass-through payments.

(iii) The base amount must be calculated on an annual basis and is recalculated annually.

(iv) States may calculate reasonable estimates of the aggregate differences in paragraphs (d)(2)(i) and (ii) of this section in accordance with the upper payment limit requirements in 42 CFR part 447.

(3) *Schedule for the reduction of the base amount of pass-through payments for hospitals under the MCO, PIHP, or PAHP contract and maximum amount of permitted pass-through payments for each year of the transition period.* For States that meet the requirement in paragraph (d)(1)(i) of this section, pass-through payments for hospitals may continue to be required under the contract but must be phased out no longer than on the 10-year schedule, beginning with rating periods for contract(s) that start on or after July 1, 2017. For rating periods for contract(s) beginning on or after July 1, 2027, the State cannot require pass-through payments for hospitals under a MCO, PIHP, or PAHP contract. Until July 1, 2027, the total dollar amount of pass-through payments to hospitals may not exceed the lesser of:

(i) A percentage of the base amount, beginning with 100 percent for rating periods for contract(s) beginning on or after July 1, 2017, and decreasing by 10 percentage points each successive year; or

(ii) The total dollar amount of pass-through payments to hospitals identified in the managed care contract(s) and rate certification(s) used to meet the requirement of paragraph (d)(1)(i) of this section.

(4) *Documentation of the base amount for pass-through payments to hospitals.* All contract arrangements that direct pass-through payments under the MCO's, PIHP's or PAHP's contract for hospitals must document the calculation of the base amount in the rate certification required in § 438.7. The documentation must include the following:

(i) The data, methodologies, and assumptions used to calculate the base amount;

(ii) The aggregate amounts calculated for paragraphs (d)(2)(i)(A), (d)(2)(i)(B), (d)(2)(ii)(A), (d)(2)(ii)(B) of this section; and

(iii) The calculation of the applicable percentage of the base amount available for pass-through payments under the schedule in paragraph (d)(3) of this section.

(5) *Pass-through payments to physicians or nursing facilities.* For States that meet the requirement in paragraph (d)(1)(i) of this section, rating periods for contract(s) beginning on or after July 1, 2017 through rating periods for contract(s) beginning on or after July 1, 2021, may continue to require pass-through payments to physicians or nursing facilities under the MCO, PIHP, or PAHP contract of no more than the total dollar amount of pass-through payments to physicians or nursing facilities, respectively, identified in the managed care contract(s) and rate certification(s) used to meet the requirement of paragraph (d)(1)(i) of this section. For rating periods for contract(s) beginning on or after July 1, 2022, the State cannot require pass-through payments for physicians or nursing facilities under a MCO, PIHP, or PAHP contract.

(6) *Pass-through payments for States transitioning services and populations from a fee-for-service delivery system to a managed care delivery system.* Notwithstanding the restrictions on pass-through payments in paragraphs (d)(1), (3), and (5) of this section, a State may require the MCO, PIHP, or PAHP to make pass-through payments to network providers that are hospitals, nursing facilities, or physicians under the contract, for each rating period of the transition period for up to 3 years, when Medicaid populations or services are initially transitioning from a fee-for-service (FFS) delivery system to a managed care delivery system, provided the following requirements are met:

(i) The services will be covered for the first time under a managed care contract and were previously provided in a FFS delivery system prior to the

first rating period of the transition period.

(ii) The State made supplemental payments, as defined in paragraph (a) of this section, to hospitals, nursing facilities, or physicians during the 12-month period immediately 2 years prior to the first year of the transition period.

(iii) The aggregate amount of the pass-through payments that the State requires the MCO, PIHP, or PAHP to make is less than or equal to the amounts calculated in paragraph (d)(6)(iii)(A), (B), or (C) of this section for the relevant provider type for each rating period of the transition period. In determining the amount of each component for the calculations contained in paragraphs (d)(6)(iii)(A) through (C), the State must use the amounts paid for services during the 12-month period immediately 2 years prior to the first rating period of the transition period.

(A) *Hospitals.* For inpatient and outpatient hospital services, calculate the product of the actual supplemental payments paid and the ratio achieved by dividing the amount paid through payment rates for hospital services that are being transitioned from payment in a FFS delivery system to the managed care contract by the total amount paid through state plan approved rates for hospital services made in the State's FFS delivery system. Both the numerator and denominator of the ratio should exclude any supplemental payments made to the applicable providers.

(B) *Nursing facilities.* For nursing facility services, calculate the product of the actual supplemental payments paid and the ratio achieved by dividing the amount paid through state plan approved rates for nursing facility services that are being transitioned from payment in a FFS delivery system to the managed care contract by the total amount paid through payment rates for nursing facility services made in the State's FFS delivery system. Both the numerator and denominator of the ratio should exclude any supplemental payments made to the applicable providers.

(C) *Physicians.* For physician services, calculate the product of the actual supplemental payments paid and the ratio achieved by dividing the amount paid through state plan approved rates for physician services that are being transitioned from payment in a FFS delivery system to the managed care contract by the total amount paid through payment rates for physician services made in the State's FFS delivery system. Both the numerator and denominator of the ratio should exclude any supplemental payments made to the applicable providers.

(iv) The State may require the MCO, PIHP, or PAHP to make pass-through payments for Medicaid populations or services that are initially transitioning from a FFS delivery system to a managed care delivery system for up to 3 years from the beginning of the first rating period in which the services were transitioned from payment in a FFS delivery system to a managed care contract, provided that during the 3 years, the services continue to be provided under a managed care contract with an MCO, PIHP, or PAHP.

(e) *Payments to MCOs and PIHPs for enrollees that are a patient in an institution for mental disease.* The State may make a monthly capitation payment to an MCO or PIHP for an enrollee aged 21–64 receiving inpatient treatment in an Institution for Mental Diseases, as defined in § 435.1010 of this chapter, so long as the facility is a hospital providing mental health or substance use disorder inpatient care or a sub-acute facility providing mental health or substance use disorder crisis residential services, and length of stay in the IMD is for a short term stay of no more than 15 days during the period of the monthly capitation payment. The provision of inpatient mental health or substance use disorder treatment in an IMD must meet the requirements for in lieu of services at § 438.3(e)(2)(i) through (iii). For purposes of rate setting, the State may use the utilization of services provided to an enrollee under this section when developing the inpatient mental health or substance use disorder component of the capitation rate, but must price utilization at the cost of the same services through

providers included under the State plan.

[81 FR 27853, May 6, 2016, as amended at 82 FR 39, Jan. 3, 2017; 82 FR 5428, Jan. 18, 2017; 85 FR 72837, Nov. 13, 2020; 85 FR 72839, Nov. 13, 2020; 89 FR 41267, May 10, 2024]

§ 438.7 Rate certification submission.

(a) *CMS review and approval of the rate certification.* States must submit to CMS for review and approval, all MCO, PIHP, and PAHP rate certifications concurrent with the review and approval process for contracts as specified in § 438.3(a).

(b) *Documentation.* The rate certification must contain the following information:

(1) *Base data.* A description of the base data used in the rate setting process (including the base data requested by the actuary, the base data that was provided by the State, and an explanation of why any base data requested was not provided by the State) and of how the actuary determined which base data set was appropriate to use for the rating period.

(2) *Trend.* Each trend factor, including trend factors for changes in the utilization and price of services, applied to develop the capitation rates must be adequately described with enough detail so CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(i) The calculation of each trend used for the rating period and the reasonableness of the trend for the enrolled population.

(ii) Any meaningful difference in how a trend differs between the rate cells, service categories, or eligibility categories.

(3) *Non-benefit component of the rate.* The development of the non-benefit component of the rate must be adequately described with enough detail so CMS or an actuary applying generally accepted actuarial principles and practices can identify each type of non-benefit expense that is included in the rate and evaluate the reasonableness of the cost assumptions underlying each expense. The actuary may document the non-benefit costs according to the types of non-benefit costs under § 438.5(e).

(4) *Adjustments.* All adjustments used to develop the capitation rates must be adequately described with enough detail so that CMS, or an actuary applying generally accepted actuarial principles and practices, can understand and evaluate all of the following:

(i) How each material adjustment was developed and the reasonableness of the material adjustment for the enrolled population.

(ii) The cost impact of each material adjustment and the aggregate cost impact of non-material adjustments.

(iii) Where in the rate setting process the adjustment was applied.

(iv) A list of all non-material adjustments used in the rate development process.

(5) *Risk adjustment.* (i) All prospective risk adjustment methodologies must be adequately described with enough detail so that CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(A) The data, and any adjustments to that data, to be used to calculate the adjustment.

(B) The model, and any adjustments to that model, to be used to calculate the adjustment.

(C) The method for calculating the relative risk factors and the reasonableness and appropriateness of the method in measuring the risk factors of the respective populations.

(D) The magnitude of the adjustment on the capitation rate per MCO, PIHP, or PAHP.

(E) An assessment of the predictive value of the methodology compared to prior rating periods.

(F) Any concerns the actuary has with the risk adjustment process.

(ii) All retrospective risk adjustment methodologies must be adequately described with enough detail so that CMS or an actuary applying generally accepted actuarial principles and practices can understand and evaluate the following:

(A) The party calculating the risk adjustment.

(B) The data, and any adjustments to that data, to be used to calculate the adjustment.

(C) The model, and any adjustments to that model, to be used to calculate the adjustment.

(D) The timing and frequency of the application of the risk adjustment.

(E) Any concerns the actuary has with the risk adjustment process.

(iii) Application of an approved risk adjustment methodology to capitation rates does not require a revised rate certification because payment of capitation rates as modified by the approved risk adjustment methodology must be within the scope of the original rate certification. The State must provide to CMS the payment terms updated by the application of the risk adjustment methodology consistent with § 438.3(c).

(6) *Special contract provisions.* A description of any of the special contract provisions related to payment in § 438.6 and ILOS in § 438.3(e)(2) that are applied in the contract.

(c) *Rates paid under risk contracts.* The State, through its actuary, must certify the final capitation rate paid per rate cell under each risk contract and document the underlying data, assumptions and methodologies supporting that specific capitation rate.

(1) The State may pay each MCO, PIHP or PAHP a capitation rate under the contract that is different than the capitation rate paid to another MCO, PIHP or PAHP, so long as each capitation rate per rate cell that is paid is independently developed and set in accordance with this part.

(2) If the State determines that a retroactive adjustment to the capitation rate is necessary, the retroactive adjustment must be supported by a rationale for the adjustment and the data, assumptions and methodologies used to develop the magnitude of the adjustment must be adequately described with enough detail to allow CMS or an actuary to determine the reasonableness of the adjustment. These retroactive adjustments must be certified by an actuary in a revised rate certification and submitted as a contract amendment to be approved by CMS. All such adjustments are also subject to Federal timely claim filing requirements.

(3) The State may increase or decrease the capitation rate per rate cell, as required in paragraph (c) of this section and § 438.4(b)(4), up to 1.5 percent during the rating period without submitting a revised rate certification, as required under paragraph (a) of this section. However, any changes of the capitation rate within the permissible range must be consistent with a modification of the contract as required in § 438.3(c) and are subject to the requirements at § 438.4(b)(1). Notwithstanding the provisions in paragraph (c) of this section, CMS may require a State to provide documentation that modifications to the capitation rate comply with the requirements in §§ 438.3(c) and (e) and 438.4(b)(1).

(4) The State must submit a revised rate certification for any changes in the capitation rate per rate cell, as required under paragraph (a) of this section for any special contract provisions related to payment described in § 438.6 and ILOS in § 438.3(e)(2) not already described in the rate certification, regardless of the size of the change in the capitation rate per rate cell.

(5) Retroactive adjustments to the capitation rates, as outlined in paragraph (c)(2) of this section, resulting from a State directed payment described in § 438.6(c) must be a result of adding or amending any State directed payment consistent with the requirements in § 438.6(c), or a material error in the data, assumptions or methodologies used to develop the initial capitation rate adjustment such that modifications are necessary to correct the error.

(6) The rate certification or retroactive adjustment to capitation rates resulting from any State directed payments must be submitted no later than 120 days after the start date of the State directed payment.

(d) *Provision of additional information.* The State must, upon CMS' request, provide additional information, whether part of the rate certification or additional supplemental materials, if CMS determines that information is pertinent to the approval of the certification under this part. The State must identify whether the information provided in addition to the rate certification is proffered by the State, the actuary, or another party.

(e) *Provision of additional guidance.* CMS will issue guidance, at least annually, which includes all of the following:

(1) The Federal standards for capitation rate development.

(2) The documentation required to determine that the capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms.

(3) The documentation required to determine that the capitation rates have been developed in accordance with the requirements of this part.

(4) Any updates or developments in the rate review process to reduce State burden and facilitate prompt actuarial reviews.

(5) The documentation necessary to demonstrate that capitation rates competitively bid through a procurement process have been established consistent with the requirements of §§ 438.4 through 438.8.

(f) *Applicability dates.* (1) Paragraph (b)(6) of this section applies to the rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 60 days following July 9, 2024. Until that applicability date, States are required to continue to comply with paragraph (b)(6) of this section contained in 42 CFR, parts 430 to 481, edition most recently published prior to the final rule.

(2) Paragraph (c)(6) of this section apply no later than the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after July 9, 2024.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72839, Nov. 13, 2020; 89 FR 41272, May 10, 2024]

§ 438.8 Medical loss ratio (MLR) standards.

(a) *Basic rule.* The State must ensure, through its contracts starting on or after July 1, 2017, that each MCO, PIHP, and PAHP calculate and report a MLR in accordance with this section. For multi-year contracts that do not start in 2017, the State must require the MCO, PIHP, or PAHP to calculate and report a MLR for the rating period that begins in 2017.

(b) *Definitions.* As used in this section, the following terms have the indicated meanings:

Credibility adjustment means an adjustment to the MLR for a partially credible MCO, PIHP, or PAHP to account for a difference between the actual and target MLRs that may be due to random statistical variation.

Full credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be sufficient for the calculation of a MLR with a minimal chance that the difference between the actual and target medical loss ratio is not statistically significant. An MCO, PIHP, or PAHP that is assigned full credibility (or is fully credible) will not receive a credibility adjustment to its MLR.

Member months mean the number of months an enrollee or a group of enrollees is covered by an MCO, PIHP, or PAHP over a specified time period, such as a year.

MLR reporting year means a period of 12 months consistent with the rating period selected by the State.

No credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be insufficient for the calculation of a MLR. An MCO, PIHP, or PAHP that is assigned no credibility (or is non-credible) will not be measured against any MLR requirements.

Non-claims costs means those expenses for administrative services that are not: Incurred claims (as defined in paragraph (e)(2) of this section); expenditures on activities that improve health care quality (as defined in paragraph (e)(3) of this section); or licensing and regulatory fees, or Federal and State taxes (as defined in paragraph (f)(2) of this section).

Partial credibility means a standard for which the experience of an MCO, PIHP, or PAHP is determined to be sufficient for the calculation of a MLR but with a non-negligible chance that the difference between the actual and target medical loss ratios is statistically significant. An MCO, PIHP, or PAHP that is assigned partial credibility (or is partially credible) will receive a credibility adjustment to its MLR.

(c) *MLR requirement.* If a State elects to mandate a minimum MLR for its MCOs, PIHPs, or PAHPs, that minimum MLR must be equal to or higher than 85 percent (the standard used for projecting actuarial soundness under § 438.4(b)) and the MLR must be calculated and reported for each MLR reporting year by the MCO, PIHP, or PAHP, consistent with this section.

(d) *Calculation of the MLR.* The MLR experienced for each MCO, PIHP, or PAHP in a MLR reporting year is the ratio of the numerator (as defined in paragraph (e) of this section) to the denominator (as defined in paragraph (f) of this section). A MLR may be increased by a credibility adjustment, in accordance with paragraph (h) of this section.

(e) *Numerator*—(1) *Required elements.* The numerator of an MCO's, PIHP's, or PAHP's MLR for a MLR reporting year is the sum of the MCO's, PIHP's, or PAHP's incurred claims (as defined in (e)(2) of this section); the MCO's, PIHP's, or PAHP's expenditures for activities that improve health care quality (as defined in paragraph (e)(3) of this section); and fraud prevention activities (as defined in paragraph (e)(4) of this section).

(2) *Incurred claims.* (i) Incurred claims must include the following:

(A) Direct claims that the MCO, PIHP, or PAHP paid to providers (including under capitated contracts with network providers) for services or supplies covered under the contract and services meeting the requirements of § 438.3(e) provided to enrollees.

(B) Unpaid claims liabilities for the MLR reporting year, including claims reported that are in the process of being adjusted or claims incurred but not reported.

(C) Withholds from payments made to network providers.

(D) Claims that are recoverable for anticipated coordination of benefits.

(E) Claims payments recoveries received as a result of subrogation.

(F) Incurred but not reported claims based on past experience, and modified to reflect current conditions, such as changes in exposure or claim frequency or severity.

(G) Changes in other claims-related reserves.

(H) Reserves for contingent benefits and the medical claim portion of lawsuits.

(ii) Amounts that must be deducted from incurred claims include the following:

(A) Overpayment recoveries received from network providers.

(B) Prescription drug rebates received and accrued.

(iii) Expenditures that must be included in incurred claims include the following:

(A) The amount of incentive and bonus payments made, or expected to be made, to network providers that are tied to clearly-defined, objectively measurable, and well-documented clinical or quality improvement standards that apply to providers.

(B) The amount of claims payments recovered through fraud reduction efforts, not to exceed the amount of fraud reduction expenses. The amount of fraud reduction expenses must not include activities specified in paragraph (e)(4) of this section.

(C) The amount of payments made to providers under State directed payments described in § 438.6(c).

(iv) Amounts that must either be included in or deducted from incurred claims include, respectively, net payments or receipts related to State mandated solvency funds.

(v) Amounts that must be excluded from incurred claims:

(A) Non-claims costs, as defined in paragraph (b) of this section, which include the following:

(*1*) Amounts paid to third party vendors for secondary network savings.

(*2*) Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management.

(*3*) Amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for State plan services or services meeting the definition in § 438.3(e) and provided to an enrollee.

(*4*) Fines and penalties assessed by regulatory authorities.

(B) Amounts paid to the State as remittance under paragraph (j) of this section.

(C) Amounts paid to network providers under to § 438.6(d).

(vi) Incurred claims paid by one MCO, PIHP, or PAHP that is later assumed by another entity must be reported by the assuming MCO, PIHP, or PAHP for the entire MLR reporting year and no incurred claims for that MLR reporting year may be reported by the ceding MCO, PIHP, or PAHP.

(3) *Activities that improve health care quality.* Activities that improve health care quality must be in one of the following categories:

(i) An MCO, PIHP, or PAHP activity that meets the requirements of 45 CFR 158.150(a) and (b) and is not excluded under 45 CFR 158.150(c).

(ii) An MCO, PIHP, or PAHP activity related to any EQR-related activity as described in § 438.358(b) and (c).

(iii) Any MCO, PIHP, or PAHP expenditure that is related to Health Information Technology and meaningful use, meets the requirements placed on issuers found in 45 CFR 158.151, and is not considered incurred claims, as defined in paragraph (e)(2) of this section.

(4) *Fraud prevention activities.* MCO, PIHP, or PAHP expenditures on activities related to fraud prevention consistent with regulations adopted for the private market at 45 CFR part 158. Expenditures under this paragraph must not include expenses for fraud reduction efforts in paragraph (e)(2)(iii)(B) of this section.

(f) *Denominator*—(1) *Required elements.* The denominator of an MCO's, PIHP's, or PAHP's MLR for a MLR reporting year must equal the adjusted premium revenue. The adjusted premium revenue is the MCO's, PIHP's, or PAHP's premium revenue (as defined in paragraph (f)(2) of this section) minus the MCO's, PIHP's, or PAHP's Federal, State, and local taxes and licensing and regulatory fees (as defined in paragraph (f)(3) of this section) and is aggregated in accordance with paragraph (i) of this section.

(2) *Premium revenue.* Premium revenue includes the following for the MLR reporting year:

(i) State capitation payments, developed in accordance with § 438.4, to the MCO, PIHP, or PAHP for all enrollees under a risk contract approved under § 438.3(a), excluding payments made under § 438.6(d).

(ii) State-developed one time payments, for specific life events of enrollees.

(iii) Other payments to the MCO, PIHP, or PAHP approved under § 438.6(b)(3).

(iv) Unpaid cost-sharing amounts that the MCO, PIHP, or PAHP could have collected from enrollees under the contract, except those amounts the MCO, PIHP, or PAHP can show it made a reasonable, but unsuccessful, effort to collect.

(v) All changes to unearned premium reserves.

(vi) Net payments or receipts related to risk sharing mechanisms developed in accordance with § 438.5 or § 438.6.

(vii) Payments to the MCO, PIHP, or PAHP for expenditures under State directed payments described in § 438.6(c).

(3) *Federal, State, and local taxes and licensing and regulatory fees.* Taxes, licensing and regulatory fees for the MLR reporting year include:

(i) Statutory assessments to defray the operating expenses of any State or Federal department.

(ii) Examination fees in lieu of premium taxes as specified by State law.

(iii) Federal taxes and assessments allocated to MCOs, PIHPs, and PAHPs, excluding Federal income taxes on investment income and capital gains and Federal employment taxes.

(iv) State and local taxes and assessments including:

(A) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State or locality directly.

(B) Guaranty fund assessments.

(C) Assessments of State or locality industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with disability benefit laws or similar taxes levied by States.

(D) State or locality income, excise, and business taxes other than premium taxes and State employment and similar taxes and assessments.

(E) State or locality premium taxes plus State or locality taxes based on reserves, if in lieu of premium taxes.

(v) Payments made by an MCO, PIHP, or PAHP that are otherwise exempt from Federal income taxes, for community benefit expenditures as defined in 45 CFR 158.162(c), limited to the highest of either:

(A) Three percent of earned premium; or

(B) The highest premium tax rate in the State for which the report is being submitted, multiplied by the MCO's, PIHP's, or PAHP's earned premium in the State.

(4) *Denominator when MCO, PIHP, or PAHP is assumed.* The total amount of the denominator for a MCO, PIHP, or PAHP which is later assumed by another entity must be reported by the assuming MCO, PIHP, or PAHP for the entire MLR reporting year and no amount under this paragraph for that year may be reported by the ceding MCO, PIHP, or PAHP.

(g) *Allocation of expense*—(1) *General requirements.* (i) Each expense must be included under only one type of expense, unless a portion of the expense fits under the definition of, or criteria for, one type of expense and the remainder fits into a different type of expense, in which case the expense must be pro-rated between types of expenses.

(ii) Expenditures that benefit multiple contracts or populations, or contracts other than those being reported, must be reported on a pro rata basis.

(2) *Methods used to allocate expenses.* (i) Allocation to each category must be based on a generally accepted accounting method that is expected to yield the most accurate results.

(ii) Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the contract incurring the expense.

(iii) Expenses that relate solely to the operation of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to the other entities.

(h) *Credibility adjustment.* (1) A MCO, PIHP, or PAHP may add a credibility adjustment to a calculated MLR if the MLR reporting year experience is partially credible. The credibility adjustment is added to the reported MLR calculation before calculating any remittances, if required by the State as described in paragraph (j) of this section.

(2) A MCO, PIHP, or PAHP may not add a credibility adjustment to a calculated MLR if the MLR reporting year experience is fully credible.

(3) If a MCO's, PIHP's, or PAHP's experience is non-credible, it is presumed to meet or exceed the MLR calculation standards in this section.

(4) CMS will publish base credibility factors for MCOs, PIHPs, and PAHPs that are developed according to the following methodology:

(i) CMS will use the most recently available and complete managed care encounter data or FFS claims data, and enrollment data, reported by the states to CMS. This data may cover more than 1 year of experience.

(ii) CMS will calculate the credibility adjustment so that a MCO, PIHP, or PAHP receiving a capitation payment that is estimated to have a medical loss ratio of 85 percent would be expected to experience a loss ratio less than 85 percent 1 out of every 4 years, or 25 percent of the time.

(iii) The minimum number of member months necessary for a MCO's, PIHP's, or PAHP's medical loss ratio to be determined at least partially credible will be set so that the credibility adjustment would not exceed 10 percent for any partially credible MCO, PIHP, or PAHP. Any MCO, PIHP, or PAHP with enrollment less than this number of member months will be determined non-credible.

(iv) The minimum number of member months necessary for an MCO's, PIHP's, or PAHP's medical loss ratio to be determined fully credible will be set so that the minimum credibility adjustment for any partially credible MCO, PIHP, or PAHP would be greater than 1 percent. Any MCO, PIHP, or PAHP with enrollment greater than this number of member months will be determined to be fully credible.

(v) A MCO, PIHP, or PAHP with a number of enrollee member months between the levels established for non-credible and fully credible plans will be deemed partially credible, and CMS will develop adjustments, using linear interpolation, based on the number of enrollee member months.

(vi) CMS may adjust the number of enrollee member months necessary for a MCO's, PIHP's, or PAHP's experience to be non-credible, partially credible, or fully credible so that the standards are rounded for the purposes of administrative simplification. The number of member months will be rounded to 1,000 or a different degree of rounding as appropriate to ensure that the credibility thresholds are consistent with the objectives of this regulation.

(i) *Aggregation of data.* MCOs, PIHPs, or PAHPs will aggregate data for all Medicaid eligibility groups covered under the contract with the State unless the State requires separate reporting and a separate MLR calculation for specific populations.

(j) *Remittance to the State if specific MLR is not met.* If required by the State, a MCO, PIHP, or PAHP must provide a remittance for an MLR reporting year if the MLR for that MLR reporting year does not meet the minimum MLR standard of 85 percent or higher if set by the State as described in paragraph (c) of this section.

(k) *Reporting requirements.* (1) The State, through its contracts, must require each MCO, PIHP, or PAHP to submit a report to the State that includes at least the following information for each MLR reporting year:

(i) Total incurred claims.

(ii) Expenditures on quality improving activities.

(iii) Fraud prevention activities as defined in paragraph (e)(4) of this section.

(iv) Non-claims costs.

(v) Premium revenue.

(vi) Taxes, licensing and regulatory fees.

(vii) Methodology(ies) for allocation of expenditures, which must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, as described in 45 CFR 158.170(b).

(viii) Any credibility adjustment applied.

(ix) The calculated MLR.

(x) Any remittance owed to the State, if applicable.

(xi) A comparison of the information reported in this paragraph with the audited financial report required under § 438.3(m).

(xii) A description of the aggregation method used under paragraph (i) of this section.

(xiii) The number of member months.

(2) A MCO, PIHP, or PAHP must submit the report required in paragraph (k)(1) of this section in a timeframe and manner determined by the State, which must be within 12 months of the end of the MLR reporting year.

(3) MCOs, PIHPs, or PAHPs must require any third party vendor providing claims adjudication activities to provide all underlying data associated with MLR reporting to that MCO, PIHP, or PAHP within 180 days of the end of the MLR reporting year or within 30 days of being requested by the MCO, PIHP, or PAHP, whichever comes sooner, regardless of current contractual limitations, to calculate and validate the accuracy of MLR reporting.

(l) *Newer experience.* A State, in its discretion, may exclude a MCO, PIHP, or PAHP that is newly contracted with the State from the requirements in this section for the first year of the MCO's, PIHP's, or PAHP's operation. Such MCOs, PIHPs, or PAHPs must be required to comply with the requirements in this section during the next MLR reporting year in which the MCO, PIHP, or PAHP is in business with the State, even if the first year was not a full 12 months.

(m) *Recalculation of MLR.* In any instance where a State makes a retroactive change to the capitation payments for a MLR reporting year where the report has already been submitted to the State, the MCO, PIHP, or PAHP must re-calculate the MLR for all MLR reporting years affected by the change and submit a new report meeting the requirements in paragraph (k) of this section.

(n) *Attestation.* MCOs, PIHPs, and PAHPs must attest to the accuracy of the calculation of the MLR in accordance with requirements of this section when submitting the report required under paragraph (k) of this section.

[81 FR 27853, May 6, 2016, as amended at 82 FR 39, Jan. 3, 2017; 85 FR 72840, Nov. 13, 2020; 89 FR 41272, May 10, 2024]

§ 438.9 Provisions that apply to non-emergency medical transportation PAHPs.

(a) For purposes of this section, Non-Emergency Medical Transportation (NEMT) PAHP means an entity that provides only NEMT services to enrollees under contract with the State, and on the basis of prepaid capitation payments, or other payment arrangements that do not use State plan payment rates.

(b) Unless listed in this paragraph (b), a requirement of this part does not apply to NEMT PAHPs, NEMT PAHP contracts, or States in connection with a NEMT PAHP. The following requirements and options apply to NEMT PAHPs, NEMT PAHP contracts, and States in connection with NEMT PAHPs, to the same extent that they apply to PAHPs, PAHP contracts, and States in connection with PAHPs.

(1) All contract provisions in § 438.3 except requirements for:

(i) Physician incentive plans at § 438.3(i).

(ii) Advance directives at § 438.3(j).

(iii) LTSS requirements at § 438.3(o).

(iv) MHPAEA at § 438.3(n).

(2) The actuarial soundness requirements in § 438.4, except § 438.4(b)(9).

(3) The information requirements in § 438.10.

(4) The provision against provider discrimination in § 438.12.

(5) The State responsibility provisions in §§ 438.56, 438.58, 438.60, 438.62(a), and 438.818.

(6) The provisions on enrollee rights and protections in subpart C of this part except for §§ 438.110 and 438.114.

(7) The PAHP standards in §§ 438.206(b)(1), 438.210, 438.214, 438.224, 438.230, and 438.242, excluding the requirement in § 438.242(b)(7), to comply with § 431.61(a) and (b) of this chapter.

(8) An enrollee's right to a State fair hearing under subpart E of part 431 of this chapter.

(9) Prohibitions against affiliations with individuals debarred or excluded by Federal agencies in § 438.610.

(10) Requirements relating to contracts involving Indians, Indian Health Care Providers, and Indian managed care entities in § 438.14.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72840, Nov. 13, 2020; 89 FR 8980, Feb. 8, 2024]

§ 438.10 Information requirements.

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Limited English proficient (LEP) means potential enrollees and enrollees who do not speak English as their primary language and who have a limited ability to read, write, speak, or understand English may be LEP and may be eligible to receive language assistance for a particular type of service, benefit, or encounter.

Prevalent means a non-English language determined to be spoken by a significant number or percentage of potential enrollees and enrollees that are limited English proficient.

Readily accessible means electronic information and services which comply with modern accessibility standards such as section 508 guidelines, section 504 of the Rehabilitation Act, and W3C's Web Content Accessibility Guidelines (WCAG) 2.0 AA and successor versions.

(b) *Applicability.* The provisions of this section apply to all managed care programs which operate under any authority in the Act.

(c) *Basic rules.* (1) Each State, enrollment broker, MCO, PIHP, PAHP, PCCM, and PCCM entity must provide all required information in this section to enrollees and potential enrollees in a manner and format that may be easily understood and is readily accessible by such enrollees and potential enrollees.

(2) The State must utilize its beneficiary support system required in § 438.71.

(3) The State must operate a website that provides the content, either directly or by linking to individual MCO, PIHP, PAHP, or PCCM entity web pages, specified at § 438.602(g) and elsewhere in this part. States must:

(i) Include clear and easy to understand labels on documents and links;

(ii) Include all content, either directly or by linking to individual MCO,

PIHP, PAHP, or PCCM entity websites, on one web page;

(iii) Verify no less than quarterly, the accurate function of the website and the timeliness of the information presented; and

(iv) Explain that assistance in accessing the required information on the website is available at no cost and include information on the availability of oral interpretation in all languages, written translation available in each prevalent non-English language, how to request auxiliary aids and services, and a toll-free and TTY/TDY telephone number.

(4) For consistency in the information provided to enrollees, the State must develop and require each MCO, PIHP, PAHP and PCCM entity to use:

(i) Definitions for managed care terminology, including appeal, co-payment, durable medical equipment, emergency medical condition, emergency medical transportation, emergency room care, emergency services, excluded services, grievance, habilitation services and devices, health insurance, home health care, hospice services, hospitalization, hospital outpatient care, medically necessary, network, non-participating provider, physician services, plan, preauthorization, participating provider, premium, prescription drug coverage, prescription drugs, primary care physician, primary care provider, provider, rehabilitation services and devices, skilled nursing care, specialist, and urgent care; and

(ii) Model enrollee handbooks and enrollee notices.

(5) The State must ensure, through its contracts, that each MCO, PIHP, PAHP and PCCM entity provides the required information in this section to each enrollee.

(6) Enrollee information required in this section may not be provided electronically by the State, MCO, PIHP, PAHP, PCCM, or PCCM entity unless all of the following are met:

(i) The format is readily accessible;

(ii) The information is placed in a location on the State, MCO's, PIHP's, PAHP's, or PCCM's, or PCCM entity's Web site that is prominent and readily accessible;

(iii) The information is provided in an electronic form which can be electronically retained and printed;

(iv) The information is consistent with the content and language requirements of this section; and

(v) The enrollee is informed that the information is available in paper form without charge upon request and provides it upon request within 5 business days.

(7) Each MCO, PIHP, PAHP, and PCCM entity must have in place mechanisms to help enrollees and potential enrollees understand the requirements and benefits of the plan.

(d) *Language and format.* The State must:

(1) Establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State, and in each MCO, PIHP, PAHP, or PCCM entity service area.

(2) Make oral interpretation available in all languages and written translation available in each prevalent non-English language. Written materials that are critical to obtaining services for potential enrollees and experience surveys for enrollees must include taglines in the prevalent non-English languages in the State, explaining the availability of written translations or oral interpretation to understand the information provided, information on how to request auxiliary aids and services, and the toll-free telephone number of the entity providing choice counseling services as required by § 438.71(a). Taglines for written materials critical to obtaining services must be printed in a conspicuously-visible font size.

(3) Require each MCO, PIHP, PAHP, and PCCM entity to make its written materials that are critical to obtaining services, including, at a minimum, provider directories, enrollee handbooks, appeal and grievance notices, and denial and termination notices, available in the prevalent non-English languages in its particular service area. Written materials that are critical to obtaining services must also be made available in alternative formats upon request of the potential enrollee or enrollee at no cost, include taglines in the prevalent non-English languages in the State and

in a conspicuously visible font size explaining the availability of written translation or oral interpretation to understand the information provided, information on how to request auxiliary aids and services, and include the toll-free and TTY/TDY telephone number of the MCO's, PIHP's, PAHP's, or PCCM entity's member/customer service unit. Auxiliary aids and services must also be made available upon request of the potential enrollee or enrollee at no cost.

(4) Make interpretation services available to each potential enrollee and require each MCO, PIHP, PAHP, and PCCM entity to make those services available free of charge to each enrollee. This includes oral interpretation and the use of auxiliary aids such as TTY/TDY and American Sign Language. Oral interpretation requirements apply to all non-English languages, not just those that the State identifies as prevalent.

(5) Notify potential enrollees, and require each MCO, PIHP, PAHP, and PCCM entity to notify its enrollees—

(i) That oral interpretation is available for any language and written translation is available in prevalent languages;

(ii) That auxiliary aids and services are available upon request and at no cost for enrollees with disabilities; and

(iii) How to access the services in paragraphs (d)(5)(i) and (ii) of this section.

(6) Provide, and require MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities to provide, all written materials for potential enrollees and enrollees consistent with the following:

(i) Use easily understood language and format.

(ii) Use a font size no smaller than 12 point.

(iii) Be available in alternative formats and through the provision of auxiliary aids and services in an appropriate manner that takes into consideration the special needs of enrollees or potential enrollees with disabilities or limited English proficiency.

(e) *Information for potential enrollees.* (1) The State or its contracted representative must provide the information specified in paragraph (e)(2) of this section to each potential enrollee, either in paper or electronic form as follows:

(i) At the time the potential enrollee first becomes eligible to enroll in a voluntary managed care program, or is first required to enroll in a mandatory managed care program; and

(ii) Within a timeframe that enables the potential enrollee to use the information in choosing among available MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities.

(2) The information for potential enrollees must include, at a minimum, all of the following:

(i) Information about the potential enrollee's right to disenroll consistent with the requirements of § 438.56 and which explains clearly the process for exercising this disenrollment right, as well as the alternatives available to the potential enrollee based on their specific circumstance;

(ii) The basic features of managed care;

(iii) Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in the program. For mandatory and voluntary populations, the length of the enrollment period and all disenrollment opportunities available to the enrollee must also be specified;

(iv) The service area covered by each MCO, PIHP, PAHP, PCCM, or PCCM entity;

(v) Covered benefits including:

(A) Which benefits are provided by the MCO, PIHP, or PAHP; and

(B) Which, if any, benefits are provided directly by the State.

(C) For a counseling or referral service that the MCO, PIHP, or PAHP does not cover because of moral or religious objections, the State must provide information about where and how to obtain the service;

(vi) The provider directory and formulary information required in paragraphs (h) and (i) of this section;

(vii) Any cost-sharing that will be imposed by the MCO, PIHP, PAHP, PCCM, or PCCM entity consistent with those set forth in the State plan;

(viii) The requirements for each MCO, PIHP or PAHP to provide adequate access to covered services, including the network adequacy standards established in § 438.68;

(ix) The MCO, PIHP, PAHP, PCCM and PCCM entity's responsibilities for coordination of enrollee care; and

(x) To the extent available, quality and performance indicators for each MCO, PIHP, PAHP and PCCM entity, including enrollee satisfaction.

(f) *Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities: General requirements.* (1) The MCO, PIHP, PAHP, and, when appropriate, the PCCM entity, must make a good faith effort to give written notice of termination of a contracted provider to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider. Notice to the enrollee must be provided by the later of 30 calendar days prior to the effective date of the termination, or 15 calendar days after receipt or issuance of the termination notice.

(2) The State must notify all enrollees of their right to disenroll consistent with the requirements of § 438.56 at least annually. Such notification must clearly explain the process for exercising this disenrollment right, as well as the alternatives available to the enrollee based on their specific circumstance. For States that choose to restrict disenrollment for periods of 90 days or more, States must send the notice no less than 60 calendar days before the start of each enrollment period.

(3) The MCO, PIHP, PAHP and, when appropriate, the PCCM entity must make available, upon request, any physician incentive plans in place as set forth in § 438.3(i).

(g) *Information for enrollees of MCOs, PIHPs, PAHPs and PCCM entities—Enrollee handbook.* (1) Each MCO, PIHP, PAHP and PCCM entity must provide each enrollee an enrollee handbook, within a reasonable time after receiving notice of the beneficiary's enrollment, which serves a similar function as the summary of benefits and coverage described in 45 CFR 147.200(a).

(2) The content of the enrollee handbook must include information that enables the enrollee to understand how to effectively use the managed care program. This information must include at a minimum:

(i) Benefits provided by the MCO, PIHP, PAHP or PCCM entity.

(ii) How and where to access any benefits provided by the State, including any cost sharing, and how transportation is provided.

(A) In the case of a counseling or referral service that the MCO, PIHP, PAHP, or PCCM entity does not cover because of moral or religious objections, the MCO, PIHP, PAHP, or PCCM entity must inform enrollees that the service is not covered by the MCO, PIHP, PAHP, or PCCM entity.

(B) The MCO, PIHP, PAHP, or PCCM entity must inform enrollees how they can obtain information from the State about how to access the services described in paragraph (g)(2)(ii)(A) of this section.

(iii) The amount, duration, and scope of benefits available under the contract in sufficient detail to ensure that enrollees understand the benefits to which they are entitled.

(iv) Procedures for obtaining benefits, including any requirements for service authorizations and/or referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.

(v) The extent to which, and how, after-hours and emergency coverage are provided, including:

(A) What constitutes an emergency medical condition and emergency services.

(B) The fact that prior authorization is not required for emergency services.

(C) The fact that, subject to the provisions of this section, the enrollee has a right to use any hospital or other setting for emergency care.

(vi) Any restrictions on the enrollee's freedom of choice among network providers.

(vii) The extent to which, and how, enrollees may obtain benefits, including family planning services and supplies from out-of-network providers. This includes an explanation that the MCO, PIHP, or PAHP cannot require an enrollee to obtain a referral before choosing a family planning provider.

(viii) Cost sharing, if any is imposed under the State plan.

(ix) Enrollee rights and responsibilities, including the elements specified

in § 438.100 and, if applicable, § 438.3(e)(2)(ii).

(x) The process of selecting and changing the enrollee's primary care provider.

(xi) Grievance, appeal, and fair hearing procedures and timeframes, consistent with subpart F of this part, in a State-developed or State-approved description. Such information must include:

(A) The right to file grievances and appeals.

(B) The requirements and timeframes for filing a grievance or appeal.

(C) The availability of assistance in the filing process.

(D) The right to request a State fair hearing after the MCO, PIHP or PAHP has made a determination on an enrollee's appeal which is adverse to the enrollee.

(E) The fact that, when requested by the enrollee, benefits that the MCO, PIHP, or PAHP seeks to reduce or terminate will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing, and that the enrollee may, consistent with state policy, be required to pay the cost of services furnished while the appeal or state fair hearing is pending if the final decision is adverse to the enrollee.

(xii) How to exercise an advance directive, as set forth in § 438.3(j). For PAHPs, information must be provided only to the extent that the PAHP includes any of the providers described in § 489.102(a) of this chapter.

(xiii) How to access auxiliary aids and services, including additional information in alternative formats or languages.

(xiv) The toll-free telephone number for member services, medical management, and any other unit providing services directly to enrollees.

(xv) Information on how to report suspected fraud or abuse;

(xvi) Any other content required by the State.

(3) Information required by this paragraph to be provided by a MCO, PIHP, PAHP or PCCM entity will be considered to be provided if the MCO, PIHP, PAHP or PCCM entity:

(i) Mails a printed copy of the information to the enrollee's mailing address;

(ii) Provides the information by email after obtaining the enrollee's agreement to receive the information by email;

(iii) Posts the information on the Web site of the MCO, PIHP, PAHP or PCCM entity and advises the enrollee in paper or electronic form that the information is available on the Internet and includes the applicable Internet address, provided that enrollees with disabilities who cannot access this information online are provided auxiliary aids and services upon request at no cost; or

(iv) Provides the information by any other method that can reasonably be expected to result in the enrollee receiving that information.

(4) The MCO, PIHP, PAHP, or PCCM entity must give each enrollee notice of any change that the State defines as significant in the information specified in this paragraph (g), at least 30 days before the intended effective date of the change.

(h) *Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities—Provider Directory.* (1) Each MCO, PIHP, PAHP, and when appropriate, the PCCM entity, must make available in paper form upon request and searchable electronic form, the following information about its network providers:

(i) The provider's name as well as any group affiliation.

(ii) Street address(es).

(iii) Telephone number(s).

(iv) Web site URL, as appropriate.

(v) Specialty, as appropriate.

(vi) Whether the provider will accept new enrollees.

(vii) The provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office.

(viii) Whether the provider's office/facility has accommodations for people with physical disabilities, including offices, exam room(s) and equipment.

(ix) Whether the provider offers covered services via telehealth.

(2) The provider directory must include the information in paragraph

(h)(1) of this section for each of the following provider types covered under the contract:

(i) Physicians, including specialists;

(ii) Hospitals;

(iii) Pharmacies;

(iv) Mental health and substance use disorder providers; and

(v) LTSS providers, as appropriate.

(3) Information included in—

(i) A paper provider directory must be updated at least—

(A) Monthly, if the MCO, PIHP, PAHP, or PCCM entity does not have a mobile-enabled, electronic directory; or

(B) Quarterly, if the MCO, PIHP, PAHP, or PCCM entity has a mobile-enabled, electronic provider directory.

(ii) An electronic provider directory must be updated no later than 30 calendar days after the MCO, PIHP, PAHP, or PCCM entity receives updated provider information.

(iii) MCOs, PIHPs, or PAHPs must use the information received from the State pursuant to §438.68(f)(1)(iii) to update provider directories no later than the timeframes specified in paragraphs (h)(3)(i) and (ii) of this section.

(4) Provider directories must be made available on the MCO's, PIHP's, PAHP's, or, if applicable, PCCM entity's Web site in a machine readable file and format as specified by the Secretary.

(i) *Information for all enrollees of MCOs, PIHPs, PAHPs, and PCCM entities: Formulary.* Each MCO, PIHP, PAHP, and when appropriate, PCCM entity, must make available in electronic or paper form, the following information about its formulary:

(1) Which medications are covered (both generic and name brand).

(2) What tier each medication is on.

(3) Formulary drug lists must be made available on the MCO's, PIHP's, PAHP's, or, if applicable, PCCM entity's Web site in a machine readable file and format as specified by the Secretary.

(j) *Applicability.* States will not be held out of compliance with the requirements of paragraph (c)(3) of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.10(c)(3) (effective as of October 1, 2023). States will not be held out of compliance with the requirements of paragraph (d)(2) of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after the July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.10(d)(2) (effective as of October 1, 2023). States will not be held out of compliance with the requirements of paragraph (h)(1) of this section prior to July 1, 2025, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.10(h)(1) (effective as of October 1, 2023). States will not be held out of compliance with the requirements of paragraph (h)(1)(ix) of this section prior to July 1, 2025. Paragraph (h)(3)(iii) of this section applies to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 4 years after July 9, 2024.

[81 FR 27853, May 6, 2016, as amended at 82 FR 39, Jan. 3, 2017; 85 FR 72840, Nov. 13, 2020; 89 FR 41273, May 10, 2024]

§ 438.12 Provider discrimination prohibited.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not discriminate in the participation, reimbursement, or indemnification of any provider who is acting within the scope of his or her license or certification under applicable State law, solely on the basis of that license or certification. If an MCO, PIHP, or PAHP declines to include individual or groups of providers in its provider network, it must give the affected providers written notice of the reason for its decision.

(2) In all contracts with network providers, an MCO, PIHP, or PAHP must comply with the requirements specified in §438.214.

(b) *Construction.* Paragraph (a) of this section may not be construed to—

(1) Require the MCO, PIHP, or PAHP to contract with providers beyond the number necessary to meet the needs of its enrollees;

(2) Preclude the MCO, PIHP, or PAHP from using different reimbursement amounts for different specialties

or for different practitioners in the same specialty; or

(3) Preclude the MCO, PIHP, or PAHP from establishing measures that are designed to maintain quality of services and control costs and are consistent with its responsibilities to enrollees.

§ 438.14 Requirements that apply to MCO, PIHP, PAHP, PCCM, and PCCM entity contracts involving Indians, Indian health care providers (IHCPs), and Indian managed care entities (IMCEs).

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Indian means any individual defined at 25 U.S.C. 1603(13), 1603(28), or 1679(a), or who has been determined eligible as an Indian, under 42 CFR 136.12. This means the individual:

(i) Is a member of a Federally recognized Indian tribe;

(ii) Resides in an urban center and meets one or more of the four criteria:

(A) Is a member of a tribe, band, or other organized group of Indians, including those tribes, bands, or groups terminated since 1940 and those recognized now or in the future by the State in which they reside, or who is a descendant, in the first or second degree, of any such member;

(B) Is an Eskimo or Aleut or other Alaska Native;

(C) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(D) Is determined to be an Indian under regulations issued by the Secretary;

(iii) Is considered by the Secretary of the Interior to be an Indian for any purpose; or

(iv) Is considered by the Secretary of Health and Human Services to be an Indian for purposes of eligibility for Indian health care services, including as a California Indian, Eskimo, Aleut, or other Alaska Native.

Indian health care provider (IHCP) means a health care program operated by the Indian Health Service (IHS) or by an Indian Tribe, Tribal Organization, or Urban Indian Organization (otherwise known as an I/T/U) as those terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

Indian managed care entity (IMCE) means a MCO, PIHP, PAHP, PCCM, or PCCM entity that is controlled (within the meaning of the last sentence of section 1903(m)(1)(C) of the Act) by the Indian Health Service, a Tribe, Tribal Organization, or Urban Indian Organization, or a consortium, which may be composed of one or more Tribes, Tribal Organizations, or Urban Indian Organizations, and which also may include the Service.

(b) *Network and coverage requirements.* All contracts between a State and a MCO, PIHP, PAHP, and PCCM entity, to the extent that the PCCM entity has a provider network, which enroll Indians must:

(1) Require the MCO, PIHP, PAHP, or PCCM entity to demonstrate that there are sufficient IHCPs participating in the provider network of the MCO, PIHP, PAHP, or PCCM entity to ensure timely access to services available under the contract from such providers for Indian enrollees who are eligible to receive services.

(2) Require that IHCPs, whether participating or not, be paid for covered services provided to Indian enrollees who are eligible to receive services from such providers as follows:

(i) At a rate negotiated between the MCO, PIHP, PAHP, or PCCM entity, and the IHCP, or

(ii) In the absence of a negotiated rate, at a rate not less than the level and amount of payment that the MCO, PIHP, PAHP, or PCCM entity would make for the services to a participating provider which is not an IHCP; and

(iii) Make payment to all IHCPs in its network in a timely manner as required for payments to practitioners in individual or group practices under 42 CFR 447.45 and 447.46.

(3) Permit any Indian who is enrolled in a MCO, PIHP, PAHP, PCCM or PCCM entity that is not an IMCE and eligible to receive services from a IHCP primary care provider participating as a network provider, to choose that IHCP as his or her primary care provider, as long as that provider has capacity to provide the services.

(4) Permit Indian enrollees to obtain services covered under the contract between the State and the MCO, PIHP, PAHP, or PCCM entity from out-of-network IHCPs from whom the enrollee is otherwise eligible to receive such services.

(5) In a State where timely access to covered services cannot be ensured due to few or no IHCPs, an MCO, PIHP, PAHP and PCCM entity will be considered to have met the requirement in paragraph (b)(1) of this section if—

(i) Indian enrollees are permitted by the MCO, PIHP, PAHP, or PCCM entity to access out-of-State IHCPs; or

(ii) If this circumstance is deemed to be good cause for disenrollment from both the MCO, PIHP, PAHP, or PCCM entity and the State's managed care program in accordance with § 438.56(c).

(6) MCOs, PIHPs, PAHPs, and PCCM entities, to the extent the PCCM entity has a provider network, must permit an out-of-network IHCP to refer an Indian enrollee to a network provider.

(c) *Payment requirements.* (1) When an IHCP is enrolled in Medicaid as a FQHC but not a participating provider of the MCO, PIHP, PAHP or PCCM entity, it must be paid an amount equal to the amount the MCO, PIHP, PAHP, or PCCM entity would pay a FQHC that is a network provider but is not an IHCP, including any supplemental payment from the State to make up the difference between the amount the MCO, PIHP, PAHP or PCCM entity pays and what the IHCP FQHC would have received under FFS.

(2) When an IHCP is not enrolled in Medicaid as a FQHC, regardless of whether it participates in the network of an MCO, PIHP, PAHP and PCCM entity or not, it has the right to receive its applicable encounter rate published annually in the FEDERAL REGISTER by the Indian Health Service, or in the absence of a published encounter rate, the amount it would receive if the services were provided under the State plan's FFS payment methodology.

(3) When the amount a IHCP receives from a MCO, PIHP, PAHP, or PCCM entity is less than the amount required by paragraph (c)(2) of this section, the State must make a supplemental payment to the IHCP to make up the difference between the amount the MCO, PIHP, PAHP, or PCCM entity pays and the amount the IHCP would have received under FFS or the applicable encounter rate.

(d) *Enrollment in IMCEs.* An IMCE may restrict its enrollment to Indians in the same manner as Indian Health Programs, as defined in 25 U.S.C. 1603(12), may restrict the delivery of services to Indians, without being in violation of the requirements in § 438.3(d).

§ 438.16 In lieu of services and settings (ILOS) requirements.

(a) *Definitions.* As used in this part, the following terms have the indicated meanings:

Final ILOS cost percentage is the annual amount calculated, in accordance with paragraph (c)(3) of this section, specific to each managed care program that includes ILOS.

Projected ILOS cost percentage is the annual amount calculated, in accordance with paragraph (c)(2) of this section, specific to each managed care program that includes ILOS.

Summary report of actual MCO, PIHP, and PAHP ILOS costs is the report calculated, in accordance with paragraph (c)(4) of this section, specific to each managed care program that includes ILOS.

(b) *General rule.* An ILOS must be approvable as a service or setting through a waiver under section 1915(c) of the Act or a State plan amendment, including section 1905(a), 1915(i), or 1915(k) of the Act.

(c) *ILOS Cost Percentage and summary report of actual MCO, PIHP, and PAHP ILOS costs.*

(1) *General rule.* (i) The projected ILOS cost percentage calculated as required in paragraph (c)(2) of this section may not exceed 5 percent and the final ILOS cost percentage calculated as required in paragraph (c)(3) of this section may not exceed 5 percent.

(ii) The projected ILOS cost percentage, the final ILOS cost percentage, and the summary report of actual MCO, PIHP, and PAHP ILOS costs must be calculated on an annual basis and recalculated annually.

(iii) The projected ILOS cost percentage, the final ILOS cost percentage, and the summary report of actual

MCO, PIHP, and PAHP ILOS costs must be certified by an actuary and developed in a reasonable and appropriate manner consistent with generally accepted actuarial principles and practices.

(2) *Calculation of the projected ILOS cost percentage.* The projected ILOS cost percentage is the result of dividing the amount determined in paragraph (c)(2)(i) of this section by the amount determined in paragraph (c)(2)(ii) of this section.

(i) The portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an IMD as specified in § 438.6(e), for each managed care program.

(ii) The projected total capitation payments for each managed care program, all State directed payments in effect under § 438.6(c), and pass-through payments in effect under § 438.6(d).

(3) *Calculation of the final ILOS cost percentage.* The final ILOS cost percentage is the result of dividing the amount determined in paragraph (c)(3)(i) of this section by the amount determined in paragraph (c)(3)(ii) of this section.

(i) The portion of the total capitation payments that is attributable to all ILOSs, excluding a short term stay in an IMD as specified in § 438.6(e), for each managed care program.

(ii) The actual total capitation payments, defined at § 438.2, for each managed care program, all State directed payments in effect under § 438.6(c), and pass-through payments in effect under § 438.6(d).

(4) *Summary report of actual MCO, PIHP, and PAHP ILOS costs.* The State must submit to CMS a summary report of the actual MCO, PIHP, and PAHP costs for delivering ILOSs based on the claims and encounter data provided by the MCO(s), PIHP(s), and PAHP(s).

(5) *CMS review of the projected ILOS cost percentage, the final ILOS cost percentage and the summary report of actual MCO, PIHP, and PAHP ILOS costs.*

(i) The State must annually submit the projected ILOS cost percentage to CMS for review as part of the rate certification required in § 438.7(a).

(ii) The State must submit the final ILOS cost percentage and the summary report of actual MCO, PIHP, and PAHP ILOS costs annually to CMS for review as a separate report concurrent with the rate certification submission required in § 438.7(a) for the rating period beginning 2 years after the completion of each 12-month rating period that includes an ILOS.

(d) *Documentation requirements*—(1) *State requirements.* All States that include an ILOS in an MCO, PIHP, or PAHP contract are required to include, at minimum, the following:

(i) The name and definition of each ILOS;

(ii) The covered service or setting under the State plan for which each ILOS is a medically appropriate and cost effective substitute;

(iii) The clinically defined target populations for which each ILOS is determined to be medically appropriate and cost effective substitute by the State;

(iv) The process by which a licensed network or MCO, PIHP, or PAHP staff provider, determines and documents in the enrollee's records that each identified ILOS is medically appropriate for the specific enrollee;

(v) The enrollee rights and protections, as defined in § 438.3(e)(2)(ii); and

(vi) A requirement that the MCO, PIHP, or PAHP will utilize specific codes established by the State that identify each ILOS in encounter data, as required under § 438.242.

(2) *Additional documentation requirements.* A State with a projected ILOS cost percentage that exceeds 1.5 percent is also required to provide the following documentation concurrent with the contract submission for review and approval by CMS under § 438.3(a).

(i) A description of the process and supporting evidence the State used to determine that each ILOS is a medically appropriate service or setting for the clinically defined target population(s), consistent with paragraph (d)(1)(iii) of this section.

(ii) A description of the process and supporting data the State used to determine that each ILOS is a cost effective substitute for the clinically defined target population(s), consistent with paragraph (d)(1)(iii) of this section.

(3) *Provision of additional information.* At the request of CMS, the State must

provide additional information, whether part of the MCO, PIHP, or PAHP contract, rate certification or supplemental materials, if CMS determines that the requested information is pertinent to the review and approval of a contract that includes ILOS.

(e) *Monitoring, evaluation, and oversight.* (1) *Retrospective evaluation.* A State is required to submit at least one retrospective evaluation of all ILOSs to CMS when the final ILOS cost percentage exceeds 1.5 percent in any of the first 5 rating periods that each ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under §438.3(e)(2)(iii) following the applicability date in paragraph (f) of this section, or as required in paragraph (v) of this section. The retrospective evaluation must:

(i) Be completed separately for each managed care program that includes an ILOS and include all ILOSs in that managed care program.

(ii) Be completed using 5 years of accurate and validated data for the ILOS with the basis of the data being the first 5 rating periods that the ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under §438.3(e)(2)(iii). The State must utilize these data to at least evaluate cost, utilization, access, grievances and appeals, and quality of care for each ILOS.

(iii) Evaluate at least:

(A) The impact each ILOS had on utilization of State plan approved services or settings, including any associated cost savings;

(B) Trends in MCO, PIHP, or PAHP and enrollee use of each ILOS;

(C) Whether encounter data supports the State's determination that each ILOS is a medically appropriate and cost effective substitute for the identified covered service and setting under the State plan or a cost effective measure to reduce or prevent the future need to utilize the covered service and setting under the State plan;

(D) The impact of each ILOS on quality of care;

(E) The final ILOS cost percentage for each year consistent with the report in paragraph (c)(5)(ii) of this section with a declaration of compliance with the allowable threshold in paragraph (c)(1)(i) of this section;

(F) Appeals, grievances, and State fair hearings data, reported separately, related to each ILOS, including volume, reason, resolution status, and trends; and

(G) The impact each ILOS had on health equity efforts undertaken by the State to mitigate health disparities.

(iv) The State must submit the retrospective evaluation to CMS no later than 2 years after the later of either the completion of the first 5 rating periods that the ILOS is authorized and identified in the MCO, PIHP, or PAHP contract as required under §438.3(e)(2)(iii) or the rating period that has a final ILOS cost percentage that exceeds 1.5 percent.

(v) CMS reserves the right to require the State to submit additional retrospective evaluations to CMS.

(2) *Oversight.* Oversight for each ILOS must include the following:

(i) *State notification requirement.* The State must notify CMS within 30 calendar days if:

(A) The State determines that an ILOS is no longer a medically appropriate or cost effective substitute for the covered service or setting under the State plan identified in the contract as required in paragraph (d)(1)(ii) of this section; or

(B) The State identifies noncompliance with requirements in this part.

(ii) *CMS oversight process.* If CMS determines that a State is out of compliance with any requirement in this part or receives a State notification in paragraph (e)(2)(i) of this section, CMS may require the State to terminate the use of an ILOS.

(iii) *Process for termination of ILOS.* Within 30 calendar days of receipt of a notice described in paragraph (e)(2)(iii)(A), (B), or (C) of this section, the State must submit an ILOS transition plan to CMS for review and approval.

(A) The notice the State provides to an MCO, PIHP, or PAHP of its decision to terminate an ILOS.

(B) The notice an MCO, PIHP, or PAHP provides to the State of its decision to cease offering an ILOS to its enrollees.

(C) The notice CMS provides to the State of its decision to require the State to terminate an ILOS.

(iv) *Requirements for an ILOS Transition Plan.* The transition plan must include at least the following:

(A) A process to notify enrollees of the termination of an ILOS that they are currently receiving as expeditiously as the enrollee's health condition requires.

(B) A transition of care policy, not to exceed 12 months, to arrange for State plan services and settings to be provided timely and with minimal disruption to care to any enrollee who is currently receiving the ILOS that will be terminated. The State must make the transition of care policy publicly available.

(C) An assurance the State will submit the modification of the MCO, PIHP, or PAHP contract to remove the ILOS and submission of the modified contracts to CMS as required in § 438.3(a), and a reasonable timeline for submitting the contract amendment.

(D) An assurance the State and its actuary will submit an adjustment to the actuarially sound capitation rate, as needed, to remove utilization and cost of the ILOS from capitation rates as required in §§ 438.4, 438.7(a) and 438.7(c)(2), and a reasonable timeline for submitting the revised rate certification.

(f) *Applicability date.* Section 438.16 applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after 60 days following July 9, 2024.

[89 FR 41273, May 10, 2024, as amended at 89 FR 52391]

Subpart B—State Responsibilities

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

§ 438.50 State Plan requirements.

(a) *General rule.* A State plan that requires Medicaid beneficiaries to enroll in MCOs, PCCMs, or PCCM entities must comply with the provisions of this section, except when the State imposes the requirement—

(1) As part of a demonstration project under section 1115(a) of the Act; or

(2) Under a waiver granted under section 1915(b) of the Act.

(b) *State plan information.* The plan must specify—

(1) The types of entities with which the State contracts.

(2) The payment method it uses (for example, whether FFS or capitation).

(3) Whether it contracts on a comprehensive risk basis.

(4) The process the State uses to involve the public in both design and initial implementation of the managed care program and the methods it uses to ensure ongoing public involvement once the State plan has been implemented.

(c) *State plan assurances.* The plan must provide assurances that the State meets applicable requirements of the following statute and regulations:

(1) Section 1903(m) of the Act, for MCOs and MCO contracts.

(2) Section 1905(t) of the Act, for PCCMs and PCCM or PCCM entity contracts.

(3) Section 1932(a)(1)(A) of the Act, for the State's option to limit freedom of choice by requiring beneficiaries to receive their benefits through managed care entities.

(4) This part, for MCOs, PCCMs, and PCCM entities.

(5) Part 434 of this chapter, for all contracts.

(6) Section 438.4, for payments under any risk contracts, and § 447.362 of this chapter for payments under any nonrisk contracts.

(d) *Limitations on enrollment.* The State must provide assurances that, in implementing the State plan managed care option, it will not require the following groups to enroll in an MCO, PCCM or PCCM entity:

(1) Beneficiaries who are also eligible for Medicare.

(2) Indians as defined in § 438.14(a), except as permitted under § 438.14(d).

(3) Children under 19 years of age who are:

(i) Eligible for SSI under Title XVI;

(ii) Eligible under section 1902(e)(3) of the Act;

(iii) In foster care or other out-of-home placement;

(iv) Receiving foster care or adoption assistance; or

(v) Receiving services through a family-centered, community-based, coordinated care system that receives grant funds under section 501(a)(1)(D) of Title V, and is defined by the State in terms of either program participation or special health care needs.

§ 438.52 Choice of MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities.

(a) *General rule.* Except as specified in paragraphs (b) and (c) of this section, a State that requires Medicaid beneficiaries to:

(1) Enroll in an MCO, PIHP, or PAHP, must give those beneficiaries a choice of at least two MCOs, PIHPs, or PAHPs.

(2) Enroll in a primary care case management system, must give those beneficiaries a choice from at least two primary care case managers employed or contracted with the State.

(3) Enroll in a PCCM entity, may limit a beneficiary to a single PCCM entity. Beneficiaries must be permitted to choose from at least two primary care case managers employed by or contracted with the PCCM entity.

(b) *Exception for rural area residents.* (1) Under any managed care program authorized by any of the following, and subject to the requirements of paragraph (b)(2) of this section, a State may limit a rural area resident to a single MCO, PIHP, or PAHP:

(i) A State plan amendment under section 1932(a) of the Act.

(ii) A waiver under section 1115(a) of the Act.

(iii) A waiver under section 1915(b) of the Act.

(2) To comply with this paragraph (b), a State, must permit the beneficiary—

(i) To choose from at least two primary care providers; and

(ii) To obtain services from any other provider under any of the following circumstances:

(A) The service or type of provider (in terms of training, experience, and specialization) is not available within the MCO, PIHP, or PAHP network.

(B) The provider is not part of the network, but is the main source of a service to the beneficiary, provided that—

(*1*) The provider is given the opportunity to become a participating provider under the same requirements for participation in the MCO, PIHP, or PAHP network as other network providers of that type.

(*2*) If the provider chooses not to join the network, or does not meet the necessary qualification requirements to join, the enrollee will be transitioned to a participating provider within 60 calendar days (after being given an opportunity to select a provider who participates).

(C) The only plan or provider available to the beneficiary does not, because of moral or religious objections, provide the service the enrollee seeks.

(D) The beneficiary's primary care provider or other provider determines that the beneficiary needs related services that would subject the beneficiary to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.

(E) The State determines that other circumstances warrant out-of-network treatment.

(3) As used in this paragraph (b), ''rural area'' is any county designated as ''micro,'' ''rural,'' or ''County with Extreme Access Considerations (CEAC)'' in the Medicare Advantage Health Services Delivery (HSD) Reference file for the applicable calendar year.

(c) *Exception for certain health insuring organizations (HIOs).* The State may limit beneficiaries to a single HIO if—

(1) The HIO is one of those described in section 1932(a)(3)(C) of the Act; and

(2) The beneficiary who enrolls in the HIO has a choice of at least two primary care providers within the entity.

(d) *Limitations on changes between primary care providers.* For an enrollee of a single MCO, PIHP, PAHP, or HIO under paragraph (b) or (c) of this section, any limitation the State imposes on his or her freedom to change between primary care providers may be no more restrictive than the limitations on disenrollment under § 438.56(c).

§ 438.54 Managed care enrollment.

(a) *Applicability.* The provisions of this section apply to all Medicaid managed care programs which operate under any authority in the Act.

(b) *General rule.* The State must have an enrollment system for its managed care programs, voluntary and mandatory, as appropriate.

(1) Voluntary managed care programs are those where one or more groups of beneficiaries as enumerated in section of 1905(a) of the Act have the option to either enroll in a MCO, PIHP, PAHP, PCCM or PCCM entity, or remain enrolled in FFS to receive Medicaid covered benefits.

(2) Mandatory managed care programs are those where one or more groups of beneficiaries as enumerated in section 1905(a) of the Act must enroll in a MCO, PIHP, PAHP, PCCM or PCCM entity to receive covered Medicaid benefits.

(3) States must provide the demographic information listed in § 438.340(b)(6) for each Medicaid enrollee to the individual's MCO, PIHP, PAHP, or PCCM entity at the time of enrollment.

(c) *Voluntary managed care programs.* (1) States that have a voluntary managed care program must have an enrollment system that:

(i) Provides an enrollment choice period during which potential enrollees may make an active choice of delivery system and, if needed, choice of an MCO, PIHP, PAHP, PCCM or PCCM entity before enrollment is effectuated; or

(ii) Employs a passive enrollment process in which the State enrolls the potential enrollee into a MCO, PIHP, PAHP, PCCM or PCCM entity and simultaneously provides a period of time for the enrollee to make an active choice of delivery system and, if needed, to maintain enrollment in the MCO, PIHP, PAHP, PCCM or PCCM entity passively assigned or to select a different MCO, PIHP, PAHP, PCCM or PCCM entity.

(2) A State must provide potential enrollees the opportunity to actively elect to receive covered services through the managed care or FFS delivery system. If the potential enrollee elects to receive covered services through the managed care delivery system, the potential enrollee must then also select a MCO, PIHP, PAHP, PCCM, or PCCM entity.

(i) If the State does not use a passive enrollment process and the potential enrollee does not make an active choice during the period allowed by the state, then the potential enrollee will continue to receive covered services through the FFS delivery system.

(ii) If the State uses a passive enrollment process, the potential enrollee must select either to accept the MCO, PIHP, PAHP, PCCM, or PCCM entity selected for them by the State's passive enrollment process, select a different MCO, PIHP, PAHP, PCCM, or PCCM entity, or elect to receive covered services through the FFS delivery system. If the potential enrollee does not make an active choice during the time allowed by the state, the potential enrollee will remain enrolled with the MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the passive enrollment process.

(3) The State must provide informational notices to each potential enrollee at the time the potential enrollee first becomes eligible to enroll in a managed care program and within a timeframe that enables the potential enrollee to use the information in choosing among available delivery system and/or managed care plan options. The notices must:

(i) Clearly explain (as relevant to the State's managed care program) the implications to the potential enrollee of: not making an active choice between managed care and FFS; selecting a different MCO, PIHP, PAHP, PCCM or PCCM entity; and accepting the MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the State;

(ii) Identify the MCOs, PIHPs, PAHPs, PCCMs or PCCM entities available to the potential enrollee should they elect the managed care delivery system;

(iii) Provide clear instructions for how to make known to the State the enrollee's selection of the FFS delivery system or a MCO, PIHP, PAHP, PCCM or PCCM entity;

(iv) Provide a comprehensive explanation of the length of the enrollment period, the 90 day without cause

disenrollment period, and all other disenrollment options as specified in § 438.56;

(v) Include the contact information for the beneficiary support system in § 438.71; and

(vi) Comply with the information requirements in § 438.10.

(4) The State's enrollment system must provide that beneficiaries already enrolled in an MCO, PIHP, PAHP, PCCM or PCCM entity are given priority to continue that enrollment if the MCO, PIHP, PAHP, PCCM or PCCM entity does not have the capacity to accept all those seeking enrollment under the program.

(5) If a State elects to use a passive enrollment process, the process must assign beneficiaries to a qualified MCO, PIHP, PAHP, PCCM or PCCM entity. To be a qualified MCO, PIHP, PAHP, PCCM or PCCM entity, it must:

(i) Not be subject to the intermediate sanction described in § 438.702(a)(4); and

(ii) Have capacity to enroll beneficiaries.

(6) A passive enrollment process must seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served Medicaid beneficiaries.

(i) An ''existing provider-beneficiary relationship'' is one in which the provider was a main source of Medicaid services for the beneficiary during the previous year. This may be established through State records of previous managed care enrollment or FFS experience, encounter data, or through contact with the beneficiary.

(ii) A provider is considered to have ''traditionally served'' Medicaid beneficiaries if it has experience in serving the Medicaid population.

(7) If the approach in paragraph (c)(6) of this section is not possible, the State must distribute the beneficiaries equitably among the MCOs, PIHPs, PAHPs, PCCMs and PCCM entities.

(i) The State may not arbitrarily exclude any MCO, PIHP, PAHP, PCCM, or PCCM entity from being considered.

(ii) The State may consider additional criteria to conduct the passive enrollment process, including the enrollment preferences of family members, previous plan assignment of the beneficiary, quality assurance and improvement performance, procurement evaluation elements, accessibility of provider offices for people with disabilities (when appropriate), and other reasonable criteria that support the objectives of the managed care program.

(8) If a passive enrollment process is used and the enrollee does not elect to be enrolled into the FFS delivery system, the State must send a notice to the enrollee:

(i) Confirming that the enrollee's time to elect to enroll in the FFS delivery system has ended and that the enrollee will remain enrolled in the managed care delivery system for the remainder of the enrollment period unless one of the disenrollment reasons specified in § 438.56 applies.

(ii) Clearly and fully explaining the enrollee's right, and process to follow, to disenroll from the passively assigned MCO, PIHP, PAHP, PCCM or PCCM entity and select a different MCO, PIHP, PAHP, PCCM or PCCM entity within 90 days from the effective date of the enrollment or for any reason specified in § 438.56(d)(2).

(iii) Within 5 calendar days of the end of the time allowed for making the delivery system selection.

(d) *Mandatory managed care programs.* (1) States must have an enrollment system for a mandatory managed care program that includes the elements specified in paragraphs (d)(2) through (8) of this section.

(2) The State's enrollment system must implement enrollment in a MCO, PIHP, PAHP, PCCM, or PCCM entity as follows:

(i) If the State does not use a passive enrollment process and the potential enrollee does not make an active choice of a MCO, PIHP, PAHP, PCCM, or PCCM entity during the period allowed by the State, the potential enrollee will be enrolled into a MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the State's default process.

(ii) If the State uses a passive enrollment process, the potential enrollee must either accept the MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the State's passive enrollment process or select a different MCO, PIHP, PAHP, PCCM, or PCCM entity. If the potential enrollee does not make an active choice during the time allowed by

the State, the MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the passive enrollment process will remain effective.

(3) A State must provide informational notices to each potential enrollee at the time the potential enrollee first becomes eligible to enroll in a managed care program and within a timeframe that enables the potential enrollee to use the information in choosing among available managed care plans. The notices must:

(i) Include the MCOs, PIHPs, PAHPs, PCCMs, or PCCM entities available to the potential enrollee;

(ii) Provide clear instructions for how to make known to the State the enrollee's selection of a MCO, PIHP, PAHP, PCCM, or PCCM entity;

(iii) Clearly explain the implications to the potential enrollee of not making an active choice of an MCO, PIHP, PAHP, PCCM or PCCM entity as well as the implications of making an active choice of an MCO, PIHP, PAHP, PCCM or PCCM entity;

(iv) Provide a comprehensive explanation of the length of the enrollment period, the 90 day without cause disenrollment period, and all other disenrollment options as specified in § 438.56;

(v) Include the contact information for the beneficiary support system in § 438.71; and

(vi) Comply with the information requirements in § 438.10.

(4) *Priority for enrollment.* The State's enrollment system must provide that beneficiaries already enrolled in an MCO, PIHP, PAHP, PCCM or PCCM entity are given priority to continue that enrollment if the MCO, PIHP, PAHP, PCCM or PCCM entity does not have the capacity to accept all those seeking enrollment under the program.

(5) *Enrollment by default.* For potential enrollees that do not select an MCO, PIHP, PAHP, PCCM or PCCM entities during the period allowed by the state, the State must have a default enrollment process for assigning those beneficiaries to qualified MCOs, PIHPs, PAHPs, PCCMs and PCCM entities. To be a qualified MCO, PIHP, PAHP, PCCM or PCCM entity, it must:

(i) Not be subject to the intermediate sanction described in § 438.702(a)(4); and

(ii) Have capacity to enroll beneficiaries.

(6) *Passive enrollment.* For States that use a passive enrollment process, the process must assign potential enrollees to qualified MCOs, PIHPs, PAHPs, PCCMs and PCCM entities. To be a qualified MCO, PIHP, PAHP, PCCM or PCCM entity, it must:

(i) Not be subject to the intermediate sanction described in § 438.702(a)(4); and

(ii) Have capacity to enroll beneficiaries.

(7) The passive and default enrollment processes must seek to preserve existing provider-beneficiary relationships and relationships with providers that have traditionally served Medicaid beneficiaries.

(i) An ''existing provider-beneficiary relationship'' is one in which the provider was a main source of Medicaid services for the beneficiary during the previous year. This may be established through State records of previous managed care enrollment or FFS experience, encounter data, or through contact with the beneficiary.

(ii) A provider is considered to have ''traditionally served'' Medicaid beneficiaries if it has experience in serving the Medicaid population.

(8) If the approach in paragraph (d)(7) of this section is not possible, the State must distribute the beneficiaries equitably among the MCOs, PIHPs, PAHPs, PCCMs and PCCM entities available to enroll them.

(i) The State may not arbitrarily exclude any MCO, PIHP, PAHP, PCCM or PCCM entity from being considered; and

(ii) The State may consider additional criteria to conduct the default enrollment process, including the enrollment preferences of family members, previous plan assignment of the beneficiary, quality assurance and improvement performance, procurement evaluation elements, accessibility of provider offices for people with disabilities (when appropriate), and other reasonable criteria related to a beneficiary's experience with the Medicaid program.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72840, Nov. 13, 2020]

§ 438.56 Disenrollment: Requirements and limitations.

(a) *Applicability.* The provisions of this section apply to all managed care programs whether enrollment is mandatory or voluntary and whether the contract is with an MCO, PIHP, PAHP, PCCM, or PCCM entity.

(b) *Disenrollment requested by the MCO, PIHP, PAHP, PCCM, or PCCM entity.* All MCO, PIHP, PAHP, PCCM and PCCM entity contracts must:

(1) Specify the reasons for which the MCO, PIHP, PAHP, PCCM, or PCCM entity may request disenrollment of an enrollee.

(2) Provide that the MCO, PIHP, PAHP, PCCM, or PCCM entity may not request disenrollment because of an adverse change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except when his or her continued enrollment in the MCO, PIHP, PAHP, PCCM or PCCM entity seriously impairs the entity's ability to furnish services to either this particular enrollee or other enrollees).

(3) Specify the methods by which the MCO, PIHP, PAHP, PCCM, or PCCM entity assures the agency that it does not request disenrollment for reasons other than those permitted under the contract.

(c) *Disenrollment requested by the enrollee.* If the State chooses to limit disenrollment, its MCO, PIHP, PAHP, PCCM, and PCCM entity contracts must provide that a beneficiary may request disenrollment as follows:

(1) For cause, at any time.

(2) Without cause, at the following times:

(i) During the 90 days following the date of the beneficiary's initial enrollment into the MCO, PIHP, PAHP, PCCM, or PCCM entity, or during the 90 days following the date the State sends the beneficiary notice of that enrollment, whichever is later.

(ii) At least once every 12 months thereafter.

(iii) Upon automatic reenrollment under paragraph (g) of this section, if the temporary loss of Medicaid eligibility has caused the beneficiary to miss the annual disenrollment opportunity.

(iv) When the State imposes the intermediate sanction specified in § 438.702(a)(4).

(d) *Procedures for disenrollment*—(1) *Request for disenrollment.* The beneficiary (or his or her representative) must submit an oral or written request, as required by the State—

(i) To the State (or its agent); or

(ii) To the MCO, PIHP, PAHP, PCCM, or PCCM entity, if the State permits MCOs, PIHP, PAHPs, PCCMs, and PCCM entities to process disenrollment requests.

(2) *Cause for disenrollment.* The following are cause for disenrollment:

(i) The enrollee moves out of the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's service area.

(ii) The plan does not, because of moral or religious objections, cover the service the enrollee seeks.

(iii) The enrollee needs related services (for example, a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the provider network; and the enrollee's primary care provider or another provider determines that receiving the services separately would subject the enrollee to unnecessary risk.

(iv) For enrollees that use MLTSS, the enrollee would have to change their residential, institutional, or employment supports provider based on that provider's change in status from an in-network to an out-of-network provider with the MCO, PIHP, or PAHP and, as a result, would experience a disruption in their residence or employment.

(v) Other reasons, including poor quality of care, lack of access to services covered under the contract, or lack of access to providers experienced in dealing with the enrollee's care needs.

(3) *MCO, PIHP, PAHP, PCCM, or PCCM entity action on request.* (i) When the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's contract with the State permits the MCO, PIHP, PAHP, PCCM, or PCCM entity to process disenrollment requests, the MCO, PIHP, PAHP, PCCM, or PCCM entity may either approve a request for

disenrollment by or on behalf of an enrollee or the MCO, PIHP, PAHP, PCCM, or PCCM entity must refer the request to the State.

(ii) If the MCO, PIHP, PAHP, PCCM, PCCM entity, or State agency (whichever is responsible) fails to make a disenrollment determination so that the beneficiary can be disenrolled within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved.

(4) *State agency action on request.* For a request received directly from the beneficiary, or one referred by the MCO, PIHP, PAHP, PCCM, or PCCM entity, the State agency must take action to approve or disapprove the request based on the following:

(i) Reasons cited in the request.

(ii) Information provided by the MCO, PIHP, PAHP, PCCM, or PCCM entity at the agency's request.

(iii) Any of the reasons specified in paragraph (d)(2) of this section.

(5) *Use of the MCO's, PIHP's, PAHP's grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO's, PHIP's, or PAHP's grievance system before making a determination on the enrollee's request.

(ii) The grievance process, if used, must be completed in time to permit the disenrollment (if approved) to be effective in accordance with the timeframe specified in paragraph (e)(1) of this section.

(iii) If, as a result of the grievance process, the MCO, PIHP, or PAHP approves the disenrollment, the State agency is not required to make a determination in accordance with paragraph (d)(4) of this section.

(e) *Timeframe for disenrollment determinations.* (1) Regardless of the procedures followed, the effective date of an approved disenrollment must be no later than the first day of the second month following the month in which the enrollee requests disenrollment or the MCO, PIHP, PAHP, PCCM, or PCCM entity refers the request to the State.

(2) If the MCO, PIHP, PAHP, PCCM, PCCM entity, or the State agency (whichever is responsible) fails to make the determination within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved for the effective date that would have been established had the State or MCO, PIHP, PAHP, PCCM, PCCM entity complied with paragraph (e)(1) of this section.

(f) *Notice and appeals.* A State that restricts disenrollment under this section must take the following actions:

(1) Provide that enrollees and their representatives are given written notice of disenrollment rights at least 60 days before the start of each enrollment period. The notice must include an explanation of all of the enrollee's disenrollment rights as specified in this section.

(2) Ensure timely access to State fair hearing for any enrollee dissatisfied with a State agency determination that there is not good cause for disenrollment.

(g) *Automatic reenrollment: Contract requirement.* If the State plan so specifies, the contract must provide for automatic reenrollment of a beneficiary who is disenrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72840, Nov. 13, 2020]

§ 438.58 Conflict of interest safeguards.

As a condition for contracting with MCOs, PIHPs, or PAHPs, a State must have in effect safeguards against conflict of interest on the part of State and local officers and employees and agents of the State who have responsibilities relating to the MCO, PIHP, or PAHP contracts or the enrollment processes specified in § 438.54(b). These safeguards must be at least as effective as the safeguards specified in section 27 of the Office of Federal Procurement Policy Act (41 U.S.C. 423).

§ 438.60 Prohibition of additional payments for services covered under MCO, PIHP or PAHP contracts.

The State agency must ensure that no payment is made to a network provider other than by the MCO, PIHP, or PAHP for services covered under the contract between the State and the MCO, PIHP, or PAHP, except when these payments are specifically required to be made by the State in Title XIX of the Act, in 42 CFR chapter IV,

or when the State agency makes direct payments to network providers for graduate medical education costs approved under the State plan.

§ 438.62 Continued services to enrollees.

(a) The State agency must arrange for Medicaid services to be provided without delay to any Medicaid enrollee of an MCO, PIHP, PAHP, PCCM, or PCCM entity the contract of which is terminated and for any Medicaid enrollee who is disenrolled from an MCO, PIHP, PAHP, PCCM, or PCCM entity for any reason other than ineligibility for Medicaid.

(b) The State must have in effect a transition of care policy to ensure continued access to services during a transition from FFS to a MCO, PIHP, PAHP, PCCM or PCCM entity or transition from one MCO, PIHP, PAHP, PCCM or PCCM entity to another when an enrollee, in the absence of continued services, would suffer serious detriment to their health or be at risk of hospitalization or institutionalization.

(1) The transition of care policy must include the following:

(i) The enrollee has access to services consistent with the access they previously had, and is permitted to retain their current provider for a period of time if that provider is not in the MCO, PIHP or PAHP network.

(ii) The enrollee is referred to appropriate providers of services that are in the network.

(iii) The State, in the case of FFS, PCCM, or PCCM entity, or the MCO, PIHP or PAHP that was previously serving the enrollee, fully and timely complies with requests for historical utilization data from the new MCO, PIHP, PAHP, PCCM, or PCCM entity in compliance with Federal and State law.

(iv) Consistent with Federal and State law, the enrollee's new provider(s) are able to obtain copies of the enrollee's medical records, as appropriate.

(v) Any other necessary procedures as specified by the Secretary to ensure continued access to services to prevent serious detriment to the enrollee's health or reduce the risk of hospitalization or institutionalization.

(2) The State must require by contract that MCOs, PIHPs, and PAHPs implement a transition of care policy consistent with the requirements in paragraph (b)(1) of this section and at least meets the State defined transition of care policy.

(3) The State must make its transition of care policy publicly available and provide instructions to enrollees and potential enrollees on how to access continued services upon transition. At a minimum, the transition of care policy must be described in the quality strategy, under § 438.340, and explained to individuals in the materials to enrollees and potential enrollees, in accordance with § 438.10.

(c) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, PAHPs, PCCMs, and PCCM entities beginning on or after July 1, 2018. Until that applicability date, states are required to continue to comply with § 438.62 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

[81 FR 27853, May 6, 2016, as amended at 85 FR 25635, May 1, 2020; 89 FR 8980, Feb. 8, 2024]

§ 438.66 State monitoring requirements.

(a) *General requirement.* The State agency must have in effect a monitoring system for all managed care programs.

(b) The State's system must address all aspects of the managed care program, including the performance of each MCO, PIHP, PAHP, and PCCM entity (if applicable) in at least the following areas:

(1) Administration and management.

(2) Appeal and grievance systems.

(3) Claims management.

(4) Enrollee materials, enrollee experience, and customer services, including the activities of the beneficiary support system.

(5) Finance, including medical loss ratio reporting.

(6) Information systems, including encounter data reporting.

(7) Marketing.

(8) Medical management, including utilization management and case management.

(9) Program integrity.

(10) Provider network management, including provider directory standards.

(11) Availability and accessibility of services, including network adequacy standards.

(12) Quality improvement.

(13) Areas related to the delivery of LTSS not otherwise included in paragraphs (b)(1) through (12) of this section as applicable to the managed care program.

(14) All other provisions of the contract, as appropriate.

(c) The State must use data collected from its monitoring activities to improve the performance of its managed care program, including at a minimum:

(1) Enrollment and disenrollment trends in each MCO, PIHP, or PAHP.

(2) Member grievance and appeal logs.

(3) Provider complaint and appeal logs.

(4) Findings from the State's External Quality Review process.

(5) Results from an annual enrollee experience survey conducted by the State (or as otherwise conducted when all enrollees are also in affiliated Medicare Advantage dual eligible special needs plans subject to the condition in § 422.107(e)(1)(i)) and any provider satisfaction survey conducted by the State or MCO, PIHP, or PAHP.

(6) Performance on required quality measures.

(7) Medical management committee reports and minutes.

(8) The annual quality improvement plan for each MCO, PIHP, PAHP, or PCCM entity.

(9) Audited financial and encounter data submitted by each MCO, PIHP, or PAHP.

(10) The medical loss ratio summary reports required by § 438.8.

(11) Customer service performance data submitted by each MCO, PIHP, or PAHP and performance data submitted by the beneficiary support system.

(12) Any other data related to the provision of LTSS not otherwise included in paragraphs (c)(1) through (11) of this section as applicable to the managed care program.

(d)(1) The State must assess the readiness of each MCO, PIHP, PAHP or PCCM entity with which it contracts as follows:

(i) Prior to the State implementing a managed care program, whether the program is voluntary or mandatory.

(ii) When the specific MCO, PIHP, PAHP, or PCCM entity has not previously contracted with the State.

(iii) When any MCO, PIHP, PAHP, or PCCM entity currently contracting with the State will provide or arrange for the provision of covered benefits to new eligibility groups.

(2) The State must conduct a readiness review of each MCO, PIHP, PAHP, or PCCM entity with which it contracts as follows:

(i) Started at least 3 months prior to the effective date of the events described in paragraph (d)(1) of this section.

(ii) Completed in sufficient time to ensure smooth implementation of an event described in paragraph (d)(1) of this section.

(iii) Submitted to CMS for CMS to make a determination that the contract or contract amendment associated with an event described in paragraph (d)(1) of this section is approved under § 438.3(a).

(3) Readiness reviews described in paragraphs (d)(1)(i) and (ii) of this section must include both a desk review of documents and on-site reviews of each MCO, PIHP, PAHP, or PCCM entity. Readiness reviews described in paragraph (d)(1)(iii) of this section must include a desk review of documents and may, at the State's option, include an on-site review. On-site reviews must include interviews with MCO, PIHP, PAHP, or PCCM entity staff and leadership that manage key operational areas.

(4) A State's readiness review must assess the ability and capacity of the MCO, PIHP, PAHP, and PCCM entity (if applicable) to perform satisfactorily for the following areas:

(i) Operations/Administration, including—

(A) Administrative staffing and resources.

(B) Delegation and oversight of MCO, PIHP, PAHP or PCCM entity responsibilities.

(C) Enrollee and provider communications.

(D) Grievance and appeals.

(E) Member services and outreach.

(F) Provider Network Management.

(G) Program Integrity/Compliance.

(ii) Service delivery, including—

(A) Case management/care coordination/service planning.

(B) Quality improvement.

(C) Utilization review.

(iii) Financial management, including—

(A) Financial reporting and monitoring.

(B) Financial solvency.

(iv) Systems management, including—

(A) Claims management.

(B) Encounter data and enrollment information management.

(e)(1) The State must submit to CMS no later than 180 days after each contract year, a report on each managed care program administered by the State, regardless of the authority under which the program operates.

(i) The initial report will be due after the contract year following the release of CMS guidance on the content and form of the report.

(ii) For States that operate their managed care program under section 1115(a) of the Act authority, submission of an annual report that may be required by the Special Terms and Conditions of the section 1115(a) demonstration program will be deemed to satisfy the requirement of this paragraph (e)(1) provided that the report includes the information specified in paragraph (e)(2) of this section.

(2) The program report must provide information on and an assessment of the operation of the managed care program on, at a minimum, the following areas:

(i) Financial performance of each MCO, PIHP, and PAHP, including MLR experience.

(ii) Encounter data reporting by each MCO, PIHP, or PAHP.

(iii) Enrollment and service area expansion (if applicable) of each MCO, PIHP, PAHP, and PCCM entity.

(iv) Modifications to, and implementation of, MCO, PIHP, or PAHP benefits covered under the contract with the State.

(v) Grievance, appeals, and State fair hearings for the managed care program.

(vi) Availability and accessibility of covered services, including any ILOS, within the MCO, PIHP, or PAHP contracts, including network adequacy standards.

(vii) Evaluation of MCO, PIHP, or PAHP performance on quality measures and results of an enrollee experience survey, including as applicable, consumer report card, provider surveys, or other reasonable measures of performance.

(viii) Results of any sanctions or corrective action plans imposed by the State or other formal or informal intervention with a contracted MCO, PIHP, PAHP, or PCCM entity to improve performance.

(ix) Activities and performance of the beneficiary support system.

(x) Any other factors in the delivery of LTSS not otherwise addressed in (e)(2)(i)–(ix) of this section as applicable.

(3) The program report required in this section must be:

(i) Posted on the website required under § 438.10(c)(3) within 30 calendar days of submitting it to CMS.

(ii) Provided to the Medical Care Advisory Committee, required under § 431.12 of this chapter.

(iii) Provided to the stakeholder consultation group specified in § 438.70, to the extent that the managed care program includes LTSS.

(f) *Applicability.* States will not be held out of compliance with the requirements of paragraphs (b)(4), (c)(5), and (e)(2)(vii) of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after July 9, 2024, so long as they comply with the corresponding standard(s) 42 CFR 438.66 (effective as of October 1, 2023).

[81 FR 27853, May 6, 2016, as amended at 89 FR 41275, May 10, 2024]

§ 438.68 Network adequacy standards.

(a) *General rule.* A State that contracts with an MCO, PIHP or PAHP to deliver Medicaid services must develop and enforce network adequacy standards consistent with this section.

(b) *Provider-specific network adequacy standards.*–(1) *Provider types.* At a minimum, a State must develop a quantitative network adequacy standard,

other than appointment wait times, for the following provider types, if covered under the contract:

(i) Primary care, adult and pediatric.

(ii) OB/GYN.

(iii) Mental health and substance use disorder, adult and pediatric.

(iv) Specialist (as designated by the State), adult, and pediatric.

(v) Hospital.

(vi) Pharmacy.

(vii) Pediatric dental.

(2) *LTSS.* States with MCO, PIHP, or PAHP contracts which cover LTSS must develop a quantitative network adequacy standard for LTSS provider types.

(3) *Scope of network adequacy standards.* Network standards established in accordance with paragraphs (b)(1) and (2) of this section must include all geographic areas covered by the managed care program or, if applicable, the contract between the State and the MCO, PIHP or PAHP. States are permitted to have varying standards for the same provider type based on geographic areas.

(c) *Development of network adequacy standards.* (1) States developing network adequacy standards consistent with paragraph (b)(1) of this section must consider, at a minimum, the following elements:

(i) The anticipated Medicaid enrollment.

(ii) The expected utilization of services.

(iii) The characteristics and health care needs of specific Medicaid populations covered in the MCO, PIHP, and PAHP contract.

(iv) The numbers and types (in terms of training, experience, and specialization) of network providers required to furnish the contracted Medicaid services.

(v) The numbers of network providers who are not accepting new Medicaid patients.

(vi) The geographic location of network providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees.

(vii) The ability of network providers to communicate with limited English proficient enrollees in their preferred language.

(viii) The ability of network providers to ensure physical access, reasonable accommodations, culturally competent communications, and accessible equipment for Medicaid enrollees with physical or mental disabilities.

(ix) The availability of triage lines or screening systems, as well as the use of telemedicine, e-visits, and/or other evolving and innovative technological solutions.

(2) States developing standards consistent with paragraph (b)(2) of this section must consider the following:

(i) All elements in paragraphs (c)(1)(i) through (ix) of this section.

(ii) Elements that would support an enrollee's choice of provider.

(iii) Strategies that would ensure the health and welfare of the enrollee and support community integration of the enrollee.

(iv) Other considerations that are in the best interest of the enrollees that need LTSS.

(d) *Exceptions process.* (1) To the extent the State permits an exception to any of the network standards developed under this section, the standard by which the exception will be evaluated and approved must:

(i) Be specified in the MCO, PIHP, or PAHP contract.

(ii) Be based, at a minimum, on the number of providers in that specialty practicing in the MCO, PIHP, or PAHP service area.

(iii) Include consideration of the payment rates offered by the MCO, PIHP, or PAHP to the provider type or for the service type for which an exception is being requested.

(2) States that grant an exception in accordance with paragraph (d)(1) of this section to an MCO, PIHP, or PAHP must monitor enrollee access to that provider type or service on an ongoing basis and include the findings to CMS in the managed care program assessment report required under § 438.66(e).

(e) *Appointment wait time standards.* States must establish and enforce appointment wait time standards.

(1) *Routine appointments.* Standards must be established for routine appointments for the following services and within the specified limits:

(i) If covered in the MCO's, PIHP's, or PAHP's contract, outpatient mental

health and substance use disorder, adult and pediatric, within State-established timeframes but no longer than 10 business days from the date of request.

(ii) If covered in the MCO's, PIHP's, or PAHP's contract, primary care, adult and pediatric, within State-established timeframes but no longer than 15 business days from the date of request.

(iii) If covered in the MCO's, PIHP's, or PAHP's contract, obstetrics and gynecological within State-established timeframes but no longer than 15 business days from the date of request.

(iv) State-selected, other than those listed in paragraphs (e)(1)(i) through (iii) of this section and covered in the MCO's, PIHP's, or PAHP's contract, chosen in an evidence-based manner within State-established timeframes.

(2) *Minimum compliance.* MCOs, PIHPs, and PAHPs will be deemed compliant with the standards established in paragraph (e)(1) of this section when secret shopper results, consistent with paragraph (f)(2) of this section, reflect a rate of appointment availability that meets the standards established at paragraph (e)(1)(i) through (iv) of this section of at least 90 percent.

(3) *Selection of additional types of services.* After consulting with States and other interested parties and providing public notice and opportunity to comment, CMS may select additional types of services to be added to paragraph (e)(1) of this section.

(f) *Secret shopper surveys.* States must contract with an entity, independent of the State Medicaid agency and any of its contracted MCOs, PIHPs and PAHPs subject to the survey, to conduct annual secret shopper surveys of each MCO's, PIHP's, and PAHP's compliance with the provider directory requirements in § 438.10(h) as specified in paragraph (f)(1) of this section and appointment wait time requirements as specified in paragraph (f)(2) of this section.

(1) *Provider directories.* (i) A secret shopper survey must be conducted to determine the accuracy of the information specified in paragraph (f)(1)(ii) of this section in each MCO's, PIHP's, and PAHP's most current electronic provider directories, as required at § 438.10(h), for the following provider types:

(A) Primary care providers, if they are included in the MCO's, PIHP's, or PAHP's provider directory;

(B) Obstetric and gynecological providers, if they are included in the MCO's, PIHP's, or PAHP's provider directory;

(C) Outpatient mental health and substance use disorder providers, if they are included in the MCO's, PIHP's, or PAHP's provider directory; and

(D) The provider type that provides the service type chosen by the State in paragraph (e)(1)(iv) of this section.

(ii) A secret shopper survey must assess the accuracy of the information in each MCO's, PIHP's, and PAHP's most current electronic provider directories for at least:

(A) The active network status with the MCO, PIHP, or PAHP;

(B) The street address(es) as required at § 438.10(h)(1)(ii);

(C) The telephone number(s) as required at § 438.10(h)(1)(iii); and

(D) Whether the provider is accepting new enrollees as required at § 438.10(h)(1)(vi).

(iii) States must receive information, sufficient to facilitate correction by the MCO, PIHP, or PAHP, on errors in directory data identified in secret shopper surveys from the entity conducting the secret shopper survey no later than 3 business days from the day the error is identified by the entity conducting the secret shopper survey.

(iv) States must send information required in paragraph (f)(1)(iii) of this section to the applicable MCO, PIHP, or PAHP no later than 3 business days from receipt.

(2) *Timely appointment access.* A secret shopper survey must be used to determine each MCO's, PIHP's, and PAHP's rate of network compliance with the appointment wait time standards in paragraph (e)(1) of this section.

(i) After consulting with States and other interested parties and providing public notice and opportunity to comment, CMS may select additional types of appointments to be added to a secret shopper survey.

(ii) Appointments offered via telehealth can only be counted toward

compliance with the appointment wait time standards in paragraph (e)(1) of this section if the provider being surveyed also offers in-person appointments to the MCO's, PIHP's, or PAHP's enrollees and must be identified separately from in-person appointments in survey results.

(3) *Independence.* An entity will be considered independent of the State as specified in paragraph (f)(3)(i) of this section and independent of the MCOs, PIHPs, or PAHPs subject to the surveys as specified in paragraph (f)(3)(ii) of this section.

(i) An entity will be considered independent of the State if it is not part of the State Medicaid agency.

(ii) An entity will be considered independent of an MCO, PIHP, or PAHP subject to the secret shopper surveys if the entity is not an MCO, PIHP, or PAHP, is not owned or controlled by any of the MCOs, PIHPs, or PAHPs subject to the surveys, and does not own or control any of the MCOs, PIHPs, or PAHPs subject to the surveys.

(4) *Methodological standards.* Secret shopper surveys required in this paragraph must:

(i) Use a random sample;

(ii) Include all areas of the State covered by the MCO's, PIHP's, or PAHP's contract; and

(iii) For secret shopper surveys required in paragraph (f)(2) of this section for appointment wait time standards, be completed for a statistically valid sample of providers.

(5) *Results reporting.* Results of the secret shopper surveys conducted pursuant to paragraphs (f)(1) and (2) of this section must be analyzed, summarized, and:

(i) Reported to CMS using the content, form, and submission times as specified at § 438.207(d); and

(ii) Posted on the State's website required at § 438.10(c)(3) within 30 calendar days of submission to CMS.

(g) *Publication of network adequacy standards.* States must publish the standards developed in accordance with paragraphs (b)(1) and (2), and (e) of this section on the website required by § 438.10(c)(3). Upon request, network adequacy standards must also be made available at no cost to enrollees with disabilities in alternate formats or through the provision of auxiliary aids and services.

(h) *Applicability.* States will not be held out of compliance with the requirements of paragraph (b)(1) and of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.68 (b) (effective as of October 1, 2023). Paragraph (d)(1)(iii) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after July 9, 2024. States will not be held out of compliance with the requirements of paragraph (d)(2) and of this section prior to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.68 (d)(2) (effective as of October 1, 2023). Paragraph (e) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 3 years after July 9, 2024. Paragraph (f) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 4 years after July 9, 2024. States will not be held out of compliance with the requirements of paragraph (g) of this section prior to the first rating period that begins on or after 3 years after July 9, 2024, so long as they comply with the corresponding standard(s) codified in paragraph 42 CFR 438.68 (g) (effective as of October 1, 2023).

[81 FR 27853, May 6, 2016, as amended at 85 FR 72840, Nov. 13, 2020; 89 FR 41275, May 10, 2024]

§ 438.70 Stakeholder engagement when LTSS is delivered through a managed care program.

The State must ensure the views of beneficiaries, individuals representing beneficiaries, providers, and other stakeholders are solicited and addressed during the design, implementation, and oversight of a State's managed LTSS program. The composition of the stakeholder group and frequency

of meetings must be sufficient to ensure meaningful stakeholder engagement.

§ 438.71 Beneficiary support system.

(a) *General requirement.* The State must develop and implement a beneficiary support system that provides support to beneficiaries both prior to and after enrollment in a MCO, PIHP, PAHP, PCCM or PCCM entity.

(b) *Elements of the support system.* (1) A State beneficiary support system must include at a minimum:

(i) Choice counseling for all beneficiaries.

(ii) Assistance for enrollees in understanding managed care.

(iii) Assistance as specified for enrollees who use, or express a desire to receive, LTSS in paragraph (d) of this section.

(2) The beneficiary support system must perform outreach to beneficiaries and/or authorized representatives and be accessible in multiple ways including phone, Internet, in-person, and via auxiliary aids and services when requested.

(c) *Choice counseling.* (1) Choice counseling, as defined in § 438.2, must be provided to all potential enrollees and enrollees who disenroll from a MCO, PIHP, PAHP, PCCM or PCCM entity for reasons specified in § 438.56(b) and (c).

(2) If an individual or entity provides choice counseling on the State's behalf under a memorandum of agreement or contract, it is considered an enrollment broker as defined in § 438.810(a) and must meet the independence and freedom from conflict of interest standards in § 438.810(b)(1) and (2).

(3) An entity that receives non-Medicaid funding to represent beneficiaries at hearings may provide choice counseling on behalf of the State so long as the State requires firewalls to ensure that the requirements for the provision of choice counseling are met.

(d) *Functions specific to LTSS activities.* At a minimum, the beneficiary support system must provide the following support to enrollees who use, or express a desire to receive, LTSS:

(1) An access point for complaints and concerns about MCO, PIHP, PAHP, PCCM, and PCCM entity enrollment, access to covered services, and other related matters.

(2) Education on enrollees' grievance and appeal rights within the MCO, PIHP or PAHP; the State fair hearing process; enrollee rights and responsibilities; and additional resources outside of the MCO, PIHP or PAHP.

(3) Assistance, upon request, in navigating the grievance and appeal process within the MCO, PIHP or PAHP, as well as appealing adverse benefit determinations by the MCO, PIHP, or PAHP to a State fair hearing. The system may not provide representation to the enrollee at a State fair hearing but may refer enrollees to sources of legal representation.

(4) Review and oversight of LTSS program data to provide guidance to the State Medicaid Agency on identification, remediation and resolution of systemic issues.

§ 438.72 Additional requirements for long-term services and supports.

(a) [Reserved]

(b) *Services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities.* The State must comply with the requirements at §§ 441.301(c)(1) through (3), 441.302(a)(6), 441.302(k), 441.311, and 441.313 for services authorized under section 1915(c) waivers and section 1915(i), (j), and (k) State plan authorities.

[89 FR 53501, June 27, 2024]

§ 438.74 State oversight of the minimum MLR requirement.

(a) *State reporting requirement.* (1) The State must annually submit to CMS a summary description of each report(s) received from the MCO(s), PIHP(s), and PAHP(s) under contract with the State, according to § 438.8(k), with the rate certification required in § 438.7.

(2) The summary description must be provided for each MCO, PIHP, or PAHP under contract with the State and must include, at a minimum, the amount of the numerator, the amount of the denominator, the MLR percentage achieved, the number of member months, and any remittances owed by each MCO, PIHP, or PAHP for that MLR reporting year.

(b) *Repayment of Federal share of remittances.* (1) If a State requires a MCO,

PIHP, or PAHP to pay remittances through the contract for not meeting the minimum MLR required by the State, the State must reimburse CMS for an amount equal to the Federal share of the remittance, taking into account applicable differences in the Federal matching rate.

(2) If a remittance is owed according to paragraph (b)(1) of this section, the State must submit a separate report describing the methodology used to determine the State and Federal share of the remittance with the report required in paragraph (a) of this section.

[81 FR 27853, May 6, 2016, as amended at 89 FR 41276, May 10, 2024]

Subpart C—Enrollee Rights and Protections

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

§ 438.100 Enrollee rights.

(a) *General rule.* The State must ensure that:

(1) Each MCO, PIHP, PAHP, PCCM and PCCM entity has written policies regarding the enrollee rights specified in this section; and

(2) Each MCO, PIHP, PAHP, PCCM and PCCM entity complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its employees and contracted providers observe and protect those rights.

(b) *Specific rights*—(1) *Basic requirement.* The State must ensure that each managed care enrollee is guaranteed the rights as specified in paragraphs (b)(2) and (3) of this section.

(2) An enrollee of an MCO, PIHP, PAHP, PCCM, or PCCM entity has the following rights: The right to—

(i) Receive information in accordance with § 438.10.

(ii) Be treated with respect and with due consideration for his or her dignity and privacy.

(iii) Receive information on available treatment options and alternatives, presented in a manner appropriate to the enrollee's condition and ability to understand. (The information requirements for services that are not covered under the contract because of moral or religious objections are set forth in § 438.10(g)(2)(ii)(A) and (B).)

(iv) Participate in decisions regarding his or her health care, including the right to refuse treatment.

(v) Be free from any form of restraint or seclusion used as a means of coercion, discipline, convenience or retaliation, as specified in other Federal regulations on the use of restraints and seclusion.

(vi) If the privacy rule, as set forth in 45 CFR parts 160 and 164 subparts A and E, applies, request and receive a copy of his or her medical records, and request that they be amended or corrected, as specified in 45 CFR 164.524 and 164.526.

(3) An enrollee of an MCO, PIHP, or PAHP (consistent with the scope of the PAHP's contracted services) has the right to be furnished health care services in accordance with §§ 438.206 through 438.210.

(c) *Free exercise of rights.* The State must ensure that each enrollee is free to exercise his or her rights, and that the exercise of those rights does not adversely affect the way the MCO, PIHP, PAHP, PCCM or PCCM entity and its network providers or the State agency treat the enrollee.

(d) *Compliance with other Federal and State laws.* The State must ensure that each MCO, PIHP, PAHP, PCCM and PCCM entity complies with any other applicable Federal and State laws (including: Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 80; the Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91; the Rehabilitation Act of 1973; Title IX of the Education Amendments of 1972 (regarding education programs and activities); Titles II and III of the Americans with Disabilities Act; and section 1557 of the Patient Protection and Affordable Care Act.

§ 438.102 Provider-enrollee communications.

(a) *General rules.* (1) An MCO, PIHP, or PAHP may not prohibit, or otherwise restrict, a provider acting within the lawful scope of practice, from advising or advocating on behalf of an enrollee who is his or her patient, for the following:

(i) The enrollee's health status, medical care, or treatment options, including any alternative treatment that may be self-administered.

(ii) Any information the enrollee needs to decide among all relevant treatment options.

(iii) The risks, benefits, and consequences of treatment or non-treatment.

(iv) The enrollee's right to participate in decisions regarding his or her health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

(2) Subject to the information requirements of paragraph (b) of this section, an MCO, PIHP, or PAHP that would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service because of the requirement in paragraph (a)(1) of this section is not required to do so if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds.

(b) *Information requirements: MCO, PIHP, and PAHP responsibility.* (1)(i) An MCO, PIHP, or PAHP that elects the option provided in paragraph (a)(2) of this section must furnish information about the services it does not cover as follows:

(A) To the State—

(*1*) With its application for a Medicaid contract.

(*2*) Whenever it adopts the policy during the term of the contract.

(B) Consistent with the provisions of § 438.10, to enrollees, within 90 days after adopting the policy for any particular service.

(ii) Although this timeframe would be sufficient to entitle the MCO, PIHP, or PAHP to the option provided in paragraph (a)(2) of this section, the overriding rule in § 438.10(g)(4) requires the State, its contracted representative, or MCO, PIHP, or PAHP to furnish the information at least 30 days before the effective date of the policy.

(2) As specified in § 438.10(g)(2)(ii)(A) and (B), the MCOs, PIHPs, and PAHPs must inform enrollees how they can obtain information from the State about how to access the service excluded under paragraph (a)(2) of this section.

(c) *Information requirements: State responsibility.* For each service excluded by an MCO, PIHP, or PAHP under paragraph (a)(2) of this section, the State must provide information on how and where to obtain the service, as specified in § 438.10.

(d) *Sanction.* An MCO that violates the prohibition of paragraph (a)(1) of this section is subject to intermediate sanctions under subpart I of this part.

§ 438.104 Marketing activities.

(a) *Definitions.* As used in this section, the following terms have the indicated meanings:

Cold-call marketing means any unsolicited personal contact by the MCO, PIHP, PAHP, PCCM or PCCM entity with a potential enrollee for the purpose of marketing as defined in this paragraph (a).

Marketing means any communication, from an MCO, PIHP, PAHP, PCCM or PCCM entity to a Medicaid beneficiary who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the beneficiary to enroll in that particular MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's Medicaid product, or either to not enroll in or to disenroll from another MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's Medicaid product. Marketing does not include communication to a Medicaid beneficiary from the issuer of a qualified health plan, as defined in 45 CFR 155.20, about the qualified health plan.

Marketing materials means materials that—

(i) Are produced in any medium, by or on behalf of an MCO, PIHP, PAHP, PCCM, or PCCM entity; and

(ii) Can reasonably be interpreted as intended to market the MCO, PIHP, PAHP, PCCM, or PCCM entity to potential enrollees.

MCO, PIHP, PAHP, PCCM or PCCM entity include any of the entity's employees, network providers, agents, or contractors.

Private insurance does not include a qualified health plan, as defined in 45 CFR 155.20.

(b) *Contract requirements.* Each contract with an MCO, PIHP, PAHP, PCCM, or PCCM entity must comply with the following requirements:

(1) Provide that the entity—

(i) Does not distribute any marketing materials without first obtaining State approval.

(ii) Distributes the materials to its entire service area as indicated in the contract.

(iii) Complies with the information requirements of § 438.10 to ensure that, before enrolling, the beneficiary receives, from the entity or the State, the accurate oral and written information he or she needs to make an informed decision on whether to enroll.

(iv) Does not seek to influence enrollment in conjunction with the sale or offering of any private insurance.

(v) Does not, directly or indirectly, engage in door-to-door, telephone, email, texting, or other cold-call marketing activities.

(2) Specify the methods by which the entity ensures the State agency that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the beneficiaries or the State agency. Statements that will be considered inaccurate, false, or misleading include, but are not limited to, any assertion or statement (whether written or oral) that—

(i) The beneficiary must enroll in the MCO, PIHP, PAHP, PCCM or PCCM entity to obtain benefits or to not lose benefits; or

(ii) The MCO, PIHP, PAHP, PCCM or PCCM entity is endorsed by CMS, the Federal or State government, or similar entity.

(c) *State agency review.* In reviewing the marketing materials submitted by the entity, the State must consult with the Medical Care Advisory Committee established under § 431.12 of this chapter or an advisory committee with similar membership.

§ 438.106 Liability for payment.

Each MCO, PIHP, and PAHP must provide that its Medicaid enrollees are not held liable for any of the following:

(a) The MCO's, PIHP's, or PAHP's debts, in the event of the entity's insolvency.

(b) Covered services provided to the enrollee, for which—

(1) The State does not pay the MCO, PIHP, or PAHP; or

(2) The State, or the MCO, PIHP, or PAHP does not pay the individual or health care provider that furnished the services under a contractual, referral, or other arrangement.

(c) Payments for covered services furnished under a contract, referral, or other arrangement, to the extent that those payments are in excess of the amount that the enrollee would owe if the MCO, PIHP, or PAHP covered the services directly.

§ 438.108 Cost sharing.

The contract must provide that any cost sharing imposed on Medicaid enrollees is in accordance with §§ 447.50 through 447.82 of this chapter.

§ 438.110 Member advisory committee.

(a) *General rule.* When LTSS are covered under a risk contract between a State and an MCO, PIHP, or PAHP, the contract must provide that each MCO, PIHP or PAHP establish and maintain a member advisory committee.

(b) *Committee composition.* The committee required in paragraph (a) of this section must include at least a reasonably representative sample of the LTSS populations, or other individuals representing those enrollees, covered under the contract with the MCO, PIHP, or PAHP.

§ 438.114 Emergency and poststabilization services.

(a) *Definitions.* As used in this section—

Emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:

(i) Placing the health of the individual (or, for a pregnant woman, the health of the woman or her unborn child) in serious jeopardy.

(ii) Serious impairment to bodily functions.

(iii) Serious dysfunction of any bodily organ or part.

Emergency services means covered inpatient and outpatient services that are as follows:

(i) Furnished by a provider that is qualified to furnish these services under this Title.

(ii) Needed to evaluate or stabilize an emergency medical condition.

Poststabilization care services means covered services, related to an emergency medical condition that are provided after an enrollee is stabilized to maintain the stabilized condition, or, under the circumstances described in paragraph (e) of this section, to improve or resolve the enrollee's condition.

(b) *Coverage and payment: General rule.* The following entities are responsible for coverage and payment of emergency services and poststabilization care services.

(1) The MCO, PIHP, or PAHP.

(2) The State, for managed care programs that contract with PCCMs or PCCM entities

(c) *Coverage and payment: Emergency services.* (1) The entities identified in paragraph (b) of this section—

(i) Must cover and pay for emergency services regardless of whether the provider that furnishes the services has a contract with the MCO, PIHP, PAHP, PCCM or PCCM entity; and

(ii) May not deny payment for treatment obtained under either of the following circumstances:

(A) An enrollee had an emergency medical condition, including cases in which the absence of immediate medical attention would not have had the outcomes specified in paragraphs (1), (2), and (3) of the definition of emergency medical condition in paragraph (a) of this section.

(B) A representative of the MCO, PIHP, PAHP, PCCM, or PCCM entity instructs the enrollee to seek emergency services.

(2) A PCCM or PCCM entity must allow enrollees to obtain emergency services outside the primary care case management system regardless of whether the case manager referred the enrollee to the provider that furnishes the services.

(d) *Additional rules for emergency services.* (1) The entities specified in paragraph (b) of this section may not—

(i) Limit what constitutes an emergency medical condition with reference to paragraph (a) of this section, on the basis of lists of diagnoses or symptoms; and

(ii) Refuse to cover emergency services based on the emergency room provider, hospital, or fiscal agent not notifying the enrollee's primary care provider, MCO, PIHP, PAHP or applicable State entity of the enrollee's screening and treatment within 10 calendar days of presentation for emergency services.

(2) An enrollee who has an emergency medical condition may not be held liable for payment of subsequent screening and treatment needed to diagnose the specific condition or stabilize the patient.

(3) The attending emergency physician, or the provider actually treating the enrollee, is responsible for determining when the enrollee is sufficiently stabilized for transfer or discharge, and that determination is binding on the entities identified in paragraph (b) of this section as responsible for coverage and payment.

(e) *Coverage and payment: Poststabilization care services.* Poststabilization care services are covered and paid for in accordance with provisions set forth at §422.113(c) of this chapter. In applying those provisions, reference to ''MA organization'' and ''financially responsible'' must be read as reference to the entities responsible for Medicaid payment, as specified in paragraph (b) of this section, and payment rules governed by Title XIX of the Act and the States.

(f) *Applicability to PIHPs and PAHPs.* To the extent that services required to treat an emergency medical condition fall within the scope of the services for which the PIHP or PAHP is responsible, the rules under this section apply.

§ 438.116 Solvency standards.

(a) *Requirement for assurances.* (1) Each MCO, PIHP, and PAHP that is not a Federally qualified HMO (as defined in section 1310 of the Public Health Service Act) must provide assurances satisfactory to the State showing that its provision against the risk of insolvency is adequate to ensure that its Medicaid enrollees will not be liable for the MCO's, PIHP's, or PAHP's debts if the entity becomes insolvent.

(2) Federally qualified HMOs, as defined in section 1310 of the Public Health Service Act, are exempt from this requirement.

(b) *Other requirements*—(1) *General rule.* Except as provided in paragraph (b)(2) of this section, an MCO or PIHP, must meet the solvency standards established by the State for private health maintenance organizations, or be licensed or certified by the State as a risk-bearing entity.

(2) *Exception.* Paragraph (b)(1) of this section does not apply to an MCO or PIHP that meets any of the following conditions:

(i) Does not provide both inpatient hospital services and physician services.

(ii) Is a public entity.

(iii) Is (or is controlled by) one or more Federally qualified health centers and meets the solvency standards established by the State for those centers.

(iv) Has its solvency guaranteed by the State.

Subpart D—MCO, PIHP and PAHP Standards

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

§ 438.206 Availability of services.

(a) *Basic rule.* Each State must ensure that all services covered under the State plan are available and accessible to enrollees of MCOs, PIHPs, and PAHPs in a timely manner. The State must also ensure that MCO, PIHP and PAHP provider networks for services covered under the contract meet the standards developed by the State in accordance with § 438.68.

(b) *Delivery network.* The State must ensure, through its contracts, that each MCO, PIHP and PAHP, consistent with the scope of its contracted services, meets the following requirements:

(1) Maintains and monitors a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to all services covered under the contract for all enrollees, including those with limited English proficiency or physical or mental disabilities.

(2) Provides female enrollees with direct access to a women's health specialist within the provider network for covered care necessary to provide women's routine and preventive health care services. This is in addition to the enrollee's designated source of primary care if that source is not a women's health specialist.

(3) Provides for a second opinion from a network provider, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee.

(4) If the provider network is unable to provide necessary services, covered under the contract, to a particular enrollee, the MCO, PIHP, or PAHP must adequately and timely cover these services out of network for the enrollee, for as long as the MCO, PIHP, or PAHP's provider network is unable to provide them.

(5) Requires out-of-network providers to coordinate with the MCO, PIHP, or PAHP for payment and ensures the cost to the enrollee is no greater than it would be if the services were furnished within the network.

(6) Demonstrates that its network providers are credentialed as required by § 438.214.

(7) Demonstrates that its network includes sufficient family planning providers to ensure timely access to covered services.

(c) *Furnishing of services.* The State must ensure that each contract with a MCO, PIHP, and PAHP complies with the following requirements.

(1) *Timely access.* Each MCO, PIHP, and PAHP must do the following:

(i) Meet and require its network providers to meet State standards for timely access to care and services taking into account the urgency of the need for services, as well as appointment wait times specified in § 438.68(e).

(ii) Ensure that the network providers offer hours of operation that are no less than the hours of operation offered to commercial enrollees or comparable to Medicaid FFS, if the provider serves only Medicaid enrollees.

(iii) Make services included in the contract available 24 hours a day, 7 days a week, when medically necessary.

(iv) Establish mechanisms to ensure compliance by network providers.

(v) Monitor network providers regularly to determine compliance.

(vi) Take corrective action if there is a failure to comply by a network provider.

(2) *Access and cultural considerations.* Each MCO, PIHP, and PAHP participates in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of sex which includes sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity and sex stereotypes.

(3) *Accessibility considerations.* Each MCO, PIHP, and PAHP must ensure that network providers provide physical access, reasonable accommodations, and accessible equipment for Medicaid enrollees with physical or mental disabilities.

(d) *Applicability date.* States will not be held out of compliance with the requirements of paragraphs (c)(1)(i) of this section prior to the first rating period that begins on or after 3 years after July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.206(c)(1)(i) (effective as of October 1, 2023).

[81 FR 27853, May 6, 2016, as amended at 85 FR 37243, June 19, 2020; 89 FR 37691, May 6, 2024; 89 FR 41276, May 10, 2024]

§ 438.207 Assurances of adequate capacity and services.

(a) *Basic rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP gives assurances to the State and provides supporting documentation that demonstrates that it has the capacity to serve the expected enrollment in its service area in accordance with the State's standards for access to care under this part, including the standards at § 438.68 and § 438.206(c)(1).

(b) *Nature of supporting documentation.* Each MCO, PIHP, and PAHP must submit documentation to the State, in a format specified by the State, to demonstrate that it complies with the following requirements:

(1) Offers an appropriate range of preventive, primary care, specialty services, and LTSS that is adequate for the anticipated number of enrollees for the service area;

(2) Maintains a network of providers that is sufficient in number, mix, and geographic distribution to meet the needs of the anticipated number of enrollees in the service area; and

(3) Except as specified in paragraphs (b)(3)(iii) and (iv) of this section and if covered by the MCO's, PIHP's, or PAHP's contract, provides an annual payment analysis using paid claims data from the immediate prior rating period that demonstrates each MCO's, PIHP's, or PAHP's level of payment as specified in paragraphs (b)(3)(i) and (ii) of this section.

(i) The payment analysis must provide the total amount paid for evaluation and management current procedural terminology codes in the paid claims data from the immediate prior rating period for primary care, obstetrical and gynecological, mental health, and substance use disorder services, as well as the percentage that results from dividing the total amount paid by the published Medicare payment rate for the same services.

(A) A separate total and percentage must be reported for primary care, obstetrics and gynecology, mental health, and substance use disorder services; and

(B) If the percentage differs between adult and pediatric services, the percentages must be reported separately.

(ii) For homemaker services, home health aide services, personal care services, and habilitation services, the payment analysis must provide the total amount paid and the percentage that results from dividing the total amount paid by the amount the State's Medicaid FFS program would have paid for the same services.

(A) A separate total and percentage must be reported for homemaker services, home health aide services, personal care services, and habilitation services; and

(B) If the percentage differs between adult and pediatric services, the percentages must be reported separately.

(iii) Payments by MCOs, PIHPS, and PAHPs for the services specified in § 438.207(b)(3)(i) and (ii) for which the

MCO, PIHP, or PAHP is not the primary payer are excluded from the analysis required in this paragraph.

(iv) Services furnished by a Federally-qualified health center as defined in section 1905(l)(2) and services furnished by a rural health clinic as defined in section 1905(l)(1) are excluded from the analysis required in this paragraph.

(c) *Timing of documentation.* Each MCO, PIHP, and PAHP must submit the documentation described in paragraph (b) of this section as specified by the State, but no less frequently than the following:

(1) At the time it enters into a contract with the State.

(2) On an annual basis.

(3) At any time there has been a significant change (as defined by the State) in the MCO's, PIHP's, or PAHP's operations that would affect the adequacy of capacity and services, including—

(i) Changes in MCO, PIHP, or PAHP services, benefits, geographic service area, composition of or payments to its provider network; or

(ii) Enrollment of a new population in the MCO, PIHP, or PAHP.

(d) *State review and certification to CMS.* After the State reviews the documentation submitted by the MCO, PIHP, or PAHP as specified in paragraph (b) of this section and the secret shopper evaluation results as required at § 438.68(f), the State must submit an assurance of compliance to CMS, in the format prescribed by CMS, that the MCO, PIHP, or PAHP meets the State's requirements for availability of services, as set forth in §§ 438.68 and 438.206.

(1) The submission to CMS must include documentation of an analysis that supports the assurance of the adequacy of the network for each contracted MCO, PIHP or PAHP related to its provider network.

(2) The analysis in paragraph (d)(1) of this section must include the payment analysis submitted by each MCO, PIHP, or PAHP, as required in paragraph (b)(3) of this section, and contain:

(i) The data provided by each MCO, PIHP, and PAHP in paragraph (b)(3) of this section; and

(ii) A State level payment percentage for each service type specified in paragraphs (b)(3)(i) and (ii) of this section produced by using the number of member months for the applicable rating period to weight each MCO's, PIHP's, or PAHP's reported percentages, as required in paragraph (b)(3) of this section.

(3) States must submit the assurance of compliance required in paragraph (d) of this section as specified in paragraphs (i) through (iii) of this section and post the report on the State's website required in § 438.10(c)(3) within 30 calendar days of submission to CMS.

(i) Sufficiently in advance to enable CMS to make a determination that the contract entered into as specified at § 438.207(c)(1) is approved under § 438.3(a).

(ii) On an annual basis and no later than 180 calendar days after each rating period.

(iii) At any time there has been a significant change as specified in paragraph (c)(3) of this section and with the submission of the associated contract, as required at § 438.3(a).

(e) *CMS's right to inspect documentation.* The State must make available to CMS, upon request, all documentation collected by the State from the MCO, PIHP, or PAHP, as well as documentation from all secret shopper surveys required at § 438.68(f).

(f) *Remedy plans to improve access.* (1) When the State, MCO, PIHP, PAHP, or CMS identifies an area in which an MCO's, PIHP's, or PAHP's access to care under the access standards in this part could be improved, including the standards at §§ 438.68 and 438.206, the State must:

(i) Submit to CMS for approval a remedy plan as specified in paragraph (f)(ii) of this section no later than 90 calendar days following the date that the State becomes aware of an MCO's, PIHP's, or PAHP's access issue;

(ii) Develop a remedy plan that addresses the identified access issue within 12 months and that identifies specific steps with timelines for implementation and completion, and responsible parties. State's and MCO's, PIHP's, or PAHP's actions may include a variety of approaches, including but not limited to: increasing payment

rates to providers, improving outreach and problem resolution to providers, reducing barriers to provider credentialing and contracting, providing for improved or expanded use of telehealth, and improving the timeliness and accuracy of processes such as claim payment and prior authorization;

(iii) Ensure that improvements in access are measurable and sustainable; and

(iv) Submit quarterly progress updates to CMS on implementation of the remedy plan.

(2) If the remedy plan required in paragraph (f)(1) of this section does not result in addressing the MCO's, PIHP's, or PAHP's access issue by improving access within 12 months, CMS may require the State to continue the remedy plan for another 12 months and may require revision to the remedy plan required in paragraph (f)(1) of this section.

(g) *Applicability date.* Paragraphs (b)(3) and (d)(2) of this section apply to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 2 years after July 9, 2024. Paragraph (d)(3) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 1 year after July 9, 2024. States will not be held out of compliance with the requirements of paragraph (e) of this section prior to the rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 4 year after July 9, 2024, so long as they comply with the corresponding standard(s) codified in 42 CFR 438.207 (e) (effective as of October 1, 2023) Paragraph (f) of this section applies to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 4 years after July 9, 2024.

[81 FR 27853, May 6, 2016, as amended at 89 FR 41277, May 10, 2024]

§ 438.208 Coordination and continuity of care.

(a) *Basic requirement*—(1) *General rule.* Except as specified in paragraphs (a)(2) and (3) of this section, the State must ensure through its contracts, that each MCO, PIHP, and PAHP complies with the requirements of this section.

(2) *PIHP and PAHP exception.* For PIHPs and PAHPs, the State determines, based on the scope of the entity's services, and on the way the State has organized the delivery of managed care services, 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, as specified in paragraph (c) of this section.

(3) *Exception for MCOs that serve dually eligible enrollees.* (i) For each MCO that serves enrollees who are also enrolled in and receive Medicare benefits from a Medicare Advantage Organization (as defined in §422.2 of this chapter), the State determines to what extent the MCO must meet the identification, assessment, and treatment planning provisions of paragraph (c) of this section for dually eligible individuals.

(ii) The State bases its determination on the needs of the population it requires the MCO to serve.

(b) *Care and coordination of services for all MCO, PIHP, and PAHP enrollees.* Each MCO, PIHP, and PAHP must implement procedures to deliver care to and coordinate services for all MCO, PIHP, and PAHP enrollees. These procedures must meet State requirements and must do the following:

(1) Ensure that each enrollee has an ongoing source of care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the services accessed by the enrollee. The enrollee must be provided information on how to contact their designated person or entity;

(2) Coordinate the services the MCO, PIHP, or PAHP furnishes to the enrollee:

(i) Between settings of care, including appropriate discharge planning for short term and long-term hospital and institutional stays;

(ii) With the services the enrollee receives from any other MCO, PIHP, or PAHP;

(iii) With the services the enrollee receives in FFS Medicaid; and

(iv) With the services the enrollee receives from community and social support providers.

(3) Provide that the MCO, PIHP or PAHP makes a best effort to conduct an initial screening of each enrollee's needs, within 90 days of the effective date of enrollment for all new enrollees, including subsequent attempts if the initial attempt to contact the enrollee is unsuccessful;

(4) Share with the State or other MCOs, PIHPs, and PAHPs serving the enrollee the results of any identification and assessment of that enrollee's needs to prevent duplication of those activities;

(5) Ensure that each provider furnishing services to enrollees maintains and shares, as appropriate, an enrollee health record in accordance with professional standards; and

(6) Ensure that in the process of coordinating care, each enrollee's privacy is protected in accordance with the privacy requirements in 45 CFR parts 160 and 164 subparts A and E, to the extent that they are applicable.

(c) *Additional services for enrollees with special health care needs or who need LTSS*—(1) *Identification.* The State must implement mechanisms to identify persons who need LTSS or persons with special health care needs to MCOs, PIHPs and PAHPs, as those persons are defined by the State. These identification mechanisms—

(i) Must be specified in the State's quality strategy under § 438.340.

(ii) May use State staff, the State's enrollment broker, or the State's MCOs, PIHPs and PAHPs.

(2) *Assessment.* Each MCO, PIHP, and PAHP must implement mechanisms to comprehensively assess each Medicaid enrollee identified by the State (through the mechanism specified in paragraph (c)(1) of this section) and identified to the MCO, PIHP, and PAHP 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. The assessment mechanisms must use appropriate providers or individuals meeting LTSS service coordination requirements of the State or the MCO, PIHP, or PAHP as appropriate.

(3) *Treatment/service plans.* MCOs, PIHPs, or PAHPs must produce a treatment or service plan meeting the criteria in paragraphs (c)(3)(i) through (v) of this section for enrollees who require LTSS and, if the State requires, must produce a treatment or service plan meeting the criteria in paragraphs (c)(3)(iii) through (v) of this section for enrollees with special health care needs that are determined through assessment to need a course of treatment or regular care monitoring. The treatment or service plan must be:

(i) Developed by an individual meeting LTSS service coordination requirements with enrollee participation, and in consultation with any providers caring for the enrollee;

(ii) Developed by a person trained in person-centered planning using a person-centered process and plan as defined in § 441.301(c)(1) and (2) of this chapter for LTSS treatment or service plans;

(iii) Approved by the MCO, PIHP, or PAHP in a timely manner, if this approval is required by the MCO, PIHP, or PAHP;

(iv) In accordance with any applicable State quality assurance and utilization review standards; and

(v) 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 per § 441.301(c)(3) of this chapter.

(4) *Direct access to specialists.* For enrollees with special health care needs determined through an assessment (consistent with paragraph (c)(2) of this section) to need a course of treatment or regular care monitoring, each MCO, PIHP, and PAHP must have a mechanism in place to allow enrollees to directly access a specialist (for example, through a standing referral or an approved number of visits) as appropriate for the enrollee's condition and identified needs.

(d) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.208 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

§ 438.210 Coverage and authorization of services.

(a) *Coverage.* Each contract between a State and an MCO, PIHP, or PAHP must do the following:

(1) Identify, define, and specify the amount, duration, and scope of each service that the MCO, PIHP, or PAHP is required to offer.

(2) Require that the services identified in paragraph (a)(1) of this section be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to beneficiaries under FFS Medicaid, as set forth in § 440.230 of this chapter, and for enrollees under the age of 21, as set forth in subpart B of part 441 of this chapter.

(3) Provide that the MCO, PIHP, or PAHP—

(i) Must ensure that the services are sufficient in amount, duration, or scope to reasonably achieve the purpose for which the services are furnished.

(ii) 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.

(4) Permit an MCO, PIHP, or PAHP to place appropriate limits on a service—

(i) On the basis of criteria applied under the State plan, such as medical necessity; or

(ii) For the purpose of utilization control, provided that—

(A) The services furnished can reasonably achieve their purpose, as required in paragraph (a)(3)(i) of this section;

(B) The services supporting individuals with ongoing or chronic conditions or who require long-term services and supports are authorized in a manner that reflects the enrollee's ongoing need for such services and supports; and

(C) Family planning services are provided in a manner that protects and enables the enrollee's freedom to choose the method of family planning to be used consistent with § 441.20 of this chapter.

(5) Specify what constitutes ''medically necessary services'' in a manner that—

(i) 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

(ii) Addresses the extent to which the MCO, PIHP, or PAHP is responsible for covering services that address:

(A) The prevention, diagnosis, and treatment of an enrollee's disease, condition, and/or disorder that results in health impairments and/or disability.

(B) The ability for an enrollee to achieve age-appropriate growth and development.

(C) The ability for an enrollee to attain, maintain, or regain functional capacity.

(D) The opportunity for an enrollee receiving long-term services and supports to have access to the benefits of community living, to achieve person-centered goals, and live and work in the setting of their choice.

(b) *Authorization of services.* For the processing of requests for initial and continuing authorizations of services, each contract must require—

(1) That the MCO, PIHP, or PAHP and its subcontractors have in place, and follow, written policies and procedures.

(2) That the MCO, PIHP, or PAHP—

(i) Have in effect mechanisms to ensure consistent application of review criteria for authorization decisions.

(ii) Consult with the requesting provider for medical services when appropriate.

(iii) Authorize LTSS based on an enrollee's current needs assessment and consistent with the person-centered service plan.

(3) 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 long-term services and supports needs.

(c) *Notice of adverse benefit determination.* Each contract must provide for the MCO, PIHP, or PAHP to notify the

requesting provider, and give the enrollee written notice of any decision by the MCO, PIHP, or PAHP to deny a service authorization request, or to authorize a service in an amount, duration, or scope that is less than requested. For MCOs, PIHPs, and PAHPs, the enrollee's notice must meet the requirements of § 438.404. For Medicaid contracts with an applicable integrated plan, as defined in § 422.561 of this chapter, in lieu of the provisions in this paragraph governing notices of adverse benefit determinations, the provisions set forth in §§ 422.629 through 422.634 of this chapter apply to determinations affecting dually eligible individuals who are also enrolled in a dual eligible special needs plan with exclusively aligned enrollment, as defined in § 422.2 of this chapter.

(d) *Timeframe for decisions.* Each MCO, PIHP, or PAHP contract must provide for the following decisions and notices:

(1) *Standard authorization decisions.* (i) For standard authorization decisions, provide notice as expeditiously as the enrollee's condition requires and:

(A) For rating periods that start before January 1, 2026, within state established time frames that may not exceed 14 calendar days after receiving the request for service.

(B) For rating periods that start on or after January 1, 2026, within state established time frames that may not exceed 7 calendar days after receiving the request for service.

(ii) Standard authorization decisions may have an extension to the timeframes in paragraph (d)(1)(i) of this section up to 14 additional calendar days if—

(A) The enrollee or the provider requests the extension; or

(B) The MCO, PIHP, or PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(2) *Expedited authorization decisions.* (i) For cases in which a provider indicates, or the MCO, PIHP, or PAHP determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function, the MCO, PIHP, or PAHP must 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.

(ii) The MCO, PIHP, or PAHP may extend the 72 hour time period by up to 14 calendar days if the enrollee requests an extension, or if the MCO, PIHP, or PAHP justifies (to the State agency upon request) a need for additional information and how the extension is in the enrollee's interest.

(3) *Covered outpatient drug decisions.* For all covered outpatient drug authorization decisions, provide notice as described in section 1927(d)(5)(A) of the Act.

(4) For Medicaid contracts with an applicable integrated plan, as defined in § 422.561 of this chapter, timelines for decisions and notices must be compliant with the provisions set forth in §§ 422.629 through 422.634 of this chapter in lieu of §§ 438.404 through 438.424.

(e) *Compensation for utilization management activities.* Each contract between a State and MCO, PIHP, or PAHP must provide that, consistent with §§ 438.3(i), and 422.208 of this chapter, compensation to individuals or entities that conduct utilization management activities is not structured so as to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary services to any enrollee.

(f) *Publicly reporting prior authorization metrics.* Beginning January 1, 2026, following each calendar year it has a contract with a State Medicaid agency, the MCO, PIHP, or PAHP must report prior authorization data, excluding data on any and all drugs covered by the MCO, PIHP, or PAHP, at the plan level by March 31. The MCO, PIHP, or PAHP must make the following data from the previous calendar year publicly accessible by posting them on its website:

(1) A list of all items and services that require prior authorization.

(2) The percentage of standard prior authorization requests that were approved, aggregated for all items and services.

(3) The percentage of standard prior authorization requests that were denied, aggregated for all items and services.

(4) The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.

(5) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.

(6) The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.

(7) The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.

(8) The average and median time that elapsed between the submission of a request and a determination by the MCO, PIHP or PAHP, for standard prior authorizations, aggregated for all items and services.

(9) The average and median time that elapsed between the submission of a request and a decision by the MCO, PIHP or PAHP, for expedited prior authorizations, aggregated for all items and services.

(g) *Applicability date.* (1) Subject to paragraph (f)(2) of this section, this section applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, States are required to continue to comply with § 438.210 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

(2) Provisions in this section affecting applicable integrated plans, as defined in § 422.561 of this chapter, are applicable no later than January 1, 2021.

[81 FR 27853, May 6, 2016, as amended at 82 FR 39, Jan. 3, 2017; 84 FR 15843, Apr. 16, 2019; 89 FR 8980, Feb. 8, 2024]

§ 438.214 Provider selection.

(a) *General rules.* The State must ensure, through its contracts, that each MCO, PIHP, or PAHP implements written policies and procedures for selection and retention of network providers and that those policies and procedures, at a minimum, meet the requirements of this section.

(b) *Credentialing and recredentialing requirements.* (1) Each State must establish a uniform credentialing and recredentialing policy that addresses acute, primary, mental health, substance use disorders, and LTSS providers, as appropriate, and requires each MCO, PIHP and PAHP to follow those policies.

(2) Each MCO, PIHP, and PAHP must follow a documented process for credentialing and recredentialing of network providers.

(c) *Nondiscrimination.* MCO, PIHP, and PAHP network provider selection policies and procedures, consistent with § 438.12, must not discriminate against particular providers that serve high-risk populations or specialize in conditions that require costly treatment.

(d) *Excluded providers.* (1) MCOs, PIHPs, and PAHPs may not employ or contract with providers excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act.

(2) States must ensure through its contracts that MCOs, PIHPs, and PAHPs terminate any providers of services or persons terminated (as described in section 1902(kk)(8) of the Social Security Act) from participation under this title, title XVIII, or title XXI from participating as a provider in any network.

(e) *State requirements.* Each MCO, PIHP, and PAHP must comply with any additional requirements established by the State.

[81 FR 27853, May 6, 2016, as amended at 89 FR 41278, May 10, 2024]

§ 438.224 Confidentiality.

The State must ensure, through its contracts, that (consistent with subpart F of part 431 of this chapter), for medical records and any other health and enrollment information that identifies a particular enrollee, each MCO, PIHP, and PAHP uses and discloses such individually identifiable health information in accordance with the privacy requirements in 45 CFR parts 160 and 164, subparts A and E, to the extent that these requirements are applicable.

§ 438.228 Grievance and appeal systems.

(a) The State must ensure, through its contracts, that each MCO, PIHP, and PAHP has in effect a grievance and appeal system that meets the requirements of subpart F of this part.

(b) If the State delegates to the MCO, PIHP, or PAHP responsibility for notice of action under subpart E of part 431 of this chapter, the State must conduct random reviews of each delegated MCO, PIHP, or PAHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

§ 438.230 Subcontractual relationships and delegation.

(a) *Applicability.* The requirements of this section apply to any contract or written arrangement that an MCO, PIHP, PAHP, or PCCM entity has with any subcontractor.

(b) *General rule.* The State must ensure, through its contracts with MCOs, PIHPs, PAHPs, and PCCM entities that—

(1) Notwithstanding any relationship(s) that the MCO, PIHP, PAHP, or PCCM entity may have with any subcontractor, the MCO, PIHP, PAHP, or PCCM entity maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with the State; and

(2) All contracts or written arrangements between the MCO, PIHP, PAHP, or PCCM entity and any subcontractor must meet the requirements of paragraph (c) of this section.

(c) Each contract or written arrangement described in paragraph (b)(2) of this section must specify that:

(1) If any of the MCO's, PIHP's, PAHP's, or PCCM entity's activities or obligations under its contract with the State are delegated to a subcontractor—

(i) The delegated activities or obligations, and related reporting responsibilities, are specified in the contract or written agreement.

(ii) The subcontractor agrees to perform the delegated activities and reporting responsibilities specified in compliance with the MCO's, PIHP's, PAHP's, or PCCM entity's contract obligations.

(iii) The contract or written arrangement must either provide for revocation of the delegation of activities or obligations, or specify other remedies in instances where the State or the MCO, PIHP, PAHP, or PCCM entity determine that the subcontractor has not performed satisfactorily.

(2) The subcontractor agrees to comply with all applicable Medicaid laws, regulations, including applicable subregulatory guidance and contract provisions;

(3) The subcontractor agrees that—

(i) The State, CMS, the HHS Inspector General, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, records, contracts, computer or other electronic systems of the subcontractor, or of the subcontractor's contractor, that pertain to any aspect of services and activities performed, or determination of amounts payable under the MCO's, PIHP's, or PAHP's contract with the State.

(ii) The subcontractor will make available, for purposes of an audit, evaluation, or inspection under paragraph (c)(3)(i) of this section, its premises, physical facilities, equipment, books, records, contracts, computer or other electronic systems relating to its Medicaid enrollees.

(iii) The right to audit under paragraph (c)(3)(i) of this section 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.

(iv) If the State, CMS, or the HHS Inspector General determines that there is a reasonable possibility of fraud or similar risk, the State, CMS, or the HHS Inspector General may inspect, evaluate, and audit the subcontractor at any time.

(d) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, PAHPs, and PCCM entities beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.230 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

§ 438.236 Practice guidelines.

(a) *Basic rule.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP meets the requirements of this section.

(b) *Adoption of practice guidelines.* Each MCO and, when applicable, each PIHP and PAHP adopts practice guidelines that meet the following requirements:

(1) Are based on valid and reliable clinical evidence or a consensus of providers in the particular field.

(2) Consider the needs of the MCO's, PIHP's, or PAHP's enrollees.

(3) Are adopted in consultation with network providers.

(4) Are reviewed and updated periodically as appropriate.

(c) *Dissemination of guidelines.* Each MCO, PIHP, and PAHP disseminates the guidelines to all affected providers and, upon request, to enrollees and potential enrollees.

(d) *Application of guidelines.* Decisions for utilization management, enrollee education, coverage of services, and other areas to which the guidelines apply are consistent with the guidelines.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72841, Nov. 13, 2020]

§ 438.242 Health information systems.

(a) *General rule.* The State must ensure, through its contracts that each MCO, PIHP, and PAHP maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this part. The systems must provide information on areas including, but not limited to, utilization, claims, 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, PIHP, and PAHP comply with the following:

(1) Section 6504(a) of the Affordable Care Act, which requires that State claims processing and retrieval systems are able to collect data elements necessary to enable the mechanized claims processing and information retrieval systems in operation by the State to meet the requirements of section 1903(r)(1)(F) of the Act.

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

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

(i) Verifying the accuracy and timeliness of reported data, including data from network providers the MCO, PIHP, or PAHP is compensating on the basis of capitation payments.

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

(iii) Collecting data from providers in standardized formats to the extent feasible and appropriate, including secure information exchanges and technologies utilized for State Medicaid quality improvement and care coordination efforts.

(4) Make all collected data available to the State and upon request to CMS.

(5) Subject to paragraph (b)(8) of this section, implement and maintain a Patient Access Application Programming Interface (API) required in § 431.60 of this chapter as if such requirements applied directly to the MCO, PIHP, or PAHP and:

(i) Include all encounter data, including encounter data from any network providers the MCO, PIHP, or PAHP is compensating based on capitation payments and adjudicated claims and encounter data from any subcontractors.

(ii) Exclude covered outpatient drugs as defined in section 1927(k)(2) of the Act.

(iii) Report metrics specified in § 431.60(f) of this chapter at the plan level.

(6) Implement, by January 1, 2021, and maintain a publicly accessible standards-based API described in § 431.70, which must include all information specified in § 438.10(h)(1) and (2) of this chapter.

(7) By the rating period beginning on or after January 1, 2027, comply with §§ 431.61(a), (b)(1) and (4) through (6), and (b)(7)(ii) and (iii) and 431.80(b) of this chapter as if such requirements applied directly to the MCO, PIHP, or PAHP

(8) By the rating period beginning on or after January 1, 2026, comply with § 431.80(a) of this chapter as if such requirements applied directly to the MCO, PIHP, or PAHP according to the decision timeframes in § 438.210(d).

(9) The following timeframes apply to paragraph (b)(5) of this section:

(i) Except for the requirements in § 431.60(b)(5), (g), and (h) of this chapter, comply with the requirements of § 431.60 of this chapter by January 1, 2021.

(ii) Comply with the requirements in § 431.60(b)(5) and (g) of this chapter by the rating period beginning on or after January 1, 2026.

(iii) Beginning in 2026, by March 31 following any year the MCO, PIHP, or PAHP operates, comply with the reporting requirements in § 431.60(h) of this chapter for the previous calendar year's data, in the form of aggregated, de-identified metrics, at the plan level.

(c) *Enrollee encounter data.* Contracts between a State and a MCO, PIHP, or PAHP must provide for:

(1) Collection and maintenance of sufficient enrollee encounter data to identify the provider who delivers any item(s) or service(s) to enrollees.

(2) Submission of enrollee encounter data to the State at a frequency and level of detail to be specified by CMS and the State, based on program administration, oversight, and program integrity needs.

(3) Submission of all enrollee encounter data, including allowed amount and paid amount, that the State is required to report to CMS under § 438.818.

(4) Specifications for submitting encounter data to the State in standardized ASC X12N 837 and NCPDP formats, and the ASC X12N 835 format as appropriate.

(d) *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 MCO, PIHP, or PAHP, meets the requirements of this section. The State must have procedures and quality assurance protocols to ensure that enrollee encounter data submitted under paragraph (c) of this section is a complete and accurate representation of the services provided to the enrollees under the contract between the State and the MCO, PIHP, or PAHP.

(e) *Applicability date.* This section applies to the rating period for contracts with MCOs, PIHPs, PAHPs, and PCCM entities beginning on or after July 1, 2017. Until that applicability date, states are required to continue to comply with § 438.242 contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

[81 FR 27853, May 6, 2016, as amended at 85 FR 25635, May 1, 2020; 85 FR 72841, Nov. 13, 2020; 89 FR 8981, Feb. 8, 2024]

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 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) and (3), (c), and (e), and §438.340 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 July 9, 2024:

(1) States must comply with updates to §438.340(c) no later than 1 year from July 9, 2024.

(2) States must comply with updates to §§438.358(a)(3), 438.358(b)(1) and 438.364(c)(2)(iii) no later than December 31, 2025.

(3) States must comply with §438.364(a)(2)(iii) no later 1 year from the issuance of the associated protocol.

[81 FR 27853, May 6, 2016, as amended at 89 FR 41278, May 10, 2024]

§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 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.

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 chronic care improvement program conducted under § 422.152(c) 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.

[81 FR 27853, May 6, 2016, as amended at 89 FR 41278, May 10, 2024]

§ 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 [Reserved]

§ 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, PAHP, and PCCM entity described in § 438.310(c)(2).

(3) A description of—

(i) The quality metrics and performance targets to be used in measuring the performance and improvement of each MCO, PIHP, PAHP, and PCCM entity described in § 438.310(c)(2) 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 website 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 beneficiaries 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, and PAHP 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. For purposes of this paragraph (b)(6), ''disability status'' means, at a minimum, whether the individual qualified for Medicaid on the basis of a disability. States must include in this plan the State's definition of disability status and how the State will make the determination that a Medicaid enrollee meets the standard including the data source(s) that the State will use to identify disability status.

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

(8) 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).

(9) The information required under § 438.360(c) (relating to nonduplication of EQR activities).

(10) 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 in accordance with paragraph (c)(3) of this section, 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, PAHP, or PCCM entity described in § 438.310(c)(2), 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, including the evaluation conducted pursuant to paragraph (c)(2)(i) of this section, available on the website 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) Prior to adopting as final, submit to CMS the following:

(i) A copy of the initial strategy for CMS comment and feedback.

(ii) A copy of the strategy—

(A) Every 3 years following the review in paragraph (c)(2) of this section;

(B) Whenever significant changes, as defined in the State's quality strategy

per paragraph (b)(10) of this section, are made to the document;

(C) 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).

[81 FR 27853, May 6, 2016, as amended at 85 FR 72841, Nov. 13, 2020; 89 FR 41278, May 10, 2024]

§ 438.350 External quality review.

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

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

(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; 89 FR 41278, May 10, 2024]

§ 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 that it will review as an EQRO, 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.

[81 FR 27853, May 6, 2016, as amended at 89 FR 41278, May 10, 2024]

§ 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, or PAHP 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 in the 12 months preceding the finalization of the annual report:

(i) Validation of performance improvement projects required in accordance with § 438.330(b)(1) that were underway during the EQR review period per paragraph (a)(3) of this section.

(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 EQR review period described in paragraph (a)(3) of this section.

(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, the disenrollment requirements and limitations described in § 438.56, the enrollee rights requirements described in § 438.100, the emergency and post-stabilization services requirements described in § 438.114, and the quality assessment and performance improvement requirements described in § 438.330.

(iv) Validation of MCO, PIHP, or PAHP network adequacy during the EQR review period per paragraph (a)(3) of this section 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 may be performed.

(3) For the EQR-related activities described in paragraph (b)(1) of this section (except paragraph (b)(1)(iii) of this section), the review period begins on the first day of the most recently concluded contract year or calendar year, whichever is nearest to the date of the EQR-related activity and is 12 months in duration.

(c) *Optional activities.* For each MCO, PIHP, PAHP, and PCCM entity (described in § 438.310(c)(2)), the following activities may be performed:

(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, or PAHP 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 or PAHP and/or 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 42 CFR part 438, subpart G.

(7) Assist with evaluations required under §§ 438.16(e)(1), 438.340(c)(2)(i), and 438.6(c)(2)(iv) and (v) pertaining to outcomes, quality, or access to health care services.

(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; 85 FR 72841, Nov. 13, 2020; 89 FR 41278, May 10, 2024]

§ 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;

(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.

[81 FR 27853, May 6, 2016, as amended at 89 FR 41279, May 10, 2024]

§ 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 accrediting organization*. (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 to fulfill certain requirements for Medicare external review under subpart D of part 422 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.

(c) *Identification of exempted MCOs*. The State must annually identify, on the website required under § 438.10(c)(3) and in the same location where the EQR technical reports are posted in accordance with § 438.364(c)(2)(i), the names of the MCOs exempt from external quality review by the State, including the beginning date of the current exemption period, or that no MCOs are exempt, as appropriate.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72842, Nov. 13, 2020; 89 FR 41279, May 10, 2024]

§ 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, or PAHP.

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

(i) Objectives;

(ii) Technical methods of data collection and analysis;

(iii) The data and a description of data obtained, including validated performance measurement, any outcomes data and results from quantitative assessments, for each activity conducted in accordance with § 438.358(b)(1)(i), (ii) and (iv) of this subpart; and

(iv) Conclusions drawn from the data.

(3) An assessment of each MCO's, PIHP's, or PAHP's-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, or PAHP, 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, or PAHPs, 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, or PAHP has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

(7) The names of the MCOs exempt from external quality review by the State, including the beginning date of the current exemption period, or that no MCOs are exempt, as appropriate.

(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 website required-under § 438.10(c)(3) by April 30th of each year and notify CMS, in a form and manner determined by CMS, within 14 calendar days of the Web posting.

(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, or PAHP, beneficiary advocacy groups, and members of the general public.

(iii) Maintain at least the previous 5 years of EQR technical reports on the on the website required under § 438.10(c)(3).

(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 (c) of this section may not disclose the identity or other protected health information of any patient.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72842, Nov. 13, 2020; 89 FR 41279, May 10, 2024]

§ 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.

Subpart F—Grievance and Appeal System

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

§ 438.400 Statutory basis, definitions, and applicability.

(a) *Statutory basis.* This subpart is based on the following statutory sections:

(1) Section 1902(a)(3) of the Act requires that a State plan provide an opportunity for a fair hearing to any person whose claim for assistance is denied or not acted upon promptly.

(2) Section 1902(a)(4) of the Act requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(3) Section 1932(b)(4) of the Act requires Medicaid managed care organizations to establish internal grievance

procedures under which Medicaid enrollees, or providers acting on their behalf, may challenge the denial of coverage of, or payment for, medical assistance.

(4) Section 1859(f)(8)(B) of the Act requires that the Secretary, to the extent feasible, establish procedures unifying grievances and appeals procedures under sections 1852(f), 1852(g), 1902(a)(3), 1902(a)(5), and 1932(b)(4) of the Act for items and services provided, by specialized Medicare Advantage plans for special needs individuals described in section 1859(b)(6)(B)(ii), under Titles XVIII and XIX of the Act.

(b) *Definitions.* As used in this subpart, the following terms have the indicated meanings:

Adverse benefit determination means, in the case of an MCO, PIHP, or PAHP, any of the following:

(1) The denial or limited authorization of a requested service, including determinations based on the type or level of service, requirements for medical necessity, appropriateness, setting, or effectiveness of a covered benefit.

(2) The reduction, suspension, or termination of a previously authorized service.

(3) The denial, in whole or in part, of payment for a service. A denial, in whole or in part, of a payment for a service solely because the claim does not meet the definition of a ''clean claim'' at § 447.45(b) of this chapter is not an adverse benefit determination.

(4) The failure to provide services in a timely manner, as defined by the State.

(5) The failure of an MCO, PIHP, or PAHP to act within the timeframes provided in § 438.408(b)(1) and (2) regarding the standard resolution of grievances and appeals.

(6) For a resident of a rural area with only one MCO, the denial of an enrollee's request to exercise his or her right, under § 438.52(b)(2)(ii), to obtain services outside the network.

(7) The denial of an enrollee's request to dispute a financial liability, including cost sharing, copayments, premiums, deductibles, coinsurance, and other enrollee financial liabilities.

Appeal means a review by an MCO, PIHP, or PAHP of an adverse benefit determination.

Grievance means an expression of dissatisfaction about any matter other than an adverse benefit determination. Grievances may include, but are not limited to, the quality of care or services provided, and aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the enrollee's rights regardless of whether remedial action is requested. Grievance includes an enrollee's right to dispute an extension of time proposed by the MCO, PIHP or PAHP to make an authorization decision.

Grievance and appeal system means the processes the MCO, PIHP, or PAHP implements to handle appeals of an adverse benefit determination and grievances, as well as the processes to collect and track information about them.

State fair hearing means the process set forth in subpart E of part 431 of this chapter.

(c) *Applicability.* (1) Subject to paragraph (c)(2) of this section, this subpart applies to the rating period for contracts with MCOs, PIHPs, and PAHPs beginning on or after July 1, 2017. Until that applicability date, States, MCOs, PIHPs, and PAHPs are required to continue to comply with subpart F contained in the 42 CFR parts 430 to 481, edition revised as of October 1, 2015.

(2) Provisions in this part affecting applicable integrated plans, as defined in § 422.561 of this chapter, are applicable no later than January 1, 2021.

[81 FR 27853, May 6, 2016, as amended at 84 FR 15844, Apr. 16, 2019; 85 FR 72842, Nov. 13, 2020]

§ 438.402 General requirements.

(a) *The grievance and appeal system.* Each MCO, PIHP, and PAHP must have a grievance and appeal system in place for enrollees. Non-emergency medical transportation PAHPs, as defined in § 438.9, are not subject to this subpart F. For grievances and appeals at the plan level, an applicable integrated plan as defined in § 422.561 of this chapter is not subject to this subpart F, and is instead subject to the requirements of §§ 422.629 through 422.634 of this chapter. For appeals of integrated reconsiderations, applicable integrated plans are subject to § 438.408(f).

(b) *Level of appeals.* Each MCO, PIHP, and PAHP may have only one level of appeal for enrollees.

(c) *Filing requirements*—(1) *Authority to file.* (i) An enrollee may file a grievance and request an appeal with the MCO, PIHP, or PAHP. An enrollee may request a State fair hearing after receiving notice under § 438.408 that the adverse benefit determination is upheld.

(A) *Deemed exhaustion of appeals processes.* In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements in § 438.408, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State fair hearing.

(B) *External medical review.* The State may offer and arrange for an external medical review if the following conditions are met.

(*1*) The review must be at the enrollee's option and must not be required before or used as a deterrent to proceeding to the State fair hearing.

(*2*) The review must be independent of both the State and MCO, PIHP, or PAHP.

(*3*) The review must be offered without any cost to the enrollee.

(*4*) The review must not extend any of the timeframes specified in § 438.408 and must not disrupt the continuation of benefits in § 438.420.

(ii) If State law permits and with the written consent of the enrollee, a provider or an authorized representative may request an appeal or file a grievance, or request a State fair hearing, on behalf of an enrollee. When the term ''enrollee'' is used throughout subpart F of this part, it includes providers and authorized representatives consistent with this paragraph, with the exception that providers cannot request continuation of benefits as specified in § 438.420(b)(5).

(2) *Timing*—(i) *Grievance.* An enrollee may file a grievance with the MCO, PIHP, or PAHP at any time.

(ii) *Appeal.* Following receipt of a notification of an adverse benefit determination by an MCO, PIHP, or PAHP, an enrollee has 60 calendar days from the date on the adverse benefit determination notice in which to file a request for an appeal to the managed care plan.

(3) *Procedures*—(i) *Grievance.* The enrollee may file a grievance either orally or in writing and, as determined by the State, either with the State or with the MCO, PIHP, or PAHP.

(ii) *Appeal.* The enrollee may request an appeal either orally or in writing.

[81 FR 27853, May 6, 2016, as amended at 84 FR 15844, Apr. 16, 2019; 85 FR 72842, Nov. 13, 2020]

§ 438.404 Timely and adequate notice of adverse benefit determination.

(a) *Notice.* The MCO, PIHP, or PAHP must give enrollees timely and adequate notice of an adverse benefit determination in writing consistent with the requirements below and in § 438.10.

(b) *Content of notice.* The notice must explain the following:

(1) The adverse benefit determination the MCO, PIHP, or PAHP has made or intends to make.

(2) The reasons for the adverse benefit determination, including the right of the enrollee to be provided upon request and free of charge, reasonable access to and copies of all documents, records, and other information relevant to the enrollee's adverse benefit determination. Such information includes medical necessity criteria, and any processes, strategies, or evidentiary standards used in setting coverage limits.

(3) The enrollee's right to request an appeal of the MCO's, PIHP's, or PAHP's adverse benefit determination, including information on exhausting the MCO's, PIHP's, or PAHP's one level of appeal described at § 438.402(b) and the right to request a State fair hearing consistent with § 438.402(c).

(4) The procedures for exercising the rights specified in this paragraph (b).

(5) The circumstances under which an appeal process can be expedited and how to request it.

(6) The enrollee's right to have benefits continue pending resolution of the appeal, how to request that benefits be continued, and the circumstances, consistent with state policy, under which the enrollee may be required to pay the costs of these services.

(c) *Timing of notice.* The MCO, PIHP, or PAHP must mail the notice within the following timeframes:

(1) For termination, suspension, or reduction of previously authorized Medicaid-covered services, within the timeframes specified in §§ 431.211, 431.213, and 431.214 of this chapter.

(2) For denial of payment, at the time of any action affecting the claim.

(3) For standard service authorization decisions that deny or limit services, within the timeframe specified in § 438.210(d)(1).

(4) If the MCO, PIHP, or PAHP meets the criteria set forth for extending the timeframe for standard service authorization decisions consistent with § 438.210(d)(1)(ii), it must—

(i) Give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision; and

(ii) Issue and carry out its determination as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(5) For service authorization decisions not reached within the timeframes specified in § 438.210(d) (which constitutes a denial and is thus an adverse benefit determination), on the date that the timeframes expire.

(6) For expedited service authorization decisions, within the timeframes specified in § 438.210(d)(2).

§ 438.406 Handling of grievances and appeals.

(a) *General requirements.* In handling grievances and appeals, each MCO, PIHP, and PAHP must give enrollees any reasonable assistance in completing forms and taking other procedural steps related to a grievance or appeal. This includes, but is not limited to, auxiliary aids and services upon request, such as providing interpreter services and toll-free numbers that have adequate TTY/TTD and interpreter capability.

(b) *Special requirements.* An MCO's, PIHP's or PAHP's process for handling enrollee grievances and appeals of adverse benefit determinations must:

(1) Acknowledge receipt of each grievance and appeal.

(2) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were neither involved in any previous level of review or decision-making nor a subordinate of any such individual.

(ii) Who, if deciding any of the following, are individuals who have the appropriate clinical expertise, as determined by the State, in treating the enrollee's condition or disease.

(A) An appeal of a denial that is based on lack of medical necessity.

(B) A grievance regarding denial of expedited resolution of an appeal.

(C) A grievance or appeal that involves clinical issues.

(iii) Who take into account all comments, documents, records, and other information submitted by the enrollee or their representative without regard to whether such information was submitted or considered in the initial adverse benefit determination.

(3) Provide that oral inquiries seeking to appeal an adverse benefit determination are treated as appeals.

(4) Provide the enrollee a reasonable opportunity, in person and in writing, to present evidence and testimony and make legal and factual arguments. The MCO, PIHP, or PAHP must inform the enrollee of the limited time available for this sufficiently in advance of the resolution timeframe for appeals as specified in § 438.408(b) and (c) in the case of expedited resolution.

(5) Provide the enrollee and his or her representative the enrollee's case file, including medical records, other documents and records, and any new or additional evidence considered, relied upon, or generated by the MCO, PIHP or PAHP (or at the direction of the MCO, PIHP or PAHP) in connection with the appeal of the adverse benefit determination. This information must be provided free of charge and sufficiently in advance of the resolution timeframe for appeals as specified in § 438.408(b) and (c).

(6) Include, as parties to the appeal—

(i) The enrollee and his or her representative; or

(ii) The legal representative of a deceased enrollee's estate.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72842, Nov. 13, 2020]

§ 438.408 Resolution and notification: Grievances and appeals.

(a) *Basic rule.* Each MCO, PIHP, or PAHP must resolve each grievance and appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(b) *Specific timeframes*—(1) *Standard resolution of grievances.* For standard resolution of a grievance and notice to the affected parties, the timeframe is established by the State but may not exceed 90 calendar days from the day the MCO, PIHP, or PAHP receives the grievance.

(2) *Standard resolution of appeals.* For standard resolution of an appeal and notice to the affected parties, the State must establish a timeframe that is no longer than 30 calendar days from the day the MCO, PIHP, or PAHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(3) *Expedited resolution of appeals.* For expedited resolution of an appeal and notice to affected parties, the State must establish a timeframe that is no longer than 72 hours after the MCO, PIHP, or PAHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(c) *Extension of timeframes.* (1) The MCO, PIHP, or PAHP may extend the timeframes from paragraph (b) of this section by up to 14 calendar days if—

(i) The enrollee requests the extension; or

(ii) The MCO, PIHP, or PAHP shows (to the satisfaction of the State agency, upon its request) that there is need for additional information and how the delay is in the enrollee's interest.

(2) *Requirements following extension.* If the MCO, PIHP, or PAHP extends the timeframes not at the request of the enrollee, it must complete all of the following:

(i) Make reasonable efforts to give the enrollee prompt oral notice of the delay.

(ii) Within 2 calendar days give the enrollee written notice of the reason for the decision to extend the timeframe and inform the enrollee of the right to file a grievance if he or she disagrees with that decision.

(iii) Resolve the appeal as expeditiously as the enrollee's health condition requires and no later than the date the extension expires.

(3) *Deemed exhaustion of appeals processes.* In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements in this section, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State fair hearing.

(d) *Format of notice*—(1) *Grievances.* The State must establish the method that an MCO, PIHP, and PAHP will use to notify an enrollee of the resolution of a grievance and ensure that such methods meet, at a minimum, the standards described at § 438.10.

(2) *Appeals.* (i) For all appeals, the MCO, PIHP, or PAHP must provide written notice of resolution in a format and language that, at a minimum, meet the standards described at § 438.10.

(ii) For notice of an expedited resolution, the MCO, PIHP, or PAHP must also make reasonable efforts to provide oral notice.

(e) *Content of notice of appeal resolution.* The written notice of the resolution must include the following:

(1) The results of the resolution process and the date it was completed.

(2) For appeals not resolved wholly in favor of the enrollees—

(i) The right to request a State fair hearing, and how to do so.

(ii) The right to request and receive benefits while the hearing is pending, and how to make the request.

(iii) That the enrollee may, consistent with state policy, be held liable for the cost of those benefits if the hearing decision upholds the MCO's, PIHP's, or PAHP's adverse benefit determination.

(f) *Requirements for State fair hearings*—(1) *Availability.* An enrollee may request a State fair hearing only after receiving notice that the MCO, PIHP, or PAHP is upholding the adverse benefit determination.

(i) *Deemed exhaustion of appeals processes.* In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements in § 438.408, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's

appeals process. The enrollee may initiate a State fair hearing.

(ii) *External medical review.* The State may offer and arrange for an external medical review if the following conditions are met.

(A) The review must be at the enrollee's option and must not be required before or used as a deterrent to proceeding to the State fair hearing.

(B) The review must be independent of both the State and MCO, PIHP, or PAHP.

(C) The review must be offered without any cost to the enrollee.

(D) The review must not extend any of the timeframes specified in § 438.408 and must not disrupt the continuation of benefits in § 438.420.

(2) *State fair hearing.* The enrollee must have no less than 90 calendar days and no more than 120 calendar days from the date of the MCO's, PIHP's, or PAHP's notice of resolution to request a State fair hearing.

(3) *Parties.* The parties to the State fair hearing include the MCO, PIHP, or PAHP, as well as the enrollee and his or her representative or the representative of a deceased enrollee's estate.

[81 FR 27853, May 6, 2016, as amended at 85 FR 72842, Nov. 13, 2020]

§ 438.410 Expedited resolution of appeals.

(a) *General rule.* Each MCO, PIHP, and PAHP must establish and maintain an expedited review process for appeals, when the MCO, PIHP, or PAHP determines (for a request from the enrollee) or the provider indicates (in making the request on the enrollee's behalf or supporting the enrollee's request) that taking the time for a standard resolution could seriously jeopardize the enrollee's life, physical or mental health, or ability to attain, maintain, or regain maximum function.

(b) *Punitive action.* The MCO, PIHP, or PAHP must ensure that punitive action is not taken against a provider who requests an expedited resolution or supports an enrollee's appeal.

(c) *Action following denial of a request for expedited resolution.* If the MCO, PIHP, or PAHP denies a request for expedited resolution of an appeal, it must—

(1) Transfer the appeal to the timeframe for standard resolution in accordance with § 438.408(b)(2).

(2) Follow the requirements in § 438.408(c)(2).

§ 438.414 Information about the grievance and appeal system to providers and subcontractors.

The MCO, PIHP, or PAHP must provide information specified in § 438.10(g)(2)(xi) about the grievance and appeal system to all providers and subcontractors at the time they enter into a contract.

§ 438.416 Recordkeeping requirements.

(a) The State must require MCOs, PIHPs, and PAHPs to maintain records of grievances and appeals and must review the information as part of its ongoing monitoring procedures, as well as for updates and revisions to the State quality strategy.

(b) The record of each grievance or appeal must contain, at a minimum, all of the following information:

(1) A general description of the reason for the appeal or grievance.

(2) The date received.

(3) The date of each review or, if applicable, review meeting.

(4) Resolution at each level of the appeal or grievance, if applicable.

(5) Date of resolution at each level, if applicable.

(6) Name of the covered person for whom the appeal or grievance was filed.

(c) The record must be accurately maintained in a manner accessible to the state and available upon request to CMS.

§ 438.420 Continuation of benefits while the MCO, PIHP, or PAHP appeal and the State fair hearing are pending.

(a) *Definition.* As used in this section—

Timely files means files for continuation of benefits on or before the later of the following:

(i) Within 10 calendar days of the MCO, PIHP, or PAHP sending the notice of adverse benefit determination.

(ii) The intended effective date of the MCO's, PIHP's, or PAHP's proposed adverse benefit determination.

(b) *Continuation of benefits.* The MCO, PIHP, or PAHP must continue the enrollee's benefits if all of the following occur:

(1) The enrollee files the request for an appeal timely in accordance with § 438.402(c)(1)(ii) and (c)(2)(ii);

(2) The appeal involves the termination, suspension, or reduction of previously authorized services;

(3) The services were ordered by an authorized provider;

(4) The period covered by the original authorization has not expired; and

(5) The enrollee timely files for continuation of benefits.

(c) *Duration of continued or reinstated benefits.* If, at the enrollee's request, the MCO, PIHP, or PAHP continues or reinstates the enrollee's benefits while the appeal or state fair hearing is pending, the benefits must be continued until one of following occurs:

(1) The enrollee withdraws the appeal or request for state fair hearing.

(2) The enrollee fails to request a state fair hearing and continuation of benefits within 10 calendar days after the MCO, PIHP, or PAHP sends the notice of an adverse resolution to the enrollee's appeal under § 438.408(d)(2).

(3) A State fair hearing office issues a hearing decision adverse to the enrollee.

(d) *Enrollee responsibility for services furnished while the appeal or state fair hearing is pending.* If the final resolution of the appeal or state fair hearing is adverse to the enrollee, that is, upholds the MCO's, PIHP's, or PAHP's adverse benefit determination, the MCO, PIHP, or PAHP may, consistent with the state's usual policy on recoveries under § 431.230(b) of this chapter and as specified in the MCO's, PIHP's, or PAHP's contract, recover the cost of services furnished to the enrollee while the appeal and state fair hearing was pending, to the extent that they were furnished solely because of the requirements of this section.

§ 438.424 Effectuation of reversed appeal resolutions.

(a) *Services not furnished while the appeal is pending.* If the MCO, PIHP, or PAHP, or the State fair hearing officer reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO, PIHP, or PAHP must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

(b) *Services furnished while the appeal is pending.* If the MCO, PIHP, or PAHP, or the State fair hearing officer reverses a decision to deny authorization of services, and the enrollee received the disputed services while the appeal was pending, the MCO, PIHP, or PAHP, or the State must pay for those services, in accordance with State policy and regulations.

Subpart G—Medicaid Managed Care Quality Rating System

SOURCE: 89 FR 41279, May 10, 2024, unless otherwise noted.

§ 438.500 Definitions.

(a) Definitions. As used in this subpart, the following terms have the indicated meanings:

Measurement period means the period for which data are collected for a measure or the performance period that a measure covers.

Measurement year means the first calendar year and each calendar year thereafter for which a full calendar year of claims and encounter data necessary to calculate a measure are available.

Medicaid managed care quality rating system framework (QRS framework) means the mandatory measure set identified by CMS in the Medicaid and CHIP managed care quality rating system technical resource manual described in § 438.530, the methodology for calculating quality ratings described in § 438.515, and the website display described in § 438.520 of this subpart.

Medicare Advantage and Part D 5-Star Rating System (MA and Part D quality rating system) means the rating system described in subpart D of parts 422 and 423 of this chapter.

Qualified health plan quality rating system (QHP quality rating system) means the health plan quality rating system developed in accordance with 45 CFR 156.1120.

Quality rating means the numeric or other value of a quality measure or an assigned indicator that data for the measure is not available.

Technical resource manual means the guidance described in § 438.530.

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.

§ 438.505 General rule and applicability.

(a) *General rule.* As part of its quality assessment and improvement strategy for its managed care program, each State contracting with an applicable managed care plan, as described in paragraph (b) of this section, to furnish services to Medicaid beneficiaries—

(1)(i) Must adopt the QRS framework developed by CMS, which must implement either the MAC QRS methodology developed by CMS or an alternative MAC QRS rating methodology approved by CMS in accordance with § 438.515(c) of this subpart.

(ii) May, in addition to the MAC QRS framework adopted under paragraph (a)(1)(i) of this section, implement website features in addition to those identified in § 438.520(a), as described in § 438.520(c).

(2) Must implement such managed care quality rating system by the end of the fourth calendar year following July 9, 2024, unless otherwise specified in this subpart.

(3) Must use the State's beneficiary support system implemented under § 438.71 to provide the services identified at § 438.71(b)(1)(i) and (ii) to beneficiaries, enrollees, or both seeking assistance using the managed care quality rating system implemented by the State under this subpart.

(b) *Applicability.* The provisions of this subpart apply to States contracting with MCOs, PIHPs, and PAHPs for the delivery of services covered under Medicaid. The provisions of this subpart do not apply to Medicare Advantage Dual Eligible Special Needs Plans that contract with States for only Medicaid coverage of Medicare cost sharing.

(c) *Continued alignment.* To maintain the QRS framework, CMS aligns the mandatory measure set and methodology described in §§ 438.510 and 438.515 of this subpart, to the extent appropriate, with the qualified health plan quality rating system developed in accordance with 45 CFR 156.1120, the MA and Part D quality rating system, and other similar CMS quality measurement and rating initiatives.

§ 438.510 Mandatory QRS measure set for Medicaid managed care quality rating system.

(a) *Measures required.* The quality rating system implemented by the State—

(1) Must include the measures that are:

(i) In the mandatory QRS measure set identified and described by CMS in the Medicaid and CHIP managed care quality rating system technical resource manual, and

(ii) Applicable to the State because the measures assess a service or action covered by a managed care program established by the State.

(2) May include other measures identified by the State as provided in § 438.520(c)(1).

(b) *Subregulatory process to update mandatory measure set.* Subject to paragraph (d) of this section, CMS will—

(1) At least every other year, engage with States and other interested parties (such as State officials, measure experts, health plans, beneficiary advocates, tribal organizations, health plan associations, and external quality review organizations) to evaluate the current mandatory measure set and make recommendations to CMS to add, remove or update existing measures based on the criteria and standards in paragraph (c) of this section; and

(2) Provide public notice and opportunity to comment through a call letter (or similar subregulatory process using written guidance) on any planned modifications to the mandatory measure set following the engagement described in paragraph (b)(1) of this section.

(c) *Standards for adding mandatory measures.* Based on available relevant information, including the input received during the process described in paragraph (b) of this section, CMS will

add a measure in the mandatory measure set when each of the standards described in (c)(1) through (3) of this section are met.

(1) The measure meets at least 5 of the following criteria:

(i) Is meaningful and useful for beneficiaries or their caregivers when choosing a managed care plan;

(ii) Aligns, to the extent appropriate, with other CMS programs described in § 438.505(c);

(iii) Measures health plan performance in at least one of the following areas: customer experience, access to services, health outcomes, quality of care, health plan administration, and health equity;

(iv) Presents an opportunity for managed care plans to influence their performance on the measure;

(v) Is based on data that are available without undue burden on States, managed care plans, and providers such that it is feasible to report by many States, managed care plans, and providers;

(vi) Demonstrates scientific acceptability, meaning that the measure, as specified, produces consistent and credible results;

(2) The proposed measure contributes to balanced representation of beneficiary subpopulations, age groups, health conditions, services, and performance areas within a concise mandatory measure set, and

(3) The burdens associated with including the measure does not outweigh the benefits to the overall quality rating system framework of including the new measure based on the criteria listed in paragraph (c)(1) of this section.

(4) When making the determinations required under paragraphs (c)(2) and (3) of this section, to add, remove, or update a measure, CMS may consider the measure set as a whole, each specific measure individually, or a comparison of measures that assess similar aspects of care or performance areas.

(d) *Removing mandatory measures.* CMS may remove existing mandatory measures from the mandatory measure set if—

(1) After following the process described in paragraph (b) of this section, CMS determines that the measure no longer meets the standards described in paragraph (c) of this section;

(2) The measure steward (other than CMS) retires or stops maintaining a measure;

(3) CMS determines that the clinical guidelines associated with the specifications of the measure change such that the specifications no longer align with positive health outcomes; or

(4) CMS determines that the measure shows low statistical reliability under the standard identified in §§ 422.164(e) and 423.184(e) of this chapter.

(e) *Updating existing mandatory measures.* CMS will modify the existing mandatory measures that undergo measure technical specifications updates as follows—

(1) *Non-substantive updates.* CMS will update changes to the technical specifications for a measure made by the measure steward; such changes will be in the technical resource manual issued under paragraph (f) of this section and § 438.530. Examples of non-substantive updates include those that:

(i) Narrow the denominator or population covered by the measure.

(ii) Do not meaningfully impact the numerator or denominator of the measure.

(iii) Update the clinical codes with no change in the target population or the intent of the measure.

(iv) Provide additional clarifications such as:

(A) Adding additional tests that would meet the numerator requirements;

(B) Clarifying documentation requirements;

(C) Adding additional instructions to identify services or procedures; or

(D) Adding alternative data sources or expanding of modes of data collection to calculate a measure.

(2) *Substantive updates.* CMS may adopt substantive updates to a mandatory measure not subject to paragraphs (e)(1)(i) through (iv) of this section only after following the process specified in paragraph (b) of this section.

(f) *Finalization and display of mandatory measures and updates.* CMS will finalize modifications to the mandatory measure set and the timeline for State implementation of such modifications in the technical resource manual. For

new or substantively updated measures, CMS will provide each State with at least 2 calendar years from the start of the measurement year immediately following the release of the annual technical resource manual in which the modification to the mandatory measure set is finalized to display measurement results and ratings using the new or updated measure(s).

§438.515 Medicaid managed care quality rating system methodology.

(a) *Quality ratings.* For each measurement year, the State must ensure that—

(1) The data necessary to calculate quality ratings for each quality measure described in §438.510(a)(1) of this subpart are collected from:

(i) The State's contracted managed care plans that have 500 or more enrollees from the State's Medicaid program, to be calculated as described by CMS in the technical resource manual; and

(ii) Sources of Medicare data (including Medicare Advantage plans, Medicare providers, and CMS), the State's Medicaid fee-for-service providers, or both if all data necessary to calculate a measure cannot be provided by the managed care plans described in paragraph (a)(1) of this section and such data are available for collection by the State to the extent feasible without undue burden.

(2) Validation of data collected under paragraph (a)(1) of this section is performed, including all Medicaid managed care data and, to the extent feasible without undue burden, all data from sources described in paragraph (a)(1)(ii) of this section. Validation of data must not be performed by any entity with a conflict of interest, including managed care plans.

(3) A measure performance rate for each managed care plan whose contract covers a service or action assessed by the measure, as determined by the State, is calculated, for each quality measure identified under §438.510(a)(1) of this subpart, using the methodology described in paragraph (b) of this section and the validated data described in paragraph (a)(2) of this section, including all Medicaid managed care data and, to the extent feasible without undue burden, all data from sources described in paragraph (a)(1)(ii) of this section.

(4) Quality ratings are issued by the State for each managed care plan for each measure that assesses a service or action covered by the plan's contract with the State, as determined by the State under paragraph (a)(3) of this section.

(b) *Methodology.* The State must ensure that the quality ratings issued under paragraph (a)(4) of this section:

(1) Include data for all enrollees who receive coverage through the managed care plan for a service or action for which data are necessary to calculate the quality rating for the managed care plan including Medicaid FFS and Medicare data for enrollees who receive Medicaid benefits for the State through FFS and managed care, are dually eligible for both Medicare and Medicaid and receive full benefits from Medicaid, or both).

(2) Are issued to each managed care plan at the plan level and by managed care program, so that a plan participating in multiple managed care programs is issued distinct ratings for each program in which it participates, resulting in quality ratings that are representative of services provided only to those beneficiaries enrolled in the plan through the rated program.

(c) *Alternative QRS methodology.* (1) A State may apply an alternative QRS methodology (that is, other than that described in paragraph (b) of this section) to the mandatory measures described in §438.510(a)(1) of this subpart provided that—

(i) The ratings generated by the alternative QRS methodology yield information regarding managed care plan performance which, to the extent feasible, is substantially comparable to that yielded by the methodology described in §438.515(b) of this subpart, taking into account such factors as differences in covered populations, benefits, and stage of delivery system transformation, to enable meaningful comparison of performance across States.

(ii) The State receives CMS approval prior to implementing an alternative QRS methodology or modifications to an approved alternative QRS methodology.

(2) To receive CMS approval for an alternative QRS methodology, a State must:

(i) Submit a request for, or modification of, an alternative QRS methodology to CMS in a form and manner and by a date determined by CMS; and

(ii) Include the following in the State's request for, or modification of, an alternative QRS methodology:

(A) The alternative QRS methodology to be used in generating plan ratings;

(B) Other information or documentation specified by CMS to demonstrate compliance with paragraph (c)(1) of this section; and

(C) Other supporting documents and evidence that the State believes demonstrates compliance with the requirements of (c)(1)(i) of this section.

(3) Subject to requirements established in paragraphs (c)(1)(i) and (ii) and (c)(2) of this section, the flexibility described in paragraph (c)(1) of this section permits the State to request and receive CMS approval to apply an alternative methodology from that described in paragraph (b)(1) and (2) of this section when calculating quality ratings issued to health plans as required under paragraph (a)(4) of this section. CMS will not review or approve an alternative methodology request submitted by the State that requests to implement a MAC QRS that—

(i) Does not comply with—

(A) The requirement to include mandatory measures established in § 438.510(a)(1).

(B) The general requirements for calculating quality ratings established in paragraphs (a)(1) through (4) of this section.

(C) The requirement to include the website features identified in § 438.520(a)(1) through (6) established in § 438.520(a).

(ii) Requests to include plans that do not meet the threshold established in paragraph (a)(1)(i) of this section, which is permitted without CMS review or approval.

(iii) Requests to implement additional measures or website features, which are permitted, without CMS review or approval, as described § 438.520(c).

(d) *Request for implementation extension.* In a form and manner determined by CMS, the State may request a one-year extension to the implementation date specified in this subpart for one or more MAC QRS requirements established in paragraph (b) of this section.

(1) A request for extension of the implementation deadline for the methodology requirements in this section must meet the following requirements:

(i) Identify the specific requirement(s) for which an extension is requested and;

(ii) Include a timeline of the steps the State has taken to meet the requirement as well as an anticipated timeline of the steps that remain;

(iii) Explain why the State will be unable to fully comply with the requirement by the implementation date, which must include a detailed description of the specific barriers the State has faced or faces in complying with the requirement; and

(iv) Include a detailed plan to implement the requirement by the end of the one-year extension including, but not limited to, the operational steps the State will take to address identified implementation barriers.

(2) The State must submit an extension request by September 1 of the fourth calendar year following July 9, 2024.

(3) CMS will approve an extension for 1 year if it determines that the request:

(i) Includes the information described in paragraph (d)(1) of this section;

(ii) Demonstrates that the State has made a good-faith effort to identify and begin executing an implementation strategy but is unable to comply with the specified requirement by the implementation date identified in this subpart; and

(iii) Demonstrates that the State has an actionable plan to implement the requirements by the end of the 1-year extension.

(e) *Domain ratings.* After engaging with States, beneficiaries, and other interested parties, CMS implements domain-level quality ratings, including care domains for which States are required to calculate and assign domain-level quality ratings for managed care plans, a methodology to calculate such

ratings, and website display requirements for displaying such ratings on the MAC QRS website display described in § 438.520.

§ 438.520 website display.

(a) *website display requirements*. In a manner that complies with the accessibility standards outlined in § 438.10(d) of this part and in a form and manner specified by CMS, the State must prominently display and make accessible to the public on the website required under § 438.10(c)(3):

(1) Information necessary for users to understand and navigate the contents of the QRS website display, including:

(i) A statement of the purpose of the Medicaid managed care quality rating system, relevant information on Medicaid, CHIP and Medicare and an overview of how to use the information available in the display to select a quality managed care plan;

(ii) Information on how to access the beneficiary support system described in § 438.71 to answer questions about using the State's managed care quality rating system to select a managed care plan; and

(iii) If users are requested to input user-specific information, including the information described in paragraph (a)(2)(i) of this section, an explanation of why the information is requested, how it will be used, and whether it is optional or required to access a QRS feature or type of information.

(2) Information that allows beneficiaries to identify managed care plans available to them that align with their coverage needs and preferences including:

(i) All available managed care programs and plans for which a user may be eligible based on the user's age, geographic location, and dually eligible status, if applicable, as well as other demographic data identified by CMS;

(ii) A description of the drug coverage for each managed care plan, including the formulary information specified in § 438.10(i) and other similar information as specified by CMS;

(iii) Provider directory information for each managed care plan including all information required by § 438.10(h)(1) and (2) and such other provider information as specified by CMS;

(iv) Quality ratings described at § 438.515(a)(4) that are calculated by the State for each managed care plan in accordance with § 438.515 for mandatory measures identified by CMS in the technical resource manual, and

(v) The quality ratings described in § 438.520(a)(2)(iv) calculated by the State for each managed care plan in accordance with § 438.515 for mandatory measures identified by CMS, stratified by dual eligibility status, race and ethnicity, and sex.

(3) Standardized information identified by CMS that allows users to compare available managed care plans and programs, including:

(i) The name of each managed care plan;

(ii) An internet hyperlink to each managed care plan's website and each available managed care plan's toll-free customer service telephone number;

(iii) Premium and cost-sharing information including differences in premium and cost-sharing among available managed care plans within a single program;

(iv) A summary of benefits including differences in benefits among available managed care plans within a single program and other similar information specified by CMS, such as whether access to the benefit requires prior authorization from the plan;

(v) Certain metrics, as specified by CMS, of managed care plan performance that States must make available to the public under subparts B and D of this part, including data most recently reported to CMS on each managed care program pursuant to § 438.66(e) of this part and the results of the secret shopper survey specified in § 438.68(f) of this part;

(vi) If a managed care plan offers an integrated Medicare-Medicaid plan or a highly or fully integrated Medicare Advantage D–SNP (as those terms are defined in § 422.2 of this chapter), an indication that an integrated plan is available and a link to the integrated plan's most recent rating under the Medicare Advantage and Part D 5-Star Rating System.

(4) Information on quality ratings displayed in accordance with paragraph (a)(2)(iv) of this section in a manner

that promotes beneficiary understanding of and trust in the ratings, including:

(i) A plain language description of the importance and impact of each quality measure assigned a quality rating;

(ii) The measurement period during which the data used to calculate the quality rating was produced; and

(iii) Information on quality ratings data validation, including a plain language description of when, how and by whom the data were validated.

(5) Information or hyperlinks directing users to resources on how and where to apply for Medicaid and enroll in a Medicaid or CHIP plan.

(6) By a date specified by CMS, which shall be no earlier than 2 years after the implementation date for the quality rating system specified in § 438.505:

(i) The quality ratings described in paragraph (a)(2)(iv) of this section calculated by the State for each managed care plan in accordance with § 438.515 for mandatory measures identified by CMS, including the display of such measures stratified by dual eligibility status, race and ethnicity, sex, age, rural/urban status, disability, language of the enrollee, or other factors specified by CMS in the annual technical resource manual.

(ii) An interactive tool that enables users to view the quality ratings described at paragraph (a)(2)(iv) of this section, stratified by the factors described in paragraph (a)(6)(i) of this section.

(iii) For managed care programs with two or more participating plans—

(A) A search tool that enables users to identify available managed care plans within the managed care program that provide coverage for a drug identified by the user; and

(B) A search tool that enables users to identify available managed care plans within the managed care program that include a provider identified by the user in the plan's network of providers.

(b) *Request for implementation extension.* In a form and manner determined by CMS, the State may request a 1-year extension to the implementation date specified in this subpart for one or more of the requirements established under paragraphs (a)(2)(v) and (6) of this section.

(1) A request for extension of the implementation deadline for the website display requirements in this section must meet the requirements described in § 438.515(d)(1);

(2) For extensions of the website requirements specified in paragraph (a)(6) of this section, the extension request must be submitted no later than 4 months prior to the implementation date specified pursuant to paragraph (a)(6) of this section for those requirements; for extensions of the requirements specified in paragraphs (a)(2)(v) of this section, the extension request must be submitted no later than September 1, 2027.

(3) CMS will approve the State's request for a 1-year extension if CMS determines that the request meets the conditions described in § 438.515(d)(3).

(c) *Additional website features.* The State may choose to display additional website features not described in § 438.520(a) in their MAC QRS, or may choose to implement the features described in § 438.520(a)(6)(i) through (iv) before the date specified by CMS as described in paragraph (a)(6) of this section.

(1) Additional website features may include additional measures not included in the mandatory measure set described in § 438.510(a)(1), supplementary data on displayed quality measures, and extra interactive functions, and may be implemented without CMS review.

(2) If the State chooses to display quality ratings for additional measures as described in paragraph (c)(1) of this section, the State must:

(i) Obtain input on the additional measures, prior to their use, from prospective users, including beneficiaries, caregivers, and, if the State enrolls American Indians/Alaska Natives in managed care, consult with Tribes and Tribal Organizations in accordance with the State's Tribal consultation policy; and

(ii) Document the input received from prospective users required under paragraph (c)(2)(i) of this section, including modifications made to the additional measure(s) in response to the

input and rationale for input not accepted.

(d) *Continued consultation.* CMS will periodically consult with States and interested parties including Medicaid managed care quality rating system users to evaluate the website display requirements described in this section for continued alignment with beneficiary preferences and values.

§ 438.525 [Reserved]

§ 438.530 Annual technical resource manual.

(a) Beginning in calendar year 2027, CMS will publish a Medicaid managed care quality rating system technical resource manual annually, which may be released in increments throughout the year. Subject to the limitation described in paragraph (a)(4) of this section, the technical resource manual must include all the following:

(1) Identification of all Medicaid managed care quality rating system measures, including:

(i) A list of the mandatory measures

(ii) Any measures newly added or removed from the prior year's mandatory measure set.

(iii) The subset of mandatory measures that must be displayed and stratified by factors such as race and ethnicity, sex, age, rural/urban status, disability, language, or such other factors as may be specified by the CMS in accordance with § 438.520(a)(2)(v) and (a)(6)(i).

(2) Guidance on the application of the methodology used to calculate and issue quality ratings as described in § 438.515(b).

(3) Measure steward technical specifications for mandatory measures.

(4) If the public notice and comment process described in § 438.510(b) of this subpart occurs in the calendar year in which the manual is published, a summary of interested party engagement and public comments received during the notice and comment process using the process identified in § 438.510(c) for the most recent modifications to the mandatory measure set including:

(i) Discussion of the feedback and recommendations received on potential modifications to mandatory measures;

(ii) The final modifications and the timeline by which such modifications must be implemented; and

(iii) The rationale for not accepting or implementing specific recommendations or feedback submitted during the consultation process.

(b) In developing and issuing the manual content described in paragraphs (a)(1) and (2) of this section, CMS will take into account whether stratification is currently required by the measure steward or other CMS programs and by which factors when issuing guidance that identifies which measures, and by which factors, States must stratify mandatory measures.

(c) No later than August 1, 2025, CMS will publish the information described at paragraph (a)(1) of this section for the initial mandatory measure set.

§ 438.535 Annual reporting.

(a) Upon CMS' request, but no more frequently than annually, the State must submit a Medicaid managed care quality rating system report in a form and manner determined by CMS. Such report must include:

(1) The following measure information:

(i) A list of all mandatory measures identified in the most recent technical resource manual that indicates for each measure:

(A) Whether the State has identified the measure as applicable or not applicable to the State's managed care program under § 438.510(a)(1) of this subpart;

(B) For any measures identified as inapplicable to the State's managed care program, a brief explanation of why the State determined that the measure is inapplicable; and,

(C) For any measure identified as applicable to the State's managed care program, the managed care programs to which the measure is applicable.

(ii) A list of any additional measures the State chooses to include in the Medicaid managed care quality rating system as permitted under § 438.510(a)(2).

(2) An attestation that all displayed quality ratings for mandatory measures were calculated and issued in compliance with § 438.515, and a description of the methodology used to calculate

ratings for any additional measures if such methodology deviates from the methodology in § 438.515.

(3) The documentation required under § 438.520(c), if including additional measures in the State's Medicaid managed care quality rating system.

(4) The date on which the State publishes or updates the quality ratings for the State's managed care plans.

(5) A link to the State's website for their Medicaid managed care quality rating system.

(6) The application of any technical specification adjustments used to calculate and issue quality ratings described in § 438.515(a)(3) and (4), at the plan- or State-level, that are outside a measure steward's allowable adjustments for a mandatory measure but that the measure steward has approved for use by the State.

(7) A summary of each alternative QRS methodology approved by CMS, including the effective dates for each approved alternative QRS.

(8) If all data necessary to calculate a measure described in § 438.510(a)(1) of this subpart cannot be provided by the managed care plans described in § 438.515(a)(1) of this subpart:

(i) A description of any Medicare data, Medicaid FFS data, or both that cannot, without undue burden, be collected, validated, or used to calculate a quality rating for the measure per § 438.515(a) and (b), including an estimate of the proportion of Medicare data or Medicaid FFS data that such missing data represent.

(ii) A description of the undue burden(s) that prevents the State from ensuring that such data are collected, validated, or used to calculate the measure, the resources necessary to overcome the burden, and the State's plan to address the burden.

(iii) An assessment of the impact of the missing data on the State's ability to fully comply with § 438.515(b)(1).

(b) States will be given no less than 90 days to submit such a report to CMS on their Medicaid managed care quality rating system.

Subpart H—Additional Program Integrity Safeguards

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

§ 438.600 Statutory basis, basic rule, and applicability.

(a) *Statutory basis.* This subpart is based on the following statutory sections:

(1) Section 1128 of the Act provides for the exclusion of certain individuals and entities from participation in the Medicaid program.

(2) Section 1128J(d) of the Act requires that persons who have received an overpayment under Medicaid report and return the overpayment within 60 days after the date on which the overpayment was identified.

(3) Section 1902(a)(4) of the Act requires that the State plan provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(4) Section 1902(a)(19) of the Act requires that the State plan provide the safeguards necessary to ensure that eligibility is determined and services are provided in a manner consistent with simplicity of administration and the best interests of the beneficiaries.

(5) Section 1902(a)(27) of the Act requires States to enroll persons or institutions that provide services under the State plan.

(6) Section 1902(a)(68) of the Act requires that any entity that receives or makes annual payments under the State plan of at least $5,000,000 must establish certain minimum written policies relating to the Federal False Claims Act.

(7) Section 1902(a)(77) of the Act requires that States comply with provider and supplier screening, oversight, and reporting requirements described in section 1902(kk)(1) of the Act.

(8) Section 1902(a)(80) of the Act prohibits payments for items or services provided under the State plan or under a waiver to any financial institution or entity located outside of the United States.

(9) Section 1902(kk)(7) of the Act requires States to enroll physicians or other professionals that order or refer services under the State plan.

(10) Section 1903(i) of the Act prohibits FFP for amounts expended by MCOs or PCCMs for providers excluded by Medicare, Medicaid, or CHIP, except for emergency services.

(11) Section 1903(m) of the Act establishes conditions for payments to the State for contracts with MCOs.

(12) Section 1932(d)(1) of the Act prohibits MCOs and PCCMs from knowingly having certain types of relationships with individuals and entities debarred under Federal regulations from participating in specified activities, or with affiliates of those individuals.

(b) *Basic rule.* As a condition for receiving payment under a Medicaid managed care program, an MCO, PIHP, PAHP, PCCM or PCCM entity must comply with the requirements in §§ 438.604, 438.606, 438.608 and 438.610, as applicable.

(c) *Applicability.* States will not be held out 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 CFR, parts 430 to 481, edition revised as of October 1, 2015:

(1) States must comply with §§ 438.602(a), 438.602(c) through (h), 438.604, 438.606, 438.608(a), and 438.608(c) and (d), no later than the rating period for contracts starting on or after July 1, 2017.

(2) States must comply with § 438.602(b) and § 438.608(b) no later than the rating period for contracts beginning on or after July 1, 2018.

§ 438.602 State responsibilities.

(a) *Monitoring contractor compliance.* Consistent with § 438.66, the State must monitor the MCO's, PIHP's, PAHP's, PCCM's or PCCM entity's compliance, as applicable, with §§ 438.604, 438.606, 438.608, 438.610, 438.230, and 438.808.

(b) *Screening and enrollment and revalidation of providers.* (1) The State must screen and enroll, and periodically revalidate, all network providers of MCOs, PIHPs, and PAHPs, in accordance with the requirements of part 455, subparts B and E of this chapter. This requirement extends to PCCMs and PCCM entities to the extent the primary care case manager is not otherwise enrolled with the State to provide services to FFS beneficiaries. This provision does not require the network provider to render services to FFS beneficiaries.

(2) MCOs, PIHPs, and PAHPs may execute network provider agreements pending the outcome of the process in paragraph (b)(1) of this section of up to 120 days, but must terminate a network provider immediately upon notification from the State that the network provider cannot be enrolled, or the expiration of one 120 day period without enrollment of the provider, and notify affected enrollees.

(c) *Ownership and control information.* The State must review the ownership and control disclosures submitted by the MCO, PIHP, PAHP, PCCM or PCCM entity, and any subcontractors as required in § 438.608(c).

(d) *Federal database checks.* Consistent with the requirements at § 455.436 of this chapter, the State must confirm the identity and determine the exclusion status of the MCO, PIHP, PAHP, PCCM or PCCM entity, any subcontractor, as well as any person with an ownership or control interest, or who is an agent or managing employee of the MCO, PIHP, PAHP, PCCM or PCCM entity through routine checks of Federal databases. This includes the Social Security Administration's Death Master File, the National Plan and Provider Enumeration System (NPPES), the List of Excluded Individuals/Entities (LEIE), the System for Award Management (SAM), and any other databases as the State or Secretary may prescribe. These databases must be consulted upon contracting and no less frequently than monthly thereafter. If the State finds a party that is excluded, it must promptly notify the MCO, PIHP, PAHP, PCCM, or PCCM entity and take action consistent with § 438.610(c).

(e) *Periodic audits.* The State must periodically, but no less frequently than once every 3 years, conduct, or contract for the conduct of, an independent audit of the accuracy, truthfulness, and completeness of the encounter and financial data submitted by, or on behalf of, each MCO, PIHP or PAHP.

(f) *Whistleblowers.* The State must receive and investigate information from whistleblowers relating to the integrity of the MCO, PIHP, PAHP, PCCM, or PCCM entity, subcontractors, or network providers receiving Federal funds under this part.

(g) *Transparency.* The State must post on its Web site, as required in § 438.10(c)(3), the following documents and reports:

(1) The MCO, PIHP, PAHP, or PCCM entity contract.

(2) The data at § 438.604(a)(5).

(3) The name and title of individuals included in § 438.604(a)(6).

(4) The results of any audits under paragraph (e) of this section.

(5) Enrollee handbooks, provider directories, and formularies required at § 438.10(g) through (i).

(6) The information on rate ranges required at § 438.4(c)(2)(iv), if applicable.

(7) The reports required at §§ 438.66(e) and 438.207(d).

(8) The network adequacy standards required at § 438.68(b)(1) through (2) and (e).

(9) The results of secret shopper surveys required at § 438.68(f).

(10) State directed payment evaluation reports required in § 438.6(c)(2)(v)(C).

(11) Information on all required Application Programming Interfaces including as specified in § 431.60(d) and (f).

(12) Quality related information as required in §§ 438.332(c)(1), 438.340(d), 438.362(c) and 438.364(c)(2)(i).

(13) Documentation of compliance with requirements in subpart K—Parity in Mental Health and Substance Use Disorder Benefits.

(h) *Contracting integrity.* The State must have in place conflict of interest safeguards described in § 438.58 and must comply with the requirement described in section 1902(a)(4)(C) of the Act applicable to contracting officers, employees, or independent contractors.

(i) *Entities located outside of the U.S.* The State must ensure that the MCO, PIHP, PAHP, PCCM, or PCCM entity with which the State contracts under this part is not located outside of the United States and that no claims paid by an MCO, PIHP, or PAHP to a network provider, out-of-network provider, subcontractor or financial institution located outside of the U.S. are considered in the development of actuarially sound capitation rates.

(j) *Applicability.* Paragraphs (g)(5) through (13) of this section apply to the first rating period for contracts with MCOs, PIHPs and PAHPs beginning on or after 2 years after July 9, 2024.

[81 FR 27853, May 6, 2016, as amended at 89 FR 41284, May 10, 2024]

§ 438.604 Data, information, and documentation that must be submitted.

(a) *Specified data, information, and documentation.* The State must require any MCO, PIHP, PAHP, PCCM or PCCM entity to submit to the State the following data:

(1) Encounter data in the form and manner described in § 438.818.

(2) Data on the basis of which the State certifies the actuarial soundness of capitation rates to an MCO, PIHP or PAHP under § 438.4, including base data described in § 438.5(c) that is generated by the MCO, PIHP or PAHP.

(3) Data on the basis of which the State determines the compliance of the MCO, PIHP, or PAHP with the medical loss ratio requirement described in § 438.8.

(4) Data on the basis of which the State determines that the MCO, PIHP or PAHP has made adequate provision against the risk of insolvency as required under § 438.116.

(5) Documentation described in § 438.207(b) on which the State bases its certification that the MCO, PIHP or PAHP has complied with the State's requirements for availability and accessibility of services, including the adequacy of the provider network, as set forth in § 438.206.

(6) Information on ownership and control described in § 455.104 of this chapter from MCOs, PIHPs, PAHPs, PCCMs, PCCM entities, and subcontractors as governed by § 438.230.

(7) The annual report of overpayment recoveries as required in § 438.608(d)(3).

(b) *Additional data, documentation, or information.* In addition to the data, documentation, or information specified in paragraph (a) of this section, an MCO, PIHP, PAHP, PCCM or PCCM entity must submit any other data, documentation, or information relating to

the performance of the entity's obligations under this part required by the State or the Secretary.

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

§ 438.606 Source, content, and timing of certification.

(a) *Source of certification.* For the data, documentation, or information specified in § 438.604, the State must require that the data, documentation or information the MCO, PIHP, PAHP, PCCM or PCCM entity submits to the State be certified by either the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's Chief Executive Officer; Chief Financial Officer; or an individual who reports directly to the Chief Executive Officer or Chief Financial Officer with delegated authority to sign for the Chief Executive Officer or Chief Financial Officer so that the Chief Executive Officer or Chief Financial Officer is ultimately responsible for the certification.

(b) *Content of certification.* The certification provided by the individual in paragraph (a) of this section must attest that, based on best information, knowledge, and belief, the data, documentation, and information specified in § 438.604 is accurate, complete, and truthful.

(c) *Timing of certification.* The State must require the MCO, PIHP, PAHP, PCCM, or PCCM entity to submit the certification concurrently with the submission of the data, documentation, or information required in § 438.604(a) and (b).

§ 438.608 Program integrity requirements under the contract.

(a) *Administrative and management arrangements or procedures to detect and prevent fraud, waste and abuse.* The State, through its contract with the MCO, PIHP or PAHP, must require that the MCO, PIHP, or PAHP, or subcontractor to the extent that the subcontractor is delegated responsibility by the MCO, PIHP, or PAHP for coverage of services and payment of claims under the contract between the State and the MCO, PIHP, or PAHP, implement and maintain arrangements or procedures that are designed to detect and prevent fraud, waste, and abuse. The arrangements or procedures must include the following:

(1) A compliance program that includes, at a minimum, all of the following elements:

(i) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable requirements and standards under the contract, and all applicable Federal and State requirements.

(ii) The designation of a Compliance Officer who is responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements of the contract and who reports directly to the Chief Executive Officer and the board of directors.

(iii) The establishment of a Regulatory Compliance Committee on the Board of Directors and at the senior management level charged with overseeing the organization's compliance program and its compliance with the requirements under the contract.

(iv) A system for training and education for the Compliance Officer, the organization's senior management, and the organization's employees for the Federal and State standards and requirements under the contract.

(v) Effective lines of communication between the compliance officer and the organization's employees.

(vi) Enforcement of standards through well-publicized disciplinary guidelines.

(vii) Establishment and implementation of procedures and a system with dedicated staff for routine internal monitoring and auditing of compliance risks, prompt response to compliance issues as they are raised, investigation of potential compliance problems as identified in the course of self-evaluation and audits, correction of such problems promptly and thoroughly (or coordination of suspected criminal acts with law enforcement agencies) to reduce the potential for recurrence, and ongoing compliance with the requirements under the contract.

(2) Provision for reporting within 30 calendar days all overpayments identified or recovered, specifying the overpayments due to potential fraud, to the State.

(3) Provision for prompt notification to the State when it receives information about changes in an enrollee's circumstances that may affect the enrollee's eligibility including all of the following:

(i) Changes in the enrollee's residence;

(ii) The death of an enrollee.

(4) Provision for notification to the State when it receives information about a change in a network provider's circumstances that may affect the network provider's eligibility to participate in the managed care program, including the termination of the provider agreement with the MCO, PIHP or PAHP.

(5) Provision for a method to verify, by sampling or other methods, whether services that have been represented to have been delivered by network providers were received by enrollees and the application of such verification processes on a regular basis.

(6) In the case of MCOs, PIHPs, or PAHPs that make or receive annual payments under the contract of at least $5,000,000, provision for written policies for all employees of the entity, and of any contractor or agent, that provide detailed information about the False Claims Act and other Federal and State laws described in section 1902(a)(68) of the Act, including information about rights of employees to be protected as whistleblowers.

(7) Provision for the prompt referral of any potential fraud, waste, or abuse that the MCO, PIHP, or PAHP identifies to the State Medicaid program integrity unit or any potential fraud directly to the State Medicaid Fraud Control Unit.

(8) Provision for the MCO's, PIHP's, or PAHP's suspension of payments to a network provider for which the State determines there is a credible allegation of fraud in accordance with § 455.23 of this chapter.

(b) *Provider screening and enrollment requirements.* The State, through its contracts with a MCO, PIHP, PAHP, PCCM, or PCCM entity must ensure that all network providers are enrolled with the State as Medicaid providers consistent with the provider disclosure, screening and enrollment requirements of part 455, subparts B and E of this chapter. This provision does not require the network provider to render services to FFS beneficiaries.

(c) *Disclosures.* The State must ensure, through its contracts, that each MCO, PIHP, PAHP, PCCM, PCCM entity, and any subcontractors:

(1) Provides written disclosure of any prohibited affiliation under § 438.610.

(2) Provides written disclosures of information on ownership and control required under § 455.104 of this chapter.

(3) Reports to the State within 60 calendar days when it has identified the capitation payments or other payments in excess of amounts specified in the contract.

(d) *Treatment of recoveries made by the MCO, PIHP or PAHP of overpayments to providers.* (1) Contracts with a MCO, PIHP, or PAHP must specify:

(i) The retention policies for the treatment of recoveries of all overpayments from the MCO, PIHP, or PAHP to a provider, including specifically the retention policies for the treatment of recoveries of overpayments due to fraud, waste, or abuse.

(ii) The process, timeframes, and documentation required for reporting the recovery of all overpayments.

(iii) The process, timeframes, and documentation required for payment of recoveries of overpayments to the State in situations where the MCO, PIHP, or PAHP is not permitted to retain some or all of the recoveries of overpayments.

(iv) This provision does not apply to any amount of a recovery to be retained under False Claims Act cases or through other investigations.

(2) Each MCO, PIHP, or PAHP requires and has a mechanism for a network provider to report to the MCO, PIHP or PAHP when it has received an overpayment, to return the overpayment to the MCO, PIHP or PAHP within 60 calendar days after the date on which the overpayment was identified, and to notify the MCO, PIHP or PAHP in writing of the reason for the overpayment.

(3) Each MCO, PIHP, or PAHP must report annually to the State on all overpayments identified or recovered.

(4) The State must use the results of the information and documentation

collected in paragraph (d)(1) of this section and the report in paragraph (d)(3) of this section for setting actuarially sound capitation rates for each MCO, PIHP, or PAHP consistent with the requirements in § 438.4.

(e) *Standards for provider incentive or bonus arrangements.* The State, through its contract with the MCO, PIHP or PAHP, must require that incentive payment contracts between managed care plans and network providers meet the requirements as specified in §§ 438.3(i)(3) and (4).

(f) *Applicability date.* Paragraphs (a)(2), (d)(3) and (e) of this section apply to the first rating period for contracts with MCOs, PIHPs, or PAHPs beginning on or after 1 year from July 9, 2024.

[81 FR 27853, May 6, 2016, as amended at 89 FR 41284, May 10, 2024]

§ 438.610 Prohibited affiliations.

(a) An MCO, PIHP, PAHP, PCCM, or PCCM entity may not knowingly have a relationship of the type described in paragraph (c) of this section with the following:

(1) An individual or entity that is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in nonprocurement activities under regulations issued under Executive Order No. 12549 or under guidelines implementing Executive Order No. 12549.

(2) An individual or entity who is an affiliate, as defined in the Federal Acquisition Regulation at 48 CFR 2.101, of a person described in paragraph (a)(1) of this section.

(b) An MCO, PIHP, PAHP, PCCM, or PCCM entity may not have a relationship with an individual or entity that is excluded from participation in any Federal health care program under section 1128 or 1128A of the Act.

(c) The relationships described in paragraph (a) of this section, are as follows:

(1) A director, officer, or partner of the MCO, PIHP, PAHP, PCCM. or PCCM entity.

(2) A subcontractor of the MCO, PIHP, PAHP, PCCM, or PCCM entity, as governed by § 438.230.

(3) A person with beneficial ownership of 5 percent or more of the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's equity.

(4) A network provider or person with an employment, consulting or other arrangement with the MCO, PIHP, PAHP, PCCM, or PCCM entity for the provision of items and services that are significant and material to the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's obligations under its contract with the State.

(d) If a State finds that an MCO, PIHP, PAHP, PCCM, or PCCM entity is not in compliance with paragraphs (a) and (b) of this section, the State:

(1) Must notify the Secretary of the noncompliance.

(2) May continue an existing agreement with the MCO, PIHP, PAHP, PCCM, or PCCM entity unless the Secretary directs otherwise.

(3) May not renew or otherwise extend the duration of an existing agreement with the MCO, PIHP, PAHP, PCCM, or PCCM entity unless the Secretary provides to the State and to Congress a written statement describing compelling reasons that exist for renewing or extending the agreement despite the prohibited affiliations.

(4) Nothing in this section must be construed to limit or otherwise affect any remedies available to the U.S. under sections 1128, 1128A or 1128B of the Act.

(e) *Consultation with the Inspector General.* Any action by the Secretary described in paragraphs (d)(2) or (3) of this section is taken in consultation with the Inspector General.

Subpart I—Sanctions

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

§ 438.700 Basis for imposition of sanctions.

(a) Each State that contracts with an MCO must, and each State that contracts with a PCCM or PCCM entity may, establish intermediate sanctions (which may include those specified in § 438.702) that it may impose if it makes any of the determinations specified in

paragraphs (b) through (d) of this section. The State may base its determinations on findings from onsite surveys, enrollee or other complaints, financial status, or any other source.

(b) A State determines that an MCO acts or fails to act as follows:

(1) Fails substantially to provide medically necessary services that the MCO is required to provide, under law or under its contract with the State, to an enrollee covered under the contract.

(2) Imposes on enrollees premiums or charges that are in excess of the premiums or charges permitted under the Medicaid program.

(3) Acts to discriminate among enrollees on the basis of their health status or need for health care services. This includes termination of enrollment or refusal to reenroll a beneficiary, except as permitted under the Medicaid program, or any practice that would reasonably be expected to discourage enrollment by beneficiaries whose medical condition or history indicates probable need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes to CMS or to the State.

(5) Misrepresents or falsifies information that it furnishes to an enrollee, potential enrollee, or health care provider.

(6) Fails to comply with the requirements for physician incentive plans, as set forth (for Medicare) in §§ 422.208 and 422.210 of this chapter.

(c) A State determines that an MCO, PCCM or PCCM entity has distributed directly, or indirectly through any agent or independent contractor, marketing materials that have not been approved by the State or that contain false or materially misleading information.

(d) A State determines that—

(1) An MCO has violated any of the other requirements of sections 1903(m) or 1932 of the Act, or any implementing regulations.

(2) A PCCM or PCCM entity has violated any of the other applicable requirements of sections 1932 or 1905(t)(3) of the Act, or any implementing regulations.

(3) For any of the violations under paragraphs (d)(1) and (2) of this section, only the sanctions specified in § 438.702(a)(3), (4), and (5) may be imposed.

§ 438.702 Types of intermediate sanctions.

(a) The types of intermediate sanctions that a State may impose under this subpart include the following:

(1) Civil money penalties in the amounts specified in § 438.704.

(2) Appointment of temporary management for an MCO as provided in § 438.706.

(3) Granting enrollees the right to terminate enrollment without cause and notifying the affected enrollees of their right to disenroll.

(4) Suspension of all new enrollment, including default enrollment, after the date the Secretary or the State notifies the MCO of a determination of a violation of any requirement under sections 1903(m) or 1932 of the Act.

(5) Suspension of payment for beneficiaries enrolled after the effective date of the sanction and until CMS or the State is satisfied that the reason for imposition of the sanction no longer exists and is not likely to recur.

(b) State agencies retain authority to impose additional sanctions under State statutes or State regulations that address areas of noncompliance specified in § 438.700, as well as additional areas of noncompliance. Nothing in this subpart prevents State agencies from exercising that authority.

§ 438.704 Amounts of civil money penalties.

(a) *General rule.* If the State imposes civil monetary penalties as provided under § 438.702(a)(1), the maximum civil money penalty the State may impose varies depending on the nature of the MCO's, PCCM or PCCM entity's action or failure to act, as provided in this section.

(b) *Specific limits.* (1) The limit is $25,000 for each determination under § 438.700(b)(1), (5), (6), and (c).

(2) The limit is $100,000 for each determination under § 438.700(b)(3) or (4).

(3) The limit is $15,000 for each beneficiary the State determines was not enrolled because of a discriminatory practice under § 438.700(b)(3). (This is

subject to the overall limit of $100,000 under paragraph (b)(2) of this section).

(c) *Specific amount.* For premiums or charges in excess of the amounts permitted under the Medicaid program, the maximum amount of the penalty is $25,000 or double the amount of the excess charges, whichever is greater. The State must deduct from the penalty the amount of overcharge and return it to the affected enrollees.

§ 438.706 Special rules for temporary management.

(a) *Optional imposition of sanction.* If the State imposes temporary management under § 438.702(a)(2), the State may do so only if it finds (through onsite surveys, enrollee or other complaints, financial status, or any other source) any of the following:

(1) There is continued egregious behavior by the MCO, including but not limited to behavior that is described in § 438.700, or that is contrary to any requirements of sections 1903(m) and 1932 of the Act.

(2) There is substantial risk to enrollees' health.

(3) The sanction is necessary to ensure the health of the MCO's enrollees—

(i) While improvements are made to remedy violations under § 438.700.

(ii) Until there is an orderly termination or reorganization of the MCO.

(b) *Required imposition of sanction.* The State must impose temporary management (regardless of any other sanction that may be imposed) if it finds that an MCO has repeatedly failed to meet substantive requirements in sections 1903(m) or 1932 of the Act, or this subpart. The State must also grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3), and must notify the affected enrollees of their right to terminate enrollment.

(c) *Hearing.* The State may not delay imposition of temporary management to provide a hearing before imposing this sanction.

(d) *Duration of sanction.* The State may not terminate temporary management until it determines that the MCO can ensure that the sanctioned behavior will not recur.

§ 438.708 Termination of an MCO, PCCM or PCCM entity contract.

A State has the authority to terminate an MCO, PCCM or PCCM entity contract and enroll that entity's enrollees in other MCOs, PCCMs or PCCM entities, or provide their Medicaid benefits through other options included in the State plan, if the State determines that the MCO, PCCM or PCCM entity has failed to do either of the following:

(a) Carry out the substantive terms of its contract.

(b) Meet applicable requirements in sections 1932, 1903(m), and 1905(t) of the Act.

§ 438.710 Notice of sanction and pre-termination hearing.

(a) *Notice of sanction.* Except as provided in § 438.706(c), before imposing any of the intermediate sanctions specified in this subpart, the State must give the affected entity timely written notice that explains the following:

(1) The basis and nature of the sanction.

(2) Any other appeal rights that the State elects to provide.

(b) *Pre-termination hearing*—(1) *General rule.* Before terminating an MCO, PCCM or PCCM entity contract under § 438.708, the State must provide the entity a pre-termination hearing.

(2) *Procedures.* The State must do all of the following:

(i) Give the MCO, PCCM or PCCM entity written notice of its intent to terminate, the reason for termination, and the time and place of the hearing.

(ii) After the hearing, give the entity written notice of the decision affirming or reversing the proposed termination of the contract and, for an affirming decision, the effective date of termination.

(iii) For an affirming decision, give enrollees of the MCO, PCCM or PCCM entity notice of the termination and information, consistent with § 438.10, on their options for receiving Medicaid services following the effective date of termination.

§ 438.722 Disenrollment during termination hearing process.

After a State notifies an MCO, PCCM or PCCM entity that it intends to terminate the contract, the State may do the following:

(a) Give the entity's enrollees written notice of the State's intent to terminate the contract.

(b) Allow enrollees to disenroll immediately without cause.

§ 438.724 Notice to CMS.

(a) The State must give CMS written notice whenever it imposes or lifts a sanction for one of the violations listed in § 438.700.

(b) The notice must adhere to all of the following requirements:

(1) Be given no later than 30 days after the State imposes or lifts a sanction.

(2) Specify the affected MCO, the kind of sanction, and the reason for the State's decision to impose or lift a sanction.

§ 438.726 State plan requirement.

(a) The State plan must include a plan to monitor for violations that involve the actions and failures to act specified in this part and to implement the provisions of this part.

(b) A contract with an MCO must provide that payments provided for under the contract will be denied for new enrollees when, and for so long as, payment for those enrollees is denied by CMS under § 438.730(e).

§ 438.730 Sanction by CMS: Special rules for MCOs.

(a) *Basis for sanction.* A State may recommend that CMS impose the denial of payment sanction specified in paragraph (e) of this section on an MCO with a contract under this part if the agency determines that the MCO acts or fails to act as specified in § 438.700(b)(1) through (6).

(b) *Effect of an agency determination.* (1) The State's determination becomes CMS' determination for purposes of section 1903(m)(5)(A) of the Act unless CMS reverses or modifies it within 15 days.

(2) When the State decides to recommend imposing the sanction described in paragraph (e) of this section, this recommendation becomes CMS' decision, for purposes of section 1903(m)(5)(B)(ii) of the Act, unless CMS rejects this recommendation within 15 days.

(c) *Notice of sanction.* If the State's determination becomes CMS' determination under paragraph (b)(2) of this section, the State takes all of the following actions:

(1) Gives the MCO written notice of the nature and basis of the proposed sanction.

(2) Allows the MCO 15 days from the date it receives the notice to provide evidence that it has not acted or failed to act in the manner that is the basis for the recommended sanction.

(3) May extend the initial 15-day period for an additional 15 days if—

(i) The MCO submits a written request that includes a credible explanation of why it needs additional time.

(ii) The request is received by CMS before the end of the initial period.

(iii) CMS has not determined that the MCO's conduct poses a threat to an enrollee's health or safety.

(d) *Informal reconsideration.* (1) If the MCO submits a timely response to the notice of sanction, the State—

(i) Conducts an informal reconsideration that includes review of the evidence by a State agency official who did not participate in the original recommendation.

(ii) Gives the MCO a concise written decision setting forth the factual and legal basis for the decision.

(iii) Forwards the decision to CMS.

(2) The State's decision under paragraph (d)(1)(ii) of this section becomes CMS' decision unless CMS reverses or modifies the decision within 15 days from date of receipt by CMS.

(3) If CMS reverses or modifies the State decision, the agency sends the MCO a copy of CMS' decision.

(e) *Denial of payment.* (1) CMS, based upon the recommendation of the agency, may deny payment to the State for new enrollees of the MCO under section 1903(m)(5)(B)(ii) of the Act in the following situations:

(i) If a CMS determination that an MCO has acted or failed to act, as described in paragraphs (b)(1) through (6) of § 438.700, is affirmed on review under paragraph (d) of this section.

(ii) If the CMS determination is not timely contested by the MCO under paragraph (c) of this section.

(2) Under § 438.726(b), CMS' denial of payment for new enrollees automatically results in a denial of agency payments to the MCO for the same enrollees. (A new enrollee is an enrollee that applies for enrollment after the effective date in paragraph (f)(1) of this section.)

(f) *Effective date of sanction.* (1) If the MCO does not seek reconsideration, a sanction is effective 15 days after the date the MCO is notified under paragraph (c) of this section of the decision to impose the sanction.

(2) If the MCO seeks reconsideration, the following rules apply:

(i) Except as specified in paragraph (d)(2) of this section, the sanction is effective on the date specified in CMS' reconsideration notice.

(ii) If CMS, in consultation with the State, determines that the MCO's conduct poses a serious threat to an enrollee's health or safety, the sanction may be made effective earlier than the date of the agency's reconsideration decision under paragraph (d)(1)(ii) of this section.

(g) *CMS' role.* (1) CMS retains the right to independently perform the functions assigned to the State under paragraphs (a) through (d) of this section.

(2) At the same time that the State sends notice to the MCO under paragraph (c)(1) of this section, CMS forwards a copy of the notice to the OIG.

(3) CMS conveys the determination described in paragraph (b) of this section to the OIG for consideration of possible imposition of civil money penalties under section 1903(m)(5)(A) of the Act and part 1003 of this title. In accordance with the provisions of part 1003, the OIG may impose civil money penalties on the MCO in addition to, or in place of, the sanctions that may be imposed under this section.

Subpart J—Conditions for Federal Financial Participation (FFP)

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

§ 438.802 Basic requirements.

FFP is available in expenditures for payments under an MCO contract only for the periods during which the contract—

(a) Meets the requirements of this part; and

(b) Is in effect.

§ 438.806 Prior approval.

(a) *Comprehensive risk contracts.* FFP is available under a comprehensive risk contract only if all of the following apply:

(1) CMS has confirmed that the contractor meets the definition of an MCO or is one of the entities described in paragraphs (b)(2) through (5) of § 438.3.

(2) The contract meets all the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of section 1932 of the Act, and the provisions of this part.

(b) *MCO contracts.* Prior approval by CMS is a condition for FFP under any MCO contract that extends for less than one full year or that has a value equal to, or greater than, the following threshold amounts:

(1) For 1998, the threshold is $1,000,000.

(2) For subsequent years, the amount is increased by the percentage increase in the consumer price index for all urban consumers.

(c) FFP is not available in an MCO contract that does not have prior approval from CMS under paragraph (b) of this section.

§ 438.808 Exclusion of entities.

(a) *General rule.* FFP is available in payments under MCO contracts or PIHP, PAHP, PCCM, or PCCM entity contracts under a section 1915(b)(1) of the Act waiver only if the State excludes from the contracts any entities described in paragraph (b) of this section.

(b) *Entities that must be excluded.* (1) An entity that could be excluded under section 1128(b)(8) of the Act as being controlled by a sanctioned individual.

(2) An entity that has a substantial contractual relationship as defined in § 431.55(h)(3) of this chapter, either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the

Act or an individual described in § 438.610(a) and (b).

(3) An entity that employs or contracts, directly or indirectly, for the furnishing of health care, utilization review, medical social work, or administrative services, with one of the following:

(i) Any individual or entity described in § 438.610(a) and (b).

(ii) Any individual or entity that would provide those services through an individual or entity described in § 438.610(a) and (b).

§ 438.810 Expenditures for enrollment broker services.

(a) *Definitions.* As used in this section—

Enrollment activities means activities such as distributing, collecting, and processing enrollment materials and taking enrollments by phone, in person, or through electronic methods of communication.

Enrollment broker means an individual or entity that performs choice counseling or enrollment activities, or both.

Enrollment services means choice counseling, or enrollment activities, or both.

(b) *Conditions that enrollment brokers must meet.* State expenditures for the use of enrollment brokers are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if the broker and its subcontractors meet the following conditions:

(1) *Independence.* The broker and its subcontractors are independent of any MCO, PIHP, PAHP, PCCM, PCCM entity or other health care provider in the State in which they provide enrollment services. A broker or subcontractor is not considered ''independent'' if it—

(i) Is an MCO, PIHP, PAHP, PCCM, PCCM entity or other health care provider in the State;

(ii) Is owned or controlled by an MCO, PIHP, PAHP, PCCM, PCCM entity or other health care provider in the State; or

(iii) Owns or controls an MCO, PIHP, PAHP, PCCM, PCCM entity, or other health care provider in the State.

(2) *Freedom from conflict of interest.* The broker and its subcontractor are free from conflict of interest. A broker or subcontractor is not considered free from conflict of interest if any person who is the owner, employee, or consultant of the broker or subcontractor or has any contract with them—

(i) Has any direct or indirect financial interest in any entity or health care provider that furnishes services in the State in which the broker or subcontractor provides enrollment services;

(ii) Has been excluded from participation under Title XVIII or XIX of the Act;

(iii) Has been debarred by any Federal agency; or

(iv) Has been, or is now, subject to civil money penalties under the Act.

(3) *Approval.* The initial contract or memorandum of agreement (MOA) for services performed by the broker has been reviewed and approved by CMS.

§ 438.812 Costs under risk and nonrisk contracts.

(a) Under a risk contract, the total amount the State agency pays for carrying out the contract provisions is a medical assistance cost.

(b) Under a nonrisk contract—

(1) The amount the State agency pays for the furnishing of medical services to eligible beneficiaries is a medical assistance cost; and

(2) The amount the State agency pays for the contractor's performance of other functions is an administrative cost.

§ 438.816 Expenditures for the beneficiary support system for enrollees using LTSS.

State expenditures for the person or entity providing the services outlined in § 438.71(d) are considered necessary for the proper and efficient operation of the State plan and thus eligible for FFP only if all of the following conditions are met:

(a) Costs must be supported by an allocation methodology that appears in the State's approved Public Assistance Cost Allocation Plan in § 433.34 of this chapter.

(b) The costs do not duplicate payment for activities that are already being offered or should be provided by other entities or paid by other programs.

(c) The person or entity providing the services must meet the requirements in § 438.810(b)(1) and (2).

(d) The initial contract or MOA for services performed has been reviewed and approved by CMS.

§ 438.818 Enrollee encounter data.

(a) FFP is available for expenditures under an MCO, PIHP, or PAHP contract only if the State meets the following conditions for providing enrollee encounter data to CMS:

(1) Enrollee encounter data reports must comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) security and privacy standards and be submitted in the format required by the Medicaid Statistical Information System or format required by any successor system to the Medicaid Statistical Information System.

(2) States must ensure that enrollee encounter data is validated for accuracy and completeness as required under § 438.242 before submitting data to CMS. States must also validate that the data submitted to CMS is a complete and accurate representation of the information submitted to the State by the MCOs, PIHPs, and PAHPs.

(3) States must cooperate with CMS to fully comply with all encounter data reporting requirements of the Medicaid Statistical Information System or any successor system.

(b) CMS will assess a State's submission to determine if it complies with current criteria for accuracy and completeness.

(c) If, after being notified of compliance issues under paragraph (b) of this section the State is unable to make a data submission compliant, CMS will take appropriate steps to defer and/or disallow FFP on all or part of an MCO, PIHP, or PAHP contract in a manner based on the enrollee and specific service type of the noncompliant data. Any deferral and/or disallowance of FFP will be effectuated utilizing the processes specified in §§ 430.40 and 430.42 of this chapter.

Subpart K—Parity in Mental Health and Substance Use Disorder Benefits

SOURCE: 81 FR 18436, Mar. 30, 2016, unless otherwise noted.

§ 438.900 Meaning of terms.

For purposes of this subpart, except where the context clearly indicates otherwise, the following terms have the meanings indicated:

Aggregate lifetime dollar limit means a dollar limitation on the total amount of specified benefits that may be paid under a MCO, PIHP, or PAHP.

Annual dollar limit means a dollar limitation on the total amount of specified benefits that may be paid in a 12-month period under a MCO, PIHP, or PAHP.

Cumulative financial requirements are financial requirements that determine whether or to what extent benefits are provided based on accumulated amounts and include deductibles and out-of-pocket maximums. (However, cumulative financial requirements do not include aggregate lifetime or annual dollar limits because these two terms are excluded from the meaning of financial requirements.)

Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits are benefits defined in section 1905(r) of the Act.

Financial requirements include deductibles, copayments, coinsurance, or out-of-pocket maximums. Financial requirements do not include aggregate lifetime or annual dollar limits.

Medical/surgical benefits means benefits for items or services for medical conditions or surgical procedures, as defined by the State and in accordance with applicable Federal and State law, but do not include mental health or substance use disorder benefits. Any condition defined by the State as being or as not being a medical/surgical condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the International Classification of Diseases (ICD) or State guidelines). Medical/surgical benefits include long term care services.

Mental health benefits means benefits for items or services for mental health conditions, as defined by the State and in accordance with applicable Federal and State law. Any condition defined by the State as being or as not being a mental health condition must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the Diagnostic and Statistical Manual of Mental Disorders (DSM), the most current version of the ICD, or State guidelines). Mental health benefits include long term care services.

Substance use disorder benefits means benefits for items or services for substance use disorders, as defined by the State and in accordance with applicable Federal and State law. Any disorder defined by the State as being or as not being a substance use disorder must be defined to be consistent with generally recognized independent standards of current medical practice (for example, the most current version of the DSM, the most current version of the ICD, or State guidelines). Substance use disorder benefits include long term care services.

Treatment limitations include limits on benefits based on the frequency of treatment, number of visits, days of coverage, days in a waiting period, or other similar limits on the scope or duration of treatment. Treatment limitations include both quantitative treatment limitations, which are expressed numerically (such as 50 outpatient visits per year), and nonquantitative treatment limitations, which otherwise limit the scope or duration of benefits for treatment under a plan or coverage. (*See* § 438.910(d)(2) for an illustrative list of nonquantitative treatment limitations.) A permanent exclusion of all benefits for a particular condition or disorder, however, is not a treatment limitation for purposes of this definition.

§ 438.905 Parity requirements for aggregate lifetime and annual dollar limits.

(a) *General parity requirement.* Each MCO, PIHP, and PAHP providing services to MCO enrollees must comply with paragraphs (b), (c), or (e) of this section for all enrollees of a MCO in States that cover both medical/surgical benefits and mental health or substance use disorder benefits under the State plan. This section details the application of the parity requirements for aggregate lifetime and annual dollar limits.

(b) *MCOs, PIHPs, or PAHPs with no limit or limits on less than one-third of all medical/surgical benefits.* If a MCO, PIHP, or PAHP does not include an aggregate lifetime or annual dollar limit on any medical/surgical benefits or includes an aggregate lifetime or annual dollar limit that applies to less than one-third of all medical/surgical benefits provided to enrollees through a contract with the State, it may not impose an aggregate lifetime or annual dollar limit, respectively, on mental health or substance use disorder benefits.

(c) *MCOs, PIHPs, or PAHPs with a limit on at least two-thirds of all medical/surgical benefits.* If a MCO, PIHP, or PAHP includes an aggregate lifetime or annual dollar limit on at least two-thirds of all medical/surgical benefits provided to enrollees through a contract with the State, it must either—

(1) Apply the aggregate lifetime or annual dollar limit both to the medical/surgical benefits to which the limit would otherwise apply and to mental health or substance use disorder benefits in a manner that does not distinguish between the medical/surgical benefits and mental health or substance use disorder benefits; or

(2) Not include an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is more restrictive than the aggregate lifetime or annual dollar limit, respectively, on medical/surgical benefits.

(d) *Determining one-third and two-thirds of all medical/surgical benefits.* For purposes of this section, the determination of whether the portion of medical/surgical benefits subject to an aggregate lifetime or annual dollar limit represents one-third or two-thirds of all medical/surgical benefits is based on the total dollar amount of all combinations of MCO, PIHP, and PAHP payments for medical/surgical benefits expected to be paid under the MCO, PIHP, or PAHP for a contract year (or

for the portion of a contract year after a change in benefits that affects the applicability of the aggregate lifetime or annual dollar limits). Any reasonable method may be used to determine whether the dollar amount expected to be paid under the MCOs, PIHPs, and PAHPs will constitute one-third or two-thirds of the dollar amount of all payments for medical/surgical benefits.

(e) *MCO, PIHP, or PAHP not described in this section*—(1) *In general.* A MCO, PIHP, or PAHP that is not described in paragraph (b) or (c) of this section for aggregate lifetime or annual dollar limits on medical/surgical benefits, must either—

(i) Impose no aggregate lifetime or annual dollar limit, on mental health or substance use disorder benefits; or

(ii) Impose an aggregate lifetime or annual dollar limit on mental health or substance use disorder benefits that is no more restrictive than an average limit calculated for medical/surgical benefits in the following manner. The average limit is calculated by taking into account the weighted average of the aggregate lifetime or annual dollar limits, as appropriate, that are applicable to the categories of medical/surgical benefits. Limits based on delivery mechanisms, such as inpatient/outpatient treatment or normal treatment of common, low-cost conditions (such as treatment of normal births), do not constitute categories for purposes of this paragraph (e)(1)(ii). In addition, for purposes of determining weighted averages, any benefits that are not within a category that is subject to a separately-designated dollar limit under the contract are taken into account as a single separate category by using an estimate of the upper limit on the dollar amount that a MCO, PIHP, or PAHP may reasonably be expected to incur for such benefits, taking into account any other applicable restrictions.

(2) *Weighting.* For purposes of this paragraph (e), the weighting applicable to any category of medical/surgical benefits is determined in the manner set forth in paragraph (d) of this section for determining one-third or two-thirds of all medical/surgical benefits.

§ 438.910 Parity requirements for financial requirements and treatment limitations.

(a) *Clarification of terms*—(1) *Classification of benefits.* When reference is made in this section to a classification of benefits, the term ''classification'' means a classification as described in paragraph (b)(2) of this section.

(2) *Type of financial requirement or treatment limitation.* When reference is made in this section to a type of financial requirement or treatment limitation, the reference to type means its nature. Different types of financial requirements include deductibles, copayments, coinsurance, and out-of-pocket maximums. Different types of quantitative treatment limitations include annual, episode, and lifetime day and visit limits. *See* paragraph (d)(2) of this section for an illustrative list of nonquantitative treatment limitations.

(3) *Level of a type of financial requirement or treatment limitation.* When reference is made in this section to a level of a type of financial requirement or treatment limitation, level refers to the magnitude of the type of financial requirement or treatment limitation.

(b) *General parity requirement*—(1) *General rule and scope.* Each MCO, PIHP and PAHP providing services to MCO enrollees in a State that covers both medical/surgical benefits and mental health or substance use disorder benefits under the State plan, must not apply any financial requirement or treatment limitation to mental health or substance use disorder benefits in any classification that is more restrictive than the predominant financial requirement or treatment limitation of that type applied to substantially all medical/surgical benefits in the same classification furnished to enrollees (whether or not the benefits are furnished by the same MCO, PIHP, or PAHP). Whether a financial requirement or treatment limitation is a predominant financial requirement or treatment limitation that applies to substantially all medical/surgical benefits in a classification is determined separately for each type of financial requirement or treatment limitation. The application of the rules of this paragraph (b) to financial requirements and quantitative treatment limitations

is addressed in paragraph (c) of this section; the application of the rules of this paragraph (b) to nonquantitative treatment limitations is addressed in paragraph (d) of this section.

(2) *Classifications of benefits used for applying rules.* If an MCO enrollee is provided mental health or substance use disorder benefits in any classification of benefits described in this paragraph (b)(2), mental health or substance use disorder benefits must be provided to the enrollee in every classification in which medical/surgical benefits are provided. In determining the classification in which a particular benefit belongs, a MCO, PIHP, or PAHP must apply the same reasonable standards to medical/surgical benefits and to mental health or substance use disorder benefits. To the extent that a MCO, PIHP, or PAHP provides benefits in a classification and imposes any separate financial requirement or treatment limitation (or separate level of a financial requirement or treatment limitation) for benefits in the classification, the rules of this section apply separately for that classification for all financial requirements or treatment limitations. The following classifications of benefits are the only classifications used in applying the rules of this section:

(i) *Inpatient.* Benefits furnished on an inpatient basis.

(ii) *Outpatient.* Benefits furnished on an outpatient basis. *See* special rules for office visits in paragraph (c)(2) of this section.

(iii) *Emergency care.* Benefits for emergency care.

(iv) *Prescription drugs.* Benefits for prescription drugs. *See* special rules for multi-tiered prescription drug benefits in paragraph (c)(2) of this section.

(c) *Financial requirements and quantitative treatment limitations*—(1) *Determining ''substantially all'' and ''predominant''*—(i) *Substantially all.* For purposes of this section, a type of financial requirement or quantitative treatment limitation is considered to apply to substantially all medical/surgical benefits in a classification of benefits if it applies to at least two-thirds of all medical/surgical benefits in that classification. If a type of financial requirement or quantitative treatment limitation does not apply to at least two-thirds of all medical/surgical benefits in a classification, then that type cannot be applied to mental health or substance use disorder benefits in that classification.

(ii) *Predominant.* (A) If a type of financial requirement or quantitative treatment limitation applies to at least two-thirds of all medical/surgical benefits in a classification as determined under paragraph (c)(1)(i) of this section, the level of the financial requirement or quantitative treatment limitation that is considered the predominant level of that type in a classification of benefits is the level that applies to more than one-half of medical/surgical benefits in that classification subject to the financial requirement or quantitative treatment limitation.

(B) If, for a type of financial requirement or quantitative treatment limitation that applies to at least two-thirds of all medical/surgical benefits in a classification, there is no single level that applies to more than one-half of medical/surgical benefits in the classification subject to the financial requirement or quantitative treatment limitation, the MCO, PIHP, or PAHP may combine levels until the combination of levels applies to more than one-half of medical/surgical benefits subject to the financial requirement or quantitative treatment limitation in the classification. The least restrictive level within the combination is considered the predominant level of that type in the classification. (For this purpose, a MCO, PIHP, or PAHP may combine the most restrictive levels first, with each less restrictive level added to the combination until the combination applies to more than one-half of the benefits subject to the financial requirement or treatment limitation.)

(iii) *Portion based on MCO, PIHP or PAHP payments.* For purposes of this section, the determination of the portion of medical/surgical benefits in a classification of benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation) is based on the total dollar amount of all combinations of MCO, PIHP, and PAHP payments for medical/surgical benefits

in the classification expected to be paid under the MCOs, PIHPs, and PAHPs for a contract year (or for the portion of a contract year after a change in benefits that affects the applicability of the financial requirement or quantitative treatment limitation).

(iv) *Clarifications for certain threshold requirements.* For any deductible, the dollar amount of MCO, PIHP, or PAHP payments includes all payments for claims that would be subject to the deductible if it had not been satisfied. For any out-of-pocket maximum, the dollar amount of MCO, PIHP, or PAHP payments includes all payments associated with out-of-pocket payments that are taken into account towards the out-of-pocket maximum as well as all payments associated with out-of-pocket payments that would have been made towards the out-of-pocket maximum if it had not been satisfied. Similar rules apply for any other thresholds at which the rate of MCO, PIHP, or PAHP payment changes.

(v) *Determining the dollar amount of MCO, PIHP, or PAHP payments.* Subject to paragraph (c)(1)(iv) of this section, any reasonable method may be used to determine the dollar amount expected to be paid under a MCO, PIHP, or PAHP for medical/surgical benefits subject to a financial requirement or quantitative treatment limitation (or subject to any level of a financial requirement or quantitative treatment limitation).

(2) *Special rules*—(i) *Multi-tiered prescription drug benefits.* If a MCO, PIHP, or PAHP applies different levels of financial requirements to different tiers of prescription drug benefits based on reasonable factors determined in accordance with the rules in paragraph (d)(1) of this section (relating to requirements for nonquantitative treatment limitations) and without regard to whether a drug is generally prescribed for medical/surgical benefits or for mental health or substance use disorder benefits, the MCO, PIHP, or PAHP satisfies the parity requirements of this section for prescription drug benefits. Reasonable factors include cost, efficacy, generic versus brand name, and mail order versus pharmacy pick-up/delivery.

(ii) *Sub-classifications permitted for office visits, separate from other outpatient services.* For purposes of applying the financial requirement and treatment limitation rules of this section, a MCO, PIHP, or PAHP may divide its benefits furnished on an outpatient basis into the two sub-classifications described in this paragraph (c)(2)(ii). After the sub-classifications are established, the MCO, PIHP or PAHP may not impose any financial requirement or quantitative treatment limitation on mental health or substance use disorder benefits in any sub-classification that is more restrictive than the predominant financial requirement or quantitative treatment limitation that applies to substantially all medical/surgical benefits in the sub-classification using the methodology set forth in paragraph (c)(1) of this section. Sub-classifications other than these special rules, such as separate sub-classifications for generalists and specialists, are not permitted. The two sub-classifications permitted under this paragraph (c)(2)(ii) are:

(A) Office visits (such as physician visits); and

(B) All other outpatient items and services (such as outpatient surgery, facility charges for day treatment centers, laboratory charges, or other medical items).

(3) *No separate cumulative financial requirements.* A MCO, PIHP, or PAHP may not apply any cumulative financial requirement for mental health or substance use disorder benefits in a classification that accumulates separately from any established for medical/surgical benefits in the same classification.

(4) *Compliance with other cost-sharing rules.* Each MCO, PIHP, and PAHP must meet the cost-sharing requirements in §438.108 when applying Medicaid cost-sharing.

(d) *Nonquantitative treatment limitations*—(1) *General rule.* A MCO, PIHP, or PAHP may not impose a nonquantitative treatment limitation for mental health or substance use disorder benefits in any classification unless, under the policies and procedures of the MCO, PIHP, or PAHP as written and in operation, any processes, strategies, evidentiary standards, or other factors

used in applying the nonquantitative treatment limitation to mental health or substance use disorder benefits in the classification are comparable to, and are applied no more stringently than, the processes, strategies, evidentiary standards, or other factors used in applying the limitation for medical/surgical benefits in the classification.

(2) *Illustrative list of nonquantitative treatment limitations.* Nonquantitative treatment limitations include –

(i) Medical management standards limiting or excluding benefits based on medical necessity or medical appropriateness, or based on whether the treatment is experimental or investigative;

(ii) Formulary design for prescription drugs;

(iii) For MCOs, PIHPs, or PAHPs with multiple network tiers (such as preferred providers and participating providers), network tier design;

(iv) Standards for provider admission to participate in a network, including reimbursement rates;

(v) MCO, PIHP, or PAHP methods for determining usual, customary, and reasonable charges;

(vi) Refusal to pay for higher-cost therapies until it can be shown that a lower-cost therapy is not effective (also known as fail-first policies or step therapy protocols);

(vii) Exclusions based on failure to complete a course of treatment;

(viii) Restrictions based on geographic location, facility type, provider specialty, and other criteria that limit the scope or duration of benefits for services provided under the MCO, PIHP, or PAHP; and

(ix) Standards for providing access to out-of-network providers.

(3) *Application to out-of-network providers.* Any MCO, PIHP or PAHP providing access to out-of-network providers for medical/surgical benefits within a classification, must use processes, strategies, evidentiary standards, or other factors in determining access to out-of-network providers for mental health or substance use disorder benefits that are comparable to, and applied no more stringently than, the processes, strategies, evidentiary standards, or other factors in determining access to out-of-network providers for medical/surgical benefits.

§ 438.915 Availability of information.

(a) *Criteria for medical necessity determinations.* The criteria for medical necessity determinations, made by a MCO or by a PIHP or PAHP providing services to an MCO enrollee, for mental health or substance use disorder benefits must be made available by the MCO, PIHP, or PAHP administrator to any enrollee, potential enrollee, or contracting provider upon request. MCOs, PIHPs, and PAHPs operating in compliance with §438.236(c) will be deemed compliant with the requirements in this paragraph (a).

(b) *Reason for any denial.* The reason for any denial by a MCO, PIHP, or PAHP of reimbursement or payment for services for mental health or substance use disorder benefits in the case of any enrollee must be made available by the MCO, PIHP, or PAHP administrator to the enrollee.

(c) *Provisions of other law.* Compliance with the disclosure requirements in paragraphs (a) and (b) of this section is not determinative of compliance with any other provision of applicable Federal or State law.

§ 438.920 Applicability.

(a) *MCOs, PIHPs, and PAHPs.* The requirements of this subpart apply to each MCO, PIHP, and PAHP offering services to enrollees of a MCO, in States covering medical/surgical and mental health or substance use disorder services under the State plan. These requirements regarding coverage for services that must be provided to enrollees of an MCO apply regardless of the delivery system of the medical/surgical, mental health, or substance use disorder services under the State plan.

(b) *State responsibilities.* (1) In any instance where the full scope of medical/surgical and mental health and substance use disorder services are not provided through the MCO, the State must review the mental health and substance use disorder and medical/surgical benefits provided through the MCO, PIHP, PAHP, and fee-for service (FFS) coverage to ensure the full scope of services available to all enrollees of

the MCO complies with the requirements in this subpart. The State must provide documentation of compliance with requirements in this subpart to the general public and post this information on the State Medicaid Web site by October 2, 2017. Such documentation must be updated prior to any change in MCO, PIHP, PAHP or FFS State plan benefits.

(2) The State must ensure that all services are delivered to the enrollees of the MCO in compliance with this subpart.

(c) *Scope.* This subpart does not—

(1) Require a MCO, PIHP, or PAHP to provide any mental health benefits or substance use disorder benefits beyond what is specified in its contract, and the provision of benefits by a MCO, PIHP, or PAHP for one or more mental health conditions or substance use disorders does not require the MCO, PIHP or PAHP to provide benefits for any other mental health condition or substance use disorder;

(2) Require a MCO, PIHP, or PAHP that provides coverage for mental health or substance use disorder benefits only to the extent required under 1905(a)(4)(D) of the Act to provide additional mental health or substance use disorder benefits in any classification in accordance with this section; or

(3) Affect the terms and conditions relating to the amount, duration, or scope of mental health or substance use disorder benefits under the Medicaid MCO, PIHP, or PAHP contract except as specifically provided in §§ 438.905 and 438.910.

§ 438.930 Compliance dates.

In general, contracts with MCOs, PIHPs, and PAHPs offering Medicaid State plan services to enrollees, and those entities, must comply with the requirements of this subpart no later than October 2, 2017.

PART 440—SERVICES: GENERAL PROVISIONS

Subpart A—Definitions

Sec.

Subpart B—Requirements and Limits Applicable to All Services