

**Medicaid Managed Care Proposed Changes to 42 C.F.R. Part 438  
Introduced by CMS May 26, 2015**

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**§ 438.1 Basis and scope.**

(a) Statutory basis. This part is based on the following statutory sections ~~1902(a)(4), 1903(m), 1905(t), and 1932 of the Act.~~

(1) Section 1902(a)(4) 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).

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

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

~~(34)~~ Section 1903(m)(2)(H) 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.

~~(45)~~ Section 1905(t) contains requirements that apply to PCCMs.

~~(56)~~ Section 1932—

(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~~;~~ and.

(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, ~~and~~ 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—

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 ~~agency~~ 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 ~~medical~~ services under the State plan. The State ~~agency~~ 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 health 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.

Health care professional means a physician or ~~any of the following: a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist, therapist assistant, speechlanguage pathologist, audiologist, registered or practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.~~ [a provider, if coverage for the physician's or provider's services is under the managed care contract.](#)

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(~~ec~~)(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).

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 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 section 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 health care professional, group of health care professionals, or entity that 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.

Non-risk 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.

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 ~~medical~~ services to enrollees under contract with the State ~~agency~~, and on the basis of ~~prepaid~~ 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 ~~medical~~ services to enrollees under contract with the State ~~agency~~, and on the basis of ~~prepaid~~ 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, ~~or~~ 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 ~~a~~

(1) A 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 behavioral health systems/providers.

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

Primary care case manager (PCCM) means a physician, a physician group practice, ~~an entity that employs or arranges with physicians to furnish primary care case management services~~ or, at State option, any of the following:

(1) A physician assistant.

(2) A nurse practitioner.

(3) A certified nurse midwife.

Rate cells 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, and region or geographic area. Each enrollee should be categorized in one of the rate cells and no enrollee should be categorized in more than one rate cell.

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.

§ ~~438.6 Contract~~ 438.3 Standard contract requirements.

(a) ~~Regional office~~ CMS review. The CMS ~~Regional Office~~ must review and approve all MCO, PIHP, and PAHP contracts, including those risk and ~~non-risk~~ nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in § 438.806. Proposed final con-tracts 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 ~~agency~~ may enter into a comprehensive risk contract only with the ~~following~~ fol-lowing:

(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 ~~added~~ amended by section 4734(2) of the Omnibus Budget Reconciliation Act of 1990).

(c) ~~Payments under risk contracts—~~ Payment. The final capitation rate for each MCO, PIHP or PAHP must be specifically identified in the applicable contract submitted for CMS review and approval. The final capitation rates must be based only upon services covered under the State plan and additional services deemed by the State to be necessary to comply with 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.

~~(1) Terminology. As used in this paragraph, the following terms have the indicated meanings:~~

~~(i) Actuarially sound capitation rates means capitation rates that—~~

~~(A) Have been developed in accordance with generally accepted actuarial principles and practices;~~

~~(B) Are appropriate for the populations to be covered, and the services to be furnished under the contract; and~~

~~(C) Have been certified, as meeting the requirements of this paragraph (c), by actuaries who meet the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.~~

~~(ii) Adjustments to smooth data means adjustments made, by cost neutral methods, across rate cells, to compensate for distortions in costs, utilization, or the number of eligible.~~

~~(iii) Cost neutral means that the mechanism used to smooth data, share risk, or adjust for risk will recognize both higher and lower expected costs and is not intended to create a net aggregate gain or loss across all payments.~~

~~(iv) Incentive arrangement means any payment mechanism under which a contractor may receive additional funds over and above the capitation rates it was paid for meeting targets specified in the contract.~~

~~(v) Risk corridor means a risk sharing mechanism in which States and contractors share in both profits and losses under the contract outside of predetermined threshold amount, so that after an initial corridor in which the contractor is responsible for all losses or retains all profits, the State contributes a portion toward any additional losses, and receives a portion of any additional profits.~~

~~(2) Basic requirements:~~

~~(i) All payments under risk contracts and all risk sharing mechanisms in contracts must be actuarially sound.~~

~~(ii) The contract must specify the payment rates and any risk sharing mechanisms, and the actuarial basis for computation of those rates and mechanisms.~~

~~(3) Requirements for actuarially sound rates. In setting actuarially sound capitation rates, the State must apply the following elements, or explain why they are not applicable:~~

~~(i) Base utilization and cost data that are derived from the Medicaid population, or if not, are adjusted to make them comparable to the Medicaid population.~~

~~(ii) Adjustments made to smooth data and adjustments to account for factors such as medical trend inflation, incomplete data, MCO, PIHP, or PAHP administration (subject to the limits in paragraph (c)(4)(ii) of this section), and utilization;~~

~~(iii) Rate cells specific to the enrolled population, by —~~

~~(A) Eligibility category;~~



~~(B) Age;~~

~~(C) Gender;~~

~~(D) Locality/region; and~~

~~(E) Risk adjustments based on diagnosis or health status (if used).~~

~~(iv) Other payment mechanisms and utilization and cost assumptions that are appropriate for individuals with chronic illness, disability, ongoing health care needs, or catastrophic claims, using risk adjustment, risk sharing, or other appropriate cost neutral methods.~~

~~(v) For rates covering CYs 2013 and 2014, complying with minimum payment for physician services under paragraph (c)(5)(vi) of this section, and part 447, subpart G, of this chapter.~~

~~(4) Documentation. The State must provide the following documentation:~~

~~(i) The actuarial certification of the capitation rates.~~

~~(ii) An assurance (in accordance with paragraph (c)(3) of this section) that all payment rates are—~~

~~(A) Based only upon services covered under the State plan (or costs directly related to providing these services, for example, MCO, PIHP, or PAHP administration).~~

~~(B) Provided under the contract to Medicaid eligible individuals.~~

~~(iii) The State's projection of expenditures under its previous year's contract (or under its FFS program if it did not have a contract in the previous year) compared to those projected under the proposed contract.~~

~~(iv) An explanation of any incentive arrangements, or stop loss, reinsurance, or any other risksharing methodologies under the contract.~~

~~(5) Special contract provisions.~~

~~(i) Contract provisions for reinsurance, stop loss limits or other risk sharing methodologies must be computed on an actuarially sound basis.~~

~~(ii) If risk corridor arrangements result in payments that exceed the approved capitation rates, these excess payments will not be considered actuarially sound to the extent that they result in total payments that exceed the amount Medicaid would have paid, on a fee for service basis, for the State plan services actually furnished to enrolled individuals, plus an amount for MCO, PIHP, or PAHP administrative costs directly related to the provision of these services.~~

~~(iii) 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.~~

~~(iv) For all incentive arrangements, the contract must provide that the arrangement is—~~

~~(A) For a fixed period of time;~~

~~(B) Not to be renewed automatically;~~

~~(C) Made available to both public and private contractors;~~

~~(D) Not conditioned on intergovernmental transfer agreements; and~~

~~(E) Necessary for the specified activities and targets.~~

~~(v) If a State makes payments to providers for graduate medical education (GME) costs under an approved State plan, the State must adjust the actuarially sound capitation rates to account for the GME payments to be made on behalf of enrollees covered under the contract, not to exceed the aggregate amount that would have been paid under the approved State plan for FFS. States must first establish actuarially sound capitation rates prior to making adjustments for GME.~~

~~(vi) For CYs 2013 and 2014, and payments to an MCO, PIHP or PAHP for primary care services furnished to enrollees under part 447, subpart G, of this chapter, the contract must require that the MCO, PIHP or PAHP meet the following requirements:~~

~~(A) Make payments to those specified physicians (whether directly or through a capitated arrangement) at least equal to the amounts set forth and required under part 447, subpart G, of this chapter.~~

~~(B) Provide documentation to the state, sufficient to enable the state and CMS to ensure that provider payments increase as required by paragraph (c)(5)(vi)(A) of this section.~~

(d) Enrollment discrimination prohibited. Contracts with MCOs, PIHPs, PAHPs, ~~and~~ 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 ~~the Regional Administrator~~ 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, ~~or~~ national origin, sex, sexual orientation, gender identity, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, sexual orientation gender identity, or disability.

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

(1) 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 ~~§ 438.6~~ paragraph (c) of this section.

(2) [Reserved]

(f) Compliance with ~~contracting rules~~ applicable laws and conflict of interest safeguards. All contracts with MCOs, PIHPs, PAHPs, PCCMs and PCCM entities must ~~meet the following provisions~~:

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

~~(2) Provide for the following:~~ 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.

~~(i) Compliance with the~~ 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 ~~subchapter.~~ chapter. MCOs, PIHPs, and PAHPs, must report all identified provider preventable conditions in a form ~~or~~ and frequency as ~~may be~~ specified by the State.

~~(3) Meet all the requirements of this section.~~ (g) Inspection and audit of financial records. Risk and access to facilities. All contracts must provide that the State ~~agency,~~ CMS, and the ~~Department may~~ Office of the Inspector General may, at any time, inspect and audit any financial 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 Medi-caid-related activities or work is conducted.

~~(h)~~ (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 “~~M+CMA~~ organization~~”~~,” “~~CMS~~,” and “Medicare beneficiaries” must be read as references to “MCO, PIHP, or PAHP~~”~~,” “~~State agency~~,” and “Medicaid beneficiaries~~”~~,” ~~respectively.~~ re-spectively.

~~(j)~~ (i) 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.

(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 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 this requirement 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.

~~(j)~~ (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 health professional. The contract must allow each enrollee to choose his or her health professional to the extent possible and appropriate.

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

(n) [Reserved]

(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 (a) of this section.

~~(k)~~ (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 ~~manager~~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 ~~reenrollment~~re-enrollment, based on the beneficiary's health status or need for health care services.

(5) Provide that enrollees have the right to dis-enroll ~~from their PCCM~~ in accordance with § 438.56(c).

~~(l) Subcontracts. All subcontracts must fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.~~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; § 438.10; and if the State's contract with the PCCM entity provides for shared savings, incentive payments or other financial reward for improved quality outcomes, § 438.330(b)(3), (c) and (e) and § 438.340, and § 438.350.

~~(m) Choice of health professional. The contract must allow each enrollee to choose his or her health professional to the extent possible and appropriate.~~

~~§ 438.8 Provisions that apply to PIHPs and PAHPs.~~

~~(a) The following requirements and options apply to PIHPs, PIHP contracts, and States with respect to PIHPs, to the same extent that they apply to MCOs, MCO contracts, and States for MCOs.~~s) Requirements for MCOs, PIHPs, or PAHPs that provide covered outpatient drugs. MCOs, PIHPs or PAHPs that are contractually obligated to provide coverage of covered outpatient drugs must include the following requirements:

(1) The ~~contract requirements of § 438.6, except for requirements that pertain to HIOs~~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 ~~information requirements in § 438.10.~~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 ~~provision against provider discrimination in § 438.12.~~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.

(4) The ~~State responsibility provisions of subpart B of this part except § 438.50.~~MCO, PIHP or PAHP must operate a drug utilization review program that complies with the requirements described in section 1927(g) of the Act, as if such requirement applied to the MCO, PIHP, or PAHP instead of the State.

(5) The MCO, 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 with Medicare for FFS, an MCO, PIHP or PAHP contract that includes responsibility for coordination of benefits for individuals dually eligible for Medicaid and Medicare must require the MCO, PIHP or PAHP to enter into a Coordination of Benefits Agreement with Medicare and participate in the automated claims crossover process.

(u) 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 receiving inpatient treatment in an Institution for Mental Diseases, as defined in § 435.1010 of this chapter, so long as the facility is an inpatient hospital facility or a sub-acute facility providing 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.

(v) 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 6 years

§ 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 do all of the following:

(1) Have been developed in accordance with standards specified in § 438.5 and generally accepted actuarial principles and practices. Any proposed differences among capitation rates according to covered populations must not be based on the Federal financial participation percentage associated with 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. Payments from any rate cell must not cross-subsidize or be cross-subsidized by payments for any other rate cell.

(5) Be certified by an actuary as meeting the applicable requirements of this part, including § 438.3(c) and (e).

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

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

(8) 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 necessary and reasonable administrative costs.

#### § 438.5 Rate development standards.

(a) Definitions. As used in this section, 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 and does not create a net aggregate gain or loss across all payments.

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 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 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; profit margin; cost of capital; or 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)(7).



(6) Consistent with paragraph (g) of this section, 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 three 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 three 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 from 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 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 appropriate and reasonable expenses related to MCO, PIHP, or PAHP administration, taxes, licensing and regulatory fees, contribution to reserves, profit margin, cost of capital, or other operational costs, consistent with § 438.3(c).

(f) Adjustments. Each adjustment must reasonably support the development of an accurate base data set for purposes of rate-setting, address appropriate programmatic changes, 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.

§ 438.6 Special contract provisions related to payment.

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

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

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

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.

(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 described in the contract.

(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. For all incentive arrangements, the contract must provide that the arrangement is

(i) For a fixed period of time.

(ii) Not to be renewed automatically.

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

(iv) Not conditioned on intergovernmental transfer agreements.

(v) Necessary for the specified activities, targets, performance measures, and quality-based outcomes that support program initiatives.

(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.

(ii) Not to be renewed automatically.

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

(iv) Not conditioned on intergovernmental transfer agreements.

(v) Necessary for the specified activities, targets, performance measures, and quality-based outcomes that support program initiatives.

(4) If a State makes payments to providers for graduate medical education (GME) costs under an approved State plan, the State must adjust the actuarially sound capitation rates to account for the GME payments to be made on behalf of enrollees covered under the contract, not to exceed the aggregate amount that would have been paid under the approved State plan for FFS. States must first establish actuarially sound capitation rates prior to making adjustments for GME.

(c) Delivery system and provider payment initiatives under MCO, PIHP, or PAHP contracts—(1) General rule. Except as specified in paragraphs (c)(1)(i) through (iii) of this section, the State may not 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 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 all providers that provide a particular service under the contract; or

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

(2) Process for approval. (i) All contract arrangements that direct the MCO's, PIHP's or PAHP's expenditures must have written approval prior to implementation. To obtain written approval, a state must demonstrate, in writing, that the arrangement

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

(B) Directs expenditures equally, and using the same terms of performance, for all public and private providers providing the service under the contract;

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

(D) Has an evaluation plan that measures the degree to which the arrangement advances at least one of the goals and objectives in the comprehensive quality strategy in § 438.340;

(E) Does not condition provider participation on intergovernmental transfer agreements; and

(F) Not to be renewed automatically.

(ii) Any contract arrangements that direct the MCO's, PIHP's or PAHP's expenditures under paragraphs (c)(1)(i) or (c)(1)(ii) must also demonstrate, in writing, that the arrangement—

(A) Must make participation in the value-based purchasing initiative, delivery system reform or performance improvement initiative available, using the same terms of performance, to all public and private providers providing services under the contract related to the reform or improvement initiative;

(B) Must use a common set of performance measures across all of the payers and providers;

(C) May not set the amount or frequency of the expenditures; and

(D) Does not allow the State to recoup any unspent funds allocated for these arrangements from the MCO, PIHP, or PAHP.

#### § 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.

(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 sufficient 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 sufficient 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.

(6) Special contract provisions. A description of any of the special contract provisions related to payment in § 438.6 that are applied in the contract.

(c) Rates paid under risk contracts. The State, through its actuary, must certify the final rate paid under each risk contract and document the underlying data, assumptions and methodologies supporting that specific 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 the rate 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 described in sufficient 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 filing requirements.

(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.

§ 438.8 Medical loss ratio (MLR) standards.

(a) Basic rule. The State must ensure, through its contracts starting on or after January 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 medical loss ratio for a partially credible MCO, PIHP, or PAHP to account for a difference between the actual and target medical loss ratios 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 medical loss ratio 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 medical loss ratio.

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 selected by the State, for which a MCO's, PIHP's, or PAHP's MLR experience is reported. This could be the contract year, calendar year, State fiscal year or Federal fiscal year, but must be consistent with the rating period used to develop the capitation rates paid to the MCO, PIHP, or PAHP.

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 medical loss ratio. An MCO, PIHP, or PAHP that is assigned no credibility (or is non-credible) will not be measured against any medical loss ratio requirements.

Non-claims cost means those expenses for administrative services that are not: Incurred claims (as defined in paragraph (e)(1) of this section); expenditures on quality improving activities (as defined in paragraph (e)(2) 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 medical loss ratio 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 medical loss ratio.

(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. (1) 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.

(2) [Reserved]

(e) Numerator. (1) 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 activities compliant with § 438.608(a)(1) through (5), (7), (8) and (b) (subject to 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 medical services meeting the requirements of § 438.3(e) provided to enrollees.

(B) Unpaid claims reserves for the MLR reporting year, including claims reported in the process of adjustment.

(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, 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 health care professionals.

(B) Prescription drug rebates received by the MCO, PIHP, or PAHP.

(C) State subsidies based on a stop-loss payment methodology.

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

(A) Payments made by an MCO, PIHP, or PAHP to mandated solvency funds.

(B) The amount of incentive and bonus payments made to network providers.

(C) 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 shall not include activities specified in § 438.8(e)(4).

(iv) Amounts that must either be included in or deducted from incurred claims include the following:



(A) Respectively, net payments or receipts related to risk adjustment and risk corridor programs developed in accordance with § 438.5 or § 438.6.

(B) [Reserved]

(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 health care professional, 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.

(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(b) and is not excluded under 45 CFR 158.150(c).

(ii) An MCO, PIHP, or PAHP activity related to any EQRO 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) Activities compliant with § 438.608. MCO, PIHP, or PAHP expenditures on activities related to the program integrity requirements in § 438.608(a)(1) through (5), (7), (8) and (b), limited to 0.5 percent of premium revenue. Expenditures under this paragraph shall not include expenses for fraud reduction efforts in § 438.8(e)(2)(iii)(C).

(f) Denominator. (1) For a MLR reporting year the denominator of the MLR 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 and State 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).

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

(iii) Other payments to the MCO, PIHP, or PAHP under the contract approved under § 438.6, such as incentive arrangement payments or withhold payments.

(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.

(3) Federal and State 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 taxes and assessments including:

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

(B) Guaranty fund assessments.

(C) Assessments of State 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 income, excise, and business taxes other than premium taxes and State employment and similar taxes and assessments.

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

(v) Payments made by an MCO, PIHP, or PAHP, which is 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) 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) On an annual basis, 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 de-termined 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—(1) Aggregation by covered population. 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.

(2) [Reserved]

(j) Remittance to the State if Specific MLR is not met. If required by the State, a MCO, PIHP, or PAHP must provide a re-mittance 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) Expenditures related to activities compliant with § 438.608(a)(1) through (5), (7), (8) and (b).

(iv) Non-claims costs.

(v) Premium revenue.

(vi) Taxes, licensing and regulatory fees.

(vii) Methodology for allocation of expenditures.

(viii) Any credibility adjustment applied.

(ix) The calculated MLR.

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

(xi) A reconciliation 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 supplying Medicaid services to its enrollees 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 con-tractual 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.

~~(5) The enrollee rights and protection provisions in subpart C of this part.~~ 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.

~~(6) The quality assessment and performance improvement provisions in subpart D of this part to the extent that they are applicable to services furnished by the PIHP.~~

~~(7) The grievance system provisions in subpart F of this part~~ § 438.9 Provisions that apply to non-emergency medical transportation PAHPs.

~~(8) The certification and program integrity protection provisions set forth in subpart H of this part.~~ 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, 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 ~~for PAHPs~~ 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) The~~ All contract requirements of § 438.6; provisions in § 438.3 except requirements for—:

~~(i) HHOs.~~ Physician Incentive plans.

~~(ii) Advance directives (unless the PAHP includes any of the providers listed in § 489.102) of this chapter.~~

(iii) LTSS requirements.

(iv) MHPAEA.

~~(2) All applicable portions of the~~ The actuarial soundness requirements in § 438.4.

(3) The information requirements in § 438.10.

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

(45) The State responsibility provisions ~~of subpart B of this part except § 438.50.~~ in §§ 438.56, 438.58, 438.60, and 438.62(a).

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

~~(6) Designated portions of subpart D of this part.~~

(7) The PAHP standards in §§ 438.206(b)(1), 438.210, 438.214, 438.224, 438.230, and 438.242.

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

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

§ 438.10 Information requirements.

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

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

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 and consistent with standards used by the Office for Civil Rights in enforcing anti-discrimination provisions.

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

Readily accessible means electronic information and services which comply with modern accessibility standards such as Section 508 guidelines or guidelines that provide greater accessibility to individuals with disabilities.

(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 ~~enrollment notices, informational materials, and instructional materials relating~~ required information in this section to enrollees and potential enrollees in a manner and format that may be easily understood. ~~(2) The State must have in place a mechanism to help and readily accessible by such~~ enrollees and potential enrollees understand the State's managed care program.

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

(3) The State must operate a Web site that provides the content specified in paragraphs (g) and (h) of this section, § 438.68(e), § 438.364(b)(2), and § 438.602(g), either directly or by linking to individual MCO, PIHP, PAHP or PCCM entity Web sites.

(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, 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, skilled nursing care, specialist, and urgent care; and

(3ii) Model member handbooks and member 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, PIHP, PAHP, or PCCM entity 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.

(v) The State, MCO, PIHP, PAHP, and PCCM entity informs the enrollee that the information is available in paper form without charge upon request and provides it upon request within 5 calendar days.

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

(e) Language and format. The State must ~~do the following:~~



(1) Establish a methodology for identifying the prevalent ~~nonEnglish~~non-English languages spoken by enrollees and potential enrollees throughout the State. ~~“Prevalent” means a nonEnglish language spoken by a significant number or percentage of potential enrollees and enrollees in the State, and in each MCO, PIHP, PAHP, or PCCM entity service area.~~

(2) Make available oral and written information in each prevalent ~~nonEnglish~~language-non-English language. All written materials for potential enrollees must include taglines in each prevalent non-English language as well as large print explaining the availability of written translations or oral interpretation to understand the information provided and the toll-free telephone number of the entity providing choice counseling services as required by § 438.71(a). Large print means printed in a font size no smaller than 18 pt.

(3) Require each MCO, PIHP, PAHP, and PCCM entity to make its written ~~information~~materials, including, at a minimum, provider di-rectories, member handbooks, appeal and grievance notices and other notices that are critical to obtaining services, available in the prevalent ~~nonEnglish~~non-English languages in its particular service area. Written materials must also be made available in alternative formats and auxiliary aids and services should be made available upon request of the potential enrollee or enrollee at no cost.

(i) All written materials for enrollees, including provider directories, member handbooks, appeal and grievance notices and other notices that are critical to obtaining services, must include taglines in each prevalent non-English language as well as large print explaining the availability of written translations or oral interpretation to understand the information provided and the toll-free and TTY/TDY telephone number of the MCO's, PIHP's, PAHP's or PCCM entity's member/customer service unit. Large print means printed in a font size no smaller than 18 pt.

(ii) [Reserved]

(4) Make ~~oral~~ 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 ~~potential enrollee and enrollee. This applies to all nonEnglish~~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 ~~enrollees and~~ 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 information is available in prevalent languages; ~~and~~

(ii) ~~How to access those services.~~That auxiliary aids and services are available upon request and at no cost for enrollees with disabilities; and

(iii) How to access those services.

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

~~(1) Written material must —~~

(i) Use easily understood language and format; ~~and.~~

(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 those who, for example, are visually limited or have limited reading ~~enrollees or potential enrollees with disabilities or limited English~~ proficiency.

~~(2) All enrollees and potential enrollees must be informed that information is available~~ iv) Include a large print tagline and information on how to request auxiliary aids and services, including the provision of the materials in alternative formats and how to access those formats. Large print means printed in a font size no smaller than 18 pt.

(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 program, or is first required to enroll in a mandatory enrollment program.

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

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

(i) ~~General information about —~~ 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.

~~(A)ii)~~ The basic features of managed care;

~~(B)iii)~~ Which populations are excluded from enrollment, subject to mandatory enrollment, or free to enroll voluntarily in the program; and.

~~(C)iv)~~ The service area covered by each MCO, PIHP, PAHP, and PCCM responsibilities for coordination of enrollee care; PCCM, or PCCM entity.

~~(ii) Information specific to each MCO, PIHP, PAHP, or PCCM program operating in potential enrollee's service area. A summary of the following information is sufficient, but the State must provide more detailed information upon request:~~v) Covered benefits including

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

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

~~(C) Service area.~~

~~(D) Names, locations, telephone numbers of, and non-English language spoken by current contracted providers, and including identification of providers that are not accepting new patients. For MCOs, PIHPs, and PAHPs, this includes at a minimum information on primary care physicians, specialists, and hospitals.~~

~~(E) Benefits that are available under the State plan but are not covered under the contract, including how and where the enrollee may obtain those benefits, any cost sharing, and how transportation is provided.~~C) For a counseling or referral service that the MCO, PIHP, or PAHP; or PCCM does not cover because of moral or religious objections, the State must provide information about where and how to obtain the service.

~~(f) General~~vi) The provider directory information required in paragraph (h) 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) MCO, PIHP, PAHP, PCCM and PCCM entity's responsibilities for coordination of enrollee care.

(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 ~~PCCMs~~. ~~Information must be furnished to MCO, PIHP, PAHP, and PCCM enrollees as follows:~~(1) The State must notify all enrollees of their disenrollment rights, at a minimum, annually. For States that choose to restrict disenrollment for periods of 90 days or more, States must send the notice no less than 60 days before the start of each enrollment period.

~~(2) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must notify all enrollees of their right to request and obtain the information listed in paragraph (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, at least once a year.~~

~~(3) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must furnish to each of its enrollees the information specified in paragraph (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, within a reasonable time after the MCO, PIHP, PAHP, or PCCM receives, from the State or its contracted representative, notice of the beneficiary's enrollment.~~

~~(4) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must give each enrollee written notice of any change (that the State defines as “significant”) in the information specified in paragraphs (f)(6) of this section and, if applicable, paragraphs (g) and (h) of this section, at least 30 days before the intended effective date of the change.~~  
(5) The MCO, PIHP, PCCM entities: General requirements. (1) The MCO, PIHP, PAHP and, when appropriate, the PAHP or PCCM entity, must make a good faith effort to give written notice of termination of a contracted provider, within 15 calendar days after receipt or issuance of the termination notice, to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider.

~~(6) The State, its contracted representative, or the MCO, PIHP, PAHP, or PCCM must provide the following information to all enrollees:~~  
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 member 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) Names, locations, telephone numbers of, and non-English languages spoken by current contracted providers in the enrollee's service area, including identification of providers that are not accepting new patients. For MCOs, PIHPs, and PAHPs this includes, at a minimum, information on primary care physicians, specialists, and hospitals.~~  
Benefits provided by the MCO, PIHP, PAHP or PCCM entity.

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

~~(B) The MCO, PIHP, PAHP, or PCCM entity must inform enrollees how they can to obtain information from the State about how to access those services.~~

~~(iii) Enrollee rights and protections, as specified in § 438.100.~~

~~(iv) Information on grievance and fair hearing procedures, and for MCO and PIHP enrollees, the information specified in § 438.10(g)(1), and for PAHP enrollees, the information specified in § 438.10(h)(1).~~ (v) 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.

~~(vi) Procedures for obtaining benefits, including authorization requirements.~~ (vii) ~~The extent to which, and how, enrollees may obtain benefits, including family planning services, from out of network providers~~ any requirements for service authorizations and/or referrals for specialty care and for other benefits not furnished by the enrollee's primary care provider.

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

(A) What constitutes an emergency medical condition, and emergency ~~services, and post stabilization~~ services, ~~with reference to the definitions in § 438.114(a).~~

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

~~(C) The process and procedures for obtaining emergency services, including use of the 911 telephone system or its local equivalent.~~

~~(D) The locations of any emergency settings and other locations at which providers and hospitals furnish emergency services and poststabilization services covered under the contract.~~ (E) 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.

~~(ix) The post stabilization care services rules set forth at § 422.113(c) of this chapter.~~ 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.

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

(ix) Enrollee rights and responsibilities, including the elements specified in § 438.100.

~~(x) Policy on referrals for specialty care and for other benefits not furnished by~~The process of selecting and changing the enrollee's primary care provider.

~~(xi) Cost sharing, if any.~~

~~(xii) How and where to access any benefits that are available under the State plan but are not covered under the contract, including any cost sharing, and how transportation is provided. For a counseling or referral service that the MCO, PIHP, PAHP, or PCCM does not cover because of moral or religious objections, the MCO, PIHP, PAHP, or PCCM need not furnish information on how and where to obtain the service. The State must provide information on how and where to obtain the service.~~

~~(g) Specific information requirements for enrollees of MCOs and PIHPs. In addition to the requirements in § 438.10(f), the State, its contracted representative, or the MCO and PIHP must provide the following information to their enrollees:~~(1) Grievance, appeal, and fair hearing procedures and timeframes, as provided in §§ 438.400 through 438.424, consistent with subpart F of this part, in a State -developed or State -approved description,~~that.~~ Such information must include ~~the following:~~

~~(i) For State fair hearing —~~

~~(A) The right to hearing;~~

~~(B) The method for obtaining a hearing; and~~

~~(C) The rules that govern representation at the hearing.~~(ii) The right to file grievances and appeals.

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

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

~~(v) The toll-free numbers that the enrollee can use to file a grievance or an appeal by phone.~~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.

~~(vi) E~~ (vi) E The fact that, when requested by the enrollee—~~(A) Benefits~~ 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 (B) The,~~ 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.~~

~~(vii) Any appeal rights that the State chooses to make available to providers to challenge the failure of the organization to cover a service.~~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.

~~(2) Advance directives, as set forth in § 438.6(i)(2).~~

~~(3) Additional information that is available upon request, including the following:~~

~~(i) Information on the structure and operation of the MCO or PIHP.~~

~~(ii) Physician incentive plans as set forth in § 438.6(h) of this chapter.~~

~~(h) Specific information for PAHPs. The State, its contracted representative, or the PAHP must provide the following information to their enrollees:~~

~~(1) The right to a State fair hearing, including the following:~~

~~(i) The right to a hearing.~~

~~(ii) The method for obtaining a hearing.~~

~~(iii) The rules that govern representation.~~

~~(2) Advance directives, as set forth in § 438.6(i)(2), to the extent that the PAHP includes any of the providers listed in § 489.102(a) of this chapter.~~

~~(3) Upon request, physician incentive plans as set forth in § 438.6(h).~~xiii) How to access auxiliary aids and services, including additional information in alternative formats or languages.

~~(i) Special rules: States with mandatory enrollment under State plan authority—~~

~~(1) Basic rule. If the State plan provides for mandatory enrollment under § 438.50, the State or its contracted representative must provide information on MCOs and PCCMs (as specified in paragraph (i)(3) of this section), either directly or through the MCO or PCCM.~~xiv) The toll-free telephone number for member services medical management and any other unit providing services directly to enrollees.

~~(2) When and how the information must be furnished. The information must be furnished as follows:~~xv) Information on how to report suspected fraud or abuse;

~~(i) For potential enrollees, within the timeframe specified in § 438.10(e)(1).~~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 electronic or paper 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.

~~(ii) For enrollees, annually and upon request~~v) Specialty, if appropriate.

~~(iii) In a comparative, chartlike format~~vi) Whether the provider will accept new enrollees.

~~(3) Required information. Some of the information is the same as the information required for potential enrollees under paragraph (e) of this section and for enrollees under paragraph (f) of this section. However, all of the information in this paragraph is subject to the timeframe and format requirements of paragraph (i)(2) of this section, and includes the following for each contracting MCO or PCCM in the potential enrollees and enrollee's service area:~~vii) The provider's cultural and linguistic capabilities, including languages spoken by the provider or by skilled medical in-terpreter at the provider's office.



~~(i) The MCO's or PCCM's service area.~~ viii) Whether the provider's office/facility is accessible for people with physical disabilities, including offices, exam room(s) and equipment.

~~(ii) The benefits.~~ 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) Any cost sharing imposed by the MCO or PCCM.~~ Pharmacies.

~~(iv) To the extent available, quality and performance indicators, including enrollee satisfaction.~~ Behavioral health providers.

(v) LTSS providers.

(3) Information included in a paper provider directory must be updated at least monthly and electronic provider directories must be updated no later than 3 business days after the MCO, PIHP, PAHP or PCCM entity receives updated provider information.

(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.

§ 438.12 Provider discrimination prohibited.

(a) General rules. (1) An MCO, PIHP, or PAHP may not discriminate ~~for~~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 health care professionals, 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 promulgated by the Secretary;

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

(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) under 42 CFR 447.51 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) under section 1932(h)(4)(B) of the Act 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 requirements. All contracts between a State and a MCO, PIHP, PAHP, PCCM, and PCCM entity, to the extent that the PCCM or PCCM entity has a provider network, which enroll Indians must:

(1) Require the MCO, PIHP, PAHP, 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, PCCM, 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 §§ 447.45 and 447.46 of this chapter.

(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, PCCM, 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 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).

(c) Payment requirements. (1) When an IHCP is enrolled in Medicaid as a FQHC but not a participating provider of the MCO, PIHP, PAHP and 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 the same amount it would be paid if the services provided to the Indian enrollee were provided under the State plan in a FFS payment methodology or the applicable encounter rate published annually in the Federal Register by the Indian Health Service.

(3) Where the amount a IHCP receives from a MCO, PIHP, PAHP, or PCCM entity is less than the amount required by para-graph (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, PCCM, 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 may restrict the delivery of services to Indians, without being in violation of the requirements in § 438.3(d).

#### Subpart B. ~~State~~ State Responsibilities

##### § 438.50 State Plan requirements.

(a) General rule. A State plan that requires Medicaid beneficiaries to enroll in ~~managed care~~ ~~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 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 ~~fee for service~~ ~~FFS~~ or capitation); ~~;~~

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

(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 ~~and~~, PCCMs, and PCCM entities.

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

(6) Section ~~438.6(e)~~, 438.4, for payments under any risk contracts, and § 447.362 of this chapter for payments under any ~~nonrisk~~ non-risk 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 ~~who are members of Federally recognized tribes, except when the MCO or PCCM is—as defined in § 438.14(a), except as permitted under § 438.14(d).~~

~~(i) The Indian Health Service; or~~

~~(ii) An Indian health program or Urban Indian program operated by a tribe or tribal organization under a contract, grant, cooperative agreement or compact with the Indian Health Service.~~

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

(i) Eligible for SSI under ~~title~~ 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~~Title V, and is defined by the State in terms of either program participation or special health care needs.

~~(e) Priority for enrollment. The State must have an enrollment system under which beneficiaries already enrolled in an MCO or PCCM are given priority to continue that enrollment if the MCO or PCCM does not have the capacity to accept all those seeking enrollment under the program.~~

~~(f) Enrollment by default.~~

~~(1) For beneficiaries who do not choose an MCO or PCCM during their enrollment period, the State must have a default enrollment process for assigning those beneficiaries to contracting MCOs and PCCMs.~~

~~(2) The process must seek to preserve existing provider beneficiary relationships and relationships with providers that have traditionally served Medicaid beneficiaries. If that is not possible, the State must distribute the beneficiaries equitably among qualified MCOs and PCCMs available to enroll them, excluding those that are subject to the intermediate sanction described in § 438.702(a)(4).~~

~~(3) An “existing provider beneficiary relationship” is one in which the provider was the 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 fee for service experience, or through contact with the beneficiary.~~

~~(4) A provider is considered to have “traditionally served” Medicaid beneficiaries if it has experience in serving the Medicaid population.~~

§ 438.52 Choice of MCOs, PIHPs, PAHPs, ~~and~~ 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 ~~enroll~~:

(1) Enroll in an MCO, PIHP, or PAHP, ~~or PCCM~~ must give those beneficiaries a choice of at least two ~~entities~~ 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 ~~programs~~, 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, ~~or PCCM system~~:

- (i) A ~~program authorized by a~~State plan amendment under section 1932(a) of the Act.
  - (ii) A waiver under section 1115 of the Act.
  - (iii) A waiver under section 1915(b) of the Act.
- (2) ~~A State that elects the option provided under~~To comply with this paragraph ~~(b)(1) of this section, a State,~~ must permit the beneficiary—
- (i) To choose from at least two ~~physicians or case managers~~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, ~~or PCCM~~ 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, ~~or PCCM~~ 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 ~~eaesarean~~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 the network treatment.
- (3) As used in this paragraph (b), “rural area” is any ~~area other than an “urban area” as defined in § 412.62(f)(1)(ii) of this chapter~~county designated as “micro,” “rural,” or “County with Extreme Access Criteria (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 both voluntary and mandatory managed care programs.

(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.

(c) Voluntary managed care programs. (1) States must have an enrollment system for a voluntary managed care program. That system may provide an enrollment choice period with the ability to make an active choice for managed care programs or may employ a passive enrollment process in which the State selects a MCO, PIHP, PAHP, PCCM or PCCM entity for a potential enrollee in a MCO, PIHP, PAHP, PCCM or PCCM entity but provides a period of time for the potential enrollee to decline the MCO, PIHP, PAHP, PCCM or PCCM entity selected for them before being enrolled in the MCO, PIHP, PAHP, PCCM or PCCM entity.

(2) A State must provide potential enrollees at least 14 calendar days of FFS coverage to provide the potential enrollee 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 choice period, the potential enrollee will be enrolled in a MCO, PIHP, PAHP, PCCM, or PCCM entity by the State using its default process. The enrollment into the MCO, PIHP, PAHP, PCCM, or PCCM entity will become effective after the end of the choice period.



(ii) If the State used 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 or select a different MCO, PIHP, PAHP, PCCM, or PCCM entity. If the potential enrollee does not make an active choice during the choice period, the MCO, PIHP, PAHP, PCCM, or PCCM entity selected for them by the passive enrollment process will become effective. The enrollment into the MCO, PIHP, PAHP, PCCM, or PCCM entity will become effective after the end of the choice period.

(3) The State must develop informational notices that clearly explain the implications to the potential enrollee of not making an active choice between managed care and FFS and declining the MCO, PIHP, PAHP, PCCM, or PCCM entity selected by the State, if relevant to the State's managed care program. These notices must:

(i) Comply with the information requirements in § 438.10.

(ii) Have a postmark or electronic date stamp that is at least 3 calendar days prior to the first day of the election period identified in paragraph (c)(2) of this section.

(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) 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).

(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 the 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 selection process is used, the State must send a confirmation of the enrollee's managed care enrollment to the enrollee within 5 calendar days of the MCO, PIHP, PAHP, PCCM or PCCM entity enrollment being processed by the State. The confirmation must clearly explain the enrollee's right to disenroll within 90 days from the effective date of the enrollment.

(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 (7) of this section.

(2) A State must provide potential enrollees at least 14 calendar days of FFS coverage to provide the potential enrollee the opportunity to actively select their MCO, PIHP, PAHP, PCCM, or PCCM entity.

(3) A State must provide informational notices to each potential enrollee that explain the process for enrolling in a MCO, PIHP, PAHP, PCCM or PCCM entity including the choice of MCOs, PIHPs, PAHPs, PCCMs or PCCM entities available, how to make the enrollee's selection of a MCO, PIHP, PAHP or PCCM known to the State, and enrollee's right to disenroll within 90 days from the effective date of the enrollment. These notices must:

(i) Comply with the information requirements in § 438.10.

(ii) Have a postmark or electronic date stamp that is at least 3 calendar days prior to the first day of the election period identified in paragraph (d)(2) of this section.

(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 enrollment period specified in paragraph (d)(2) of this section, 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).

(ii) Have capacity to enroll beneficiaries.

(6) The 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 the 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 (d)(6) 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, and other reasonable criteria related to a beneficiary's experience with the Medicaid program.

§ 438.56 Disenrollment: Requirements and limitations.

(a) Applicability. The provisions of this section apply to all managed care ~~arrangements~~ programs whether enrollment is mandatory or voluntary and whether the contract is with an MCO, ~~a~~-PIHP, ~~a~~-PAHP, PCCM or ~~a~~-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~~ un-cooperative 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); ~~and~~;

(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 ~~with the~~[into a](#) MCO, PIHP, PAHP, [PCCM](#) or [PCCM entity](#), or the date the State sends the beneficiary notice of the 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)(~~34~~).

(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 ~~agency~~ (or its agent); or

(ii) To the MCO, PIHP, PAHP, [PCCM](#) or [PCCM entity](#), if the State permits MCOs, PIHP, PAHPs, ~~and~~ [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 ~~caesarean~~[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 services, 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.

(v) Other reasons, including ~~but not limited to~~, 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 health care needs.

(3) MCO, PIHP, PAHP, PCCM, or PCCM entity action on request. (i) ~~An~~ When the MCO's, PIHP's, PAHP, or PCCM's, PCCM's or PCCMs 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 ~~or~~ 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 ~~dis-enrolled~~ 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, ~~or~~ PCCM's or PCCMs entity's grievance procedures. (i) The State agency may require that the enrollee seek redress through the MCO's, PIHP's, PAHP's, PCCM's or PCCM entity'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~~ ac-cordance with the timeframe specified in ~~§ 438.56~~ paragraph (e)(1) of this section.

(iii) If, as a result of the grievance process, the MCO, PIHP, PAHP, PCCM or PCCM entity 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 ~~files~~entity refers the request to the State.

(2) If the MCO, PIHP, PAHP, ~~or~~ PCCM, PCCM entity, or the State agency (whichever is responsible) fails to make the ~~determination~~deter-mination 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.

(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~~dis-enrolled solely because he or she loses Medicaid eligibility for a period of 2 months or less.

§ 438.58 Conflict of interest safeguards.

~~(a)~~ 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 ~~default~~ enrollment ~~process~~processes specified in § ~~438.50(f)~~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 ~~Limit on payment to other providers.~~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 ~~available~~covered under the contract between the State and the MCO, PIHP, or PAHP, except when these payments are ~~provided for in title~~specifically required to be made by the State in Title XIX of the Act, in 42 CFR, or when the State agency has adjusted the ~~capitation~~capi-tation rates paid under the contract, ~~in accordance with § 438.6(e)(5)(v), to make~~ to account for payments for graduate medical education, in accordance with § 438.6(b)(4).

§ 438.62 Continued services to ~~beneficiaries~~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 ~~whose 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 hospital-ization 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 comprehensive quality strategy, as required by § 438.340, and explained to individuals in the materials to enrollees and potential enrollees, in accordance with § 438.10.

§ 438.66 ~~Monitoring procedures.~~ State monitoring requirements.

(a) General requirement. The State agency must have in effect ~~procedures for monitoring the MCO's, PIHP's, or PAHP's operations, including, at a minimum, operations related to the following:~~ 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 and customer services.

(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.

(11) Availability and accessibility of services.

(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:

~~(a) Beneficiary enrollment~~1) Enrollment and disenrollment trends in each MCO, PIHP, or PAHP.

~~(b) Processing of grievances and appeals.~~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 any enrollee 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.

(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 provisions of covered benefits to new eligibility groups.

(iv) When any MCO, PIHP, PAHP or PCCM entity currently contracting with the State will provide a new set of benefits to current or new eligibility groups; or

(v) When any MCO, PIHP, PAHP or PCCM entity currently contacting with the State will expand coverage to new geographic areas.

(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 in order 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.

(3) Readiness reviews must include both a desk review of documents and on-site reviews of each MCO, PIHP, PAHP or PCCM entity. 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 150 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. For States that operate their managed care program under section 1115 of the Act authority, submission of an annual report that may be required by the Special Terms and Conditions of the demonstration program will be deemed to satisfy the requirement of this paragraph 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 and include, at a minimum, the following:

(i) Financial performance of each MCO, PIHP and PAHP.

(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 within the MCO, PIHP, or PAHP contracts.

(vii) Evaluation of MCO, PIHP, or PAHP performance on quality measures, including as applicable, consumer report card, surveys, or other reasonable measures of performance.

~~(e) Violations subject to intermediate sanctions, as set forth in subpart I of this part.~~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.

~~(d) Violations of the conditions for FFP, as set forth in subpart J of this part.~~ix) Any other factors in the delivery of LTSS not otherwise addressed in (e)(2)(i)-(viii) of this section as applicable.

(3) The program report required in this section must be:

(i) Posted on the Web site required under § 438.10.

(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.

§ 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) At a minimum, a State must develop time and distance standards for the following provider types, if covered under the contract:

(i) Primary care, adult and pediatric.

(ii) OB/GYN.

(iii) Behavioral health.

(iv) Specialist, adult and pediatric.

(v) Hospital.

(vi) Pharmacy.

(vii) Pediatric dental.

(viii) Additional provider types when it promotes the objectives of the Medicaid program, as determined by CMS, for the provider type to be subject to time and distance access standards.

(2) LTSS. States with MCO, PIHP or PAHP contracts which cover LTSS must develop:

(i) Time and distance standards for LTSS provider types in which an enrollee must travel to the provider to receive services; and

(ii) Network adequacy standards other than time and distance standards for LTSS provider types that travel to the enrollee to deliver services.

(3) Scope of network adequacy standards. Network standards established in accordance with paragraphs (b)(1) and (b)(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 health care professionals required to furnish the contracted Medicaid services.

(v) The numbers of network health care professionals who are not accepting new Medicaid patients.

(vi) The geographic location of health care professionals and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees.

(vii) The ability of health care professionals to communicate with limited English proficient enrollees in their preferred language.

(viii) The ability of healthcare professionals to ensure physical access, reasonable accommodations, culturally competent communications, and accessible equipment for Medicaid enrollees with physical or mental disabilities.

(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 (viii) 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 provider-specific network standards developed under this section, the standard by which the exception will be evaluated and approved must be:

(i) Specified in the MCO, PIHP or PAHP contract.

(ii) Based, at a minimum, on the number of health care professionals in that specialty practicing in the MCO, PIHP, or PAHP service area.

(2) States that grant an exception in accordance with paragraph (d)(1) of this section to a MCO, PIHP or PAHP must monitor enrollee access to that provider type on an ongoing basis and include the findings to CMS in the managed care program assessment report required under § 438.66.

(e) Publication of network adequacy standards. States must publish the standards developed in accordance with paragraphs (b)(1) and (b)(2) of this section on the Web site required by § 438.10. 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.

§ 438.70 Stakeholder engagement when LTSS is delivered through a managed care program.

The State must ensure the views of 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) Training for network providers as specified in paragraph (d) of this section.

(iii) Assistance for enrollees in understanding managed care.

(iv) Assistance for enrollees who use, or express a desire to receive, LTSS as specified in paragraph (e) 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 dis-enroll 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).

(d) Training. The beneficiary support system must provide training to MCOs, PIHPs, PAHPs, PCCMs, PCCM entities and network providers on community-based resources and supports that can be linked with covered benefits.

(e) 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 ap-pealing 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.

(i) An entity that receives non-Medicaid funding to represent beneficiaries at hearings, may, subject to approval by CMS, establish firewalls to provide choice counseling as an independent function.

(ii) [Reserved].

(4) Review and oversight of LTSS program data to provide guidance to the State Medicaid Agency on identification, remediation and resolution of systemic issues.

§ 438.74 State oversight of the minimum MLR requirement.

(a) State reporting requirement. (1) The State must annually submit to CMS a summary description of the report(s) received from the MCO(s), PIHP(s), and PAHP(s) under contract with the State under § 438.8(k) with the actuarial certification described in § 438.7.

(2) The summary description must include, at a minimum, the amount of the numerator, denominator, MLR experienced, 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 Federal matching rate.

~~(e) All other provisions of the contract, as appropriate.~~

(2) If a remittance is owed according to paragraph (b)(1) of this section, the State must submit a 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.

Subpart C. ~~Enrollee~~ Rights and Protections

§ 438.100 Enrollee rights.

(a) General rule. The State must ensure that ~~—~~:

(1) Each MCO, PIHP, PAHP, PCCM and ~~PHHP~~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 ~~staff~~employees and ~~affiliated~~contracted providers ~~take~~observe and protect those rights ~~into account when furnishing services to enrollees.~~

(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 (b)(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(~~fg~~)(~~62~~)(~~xiii~~)(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 ~~(such as: title 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; and titles Titles II and III of the Americans with Disabilities Act; and other laws regarding privacy and confidentiality).~~

#### § 438.102 Provider -enrollee communications.

(a) General rules. (1) An MCO, PIHP, or PAHP may not prohibit, or otherwise restrict, a health care professional 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 ~~in order~~ 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~~par-agraph (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) 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:

(i) To the State—

(A) With its application for a Medicaid contract; ~~and~~ .

(B) Whenever it adopts the policy during the term of the contract.

(ii) Consistent with the provisions of § 438.10—

(A) To potential enrollees, before and during enrollment;~~and.~~

(B) To enrollees, within 90 days after adopting the policy ~~with respect to~~for any particular service.

(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(~~f~~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, paragraphs (e)~~438.10(g)(2)(ii)(A) and (~~f~~B), the information that MCOs, PIHPs, and PAHPs must furnish to enrollees and potential enrollees does not include how and where to obtain 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, paragraphs (e)(2)(ii)(E) and (f)(6)(xii).~~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) ~~Terminology~~Definitions. As used in this section, the following terms have the indicated meanings:

~~Coldcall~~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—

(1) Are produced in any medium, by or on behalf of an MCO, PIHP, PAHP, or PCCM; and

(2) 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, ~~affiliated~~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; ~~and~~

(v) Does not, directly or indirectly, engage in door ~~to~~ door, telephone, email, texting, or other ~~cold-call~~cold-call marketing activities.

(2) Specify the methods by which the entity ~~assures~~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 ~~in order~~entity to obtain benefits or ~~in order~~ 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 ~~furnishes~~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 ~~provided~~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 ~~447.57~~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 covered under the contract with the MCO, PIHP, or PAHP.

§ 438.114 Emergency and ~~poststabilization~~post stabilization 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:

- (~~1~~i) Placing the health of the individual (or, ~~with respect to~~for a pregnant woman, the health of the woman or her unborn child) in serious jeopardy.
- (~~2~~ii) Serious impairment to bodily functions.

~~(3)~~iii) Serious dysfunction of any bodily organ or part.

Emergency services means covered inpatient and outpatient services that are as follows:

~~(4)~~i) Furnished by a provider that is qualified to furnish these services under this title.

~~(2)~~ii) Needed to evaluate or stabilize an emergency medical condition.

Post stabilization care services means covered services, related to an emergency medical condition that are provided after an enrollee is stabilized ~~in order~~ 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 ~~post stabilization~~ poststabilization care services.

(1) The MCO, PIHP, or PAHP.

~~(2) The PCCM that has a risk contract that covers these services.~~ (3) The State, ~~in the case of a PCCM that has a fee for service~~ for managed care programs that contract ~~with PCCMs or PCCM entities~~ 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—~~(i) Allow~~ 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; ~~and (ii) Pay for the services if the manager's contract is a risk contract that covers those 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~~[para-graph](#) (b) of this section as responsible for coverage and payment.

(e) Coverage and payment: Post stabilization care services. Post stabilization 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 “~~M+CMA~~ 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: ~~Quality Assessment and Performance Improvement~~—MCO, PIHP and PAHP Standards

~~§ 438.200 Scope.~~

~~This subpart implements section 1932(c)(1) of the Act and sets forth specifications for quality assessment and performance improvement strategies that States must implement to ensure the delivery of quality health care by all MCOs, PIHPs, and PAHPs. It also establishes standards that States, MCOs, PIHPs, and PAHPs must meet.~~

~~§ 438.202 State responsibilities.~~

~~Each State contracting with an MCO or PIHP must do the following:~~

~~(a) Have a written strategy for assessing and improving the quality of managed care services offered by all MCOs and PIHPs.~~

~~(b) Obtain the input of beneficiaries and other stakeholders in the development of the strategy and make the strategy available for public comment before adopting it in final.~~

~~(c) Ensure that MCOs, PIHPs, and PAHPs comply with standards established by the State, consistent with this subpart.~~

~~(d) Conduct periodic reviews to evaluate the effectiveness of the strategy, and update the strategy periodically, as needed.~~

~~(e) Submit to CMS the following:~~

~~(1) A copy of the initial strategy, and a copy of the revised strategy whenever significant changes are made.~~

~~(2) Regular reports on the implementation and effectiveness of the strategy.~~

~~§ 438.204 Elements of State quality strategies.~~

~~At a minimum, State strategies must include the following:~~

~~(a) The MCO and PIHP contract provisions that incorporate the standards specified in this subpart.~~

~~(b) Procedures that —~~

~~(1) Assess the quality and appropriateness of care and services furnished to all Medicaid enrollees under the MCO and PIHP contracts, and to individuals with special health care needs.~~

~~(2) Identify the race, ethnicity, and primary language spoken of each Medicaid enrollee. States must provide this information to the MCO and PIHP for each Medicaid enrollee at the time of enrollment.~~

~~(3) Regularly monitor and evaluate the MCO and PIHP compliance with the standards.~~

~~(c) For MCOs and PIHPs, any national performance measures and levels that may be identified and developed by CMS in consultation with States and other relevant stakeholders.~~

~~(d) Arrangements for annual, external independent reviews of the quality outcomes and timeliness of, and access to, the services covered under each MCO and PIHP contract.~~

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

~~(f) An information system that supports initial and ongoing operation and review of the State's quality strategy.~~

~~(g) Standards, at least as stringent as those in the following sections of this subpart, for access to care, structure and operations, and quality measurement and improvement.~~

~~Access Standards~~

§ 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, ~~and each~~ PIHP and PAHP, consistent with the scope of ~~the PIHP's or PAHP's~~ 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. ~~In establishing and maintaining the network, each MCO, PIHP, and PAHP must consider the following:~~



~~(i) The anticipated Medicaid enrollment.~~

~~(ii) The expected utilization of services, taking into consideration the characteristics and health care needs of specific Medicaid populations represented in the particular MCO, PIHP, and PAHP.~~

~~(iii) The numbers and types (in terms of training, experience, and specialization) of providers required to furnish the contracted Medicaid services.~~

~~(iv) The numbers of network providers who are not accepting new Medicaid patients.~~  
~~(v) The geographic location of providers and Medicaid enrollees, considering distance, travel time, the means of transportation ordinarily used by Medicaid enrollees, and whether the location provides physical access for Medicaid for all enrollees with, including those with limited English pro-ficiency 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 qualified health care professional within the provider network, 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 ~~or~~ PIHP ~~with respect to~~ or PAHP for payment and ensures ~~that~~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.

(c) Furnishing of services. The State must ensure that each contract with a MCO, PIHP, and PAHP ~~contract~~ complies with the following requirements ~~of this paragraph~~.

(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.

(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 ~~fee for service~~ 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) ~~Cultural~~[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 gender, sexual orientation or gender identity](#).

[\(3\) Accessibility considerations. Each MCO, PIHP, and PAHP must ensure that network providers provide physical access, accommodations, and accessible equipment for Medicaid enrollees with physical or mental disabilities.](#)

§ 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 subpart.

(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, ~~and~~ 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.

(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 ~~adequate~~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, the State must ~~certify~~submit an assurance of compliance to CMS that the MCO, PIHP, or PAHP ~~has complied with~~meets the State's requirements for availability of services, as set forth in § 438.206. 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.

(e) CMS' 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.

§ 438.208 Coordination and continuity of care.

(a) Basic requirement—(1) General rule. Except as specified in paragraphs (a)(2) and (a)(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—

~~(i) Meet the primary care requirement of paragraph (b)(1) of this section; and (ii) Implement~~ 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 ~~+Choice plan~~ Advantage Organization, the State determines to what extent the MCO must meet the ~~primary care coordination~~, identification, assessment, and treatment planning provisions of ~~paragraphs (b) and paragraph~~ (c) of this section ~~with respect to~~ for dually eligible individuals.

(ii) The State bases its determination on the ~~services~~ needs of the population it requires the MCO to ~~furnish to dually eligible enrollees~~ serve.

(b) ~~Primary care~~ Care and coordination of ~~health care~~ services for all MCO, PIHP, and PAHP enrollees. Each MCO, PIHP, and PAHP must implement procedures to deliver ~~primary~~ care to and coordinate ~~health care services~~ 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 ~~primary~~ care appropriate to his or her needs and a person or entity formally designated as primarily responsible for coordinating the ~~health care~~ services ~~furnished to~~ accessed by the enrollee.

(2) Coordinate the services the MCO, PIHP, or PAHP furnishes to the enrollee ~~with~~:

(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; and

(iii) With the services the enrollee receives in FFS Medicaid.

(3) Provide that the MCO, PIHP or PAHP, within 90 days of the effective date of enrollment for all new enrollees, makes a best effort to conduct an initial assessment of each enrollee's needs, including subsequent attempts if the initial attempt to contact the enrollee is unsuccessful.

(4) Share with the State or other MCOs, PIHPs, and ~~PAHPs~~ PAHP serving the enrollee ~~with special health care needs~~ the results of ~~its~~ any identification and assessment of that enrollee's needs to prevent duplication of those activities.

(45) Ensure that each provider furnishing services to enrollees maintains and shares, as appropriate, an enrollee health record in accordance with professional standards.

(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~~ im-plement 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 comprehensive quality ~~improvement~~ strategy in § ~~438.202;~~ and 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 ~~in order~~ 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 health care professionals or individuals meeting

LTSS service coordination requirements of the State or the MCO, PIHP, or PAHP as appropriate.

(3) Treatment/service plans. If the State requires MCOs, PIHPs, ~~and~~ or PAHPs to produce a treatment or service plan for enrollees who require LTSS or with special health care needs ~~who~~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 the enrollee's ~~primary care~~ provider or individual meeting LTSS service coordination requirements with enrollee participation, and in consultation with any ~~specialists~~other health care professionals 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;~~and.~~

(~~iii~~iv) In accord with any applicable State quality assurance and utilization review standards.

(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 section § 441.301(c)(3) of this chapter.

(4) Direct access to specialists. For enrollees with special health care needs determined through an assessment by appropriate health care professionals (consistent with ~~§ 438.208~~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.

§ 438.210 Coverage and authorization of services.

(a) Coverage. Each contract ~~with~~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 ~~feeforservice~~FFS Medicaid, as set forth in § ~~440.230~~440.230 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 ~~be expected to~~ 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;

~~(iii) May~~ 4) Permit an MCO, PIHP, or PAHP to place appropriate limits on a service—

~~(A)~~ i) On the basis of criteria applied under the State plan, such as medical necessity; or

~~(B)~~ ii) For the purpose of utilization control, provided ~~the~~ that

(A) The services furnished can reasonably ~~be expected to~~ achieve their purpose, as required in paragraph (a)(3)(i) of this section; ~~and~~

(4B) 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.

(5) Specify what constitutes “medically necessary services” in a manner that—

(i) Is no more restrictive than that used in the State Medicaid program as indicated in State statutes and regulations, the State Plan, and other State policy and procedures; ~~and~~

(ii) Meets the requirements for providing early and periodic screening and diagnosis of beneficiaries under age 21 to ascertain physical and mental defects, and treatment to correct or ameliorate defects and chronic conditions found (EPSDT); and

(iii) Addresses the extent to which the MCO, PIHP, or PAHP is responsible for covering services ~~related to the following~~ 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.

(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; ~~and,~~

(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 a health care professional who has appropriate ~~clinical~~ expertise in treating/addressing the enrollee's ~~condition or disease~~ medical, behavioral health, or long-term services and supports needs.

(c) Notice of adverse ~~action~~ 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 ~~and,~~ PIHPs, and PAHPs the notice must meet the requirements of § ~~438.404, except that the notice to the provider need not be in writing.~~ 438.404.

(d) Timeframe for decisions. Each MCO, PIHP, or PAHP contract must provide for the following decisions and notices:

(1) Standard authorization decisions. For standard authorization decisions, provide notice as expeditiously as the enrollee's ~~health~~ condition requires and within State ~~established~~ timeframes that may not exceed 14 calendar days following receipt of the request for service, with a possible extension of up to 14 additional calendar days, if—

(i) The enrollee, or the provider, requests extension; or

(ii) 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~~expeditiously as the enrollee's health condition requires and no later than ~~3~~3 ~~working days~~72 hours after receipt of the request for service.

(ii) The MCO, PIHP, or PAHP may extend the ~~3 working days~~72 hour time period by up to 14 calendar days if the enrollee requests an ~~extension~~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.

(e) Compensation for utilization management activities. Each contract between a State and MCO, PIHP, or PAHP must provide that, consistent with § ~~438.6~~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.

#### ~~Structure and Operation Standards~~

##### § 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 providers and that those policies and procedures ~~include~~, at a minimum, meet the requirements of this section.

(b) Credentialing and ~~re-credentialing~~recredentialing requirements. (1) Each State must establish a uniform credentialing and ~~re-credentialing policy that each MCO, PIHP,~~recredentialing policy that addresses acute, primary, behavioral, substance use disorders, and LTSS providers, as appropriate, and require each MCO, PIHP and PAHP ~~must~~to follow those policies.

(2) Each MCO, PIHP, and PAHP must follow a documented process for credentialing and ~~re-credentialing~~recredentialing of providers who have signed contracts or participation agreements with the MCO, PIHP, or PAHP.

(c) Nondiscrimination. MCO, PIHP, and PAHP 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~~treat-ment.

(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.

(e) State requirements. Each MCO, PIHP, and PAHP must comply with any additional requirements established by the State.

##### ~~§ 438.218 Enrollee information:~~

~~The requirements that States must meet under § 438.10 constitute part of the State's quality strategy at § 438.204.~~



§ 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~~dis-closes 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.

~~§ 438.226 Enrollment and disenrollment.~~

~~The State must ensure that each MCO, PIHP, and PAHP contract complies with the enrollment and disenrollment requirements and limitations set forth in § 438.56.~~

§ 438.228 Grievance systems.

(a) The State must ensure, through its contracts, that each MCO, PIHP, and ~~PIHP~~PAHP has in effect a grievance system that meets the requirements of subpart F of this part.

(b) If the State delegates to the MCO~~-or~~, 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~~-or~~, PIHP, or PAHP and its providers and subcontractors to ensure that they are notifying enrollees in a timely manner.

§ 438.230 ~~Sub-contractual~~Subcontractual relationships and delegation.

(a) ~~General rule. The State must ensure, through its contracts, that each MCO, PIHP, and PAHP—~~Applicability. The requirements of this section apply to any contract or written arrangement that an MCO, PIHP, or PAHP has with any individual or entity that relates directly or indirectly to the performance of the MCO's PIHP's or PAHP's obligations under its contract with the State.

(b) General rule. The State must ensure, through its contracts with MCOs, PIHPs, and PAHPs, that

(1) ~~Oversees and is accountable for any functions and responsibilities that it delegates to any subcontractor; and~~ Notwithstanding any relationship(s) that the MCO, PIHP, or PAHP may have with any other individual or entity, the MCO, PIHP, or PAHP 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, or PAHP and any individual or entity that relates directly or indirectly to the performance of the MCO's PIHP's or PAHP's activities or obligations under its contract with the State 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, or PAHP's activities or obligations under its contract with the State are delegated to another individual or entity—

~~(2) Meets the conditions of paragraph (b) of this section~~

(i) The delegated activities or obligations, and related reporting responsibilities, are specified in the contract or written agreement.

~~(b) Specific conditions~~ii) The individual or entity agrees to perform the delegated activities and reporting responsibilities specified in compliance with the MCO's, PIHP's or PAHP's contract obligations.

~~(1) Before any delegation, each MCO, PIHP, and PAHP evaluates the prospective subcontractor's ability to perform the activities to be delegated~~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, or PAHP determine that the individual or entity has not performed satisfactorily.

~~(2) There is a written agreement that~~—The individual or entity agrees to comply with all applicable Medicaid laws, regulations, subregulatory guidance, and contract provisions;

~~(i) Specifies the activities and report responsibilities delegated to the subcontractor; and~~3) The individual or entity agrees that

~~(ii) Provides for revoking delegation or imposing other sanctions if the subcontractor's performance is inadequate.~~i) The State, CMS, the HHS Inspector General, the Comptroller General, or their designees have the right to audit, evaluate, and inspect any books, contracts, computer or other electronic systems of the individual or entity, or of the individual's or entity's contractor or subcontractor, that pertain to any aspect of services and activities performed, or determination of amounts payable under the contract with the State, if the reasonable possibility of fraud is determined to exist by any of these entities.

~~(3) The MCO, PIHP, or PAHP monitors the subcontractor's performance on an ongoing basis and subjects it to formal review according to a periodic schedule established by the State, consistent with industry standards or State MCO laws and regulations~~

(ii) The individual or entity will make available, for purposes of an audit, evaluation, or inspection under paragraph (c)(3)(i) of this section, its premises, physical facilities, equipment, and records relating to its Medicaid enrollees.

~~(4) If any MCO, PIHP, or PAHP identifies deficiencies or areas for improvement, the MCO, PIHP, or PAHP and the subcontractor take corrective action.~~ 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.

#### ~~Measurement and Improvement Standards~~

(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 individual or entity at any time.

#### § 438.236 Practice guidelines.

(a) Basic rule: ~~The State must ensure, through its contracts, that each MCO and, when applicable, each~~ The State must ensure, through its contracts, that each MCO and, when applicable, each PIHP ~~and PAHP meets the requirements of this section.~~ 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 health care professionals in the particular field.

(2) Consider the needs of the MCO's, PIHP's, or PAHP's enrollees.

(3) Are adopted in consultation with contracting health care professionals.

(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.

#### ~~§ 438.240 Quality assessment and performance improvement program:~~

##### ~~(a) General rules:~~

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

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

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

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

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

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

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

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

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

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

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

~~(d) Performance improvement projects:~~

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

~~(i) Measurement of performance using objective quality indicators.~~

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

~~(iii) Evaluation of the effectiveness of the interventions.~~

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

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

~~(e) Program review by the State.~~

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

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

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

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

§ 438.242 Health information systems.

(a) General rule. The State must ensure, through its contracts, that each MCO, PIHP, and PHHP/PAHP maintains a health information system that collects, analyzes, integrates, and reports data and can achieve the objectives of this ~~subpart~~part. The ~~system~~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 PHHP/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.

~~(23)~~ 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; ~~and~~

(iii) Collecting ~~service information~~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.

~~(34)~~ Make all collected data available to the State and upon request to CMS, as required in this ~~subpart~~part.

(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.

(3) Submission of all enrollee encounter data 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.

Subpart E- Quality Measurement and Improvement; External Quality Review ~~(Refs & Annos)~~

§ 438.310 Basis, scope, and applicability.

(a) Statutory basis. This subpart is based on sections 1932(c)(1), 1932(c)(2), 1903(a)(3)(C)(ii), 1902(a)(4), and 1902(a)(~~419~~) of the Act.

(b) Scope. This subpart sets forth ~~requirements for annual external quality reviews of:~~

(1) Specifications for a quality assessment and performance improvement program that States must require each contracting managed care organization (MCO) ~~and~~, prepaid inpatient health plan (PIHP), and prepaid ambulatory health plan (PAHP) to implement and maintain.

(2) Requirements for the state review and approval 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 managed care elements of the comprehensive quality strategy that States must implement to ensure the delivery of quality health care.

(5) Requirements for annual external quality reviews of each contracting MCO, PIHP, and PAHP including—

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

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

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

~~(4) Standards~~iv) Requirements for making ~~available~~ the results of the reviews publicly available.

(c) Applicability. (1) The provisions of this subpart apply to MCOs, PIHPs, and ~~to health insuring organizations (HIOs) that began on or after January 1, 1986 that the statute does not explicitly exempt from requirements in section 1903(m) of the Act~~ PAHPs. For purposes of this subpart, HIOs that are not expressly exempt by statute are required to comply with this subpart as an MCO.

(2) PCCM entities. Notwithstanding paragraphs (b) and (c)(1) of this section, the State must assess the performance of each PCCM entity consistent with the requirements of § 438.3(r). That assessment must, at a minimum, include the elements de-scribed in § 438.330(b)(3), (c), and (e).

§ 438.320 Definitions.

As used in this subpart—

Access, as it pertains to external quality review, means the timely use of services to achieve the best outcomes possible, as evidenced by 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 ~~or~~ PIHP, or PAHP, 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~~holds a contract with a State to perform external quality review, other EQR ~~—~~ related activities as set forth in § 438.358, or both.

Financial relationship means—

(1) A direct or indirect ownership or investment interest (including an option or nonvested interest) in any entity. This direct or indirect interest may be in the form of equity, debt, or other means, and includes any indirect ownership or investment interest no matter how many levels removed from a direct interest; or

(2) A compensation arrangement with an entity.

Quality, as it pertains to external quality review, means the degree to which an MCO ~~or~~ PIHP or PAHP increases the likelihood of desired health outcomes of its enrollees through ~~its~~:

(1) Its structural and operational characteristics ~~and through the~~

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

(3) Positive trends in performance measures and clinically significant results from 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.

~~§ 438.350 State responsibilities.~~ 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.

(2) CMS, through a public notice and comment process in consultation with States and other stakeholders, may specify per-formance measures for collection in accordance with paragraph (c) of this section, a methodology for calculating quality ratings, and topics with performance indicators for performance improvement projects in accordance with paragraph (d) of this section to be required by States in their contracts with MCOs, PIHPs, and PAHPs.

(i) In addition to those required by CMS under paragraph (a)(2) of this section, States may select their own performance im-provement projects topics and performance measures to satisfy the requirements of paragraphs (b)(1) and (b)(2) of this section.

(ii) A State may apply for an exemption from collecting and reporting on the performance measures or performance im-provement projects established under (a)(2) of this section, by submitting a request, in writing, to CMS which details the reason for such an exemption.

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

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

(2) Collect and submit performance measurement data in accordance with ~~paragraph (c) of this section.~~

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



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

(5) Have in effect mechanisms to assess the quality and appropriateness of care furnished to enrollees using LTSS, including assessment of care between care settings and a comparison of services received with those set forth in the enrollee's treatment plan.

(6) Participate in efforts by the State to prevent, detect, and remediate critical incidents that are based, at a minimum, on the requirements on the State for home and community-based waiver programs.

(c) Performance measurement. Annually each MCO, PIHP, and PAHP must

(1) Measure and report to the State its performance, using standard measures required by the State, including those performance measures specified by CMS under paragraph (a)(2) of this section.

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

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

(4) LTSS performance measurement. The State must require, through its contracts, each MCO, PIHP, and PAHP that provides LTSS services to include, as a part of its performance measurement activities under this paragraph and in addition to other measures required of all MCOs, PIHPs, and PAHPs, measures that assess the quality of life of beneficiaries and the outcomes of the MCO, PIHP, or PAHP's rebalancing and community integration activities for beneficiaries receiving LTSS.

(d) Performance improvement projects. (1) MCOs, PIHPs, and PAHPs must have an ongoing program of performance improvement projects that focuses on both clinical and nonclinical areas. These projects must be designed to achieve, through ongoing measurements and intervention, significant improvement, sustained over time, in clinical care and nonclinical care areas that are expected to have a favorable effect on health outcomes and enrollee satisfaction. Each project 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.

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

(2) Each MCO, PIHP, and PAHP must report the status and results of each project to the State as requested, including those topics specified by CMS under paragraph (a)(3) of this section. Each performance improvement project must be completed in a reasonable time period so as to generally allow information on the success of performance improvement projects in the aggregate to produce new information on quality of care every year.

(3) Option for MCOs, PIHPs, or PAHPs serving only dual eligibles. At State option, MCOs, PIHPs, or PAHPs exclusively serving dual eligibles may substitute a MA Organization quality improvement project conducted under § 422.152(d) of this chapter for a performance improvement project required under this paragraph (d)(1) of this section.

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

(i) The MCO's, PIHP's, and PAHP'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 LTSS.

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

§ 438.332 State review and approval of MCOs, PIHPs, and PAHPs.

(a) General requirement. (1) To enter into a contract with the State under this part, MCOs, PIHPs, and PAHPs must be reviewed and approved by the State on the basis of performance in accordance with standards that are at least as stringent as the standards used by a private accreditation entity recognized by CMS under 45 CFR 156.275(c) or approved under § 422.157 of this chapter.

(2) Following initial approval, the State must review and reapprove each MCO, PIHP, and PAHP in accordance with paragraph (a)(1) of this section at least once every 3 years.

(3) Upon obtaining initial State approval in accordance with paragraph (a)(1) of this section, MCOs, PIHPs, and PAHPs must perform consistent with the level required for approval so long as they participate in the State's Medicaid managed care program.

(b) Compliance deemed on the basis of accreditation by a private independent entity. (1) The State may elect to use proof of MCO, PIHP, or PAHP accreditation by a private independent

entity recognized by CMS under 45 CFR 156.275(c) or approved under § 422.157 of this chapter to satisfy the requirement described in paragraph (a) of this section.

(2) If the State chooses to exercise this option, the MCO, PIHP, or PAHP must authorize the private accreditation entity to release to the State a copy of its most recent accreditation survey, including:

(i) Accreditation status, survey type, or level (if applicable).

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

(iii) Expiration date of accreditation.

(c) The State must make the final approval status, whether based on State review or private accreditation, for all MCOs, PIHPs, and PAHPs available on the State's Medicaid Web site required under § 438.10(c)(3).

#### § 438.334 Medicaid managed care quality rating system.

(a)(1) Each State contracting with an MCO, PIHP, or PAHP must establish a quality rating system for Medicaid managed care plans that meets the requirements of this section.

(2) The quality rating system must be based on the following three components:

(i) Clinical quality management.

(ii) Member experience.

(iii) Plan efficiency, affordability, and management.

(3) The quality rating system must measure and report on the performance of each MCO, PIHP, or PAHP on measures identified by CMS, under § 438.330(a)(2). Such measures will be categorized within each of the components listed in paragraph (a)(1) of this section. The quality rating system may also measure and report on additional measures identified by the State.

(b) Each State must collect data from each MCO, PIHP, and PAHP with which it contracts, which includes, at a minimum, data evidencing the MCO's, PIHP's, or PAHP's performance on the measures described in paragraph (a)(2) of this section. The State must apply the methodology established by CMS, under § 438.330(a)(2), to these performance measures to determine a quality rating or ratings for each MCO, PIHP, or PAHP.

(c) Alternative quality rating system. Upon CMS approval, a State may opt to use an alternative quality rating system that utilizes different components than those described in paragraph (a)(2) of this section, incorporates the use of different performance measures than those described in

paragraph (a)(3) of this section, or applies a different methodology from that described in paragraph (b) of this section.

(d) Option for MCOs, PIHPs, or PAHPs serving only dual eligibles. The State may opt to utilize the MA five-star rating for MCOs, PIHPs, or PAHPs exclusively serving dual eligible in place of the quality rating system established under this section.

(e) The State must prominently display on its Web site the quality rating of each MCO, PIHP, or PAHP in a manner that complies with the standards in § 438.10(d).

#### § 438.340 Managed care elements of the State comprehensive quality strategy.

In addition to the requirements set forth in part 431, subpart I of this chapter, any State contracting with an MCO, PIHP, or PAHP must also address the following elements in the State's comprehensive quality strategy:

(a) The State-defined MCO, PIHP, and PAHP network adequacy and availability of services standards required by §§ 438.68 and 438.206 and examples of evidence-based clinical practice guidelines the State requires its MCOs, PIHPs, and PAHPs to adopt in accordance with § 438.236.

(b) The State's goals and objectives for continuous quality improvement must be developed in accordance with § 431.502(b)(1) of this chapter and must incorporate a description of:

(1) Quality metrics and performance targets for measuring improvement and performance regarding MCOs, PIHPs, and PAHPs, and include, at a minimum, performance measures to be reported in accordance with § 438.330(c); and

(2) Performance improvement projects to be implemented in accordance with § 438.330(d), including a description of any interventions the State proposes to achieve improvement in access, quality, or timeliness of care for enrollees in MCOs, PIHPs, and PAHPs.

(c) Arrangements for annual, external independent reviews of the quality outcomes and timeliness of, and access to, the services covered under each MCO, PIHP, and PAHP contract.

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

(e) A description of how the State will assess the performance and quality outcomes achieved by each PCCM entity, consistent with the requirements in § 438.3(r).

#### § 438.350 External quality review.

(a) Each State that contracts with MCOs ~~or~~, PIHPs, or PAHPs must ensure that—

~~(a1)~~ Except as provided in § 438.362, a qualified EQRO performs an annual EQR for each contracting MCO ~~or~~ PIHP; and PAHP.

~~(b2)~~ The EQRO has sufficient information to use in performing the review;

~~(e3)~~ The information used to carry out the review must be obtained from the EQR-related activities described in § ~~438.358~~ 438.358 or from a Medicare or private accreditation review as described in § 438.360.

~~(d4)~~ For each ~~EQR-related~~ EQR-related activity, the information gathered for use in the EQR must include the elements described in § 438.364(a)(1)(i) through ~~(a)(1)(iv)~~;

~~(e5)~~ The information provided to the EQRO in accordance with paragraph ~~(ea)(2)~~ of this section is obtained through methods consistent with the protocols established under § ~~438.352~~; and 438.352.

~~(f6)~~ The results of the reviews are made available as specified in § 438.364.

(b) A State may require that a qualified EQRO performs an annual EQR for each PCCM entity consistent with the requirements of § 438.3(r). If an EQR is performed, the requirements in paragraphs (a)(2) through (6) of this section apply.

§ 438.352 External quality review protocols.

Each protocol 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 are independent from the State Medicaid agency and from the MCOs ~~or~~ PIHPs, or PAHPs that they review. To qualify as “independent”
- (1) A State agency, department, university, or other State entity may not have Medicaid purchasing or managed care licensing authority; and
  - (2) A State agency, department, university, or other State entity must be governed by a Board or similar body the majority of whose members are not government employees.
  - (3) An EQRO may not—
    - (i) Review a particular MCO ~~or~~ PIHP, or PAHP if either the EQRO or the MCO ~~or~~ PIHP, or PAHP exerts control over the other (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 ~~or~~ PIHP, or PAHP services, except for the related activities specified in § 438.358; ~~or~~

(iv) Conduct or have conducted within the previous 3 years, an accreditation review on any contracting MCO, PIHP, or PAHP; or

(v) Have a present, or known future, direct or indirect financial relationship with an MCO-~~or~~, PIHP, or PAHP that it will review as an EQRO.

§ 438.356 State contract options for external quality review.

(a) The State—:

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

(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 ~~and consistent~~. In addition, the State must comply with 45 CFR part ~~74~~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-~~or~~, 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 as described in § 438.350(a)(3).

(b) Mandatory activities. For each MCO ~~and~~, PIHP, ~~the EQR must use information from~~ and PAHP, the following EQR-related activities must be performed:

(1) Validation of performance improvement projects, required by the State and CMS to comply with requirements set forth in § ~~438.240~~438.330(b)(1) ~~and~~, that were underway during the preceding 12 months.

(2) Validation of MCO-~~or~~ PIHP, or PAHP performance measures reported (as required by the State and CMS) or MCO-~~or~~ PIHP, or PAHP performance ~~measure~~measures calculated by the State during the preceding 12 months to comply with requirements set forth in § ~~438.240~~438.330(b)(2).

(3) A review, conducted within the previous 3-~~year~~ period, to determine the MCO's-~~or~~ PIHP's, or PAHP's compliance with the standards ~~(except with respect to standards under §§ 438.240(b)(1) and (2), for the conduct of~~set forth in subpart D and the quality assessment and performance improvement projects and calculation of performance measures respectively) ~~established by the State to comply with the~~requirements described in § 438.330.

(4) Validation of MCO, PIHP, and PAHP network adequacy during the preceding 12 months to comply with requirements ~~of § 438.204(g).~~set forth in § 438.68.

(c) Optional activities. ~~The EQR may also use~~For each MCO, PIHP, and PAHP, the following activities may be performed by using information derived during the preceding 12 months ~~from the following optional activities:~~

(1) Validation of encounter data reported by an MCO, PIHP, or ~~PHHP~~PAHP.

(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-~~or~~ PIHP, or PAHP and validated by an EQRO.

(4) Conduct of performance improvement projects in addition to those conducted by an MCO-~~or~~ PIHP, or PAHP and validated by an EQRO.

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

(d) Technical assistance. The EQRO may, at the State's direction, provide technical guidance to groups of MCOs-~~or~~ PIHPs, or PAHPs 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.

§ 438.360 ~~Non-duplication~~Nonduplication of mandatory activities.

(a) General rule. To avoid duplication, the State may use, ~~in place of a Medicaid review by the State, its agent, or EQRO,~~ information about the an MCO-~~or~~ PIHP, or PAHP obtained from a Medicare or private accreditation review to provide information otherwise obtained from the mandatory activities specified in § 438.358 if the conditions of paragraph (b) ~~or paragraph (c)~~ of this section are met.

(b) MCOs-~~or~~ PIHPs, or PAHPs reviewed by Medicare or private accrediting organizations. For information about an MCO's-~~or~~ PIHP's ~~compliance with one or more standards required under §~~



~~438.204(g), (except with respect to standards under §§ 438.240(b)(1) and (2), for the conduct of PIHP's, or PAHP's performance for the validation of performance improvement projects and calculation of (as required by § 438.358(b)(1)) or performance measures respectively) the following conditions must be met:~~

~~(1) The MCO or PIHP is in (as required by § 438.358(b)(2)) or compliance with the standards established by CMS for Medicare Choice or a national accrediting organization. The CMS or national accreditation standards are comparable to standards established by the State to comply with § 438.204(g) and the EQR-related activity under § 438.358(b)(3).~~

~~(2) Compliance with the standards is determined either by—~~

~~(i) CMS or its contractor for Medicare; or~~

~~(ii) A private national accrediting organization that CMS has approved as applying standards at least as stringent as Medicare under the procedures in § 422.158.(3) The MCO or PIHP provides to the State all the reports, findings, and other results of the in subpart D of this part (as required by § 438.358(b)(3)), the State may use information from a Medicare or private accreditation review applicable to the standards provided for in § 438.204(g); and the State provides the information to the EQRO.~~

~~(4) In its quality strategy, the State identifies the standards for which the EQR will use information from Medicare or private accreditation reviews, and explains its rationale for why the standards are duplicative. (c) Additional provisions for MCOs or PIHPs serving only dually eligibles. The State may use information obtained from the Medicare program in place of information produced by the State, its agent, or EQRO with respect to the mandatory activities specified in § 438.358 (b)(1) and (b)(2) if the following conditions are met:~~

~~(1) The MCO or PIHP serves only individuals who receive both Medicare and Medicaid benefits, PIHP, or PAHP is in compliance with the standards established by CMS for Medicare or has obtained accreditation from a private accrediting organization recognized by CMS. (2) The Medicare or private accreditation review activities are standards must be substantially comparable to the State specified mandatory activities set forth in §§ 438.358(b)(1) and through (b)(23).~~

~~(3) The MCO or PIHP, or PAHP provides to the State all the reports, findings, and other results of the Medicare or private accreditation review from related to the mandatory activities specified under set forth in § 438.358(b)(1) and (b)(2), and (b)(3) and the State provides the information to the EQRO. The EQRO must include an analysis and aggregation of this information in the final EQR technical report as described in § 438.364.~~

~~(4c) In its comprehensive quality strategy, the State identifies must identify the mandatory activities for which it has exercised this option and explains explain its rationale for why these activities are duplicative.~~

§ 438.362 Exemption from external quality review.

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

(1) The MCO ~~or PHP~~ has a current Medicare contract under part C of ~~title~~ 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 ~~or PHP~~ has been subject to EQR under this part, and found to be performing acceptably ~~with respect to~~ for the quality, timeliness, and access to health care services it provides to Medicaid beneficiaries.

(b) Information on exempted MCOs ~~or PHPs~~. 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 ~~or PHP~~ that it exempts from EQR the most recent Medicare review findings reported on the MCO ~~or PHP~~ including—

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

(ii) All measures of the MCO's ~~or PHP's~~ performance; and

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

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

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

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

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

§ 438.364 External quality review results.

(a) Information that must be produced. The State must ensure that the EQR ~~produces at least the following information:~~(1) A results in an annual detailed technical report that ~~describes~~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 ~~or~~, PIHP, or PAHP. The report must also include the following for each EQR-related activity conducted in accordance with § 438.358:

(i) Objectives.

(ii) Technical methods of data collection and analysis.

(iii) Description of data obtained, including performance measurement data for each activity conducted in accordance with § 438.358(b)(1) and (2).

(iv) Conclusions drawn from the data.

(2) An assessment of each MCO's ~~or~~, PIHP's, or PAHP's strengths and weaknesses ~~with respect to~~for the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(3) Recommendations for improving the quality of health care services furnished by each MCO ~~or PIHP~~, PIHP, or PAHP, including how the State can target goals and objectives in the comprehensive quality strategy to better support improvement in the quality, timeliness, and access to health care services furnished to Medicaid beneficiaries.

(4) ~~As the State determines, methodologically~~Methodologically appropriate, comparative information about all MCOs ~~and~~, PIHPs, and PAHPs.

(5) An assessment of the degree to which each MCO ~~or~~, PIHP, or PAHP has addressed effectively the recommendations for quality improvement made by the EQRO during the previous year's EQR.

(b) 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 annual technical report must be finalized no later than April 30th of each year. States may not substantively revise the content of the final EQR technical report without evidence of error or omission.

(2) The State must provide copies of the information specified in paragraph (a) of this section, upon request, through print or electronic media, to interested parties such as participating health care providers, enrollees and potential enrollees of the MCO ~~or~~, PIHP, or PAHP, beneficiary advocacy groups, and members of the general public. The State must make ~~this~~the most recent

copy of the annual EQR technical report publicly available on the State's Web site 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 ~~sensory impairments~~disabilities, when requested.

(c) Safeguarding patient identity. The information released under paragraph (b) of this section may not disclose the identity of any patient.

§ 438.370 Federal financial participation (FFP).

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

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

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

#### Subpart F- Grievance System

§ 438.400 Statutory basis and definitions.

(a) Statutory basis. This subpart is based on the following statutory sections ~~1902(a)(3), 1902(a)(4), and 1932(b)(4) of the Act.~~

(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.

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

~~Action~~Adverse benefit determination means ~~In, in~~ the case of an MCO ~~or~~, 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, health care 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;
- (4) The failure to provide services in a timely manner, as defined by the State;
- (5) The failure of an MCO ~~or~~ PIHP or PAHP to act within the timeframes provided in § 438.408(b)(1) and (b)(2) regarding the standard disposition of grievances and standard disposition and resolution of appeals; or
- (6) For a resident of a rural area with only one MCO, the denial of ~~a Medicaid~~ an enrollee's request to exercise his or her right, under § 438.52(b)(2)(ii), to obtain services outside the network.

Appeal means a ~~request for review of an action, as “action” is defined in this section~~ review by a MCO, PIHP, or PAHP of an adverse benefit determination.

Grievance means an expression of dissatisfaction about any matter other than an ~~action, as “action” is defined in this section. The term is also used to refer to the overall system that includes grievances and appeals handled at the MCO or PIHP level and access to the State fair hearing process. (Possible subjects for grievances~~ 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 au-thorization decision.

Grievance system means the processes the MCO, PIHP, or PAHP implements to handle appeals of an adverse benefit deter-mination and grievances, as well as the processes to collect and track information about them.

§ 438.402 General requirements.

- (a) The grievance system. Each MCO, PIHP, and ~~PHHP~~ PAHP must have a grievance system in place for enrollees ~~that includes a grievance process, an appeal process, and access to the State's fair hearing system.~~ Non-emergency medical transportation PAHPs, as defined in § 438.9, are not subject to subpart 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 an appeal with the MCO or, PIHP-level appeal, and, or PAHP. An enrollee may request a State fair hearing after receiving notice under § 438.408 that the adverse benefit determination is upheld.

(ii) A provider, acting on behalf of the enrollee ~~and with the enrollee's written consent~~, may file an appeal. A provider may file a grievance or request a State fair hearing on behalf of an enrollee, if the State permits the provider to act as the enrollee's authorized representative in doing so.

(2) Timing. ~~The State specifies a reasonable timeframe that may be no less than 20 days and not to exceed 90 days from the date on the MCO's or PIHP's notice of action. Within that timeframe—~~(i) Grievance. An enrollee may file a grievance with the MCO, PIHP, or PAHP at any time.

~~(i) The~~(ii) Appeal. Following receipt of a notification of an adverse benefit determination by an MCO, PIHP, or PAHP, an enrollee or the provider may has 60 calendar days in which to file an appeal; and (ii) In a State that does not require exhaustion of MCO and PIHP level appeals, the enrollee may request a State fair hearing.

(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 ~~or the,~~ PIHP, or PAHP.

(ii) Appeal. The enrollee or ~~the~~ provider may file an appeal either orally or in writing, ~~and,~~ Further, unless ~~he or she~~ the enrollee requests an expedited resolution, ~~must follow~~ an oral filing with appeal must be followed by a written, signed, appeal.

§ 438.404 Timely and adequate notice of adverse benefit determination.

(a) Notice of action. ~~(a) Language and format requirements. The notice must be in writing and must meet.~~ The MCO, PIHP, or PAHP must give enrollees timely and adequate notice of adverse benefit determination in writing consistent with the language and format requirements of § 438.10(c) and (d) to ensure ease of understanding below and in § 438.10.

(b) Content of notice. The notice must explain the following:

(1) The action adverse benefit determination the MCO ~~or,~~ PIHP, ~~or its contractor~~ PAHP has ~~taken~~ made or intends to ~~take~~ make.

(2) The reasons for the ~~action~~ 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 claim for benefits. Such information includes medical necessity criteria, and any processes, strategies, or evidentiary standards used in setting coverage limits.

(3) The enrollee's ~~or~~ and the provider's right to file an appeal of the MCO ~~or PIHP~~ appeal's, PIHP's, or PAHP's adverse benefit determination.

(4) ~~If the State does not require the enrollee to exhaust the MCO or PIHP level appeal procedures, the enrollee's right to request a State fair hearing.~~(5) The procedures for exercising the rights specified in this paragraph (b).

(~~6~~5) The circumstances under which an appeal process can be expedited ~~resolution is available~~ and how to request it.

(~~7~~6) The enrollee's right to have benefits ~~continue~~continues 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 ~~or~~, 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 ~~or PIHP extends~~, PIHP, or PAHP meets the criteria set forth for extending the timeframe ~~in accordance~~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 ~~action~~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 ~~and each~~, PIHP, and PAHP must ~~meet the following requirements:~~(1) Givegive enrollees any reasonable assistance in completing forms and taking other procedural steps. 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.

(2b) 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.

(32) Ensure that the individuals who make decisions on grievances and appeals are individuals—

(i) Who were ~~not~~neither involved in any previous level of review or decision -making;~~and~~ nor a subordinate of any such individual.

(ii) Who, if deciding any of the following, are health care professionals who have the appropriate clinical expertise, as ~~determined~~deter-mined 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.

~~(b) Special requirements for appeals. The process for appeals must:~~iii) That takes into account all comments, documents, records, and other information submitted by the enrollee or their rep-resentative without regard to whether such information was submitted or considered in the initial adverse benefit determination.

(43) Provide that oral inquiries seeking to appeal an ~~action~~adverse benefit determination are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the enrollee or the provider requests expedited resolution.

(24) Provide the enrollee a reasonable opportunity ~~to present evidence, and allegations of fact or law,~~ in person ~~as well as~~and in writing, to present evidence and testimony and make legal and factual arguments. ~~(The MCO or, 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.)

(35) Provide the enrollee and his or her representative ~~opportunity, before and during the appeals process, to examine~~(free of charge and sufficiently in advance of the resolution timeframe for appeals as specified in § 438.408(b) and (c)) the enrollee's case file, including medical records, ~~and any~~ other documents and records, and any new or additional evidence considered ~~during the appeals process,~~ 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.



(4) 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.

§ 438.408 Resolution and notification: Grievances and appeals.

(a) Basic rule. ~~The~~Each MCO-~~or~~, PIHP, or PAHP must dispose of each grievance and resolve each appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within ~~State-established~~State-established timeframes that may not exceed the timeframes specified in this section.

(b) Specific timeframes—(1) Standard disposition of grievances. For standard disposition 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-~~or~~, 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 ~~45~~30 calendar days from the day the MCO-~~or~~, 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 ~~3 working days~~72 hours after the MCO-~~or~~, PIHP, or PAHP receives the appeal. This timeframe may be extended under paragraph (c) of this section.

(c) Extension of timeframes—(1) The MCO-~~or~~, 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-~~or~~, 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-~~or~~, PIHP, or PAHP extends the timeframes, ~~it must—for any extension not requested by~~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 ~~delay~~ 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.

(d) Format of notice—(1) Grievances. The State must establish the method ~~MCOs~~that an MCO, PIHP, and ~~PIHPs~~PAHP will use to notify an enrollee of the disposition 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-~~or~~, PIHP, or PAHP must provide written notice of disposition- 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-~~or~~, 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 ~~to~~and receive benefits while the hearing is pending, and how to make the request;and

(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-~~or~~, PIHP's-~~action~~, or PAHP's adverse benefit determination.

(f) Requirements for State fair hearings—(1) Availability. ~~The State must permit the enrollee to~~An enrollee may request a State fair hearing only after receiving notice that the MCO, PIHP or PAHP is upholding the adverse benefit determination.

(2) The enrollee must request a State fair hearing ~~within a reasonable time period specified by the State, but not less than 20 or in excess of 90 days from whichever of the following dates applies—(i) If the State requires exhaustion of the MCO or PIHP level appeal procedures, no later than 120 calendar days~~ from the date of the MCO's-~~or~~, PIHP's, or PAHP's notice of resolution;~~or(ii) If the State does not require exhaustion of the MCO or PIHP level appeal procedures and the enrollee appeals directly to the State for a fair hearing, from the date on the MCO's or PIHP's notice of action.~~

(23) Parties. The parties to the State fair hearing include the MCO-~~or~~, PIHP, or PAHP as well as the enrollee and his or her ~~representative~~rep-representative or the representative of a deceased enrollee's estate.

§ 438.410 Expedited resolution of appeals.

(a) General rule. Each MCO, PIHP, and PHHP/PAHP must establish and maintain an expedited review process for appeals, when the MCO, PIHP, or PHHP/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 or health or ability to attain, maintain, or regain maximum function.

(b) Punitive action. The MCO, ~~or~~ PIHP, or PAHP must ensure that punitive action is ~~neither~~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, ~~or~~ 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) ~~Make reasonable efforts to give the enrollee prompt oral notice of the denial, and follow up within two calendar days with a written notice.~~ Follow the requirements in § 438.408(c)(2).

§ 438.414 Information about the grievance system to providers and subcontractors.

The MCO, ~~or~~ PIHP, or PAHP must provide ~~the~~ information specified ~~at~~in § 438.10(g)(~~1~~2)(xi) about the grievance system to all providers and subcontractors at the time they enter into a contract.

§ 438.416 Recordkeeping ~~and reporting~~ requirements.

(a) The State must require MCOs ~~and~~ 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-~~or~~, PIHP, or PAHP appeal and the State fair hearing are pending.

(a) ~~Terminology~~Definitions. As used in this section, ~~“timely”~~

Timely filing means filing on or before the later of the following:

~~(1)~~ Within ~~ten~~10 calendar days of the MCO-~~or~~, PIHP, or PAHP mailing the notice of ~~action~~adverse benefit determination.

~~(2)~~(i) The intended effective date of the MCO's-~~or~~, PIHP's, or PAHP's proposed ~~action~~adverse benefit determination.

(b) Continuation of benefits. The MCO-~~or~~, PIHP, or PAHP must continue the enrollee's benefits if ~~—~~ all of the following occur:

(1) The enrollee or the provider files the appeal timely;;

(2) The appeal involves the termination, suspension, or reduction of a previously authorized course of treatment;;

(3) The services were ordered by an authorized provider;;

(4) The original period covered by the original authorization has not expired;; ~~and~~.

(5) The enrollee requests extension of benefits.

(c) Duration of continued or reinstated benefits. If, at the enrollee's request, the MCO-~~or~~, PIHP, or PAHP continues or reinstates the enrollee's benefits while the appeal is pending, the benefits must be continued until one of following occurs:

(1) The enrollee withdraws the appeal.

(2) Ten days pass after the MCO-~~or~~, PIHP, or PAHP mails the notice, providing the resolution of the appeal against the enrollee, unless the enrollee, within the 10-day timeframe, has requested a State fair hearing with continuation of benefits until a State fair hearing decision is reached.

(3) A State fair hearing ~~Office~~office issues a hearing decision adverse to the enrollee.

~~(4) The time period or service limits of a previously authorized service has been met.~~

(d) Enrollee responsibility for services furnished while the appeal and state fair hearing is pending. If the final resolution of the appeal is adverse to the enrollee, that is, upholds the MCO's ~~or~~ PIHP's action, or PAHP's adverse benefit determination, the MCO ~~or~~ PIHP, or PAHP may recover the cost of the services furnished to the enrollee while the appeal ~~is~~ and state fair hearing was pending, to the extent that they were furnished solely because of the requirements of this section, and in accordance with the policy set forth in § 431.230(b) of this chapter. The ability of the MCO, PIHP or PAHP to recoup the costs of services from the enrollee must be specified in the contract. Such practices must be consistently applied within the State under managed care and FFS delivery systems.

§ 438.424 Effectuation of reversed appeal resolutions.

(a) Services not furnished while the appeal is pending. If the MCO ~~or~~ 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 ~~or~~ 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 ~~or~~ 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 ~~or the~~ PIHP, or PAHP, or the State must pay for those services, in accordance with State policy and regulations.

Subpart G ~~—~~ [Reserved]

## ~~Title 42. Public Health~~

### ~~Chapter IV. Centers for Medicare & Medicaid Services, Department of Health and Human Services (Refs & Annos)~~

#### ~~Subchapter C. Medical Assistance Programs~~

#### ~~Part 438. Managed Care (Refs & Annos)~~

Subpart H ~~Certifications and~~ Additional Program Integrity Safeguards

§ 438.600 Statutory basis.

This subpart is based on ~~sections 1902(a)(4), 1902(a)(19), 1903(m), and 1932(d)(1) of the Act.~~ the following statutory sections:

(a) Section 1128 of the Act provides for the exclusion of certain individuals and entities from participation in the Medicaid program.

(b) 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.

~~(a)~~ 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.

~~(b)~~ 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.

~~(e) Section 1903(m) establishes conditions for payments to the State with respect to contracts with MCOs.~~ e) Section 1902(a)(27) of the Act requires States to enroll persons or institutions that provide services under the State plan.

(f) Section 1902(a)(68) of the Act requires that any entity receiving 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.

(g) 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.

(h) 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.

(i) Section 1902(kk)(7) of the Act requires States to enroll physicians or other professionals that order or refer services under the State plan.

(j) 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.

(k) Section 1903(m) of the Act establishes conditions for payments to the State for contracts with MCOs.

~~(d)~~ Section 1932(d)(1) of the Act prohibits MCOs and PCCMs from knowingly having certain types of relationships with individuals ~~excluded~~ and entities debarred under Federal regulations from participating in specified activities, or with affiliates of those individuals.

§ 438.602 ~~Basic rule~~ 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. 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.

(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, subject to the requirements in § 438.230, in accordance with subpart B of part 455 of this chapter.

(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 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 determines a match, 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 or make available upon request the following documents and reports:

(1) The MCO, PIHP, PAHP, or PCCM entity contract.

(2) The data submitted under § 438.604.

(3) The results of any audits under paragraph (e) of this section.

(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.

§ 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 § 438.3, 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.

~~As a condition for receiving payment under the Medicaid managed care program, an MCO, PCCM~~

(5) Documentation described in § 438.207(b) on which the State bases its certification that the MCO, PIHP, or PAHP ~~must comply with the applicable certification, program integrity and prohibited affiliation requirements of this subpart.~~ 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.

~~§ 438.604 Data that must be certified.~~

(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.

~~(a) Data certifications. When State payments to an MCO or PIHP are based on data submitted by the MCO or PIHP, the State must require certification of the data as provided in § 438.606. The data that must be certified include, but are not limited to, enrollment information, encounter data, and other information required by the State and contained in contracts, proposals, and related documents.~~7) The annual report of overpayment recoveries as required in § 438.608(d)(3).

~~(b) Additional certifications. Certification is required, as provided in § 438.606, for all documents specified by the State.~~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.

§ 438.606 Source, content, and timing of certification.

(a) Source of certification. For the data, documentation, or information specified in § 438.604, the ~~data~~ State must require that the data, documentation or information the MCO-~~or~~, PIHP, PAHP, PCCM or PCCM entity submits to the State ~~must~~ be certified by ~~one of the following:~~

~~(1) The MCO's or PIHP's Chief Executive Officer.~~

~~(2) The MCO's or PIHP's Chief Financial Officer.~~ (3) ~~An individual who has delegated authority to sign for, and who reports directly to, the MCO's or PIHP~~ either the MCO's, PIHP's, PAHP's, PCCM's, or PCCM entity's Chief Executive Officer or Chief Financial Officer.

(b) Content of certification. The certification provided by the individual in paragraph (a) of this section must attest, ~~based on best knowledge, information, and belief, as follows:~~ that the MCO, PIHP, PAHP, PCCM, or PCCM entity has conducted a reasonably diligent review of the data, documentation, and information specified in § 438.604(a) and (b), and that the data, documentation, and information is accurate, complete, and truthful.

~~(1) To the accuracy, completeness and truthfulness of the data.~~

~~(2) To the accuracy, completeness and truthfulness of the documents specified by the State.~~

(c) Timing of certification. The State must require the MCO-~~or~~, PIHP-~~must~~, PAHP, PCCM, or PCCM entity to submit the certification concurrently with the ~~certified data~~ submission of the data, documentation, or information required in § 438.604(a) and (b).

§ 438.608 Program integrity requirements under the contract.

(a) ~~General requirement. The MCO or PIHP must have administrative~~ Administrative and management arrangements or procedures, ~~including a mandatory compliance plan, that are designed to guard against~~ 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. ~~(b) Specific requirements.~~ 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 standards requirements.

~~(2) The designation of a compliance officer and a compliance committee that are accountable to senior management.~~ 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.

~~(3) Effective~~ iv) A system for training and education for the ~~compliance officer~~ Compliance Officer, the organization's senior management, and the organization's employees for the Federal and State standards and requirements under the contract.

(4v) Effective lines of communication between the compliance officer and the organization's employees.

~~(5vi)~~ Enforcement of standards through well publicized disciplinary guidelines.

~~(6) Provision for internal monitoring and auditing.~~ 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 prompt reporting of all improper payments identified or recovered, specifying the improper payments due to potential fraud, to the State or law enforcement.

(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 or notification of an enrollee's mail that is returned as undeliverable.

(ii) Changes in the enrollee's income.

(iii) The death of an enrollee.

(4) Provision for notification to the State when it receives information about a change in a provider's circumstances that may affect the 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 receive annual payments under the contract of at least \$5,000,000, written policies for all employees of the entity, and of any contractor or agent, providing 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 are in place.

(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.

(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 that the MCO, PIHP or PAHP retains the following:

(i) Payments made to a network provider that was otherwise excluded from participation in the Medicaid program, and subsequently recovered from that network provider, by an MCO, PIHP or PAHP.

(ii) Payments made to a network provider due to fraud, waste or abuse, and subsequently recovered from that network provider, by an MCO, PIHP or PAHP.

(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 their recoveries of overpayments.

(4) The State must use the results of 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.

~~(7) Provision for prompt response to detected offenses, and for development of corrective action initiatives relating to the MCO's or PIHP's contract.~~5) For purposes of paragraph (d) of this section, an overpayment is 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.

§ 438.610 Prohibited affiliations ~~with individuals debarred by Federal agencies.~~

(a) ~~General requirement.~~ An MCO, ~~PCCM,~~ PIHP, ~~or~~ PAHP, PCCM, or PCCM entity may not knowingly have a relationship of the type described in paragraph ~~(b)~~ (c) of this section with the following:

(1) An individual ~~who~~ or entity that is debarred, suspended, or otherwise excluded from participating in procurement activities under the Federal Acquisition Regulation or from participating in ~~non-procurement~~ 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, of a person described in ~~paragraph~~ par-agraph (a)(1) of this section.

(b) ~~Specific requirements~~ 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 ~~this~~ paragraph (a) of this section, are as ~~follow~~ follows:

(1) A director, officer, or partner of the MCO, ~~PCCM,~~ PIHP, ~~or~~ PAHP, PCCM, or PCCM entity.

(2) A subcontractor of the MCO, PIHP, PAHP, PCCM, or PCCM entity, as governed by § 438.230.

~~(23)~~ A person with beneficial ownership of ~~five~~ 5 percent or more of the MCO's, ~~PCCM's,~~ PIHP's, ~~or~~ PAHP's, PCCM's, or PCCM entity's equity.

~~(3)~~ A ~~person~~network provider or persons with an employment, consulting or other arrangement with the MCO, ~~PCCM~~, PIHP, ~~or~~ PAHP, PCCM, or PCCM entity for the provision of items and services that are significant and material to the MCO's, ~~PCCM's~~, PIHP's, ~~or~~ PAHP's, PCCM's, or PCCM entity's obligations under its contract with the State.

~~(e)~~ Effect of ~~None~~noncompliance. If a State finds that an MCO, ~~PCCM~~, PIHP, ~~or~~ 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, ~~PCCM~~, PIHP, ~~or~~ 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, ~~PCCM~~, PIHP, ~~or~~ 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.

~~(d)~~ 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 ~~(e)~~(2) or ~~(e)~~(3) of this section is taken in consultation with the Inspector General.

#### Subpart I. ~~Sanctions~~

§ 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, ~~as (which may include those~~ specified in § ~~438.702, 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 whether 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~~inter-mination 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 whether an MCO, ~~PHHP, PAHP~~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 whether—

(1) An MCO has violated any of the other requirements of sections 1903(m) or 1932 of the Act, ~~and~~or any implementing ~~regulations;~~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 ~~and~~or any implementing ~~regulations;~~regulations.

(3) For any of the violations under paragraphs (d)(1) and (d)(2) of this section, only the sanctions specified in § 438.702, paragraphs (a)(3), (a)(4), and (a)(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 ~~dis-enroll~~disenroll.

(4) Suspension of all new enrollment, including default enrollment, after the ~~effective date of the sanction~~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. ~~The limit on,~~ 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 ~~the following paragraphs of § 438.700:~~ (b)(1), (b)(5), (b)(6), and (c).

~~(i) Paragraph (b)(1) (Failure to provide services):~~

~~(ii) Paragraph (b)(5) (Misrepresentation or false statements to enrollees, potential enrollees, or health care providers):~~

~~(iii) Paragraph (b)(6) (Failure to comply with physician incentive plan requirements):~~

~~(iv) Paragraph (c) (Marketing violations):~~

(2) The limit is \$100,000 for each determination under ~~paragraph § 438.700(b)(3) (discrimination) or (b)(4) (Misrepresentation or false statements to CMS or the State) of § 438.700.~~

(3) The limit is \$15,000 for each beneficiary the State determines was not enrolled because of a discriminatory practice under ~~paragraph § 438.700 (b)(3) of § 438.700.~~ (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. ~~The~~ If the State ~~may impose~~ imposes temporary management under § 438.702(a)(3), the State may do so only if it finds (through onsite ~~surveys~~ surveys, enrollee ~~or other~~ complaints, financial ~~audits~~ status, or any other ~~means~~) that—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;~~or~~.

(2) There is substantial risk to enrollees' health;~~or~~.

(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~~; ~~or~~ [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 ~~section~~[sections](#) 1903(m) or ~~section~~ 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~~or~~, 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;~~or~~.

(b) Meet applicable requirements in sections 1932, 1903(m), and 1905(t) of the Act.

§ 438.710 ~~Due process~~: 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 ~~due process protections~~[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; ~~and~~

(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 ~~dis-enroll~~ disenroll immediately without cause.

§ 438.724 Notice to CMS.

(a) The State must give ~~the~~ CMS ~~Regional Office~~ 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; ~~and~~

(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 ~~section~~ § 438.730(e).

§ 438.730 Sanction by CMS: Special rules for MCOs.

(a) Basis for sanction. ~~(1)~~ A State ~~agency~~ 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 (b)(6).

(b) Effect of an ~~Agency Determination~~ agency determination. (1) The State ~~agency's~~ determination becomes CMS's determination for purposes of section 1903(m)(5)(A) of the Act unless CMS reverses or modifies it within 15 days.

(2) When the ~~agency~~ State decides to recommend imposing the sanction described in paragraph (e) of this section, this recommendation becomes CMS's 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 ~~agency's~~ determination becomes CMS's determination under ~~section~~ paragraph (b)(2) of this section, the State ~~agency~~ takes all of the following actions:

(1) Gives the MCO written notice of the nature and basis of the proposed sanction; and

(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; and

(3) May extend the initial 15 ~~—~~ — day period for an additional 15 days if—

(i) ~~the~~ The MCO submits a written request that includes a credible explanation of why it needs additional time; and

(ii) ~~the~~ The request is received by CMS before the end of the initial period; and

(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 ~~agency~~—

(i) Conducts an informal reconsideration that includes review of the evidence by a State agency official who did not participate in the original recommendation; and

(ii) Gives the MCO a concise written decision setting forth the factual and legal basis for the decision; and

(iii) Forwards the decision to CMS.

(2) The ~~agency~~ State's decision under paragraph (d)(1)(ii) of this section becomes CMS's 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 ~~agency~~ decision, the agency sends the MCO a copy of CMS's 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 ~~HMO~~ ~~[FNI]~~ MCO under section 1903(m)(5)(B)(ii) of the Act in the following situations:

~~1 So in original. 67 FR 65505, instruction 13, appears to have inadvertently purported to substituted "MCO" for "HMO" in § 438.703 rather than in this section as intended.~~

(i) If a CMS determination that an MCO has acted or failed to act, as described in paragraphs (b)(1) through (b)(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's denial of payment for new enrollees automatically results in a denial of agency payments to the ~~HMO~~ ~~[FNI]~~ 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.)

~~1 So in original. 67 FR 65505, instruction 13, appears to have inadvertently purported to substituted "MCO" for "HMO" in § 438.703 rather than in this section as intended.~~

(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 (~~bc~~) 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)(~~ii~~) of this section, the sanction is effective on the date specified in CMS's reconsideration notice.

(ii) If CMS, in consultation with the State ~~agency~~, 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 (~~ed~~)(1)(ii) of this section.

(g) CMS's role. (1) CMS retains the right to independently perform the functions assigned to the State ~~agency~~ under paragraphs (a) through (d) of this section.

(2) At the same time that the ~~agency~~ State sends notice to the MCO under paragraph (c)(1)(~~i~~) 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.~~ 1003. 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)

§ 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.

~~§ 438.804 Primary care provider payment increases.~~

~~(a) For MCO, PIHP or PAHP contracts that cover calendar years 2013 and 2014, FFP is available at an enhanced rate of 100 percent for the portion of the expenditures for capitation payments made under those contracts to comply with the contractual requirement under § 438.6(c)(5)(vi) only if the following requirements are met:~~

~~(1) The state must submit to CMS the following methodologies for review and approval:~~

~~(i) The state develops a reasonable methodology, based on rational and documented data and assumptions, for identifying the provider payments that would have been made by MCO, PIHP or PAHP for specified primary care services furnished as of July 1, 2009. This methodology can take into consideration the availability of data, and the costs and burden of administering the method, but should produce a reliable and accurate result to the fullest extent possible.~~

~~(ii) The state develops a reasonable methodology, based on rational and documented data and assumptions, for identifying the differential in payment between the provider payments that would have been made by the MCO, PIHP or PAHP on July 1, 2009 and the amount needed to comply with the contractual requirement under § 438.6(c)(5)(vi). This methodology can take into consideration the availability of data, and the costs and burden of administering the method, but should produce a reliable and accurate result to the fullest extent possible.~~

~~(2) The state must submit the methodologies in paragraphs (a)(1)(i) and (ii) of this section to CMS for review no later than the end of the first quarter of CY 2013.~~

~~(3) CMS will use the approved methodologies required under this section in the review and approval of MCO, PIHP or PAHP contracts and rates consistent with § 438.6(a).~~

~~(b) [Reserved]~~

§ 438.806 Prior approval.

(a) Comprehensive risk contracts. FFP is available under a comprehensive risk contract only if—  
all of the following apply:

(1) ~~The Regional Office~~CMS has confirmed that the contractor meets the definition of an MCO or is one of the entities described in paragraphs (b)(2) through (b)(5) of § ~~438.6; and~~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 ~~implementing regulations in~~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~~con-sumers.

(c) FFP is not available in an MCO contract that does not have prior approval from CMS under paragraph (b) of this section.

#### § 438.807 Deferral and/or disallowance of FFP for non-compliance with Federal requirements.

CMS may defer and/or disallow FFP under a contract subject to approval under this part, payment amounts associated with services under a MCO contract, in accordance with the requirements in § 430.40 and § 430.42 of this chapter, respectively, if the Administrator finds that

(a) The contract, as submitted for approval or as administered by the State, is non-compliant with the requirements of section 1903(m)(2)(A) of the Act, the applicable requirements of section 1932 of the Act, or the provisions of this part for the service or services; or

(b) The final capitation rates as developed and described in the rate certification are noncompliant with the requirements in §§ 438.4 through 438.7 for the service or services.

#### § 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~~indi-rectly, 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).

(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 ~~excluded from participation in Federal health care programs under either section 1128 or section 1128A of the Act~~described in § 438.610(a).

(ii) Any individual or entity that would provide those services through an ~~excluded~~ individual or entity described in § 438.610(a).

§ 438.810 Expenditures for enrollment broker services.

(a) ~~Terminology~~Definitions. As used in this section—

~~Choice counseling means activities such as answering questions and providing information (in an unbiased manner) on available MCO, PIHP, PAHP, or PCCM delivery system options, and advising on what factors to consider when choosing among them and in selecting a primary care provider;~~

Enrollment activities means activities such as distributing, collecting, and processing enrollment materials and taking enrollments by phone ~~or~~, in person, or through electronic methods of communication.

Enrollment broker means an individual or entity that performs choice counseling or enrollment activities, or both, ~~and~~.

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~~in-dependent” 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~~subcon-tractor 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~~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 ~~non-risk~~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 independent consumer support services for enrollees using LTSS.

State expenditures for the person or entity providing the services outlined in § 438.71(e) 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 Allo-cation 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 sufficient and timely 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 before each data submission. States may use the external quality review activity required in § 438.358 for the validation of encounter data to meet this requirement.

(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.

(d) States must, within 90 days of the effective date of this requirement, submit to CMS a detailed plan of their procedures and processes to ensure that complete and accurate enrollee encounter data are being submitted timely.



