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Electronic Code of Federal Regulations

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e-CFR Data is current as of February 23, 2012

Title 42: Public Health

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PART 438—MANAGED CARE

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

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

Subpart A—General Provisions



§ 438.1 Basis and scope.



(a) *Statutory basis.* This part is based on 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(m) contains requirements that apply to comprehensive risk contracts.

(3) 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.

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

(5) Section 1932—

(i) Provides that, with specified exceptions, a State may require Medicaid recipients 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) 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. 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—

Capitation payment means a payment the State agency makes periodically to a contractor on behalf of each recipient enrolled under a contract for the provision of medical services under the State plan. The State agency makes the payment regardless of whether the particular recipient receives services during the period covered by the payment.

Comprehensive risk contract means a risk contract 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) 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.

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, speech-language 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.

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

- (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(e)(3) of the Omnibus Budget Reconciliation Act of 1985 (as amended by section 4734 of the Omnibus Budget Reconciliation Act of 1990).

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 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 recipients within the area served by the entity.

(ii) Meets the solvency standards of §438.116.

Nonrisk contract means a contract 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.

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, 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 PCCM contracts with the State to furnish case management services (which include the location, coordination and monitoring of primary health care services) to Medicaid recipients.

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.

Risk contract means a contract 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.

§ 438.6 Contract requirements.



(a) *Regional office review.* The CMS Regional Office must review and approve all MCO, PIHP, and PAHP contracts, including those risk and nonrisk contracts that, on the basis of their value, are not subject to the prior approval requirement in §438.806.

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

(1) An MCO.

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

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

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

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

(c) *Payments under risk contracts* —(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 eligibles.

(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) 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.

(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 risk-sharing 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.

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

(1) The MCO, PIHP, PAHP, or PCCM accepts individuals eligible for enrollment in the order in which they apply without restriction (unless authorized by the Regional Administrator), 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, or PCCM 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, or PCCM will not discriminate against individuals eligible to enroll on the basis of race, color, or national origin, and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin.

(e) *Services that may be covered.* An MCO, PIHP, or PAHP contract may cover, for enrollees, services that are in addition to those covered under the State plan, although the cost of these services cannot be included when determining the payment rates under §438.6(c).

(f) *Compliance with contracting rules.* All contracts must meet the following provisions:

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

(2) Provide for the following:

(i) Compliance 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.

(ii) Reporting all identified provider-preventable conditions in a form or frequency as may be specified by the State.

(3) Meet all the requirements of this section.

(g) *Inspection and audit of financial records.* Risk contracts must provide that the State agency and the Department may inspect and audit any financial records of the entity or its subcontractors.

(h) *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+C organization", "CMS", and "Medicare beneficiaries" must be read as references to "MCO, PIHP, or PAHP", "State agency" and "Medicaid recipients", respectively.

(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) *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) *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 recipients who reside sufficiently near one of the manager's delivery sites to reach that site within a reasonable time using available and affordable modes of transportation.

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

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

(5) Provide that enrollees have the right to disenroll 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.

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

[67 FR 41095, June 14, 2002, as amended at 76 FR 32837, June 6, 2011]

§ 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.

(1) The contract requirements of §438.6, except for requirements that pertain to HIOs.

(2) The information requirements in §438.10.

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

(4) The State responsibility provisions of subpart B of this part except §438.50.

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

(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.

- (8) The certification and program integrity protection provisions set forth in subpart H of this part.
- (b) The following requirements and options for PAHPs apply to PAHPs, PAHP contracts, and States.
 - (1) The contract requirements of §438.6, except requirements for—
 - (i) HIOs.
 - (ii) Advance directives (unless the PAHP includes any of the providers listed in §489.102) of this chapter.
 - (2) All applicable portions of the information requirements in §438.10.
 - (3) The provision against provider discrimination in §438.12.
 - (4) The State responsibility provisions of subpart B of this part except §438.50.
 - (5) The provisions on enrollee rights and protections in subpart C of this part.
 - (6) Designated portions of subpart D of this part.
 - (7) An enrollee's right to a State fair hearing under subpart E of part 431 of this chapter.
 - (8) Prohibitions against affiliations with individuals debarred by Federal agencies in §438.610.

[67 FR 41095, June 14, 2002, as amended at 67 FR 65505, Oct. 25, 2002]

§ 438.10 Information requirements.



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

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

Potential enrollee means a Medicaid recipient 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.

- (b) *Basic rules.* (1) Each State, enrollment broker, MCO, PIHP, PAHP, and PCCM must provide all enrollment notices, informational materials, and instructional materials relating 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 enrollees and potential enrollees understand the State's managed care program.

- (3) Each MCO and PIHP must have in place a mechanism to help enrollees and potential enrollees understand the requirements and benefits of the plan.

- (c) *Language.* The State must do the following:

- (1) Establish a methodology for identifying the prevalent non-English languages spoken by enrollees and potential enrollees throughout the State. "Prevalent" means a non-English language spoken by a significant number or percentage of potential enrollees and enrollees in the State.

- (2) Make available written information in each prevalent non-English language.

- (3) Require each MCO, PIHP, PAHP, and PCCM to make its written information available in the prevalent non-English languages in its particular service area.

- (4) Make oral interpretation services available and require each MCO, PIHP, PAHP, and PCCM to make

those services available free of charge to each potential enrollee and enrollee. This applies 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 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.

(d) *Format.* (1) Written material must—

(i) Use easily understood language and format; and

(ii) Be available in alternative formats and in an appropriate manner that takes into consideration the special needs of those who, for example, are visually limited or have limited reading proficiency.

(2) All enrollees and potential enrollees must be informed that information is available in alternative formats and how to access those formats.

(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 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.

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

(i) General information about—

(A) The basic features of managed care;

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

(C) MCO, PIHP, PAHP, and PCCM responsibilities for coordination of enrollee care;

(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:

(A) Benefits covered.

(B) Cost sharing, if any.

(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. For a counseling or referral service that the MCO, PIHP, 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 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 recipient'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, and, when appropriate, the PAHP or PCCM, must make a good faith effort to give written notice of termination of a contracted provider, within 15 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:

(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.

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

(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.

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

(A) What constitutes emergency medical condition, emergency services, and poststabilization 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 poststabilization care services rules set forth at §422.113(c) of this chapter.
- (x) Policy on referrals for specialty care and for other benefits not furnished by 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, in a State-developed or State-approved description, that 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) The requirements and timeframes for filing a grievance or appeal.
 - (iv) 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.
 - (vi) The fact that, when requested by the enrollee—
 - (A) Benefits will continue if the enrollee files an appeal or a request for State fair hearing within the timeframes specified for filing; and
 - (B) The enrollee may be required to pay the cost of services furnished while the appeal 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.
 - (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).

(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.

(2) *When and how the information must be furnished.* The information must be furnished as follows:

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

(ii) For enrollees, annually and upon request.

(iii) In a comparative, chart-like format.

(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:

(i) The MCO's or PCCM's service area.

(ii) The benefits covered under the contract.

(iii) Any cost sharing imposed by the MCO or PCCM.

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

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.12 Provider discrimination prohibited.



(a) *General rules.* (1) An MCO, PIHP, or PAHP may not discriminate for 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 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.

Subpart B—State Responsibilities**§ 438.50 State Plan requirements.**

(a) *General rule.* A State plan that requires Medicaid recipients to enroll in managed care 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 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 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 contracts.

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

(4) This part, for MCOs and PCCMs.

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

(6) Section 438.6(c), for payments under any risk contracts, and §447.362 of this chapter for payments under any nonrisk contracts.

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

(1) Recipients who are also eligible for Medicare.

(2) Indians who are members of Federally recognized tribes, except when the MCO or PCCM is—

(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 XVI;

- (ii) Eligible under section 1902(e)(3) of the Act;
 - (iii) In foster care or other out-of-home placement;
 - (iv) Receiving foster care or adoption assistance; or
 - (v) Receiving services through a family-centered, community-based, coordinated care system that receives grant funds under section 501(a)(1)(D) of title V, and is defined by the State in terms of either program participation or special health care needs.
- (e) *Priority for enrollment.* The State must have an enrollment system under which recipients 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 recipients who do not choose an MCO or PCCM during their enrollment period, the State must have a default enrollment process for assigning those recipients to contracting MCOs and PCCMs.
- (2) The process must seek to preserve existing provider-recipient relationships and relationships with providers that have traditionally served Medicaid recipients. If that is not possible, the State must distribute the recipients 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-recipient relationship" is one in which the provider was the main source of Medicaid services for the recipient 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 recipient.
- (4) A provider is considered to have "traditionally served" Medicaid recipients if it has experience in serving the Medicaid population.

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



- (a) *General rule.* Except as specified in paragraphs (b) and (c) of this section, a State that requires Medicaid recipients to enroll in an MCO, PIHP, PAHP, or PCCM must give those recipients a choice of at least two entities.
- (b) *Exception for rural area residents.* (1) Under 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, PAHP, or PCCM system:
- (i) A program authorized by a 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 paragraph (b)(1) of this section, must permit the recipient—
- (i) To choose from at least two physicians or case managers; 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, PAHP, or PCCM network.
 - (B) The provider is not part of the network, but is the main source of a service to the recipient, provided that—

(1) The provider is given the opportunity to become a participating provider under the same requirements for participation in the MCO, PIHP, 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 days (after being given an opportunity to select a provider who participates).

(C) The only plan or provider available to the recipient does not, because of moral or religious objections, provide the service the enrollee seeks.

(D) The recipient's primary care provider or other provider determines that the recipient needs related services that would subject the recipient to unnecessary risk if received separately (for example, a cesarean section and a tubal ligation) and not all of the related services are available within the network.

(E) The State determines that other circumstances warrant out-of-network treatment.

(3) As used in this paragraph, "rural area" is any area other than an "urban area" as defined in §412.62(f)(1)(ii) of this chapter.

(c) *Exception for certain health insuring organizations (HIOs).* The State may limit recipients 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 recipient 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).

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.56 Disenrollment: Requirements and limitations.



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

(b) *Disenrollment requested by the MCO, PIHP, PAHP, or PCCM.* All MCO, PIHP, PAHP, and PCCM contracts must—(1) Specify the reasons for which the MCO, PIHP, PAHP, or PCCM may request disenrollment of an enrollee;

(2) Provide that the MCO, PIHP, PAHP, or PCCM may not request disenrollment because of an adverse change in the enrollee's health status, or because of the enrollee's utilization of medical services, diminished mental capacity, or uncooperative or disruptive behavior resulting from his or her special needs (except when his or her continued enrollment in the MCO, PIHP, PAHP, or PCCM 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, or PCCM 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, and PCCM contracts must provide that a recipient 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 recipient's initial enrollment with the MCO, PIHP, PAHP, or PCCM, or the date the State sends the recipient 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 recipient to miss the annual disenrollment opportunity.

(iv) When the State imposes the intermediate sanction specified in §438.702(a)(3).

(d) *Procedures for disenrollment*—(1) *Request for disenrollment.* The recipient (or his or her representative) must submit an oral or written request—

(i) To the State agency (or its agent); or

(ii) To the MCO, PIHP, PAHP, or PCCM, if the State permits MCOs, PIHP, PAHPs, and PCCMs 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, or PCCM's service area.

(ii) The plan does not, because of moral or religious objections, cover the service the enrollee seeks.

(iii) The enrollee needs related services (for example a cesarean section and a tubal ligation) to be performed at the same time; not all related services are available within the 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) 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, or PCCM action on request.* (i) An MCO, PIHP, PAHP, or PCCM may either approve a request for disenrollment or refer the request to the State.

(ii) If the MCO, PIHP, PAHP, PCCM, or State agency (whichever is responsible) fails to make a disenrollment determination so that the recipient can be disenrolled within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved.

(4) *State agency action on request.* For a request received directly from the recipient, or one referred by the MCO, PIHP, PAHP, or PCCM, 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, or PCCM at the agency's request.

(iii) Any of the reasons specified in paragraph (d)(2) of this section.

(5) *Use of the MCO, PIHP, PAHP, or PCCM grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO, PIHP, PAHP, or PCCM's grievance system before making a determination on the enrollee's request.

(ii) The grievance process, if used, must be completed in time to permit the disenrollment (if approved) to be effective in accordance with the timeframe specified in §438.56(e)(1).

(iii) If, as a result of the grievance process, the MCO, PIHP, PAHP, or PCCM approves the disenrollment, the State agency is not required to make a determination.

(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 or the MCO, PIHP, PAHP, or PCCM files the request.

(2) If the MCO, PIHP, PAHP, or PCCM or the State agency (whichever is responsible) fails to make the determination within the timeframes specified in paragraph (e)(1) of this section, the disenrollment is considered approved.

(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 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 recipient who is disenrolled 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 specified in §438.50(f).

(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.



The State agency must ensure that no payment is made to a provider other than the MCO, PIHP, or PAHP for services available under the contract between the State and the MCO, PIHP, or PAHP, except when these payments are provided for in title XIX of the Act, in 42 CFR, or when the State agency has adjusted the capitation rates paid under the contract, in accordance with §438.6(c)(5)(v), to make payments for graduate medical education.

§ 438.62 Continued services to recipients.



The State agency must arrange for Medicaid services to be provided without delay to any Medicaid enrollee of an MCO, PIHP, PAHP, or PCCM whose contract is terminated and for any Medicaid enrollee who is disenrolled from an MCO, PIHP, PAHP, or PCCM for any reason other than ineligibility for Medicaid.

§ 438.66 Monitoring procedures.



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) Recipient enrollment and disenrollment.

(b) Processing of grievances and appeals.

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

(d) Violations of the conditions for FFP, as set forth in subpart J of this part.

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

Subpart C—Enrollee Rights and Protections



§ 438.100 Enrollee rights.



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

(1) Each MCO and PIHP has written policies regarding the enrollee rights specified in this section; and

(2) Each MCO, PIHP, PAHP, and PCCM complies with any applicable Federal and State laws that pertain to enrollee rights, and ensures that its staff and affiliated providers take 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, or PCCM 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(f)(6)(xii).)

(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, or PCCM and its 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, and PCCM complies with any other applicable Federal and State laws (such as: 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 II and III of the Americans with Disabilities Act; and other laws regarding privacy and confidentiality).

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 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 nontreatment.

(iv) The enrollee's right to participate in decisions regarding his or her health care, including the right to refuse treatment, and to express preferences about future treatment decisions.

(2) Subject to the information requirements of paragraph (b) of this section, an MCO, PIHP, or PAHP that would otherwise be required to provide, reimburse for, or provide coverage of, a counseling or referral service because of the requirement in paragraph (a)(1) of this section is not required to do so if the MCO, PIHP, or PAHP objects to the service on moral or religious grounds.

(b) *Information requirements: MCO, PIHP, and PAHP responsibility.* (1) 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 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)(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) and (f), 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).

(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.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 438.104 Marketing activities.



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

Cold-call marketing means any unsolicited personal contact by the MCO, PIHP, PAHP, or PCCM with a potential enrollee for the purpose of marketing as defined in this paragraph.

Marketing means any communication, from an MCO, PIHP, PAHP, or PCCM to a Medicaid recipient who is not enrolled in that entity, that can reasonably be interpreted as intended to influence the recipient to enroll in that particular MCO's, PIHP's, PAHP's, or PCCM's Medicaid product, or either to not enroll in, or to disenroll from, another MCO's, PIHP's, PAHP's, or PCCM's Medicaid product.

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 to potential enrollees.

MCO, PIHP, PAHP, or PCCM include any of the entity's employees, affiliated providers, agents, or contractors.

(b) *Contract requirements.* Each contract with an MCO, PIHP, PAHP, or PCCM 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 recipient 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, or other cold-call marketing activities.
 - (2) Specify the methods by which the entity assures the State agency that marketing, including plans and materials, is accurate and does not mislead, confuse, or defraud the recipients 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 recipient must enroll in the MCO, PIHP, PAHP, or PCCM in order to obtain benefits or in order to not lose benefits; or
 - (ii) The MCO, PIHP, PAHP, or PCCM 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 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 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 447.60 of this chapter.

§ 438.114 Emergency and poststabilization services.



(a) *Definitions.* As used in this section—

Emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:

- (1) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy.
- (2) Serious impairment to bodily functions.
- (3) Serious dysfunction of any bodily organ or part.

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

- (1) Furnished by a provider that is qualified to furnish these services under this title.
- (2) Needed to evaluate or stabilize an emergency medical condition.

Poststabilization care services means covered services, related to an emergency medical condition that are provided after an enrollee is stabilized 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 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 contract.

(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, or PCCM; 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, or PCCM instructs the enrollee to seek emergency services.

(2) A PCCM must—

(i) 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 (b) of this section as responsible for coverage and payment.

(e) *Coverage and payment: Poststabilization care services.* Poststabilization care services are covered and paid for in accordance with provisions set forth at §422.113(c) of this chapter. In applying those provisions, reference to "M+C organization" must be read as reference to the entities responsible for Medicaid payment, as specified in paragraph (b) of this section.

(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.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

§ 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.

[67 FR 41095, June 14, 2002; 67 FR 65505, Oct. 25, 2002]

Subpart D—Quality Assessment and Performance Improvement



§ 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 recipients 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



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§ 438.206 Availability of services.



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(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.

(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 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 enrollees with disabilities.

(2) Provides female enrollees with direct access to a women's health specialist within the 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 network, or arranges for the enrollee to obtain one outside the network, at no cost to the enrollee.

(4) If the network is unable to provide necessary services, covered under the contract, to a particular