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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 require-

ments 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 Rec-

onciliation 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