

(g) *Reclaim of refunds.* (1) If a provider is determined bankrupt or out of business under this section after the 60-day period following discovery of the overpayment ends and the State has not been able to make complete recovery, the agency may reclaim the amount of the Federal share of any unrecovered overpayment amount previously refunded to HCFA. HCFA allows the reclaim of a refund by the agency if the agency submits to HCFA documentation that it has made reasonable efforts to obtain recovery.

(2) If the agency reclaims a refund of the Federal share of an overpayment—

(i) In bankruptcy cases, the agency must submit to HCFA a statement of its efforts to recover the overpayment during the period before the petition for bankruptcy was filed; and

(ii) In out-of-business cases, the agency must submit to HCFA a statement of its efforts to locate the provider and its assets and to recover the overpayment during any period before the provider is found to be out of business in accordance with § 433.318.

(h) *Supporting reports.* The agency must report the following information to support each Quarterly Statement of Expenditures Form HCFA-64:

(1) Amounts of overpayments not collected during the quarter but refunded because of the expiration of the 60-day period following discovery;

(2) Upward and downward adjustments to amounts credited in previous quarters;

(3) Amounts of overpayments collected under court-approved discharges of bankruptcy;

(4) Amounts of previously reported overpayments to providers certified as bankrupt or out of business during the quarter; and

(5) Amounts of overpayments previously credited and reclaimed by the State.

#### § 433.322 Maintenance of records.

The Medicaid agency must maintain a separate record of all overpayment activities for each provider in a manner that satisfies the retention and access requirements of 45 CFR part 74, subpart D.

## PART 434—CONTRACTS

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

SOURCE: 48 FR 54020, Nov. 30, 1983, unless otherwise noted.

### Subpart A—General Provisions

#### § 434.1 Basis and scope.

(a) *Basis*. This part is based on sections 1902(a)(4) and 1903(m) of the Act. Section 1902(a)(4) requires that the State plan provide for methods of administration that the Secretary finds necessary for proper and efficient operation of the plan. Section 1903(m)(1)(A) of the Act defines an HMO as an entity that meets the requirements of the Public Health Service (PHS) Act to be a Federally qualified HMO, or meets two specified requirements pertaining to accessibility of services and fiscal solvency. Section 1903(m)(2)(A) limits risk-basis contracts for specified health services to entities that meet the HMO definition of section 1903(m)(1)(A) and sets forth certain enrollment and other requirements that these contracts must meet as a condition for FFP. Section 1903(m)(2)(B) exempts, from the limitations of section 1903(m)(2)(A), certain specified prepayment plans that are not HMOs.

(b) *Scope*. This part sets forth the requirements for contracts with certain organizations for furnishing Medicaid services or processing or paying Medicaid claims, or enhancing the agency's capability for effective administration of the program.

[48 FR 54020, Nov. 30, 1983; 48 FR 55128, Dec. 9, 1983]

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### § 434.2 Definitions.

As used in this part, unless the context indicates otherwise—

*Capitation fee* means the fee the agency pays periodically to a contractor for each recipient enrolled under a contract for the provision of medical services under the State plan, whether or not the recipient receives the services during the period covered by the fee.

*Clinical laboratory* means a facility that examines materials derived from the human body, for the purpose of providing information for the diagnosis, prevention or treatment of a disease or the assessment of a medical condition.

*Contractor* means any of the following entities that contract with the Medicaid agency under a State plan and in return for a payment, to process claims, to pay for or provide medical services, or to enhance the agency's capability for effective administration of the program:

- (a) A fiscal agent.
- (b) A health care project grant center.
- (c) A private nonmedical institution.
- (d) A health insuring organization.
- (e) A health maintenance organization.
- (f) A prepaid health plan.
- (g) A clinical laboratory.
- (h) A professional management service or consultant firm.

*Enrolled recipient* means an individual who is eligible for Medicaid and who enters into an agreement to receive services from a health maintenance organization or prepaid health plan that contracts with the agency under this part.

*Federally qualified HMO* means an HMO that has been determined by HCFA to be a qualified HMO under section 1310(d) of the PHS Act.

*Fiscal agent* means an entity that processes or pays vendor claims for the agency.

*Health care projects grant center* means an entity that—

- (a) Is supported in whole or in part by Federal project grant financial assistance; and

- (b) Provides or arranges for medical services to recipients.

*Health insuring organization (HIO)* means an entity that—

(a) Covers (through payments or arrangements with providers) services for recipients in exchange for a premium or subscription charge paid; and

(b) Assumes risk for the costs of services it covers.

*Health maintenance organization (HMO)* means a public or private organization organized under State law that—

(a) Is a federally qualified HMO; or

(b) Meets the State plan's definition of an HMO.

*Nonrisk* means that the contractor is not at financial risk for changes in the cost or utilization of services provided for in the payment rate agreed upon at the beginning of the contract period. Under a nonrisk contract, the State agency may make retroactive adjustment during and at the end of the contract period so that the contractor is reimbursed for costs actually incurred, subject to the upper limit of payment established in § 447.362 of this chapter, or any lower limit specified in the contract.

*Prepaid health plan (PHP)* means an entity that provides medical services to enrolled recipients, under contract with the Medical agency and on the basis of prepaid capitation fees, but is not subject to requirements in section 1903(m)(2)(A) of the Act.

*Private nonmedical institution* means an institution (such as a child-care facility or a maternity home) that—

(a) Is not, as a matter of regular business, a health insuring organization or a community health care center;

(b) Provides medical care to its residents through contracts or other arrangements with medical providers; and

(c) Receives capitation payments from the Medicaid agency, under a nonrisk contract, for its residents who are eligible for Medicaid.

*Professional management service or consultant firm* means a firm that performs management services such as auditing or staff training, or carries out studies or provides consultation aimed at improving State Medicaid operations, for example, with respect to reimbursement formulas or accounting systems.

*Provisional status HMO* means an HMO that the State agency has determined is a provisional status Federally

qualified HMO because more than 90 days have elapsed since the HMO applied to the PHS for Federal qualification and the PHS has not made a final determination. The provisional status continues until the PHS makes the final determination or the contract with the Medicaid agency is terminated, whichever occurs first.

*Risk or underwriting risk* means the possibility that a contractor may incur a loss because the cost of providing services may exceed the payments made by the agency to the contractor for services covered under the contract.

[48 FR 54020, Nov. 30, 1983; 48 FR 55128, Dec. 9, 1983, as amended at 52 FR 22322, June 11, 1987; 55 FR 51295, Dec. 13, 1990]

#### § 434.4 State plan requirement.

If the State plan provides for contracts of the types covered by this part, the plan must also provide for meeting the applicable requirements of this part.

#### § 434.6 General requirements for all contracts and subcontracts.

(a) *Contracts.* All contracts under this part must—

(1) Include provisions that define a sound and complete procurement contract, as required by 45 CFR part 74, appendix G;

(2) Identify the population covered by the contract;

(3) Specify any procedures for enrollment or reenrollment of the covered population;

(4) Specify the amount, duration, and scope of medical services to be provided or paid for;

(5) Provide that the agency and HHS may evaluate through inspection or other means, the quality, appropriateness and timeliness of services performed under the contract;

(6) Specify procedures and criteria for terminating the contract, including a requirement that the contractor promptly supply all information necessary for the reimbursement of any outstanding Medicaid claims;

(7) Provide that the contractor maintains an appropriate record system for services to enrolled recipients;

(8) Provide that the contractor safeguards information about recipients as

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required by part 431, subpart F of this chapter;

(9) Specify any activities to be performed by the contractor that are related to third party liability requirements in part 433, subpart D of this chapter;

(10) Specify which functions may be subcontracted; and

(11) Provide that any subcontracts meet the requirements of paragraph (b) of this section.

(b) *Subcontracts.* All subcontracts must be in writing and fulfill the requirements of this part that are appropriate to the service or activity delegated under the subcontract.

(c) *Continued responsibility of contractor.* No subcontract terminates the legal responsibility of the contractor to the agency to assure that all activities under the contract are carried out.

## Subpart B—Contracts with Fiscal Agents and Private Nonmedical Institutions

### § 434.10 Contracts with fiscal agents.

Contracts with fiscal agents must—

(a) Meet the requirements of § 434.6;

(b) Include termination procedures that require the contractors to supply promptly all material necessary for continued operation of payment and related systems. This material includes—

(1) Computer programs;

(2) Data files;

(3) User and operation manuals, and other documentation;

(4) System and program documentation; and

(5) Training programs for Medicaid agency staff, their agents or designated representatives in the operation and maintenance of the system;

(c) Offer to the State one or both of the following options, if the fiscal agent or the fiscal agent's subcontractor has a proprietary right to material specified in paragraph (b) of this section:

(1) Purchasing the material; or

(2) Purchasing the use of the material through leasing or other means; and

(d) State that payment to providers will be made in accordance with part 447 of this chapter.

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### § 434.12 Contracts with private non-medical institutions.

Contracts with private nonmedical institutions must—

(a) Meet the requirements of § 434.6;

(b) Specify a capitation fee based on the cost of the services provided, in accordance with the reimbursement requirements prescribed in part 447 of this chapter; and

(c) Specify when the capitation fee must be paid.

### § 434.14 [Reserved]

## Subpart C—Contracts With HMOs and PHPs: Contract Requirements

### GENERAL REQUIREMENTS

### § 434.20 Basic rules.

(a) *Entities eligible for risk contracts for services specified in § 434.21.* A Medicaid agency may enter into a risk contract for the scope of services specified in § 434.21, only with an entity that—

(1) Is a Federally qualified HMO, including a provisional status Federally qualified HMO;

(2) Meets the State plan's definition of an HMO, as specified in paragraph (c) of this section;

(3) Is one of several entities identified in section 1903(m)(2)(B) (i), (ii) and (iii) of the Act, and considered as PHPs;

(4) Is one of certain 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), these entities are subject to the regulations governing HMOs under this part, with the exception of the requirements of section 1903(m)(2)(A) (i) and (ii) of the Act; or

(5) Is an HIO that arranges for services and becomes operational before January 1, 1986.

(b) *Entities eligible for other kinds of contracts.* A Medicaid agency may enter into a nonrisk contract, or a risk contract for a scope of services other than the scope specified in § 434.21(b), with any of the entities identified in paragraph (a) of this section, or with any other PHP.

(c) *State plan definition of HMO.* If the plan provides for risk contracts with

entities that are not Federally qualified HMOs, for the services specified in § 434.21(b), the plan must include a State definition of an HMO. Under the definition, the HMO must meet at least the following requirements:

(1) Be organized primarily for the purpose of providing health care services.

(2) Make the services it provides to its Medicaid enrollees as accessible to them (in terms of timeliness, amount, duration, and scope) as those services are to nonenrolled Medicaid recipients within the area served by the HMO.

(3) Make provision, satisfactory to the Medicaid agency, against the risk of insolvency, and assure that Medicaid enrollees will not be liable for the HMO's debts if it does become insolvent.

(d) *Services that may be covered.* A contract with an HMO or a PHP may cover services to enrolled recipients that are not provided under the plan to non-enrolled recipients as permitted under § 440.250(g) of this chapter.

(e) *Requirements for all contracts.* For all contracts with HMOs or PHPs—

(1) The contract must meet the requirements of § 434.6;

(2) The Medicaid agency must carry out the responsibilities specified in subpart E of this part; and

(3) The contract must provide that any cost-sharing requirements imposed for services furnished to recipients are in accordance with §§ 447.50 through 447.58 of this chapter.

[48 FR 54020, Nov. 30, 1983, as amended at 55 FR 23744, June 12, 1990; 55 FR 51295, Dec. 13, 1990; 56 FR 10515, Mar. 13, 1991]

#### ADDITIONAL REQUIREMENTS

##### § 434.21 Contracts that must meet additional requirements.

(a) Unless otherwise indicated, the additional requirements set forth in §§ 434.23 through 434.38 must be met in all types of contracts with HMOs and PHPs:

(1) Nonrisk contracts;

(2) Risk comprehensive contracts; and

(3) Other risk contracts.

(b) Risk comprehensive contracts are risk contracts for furnishing or arranging for comprehensive services, that is,

inpatient hospital services and any of the following services, or any three or more of the following services or groups of services:

(1) Outpatient hospital services and rural health clinic services.

(2) Other laboratory and X-ray services.

(3) Skilled nursing facility (SNF) services, early and periodic screening, diagnosis and treatment (EPSDT), and family planning.

(4) Physicians' services.

(5) Home health services.

(c) Other risk contracts are risk contracts for a scope of services other than those specified in paragraph (b) of this section.

[48 FR 54020, Nov. 30, 1983, as amended at 55 FR 51295, Dec. 13, 1990]

##### § 434.22 Application of sanctions to risk comprehensive contracts.

A risk comprehensive contract 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 HCFA under § 434.67(e).

[59 FR 36084, July 15, 1994]

##### § 434.23 Capitation fees.

The contract must specify—

(a) The actuarial basis for computation of the capitation fees; and

(b) That the capitation fees and any other payments provided for in the contract do not exceed the payment limits set forth in §§ 447.361 and 447.362 of this chapter.

##### § 434.25 Coverage and enrollment.

(a) The contract must provide that—

(1) There will be an open enrollment period during which the HMO or PHP will accept individuals who are eligible to be covered under the contract—

(i) In the order in which they apply;

(ii) Without restriction, unless authorized by the Regional Administrator; and

(iii) Up to the limits set under the contract; and

(2) Enrollment is voluntary.

(b) Risk comprehensive contracts with HMOs must also provide that the HMO will not discriminate, against individuals eligible to be covered under

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contract, on the basis of health status or need for health services.

**§ 434.26 Composition of enrollment.**

(a) *Basic rule.* Except as provided in paragraph (b) of this section, the contract must provide that Medicare beneficiaries and Medicaid recipients constitute less than 75 percent of the total enrollment of the HMO or PHP.

(b) *Exceptions—(1) Waiver for new HMOs with risk comprehensive contracts.* The requirement of paragraph (a) of this section may be waived for up to three years from the date the Regional Administrator determines the entity to be an HMO (as provided in § 434.71) if the HMO submits annual reports demonstrating to the Regional Administrator's satisfaction, that it is making continuous efforts and progress toward achieving compliance with paragraph (a) of this section.

(2) *Waiver for public HMOs with risk comprehensive contracts.* The Regional Administrator may approve waiver or modification of the requirement of paragraph (a) of this section, for an HMO that is owned or operated by a State, county or municipal health department or hospital, if—

(i) There are special circumstances that justify modification or waiver; and

(ii) The HMO has made and continues to make reasonable efforts to enroll individuals who are not eligible for Medicare or Medicaid.

(3) *Waiver for certain nonprofit HMOs with risk comprehensive contracts.* The Regional Administrator may approve waiver or modification of the requirement of paragraph (a) of this section, for a nonprofit HMO which has a minimum of 25,000 members, is and has been federally qualified for a period of at least 4 years, provides basic health services through members of its staff, is located in an area designated as medically underserved under section 1302(7) of the Public Health Service Act, and has previously received a waiver under section 1115 of the Act of the requirement described in paragraph (a) of this section, if—

(i) There are special circumstances that justify modification or waiver; and

(ii) The HMO has made and continues to make reasonable efforts to enroll individuals who are not eligible for Medicare or Medicaid.

(4) *Waiver for PHPs and for HMOs that have contracts other than risk comprehensive.* The Medicaid agency may waive the requirement of paragraph (a) of this section if the PHP or HMO requests waiver and shows good cause.

(5) *Special exemption.* (i) Community, Migrant and Appalachian Health Centers identified in section 1903(m)(2)(G) of the Act are exempt from the basic rule; and

(ii) Health maintenance organizations (as defined in section 1903(m)(1)(A) of the Act) that are primarily owned and controlled by centers specified in paragraph (b)(5)(i) of this section are exempt from the basic rule if they furnish primary care services substantially through such centers.

[48 FR 54020, Nov. 30, 1983, as amended at 55 FR 23744, June 12, 1990; 55 FR 25774, June 22, 1990]

**§ 434.27 Termination of enrollment.**

(a) All HMO and PHP contracts must specify—

(1) The reasons for which the HMO or PHP may terminate a recipient's enrollment;

(2) That the HMO or PHP will not terminate enrollment because of an adverse change in the recipient's health; and

(3) The methods by which the HMO or PHP will assure the agency that terminations are consistent with the reasons permitted under the contract and are not due to an adverse change in the recipient's health.

(b) An HMO risk comprehensive contract must specify either—

(1) That an enrollee of an organization with a risk comprehensive contract may terminate enrollment freely at any time, effective no later than the first day of the second month after the month in which he or she requests termination; or

(2) If an agency chooses to restrict disenrollment rights under paragraph (d) of this section, that an enrollee

may terminate enrollment freely during the first month of any period of enrollment up to 6 months, and may terminate enrollment during the remainder of the enrollment period only as provided under paragraph (e) of this section. Termination of enrollment during the first month of period of enrollment is effective no later than the first day of the second month after the month in which he or she requests termination. Termination of enrollment during the remainder of a period of enrollment is in accordance with paragraph (f) of this section.

(c) An HMO risk comprehensive contract under paragraph (b) of this section must specify that the HMO will inform each recipient at the time of enrollment, of the right to terminate enrollment.

(d) A State plan may provide for contracts with certain organizations which restrict disenrollment rights of Medicaid enrollees under paragraph (b)(2) of this section if the following conditions are met—

(1) The organization is—

(i) A federally qualified HMO whose Medicare and Medicaid enrollment constitutes less than 75 percent of its total enrollment; or

(ii) One of the entities identified in section 1903(m)(2)(G) of the Act; or

(iii) One of the entities described in § 434.26(b)(5)(ii); or

(iv) The entity described in section 1903(m)(6) of the Act; or

(v) An entity described in § 434.26(b)(3); and

(2) The disenrollment requirements of paragraphs (e), (f) and (g) of this section are met.

(e) An agency choosing to restrict enrollee disenrollment rights under paragraph (b)(2) of this section in its contract with the organization—

(1) Must permit the enrollee to request disenrollment without cause during the first month of any enrollment period (an enrollment period may not exceed 6 months);

(2) Must permit an enrollee to disenroll during the remainder of any period of enrollment following the first month, if (in accordance with the organization's contract with the State agency) the organization approves the enrollee's request to disenroll, or if all

of the following requirements are met—

(i) An enrollee requests in writing to the State agency and the organization disenrollment for good cause;

(ii) The request cites the reason(s) why he or she wishes to disenroll, such as poor quality care, lack of access to necessary specialty services covered under the State plan, or other reasons satisfactory to the State agency;

(iii) The organization provides information that the agency may require; and

(iv) The agency determines that good cause for disenrollment exists.

(3) May require that the recipient seek to redress the problem through use of the organization's grievance process prior to a State agency determination in a disenrollment for cause request, except in cases in which immediate risk of permanent damage to the recipient's health is alleged. The grievance process, when utilized, must be completed in time to permit the enrollee to disenroll no later than the first day of the second month after the month the disenrollment request was made. If the organization, as a result of the grievance process, approves an enrollee's request to disenroll, the State agency is not required to make a determination in the case.

(f) The State agency must make a determination and take final action on the recipient's request so that disenrollment occurs no later than the first day of the second month after the month the request was made. If the agency fails to act within the specified timeframe, the recipient's request to disenroll is deemed to be approved as of the date that agency action was required.

(g) An agency which restricts disenrollment under paragraph (b)(2) of this section must also—

(1) Establish an appeal procedure for enrollees who disagree with the agency's finding that good cause does not exist for disenrollment.

(2) Require the organization to inform recipients who are potential enrollees prior to enrollment of their disenrollment rights; and

(3) Require the organization to notify enrollees of their disenrollment rights under this section—

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- (i) At least 30 days before the start of each new period of enrollment; and
- (ii) No less than twice per year.

[48 FR 54020, Nov. 30, 1983, as amended at 53 FR 12016, Apr. 12, 1988; 55 FR 23744, June 12, 1990; 55 FR 33407, Aug. 15, 1990]

**§ 434.28 Advance directives.**

A risk comprehensive contract with an HMO must provide for compliance with the requirements of subpart I of part 489 of this chapter relating to maintaining written policies and procedures respecting advance directives. This requirement includes provisions to inform and distribute written information to adult individuals concerning policies on advance directives, including a description of applicable State law. Such information must reflect changes in State law as soon as possible, but no later than 90 days after the effective date of the State law.

[60 FR 33293, June 27, 1995]

**§ 434.29 Choice of health professional.**

The contract must allow each enrolled recipient to choose his health professional in the HMO or the PHP to the extent possible and appropriate.

**§ 434.30 Emergency medical service.**

If the contract covers emergency medical services, it must—

(a) Provide that all covered emergency services are available 24 hours a day and 7 days a week, either in the contractor's own facilities or through arrangements, approved by the agency, with other providers;

(b) Specify the circumstances under which the emergency services will be covered when furnished by a provider with which the contractor does not have arrangements, including at least the following circumstances:

(1) The services were needed immediately because of an injury or sudden illness; and

(2) The time required to reach the contractor's facilities, or the facilities of a provider with which the contractor has arrangements, would have meant risk of permanent damage to the recipient's health; and

(c) Specify whether it is the contractor, or the agency, that will make

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prompt payment for covered emergency services that are furnished by providers specified in paragraph (b) of this section.

**§ 434.32 Grievance procedure.**

The contract must provide for an internal grievance procedure that—

(a) Is approved in writing by the agency;

(b) Provides for prompt resolution; and

(c) Assures the participation of individuals with authority to require corrective action.

**§ 434.34 Quality assurance system.**

The contract must provide for an internal quality assurance system that:

(a) Is consistent with the utilization control requirement of part 456 of this chapter;

(b) Provides for review by appropriate health professionals of the process followed in providing health services;

(c) Provides for systematic data collection of performance and patient results;

(d) Provides for interpretation of this data to the practitioners; and

(e) Provides for making needed changes.

[48 FR 54013, Nov. 30, 1983; 49 FR 9173, Mar. 12, 1984]

**§ 434.36 Marketing.**

The contract must specify the methods by which the HMO or PHP will assure the agency that marketing plans, procedures, and materials are accurate, and do not mislead, confuse, or defraud either recipients or the agency.

[53 FR 12016, Apr. 12, 1988]

**§ 434.38 Inspection and audit of HMO's financial records.**

A risk comprehensive contract with an HMO must provide that the agency and the Department may inspect and audit any financial records of the HMO or its subcontractors relating to the HMO's capacity to bear the risk of potential financial losses.

### Subpart D—Contracts With Health Insuring Organizations

SOURCE: 55 FR 51295, Dec. 13, 1990, unless otherwise noted.

#### § 434.40 Contract requirements.

(a) Contracts with health insuring organizations that are not subject to the requirements in section 1903(m)(2)(A) must:

(1) Meet the general requirements for all contracts and subcontracts specified in § 434.6;

(2) Specify that the contractor assumes at least part of the underwriting risk and:

(i) If the contractor assumes the full underwriting risk, specify that payment of the capitation fees to the contractor during the contract period constitutes full payment by the agency for the cost of medical services provided under the contract;

(ii) If the contractor assumes less than the full underwriting risk, specify how the risk is apportioned between the agency and the contractor;

(3) Specify whether the contractor returns to the agency part of any savings remaining after the allowable costs are deducted from the capitations fees, and if savings are returned, the apportionment between agency and the contractor; and

(4) Specify the extent, if any, to which the contractor may obtain reinsurance of a portion of the underwriting risk.

(b) The contract must—

(1) Specify that the capitation fee will not exceed the limits set forth under part 447 of this chapter.

(2) Specify that, except as permitted under paragraph (b) of this section, the capitation fee paid on behalf of each recipient may not be renegotiated—

(i) During the contract period if the contract period is 1 year or less; or

(ii) More often than annually if the contract period is for more than 1 year.

(3) Specify that the capitation fee will not include any amount for recoupment of any specific losses suffered by the contractor for risks assumed under the same contract or a prior contract with the agency; and

(4) Specify the actuarial basis for computation of the capitation fee.

(c) The capitation fee may be renegotiated more frequently than annually for recipients who are not enrolled at the time of renegotiation or if the renegotiation is required by changes in Federal or State law.

#### § 434.42 Application of sanctions to risk comprehensive contracts.

A risk comprehensive contract 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 HCFA under § 434.67(e).

[59 FR 36084, July 15, 1994]

#### § 434.44 Special rules for certain health insuring organizations.

(a) A health insuring organization that first enrolls patients on or after January 1, 1986, and arranges with other providers (through subcontract, or through other arrangements) for the delivery of services (as described in § 434.21(b)) to Medicaid enrollees on a prepaid capitation risk basis is—

(1) Subject to the general requirements set forth in § 434.20(d) concerning services that may be covered; § 434.20(e), which sets forth the requirements for all contracts; the additional requirements set forth in §§ 434.21 through 434.38; and the Medicaid agency responsibilities specified in subpart E of this part; and

(2) To be organized under the appropriate laws, including corporation laws, of the State in which it operates. There is no Federal requirement that an HIO be organized under a State's HMO law, if it has one. However, the health insuring organization must meet the State plan definition requirements in § 434.20(c) (1), (2) and (3) of this chapter.

(b) *Special exemption.* Any health insuring organization subject to the requirements in paragraph (a) of this section, that is operating under the authority of a waiver granted to a State under section 1915(b) of the Act prior to January 1, 1986, is exempt from those requirements relating to composition

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of enrollment and disenrollment without cause in §§ 434.26 and 434.27(b), during the effective period of the waiver, including extensions and renewals.

[55 FR 51295, Dec. 13, 1990, as amended at 61 FR 69050, Dec. 31, 1996]

**Subpart E—Contracts with HMOs and PHPs: Medicaid Agency Responsibilities**

SOURCE: 48 FR 54020, Nov. 20, 1983, unless otherwise noted. Redesignated at 55 FR 51295, Dec. 13, 1990.

**§ 434.50 Proof of HMO or PHP capability.**

The agency must obtain from each contractor proof of—

(a) Financial responsibility, including proof of adequate protection against insolvency; and

(b) The contractor's ability to provide the services under the contract efficiently, effectively, and economically.

[48 FR 54020, Nov. 30, 1983; 48 FR 55128, Dec. 9, 1983]

**§ 434.52 Furnishing of required services.**

The agency must obtain assurances from each contractor that—

(a) It furnishes the health services required by enrolled recipients as promptly as is appropriate; and

(b) The services meet the agency's quality standards.

**§ 434.53 Periodic medical audits.**

(a) The agency must establish a system of periodic medical audits to insure that each contractor furnishes quality and accessible health care to enrolled recipients.

(b) The system of periodic medical audits must—

(1) Provide for audits conducted at least once a year for each contractor;

(2) Identify and collect management data for use by medical audit personnel; and

(3) Provide that the data includes—

(i) Reasons for enrollment and termination; and

(ii) Use of services.

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**§ 434.57 Limit on payment to other providers.**

The agency must ensure that, except as specified in § 434.30(b) for emergency services, no payment is made for services furnished by a provider other than the contractor, if the services were available under the contract.

**§ 434.59 Continued service to recipients whose enrollment is terminated.**

The agency must arrange for Medicaid services without delay for any recipient whose enrollment is terminated, unless it is terminated because of ineligibility for Medicaid.

**§ 434.61 Computation of capitation fees.**

The agency must determine that the capitation fees and any other payments provided for in the contract are computed on an actuarially sound basis.

**§ 434.63 Monitoring procedures.**

The agency must have procedures to do the following:

(a) Monitor enrollment and termination practices.

(b) Ensure proper implementation of the contractor's grievance procedures.

(c) Monitor for violations of the requirements specified in § 434.67 and the conditions necessary for FFP in contracts with HMOs specified in § 434.80.

[59 FR 36084, July 15, 1994]

**§ 434.65 Services included in the State plan but not covered by the contract.**

If the contract does not cover all services available under the State plan, the agency must arrange for services not included to be available and accessible. This may be done by having the contractor refer enrolled recipients to other providers or by some other means.

**§ 434.67 Sanctions against HMOs with risk comprehensive contracts.**

(a) *Basis for imposition of sanctions.* The agency may recommend that the intermediate sanction specified in paragraph (e) of this section be imposed if the agency determines that an HMO with a risk comprehensive contract does one or more of the following:

(1) Fails substantially to provide the medically necessary items and services required under law or under the contract to be provided to an enrolled recipient and the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual.

(2) Imposes on Medicaid enrollees premium amounts in excess of premiums permitted.

(3) Engages in any practice that discriminates among individuals on the basis of their health status or requirements for health care services, including expulsion or refusal to reenroll an individual, or any practice that could reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by section 1903(m) of the Act) by eligible individuals whose medical conditions or histories indicate a need for substantial future medical services.

(4) Misrepresents or falsifies information that it furnishes, under section 1903(m) of the Act to HCFA, the State agency, an individual, or any other entity.

(5) Fails to comply with the requirements of §§417.479(d) through (g) of this chapter relating to physician incentive plans, or fails to submit to the State Medicaid agency its physician incentive plans as required or requested in §434.70.

(b) *Effect of an agency determination.*

(1) When the agency determines that an HMO with a risk comprehensive contract has committed one of the violations identified in paragraph (a) of this section, the agency must forward this determination to HCFA. This determination becomes HCFA's determination for purposes of section 1903(m)(5)(A) of the Act, unless HCFA reverses or modifies the determination within 15 days.

(2) When the agency decides to recommend imposition of the sanction specified in paragraph (e) of this section, this recommendation becomes HCFA's decision, for purposes of section 1903(m)(5)(B)(ii) of the Act, unless HCFA rejects this recommendation within 15 days.

(c) *Notice of sanction.* If a determination to impose a sanction becomes HCFA's determination under paragraph (b)(2) of this section, the agency must

send a written notice to the HMO stating the nature and basis of the proposed sanction. A copy of the notice is forwarded to the OIG at the same time it is sent to the HMO. The agency allows the HMO 15 days from the date it receives the notice to provide evidence that it has not committed an act or failed to comply with a requirement described in paragraph (a) of this section, as applicable. The agency may allow a 15-day addition to the original 15 days upon receipt of a written request from the organization. To be approved, the request must provide a credible explanation of why additional time is necessary and be received by HCFA before the end of the 15-day period following the date the organization received the sanction notice. An extension is not granted if HCFA determines that the organization's conduct poses a threat to an enrollee's health and safety.

(d) *Informal reconsideration.* (1) If the HMO submits a timely response to the agency's notice of sanction, the agency conducts an informal reconsideration that includes—

(i) Review of the evidence by an agency official who did not participate in the initial recommendation to impose the sanction; and

(ii) A concise written decision setting forth the factual and legal basis for the decision.

(2) The agency decision under paragraph (d)(1)(ii) of this section is forwarded to HCFA and becomes HCFA's decision unless HCFA reverses or modifies the decision within 15 days from the date of HCFA's receipt of the agency determination. In the event HCFA modifies or reverses the agency decision, the agency sends the HMO a copy of HCFA's decision under this paragraph.

(e) *Denial of payment.* If a HCFA determination that a HMO has committed a violation described in paragraph (a) of this section is affirmed on review under paragraph (d) of this section, or is not timely contested by the HMO under paragraph (c) of this section, HCFA, based upon the recommendation of the agency, may deny payment for new enrollees of the HMO under section 1903(m)(5)(B)(ii) of the Act. Under §§434.22 and 434.42, HCFA's

denial of payment for new enrollees automatically results in a denial of agency payments to the HMO for the same enrollees. A new enrollee is an enrollee that applies for enrollment after the effective date in paragraph (f)(1) of this section.

(f) *Effective date and duration of sanction.* (1) Except as specified in paragraphs (f)(2) and (f)(3) of this section, a sanction is effective 15 days after the date the HMO is notified of the decision to impose the sanction under paragraph (c) of this section.

(2) If the HMO seeks reconsideration under paragraph (d) of this section, the sanction is effective on the date specified in HCFA's reconsideration notice.

(3) If HCFA, in consultation with the agency, determines that the HMO's conduct poses a serious threat to an enrollee's health and safety, the sanction may be made effective on a date prior to issuance of the decision under paragraph (d)(1)(ii) of this section.

(g) *Civil money penalties.* If a determination that an organization has committed a violation under paragraph (a) of this section becomes HCFA's determination under paragraph (b)(1) of this section, HCFA conveys the determination to the OIG. In accordance with the provisions of 42 CFR part 1003, the OIG may impose civil money penalties on the organization in addition to or in place of the sanctions that may be imposed under this section.

(h) *HCFA's role.* HCFA retains the right to independently perform the functions assigned to the agency in paragraphs (a) through (f) of this section.

(i) *State Plan requirements.* The State Plan must include a plan to monitor for violations specified in paragraph (a) of this section and for implementing the provisions of this section.

[59 FR 36084, July 15, 1994, as amended at 61 FR 13449, Mar. 27, 1996]

### Subpart F—Federal Financial Participation

SOURCE: 48 FR 54020, Nov. 20, 1983, unless otherwise noted. Redesignated at 55 FR 51295, Dec. 13, 1990.

### § 434.70 Condition for FFP.

(a) FFP is available in expenditures for payments to contractors only for the periods that—

- (1) The contract—
  - (i) Meets the requirements of this part;
  - (ii) Meets the appropriate requirements of 45 CFR part 74; and
  - (iii) Is in effect;

(2) The HMO or HIO complies with the physician incentive plan requirements specified in §§ 417.479(d) through (g) of this chapter and the requirements related to subcontracts set forth at § 417.479(i) of this chapter if the subcontract is for the provision of services to Medicaid recipients;

(3) The HMO, HIO (or, in accordance with § 417.479(i) of this chapter, the subcontracting entity) has supplied the information on its physician incentive plan listed in § 417.479(h)(1) of this chapter to the State Medicaid agency. The information must contain detail sufficient to enable the State to determine whether the plan complies with the requirements of § 417.479 (d) through (g) of this chapter. The HMO or HIO must supply the information required under § 417.479 (h)(1)(i) through (h)(1)(v) of this chapter to the State Medicaid agency as follows:

(i) Prior to approval of its contract or agreement.

(ii) Upon the contract or agreements anniversary or renewal effective date.

(4) The HMO or HIO has provided the information on physician incentive plans listed in § 417.479(h)(3) of this chapter to any Medicaid recipient who requests it.

(b) HCFA may withhold FFP for any period during which—

(1) The State fails to meet the State plan requirements of this part;

(2) Either party to a contract substantially fails to carry out the terms of the contract; or

(3) The State fails to obtain from each HMO or HIO contractor proof that it meets the requirements for physician incentive plans specified in §§ 417.479(d) through (g) and (i) of this chapter.

[61 FR 13449, Mar. 27, 1996, as amended at 61 FR 69050, Dec. 31, 1996]

**§ 434.71 Condition for FFP: Prior approval.**

FFP is not available in expenditures under an HMO contract unless the agency secured prior written notice from the Regional Office, indicating that the contractor meets the definition of an HMO.

**§ 434.72 Effect of a final determination that a provisional status HMO is not an HMO.**

(a) FFP is available in expenditures for payments to a provisional status HMO until the Public Health Service reaches a final determination that it is not a federally qualified HMO.

(b) The Public Health Service's determination that the entity with provisional status is not an HMO is not considered final until—

(1) All administrative, but not judicial, appeal procedures are exhausted; or

(2) The time for requesting administrative review has lapsed without a request from the HMO.

**§ 434.74 Costs under risk-basis contracts.**

Under each contract in which the contractor assumes an underwriting risk, the total amount paid by the agency for carrying out the provisions of the contract is a medical assistance cost.

**§ 434.75 Costs under no-risk contracts.**

Under each contract in which the contractor assumes no underwriting risk—

(a) The amount paid by the agency for furnishing medical services to eligible recipients is a medical assistance cost; and

(b) The amount paid by the agency for the contractor's performance of other functions is an administrative cost.

**§ 434.76 Costs under fiscal agent contracts.**

Under each contract with a fiscal agent—

(a) The amount paid to the provider of medical services is a medical assistance cost; and

(b) The amount paid to the contractor for performing the agreed-upon functions is an administrative cost.

**§ 434.78 Right to reconsideration of disallowance.**

A Medicaid agency dissatisfied with a disallowance of FFP under this subpart may request and will be granted reconsideration in accordance with 45 CFR part 16.

**§ 434.80 Condition for FFP in contracts with HMOs.**

(a) *Basic rule.* FFP in payments to an HMO is available only if the agency excludes from participation as such an entity any entity 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)(2), either directly or indirectly, with an individual convicted of certain crimes as described in section 1128(b)(8)(B) of the Act.

(3) An entity that employs or contracts, directly or indirectly, with one of the following:

(i) Any individual or entity excluded from Medicaid participation under section 1128 or section 1128A of the Act for the furnishing of health care, utilization review, medical social work, or administrative services.

(ii) Any entity for the provision through an excluded individual or entity of services described in paragraph (b)(3)(i) of this section.

[59 FR 36085, July 15, 1994]

**PART 435—ELIGIBILITY IN THE STATES, DISTRICT OF COLUMBIA, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA**

**Subpart A—General Provisions and Definitions**

- Sec. 435.2 Purpose and applicability.
- 435.3 Basis.
- 435.4 Definitions and use of terms.
- 435.10 State plan requirements.