

§ 434.26

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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.