

(2) Has at least 5,000 enrollees or 1,500 enrollees if it serves a primarily rural area as defined in §417.413(b)(3);

(3) Has at least 75 Medicare enrollees or has an acceptable plan to achieve this Medicare membership within 2 years;

(4) Satisfies CMS that it can bear the potential losses of a risk contract; and

(5) Has not previously terminated or failed to renew a risk contract within the preceding 5 years, unless CMS determines that circumstances warrant special consideration.

(f) *Requirements for a reasonable cost contract.* An HMO or CMP may enter into a reasonable cost contract if it meets one of the following:

(1) The HMO or CMP qualifies for a risk contract, but chooses a reasonable cost contract.

(2) The HMO or CMP meets the conditions for entering into a risk contract specified in paragraph (e) of this section except that CMS does not judge the HMO or CMP capable of bearing the potential losses of a risk contract.

(g) Regulations on reasonable cost and risk reimbursement are set forth in subparts O and P of this part.

[50 FR 20570, May 17, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§417.412 Qualifying condition: Administration and management.

The HMO or CMP must demonstrate that it—

(a) Has sufficient administrative capability to carry out the requirements of the contract; and

(b) Does not have any agents or management staff or persons with ownership or control interests who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, or social service programs under title XX of the Act.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45676, Sept. 1, 1995]

§417.413 Qualifying condition: Operating experience and enrollment.

(a) *Condition.* The HMO or CMP must demonstrate that it has operating experience and an enrolled population sufficient to provide a reasonable basis for establishing a prospective per cap-

ita reimbursement rate or a reasonable cost reimbursement rate, as appropriate.

(b) *Standard: Enrollment and operating experience for HMOs or CMPs to contract on a risk basis.* To be eligible to contract on a risk basis—

(1) A nonrural HMO or CMP must currently have the following:

(i) At least 5,000 enrollees; and

(ii) At least 75 Medicare enrollees or a plan acceptable to CMS for achieving a Medicare enrollment of 75 within 2 years from the beginning of its initial contract period.

(2) A rural HMO or CMP must currently have—

(i) At least 1,500 enrollees; and

(ii) At least 75 Medicare enrollees or a plan acceptable to CMS for achieving a Medicare enrollment of 75 within 2 years from the beginning of its initial contract period.

(3) For purposes of this paragraph, an HMO or CMP is considered rural if at least 50 percent of its enrollees reside in nonmetropolitan areas. A nonmetropolitan area is an area—

(i) No part of which is within a metropolitan statistical area (MSA) as designated by the Executive Office of Management and Budget; and

(ii) That does not contain a city whose population exceeds 50,000 individuals.

(4) A subdivision or subsidiary of an HMO or CMP that meets the requirements of paragraph (b)(1) or (b)(2) of this section need not demonstrate that it meets those requirements as an independent unit if the HMO or CMP assumes responsibility for the financial risk, and adequate management and supervision of health care services furnished by its subdivision or subsidiary.

(c) *Standard: Enrollment and operating experience for HMOs or CMPs to contract on a cost basis.* To be eligible to contract on a reasonable cost basis, an HMO or CMP must currently have enrollees sufficient in number to provide a reasonable basis for entering into a contract, as follows:

(1) At least 1,500 enrollees.

(2) At least 75 Medicare enrollees, or a plan acceptable to CMS for achieving—

(i) A Medicare enrollment of 75 within 2 years from the beginning of its initial contract period; and

(ii) At least 250 Medicare enrollees by the beginning of its fourth contract period.

(d) *Standard: Composition of enrollment*—(1) *Requirement.* Except as specified in paragraphs (d)(2) and (e) of this section, not more than 50 percent of an HMO's or CMP's enrollment may be Medicare beneficiaries.

(2) *Waiver of composition of enrollment standard.* CMS may waive compliance with the requirements of paragraph (d)(1) of this section if the HMO or CMP has made and is making reasonable efforts to enroll individuals who are not Medicare beneficiaries and it meets one of the following requirements:

(i) The HMO or CMP serves a geographic area in which Medicare beneficiaries and Medicaid recipients constitute more than 50 percent of the population. (CMS does not grant a waiver that would permit the percentage of Medicare and Medicaid enrollees to exceed the percentage of Medicare beneficiaries and Medicaid recipients in the population of the geographic area.)

(ii) The HMO or CMP is owned and operated by a government entity. The waiver may be for a period up to three years after the date the HMO or CMP first enters into a contract under this subpart, and may not be extended.

(iii) The HMO or CMP requests waiver of the composition rule because it is in the public interest. The organization provides documentation that supports one of the following:

(A) The organization serves a medically underserved rural or urban area.

(B) The organization demonstrates a long-term business and community service commitment to the area.

(C) The organization believes that a waiver is necessary to promote managed care choices in an area with limited or no managed care choices.

(3) *Waiver granted on or before October 21, 1986.* An HMO or CMP (or a successor HMO or CMP) that as of October 21, 1986, had been granted an exception, waiver, or modification of the requirements of paragraph (d)(1) of this section, but that does not meet the requirements of paragraph (d)(2) of this

section, must make (and throughout the period of the exception, waiver, or modification continue to make) reasonable efforts to meet scheduled enrollment goals, consistent with a schedule of compliance approved by CMS.

(i) If CMS determines that the HMO or CMP has complied, or made significant progress toward compliance, with the approved schedule, and that an extension is in the best interest of the Medicare program, CMS may extend the waiver of modification.

(ii) If CMS determines that the HMO or CMP has not complied with the approved schedule, CMS may apply the sanctions described in paragraphs (d)(6) and (d)(7) of this section.

(4) *Basis for application of sanctions.* CMS may, as an alternative to contract termination, apply the sanctions specified in paragraph (d)(6) of this section if CMS determines that the HMO or CMP is not complying with the requirements in paragraphs (d)(1), (d)(2), or (d)(3) of this section, as applicable.

(5) *Notice of sanction.* Before applying the sanctions specified in paragraph (d)(6) of this section, CMS sends a written notice to the HMO or CMP stating the proposed action and its basis. CMS gives the HMO or CMP 15 days after the date of the notice to provide evidence establishing the HMO's or CMP's compliance with the requirements in paragraph (d)(1), (d)(2), or (d)(3) of this section, as applicable.

(6) *Sanctions.* If, following review of the HMO's or CMP's timely response to CMS's notice, CMS determines that an HMO or CMP does not comply with the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section, CMS may apply either of the following sanctions:

(i) Require the HMO or CMP to stop accepting new enrollment applications after a date specified by CMS.

(ii) Deny payment for individuals who are formally added or "accreted" to CMS's records as Medicare enrollees after a date specified by CMS.

(7) *Termination by CMS.* In addition to the sanctions described in paragraph (d)(6) of this section, CMS may decline to renew an HMO's or CMP's contract in accordance with §417.492(b), or terminate its contract in accordance with

§417.494(b) if CMS determines that the HMO or CMP no longer substantially meets the requirements of paragraphs (d)(1), (d)(2), or (d)(3) of this section.

(8) *Termination of composition standard.* The 50 percent composition of Medicare beneficiaries terminates for all managed care plans on December 31, 1998.

(e) *Standard: Open enrollment.* (1) Except as specified in paragraph (e)(2) of this section, an HMO or CMP must enroll Medicare beneficiaries on a first-come, first-served basis to the limit of its capacity and provide annual open enrollment periods of at least 30 days duration for Medicare beneficiaries.

(2) CMS may waive the requirement of paragraph (e)(1) of this section if compliance would prevent compliance with the limitation on enrollment of Medicare beneficiaries and Medicaid recipients (paragraph (d) of this section) or result in an enrollment substantially nonrepresentative of the population of the HMO's or CMP's geographic area. The enrollment would be "substantially nonrepresentative" if the proportion of a subgroup to the total enrollment exceeded, by 10 percent or more, its proportion of the population in the HMO's or CMP's geographic area, as shown by census data or other data acceptable to CMS. For purposes of this paragraph, a subgroup means a class of Medicare enrollees as defined in §417.582.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 46570, Sept. 13, 1991; 58 FR 38082, July 15, 1993; 60 FR 45676, Sept. 1, 1995; 63 FR 35066, June 26, 1998]

§417.414 Qualifying condition: Range of services.

(a) *Condition.* The HMO or CMP must demonstrate that it is capable of delivering to Medicare enrollees the range of services required in accordance with this section.

(b) *Standard: Range of services furnished by eligible HMOs or CMPs—(1) Basic requirement.* Except as specified in paragraph (b)(3) of this section, an HMO or CMP must furnish to its Medicare enrollees (directly or through arrangements with others) all the Medicare services to which those enrollees are entitled to the extent that they are available to Medicare beneficiaries who

reside in the HMO's or CMP's geographic area but are not enrolled in the HMO or CMP.

(2) *Criteria for availability.* The services are considered available if—

(i) The sources are located within the HMO's or CMP's geographic area; or

(ii) It is common practice to refer patients to sources outside that geographic area.

(3) *Exception for hospice care.* An HMO or CMP is not required to furnish hospice care as described in part 418 of this chapter. However, HMOs or CMPs must inform their Medicare enrollees about the availability of hospice care if—

(i) A hospice participating in Medicare is located within the HMO's or CMP's geographic area; or

(ii) It is common practice to refer patients to hospices outside the geographic area.

(c) *Standard: Financial responsibility for services furnished outside the HMO or CMP.* (1) An HMO or CMP must assume financial responsibility and provide reasonable reimbursement for emergency services and urgently needed services (as defined in §417.401) that are obtained by its Medicare enrollees from providers and suppliers outside the HMO or CMP even in the absence of the HMO's or CMP's prior approval.

(2) An HMO or CMP must assume financial responsibility for services that the Medicare enrollee attempted to obtain from the HMO or CMP, but that the HMO or CMP failed to furnish or unreasonably denied, and that are found, upon appeal by the enrollee under subpart Q of this part, to be services that the enrollee was entitled to have furnished to him or her by the HMO or CMP.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38078, July 15, 1993; 60 FR 45677, Sept. 1, 1995]

§417.416 Qualifying condition: Furnishing of services.

(a) *Condition.* The HMO or CMP must furnish the required services to its Medicare enrollees through providers and suppliers that meet applicable Medicare statutory definitions and implementing regulations. The HMO or CMP must also ensure that the required services, additional services, and any other supplemental services