

classes after it receives written approval of the factors from CMS. CMS will give approval if it concludes that the factors can reasonably be used to predict the use of health services by individuals and families.

(1) An HMO must make a written request to CMS, listing the factors to be used in the community rating by class system under paragraph (b)(2) of this section.

(2) CMS will notify each HMO within 30 days of receipt of the request and application of one of the following:

- (i) The application is approved;
- (ii) Additional information or data are required and CMS will notify the HMO of its decision within 30 days from the date of receipt of this information or data; or
- (iii) CMS needs additional time to review the written request and the HMO will be notified of CMS's decision within 90 days.

(Approved by the Office of Management and Budget under control number 0915-0051)

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301-1318, as amended, Pub. L. 97-35, 95 Stat. 572-578 (42 U.S.C. 300e-300e-17))

[45 FR 72528, Oct. 31, 1980, as amended at 47 FR 19339, May 5, 1982; 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38082, 38083, July 15, 1993]

#### **§417.105 Payment for supplemental health services.**

(a) An HMO may require supplemental health services payments, in addition to the basic health services payments, for the provision of each health service included in the supplemental health services set forth in §417.102 for which subscribers have contracted, or it may include supplemental health services in the basic health services provided its enrollees for a basic health services payment.

(b) Supplemental health services payments may be made in any agreed upon manner, such as prepayment or fee-for-service. Supplemental health services

payments that are fixed on a prepayment basis, however, must be fixed under a community rating system, unless the supplemental health services payment is for a supplemental health service provided an enrollee who is a full-time student at an accredited institution of higher education. In the case of an HMO that provided comprehensive health services on a prepaid basis before it became a qualified HMO, the community rating requirement shall not apply to that HMO during the forty-eight month period beginning with the month following the month in which it became a qualified HMO.

(Sec. 215 of the Public Health Service Act, as amended, 58 Stat. 690, 67 Stat. 631 (42 U.S.C. 216); secs. 1301-1318, as amended, Pub. L. 97-35, 95 Stat. 572-578 (42 U.S.C. 300e-300e-17))

[45 FR 72528, Oct. 31, 1980, as amended at 50 FR 6175, Feb. 14, 1985. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38082, 38083, July 15, 1993]

#### **§417.106 Quality assurance program; Availability, accessibility, and continuity of basic and supplemental health services.**

(a) *Quality assurance program.* Each HMO or CMP must have an ongoing quality assurance program for its health services that meets the following conditions:

(1) Stresses health outcomes to the extent consistent with the state of the art.

(2) Provides review by physicians and other health professionals of the process followed in the provision of health services.

(3) Uses systematic data collection of performance and patient results, provides interpretation of these data to its practitioners, and institutes needed change.

(4) Includes written procedures for taking appropriate remedial action whenever, as determined under the quality assurance program, inappropriate or substandard services have been provided or services that ought to have been furnished have not been provided.

(b) *Availability and accessibility of health care services.* Basic health services and those supplemental health services for which enrollees have contracted must be provided or arranged

<sup>1</sup>Further information entitled "Guidelines for Rating by Class" may be obtained from the Office of Prepaid Health Care, Division of Qualification Analysis, HHS Cohen Bldg., room 4360, 330 Independence Ave. SW., Washington, DC 20201.

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for by the HMO in accordance with the following rules:

(1) Except as provided in paragraph (b)(2) of this section, the services must be available to each enrollee within the HMO's service area.

(2) *Exception.* If the HMO's service area is located wholly within a non-metropolitan area, the HMO may make available outside its service area any basic health service that is not a primary care or emergency care service, if the number of providers of that basic health service who will provide the service to the HMO's enrollees is insufficient to meet the demand. As used in this paragraph, primary care includes general practice, family practice, general internal medicine, general pediatrics, and general obstetrics and gynecology. An HMO that provides the services covered by these fields through at least a general or family practitioner, or a pediatrician and a general internist, is considered to be providing primary care.

(3) The services must be available and accessible with reasonable promptness to each of the HMO's enrollees as ensured through—

(i) Staffing patterns within generally accepted norms for meeting the projected enrollment needs; and

(ii) Geographic location, hours of operation, and arrangements for after-hours services. (Medically necessary emergency services must be available 24 hours a day, 7 days a week.)

(c) *Continuity of care.* The HMO must ensure continuity of care through arrangements that include but are not limited to the following:

(1) Use of a health professional who is primarily responsible for coordinating the enrollee's overall health care.

(2) A system of health and medical records that accumulates pertinent information about the enrollee's health care and makes it available to appropriate professionals.

(3) Arrangements made directly or through the HMO's providers to ensure that the HMO or the health professional who coordinates the enrollee's overall health care is kept informed about the services that the referral resources furnish to the enrollee.

(d) *Confidentiality of health records.* Each HMO must establish adequate

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procedures to ensure the confidentiality of the health and medical records of its enrollees.

[58 FR 38068, July 15, 1993]

### Subpart C—Qualified Health Maintenance Organizations: Organization and Operation

SOURCE: 58 FR 38068, July 15, 1993, unless otherwise noted.

#### § 417.120 Fiscally sound operation and assumption of financial risk.

(a) *Fiscally sound operation.*—(1) *General requirements.* Each HMO must have a fiscally sound operation, as demonstrated by the following:

(i) Total assets greater than total unsubordinated liabilities. In evaluating assets and liabilities, loan funds awarded or guaranteed under section 1306 of the PHS Act are not included as liabilities.

(ii) Sufficient cash flow and adequate liquidity to meet obligations as they become due.

(iii) A net operating surplus, or a financial plan that meets the requirements of paragraph (a)(2) of this section.

(iv) An insolvency protection plan that meets the requirements of § 417.122(b) for protection of enrollees.

(v) A fidelity bond or bonds, procured and maintained by the HMO, in an amount fixed by its policymaking body but not less than \$100,000 per individual, covering each officer and employee entrusted with the handling of its funds. The bond may have reasonable deductibles, based upon the financial strength of the HMO.

(vi) Insurance policies or other arrangements, secured and maintained by the HMO and approved by CMS to insure the HMO against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(2) *Financial plan requirement.* (i) If an HMO has not earned a cumulative net operating surplus during the three most recent fiscal years, did not earn a net operating surplus during the most recent fiscal year or does not have positive net worth, the HMO must submit a financial plan satisfactory to

CMS to achieve net operating surplus within available fiscal resources.

(ii) This plan must include—

(A) A detailed marketing plan;

(B) Statements of revenue and expense on an accrual basis;

(C) Sources and uses of funds statements; and

(D) Balance sheets.

(b) *Assumption of financial risk.* Each HMO must assume full financial risk on a prospective basis for the provision of basic health services, except that it may obtain insurance or make other arrangements as follows:

(1) For the cost of providing to any enrollee basic health services with an aggregate value of more than \$5,000 in any year.

(2) For the cost of basic health services obtained by its enrollees from sources other than the HMO because medical necessity required that they be furnished before they could be secured through the HMO.

(3) For not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for that fiscal year.

(4) For physicians or other health professionals, health care institutions, or any other combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for their furnishing of basic health services to the HMO's enrollees.

#### §417.122 Protection of enrollees.

(a) *Liability protection.* (1) Each HMO must adopt and maintain arrangements satisfactory to CMS to protect its enrollees from incurring liability for payment of any fees that are the legal obligation of the HMO. These arrangements may include any of the following:

(i) Contractual arrangements that prohibit health care providers used by the enrollees from holding any enrollee liable for payment of any fees that are the legal obligation of the HMO.

(ii) Insurance, acceptable to CMS.

(iii) Financial reserves, acceptable to CMS, that are held for the HMO and restricted for use only in the event of insolvency.

(iv) Any other arrangements acceptable to CMS.

(2) The requirements of this paragraph do not apply to an HMO if CMS determines that State law protects the HMO enrollees from liability for payment of any fees that are the legal obligation of the HMO.

(b) *Protection against loss of benefits if the HMO becomes insolvent.* The insolvency protection plan required under §417.120(a) must provide for continuation of benefits as follows:

(1) For all enrollees, for the duration of the contract period for which payment has been made.

(2) For enrollees who are in an inpatient facility on the date of insolvency, until they are discharged from the facility.

#### §417.124 Administration and management.

(a) *General requirements.* Each HMO must have administrative and managerial arrangements satisfactory to CMS, as demonstrated by at least the following:

(1) A policymaking body that exercises oversight and control over the HMO's policies and personnel to ensure that management actions are in the best interest of the HMO and its enrollees.

(2) Personnel and systems sufficient for the HMO to organize, plan, control and evaluate the financial, marketing, health services, quality assurance program, administrative and management aspects of the HMO.

(3) At a minimum, management by an executive whose appointment and removal are under the control of the HMO's policymaking body.

(b) *Full and fair disclosure—(1) Basic rule.* Each HMO must prepare a written description of the following:

(i) Benefits (including limitations and exclusions).

(ii) Coverage (including a statement of conditions on eligibility for benefits).

(iii) Procedures to be followed in obtaining benefits and a description of circumstances under which benefits may be denied.

(iv) Rates.

(v) Grievance procedures.

(vi) Service area.

(vii) Participating providers.

(viii) Financial condition including at least the following most recently audited information: Current assets, other assets, total assets; current liabilities, long term liabilities; and net worth.

(2) *Requirements for the description.* (i) The description must be written in a way that can be easily understood by the average person who might enroll in the HMO.

(ii) The description of benefits and coverage may be in general terms if reference is made to a detailed statement of benefits and coverage that is available without cost to any person who enrolls in the HMO or to whom the opportunity for enrollment is offered.

(iii) The HMO must provide the description to any enrollee or person who is eligible to elect the HMO option and who requests the material from the HMO or the administrator of a health benefits plan. For purposes of this requirement, “administrator” (of a health benefits plan) has the meaning it is given in the Employment Retirement Income Security Act of 1974 (ERISA) at 29 U.S.C. 1002(16)(A).

(iv) If the HMO provides health services through individual practice associations (IPAs), the HMO must specify the number of member physicians by specialty, and a listing of the hospitals where HMO enrollees will receive basic and supplemental health services.

(v) If the HMO provides health services other than through IPAs, the HMO must specify, for each ambulatory care facility, the facility’s address, days and hours of operation, and the number of physicians by specialty, and a listing of the hospitals where HMO enrollees will receive basic and supplemental health services.

(c) *Broadly representative enrollment.* (1) Each HMO must offer enrollment to persons who are broadly representative of the various age, social, and income groups within its service area.

(2) If an HMO has a medically underserved population located in its service area, not more than 75 percent of its enrollees may be from the medically underserved population unless the area in which that population resides is a rural area.

(d) *Health status and enrollment.* (1) The HMO may not, on the basis of

health status, health care needs, or age of the individual—

(i) Expel or refuse to reenroll any enrollee; or

(ii) Refuse to enroll individual members of a group.

(2) For purposes of this paragraph, a “group” is composed of individuals who enroll in the HMO under a contract or other arrangement that covers two or more subscribers. Examples of groups are employees who enroll under a contract between their employer and the HMO, or members of an organization that arranges coverage for its membership.

(3) Nothing in this subpart prohibits an HMO from requiring that, as a condition for continued eligibility for enrollment, enrolled dependent children, upon reaching a specified age, convert to individual enrollment, consistent with paragraph (e) of this section.

(e) *Conversion of enrollment.* (1) Each HMO must offer individual enrollment to the following:

(i) Each enrollee (and his or her enrolled dependents) leaving a group.

(ii) Each enrollee who would otherwise cease to be eligible for HMO enrollment because of his or her age, or the death or divorce of an enrollee.

(2) The individual enrollment offered must meet the conditions of subpart B of this part and this subpart C.

(3) The HMO is not required to offer individual enrollment except to the enrollees specified in this paragraph.

(4) The HMO must offer the enrollment on the same terms and conditions that it makes available to other nongroup enrollees.

(f) [Reserved]

(g) *Grievance procedures.* Each HMO must have and use meaningful procedures for hearing and resolving grievances between the HMO’s enrollees and the HMO, including the HMO staff and medical groups and IPAs that furnish services. These procedures must ensure that:

(1) Grievances and complaints are transmitted in a timely manner to appropriate HMO decisionmaking levels that have authority to take corrective action; and

(2) Appropriate action is taken promptly, including a full investigation if necessary and notification of

concerned parties as to the results of the HMO's investigation.

(h) *Certification of institutional providers.* Each HMO must ensure that its affiliated institutional providers meet one of the following conditions:

(1) In the case of hospitals, are either accredited by the Joint Commission on Accreditation of Health Care Organizations, or certified by Medicare.

(2) In the case of laboratories, are either CLIA-exempt, or have in effect a valid certificate of one of the following types, issued by CMS in accordance with section 353 of the PHS Act and part 493 of this chapter:

(i) Registration certificate.

(ii) Certificate.

(iii) Certificate of waiver.

(iv) Certificate of accreditation.

(3) In the case of other affiliated institutional providers, are certified for participation in Medicare and Medicaid in accordance with part 405, 416, 418, 488, or 491 of this chapter, as appropriate.

[58 FR 38068, July 15, 1993, as amended at 59 FR 49843, Sept. 30, 1994]

#### §417.126 Recordkeeping and reporting requirements.

(a) *General reporting and disclosure requirements.* Each HMO must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information with respect to the following:

(1) The cost of its operations.

(2) The patterns of utilization of its services.

(3) The availability, accessibility, and acceptability of its services.

(4) To the extent practical, developments in the health status of its enrollees.

(5) Information demonstrating that the HMO has a fiscally sound operation.

(6) Other matters that CMS may require.

(b) *Significant business transactions.* Each HMO must report to CMS annually, within 120 days of the end of its fiscal year (unless for good cause

shown, CMS authorizes an extension of time), the following:

(1) A description of significant business transactions (as defined in paragraph (c) of this section) between the HMO and a party in interest.

(2) With respect to those transactions—

(i) A showing that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or

(ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.

(3) A combined financial statement for the HMO and a party in interest if either of the following conditions is met:

(i) Thirty-five percent or more of the costs of operation of the HMO go to a party in interest.

(ii) Thirty-five percent or more of the revenue of a party in interest is from the HMO.

(c) *“Significant business transaction” defined.* As used in paragraph (b) of this section—

(1) Business transaction means any of the following kinds of transactions:

(i) Sale, exchange or lease of property.

(ii) Loan of money or extension of credit.

(iii) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(A) Salaries paid to employees for services performed in the normal course of their employment; or

(B) Health services furnished to the HMO's enrollees by hospitals and other providers, and by HMO staff, medical groups, or IPAs, or by any combination of those entities.

(2) *Significant business transaction* means any business transaction or series of transactions of the kind specified in paragraph (c)(1) of this section that, during any fiscal year of the HMO, have a total value that exceeds \$25,000 or 5 percent of the HMO's total operating expenses, whichever is less.

(d) *Requirements for combined financial statements.* (1) The combined financial