

fact and of law upon which the entity relies.

(3) CMS bases its reconsideration upon the record compiled during the qualification review proceedings, materials submitted in support of the request for reconsideration, and other relevant materials available to CMS.

(4) CMS gives the entity written notice of the reconsidered determination and the basis for the determination.

(e) *Information on qualified HMOs*—(1) **FEDERAL REGISTER notices.** In quarterly **FEDERAL REGISTER** notices, CMS gives the names, addresses, and service areas of newly qualified HMOs and describes the expanded service areas of other qualified HMOs.

(2) *Listings.* A cumulative list of qualified HMOs is available from the following office, which is open from 8:30 a.m. to 5 p.m., Monday through Friday: Office of Managed Care, room 4360, Cohen Building, 400 Independence Avenue SW., Washington, DC 20201.

[59 FR 49837, Sept. 30, 1994]

## Subpart E—Inclusion of Qualified Health Maintenance Organizations in Employee Health Benefits Plans

SOURCE: 45 FR 72517, Oct. 31, 1980, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

### §417.150 Definitions.

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

*Agreement* means a collective bargaining agreement.

*Bargaining representative* means an individual or entity designated or selected, under any applicable Federal, State, or local law, or public entity collective bargaining agreement, to represent employees in collective bargaining, or any other employee representative designated or selected under any law.

*Carrier* means a voluntary association, corporation, partnership, or other organization that is engaged in providing, paying for, or reimbursing all or part of the cost of health benefits under group insurance policies or contracts, medical or hospital service agreements, enrollment or subscription

contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier.

*Collective bargaining agreement* means an agreement entered into between an employing entity and the bargaining representative of its employees.

*Contract* means an employer-employee or public entity-employee contract, or a contract for health benefits.

*Designee* means any person or entity authorized to act on behalf of an employing entity or a group of employing entities to offer the option of enrollment in a qualified health maintenance organization to their eligible employees.

*Eligible employee* means an employee who meets the employer's requirements for participation in the health benefits plan.

*Employee* means any individual employed by an employer or public entity on a full-time or part-time basis.

*Employer* has the meaning given that term in section 3(d) of the Fair Labor Standards Act of 1938, except that it—

(1) Includes non-appropriated fund instrumentalities of the United States Government; and

(2) Excludes the following:

(i) The governments of the United States, the District of Columbia and the territories and possessions of the United States, the 50 States and their political subdivisions, and any agencies or instrumentalities of any of the foregoing, including the United States Postal Service and Postal Rate Commission.

(ii) Any church, or convention or association of churches, and any organization operated, supervised, or controlled by a church, or convention or association of churches that meets the following conditions:

(A) Is an organization that is described in section 501(c)(3) of the Internal Revenue Code of 1954.

(B) Does not discriminate, in the employment, compensation, promotion or termination of employment of any personnel, or in the granting of staff and other privileges to physicians or other health personnel, on the grounds that the individuals obtain health care through HMOs, or participate in furnishing health care through HMOs.

## § 417.151

## 42 CFR Ch. IV (10–1–23 Edition)

*Employing entity* means an employer or public entity.

*Employing entity-employee contract* means a legally enforceable agreement (other than a collective bargaining agreement) between an employing entity and its employees for the provision of, or payment for, health benefits for its employees, or for its employees and their eligible dependents.

*Group enrollment period* means the period of at least 10 working days each calendar year during which each eligible employee is given the opportunity to select among the alternatives included in a health benefits plan.

*Health benefits contract* means a contract or other agreement between an employing entity or a designee and a carrier for the provision of, or payment for, health benefits to eligible employees or to eligible employees and their eligible dependents.

*Health benefits plan* means any arrangement, to provide or pay for health services, that is offered to eligible employees, or to eligible employees and their eligible dependents, by or on behalf of an employing entity.

*Public entity* means the 50 states, Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands and American Samoa and their political subdivisions, the District of Columbia, and any agency or instrumentality of the foregoing, and *political subdivisions* include counties, parishes, townships, cities, municipalities, towns, villages, and incorporated villages.

*Qualified HMO* means an HMO that has in effect a determination, made under subpart D of this part, that the HMO is an operational, preoperational, or transitional qualified HMO.

*To offer a health benefits plan* means to make participation in a health benefits plan available to eligible employees, or to eligible employees and their eligible dependents regardless of whether the employing entity makes a financial contribution to the plan on behalf of these employees, directly or indirectly, for example, through pay-

ments on any basis into a health and welfare trust fund.

[45 FR 72517, Oct. 31, 1980, as amended at 47 FR 19341, May 5, 1982. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38077, July 15, 1993; 59 FR 49837, 49843, Sept. 30, 1994]

### § 417.151 Applicability.

(a) *Basic rule.* Effective October 24, 1995,<sup>1</sup> this subpart applies to any employing entity that offers a health benefits plan to its employees, meets the conditions specified in paragraphs (b) through (e) of this section, and elects to include one or more qualified HMOs in the health plan alternatives it offers its employees.

(b) *Number of employees.* During any calendar quarter of the preceding calendar year, the employer or public entity employed an average of not less than 25 employees.

(c) *Minimum wage.* During any calendar quarter of the preceding calendar year, the employer was required to pay the minimum wage specified in section 6 of the Fair Labor Standards Act of 1938, or would have been required to pay that wage but for section 13(a) of that Act.

(d) *Federal assistance under section 317 of the PHS Act.* The public entity has a pending application for, or is receiving, assistance under section 317 of the PHS Act.

(e) *Employees in HMO's service area.* At least 25 of the employing entity's employees reside within the HMO's service area.

[59 FR 49838, Sept. 30, 1994, as amended at 61 FR 27287, May 31, 1996]

### § 417.153 Offer of HMO alternative.

(a) *Basic rule.* An employing entity that is subject to this subpart and that elects to include one or more qualified HMOs must offer the HMO alternative in accordance with this section.

<sup>1</sup>Before October 24, 1995, an employing entity that met the conditions specified in § 417.151 was required to include one or more qualified HMOs, if it received from at least one qualified HMO a written request for inclusion and that request met the timing, content, and procedural requirements specified in § 417.152.

(b) *Employees to whom the HMO option must be offered.* Each employing entity must offer the option of enrollment in a qualified HMO to each eligible employee and his or her eligible dependents who reside in the HMO's service area.

(c) *Manner of offering the HMO option.*

(1) For employees who are represented by a bargaining representative, the option of enrollment in a qualified HMO—

(i) Must first be presented to the bargaining representative; and

(ii) If the representative accepts the option, must then be offered to each represented employee.

(2) For employees not represented by a bargaining representative, the option must be offered directly to those employees.

[59 FR 49839, Sept. 30, 1994, as amended at 61 FR 27287, May 31, 1996]

**§417.155 How the HMO option must be included in the health benefits plan.**

(a) *HMO access to employees—(1) Purpose and timing—(i) Purpose.* The employing entity must provide each HMO included in its health benefits plan fair and reasonable access to all employees specified in §417.153(b), so that the HMO can explain its program in accordance with §417.124(b).

(ii) *Timing.* The employing entity must provide access beginning at least 30 days before, and continuing during, the group enrollment period.

(2) *Nature of access.* (i) Access must include, at a minimum, opportunity to distribute educational literature, brochures, announcements of meetings, and other relevant printed materials that meet the requirements of §417.124(b).

(ii) Access may not be more restrictive or less favorable than the access the employing entity provides to other offerors of options included in the health benefits plan, whether or not those offerors elect to avail themselves of that access.

(b) *Review of HMO offering materials.*

(1) The HMO must give the employing entity or designee opportunity to review, revise, and approve HMO educational and offering materials before distribution.

(2) Revisions must be limited to correcting factual errors and misleading or ambiguous statements, unless—

(i) The HMO and the employing entity agree otherwise; or

(ii) Other revisions are required by law.

(3) The employing entity or designee must complete revision of the materials promptly so as not to delay or otherwise interfere with their use during the group enrollment period.

(c) *Group enrollment period; prohibition of restrictions; effective date of HMO coverage—(1) Prohibition of restrictions.*

If an employing entity or designee includes the option of enrollment in a qualified HMO in the health benefits plan offered to its eligible employees, it must provide a group enrollment period before the effective date of HMO coverage. The employing entity may not impose waiting periods as a condition of enrollment in the HMO or of transfer from HMO to non-HMO coverage, or exclusions, or limitations based on health status.

(2) *Effective date of coverage.* Unless otherwise agreed to by the employing entity, or designee, and the HMO, coverage under the HMO contract for employees selecting the HMO option begins on the day the non-HMO contract expires or is renewed without lapse.

(3) *Coordination of benefits.* Nothing in this subpart precludes the uniform application of coordination of benefits agreements between the HMOs and the other carriers that are included in the health benefits plan.

(d) *Continued eligibility for “free-standing” health benefits—(1) Basic requirement.*

At the request of a qualified HMO, the employing entity or its designee must provide that employees selecting the option of HMO membership will not, because of this selection, lose their eligibility for free-standing dental, optical, or prescription drug benefits for which they were previously eligible or would be eligible if selecting a non-HMO option and that are not included in the services provided by the HMO to its enrollees as part of the HMO prepaid benefit package.

(2) *“Free-standing” defined.* For purposes of this paragraph, the term “free-standing” refers to a benefit that—

(i) Is not integrated or incorporated into a basic health benefits package or major medical plan, and

(ii) Is—

(A) Offered by a carrier other than the one offering the basic health benefits package or major medical plan; or

(B) Subject to a premium separate from the premium for the basic health benefits package or major medical plan.

(3) *Examples of the employing entity's obligation with respect to the continued eligibility.* (i) The health benefits plan includes a free-standing dental benefit. The HMO does not offer any dental coverage as part of its health services provided to members on a prepaid basis. The employing entity must provide that employees who select the HMO option continue to be eligible for dental coverage. (If the dental coverage is not optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be made optional for employees selecting the HMO option. Conversely, if this coverage is optional for employees selecting the non-HMO option, nothing in this regulation requires that the coverage be mandatory for employees selecting the non-HMO option.) -

(ii) The non-HMO option provides free-standing coverage for optical services (such as refraction and the provision of eyeglasses), and the HMO does not. The employing entity must provide that employees who select the HMO option continue to be eligible for optical coverage.

(iii) The non-HMO option includes dental coverage in its major medical package, with a common deductible applied to dental as well as non-dental benefits. The HMO provides no dental coverage as part of its pre-paid health services. Because the dental coverage is not free-standing, the employing entity is not required to provide that employees who select the HMO option continue to be eligible for dental coverage, but is free to do so.

(e) *Opportunity to select among coverage options: Requirement for affirmative written selection—*(1) *Opportunity other than during a group enrollment period.* The employing entity or designee must provide opportunity (in addition to the group enrollment period) for selection

among coverage options, by eligible employees who meet any of the following conditions:

(i) Are new employees.

(ii) Have been transferred or have changed their place of residence, resulting in—

(A) Eligibility for enrollment in a qualified HMO for which they were not previously eligible by place of residence; or

(B) Residence outside the service area of a qualified HMO in which they were previously enrolled.

(iii) Are covered by any coverage option that ceases operation.

(2) *Prohibition of restrictions.* When the employees specified in paragraph (e)(1) of this section are eligible to participate in the health benefits plan, the employing entity or designee must make available, without waiting periods or exclusions based on health status as a condition, the opportunity to enroll in an HMO, or transfer from HMO coverage to non-HMO coverage.

(3) *Affirmative written selection.* The employing entity or designee must require that the eligible employee make an affirmative written selection in any of the following circumstances:

(i) Enrollment in a particular qualified HMO is offered for the first time.

(ii) The eligible employee elects to change from one option to another.

(iii) The eligible employee is one of those specified in paragraph (e)(1) of this section.

(f) *Determination of copayment levels and supplemental health services.* The selection of a copayment level and of supplemental health services to be contracted for must be made as follows:

(1) For employees represented by a collective bargaining representative, the selection of copayment levels and supplemental health services is subject to the collective bargaining process.

(2) For employees not represented by a bargaining representative, the selection of copayment levels and supplemental health services is subject to the same decisionmaking process used by the employing entity with respect to the non-HMO option in its health benefits plan.

(3) In all cases, the HMO has the right to include, with the basic benefits package it provides to its enrollees for

a basic health services payment, on a non-negotiable basis, those supplemental health services that meet the following conditions:

- (i) Are required to be offered under State law.
- (ii) Are included uniformly by the HMO in its prepaid benefit package.
- (iii) Are available to employees who select the non-HMO option but not available to those who select the HMO option.

[59 FR 49840, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

**§417.156 When the HMO must be offered to employees.**

(a) *General rules.* (1) The employing entity or designee must offer eligible employees the option of enrollment in a qualified HMO at the earliest date permitted under the terms of existing agreements or contracts.

(2) If the HMO's request for inclusion in a health benefits plan is received at a time when existing contracts or agreements do not provide for inclusion, the employing entity must include the HMO option in the health benefits plan at the time that new agreements or contracts are offered or negotiated.

(b) *Specific requirements.* Unless mutually agreed otherwise, the following rules apply:

(1) *Collective bargaining agreement.* The employing entity or designee must raise the HMO's request during the collective bargaining process—

- (i) When a new agreement is negotiated;
- (ii) At the time prescribed, in an agreement with a fixed term of more than 1 year, for discussion of change in health benefits; or
- (iii) In accordance with a specific process for review of HMO offers.

(2) *Contracts.* For employees not covered by a collective bargaining agreement, the employing entity or designee must include the HMO option in any health benefits plan offered to eligible employees when the existing contract is renewed or when a new health benefits contract or other arrangement is negotiated.

(i) If a contract has no fixed term or has a term in excess of 1 year, the con-

tract must be treated as renewable on its earliest anniversary date.

(ii) If the employing entity or designee is self-insured, the budget year must be treated as the term of the existing contract.

(3) *Multiple arrangements.* In the case of a health benefits plan that includes multiple contracts or other arrangements with varying expiration or renewal dates, the employing entity must include the HMO option, in accordance with paragraphs (b)(1) and (b)(2) of this section,—

- (i) At the time each contract or arrangement is renewed or reissued; or
- (ii) The benefits provided under the contract or arrangement are offered to employees.

[59 FR 49841, Sept. 30, 1994]

**§417.157 Contributions for the HMO alternative.**

(a) *General principles*—(1) *Non-discrimination.* The employer contribution to an HMO must be in an amount that does not discriminate financially against an employee who enrolls in an HMO. A contribution does not discriminate financially if the method of determining the contribution is reasonable and is designed to ensure that employees have a fair choice among health benefits plan alternatives.

(2) *Effect of agreements or contracts.* The employing entity or designee is not required to pay more for health benefits as a result of offering the HMO alternative than it would otherwise be required to pay under a collective bargaining agreement or contract that provides for health benefits and is in effect at the time the HMO alternative is included.

(3) *Examples of acceptable employer contributions.* The following are methods that are considered nondiscriminatory:

- (i) The employer contribution to the HMO is the same, per employee, as the contribution to non-HMO alternatives.
- (ii) The employer contribution reflects the composition of the HMO's enrollment in terms of enrollee attributes that can reasonably be used to predict utilization, experience, costs, or risk. For each enrollee in a given class established on the basis of those attributes, the employer contributes

an equal amount, regardless of the health benefits plan chosen by the employee.

(iii) The employer contribution is a fixed percentage of the premium for each of the alternatives offered.

(iv) The employer contribution is determined under a mutually acceptable arrangement negotiated by the HMO and the employer. In negotiating the arrangement, the employer may not insist on terms that would cause the HMO to violate any of the requirements of this part.

(4) *Adjustment of employer contribution.* An employer contribution determined by an acceptable method may in some cases be adjusted if it would result in a nominal payment or no payment at all by HMO enrollees (because the HMO premium is lower than the premiums for the other alternatives offered). If, for example the employer has a policy of requiring all employees to contribute to their health benefits plan, the employer may require HMO enrollees who would otherwise pay little or nothing at all, to make a payment that does not exceed 50 percent of the employee contribution to the principal non-HMO alternative. The principal non-HMO alternative is the one that covers the largest number of enrollees from the particular employer.

(b) *Administrative expenses.* (1) In determining the amount of its contribution to the HMO, the employing entity or designee may not consider administrative expenses incurred in connection with offering any alternative in the health benefits plan.

(2) However, if the employing entity or designee has special requirements for other than standard solicitation brochures and enrollment literature, it must, in the case of the HMO alternative, determine and distribute any administrative costs attributable to those requirements in a manner consistent with its method of determining and distributing those costs for the non-HMO alternatives.

(c) *Exclusion for contribution for certain benefits.* In determining the amount of the employing entity's contribution or the designee's cost for the HMO alternative, the employing entity or designee may exclude those portions of the contribution allocable to bene-

fits (such as life insurance or insurance for supplemental health benefits)—

(1) For which eligible employees and their eligible dependents are covered notwithstanding selection of the HMO alternative; and

(2) That are not offered on a prepayment basis by the HMO to the employing entity's employees.

(d) *Contributions determined by agreements or contracts or by law.* If the specific amount of the employing entity's contribution for health benefits is fixed by an agreement or contract, or by law, that amount constitutes the employing entity's obligation for contribution toward the HMO premiums.

(e) *Allocation of portion of a contribution determined by an agreement.* In some cases, the employing entity's contribution for health benefits is determined by an agreement that also provides for benefits other than health benefits. In that case, the employing entity must determine, or instruct its designee to determine, what portion of its contribution is applicable to health benefits.

(f) *Retention and availability of data.* Each employing entity or designee must retain the following data for three years and make it available to CMS upon request:

(1) The data used to compute the level of contribution for each of the plans offered to employees.

(2) Related data about the employees who are eligible to enroll in a plan.

(3) A description of the methodology for computation.

(g) *CMS review of data.* (1) CMS may request and review the data specified in paragraph (f) of this section on its own initiative or in response to requests from HMOs or employees.

(2) The purpose of CMS's review is to determine whether the methodology and the level of contribution comply with the requirements of this subpart.

(3) HMOs and employees that request CMS to review must set forth reasonable grounds for making the request.

[61 FR 27287, May 31, 1996]

#### § 417.158 Payroll deductions.

Each employing entity that provides payroll deductions as a means of paying employees' contributions for health benefits or provides a health benefits

plan that does not require an employee contribution must, with the consent of an employee who selects the HMO option, arrange for the employee's contribution, if any, to be paid through payroll deductions.

[59 FR 49841, Sept. 30, 1994]

**§ 417.159 Relationship of section 1310 of the Public Health Service Act to the National Labor Relations Act and the Railway Labor Act.**

The decision of an employing entity subject to this subpart to include the HMO alternative in any health benefits plan offered to its eligible employees must be carried out consistently with the obligations imposed on that employing entity under the National Labor Relations Act, the Railway Labor Act, and other laws of similar effect.

[59 FR 49841, Sept. 30, 1994, as amended at 61 FR 27288, May 31, 1996]

**Subpart F—Continued Regulation of Federally Qualified Health Maintenance Organizations**

SOURCE: 43 FR 32255, July 25, 1978, unless otherwise noted. Redesignated at 52 FR 36746, Sept. 30, 1987.

**§ 417.160 Applicability.**

This subpart applies to any entity that has been determined to be a qualified HMO under subpart D of this part.

[59 FR 49841, Sept. 30, 1994]

**§ 417.161 Compliance with assurances.**

Any entity subject to this subpart must comply with the assurances that it provided to CMS, unless compliance is waived under § 417.166.

[58 FR 38071, July 15, 1993]

**§ 417.162 Reporting requirements.**

Entities subject to this subpart must submit:

- (a) The reports that may be required by CMS under § 417.126, and
- (b) Any additional reports CMS may reasonably require.

[58 FR 38071, July 15, 1993]

**§ 417.163 Enforcement procedures.**

(a) *Complaints.* Any person, group, association, corporation, or other entity may file with CMS a written complaint with respect to an HMO's compliance with assurances it gave under subpart D of this part. A complaint must—

- (1) State the grounds and underlying facts of the complaint;
- (2) Give the names of all persons involved; and
- (3) Assure that all appropriate grievance and appeals procedures established by the HMO and available to the complainant have been exhausted.

(b) *Investigations.* (1) CMS may initiate investigations when, based on a report, a complaint, or any other information, CMS has reason to believe that a Federally qualified HMO is not in compliance with any of the assurances it gave under subpart D of this part.

(2) When CMS initiates an investigation, it gives the HMO written notice that includes a full statement of the pertinent facts and of the matters being investigated and indicates that the HMO may submit, within 30 days of the date of the notice, a written report concerning these matters.

(3) CMS obtains any information it considers necessary to resolve issues related to the assurances, and may use site visits, public hearings, or any other procedures that CMS considers appropriate in seeking this information.

(c) *Determination and notice by CMS—*(1) *Determination.* (i) On the basis of the investigation, CMS determines whether the HMO has failed to comply with any of the assurances it gave under subpart D of this part.

(ii) CMS publishes in the FEDERAL REGISTER a notice of each determination of non-compliance.

(2) *Notice of determination: Corrective action.* (i) CMS gives the HMO written notice of the determination.

(ii) The notice specifies the manner in which the HMO has not complied with its assurances and directs the HMO to initiate the corrective action that CMS considers necessary to bring the HMO into compliance.

(iii) The HMO must initiate this corrective action within 30 days of the date of the notice from CMS, or within any longer period that CMS determines