

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