

need not comply with the community rating requirements of §§ 417.104(b) and 417.105(b).

(5) *Contracts in effect on the date of CMS's determination.* The entity gives assurances that it will meet the following conditions with respect to its group and individual contracts that are in effect on the date of CMS's determination, and which are renewed or renegotiated during the period approved by CMS under paragraph (d)(6) of this section:

(i) Continue to provide services in accordance with paragraph (d)(3) of this section.

(ii) Continue to be organized and operated and to pay for basic health services in accordance with paragraphs (d)(2) and (d)(4) of this section, respectively.

(6) *Time-phased plan.* The entity gives assurances as follows:

(i) It will implement a time-phased plan acceptable to CMS that—

(A) May not extend for more than 3 years from the date of CMS's determination; and

(B) Specifies definite steps for meeting, at the time of renewal of each group or individual contract, all the requirements of subparts B and C of this part.

(ii) Upon completion of this time-phased plan, it will—

(A) Provide basic and supplemental services to all of its enrollees; and

(B) Be organized and operated, and provide services, in accordance with subparts B and C of this part.

(7) *Contracts entered into after the date of CMS's determination.* The entity gives assurances that, with respect to any group or individual contract entered into after the date of CMS's determination, it will—

(i) Be organized and operated in accordance with subpart C of this part; and

(ii) Provide basic health services and any supplemental health services included in the contract, in accordance with subpart B of this part.

(e) *Failure to sign assurances timely.* If CMS determines that an entity meets the requirements for qualification and the entity fails to sign its assurances within 30 days following the date of the determination, CMS gives the entity

written notice that its application is considered withdrawn and that it is not a qualified HMO.

(f) *Qualification of regional components.* An HMO that has more than one regional component is considered qualified for those regional components for which assurances have been signed in accordance with this section.

(g) *Special rules: Enrollees entitled to Medicare or Medicaid.* For an HMO that accepts enrollees entitled to Medicare or Medicaid, the following rules apply:

(1) The requirements of titles XVIII and XIX of the Act, as appropriate, take precedence over conflicting requirements of sections 1301(b) and 1301(c) of the PHS Act.

(2) The HMO must, with respect to its enrollees entitled to Medicare or Medicaid, comply with the applicable requirement of title XVIII or XIX, including those that pertain to—

(i) Deductibles and coinsurance;

(ii) Enrollment mix and enrollment practices;

(iii) State plan rules on copayment options; and

(iv) Grievance procedures.

(3) An HMO that complies with paragraph (g)(2) of this section may obtain and retain Federal qualification if, for its other enrollees, the HMO meets the requirements of sections 1301(b) and 1301(c) of the PHS Act and implementing regulations in this subpart D and in subparts B and C of this part.

(h) *Special rules: Enrollees under the Federal employee health benefits program (FEHBP).* An HMO that accepts enrollees under the FEHBP (Chapter 89 of title 5 of the U.S.C.) may obtain and retain Federal qualification if, for its other enrollees, it complies with the requirements of section 1301(b) and 1301(c) of the PHS Act and implementing regulations in this subpart D and subparts B and C of this part.

[59 FR 49836, Sept. 30, 1994]

#### § 417.143 Application requirements.

(a) *General requirements.* This section sets forth application requirements for entities that seek qualification as HMOs; HMOs that seek expansion of their service areas; and HMOs that seek qualification of their regional components as HMOs.

(b) *Completion of an application form.*

(1) In order to receive a determination concerning whether an entity is a qualified HMO, an individual authorized to act for the entity (the applicant) must complete an application form provided by CMS.

(2) The authorized individual must describe thoroughly how the entity meets, or will meet, the requirements for qualified HMOs described in the PHS Act and in subparts B and C of this part, this subpart D, and 417.168 and 417.169 of subpart F.

(c) *Collection of an application fee.* In accordance with the requirements of 31 U.S.C. 9701, Fees and charges for Government services and things of value, CMS determines the amount of the application fee that must be submitted with each type of application.

(1) The fee is reasonably related to the Federal government's cost of qualifying an entity and may vary based on the type of application.

(2) Each type of application has one set fee rather than a charge based on the specific cost of each determination. (For example, each Federally qualified HMO applicant seeking Federal qualification of one of its regional components as an HMO is charged the same amount, unless the amount of the fee has been changed under paragraph (f) of this section.)

(d) *Application fee amounts.* The application fee amounts for applications completed on or after July 13, 1987 are as follows:

(1) \$18,400 for an entity seeking qualification as an HMO or qualification of a regional component of an HMO.

If, in the case of an HMO seeking qualification of a regional component, CMS determines that there is no need for a site visit, \$8,000 will be returned to the applicant.

(2) \$6,900 for an HMO seeking expansion of its service area.

(3) \$3,100 for a CMP seeking qualification as an HMO.

(e) *Refund of an application fee.* CMS refunds an application fee only if the entity withdraws its application within 10 working days after receipt by CMS. Application fees are not returned in any other circumstance, even if qualification or certification is denied.

(f) *Procedure for changing the amount of an application fee.* If CMS determines that a change in the amount of a fee is appropriate, CMS issues a notice of proposed rulemaking in the FEDERAL REGISTER to announce the proposed new amount.

(g) *New application after denial.* An entity may not submit another application under this subpart for the same type of determination for four full months after the date of the notice in which CMS denied the application.

(h) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exceptions provided in 45 CFR part 5, the Department's regulations providing exceptions to disclosure, should label the material "privileged" and include an explanation of the applicability of an exception described in 45 CFR part 5.

[52 FR 22321, June 11, 1987. Redesignated at 52 FR 36746, Sept. 30, 1987, as amended at 58 FR 38077, July 15, 1993]

#### §417.144 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) CMS evaluates an application for Federal qualification on the basis of information contained in the application itself and any additional information that CMS obtains through on-site visits, public hearings, and any other appropriate procedures.

(2) If the application is incomplete, CMS notifies the entity and allows 60 days from the date of the notice for the entity to furnish the missing information.

(3) After evaluating all relevant information, CMS determines whether the entity meets the applicable requirements of §§417.142 and 417.143.

(b) *Notice of determination.* CMS notifies each entity that applies for qualification under this subpart of its determination and the basis for the determination. The determination may be granting of qualification, intent to deny, or denial.

(c) *Intent to deny.* (1) If CMS finds that the entity does not appear to meet the requirements for qualification and