

§ 422.516

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(b)(1)(i) of this section and stop-loss insurance that is adequate and acceptable to HCFA; and,

(iii) The organization is able to establish a marketing and enrollment process that will allow it to meet the applicable enrollment requirement specified in paragraph (a) of this section prior to completion of the third contract year.

(2) If an M+C organization fails to meet the enrollment requirement in the first year, HCFA may waive the minimum requirements for another year provided that the organization—

(i) Requests an additional minimum enrollment waiver no later than 120 days before the end of the first year;

(ii) Continues to demonstrate it is capable of administering and managing an M+C contract and is able to manage the level of risk; and,

(iii) Demonstrates an acceptable marketing and enrollment process. Enrollment projections for the second year of the waiver will become the organization's transitional enrollment standard.

(3) If an M+C organization fails to meet the enrollment requirement in the second year, HCFA may waive the minimum requirements for the third year only if the organization has attained the transitional enrollment standard as described in paragraph (b)(2)(iii) of this section.

(c) Failure to meet enrollment requirements. HCFA may elect not to renew its contract with an M+C organization that fails to meet the applicable enrollment requirement in paragraph (a) of this section

§ 422.516 Reporting requirements.

(a) *Required information.* Each M+C organization must have an effective procedure to develop, compile, evaluate, and report to HCFA, to its enrollees, and to the general public, at the times and in the manner that HCFA 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 M+C organization has a fiscally sound operation.

(6) Other matters that HCFA may require.

(b) *Significant business transactions.* Each M+C organization must report to HCFA annually, within 120 days of the end of its fiscal year (unless for good cause shown, HCFA authorizes an extension of time), the following:

(1) A description of significant business transactions (as defined in § 422.500) between the M+C organization 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 M+C organization 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 M+C organization go to a party in interest.

(ii) Thirty-five percent or more of the revenue of a party in interest is from the M+C organization.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the M+C organization and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must have been examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from an M+C organization showing good cause, HCFA may waive the requirement that the organization's combined financial

statement include the financial information required in this paragraph (c) with respect to a particular entity.

(d) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an M+C organization in its offerings, the M+C organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular M+C organization) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The M+C organization must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA.

(e) *Loan information.* Each organization must notify HCFA of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to information.* Each M+C organization must make the information reported to HCFA under § 422.502(f)(1) available to its enrollees upon reasonable request.

§ 422.520 Prompt payment by M+C organization.

(a) *Contract between HCFA and the M+C organization.*

(1) The contract between HCFA and the M+C organization must provide that the M+C organization will pay 95 percent of the "clean claims" within 30 days of receipt if they are submitted by, or on behalf of, an enrollee of an M+C private fee-for-service plan or are claims for services that are not furnished under a written agreement between the organization and the provider.

(2) The M+C organization must pay interest on clean claims that are not paid within 30 days in accordance with sections 1816(c)(2)(B) and 1842(c)(2)(B).

(3) All other claims must be approved or denied within 60 calendar days from the date of the request.

(b) *Contracts between M+C organizations and providers and suppliers.* Contracts or other written agreements between M+C organizations and providers must contain a prompt payment provision, the terms of which are developed

and agreed to by both the M+C organization and the relevant provider.

(c) *Failure to comply.* If HCFA determines, after giving notice and opportunity for hearing, that an M+C organization has failed to make payments in accordance with paragraph (a) of this section, HCFA may provide—

(1) For direct payment of the sums owed to providers, or M+C private fee-for-service plan enrollees; and

(2) For appropriate reduction in the amounts that would otherwise be paid to the organization, to reflect the amounts of the direct payments and the cost of making those payments.

§ 422.524 Special rules for RFB societies.

In order to participate as an M+C organization, an RFB society—

(a) May not impose any limitation on membership based on any factor related to health status; and

(b) Must offer, in addition to the M+C RFB plan, health coverage to individuals who are members of the church or convention or group of churches with which the society is affiliated, but who are not entitled to receive benefits from the Medicare program.

Subpart L—Effect of Change of Ownership or Leasing of Facilities During Term of Contract

SOURCE: 63 FR 35067, June 26, 1998, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to subpart L appear at 63 FR 35106, June 26, 1998.

§ 422.550 General provisions.

(a) *What constitutes change of ownership—*(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise as permitted by applicable State law, constitutes a change of ownership.

(2) *Unincorporated sole proprietor.* Transfer of title and property to another party constitutes change of ownership.

(3) *Corporation.* (i) The merger of the M+C organization's corporation into another corporation or the consolidation of the M+C organization with one