

§ 422.501

42 CFR Ch. IV (10–1–00 Edition)

(1) Any director, officer, partner, or employee responsible for management or administration of an M+C organization.

(2) Any person who is directly or indirectly the beneficial owner of more than 5 percent of the organization's equity; or the beneficial owner of a mortgage, deed of trust, note, or other interest secured by and valuing more than 5 percent of the organization.

(3) In the case of an M+C organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law.

(4) Any entity in which a person described in paragraph (1), (2), or (3) of this definition:

(i) Is an officer, director, or partner; or

(ii) Has the kind of interest described in paragraphs (1), (2), or (3) of this definition.

(5) Any person that directly or indirectly controls, is controlled by, or is under common control with, the M+C organization.

(6) Any spouse, child, or parent of an individual described in paragraph (1), (2), or (3) of this definition.

Related entity means any entity that is related to the M+C organization by common ownership or control and—

(1) Performs some of the M+C organization's management functions under contract or delegation;

(2) Furnishes services to Medicare enrollees under an oral or written agreement; or

(3) Leases real property or sells materials to the M+C organization at a cost of more than \$2,500 during a contract period.

Significant business transaction means any business transaction or series of transactions of the kind specified in the above definition of "business transaction" that, during any fiscal year of the M+C organization, have a total value that exceeds \$25,000 or 5 percent of the M+C organization's total operating expenses, whichever is less.

[65 FR 35099, June 26, 1998, as amended at 65 FR 40327, June 29, 2000]

§ 422.501 General provisions.

(a) *Basic rule.* In order to qualify as an M+C organization, enroll bene-

ficiaries in any M+C plans it offers, and be paid on behalf of Medicare beneficiaries enrolled in those plans, an M+C organization must enter into a contract with HCFA.

(b) *Conditions necessary to contract as an M+C organization.* Any entity seeking to contract as an M+C organization must:

(1) Be licensed by the State as a risk bearing entity in each State in which it seeks to offer an M+C plan as defined in § 422.2.

(2) Meet the minimum enrollment requirements of § 422.514, unless waived under § 422.514(b).

(3) Have administrative and management arrangements satisfactory to HCFA, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the M+C organization's policies and personnel to ensure that management actions are in the best interest of the organization and its enrollees.

(ii) Personnel and systems sufficient for the M+C organization to organize, plan, control, and evaluate financial and marketing activities, the furnishing of services, the quality assurance program, and the administrative and management aspects of the organization.

(iii) At a minimum, an executive manager whose appointment and removal are under the control of the policy making body.

(iv) A fidelity bond or bonds, procured and maintained by the M+C organization, 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 M+C organization.

(v) Insurance policies or other arrangements, secured and maintained by the M+C organization and approved by HCFA to insure the M+C organization against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) A compliance plan that consists of the following:

(A) Written policies, procedures, and standards of conduct that articulate the organization's commitment to comply with all applicable Federal and State standards.

(B) The designation of a compliance officer and compliance committee that are accountable to senior management.

(C) Effective training and education between the compliance officer and organization employees.

(D) Effective lines of communication between the compliance officer and the organization's employees.

(E) Enforcement of standards through well-publicized disciplinary guidelines.

(F) Provision for internal monitoring and auditing.

(G) Procedures for ensuring prompt response to detected offenses and development of corrective action initiatives relating to the organization's M+C contract.

(4) Not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an M+C plan.

(5) The M+C organization's contract must not have been terminated by HCFA under §422.510 within the past 2 years unless—

(i) During the 6-month period beginning on the date the organization notified HCFA of the intention to terminate the most recent previous contract, there was a change in the statute or regulations that had the effect of increasing M+C payments in the payment area or areas at issue; or

(ii) HCFA has otherwise determined that circumstances warrant special consideration.

(c) *Contracting authority.* Under the authority of section 1857(c)(5) of the Act, HCFA may enter into contracts under this part without regard to Federal and Departmental acquisition regulations set forth in title 48 of the CFR and provisions of law or other regulations relating to the making, performance, amendment, or modification of contracts of the United States if HCFA determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(d) *Protection against fraud and beneficiary protections.* (1) HCFA annually

audits the financial records (including data relating to Medicare utilization, costs, and computation of the ACR) of at least one-third of the M+C organizations offering M+C plans. These auditing activities are subject to monitoring by the Comptroller General.

(2) Each contract under this section must provide that HCFA, or any person or organization designated by HCFA has the right to:

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the M+C contract;

(ii) Inspect or otherwise evaluate the facilities of the organization when there is reasonable evidence of some need for such inspection; and

(iii) Audit and inspect any books, contracts, and records of the M+C organization that pertain to—

(A) The ability of the organization or its first tier or downstream providers to bear the risk of potential financial losses; or

(B) Services performed or determinations of amounts payable under the contract.

(e) *Severability of contracts.* The contract must provide that, upon HCFA's request—

(1) The contract will be amended to exclude any M+C plan or State-licensed entity specified by HCFA; and

(2) A separate contract for any such excluded plan or entity will be deemed to be in place when such a request is made.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40327, June 29, 2000]

§ 422.502 Contract provisions.

The contract between the M+C organization and HCFA must contain the following provisions:

(a) *Agreement to comply with regulations and instructions.* The M+C organization agrees to comply with all the applicable requirements and conditions set forth in this part and in general instructions. An M+C organization's compliance with paragraphs (a)(1) through (a)(13) of this section is material to performance of the contract. The M+C organization agrees—