

(b) *Specific preemption.* As they might otherwise apply to the M+C plans of an M+C organization in a State, State laws and regulations pertaining to the following areas are specifically preempted by this part:

(1) Benefit requirements, such as mandating the inclusion in an M+C plan of a particular service, or specifying the scope or duration of a service (for example, length of hospital stay, number of home health visits). State cost-sharing standards with respect to any benefits are preempted only if they are inconsistent with this part, as provided for in paragraph (a) of this section.

(2) Requirements relating to inclusion or treatment of providers and suppliers.

(3) Coverage determinations (including related appeal and grievance processes for all benefits included under an M+C contract). Determinations on issues other than whether a service is covered under an M+C contract, and the extent of enrollee liability under the M+C plan for such a service, are not considered coverage determinations for purposes of this paragraph.

(c) Except as provided in paragraphs (a) and (b) of this section, nothing in this section may be construed to affect or modify the provisions of any other law or regulation that imposes or preempts a specific State authority.

§ 422.404 State premium taxes prohibited.

(a) *Basic rule.* No premium tax, fee, or other similar assessment may be imposed by any State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa, or any of their political subdivision or other governmental authorities with respect to any payment HCFA makes on behalf of M+C enrollees under subpart F of this part.

(b) *Construction.* Nothing in this section shall be construed to exempt any M+C organization from taxes, fees, or other monetary assessments related to the net income or profit that accrues to, or is realized by, the organization from business conducted under this part, if that tax, fee, or payment is applicable to a broad range of business activity.

Subpart J [Reserved]

Subpart K—Contracts With Medicare+Choice Organizations

SOURCE: 63 FR 35099, June 26, 1998, unless otherwise noted.

§ 422.500 Definitions.

For purposes of this subpart, the following definitions apply:

Business transaction means any of the following kinds of transactions:

(1) Sale, exchange, or lease of property.

(2) Loan of money or extension of credit.

(3) Goods, services, or facilities furnished for a monetary consideration, including management services, but not including—

(i) Salaries paid to employees for services performed in the normal course of their employment; or

(ii) Health services furnished to the M+C organization's enrollees by hospitals and other providers, and by M+C organization staff, medical groups, or independent practice associations, or by any combination of those entities.

Clean claim means—

(1) A claim that has no defect, impropriety, lack of any required substantiating documentation (consistent with § 422.257(d)) or particular circumstance requiring special treatment that prevents timely payment; and

(2) A claim that otherwise conforms to the clean claim requirements for equivalent claims under original Medicare.

Downstream entity means any party that enters into an acceptable written arrangement below the level of the arrangement between an M+C organization (or contract applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

First tier entity means any party that enters into an acceptable written arrangement with an M+C organization or contract applicant to provide administrative services or health care services for a Medicare eligible individual.

Party in interest includes the following:

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(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: