

less than the time period granted in paragraph (g)(1) of this section.

[63 FR 25379, May 7, 1998]

Subpart I—Organization Compliance With State Law and Preemption by Federal Law

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

§ 422.400 State licensure requirement.

Except in the case of a PSO granted a waiver under subpart H of this part, each M+C organization must—

(a) Be licensed under State law, or otherwise authorized to operate under State law, as a risk-bearing entity (as defined in §422.2) eligible to offer health insurance or health benefits coverage in each State in which it offers one or more M+C plans;

(b) If not commercially licensed, obtain certification from the State that the organization meets a level of financial solvency and such other standards as the State may require for it to operate as an M+C organization; and

(c) Demonstrate to HCFA that—

(1) The scope of its license or authority allows the organization to offer the type of M+C plan or plans that it intends to offer in the State; and

(2) If applicable, it has obtained the State certification required under paragraph (b) of this section.

§ 422.402 Federal preemption of State law.

(a) *General preemption.* Except as provided in paragraph (b) of this section, the rules, contract requirements, and standards established under this part supersede any State laws, regulations, contract requirements, or other standards that would otherwise apply to M+C organizations and their M+C plans only to the extent that such State laws are inconsistent with the standards established under this part. This preemption of State laws and other standards applies only to coverage pursuant to an M+C contract, and does not extend to benefits outside of such contract or to individuals who are not M+C enrollees of an organization with an M+C contract.

(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 a claim that has no defect, impropriety, lack of any required substantiating documentation, or particular circumstance requiring special treatment that prevents timely payment.

Party in interest includes the following:

- (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.

§ 422.501 General provisions.

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