(3) All other claims from non-contracted providers must be paid or denied within 60 calendar days from the date of the request.

(b)(1) *Contracts between MA organizations and providers and suppliers.* Contracts or other written agreements between MA organizations and providers must contain a prompt payment provision, the terms of which are developed and agreed to by both the MA organization and the relevant provider.

(2) The MA organization is obligated to pay contracted providers under the terms of the contract between the MA organization and the provider.

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

(1) For direct payment of the sums owed to providers, or MA 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.

(d) A CMS decision to not conduct a hearing under paragraph (c) of this section does not disturb any potential remedy under State law for 1866(a)(1)(O) of the Act.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 70 FR 4738, Jan. 28, 2005]

§ 422.521 Effective date of new significant regulatory requirements.

CMS will not implement, other than at the beginning of a calendar year, requirements under this part that impose a new significant cost or burden on MA organizations or plans, unless a different effective date is required by statute.

[68 FR 50858, Aug. 22, 2003]

§ 422.524 Special rules for RFB societies.

In order to participate as an MA 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 MA 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.

§ 422.527 Agreements with Federally qualified health centers.

The contract between the MA organization and CMS must specify that—

(a) The MA organization must pay a Federally qualified health center (FQHC) a similar amount to what it pays other providers for similar services.

(b) Under such a contract, the FQHC must accept this payment as payment in full, except for allowable cost sharing which it may collect.

(c) Financial incentives, such as risk pool payments or bonuses, and financial withholdings are not considered in determining the payments made by CMS under § 422.316(a).

[70 FR 4738, Jan. 28, 2005]

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) *Asset transfer.* Transfer of title and property to another party constitutes change of ownership.

(3) *Corporation.* (i) The merger of the MA organization's corporation into another corporation or the consolidation of the MA organization with one or more other corporations, resulting in a new corporate body, constitutes a change of ownership.

(ii) Transfer of corporate stock or the merger of another corporation into the MA organization's corporation, with the MA organization surviving, does

not ordinarily constitute change of ownership.

(b) *Advance notice requirement.* (1) An MA organization that has a Medicare contract in effect and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The MA organization must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) If the MA organization fails to give CMS the required notice timely, it continues to be liable for capitation payments that CMS makes to it on behalf of Medicare enrollees after the date of change of ownership.

(c) *Novation agreement defined.* A novation agreement is an agreement among the current owner of the MA organization, the prospective new owner, and CMS—

(1) That is embodied in a document executed and signed by all three parties;

(2) That meets the requirements of § 422.552; and

(3) Under which CMS recognizes the new owner as the successor in interest to the current owner's Medicare contract.

(d) *Effect of change of ownership without novation agreement.* Except to the extent provided in paragraph (b)(2) of this section, the effect of a change of ownership without a novation agreement is that—

(1) The existing contract becomes invalid; and

(2) If the new owner wishes to participate in the Medicare program, it must apply for, and enter into, a contract in accordance with subpart K of this part.

(e) *Effect of change of ownership with novation agreement.* If the MA organization submits a novation agreement that meets the requirements of § 422.552, and CMS signs it, the new owner becomes the successor in interest to the current owner's Medicare contract.

[60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 63 FR 52614, Oct. 1, 1998; 65 FR 40328, June 29, 2000; 70 FR 4738, Jan. 28, 2005]

§ 422.552 Novation agreement requirements.

(a) *Conditions for CMS approval of a novation agreement.* CMS approves a novation agreement if the following conditions are met:

(1) *Advance notification.* The MA organization notifies CMS at least 60 days before the date of the proposed change of ownership. The MA organization also provides CMS with updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

(2) *Advance submittal of agreement.* The MA organization submits to CMS, at least 30 days before the proposed change of ownership date, three signed copies of the novation agreement containing the provisions specified in paragraph (b) of this section, and one copy of other relevant documents required by CMS.

(3) *CMS's determination.* CMS determines that—

(i) The proposed new owner is in fact a successor in interest to the contract;

(ii) Recognition of the new owner as a successor in interest to the contract is in the best interest of the Medicare program; and

(iii) The successor organization meets the requirements to qualify as an MA organization under subpart K of this part.

(b) *Provisions of a novation agreement*—(1) *Assumption of contract obligations.* The new owner must assume all obligations under the contract.

(2) *Waiver of right to reimbursement.* The previous owner must waive its rights to reimbursement for covered services furnished during the rest of the current contract period.

(3) *Guarantee of performance.* (i) The previous owner must guarantee performance of the contract by the new owner during the contract period; or

(ii) The new owner must post a performance bond that is satisfactory to CMS.

(4) *Records access.* The previous owner must agree to make its books and records and other necessary information available to the new owner and to

CMS to permit an accurate determination of costs for the final settlement of the contract period.

[50 FR 1346, Jan. 10, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 70 FR 52027, Sept. 1, 2005]

§ 422.553 Effect of leasing of an MA organization's facilities.

(a) *General effect of leasing.* If an MA organization leases all or part of its facilities to another entity, the other entity does not acquire MA organization status under section 1876 of the Act.

(b) *Effect of lease of all facilities.* (1) If an MA organization leases all of its facilities to another entity, the contract terminates.

(2) If the other entity wishes to participate in Medicare as an MA organization, it must apply for and enter into a contract in accordance with subpart K of this part.

(c) *Effect of partial lease of facilities.* If the MA organization leases part of its facilities to another entity, its contract with CMS remains in effect while CMS surveys the MA organization to determine whether it continues to be in compliance with the applicable requirements and qualifying conditions specified in subpart K of this part.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 58 FR 38079, July 15, 1993; 60 FR 45681, Sept. 1, 1995. Redesignated and amended at 63 FR 35067, 35106, June 26, 1998; 70 FR 52027, Sept. 1, 2005]

Subpart M—Grievances, Organization Determinations and Appeals

SOURCE: 63 FR 35107, June 26, 1998, unless otherwise noted.

§ 422.560 Basis and scope.

(a) *Statutory basis.* (1) Section 1852(f) of the Act provides that an MA organization must establish meaningful grievance procedures.

(2) Section 1852(g) of the Act establishes requirements that an MA organization must meet concerning organization determinations and appeals.

(3) Section 1869 of the Act specifies the amount in controversy needed to pursue a hearing and judicial review and authorizes representatives to act on behalf of individuals that seek appeals. These provisions are incorporated for MA appeals by section 1852(g)(5) of the Act and part 405 of this chapter.

(b) *Scope.* This subpart sets forth—

(1) Requirements for MA organizations with respect to grievance procedures, organization determinations, and appeal procedures.

(2) The rights of MA enrollees with respect to organization determinations, and grievance and appeal procedures.

(3) The rules concerning notice of noncoverage of inpatient hospital care.

(4) The rules that apply when an MA enrollee requests immediate QIO review of a determination that he or she no longer needs inpatient hospital care.

(c) *Relation to ERISA requirements.* Consistent with section 1857(i)(2) of the Act, provisions of this subpart may, to the extent applicable under regulations adopted by the Secretary of Labor, apply to claims for benefits under group health plans subject to the Employee Retirement Income Security Act.

[63 FR 35107, June 26, 1998, as amended at 70 FR 4738, Jan. 28, 2005]

§ 422.561 Definitions.

As used in this subpart, unless the context indicates otherwise—

Appeal means any of the procedures that deal with the review of adverse organization determinations on the health care services the enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service, as defined under § 422.566(b). These procedures include reconsiderations by the MA organization, and if necessary, an independent review entity, hearings before ALJs, review by the Medicare Appeals Council (MAC), and judicial review.

Enrollee means an MA eligible individual who has elected an MA plan offered by an MA organization.