

(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—

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(1) To accept new enrollments, make enrollments effective, process voluntary disenrollments, and limit involuntary disenrollments, as provided in subpart B of this part.

(2) That it will comply with the prohibition in §422.110 on discrimination in beneficiary enrollment.

(3) To provide—

(i) The basic benefits as required under §422.101 and, to the extent applicable, supplemental benefits under §422.102; and

(ii) Access to benefits as required under subpart C of this part;

(iii) In a manner consistent with professionally recognized standards of health care, all benefits covered by Medicare.

(4) To disclose information to beneficiaries in the manner and the form prescribed by HCFA as required under §422.111;

(5) To operate a quality assurance and performance improvement program and have an agreement for external quality review as required under subpart D of this part;

(6) To comply with all applicable provider requirements in subpart E of this part, including provider certification requirements, anti-discrimination requirements, provider participation and consultation requirements, the prohibition on interference with provider advice, limits on provider indemnification, rules governing payments to providers, and limits on physician incentive plans;

(7) To comply with all requirements in subpart M of this part governing coverage determinations, grievances, and appeals;

(8) To comply with the reporting requirements in §422.516 and the requirements in §422.257 for submitting encounter data to HCFA;

(9) That it will be paid under the contract in accordance with the payment rules in subpart F of this part;

(10) To develop its annual ACR, and submit all required information on premiums, benefits, and cost-sharing by May 1, as provided in subpart G of this part;

(11) That its contract may not be renewed or may be terminated in accordance with this subpart and subpart N of this part.

(12) To comply with all requirements that are specific to a particular type of M+C plan, such as the special rules for private fee-for-service plans in §§422.114 and 422.216 and the MSA requirements in §§422.56, 422.103, and 422.262; and

(13) To comply with the confidentiality and enrollee record accuracy requirements in §422.118.

(14) An M+C organization's compliance with paragraphs (a)(1) through (a)(13) and (c) of this section is material to performance of the contract.

(b) *Communication with HCFA.* The M+C organization must have the capacity to communicate with HCFA electronically.

(c) *Prompt payment.* The M+C organization must comply with the prompt payment provisions of §422.520 and with instructions issued by HCFA, as they apply to each type of plan included in the contract.

(d) *Maintenance of records.* The M+C organization agrees to maintain for 6 years books, records, documents, and other evidence of accounting procedures and practices that—

(1) Are sufficient to do the following:

(i) Accommodate periodic auditing of the financial records (including data related to Medicare utilization, costs, and computation of the ACR) of M+C organizations.

(ii) Enable HCFA to inspect or otherwise evaluate the quality, appropriateness and timeliness of services performed under the contract, and the facilities of the organization.

(iii) Enable HCFA to audit and inspect any books and records of the M+C organization that pertain to the ability of the organization to bear the risk of potential financial losses, or to services performed or determinations of amounts payable under the contract.

(iv) Properly reflect all direct and indirect costs claimed to have been incurred and used in the preparation of the ACR proposal.

(v) Establish component rates of the ACR for determining additional and supplementary benefits.

(vi) Determine the rates utilized in setting premiums for State insurance agency purposes and for other government and private purchasers; and

(2) Include at least records of the following:

(i) Ownership and operation of the M+C organization's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and six prior periods.

(iii) Federal income tax or informational returns for the current contract period and six prior periods.

(iv) Asset acquisition, lease, sale, or other action.

(v) Agreements, contracts, and sub-contracts.

(vi) Franchise, marketing, and management agreements.

(vii) Schedules of charges for the M+C organization's fee-for-service patients.

(viii) Matters pertaining to costs of operations.

(ix) Amounts of income received by source and payment.

(x) Cash flow statements.

(xi) Any financial reports filed with other Federal programs or State authorities.

(e) *Access to facilities and records.* The M+C organization agrees to the following:

(1) HHS, the Comptroller General, or their designee may evaluate, through inspection or other means—

(i) The quality, appropriateness, and timeliness of services furnished to Medicare enrollees under the contract;

(ii) The facilities of the M+C organization; and

(iii) The enrollment and disenrollment records for the current contract period and six prior periods.

(2) HHS, the Comptroller General, or their designees may audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of the M+C organization, related entity, contractor, sub-contractor, or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract, or as the Secretary may deem necessary to enforce the contract.

(3) The M+C organization agrees to make available, for the purposes specified in paragraph (d) of this section, its premises, physical facilities and equipment, records relating to its Medicare

enrollees, and any additional relevant information that HCFA may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 6 years from the final date of the contract period or completion of audit, whichever is later unless—

(i) HCFA determines there is a special need to retain a particular record or group of records for a longer period and notifies the M+C organization at least 30 days before the normal disposition date;

(ii) There has been a termination, dispute, or fraud or similar fault by the M+C organization, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault; or

(iii) HCFA determines that there is a reasonable possibility of fraud, in which case it may inspect, evaluate, and audit the M+C organization at any time.

(f) *Disclosure of information.* The M+C organization agrees to submit—

(1) To HCFA, certified financial information that must include the following:

(i) Such information as HCFA may require demonstrating that the organization has a fiscally sound operation.

(ii) Such information as HCFA may require pertaining to the disclosure of ownership and control of the M+C organization.

(2) To HCFA, all information that is necessary for HCFA to administer and evaluate the program and to simultaneously establish and facilitate a process for current and prospective beneficiaries to exercise choice in obtaining Medicare services. This information includes, but is not limited to:

(i) The benefits covered under an M+C plan;

(ii) The M+C monthly basic beneficiary premium and M+C monthly supplemental beneficiary premium, if any, for the plan or in the case of an MSA plan, the M+C monthly MSA premium.

(iii) The service area and continuation area, if any, of each plan and the enrollment capacity of each plan;

(iv) Plan quality and performance indicators for the benefits under the plan including —

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(A) Disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years;

(B) Information on Medicare enrollee satisfaction;

(C) Information on health outcomes;

(D) The recent record regarding compliance of the plan with requirements of this part, as determined by HCFA; and

(E) Other information determined by HCFA to be necessary to assist beneficiaries in making an informed choice among M+C plans and traditional Medicare;

(v) Information about beneficiary appeals and their disposition;

(vi) Information regarding all formal actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization;

(vii) For M+C organizations offering an MSA plan, information specified by HCFA for HCFA's use in preparing its report to the Congress on the MSA demonstration, including data specified by HCFA in the areas of selection, use of preventative care, and access to services.

(viii) To HCFA, any other information deemed necessary by HCFA for the administration or evaluation of the Medicare program.

(3) To its enrollees all informational requirements under §422.64 and, upon an enrollee's, request the financial disclosure information required under §422.516.

(g) *Beneficiary financial protections.* The M+C organization agrees to comply with the following requirements:

(1) Each M+C organization must adopt and maintain arrangements satisfactory to HCFA to protect its enrollees from incurring liability (for example, as a result of an organization's insolvency or other financial difficulties) for payment of any fees that are the legal obligation of the M+C organization. To meet this requirement, the M+C organization must—

(i) Ensure that all contractual or other written arrangements with providers prohibit the organization's providers from holding any beneficiary enrollee liable for payment of any such fees; and

(ii) Indemnify the beneficiary enrollee for payment of any fees that are the legal obligation of the M+C organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the M+C organization, to provide services to the organization's beneficiary enrollees.

(2) The M+C organization must provide for continuation of enrollee health care benefits—

(i) For all enrollees, for the duration of the contract period for which HCFA payments have been made; and

(ii) For enrollees who are hospitalized on the date its contract with HCFA terminates, or, in the event of an insolvency, through discharge.

(3) In meeting the requirements of this paragraph, other than the provider contract requirements specified in paragraph (g)(1)(i) of this section, the M+C organization may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to HCFA;

(iii) Financial reserves acceptable to HCFA; or

(iv) Any other arrangement acceptable to HCFA.

(h) *Requirements of other laws and regulations.* (1) The M+C organization agrees to comply with—

(i) Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR part 84;

(ii) The Age Discrimination Act of 1975 as implemented by regulations at 45 CFR part 91;

(iii) The Rehabilitation Act of 1973;

(iv) The Americans With Disabilities Act;

(v) Other laws applicable to recipients of Federal funds; and

(vi) All other applicable laws and rules.

(2) M+C organizations receiving Federal payments under M+C contracts, and related entities, contractors, and subcontractors paid by an M+C organization to fulfill its obligations under its M+C contract are subject to certain laws that are applicable to individuals and entities receiving Federal funds. M+C organizations must inform all related entities, contractors and subcontractors that payments that they receive are, in whole or in part, from Federal funds.

(i) *M+C organization relationship with related entities, contractors, and subcontractors.* (1) Notwithstanding any relationship(s) that the M+C organization may have with related entities, contractors, or subcontractors, the M+C organization maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with HCFA.

(2) The M+C organization agrees to require all related entities, contractors, or subcontractors to agree that—

(i) HHS, the Comptroller General, or their designees have the right to inspect, evaluate, and audit any pertinent contracts, books, documents, papers, and records of the related entity(s), contractor(s), or subcontractor(s) involving transactions related to the M+C contract; and

(ii) HHS', the Comptroller General's, or their designee's right to inspect, evaluate, and audit any pertinent information for any particular contract period will exist through 6 years from the final date of the contract period or from the date of completion of any audit, whichever is later.

(3) All contracts or written arrangements between M+C organizations and providers, related entities, contractors, subcontractors, first tier and downstream entities must contain the following:

(i) Enrollee protection provisions that provide, consistent with paragraph (g)(1) of this section, arrangements that prohibit providers from holding an enrollee liable for payment of any fees that are the obligation of the M+C organization.

(ii) Accountability provisions that indicate that—

(A) The M+C organization oversees and is accountable to HCFA for any functions or responsibilities that are described in these standards; and

(B) The M+C organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with requirements set forth at paragraph (i)(4) of this section.

(iii) A provision requiring that any services or other activity performed by a related entity, contractor, subcontractor, or first-tier or downstream en-

tity in accordance with a contract or written agreement are consistent and comply with the M+C organization's contractual obligations.

(4) If any of the M+C organizations' activities or responsibilities under its contract with HCFA are delegated to other parties, the following requirements apply to any related entity, contractor, subcontractor, or provider:

(i) Written arrangements must specify delegated activities and reporting responsibilities.

(ii) Written arrangements must either provide for revocation of the delegation activities and reporting requirements or specify other remedies in instances where HCFA or the M+C organization determine that such parties have not performed satisfactorily.

(iii) Written arrangements must specify that the performance of the parties is monitored by the M+C organization on an ongoing basis.

(iv) Written arrangements must specify that either—

(A) The credentials of medical professionals affiliated with the party or parties will be either reviewed by the M+C organization; or

(B) The credentialing process will be reviewed and approved by the M+C organization and the M+C organization must audit the credentialing process on an ongoing basis.

(v) All contracts or written arrangements must specify that the related entity, contractor, or subcontractor must comply with all applicable Medicare laws, regulations, and HCFA instructions.

(5) If the M+C organization delegates selection of the providers, contractors, or subcontractor to another organization, the M+C organization's written arrangements with that organization must state that the HCFA-contracting M+C organization retains the right to approve, suspend, or terminate any such arrangement.

(j) *Additional contract terms.* The M+C organization agrees to include in the contract such other terms and conditions as HCFA may find necessary and appropriate in order to implement requirements in this part.

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

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(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.

(1) *Certification of data that determine payment.* As a condition for receiving a monthly payment under subpart F of this part, the M+C organization agrees that its chief executive officer (CEO), chief financial officer (CFO), or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must request payment under the contract on a document that certifies (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of relevant data that HCFA requests. Such data include specified enrollment information, encounter data, and other information that HCFA may specify.

(1) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify that each enrollee for whom the organization is requesting payment is validly enrolled in an M+C plan offered by the organization and the information relied upon by HCFA in determining payment (based on best knowledge, information, and belief) is accurate, complete, and truthful.

(2) The CEO, CFO, or an individual delegated with the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the encounter data it submits under § 422.257 are accurate, complete, and truthful.

(3) If such encounter data are generated by a related entity, contractor, or subcontractor of an M+C organization, such entity, contractor, or subcontractor must similarly certify (based on best knowledge, information, and belief) the accuracy, completeness, and truthfulness of the data.

(4) The CEO, CFO, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to such officer, must certify (based on best knowledge, information, and belief) that the informa-

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tion in its ACR submission is accurate, complete, and truthful and fully conforms to the requirements in § 422.310.

[63 FR 35099, June 26, 1998; 63 FR 52614, Oct. 1, 1998, as amended at 64 FR 7980, Feb. 17, 1999; 65 FR 40327, June 29, 2000]

§ 422.504 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the M+C organization and HCFA and, for a contract that provides for coverage under an MSA plan, not earlier than January 1999.

(b) *Term of contract.* Each contract is for a period of at least 12 months.

(c) *Renewal of contract.* In accordance with § 422.506, contracts are renewed annually only if—

(1) HCFA informs the M+C organization that it authorizes a renewal; and

(2) The M+C organization has not provided HCFA with a notice of intention not to renew.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000]

§ 422.506 Nonrenewal of contract.

(a) *Nonrenewal by an M+C organization.* (1) An M+C organization may elect not to renew its contract with HCFA as of the end of the term of the contract for any reason provided it meets the timeframes for doing so set forth in paragraphs (a)(2) and (a)(3) of this section.

(2) If an M+C organization does not intend to renew its contract, it must notify—

(i) HCFA in writing, by July 1 of the year in which the contract would end;

(ii) Each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective. This notice must include a written description of alternatives available for obtaining Medicare services within the service area, including alternative M+C plans, Medigap options, and original Medicare and must receive HCFA approval.

(iii) The general public, at least 90 days before the end of the current calendar year, by publishing a notice in one or more newspapers of general circulation in each community located in the M+C organization's service area.

(3) HCFA may accept a nonrenewal notice submitted after July 1 if—