

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

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

(c) *Contracting authority.* Under the authority of section 1857(c)(5) of the Act, CMS 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 CMS determines that those provisions are inconsistent with the efficient and effective administration of the Medicare program.

(d) *Protection against fraud and beneficiary protections.* (1) CMS annually audits the financial records (including data relating to Medicare utilization, costs, and computation of the bid) of at least one-third of the MA organizations offering MA plans. These auditing activities are subject to monitoring by the Comptroller General.

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

(i) Inspect or otherwise evaluate the quality, appropriateness, and timeliness of services performed under the MA 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 MA 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 CMS's request—

(1) The contract will be amended to exclude any MA plan or State-licensed entity specified by CMS; 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.

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§ 422.504 Contract provisions.

The contract between the MA organization and CMS must contain the following provisions:

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

(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 CMS 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 § 422.310 for submitting data to CMS;

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

(10) To develop its annual bid, and submit all required information on premiums, benefits, and cost-sharing by not later than the first Monday in June, as provided in subpart F 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 MA 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 MA 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 CMS.* The MA organization must have the capacity to communicate with CMS electronically.

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

(d) *Maintenance of records.* The MA organization agrees to maintain for 10 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 bid) of MA organizations.

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

(iii) Enable CMS to audit and inspect any books and records of the MA 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 bid proposal.

(v) Establish component rates of the bid 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 MA organization's financial, medical, and other record keeping systems.

(ii) Financial statements for the current contract period and 10 prior periods.

(iii) Federal income tax or informational returns for the current contract period and 10 prior periods.

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

(v) Agreements, contracts, and subcontracts.

(vi) Franchise, marketing, and management agreements.

(vii) Schedules of charges for the MA 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 MA 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 MA organization; and

(iii) The enrollment and disenrollment records for the current contract period and 10 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 MA organization, related entity, contractor, subcontractor, 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 MA 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 CMS may require.

(4) HHS, the Comptroller General, or their designee's right to inspect, evaluate, and audit extends through 10 years from the end of the final contract period or completion of audit, whichever is later unless—

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

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

(iii) CMS determines that there is a reasonable possibility of fraud or similar fault, in which case CMS may inspect, evaluate, and audit the MA organization at any time.

(f) *Disclosure of information.* The MA organization agrees to submit—

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

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

(ii) Such information as CMS may require pertaining to the disclosure of ownership and control of the MA organization.

(2) To CMS, all information that is necessary for CMS 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 MA plan;

(ii) The MA monthly basic beneficiary premium and MA monthly supplemental beneficiary premium, if any, for the plan or in the case of an MSA plan, the MA 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—

(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 CMS; and

(E) Other information determined by CMS to be necessary to assist beneficiaries in making an informed choice among MA 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) To CMS, any other information deemed necessary by CMS for the administration or evaluation of the Medicare program.

(3) To its enrollees all informational requirements under § 422.64 and, upon

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an enrollee's, request the financial disclosure information required under § 422.516.

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

(1) Each MA organization must adopt and maintain arrangements satisfactory to CMS 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 MA organization. To meet this requirement, the MA 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 MA organization for services furnished by providers that do not contract, or that have not otherwise entered into an agreement with the MA organization, to provide services to the organization's beneficiary enrollees.

(2) The MA organization must provide for continuation of enrollee health care benefits—

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

(ii) For enrollees who are hospitalized on the date its contract with CMS 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 MA organization may use—

(i) Contractual arrangements;

(ii) Insurance acceptable to CMS;

(iii) Financial reserves acceptable to CMS; or

(iv) Any other arrangement acceptable to CMS.

(h) *Requirements of other laws and regulations.* The MA organization agrees to comply with—

(1) Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse, including, but not limited to, applicable provisions of

Federal criminal law, the False Claims Act (31 U.S.C. 3729 et. seq.), and the anti-kickback statute (section 1128B(b) of the Act); and

(2) HIPAA administrative simplification rules at 45 CFR parts 160, 162, and 164.

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

(2) The MA 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 MA 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 10 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 MA 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 MA organization.

(ii) Accountability provisions that indicate that the MA organization may only delegate activities or functions to a provider, related entity, contractor, or subcontractor in a manner consistent with the 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 entity in accordance with a contract or written agreement are consistent and comply with the MA organization's contractual obligations.

(4) If any of the MA organizations' activities or responsibilities under its contract with CMS 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 CMS or the MA organization determine that such parties have not performed satisfactorily.

(iii) Written arrangements must specify that the performance of the parties is monitored by the MA 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 MA organization; or

(B) The credentialing process will be reviewed and approved by the MA organization and the MA 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 CMS instructions.

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

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

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

(1) The contract will be amended to exclude any MA plan or State-licensed entity specified by CMS; 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 G of this part, the MA 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 CMS requests. Such data include specified enrollment information, encounter data, and other information that CMS 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 MA plan offered by the organization and the information relied upon by CMS 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 data it submits under § 422.310 are accurate, complete, and truthful.

(3) If such data are generated by a related entity, contractor, or subcontractor of an MA 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

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reports directly to such officer, must certify (based on best knowledge, information, and belief) that the information in its bid submission is accurate, complete, and truthful and fully conforms to the requirements in § 422.254.

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§ 422.505 Effective date and term of contract.

(a) *Effective date.* The contract is effective on the date specified in the contract between the MA organization and CMS 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) CMS informs the MA organization that it authorizes a renewal; and

(2) The MA organization has not provided CMS with a notice of intention not to renew.

(d) *Renewal of contract contingent on reaching agreement on the bid.* Although an MA organization may be determined qualified to renew its contract under this section, if the organization and CMS cannot reach agreement on the bid under subpart F of this part, no renewal will take place, and the failure to reach an agreement is not subject to the appeals provisions in subpart N of this part.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000. Redesignated at 70 FR 4736, Jan. 28, 2005 and amended at 70 FR 4737, Jan. 28, 2005]

§ 422.506 Nonrenewal of contract.

(a) *Nonrenewal by an MA organization.* (1) An MA organization may elect not to renew its contract with CMS 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 MA organization does not intend to renew its contract, it must notify—

(i) CMS in writing, by the first Monday in June 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 MA plans, Medigap options, and original Medicare and must receive CMS approval prior to issuance.

(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 MA organization's service area.

(3) CMS may accept a nonrenewal notice submitted after the first Monday in June if—

(i) The MA organization notifies its Medicare enrollees and the public in accordance with paragraph (a)(2)(ii) and (a)(2)(iii) of this section; and

(ii) Acceptance is not inconsistent with the effective and efficient administration of the Medicare program.

(4) If an MA organization does not renew a contract under this paragraph (a), CMS will not enter into a contract with the organization for 2 years unless there are special circumstances that warrant special consideration, as determined by CMS.

(b) *CMS decision not to renew.* (1) CMS may elect not to authorize renewal of a contract for any of the following reasons:

(i) The MA organization has not fully implemented or shown discernable progress in implementing quality improvement projects as defined in § 422.152(d).

(ii) For any of the reasons listed in § 422.510(a), which would also permit CMS to terminate the contract.

(iii) The MA organization has committed any of the acts in § 422.752(a) that would support the imposition of intermediate sanctions or civil money penalties under subpart O of this part.

(2) *Notice.* CMS provides notice of its decision whether to authorize renewal of the contract as follows:

(i) To the MA organization by May 1 of the contract year.