

103 percent, but not greater than 108 percent, of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount equal to 50 percent of the difference between those allowable costs and 103 percent of that target amount.

(ii) *Costs above 108 percent of target amount.* If the allowable costs for the plan for the year are greater than 108 percent of the target amount for the plan and year, CMS will increase the total of the monthly payments made to the organization offering the plan for the year under section 1853(a) of the Act by an amount equal to the sum of—

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between those allowable costs and 108 percent of that target amount.

(3) *Reduction in payment if allowable costs below 97 percent of target amount—*

(i) *Costs between 92 and 97 percent of target amount.* If the allowable costs for the plan for the year are less than 97 percent, but greater than or equal to 92 percent, of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount (or otherwise recover from the plan an amount) equal to 50 percent of the difference between 97 percent of the target amount and those allowable costs.

(ii) *Costs below 92 percent of target amount.* If the allowable costs for the plan for the year are less than 92 percent of the target amount for the plan and year, CMS will reduce the total of the monthly payments made to the organization offering the plan for the year under § 422.302(a) (section 1853(a) of the Act) by an amount (or otherwise recover from the plan an amount) equal to the sum of—

(A) 2.5 percent of that target amount; and

(B) 80 percent of the difference between 92 percent of that target amount and those allowable costs.

(d) *Disclosure of information—(1) General rule.* Each MA organization offer-

ing an MA regional plan must provide CMS with information as CMS determines is necessary to implement this section; and

(2) According to § 422.504(d)(1)(iii), CMS has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs provided to CMS under paragraph (b)(2) of this section.

(3) *Restriction on use of information.* Information disclosed or obtained for the purposes of this section may be used by officers, employees, and contractors of DHHS only for the purposes of, and to the extent necessary in, implementing this section.

(e) *Organizational and financial requirements—(1) General rule.* Regional MA plans offered by MA organizations must be licensed under State law, or otherwise authorized 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 plans. However, as provided for under this section, MA organizations offering MA regional plans may obtain a temporary waiver of State licensure. In the case of an MA organization that is offering an MA regional plan in an MA region, and is not licensed in each State in which it offers such an MA regional plan, the following rules apply:

(i) The MA organization must be licensed to bear risk in at least one State of the region.

(ii) For the other States in a region in which the organization is not licensed to bear risk, if it demonstrates to CMS that it has filed the necessary application to meet those requirements, CMS may temporarily waive the licensing requirement with respect to each State for a period of time as CMS determines appropriate for the timely processing of the application by the State or States.

(iii) If the State licensing application or applications are denied, CMS may extend the licensing waiver through the end of the plan year or as CMS determines appropriate to provide for a transition.

(2) *Selection of appropriate State.* In the case of an MA organization to which CMS grants a waiver and that is

licensed in more than one State in a region, the MA organization will select one of the States, the rules of which shall apply in States where the organization is not licensed for the period of the waiver.

[70 FR 4732, Jan. 28, 2005, as amended at 70 FR 52027, Sept. 1, 2005; 76 FR 21568, Apr. 15, 2011]

Subpart K—Application Procedures and Contracts for Medicare Advantage Organizations

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

§ 422.500 Scope and definitions.

(a) *Scope*. This subpart sets forth application requirements for entities seeking a contract as a Medicare organization offering an MA plan, including MA organizations offering a specialized MA plan for special needs individuals. MA organizations offering prescription drug plans must, in addition to the requirements of this part, follow the requirements of part 423 of this chapter specifically related to the prescription drug benefit.

(b) *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 MA organization's enrollees by hospitals and other providers, and by MA 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 § 422.310(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 MA 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.

Final settlement adjustment period means the period of time between when the contract terminates and the date the MA organization is issued a notice of the final settlement amount.

Final settlement amount is the final payment amount that CMS owes and ultimately pays to an MA organization, or that an MA organization owes and ultimately pays to CMS, with respect to an MA contract that has consolidated, nonrenewed, or terminated. The final settlement amount is calculated by summing final retroactive payment adjustments for a specific contract that accumulated after that contract ceases operation but before the calculation of the final settlement amount and the following applicable reconciliation amounts that have been completed as of the date the notice of final settlement has been issued, without accounting for any data submitted after the data submission deadlines for calculating these reconciliation amounts:

(1) Risk adjustment reconciliation (described in § 422.310);

(2) Part D annual reconciliation (described in § 423.343);

(3) Coverage Gap Discount Program annual reconciliation (described in § 423.2320) and;

(4) MLR remittances (described in §§ 422.2470 and 423.2470).

Final settlement process means for a contract that has been consolidated, nonrenewed, or terminated, the process by which CMS calculates the final settlement amount, issues the final settlement amount along with supporting documentation in the notice of final

settlement to the MA organization, receives responses from the MA organization requesting an appeal of the final settlement amount, and takes final actions to adjudicate an appeal (if requested) and make payments to or receive payments from the MA organization. The final settlement amount is calculated after all applicable reconciliations have occurred after a contract has been consolidated, non-renewed, or terminated.

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

Fraud hotline tip is a complaint or other communications that are submitted through a fraud reporting phone number or a website intended for the same purpose, such as the Federal Government's HHS OIG Hotline or a health plan's fraud hotline.

Inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by MA organizations and Part D plan sponsors, there is an established pattern of potential fraud, waste, and abuse related to prescribing of opioids, as reported by the plan sponsors. Beneficiaries with cancer and sickle-cell disease, as well as those patients receiving hospice and long term care (LTC) services are excluded, when determining inappropriate prescribing. Plan sponsors may consider any number of factors including, but not limited to the following:

- (1) Documentation of a patient's medical condition.
- (2) Identified instances of patient harm or death.
- (3) Medical records, including claims (if available).
- (4) Concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm.
- (5) Levels of morphine milligram equivalent (MME) dosages prescribed.
- (6) Absent clinical indication or documentation in the care management plan or in a manner that may indicate diversion.

(7) State-level prescription drug monitoring program (PDMP) data.

(8) Geography, time, and distance between a prescriber and the patient.

(9) Refill frequency and factors associated with increased risk of opioid overdose.

Party in interest includes the following:

(1) Any director, officer, partner, or employee responsible for management or administration of an MA 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 MA 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 MA 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 MA organization by common ownership or control and—

(1) Performs some of the MA 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 MA 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 MA organization, have a total

value that exceeds \$25,000 or 5 percent of the MA organization's total operating expenses, whichever is less.

Substantiated or suspicious activities of fraud, waste, or abuse means and includes, but is not limited to, allegations that a provider of services (including a prescriber) or supplier—

(1) Engaged in a pattern of improper billing;

(2) Submitted improper claims with suspected knowledge of their falsity;

(3) Submitted improper claims with reckless disregard or deliberate ignorance of their truth or falsity; or

(4) Is the subject of a fraud hotline tip verified by further evidence.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40327, June 29, 2000; 70 FR 4736, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 77 FR 22167, Apr. 12, 2012; 86 FR 6098, Jan. 19, 2021; 89 FR 30823, Apr. 23, 2024]

§ 422.501 Application requirements.

(a) *Scope.* This section sets forth application requirements for entities that seek a contract as an MA organization offering an MA plan and additional application requirements for MA organizations seeking to offer a Specialized MA Plan for Special Needs Individuals.

(b) *Completion of a notice of intent to apply.* (1) An organization submitting an application under this section for a particular contract year must first submit a completed Notice of Intent to Apply by the date established by CMS. CMS will not accept applications from organizations that do not first submit a timely Notice of Intent to Apply.

(2) Submitting a Notice of Intent to Apply does not bind that organization to submit an application for the applicable contract year.

(3) An organization's decision not to submit an application after submitting a Notice of Intent To Apply will not form the basis of any action taken against the organization by CMS.

(c) *Completion of an application.* (1) In order to obtain a determination on whether it meets the requirements to become an MA organization and is qualified to provide a particular type of MA plan, an entity, or an individual authorized to act for the entity (the applicant) must fully complete all parts of a certified application, in the

form and manner required by CMS, including the following:

(i) Documentation of appropriate State licensure or State certification that the entity is able to offer health insurance or health benefits coverage that meets State-specified standards applicable to MA plans, and is authorized by the State to accept prepaid capitation for providing, arranging, or paying for the comprehensive health care services to be offered under the MA contract.

(ii) For regional plans, documentation of application for State licensure in any State in the region that the organization is not already licensed.

(iii) For Specialized MA Plans for Special Needs Individuals, documentation that the entity meets the requirements of §§ 422.2; 422.4(a)(1)(iv); 422.101(f); 422.107, if applicable; and 422.152(g) of this part.

(iv) Documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.

(2) The authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, including providing documentation that payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2.

(d) *Responsibility for making determinations.* (1) CMS is responsible for determining whether an entity qualifies as an MA organization and whether proposed MA plans meet the requirements of this part.

(2) A CMS determination that an entity is qualified to act as an MA organization is distinct from the bid negotiation that occurs under subpart F of this part and such negotiation is not subject to the appeals provisions included in subpart N of this part.

(e) *Resubmittal of an application.* An application that has been denied by CMS for a particular contract year may not be resubmitted until the beginning of the application cycle for the following contract year.

(f) *Disclosure of application information under the Freedom of Information Act.* An applicant submitting material that

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he or she believes is protected from disclosure under 5 U.S.C. 552, the Freedom of Information Act, or because of exemptions provided in 45 CFR part 5 (the Department's regulations providing exceptions to disclosure), must label the material "privileged" and include an explanation of the applicability of an exception described in 45 CFR part 5. Any final decisions as to whether material is privileged is the final decision of the Secretary.

[70 FR 4736, Jan. 28, 2005, as amended at 75 FR 19809, Apr. 15, 2010; 77 FR 22167, Apr. 12, 2012; 81 FR 80557, Nov. 15, 2016; 83 FR 16733, Apr. 16, 2018]

§ 422.502 Evaluation and determination procedures.

(a) *Basis for evaluation and determination.* (1) *Information used to evaluate applications.* With the exception of evaluations conducted under paragraph (b) of this section, CMS evaluates an application for an MA contract or for a Specialized MA Plan for Special Needs Individuals solely on the basis of information contained in the application itself and any additional information that CMS obtains through other means such as on-site visits.

(2) *Issuing application determination.* After evaluating all relevant information, CMS determines whether the applicant's application meets all the requirements described in this part.

(3) *Substantially incomplete applications.* (i) CMS does not evaluate or issue a notice of determination described in § 422.502(c) when an organization submits a substantially incomplete application.

(ii) An application is substantially incomplete when the submission as of the deadline for applications established by CMS is missing content or responsive materials for one or more sections of the application form required by CMS.

(iii) A determination that an application is substantially incomplete is not a contract determination as defined in § 422.641 and a determination that an organization submitted a substantially incomplete application is not subject to the appeals provisions of subpart N of this part.

(b) *Use of information from a current or prior contract.* (1) Except as provided in

paragraphs (b)(2) through (4) of this section, if an MA organization fails during the 12 months preceding the deadline established by CMS for the submission of contract qualification applications to comply with the requirements of the Part C program under any current or prior contract with CMS under title XVIII of the Act, CMS may deny an application based on the applicant's failure to comply with the requirements of the Part C program under any current or prior contract with CMS even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with a contract for purposes of an application denial under paragraph (b)(1) of this section if during the applicable review period the applicant does any of the following:

(A) Was under intermediate sanction under subpart O of this part or a determination by CMS to prohibit the enrollment of new enrollees in accordance with § 422.2410(c), with the exception of a sanction imposed under § 422.752(d).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(a)(14).

(C) Filed for or is currently in federal or state bankruptcy proceedings.

(D) Received any combination of Part C or D summary ratings of 2.5 or less in both of the two most recent Star Rating periods, as identified in § 422.166.

(E) Met or exceeded 13 points for compliance actions for any one contract.

(1) CMS determines the number of points each MA organization accumulated during the performance period for compliance actions based on the following point values:

(i) Each corrective action plan issued during the performance period under § 422.504(m) counts for 6 points.

(ii) Each warning letter issued during the performance period under § 422.504(m) counts for 3 points.

(iii) Each notice of noncompliance issued during the performance period under § 422.504(m) counts for 1 point.

(2) CMS adds all the point values for each MA organization to determine if any organization meets CMS' identified threshold.

(ii) CMS may deny an application submitted by an organization that does not hold a Part C contract at the time of the submission when the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (b)(1)(i) of this section. This paragraph does not apply when the parent organization completed the acquisition of the subsidiary that meets the criteria within the 24 months preceding the application submission deadline.

(2) In the absence of 12 months of performance history, CMS may deny an application based on a lack of information available to determine an applicant's capacity to comply with the requirements of the MA program.

(3) If CMS has terminated, under § 422.510, or non-renewed, under § 422.506(b), an MA organization's contract, effective within the 38 months preceding the deadline established by CMS for the submission of contract qualification applications, CMS may deny an application for a new contract or service area expansion based on the applicant's substantial failure to comply with the requirements of the Part C program even if the applicant currently meets all of the requirements of this part.

(4) During the same 38-month period as specified in (b)(3) of this section, CMS may deny an application where the applicant's covered persons also served as covered persons for the terminated or non-renewed contract. A "covered person" as used in this paragraph means one of the following:

(i) All owners of terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity, if the organization is organized as a corporation.

(c) *Notice of determination.* Within timeframes determined by CMS, it notifies each applicant that applies for an MA contract or to be designated a Specialized MA Plan for Special Needs Individuals under this part of its determination and the basis for the determination. The determination is one of the following:

(1) *Approval of application.* If CMS approves the application, it gives written notice to the applicant, indicating that it qualifies to contract as an MA organization.

(2) *Intent to deny.* (i) If CMS finds that the applicant does not appear to be able to meet the requirements for an MA organization or Specialized MA Plan for Special Needs Individuals, CMS gives the applicant notice of intent to deny the application for an MA contract or for a Specialized MA Plan for Special Needs Individuals a summary of the basis for this preliminary finding.

(ii) Within 10 days from the intent to deny, the applicant must respond in writing to the issues or other matters that were the basis for CMS' preliminary finding and must revise its application to remedy any defects CMS identified.

(iii) If CMS does not receive a revised application within 10 days from the date of the notice, or if after timely submission of a revised application, CMS still finds that the applicant does not appear qualified or has not provided CMS enough information to allow CMS to evaluate the application, CMS will deny the application.

(3) *Denial of application.* If CMS denies the application, it gives written notice to the contract applicant indicating—

(i) That the applicant is not qualified to contract as an MA organization under Part C of title XVIII of the Act and/or is not qualified to offer a Specialized MA Plan for Special Needs Individuals;

(ii) The reasons why the applicant is not qualified; and

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(iii) The applicant's right to request a hearing in accordance with the procedures specified in subpart N of this part.

[70 FR 4736, Jan. 28, 2005, as amended at 75 FR 19809, Apr. 15, 2010; 76 FR 21568, Apr. 15, 2011; 77 FR 22167, Apr. 12, 2012; 80 FR 7960, Feb. 12, 2015; 83 FR 16733, Apr. 16, 2018; 86 FR 6099, Jan. 19, 2021; 87 FR 27896, May 9, 2022; 89 FR 30824, Apr. 23, 2024]

§ 422.503 General provisions.

(a) *Basic rule.* In order to qualify as an MA organization, enroll beneficiaries in any MA plans it offers, and be paid on behalf of Medicare beneficiaries enrolled in those plans, an MA organization must enter into a contract with CMS.

(b) *Conditions necessary to contract as an MA organization.* Any entity seeking to contract as an MA organization must:

(1) Complete an application as described in § 422.501.

(2) Be licensed by the State as a risk bearing entity in each State in which it seeks to offer an MA plan as defined in § 422.2.

(3) Meet the minimum enrollment requirements of § 422.514, unless waived under § 422.514(b).

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(i) A policy making body that exercises oversight and control over the MA 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 MA organization to organize, implement, control, and evaluate financial and communication activities, the furnishing of services, the quality improvement 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 MA 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 MA organization.

(v) Insurance policies or other arrangements, secured and maintained by the MA organization and approved by CMS to insure the MA organization against losses arising from professional liability claims, fire, theft, fraud, embezzlement, and other casualty risks.

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

(A) Written policies, procedures, and standards of conduct that—

(1) Articulate the organization's commitment to comply with all applicable Federal and State standards;

(2) Describe compliance expectations as embodied in the standards of conduct;

(3) Implement the operation of the compliance program;

(4) Provide guidance to employees and others on dealing with potential compliance issues;

(5) Identify how to communicate compliance issues to appropriate compliance personnel;

(6) Describe how potential compliance issues are investigated and resolved by the organization; and

(7) Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including but not limited to reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

(B) The designation of a compliance officer and a compliance committee who report directly and are accountable to the organization's chief executive or other senior management.

(1) The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the MA organization, parent organization or corporate affiliate. The

compliance officer may not be an employee of the MA organization's first tier, downstream or related entity.

(2) The compliance officer and the compliance committee must periodically report directly to the governing body of the MA organization on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

(3) The governing body of the MA organization must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance programs.

(C)(1) Each MA organization must establish and implement effective training and education for its compliance officer and organization employees, the MA organization's chief executive and other senior administrators, managers and governing body members.

(2) Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee and new appointment to a chief executive, manager, or governing body member.

(D) Establishment and implementation of effective lines of communication, ensuring confidentiality, between the compliance officer, members of the compliance committee, the MA organization's employees, managers and governing body, and the MA organization's first tier, downstream, and related entities. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

(E) Well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that—

(1) Articulate expectations for reporting compliance issues and assist in their resolution,

(2) Identify noncompliance or unethical behavior; and

(3) Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.

(F) Establishment and implementation of an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the MA organization, including first tier entities', compliance with CMS requirements and the overall effectiveness of the compliance program.

(G) Establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

(1) If the MA organization discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.

(2) The MA organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation referenced in paragraph (b)(4)(vi)(G)(1) of this section.

(3) The MA organization should have procedures to voluntarily self-report potential fraud or misconduct related to the MA program to CMS or its designee.

(4) The MA organization must have procedures to identify, and must report to CMS or its designee either of the following, in the manner described in paragraphs (b)(4)(vi)(G)(4) through (6) of this section:

(i) Any payment suspension implemented by a plan, pending investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary does under section 1862(o)(1) of the Act.

(ii) Any information concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan related to the inappropriate prescribing of opioids.

(5) The MA organization must submit data, as specified in this section, in the program integrity portal when reporting payment suspensions pending investigations of credible allegations of fraud by pharmacies; information related to the inappropriate prescribing of opioids and concerning investigations and credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the MA organization; or if the plan reports a referral, through the portal, of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste, or abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners. The data categories, as applicable, include referral information and actions taken by the MA organization on the referral.

(6)(i) The MA organization is required to notify the Secretary, or its designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(4)(i) of this section 7 days prior to implementation of the payment suspension. The MA organization may request an exception to the 7-day prior notification to the Secretary, or its designee, if circumstances warrant a reduced reporting time frame, such as potential beneficiary harm.

(ii) The MA organization is required to submit the information described in paragraph (b)(4)(vi)(G)(4)(ii) of this section no later than January 30, April 30, July 30, and October 30 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. For the first reporting period (January 30, 2022), the reporting will reflect the data gathered and analyzed for the previous quarter in the calendar year (October 1–December 31).

(7)(i) CMS will provide MA organizations with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(4)(i) and (ii) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

(ii) Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

(iii) Are anonymized information submitted by plans without identifying the source of such information.

(iv) For the first quarterly report (April 15, 2022), that the report reflect the data gathered and analyzed for the previous quarter submitted by the plan sponsors on January 30, 2022.

(5) Not accept new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan.

(i) Not accept, or share a corporate parent organization owning a controlling interest in an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan that is not a dual eligible special needs plan.

(ii) Not accept, or be either the parent organization owning a controlling interest of or subsidiary of an entity that accepts, new enrollees under a section 1876 reasonable cost contract in any area in which it seeks to offer an MA plan that is not a dual eligible special needs plan.

(6) The MA organization's contract must not have been non-renewed under § 422.506 within the past 2 years unless—

(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.

(7) Not have terminated a contract by mutual consent under which, as a condition of the consent, the MA organization agreed that it was not eligible to apply for new contracts or service area expansions for a period of 2 years per § 422.508(c) of this subpart.

(8) Not newly offer a dual eligible special needs plan that would result in noncompliance with § 422.514(h).

(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.

(iv) CMS may require that the MA organization hire an independent auditor to provide CMS with additional information to determine if deficiencies

found during an audit or inspection have been corrected and are not likely to recur. The independent auditor must work in accordance with CMS specifications and must be willing to attest that a complete and full independent review has been performed.

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

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

(2) A separate contract for any such excluded plan, segment, 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. Redesignated at 70 FR 4736, Jan. 28, 2005, and amended at 70 FR 4737, Jan. 28, 2005; 70 FR 52027, Sept. 1, 2005; 70 FR 76198, Dec. 23, 2005; 72 FR 68722, Dec. 5, 2007; 75 FR 19809, Apr. 15, 2010; 79 FR 29958, May 23, 2014; 80 FR 7960, Feb. 12, 2015; 83 FR 16733, Apr. 16, 2018; 86 FR 6099, Jan. 19, 2021; 87 FR 27896, May 9, 2022; 88 FR 22334, Apr. 12, 2023; 89 FR 30824, Apr. 23, 2024]

§ 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. Compliance with the terms of this paragraph (a) is material to the performance of the MA 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

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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 and supplier 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, limits on physician incentive plans, and the preclusion list requirements in §§ 422.222 and 422.224.

(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) Maintain a fiscally sound operation by at least maintaining a positive net worth (total assets exceed total liabilities).

(15) As described in § 422.125 of this part, address and resolve complaints received by CMS against the MA organization in the Complaints Tracking Module.

(16) To maintain administrative and management capabilities sufficient for the organization to organize, implement, and control the financial, marketing, benefit administration, and quality improvement activities related to the delivery of Part C services.

(17) To maintain a Part C summary plan rating score of at least 3 stars under the 5-star rating system specified in subpart D of this part. A Part C summary plan rating is calculated as provided in § 422.166.

(18) To comply with the requirements for access to health data and plan information under §§ 422.119 and 422.120 of this chapter.

(19) Not to establish a segment of an MA plan that meets the criteria in § 422.514(d), as determined in the procedures described in § 422.514(e)(3), with the addition of the newly enrolled individuals.

(20) To comply with the requirements established in § 422.514(h).

(21) Not to establish additional MA plans that are not facility based I-SNPs to contracts described in § 422.116(f)(3).

(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, audit, or other means—

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

(ii) Compliance with CMS requirements for maintaining the privacy and security of protected health information and other personally identifiable information of Medicare enrollees;

(iii) The facilities of the MA organization to include computer and other electronic systems; and

(iv) 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 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) Effective January 1, 2010, 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 enrollee liable for payment of any such fees;

(ii) Indemnify the 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 enrollees; and

(iii) For all MA organizations with enrollees eligible for both Medicare and Medicaid, specify in contracts with providers that such enrollees will not be held liable for Medicare Part A and B cost sharing when the State is responsible for paying such amounts, and inform providers of Medicare and Medicaid benefits, and rules for enrollees eligible for Medicare and Medicaid. The MA plans may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX if the individual were not enrolled in such a plan. The contracts must state that providers will—

(A) Accept the MA plan payment as payment in full, or

(B) Bill the appropriate State source.

(iv) Ensure that the enrollee does not have any financial liability for services, items, or drugs furnished, ordered, or prescribed to the enrollee by an MA contracted individual or entity on the preclusion list, as defined in § 422.2 and as described in § 422.222.

(v) Ensure that the plan's provider agreement contains a provision stating that after the expiration of the 60-day period specified in § 422.222:

(A) The provider will no longer be eligible for payment from the plan and will be prohibited from pursuing payment from the beneficiary as stipulated by the terms of the contract between CMS and the plan per § 422.504(g)(1)(iv); and

(B) The provider will hold financial liability for services, items, and drugs that are furnished, ordered, or prescribed after this 60-day period, at which point the provider and the beneficiary will have already received notification of the preclusion.

(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 first tier, downstream, and related entities.* (1) Notwithstanding any relationship(s) that the MA organization may have with first tier, downstream, and related entities, 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 first tier, downstream, and related entities to agree that—

(i) HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any books, contracts, computer or other electronic systems, including medical records and documentation of the first tier, downstream, and entities related to CMS' contract with the MA organization.

(ii) HHS, the Comptroller General, or their designees have the right to audit, evaluate, collect, and inspect any records under paragraph (i)(2)(i) of this section directly from any first tier, downstream, or related entity.

(iii) For records subject to review under paragraph (i)(2)(ii) of this section, except in exceptional circumstances, CMS will provide notification to the MA organization that a direct request for information has been initiated.

(iv) 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.

(v) They will ensure that payments are not made to individuals and entities included on the preclusion list, defined in § 422.2.

(3) All contracts or written arrangements between MA organizations and first tier, downstream, and related 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 first tier, downstream, or related entity, 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 first tier, downstream, and related entity in accordance with a contract

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 first tier, downstream and related entity:

(i) Each and every contract must specify delegated activities and reporting responsibilities.

(ii) Each and every contract 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) Each and every contract must specify that the performance of the parties is monitored by the MA organization on an ongoing basis.

(iv) Each and every contract 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 contract 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 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.

(5) *Certification of accuracy of data for overpayments.* The CEO, CFO, or COO must certify (based on best knowledge, information, and belief) that the information provided for purposes of reporting and returning of overpayments under § 422.326 is accurate, complete, and truthful.

(m) *Issuance of compliance actions for failure to comply with the terms of the contract.* The MA organization acknowledges that CMS may take compliance actions as described in this section or intermediate sanctions as defined in subpart O of this part.

(1) CMS may take compliance actions as described in paragraph (m)(3) of this section if it determines that the MA organization has not complied with the terms of a current or prior Part C contract with CMS.

(i) CMS may determine that an MA organization is out of compliance with a Part C requirement when the organization fails to meet performance standards articulated in the Part C statutes, regulations in this chapter, or guidance.

(ii) If CMS has not already articulated a measure for determining noncompliance, CMS may determine that an MA organization is out of compliance when its performance in fulfilling Part C requirements represents an outlier relative to the performance of other MA organizations.

(2) CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the noncompliance, including all of the following:

- (i) The nature of the conduct.
- (ii) The degree of culpability of the MA organization.
- (iii) The adverse effect to beneficiaries which resulted or could have resulted from the conduct of the MA organization.
- (iv) The history of prior offenses by the MA organization or its related entities.
- (v) Whether the noncompliance was self-reported.
- (vi) Other factors which relate to the impact of the underlying noncompliance or the lack of the MA organization's oversight of its operations that contributed to the noncompliance.

(3) CMS may take one of three types of compliance actions based on the nature of the noncompliance.

(i) *Notice of noncompliance.* A notice of noncompliance may be issued for any failure to comply with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section.

(ii) *Warning letter.* A warning letter may be issued for serious and/or continued noncompliance with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section and as assessed in accordance with paragraph (m)(2) of this section.

(iii) *Corrective action plan.* (A) Corrective action plans are requested for particularly serious or continued noncompliance with the requirements of the MA organization's current or prior Part C contract with CMS, as described in paragraph (m)(1) of this section and as assessed in accordance with paragraph (m)(2) of this section.

(B) CMS issues a corrective action plan if CMS determines that the MA organization has repeated or not corrected noncompliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its noncompliance, or must implement a detailed plan to correct the underlying causes of the noncompliance.

(n) *Acknowledgements of CMS release of data—(1) Summary CMS payment data.* The contract must provide that the MA organization acknowledges that CMS releases to the public summary reconciled CMS payment data after the reconciliation of Part C and Part D payments for the contract year as follows:

- (i) For Part C, the following data—
 - (A) Average per member per month CMS payment amount for A/B (original Medicare) benefits for each MA plan offered, standardized to the 1.0 (average risk score) beneficiary.
 - (B) Average per member per month CMS rebate payment amount for each MA plan offered (or, in the case of MSA plans, the monthly MSA deposit amount).
 - (C) Average Part C risk score for each MA plan offered.

(D) County level average per member per month CMS payment amount for each plan type in that county, weighted by enrollment and standardized to the 1.0 (average risk score) beneficiary in that county.

(ii) For Part D plan sponsors, plan payment data in accordance with § 423.505(o) of this subchapter.

(2) *MA bid pricing data and Part C MLR data.* The contract must provide that the MA organization acknowledges that CMS releases to the public data as described at §§ 422.272 and 422.2490.

(o) *Business continuity.* (1) The MA organization agrees to develop, maintain, and implement a business continuity plan containing policies and procedures to ensure the restoration of business operations following disruptions to business operations which would include natural or man-made disasters, system failures, emergencies, and other similar circumstances and the threat of such occurrences. To meet the requirement, the business continuity plan must, at a minimum, include the following:

(i) *Risk assessment.* Identify threats and vulnerabilities that might affect business operations.

(ii) *Mitigation strategy.* Design strategies to mitigate hazards. Identify essential functions in addition to those specified in paragraph (o)(2) of this section and prioritize the order in which to restore all other functions to normal operations. At a minimum, each MA organization must do the following:

(A) Identify specific events that will activate the business continuity plan.

(B) Develop a contingency plan to maintain, during any business disruption, the availability and, as applicable, confidentiality of communication systems and essential records in all forms (including electronic and paper copies). The contingency plan must do the following:

(1) Ensure that during any business disruption the following systems will operate continuously or, should they fail, be restored to operational capacity on a timely basis:

(i) Information technology (IT) systems including those supporting claims processing at point of service.

(ii) Provider and enrollee communication systems including telephone, Web site, and email.

(2) With respect to electronic protected health information, comply with the contingency plan requirements of the Health Insurance Portability and Accountability Act of 1996 Security Regulations at 45 CFR parts 160 and 164, subparts A and C.

(C) Establish a chain of command.

(D) Establish a business communication plan that includes emergency capabilities and procedures to contact and communicate with the following:

(1) Employees.

(2) First tier, downstream, and related entities.

(3) Other third parties (including pharmacies, providers, suppliers, and government and emergency management officials).

(E) Establish employee and facility management plans to ensure that essential operations and job responsibilities can be assumed by other employees or moved to alternate sites as necessary.

(F) Establish a restoration plan including procedures to transition to normal operations.

(G) Comply with all applicable Federal, State, and local laws.

(iii) *Testing and revision.* On at least an annual basis, test and update the business operations continuity plan to ensure the following:

(A) That it can be implemented in emergency situations.

(B) That employees understand how it is to be executed.

(iv) *Training.* On at least an annual basis, educate appropriate employees about the business continuity plan and their own respective roles.

(v) *Records.* (A) Develop and maintain records documenting the elements of the business continuity plan described in paragraphs (o)(1)(i) through (iv) of this section.

(B) Make the information specified in paragraph (o)(1)(v)(A) of this section available to CMS upon request.

(2) *Restoration of essential functions.* Every MA organization must plan to restore essential functions within 72 hours after any of the essential functions fail or otherwise stop functioning as usual. In addition to any essential

functions that the MA organization identifies under paragraph (o)(1)(ii) of this section, for purposes of this paragraph (o)(2) of the section essential functions include, at a minimum, the following:

(i) Benefit authorization (if not waived) for services to be immediately furnished at a hospital, clinic, provider office, or other place of service.

(ii) Operation of call center customer services.

[63 FR 35099, June 26, 1998]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 422.504, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.govinfo.gov.

§ 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 the MA organization has not provided CMS with a notice of intention not to renew and CMS has not provided the MA organization 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, as amended at 70 FR 4737, Jan. 28, 2005; 72 FR 68723, Dec. 5, 2007]

§ 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 time-

frames 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 by mail at least 90 calendar days before the date on which the nonrenewal is effective. The MA organization must also provide information about alternative enrollment options by doing one or more of the following:

(A) Provide a CMS approved written description of alternative MA plan, MA-PD plan, and PDP options available for obtaining qualified Medicare services within the beneficiaries' region.

(B) Place outbound calls to all affected enrollees to ensure beneficiaries know who to contact to learn about their enrollment options.

(3) If an MA organization does not renew a contract under paragraph (a) of this section, CMS may deny an application for a new contract or a service area expansion from the MA organization for 2 years unless there are circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the product type, contract type or service area of the previous contract.

(4) During the same 2-year period as specified in paragraph (a)(3) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the non-renewing sponsor. A "covered person" as used in this paragraph means one of the following:

(i) All owners of nonrenewed or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(iii) A member of the board of directors or board of trustees of the entity,

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if the organization is organized as a corporation.

(b) [Reserved]

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 67 FR 13289, Mar. 22, 2002; 70 FR 4737, Jan. 28, 2005; 72 FR 68723, Dec. 5, 2007; 74 FR 1542, Jan. 12, 2009; 75 FR 19811, Apr. 15, 2010; 76 FR 21568, Apr. 15, 2011; 80 FR 7961, Feb. 12, 2015; 83 FR 16734, Apr. 16, 2018]

§ 422.508 Modification or termination of contract by mutual consent.

(a) A contract may be modified or terminated at any time by written mutual consent.

(1) If the contract is terminated by mutual consent, except as provided in paragraph (b) of this section, the MA organization must provide notice to its Medicare enrollees and the general public as provided in § 422.512(b)(2) and (b)(3).

(2) If the contract is modified by mutual consent, the MA organization must notify its Medicare enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(3) If the organization submits a request to end the term of its contract after the deadline provided in § 422.506(a)(2)(i), the contract may be terminated by mutual consent in accordance with paragraphs (a) through (d) of this section. CMS may mutually consent to the contract termination if the contract termination does not negatively affect the administration of the Medicare program.

(b) If the contract terminated by mutual consent is replaced the day following such termination by a new MA contract, the MA organization is not required to provide the notice specified in paragraph (a)(1) of this section.

(c) *Agreement to limit new MA applications.* As a condition of the consent to a mutual termination CMS will require, as a provision of the termination agreement language prohibiting the MA organization from applying for new contracts or service area expansions for a period of 2 years, absent circumstances warranting special consideration. This prohibition may apply regardless of the product type, contract type or service area of the previous contract.

(d) *Prohibition against Part C program participation by organizations whose owners, directors, or management employees served in a similar capacity with another organization that mutually terminated its Medicare contract within the previous 2 years.* During the same 2-year period, CMS will not contract with an organization whose covered persons also served as covered persons for the mutually terminating sponsor. A “covered person” as used in this paragraph means one of the following:

(1) All owners of nonrenewal or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(2) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 percent of the total property, and assets of the organization.

(3) A member of the board of directors of the entity, if the organization is organized as a corporation.

[63 FR 35099, June 26, 1998, as amended at 75 FR 19811, Apr. 15, 2010; 76 FR 21569, Apr. 15, 2011; 80 FR 7961, Feb. 12, 2015; 83 FR 16734, Apr. 16, 2018]

§ 422.510 Termination of contract by CMS.

(a) *Termination by CMS.* CMS may at any time terminate a contract if CMS determines that the MA organization meets any of the following:

(1) Has failed substantially to carry out the contract.

(2) Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of this part.

(3) No longer substantially meets the applicable conditions of this part.

(4) CMS may make a determination under paragraph (a)(1), (2), or (3) of this section if the MA organization has had one or more of the following occur:

(i) Based on creditable evidence, has committed or participated in false, fraudulent or abusive activities affecting the Medicare, Medicaid or other State or Federal health care programs, including submission of false or fraudulent data.

(ii) Substantially failed to comply with the requirements in subpart M of this part relating to grievances and appeals.

(iii) Failed to provide CMS with valid data as required under §422.310.

(iv) Failed to implement an acceptable quality assessment and performance improvement program as required under subpart D of this part.

(v) Substantially failed to comply with the prompt payment requirements in §422.520.

(vi) Substantially failed to comply with the service access requirements in §422.112 or §422.114.

(vii) Failed to comply with the requirements of §422.208 regarding physician incentive plans.

(viii) Substantially fails to comply with the requirements in subpart V of this part.

(ix) Failed to comply with the regulatory requirements contained in this part or part 423 of this chapter or both.

(x) Failed to meet CMS performance requirements in carrying out the regulatory requirements contained in this part or part 423 of this chapter or both.

(xi) Achieves a Part C summary plan rating of less than 3 stars for 3 consecutive contract years. Plan ratings issued by CMS before September 1, 2012 are not included in the calculation of the 3-year period.

(xii) Has failed to report MLR data in a timely and accurate manner in accordance with §422.2460 or that any MLR data required by this subpart is found to be materially incorrect or fraudulent.

(xiii) Fails to meet the preclusion list requirements in accordance with §422.222 and 422.224.

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

(xv) Following the issuance of a notice to the MA organization no later than August 1, CMS must terminate, effective December 31 of the same year, an individual MA plan if that plan does not have a sufficient number of enrollees to establish that it is a viable independent plan option.

(xvi) Meets the criteria in §422.514(d)(1) or (2).

(b) *Notice.* If CMS decides to terminate a contract it gives notice of the termination as follows:

(1) *Termination of contract by CMS.*

(i) CMS notifies the MA organization in writing at least 45 calendar days before the intended date of the termination.

(ii) The MA organization notifies its Medicare enrollees of the termination by mail at least 30 calendar days before the effective date of the termination.

(iii) The MA organization notifies the general public of the termination at least 30 calendar days before the effective date of the termination by releasing a press statement to news media serving the affected community or county and posting the press statement prominently on the organization's Web site.

(iv) In the event that CMS issues a termination notice to an MA organization on or before August 1 with an effective date of the following December 31, the MA organization must issue notification to its Medicare enrollees at least 90 days prior to the effective date of the termination.

(2) *Immediate termination of contract by CMS.* (i) The procedures specified in paragraph (b)(1) of this section do not apply if—

(A) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization; or

(B) The MA organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(C) The contract is being terminated based on the grounds specified in paragraph (a)(4)(i) of this section.

(ii) CMS notifies the MA organization in writing that its contract will be terminated on a date specified by CMS. If a termination is effective in the middle of a month, CMS has the right to

recover the prorated share of the capitation payments made to the MA organization covering the period of the month following the contract termination.

(iii) CMS notifies the MA organization's Medicare enrollees in writing of CMS's decision to terminate the MA organization's contract. This notice occurs no later than 30 days after CMS notifies the plan of its decision to terminate the MA contract. CMS simultaneously informs the Medicare enrollees of alternative options for obtaining Medicare services, including alternative MA organizations in a similar geographic area and original Medicare.

(iv) CMS notifies the general public of the termination no later than 30 days after notifying the plan of CMS's decision to terminate the MA contract. This notice is published in one or more newspapers of general circulation in each community or county located in the MA organization's service area.

(c) *Opportunity to develop and implement a corrective action plan*—(1) *General*. (i) Before providing a notice of intent to terminate the contract, CMS will provide the MA organization with notice specifying the MA organization's deficiencies and a reasonable opportunity of at least 30 calendar days to develop and implement a corrective action plan to correct the deficiencies.

(ii) The MA organization is solely responsible for the identification, development, and implementation of its corrective action plan and for demonstrating to CMS that the underlying deficiencies have been corrected within the time period specified by CMS in the notice requesting corrective action.

(2) *Exceptions*. The MA organization will not be provided with an opportunity to develop and implement a corrective action plan prior to termination if—

(i) CMS determines that a delay in termination, resulting from compliance with the procedures provided in this part prior to termination, would pose an imminent and serious risk to the health of the individuals enrolled with the MA organization;

(ii) The MA organization experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point

of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists; or

(iii) The contract is being terminated based on the violation specified in (a)(4)(i) of this section.

(d) *Appeal rights*. If CMS decides to terminate a contract, it sends written notice to the MA organization informing it of its termination appeal rights in accordance with subpart N of this part.

(e) If CMS makes a determination to terminate a MA organization's contract under § 422.510(a), CMS also imposes the intermediate sanctions at § 422.750(a)(1) and (3) in accordance with the following procedures:

(1) The sanction goes into effect 15 days after the termination notice is sent.

(2) The MA organization has a right to appeal the intermediate sanction in the same proceeding as the termination appeal specified in paragraph (d) of this section.

(3) A request for a hearing does not delay the date specified by CMS when the sanction becomes effective.

(4) The sanction remains in effect—

(i) Until the effective date of the termination; or

(ii) If the termination decision is overturned on appeal, when a final decision is made by the hearing officer or Administrator.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 70 FR 52027, Sept. 1, 2005; 72 FR 68723, Dec. 5, 2007; 75 FR 19811, Apr. 15, 2010; 77 FR 22168, Apr. 12, 2012; 78 FR 31307, May 23, 2013; 79 FR 29959, May 23, 2014; 81 FR 80557, Nov. 15, 2016; 83 FR 16734, Apr. 16, 2018; 88 FR 22334, Apr. 12, 2023; 89 FR 30824, Apr. 23, 2024]

§ 422.512 Termination of contract by the MA organization.

(a) *Cause for termination*. The MA organization may terminate the MA contract if CMS fails to substantially carry out the terms of the contract.

(b) *Notice*. The MA organization must give advance notice as follows:

(1) To CMS, at least 90 days before the intended date of termination. This notice must specify the reasons why the MA organization is requesting contract termination.

(2) To its Medicare enrollees, at least 60 days before the termination effective date. This notice must include a written description of alternatives available for obtaining Medicare services within the services area, including alternative MA plans, Medigap options, original Medicare and must receive CMS approval.

(3) To the general public at least 60 days before the termination effective date by publishing an CMS-approved notice in one or more newspapers of general circulation in each community or county located in the MA organization's geographic area.

(c) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the MA organization's notice of intent to terminate.

(d) *CMS's liability.* CMS's liability for payment to the MA organization ends as of the first day of the month after the last month for which the contract is in effect.

(e) *Effect of termination by the organization.* (1) CMS may deny an application for a new contract or a service area expansion from an MA organization that has terminated its contract within the preceding 2 years unless there are circumstances that warrant special consideration, as determined by CMS. This prohibition may apply regardless of the contract type, product type, or service area of the previous contract.

(2) During the same 2-year period specified in paragraph (e)(1) of this section, CMS will not contract with an organization whose covered persons also served as covered persons for the terminating sponsor. A "covered person" as used in this paragraph means one of the following:

(i) All owners of nonrenewal or terminated organizations who are natural persons, other than shareholders who have an ownership interest of less than 5 percent.

(ii) An owner in whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the organization, or any of the property or assets thereof, which whole or part interest is equal to or ex-

ceeds 5 percent of the total property and assets of the organization.

(iii) A member of the board of directors of the entity, if the organization is organized as a corporation.

[63 FR 35099, June 26, 1998, as amended at 67 FR 13288, Mar. 22, 2002; 76 FR 21569, Apr. 15, 2011; 80 FR 7961, Feb. 12, 2015]

§ 422.514 Enrollment requirements.

(a) *Minimum enrollment rules.* Except as provided in paragraph (b) of this section, CMS does not enter into a contract under this subpart unless the organization meets the following minimum enrollment requirement—

(1) At least 5,000 individuals (or 1,500 individuals if the organization is a PSO) are enrolled for the purpose of receiving health benefits from the organization; or

(2) At least 1,500 individuals (or 500 individuals if the organization is a PSO) are enrolled for purposes of receiving health benefits from the organization and the organization primarily serves individuals residing outside of urbanized areas as defined in § 412.62(f) (or, in the case of a PSO, the PSO meets the requirements in § 422.352(c)).

(3) Except as provided for in paragraph (b) of this section, an MA organization must maintain a minimum enrollment as defined in paragraphs (a)(1) and (a)(2) of this section for the duration of its contract.

(b) *Minimum enrollment waiver.* For a contract applicant that does not meet the applicable requirement of paragraph (a) of this section at application for an MA contract, CMS may waive the minimum enrollment requirement for the first 3 years of the contract. To receive a waiver, a contract applicant must demonstrate to CMS's satisfaction that it is capable of administering and managing an MA contract and is able to manage the level of risk required under the contract during the first 3 years of the contract. Factors that CMS takes into consideration in making this evaluation include the extent to which—

(1) The contract applicant management and providers have previous experience in managing and providing health care services under a risk-based payment arrangement to at least as

many individuals as the applicable minimum enrollment for the entity as described in paragraph (a) of this section; or

(2) The contract applicant has the financial ability to bear financial risk under an MA contract. In determining whether an organization is capable of bearing risk, CMS considers factors such as the organization's management experience as described in paragraph (b)(1) of this section and stop-loss insurance that is adequate and acceptable to CMS; and

(3) The contract applicant is able to establish a marketing and enrollment process that allows it to meet the applicable enrollment requirement specified in paragraph (a) of this section before completion of the third contract year.

(c) Failure to meet enrollment requirements. CMS may elect not to renew its contract with an MA organization that fails to meet the applicable enrollment requirement in paragraph (a) of this section.

(d) *Rule on dual eligible enrollment.* In any state where there is a dual eligible special needs plan or any other plan authorized by CMS to exclusively enroll individuals entitled to medical assistance under a state plan under title XIX, CMS does not:

(1) Enter into or renew a contract under this subpart for a MA plan that—

(i) Is not a specialized MA plan for special needs individuals as defined in § 422.2; and

(ii) Projects enrollment in its bid submitted under § 422.254 in which enrollees entitled to medical assistance under a State plan under title XIX constitute a percentage of the plan's total enrollment that meets or exceeds one of the following:—

(A) For plan year 2024, 80 percent.

(B) For plan year 2025, 70 percent.

(C) For plan year 2026 and subsequent years, 60 percent.

(2) Renew a contract under this subpart for an MA plan that—

(i) Is not a specialized MA plan for special needs individuals as defined in § 422.2; and

(ii) Unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination, has actual

enrollment, as determined by CMS using the January enrollment of the current year in which enrollees who are entitled to medical assistance under a state plan under title XIX, constitute a percentage of the plan's total enrollment that meets or exceeds one of the following:

(A) For renewals for plan year 2024, 80 percent.

(B) For renewals for plan year 2025, 70 percent.

(C) For renewals for plan year 2026 and subsequent years, 60 percent.

(e) *Transition process and procedures.*

(1) For coverage effective January 1 of the next year, and subject to the disclosure requirements described in paragraph (e)(2) of this section, an MA organization may transition enrollees in a plan specified in paragraph (d)(2) of this section into another MA plan or plans (including into a dual eligible special needs plan for enrollees who are eligible for such a plan) offered by the MA organization, or another MA organization that shares the same parent organization as the MA organization, for which the individual is eligible in accordance with §§ 422.50 through 422.53 if the MA plan or plans receiving such enrollment—

(i) Would not meet the criteria in paragraph (d)(2)(ii) of this section, as determined in the procedures described in paragraph (e)(3) of this section, with the addition of the newly enrolled individuals (unless such plan is a specialized MA plan for special needs individuals as defined in § 422.2);

(ii) Is an MA-PD plan described at § 422.2;

(iii) Has a combined Part C and Part D premium of \$0.00 for individuals eligible for the premium subsidy for full subsidy eligible individuals described in § 423.780(a) of this chapter;

(iv) Is of the same plan type (for example, HMO or PPO) as the plan specified in paragraph (d)(2) of this section; and

(v) For transitions for plan year 2027 and subsequent years, is a dual eligible special needs plan as defined in § 422.2.

(2) An MA organization may transition individuals under paragraph (e)(1) of this section without requiring the individual to file the election form under § 422.66(a) if—

(i) The enrolled individual is eligible to enroll in the MA plan; and

(ii) The MA-PD plan into which individuals are transitioned describes changes to MA-PD benefits and provides information about the MA-PD plan in the Annual Notice of Change, which must be sent consistent with § 422.111(a), (d), and (e).

(3) For the purpose of approving a MA organization to transition enrollment under this paragraph (e), CMS determines whether a non-SNP MA plan would meet the criteria in paragraph (d)(2) of this section by adding the cohort of individuals identified by the MA organization for enrollment in a non-SNP MA plan to the April enrollment of such plan and calculating the resulting percentage of dual eligible enrollment.

(4) In cases where an MA organization does not transition current enrollees under paragraph (e)(1) of this section, the MA organization must send a written notice to enrollees who are not transitioned, consistent with § 422.506(a)(2).

(f) *Special considerations.* Actions taken pursuant to paragraph (d) of this section warrant special consideration to exempt affected MA organizations from the denial of an application for a new contract or service area expansion in accordance with §§ 422.502(b)(3) and (4), 422.503(b)(6) and (7), 422.506(a)(3) and (4), 422.508(c) and (d), and 422.512(e)(1) and (2).

(g) *Applicability to segments.* The rules under paragraphs (d) through (f) of this section also apply to segments of the MA plan as provided for local MA plans under § 422.262(c)(2).

(h) *Rule on dual eligible special needs plans in relation to Medicaid managed care.*

(1) Beginning in 2027, where an MA organization offers a dual eligible special needs plan and the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid managed care organization (MCO) (as defined in § 438.2) that enrolls full-benefit dual eligible individuals as defined in § 423.772, during the effective dates and in the same service area (even if there is only partial overlap of the

service areas) of that Medicaid MCO contract, the MA organization—

(i) May only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D-SNP for full-benefit dual eligible individuals, except as permitted in paragraph (h)(3) of this section; and

(ii) Must limit new enrollment in the D-SNP to individuals enrolled in, or in the process of enrolling in, the Medicaid MCO.

(2) Beginning in 2030, such D-SNPs may only enroll (or continue to cover) individuals enrolled in (or in the process of enrolling in) the Medicaid MCO, except that such D-SNPs may continue to implement deemed continued eligibility requirements as described in § 422.52(d).

(3)(i) If a State Medicaid agency's contract(s) with the MA organization differentiates enrollment into D-SNPs by age group or to align enrollment in each D-SNP with the eligibility or benefit design used in the State's Medicaid managed care program(s) (as defined in § 438.2), the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization may offer one or more additional D-SNPs for full-benefit dual eligible individuals in the same service area in accordance with the group (or groups) eligible for D-SNPs based on provisions of the contract with the State Medicaid agency under § 422.107.

(ii) If the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization offers both HMO D-SNP(s) and PPO D-SNP(s), and one or more of the—

(A) HMO D-SNPs is subject to paragraph (h)(1) of this section, the PPO D-SNP(s) not subject to paragraph (h)(1) of this section may continue if they no longer accept new enrollment of full-benefit dual eligible individuals in the same service area as the plan (or plans) subject to paragraph (h)(1) of this section.

(B) PPO D-SNPs is subject to paragraph (h)(1) of this section, the HMO D-SNP(s) not subject to paragraph (h)(1) of this section may continue if they no longer accept new enrollment of full-benefit dual eligible individuals in the

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same service area as the plan (or plans) subject to paragraph (h)(1) of this section.

[63 FR 35099, June 26, 1998, as amended at 65 FR 40328, June 29, 2000; 83 FR 16734, Apr. 16, 2018; 85 FR 33908, June 2, 2020; 88 FR 22334, Apr. 12, 2023; 89 FR 30824, Apr. 23, 2024; 89 FR 79451, Sept. 30, 2024]

§ 422.516 Validation of Part C reporting requirements.

(a) *Required information.* Each MA organization must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the provider-patient relationship, information with respect to the following:

- (1) The cost of its operations.
- (2) The procedures related to and utilization of its services and items.
- (3) The availability, accessibility, and acceptability of its services.
- (4) To the extent practical, developments in the health status of its enrollees.
- (5) Information demonstrating that the MA organization has a fiscally sound operation.
- (6) Other matters that CMS may require.

(b) *Significant business transactions.* Each MA organization must report to CMS annually, within 120 days of the end of its fiscal year (unless for good cause shown, CMS authorizes an extension of time), the following:

- (1) A description of significant business transactions (as defined in § 422.500) between the MA organization and a party in interest.
- (2) With respect to those transactions—
 - (i) A showing that the costs of the transactions listed in paragraph (c) of this section do not exceed the costs that would be incurred if these transactions were with someone who is not a party in interest; or
 - (ii) If they do exceed, a justification that the higher costs are consistent with prudent management and fiscal soundness requirements.
- (3) A combined financial statement for the MA organization and a party in

interest if either of the following conditions is met:

- (i) Thirty-five percent or more of the costs of operation of the MA organization go to a party in interest.
- (ii) Thirty-five percent or more of the revenue of a party in interest is from the MA organization.

(c) *Requirements for combined financial statements.* (1) The combined financial statements required by paragraph (b)(3) of this section must display in separate columns the financial information for the MA organization and each of the parties in interest.

(2) Inter-entity transactions must be eliminated in the consolidated column.

(3) The statements must have been examined by an independent auditor in accordance with generally accepted accounting principles and must include appropriate opinions and notes.

(4) Upon written request from an MA organization showing good cause, CMS may waive the requirement that the organization's combined financial statement include the financial information required in this paragraph (c) with respect to a particular entity.

(d) *Reporting and disclosure under ERISA.* (1) For any employees' health benefits plan that includes an MA organization in its offerings, the MA organization must furnish, upon request, the information the plan needs to fulfill its reporting and disclosure obligations (with respect to the particular MA organization) under the Employee Retirement Income Security Act of 1974 (ERISA).

(2) The MA organization must furnish the information to the employer or the employer's designee, or to the plan administrator, as the term "administrator" is defined in ERISA.

(e) *Loan information.* Each organization must notify CMS of any loans or other special financial arrangements it makes with contractors, subcontractors and related entities.

(f) *Enrollee access to information.* Each MA organization must make the information reported to CMS under § 422.502(f)(1) available to its enrollees upon reasonable request.

(g) *Data validation.* Each Part C sponsor must subject information collected under paragraph (a) of this section to a yearly independent audit to determine

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their reliability, validity, completeness, and comparability in accordance with specifications developed by CMS.

[63 FR 35099, June 26, 1998, as amended at 75 FR 19812, Apr. 15, 2010; 89 FR 30825, Apr. 23, 2024]

§ 422.520 Prompt payment by MA organization.

(a) *Contract between CMS and the MA organization.* (1) The contract between CMS and the MA organization must provide that the MA organization will pay 95 percent of the “clean claims” within 30 days of receipt if they are submitted by, or on behalf of, an enrollee of an MA private fee-for-service plan or are claims for services that are not furnished under a written agreement between the organization and the provider.

(2) The MA organization must pay interest on clean claims that are not paid within 30 days in accordance with sections 1816(c)(2)(B) and 1842(c)(2)(B).

(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]

§ 422.528 Final settlement process and payment.

(a) *Notice of final settlement.* After the calculation of the final settlement amount, CMS sends the MA organization a notice of final settlement. The

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notice of final settlement contains at least all of the following information:

(1) A final settlement amount, which may be either an amount due to the MA organization, or an amount due from the MA organization, or \$0 if nothing is due to or from the MA organization, for the contract that has been consolidated, nonrenewed, or terminated.

(2) Relevant banking and financial mailing instructions for MA organizations that owe CMS a final settlement amount.

(3) Relevant CMS contact information.

(4) A description of the steps for requesting an appeal of the final settlement amount calculation, in accordance with the requirements specified in § 422.529.

(b) *Request for an appeal.* An MA organization that disagrees with the final settlement amount has 15 calendar days from issuance of the notice of final settlement, as described in paragraph (a) of this section, to request an appeal of the final settlement amount under the process described in § 422.529.

(1) If an MA organization agrees with the final settlement amount, no response is required.

(2) If an MA organization disagrees with the final settlement amount but does not request an appeal within 15 calendar days from the date of the issuance of the notice of final settlement, CMS does not consider subsequent requests for appeal.

(c) *Actions if an MA organization does not request an appeal.* (1) For MA organizations that are owed money by CMS, CMS remits payment to the MA organization within 60 calendar days from the date of the issuance of the notice of final settlement.

(2) For MA organizations that owe CMS money, the MA organization is required to remit payment to CMS within 120 calendar days from issuance of the notice of final settlement. If the MA organization fails to remit payment within that 120-calendar-day period, CMS refers the debt owed to CMS to the Department of the Treasury for collection.

(d) *Actions following submission of a request for appeal.* If an MA organization responds to the notice of final settle-

ment disagreeing with the final settlement amount and requesting appeal, CMS conducts a review under the process described at § 422.529.

(e) *No additional payment adjustments.* After the final settlement amount is calculated and the notice of final settlement, as described under § 422.528(a), is issued to the MA organization, CMS no longer apply retroactive payment adjustments to the terminated, consolidated or nonrenewed contract and there are no adjustments applied to amounts used in the calculation of the final settlement amount.

[89 FR 30825, Apr. 23, 2024]

§ 422.529 Requesting an appeal of the final settlement amount.

(a) *Appeals process.* If an MA organization does not agree with the final settlement amount described in § 422.528(a), it may appeal under the following three-level appeal process:

(1) *Reconsideration.* An MA organization may request reconsideration of the final settlement amount described in § 422.528(a) according to the following process:

(i) *Manner and timing of request.* A written request for reconsideration must be filed within 15 calendar days from the date that CMS issued the notice of final settlement to the MA organization.

(ii) *Content of request.* The written request for reconsideration must do all of the following:

(A) Specify the calculation with which the MA organization disagrees and the reasons for its disagreement.

(B) Include evidence supporting the assertion that CMS' calculation of the final settlement amount is incorrect.

(C) Not include new reconciliation data or data that was submitted to CMS after the final settlement notice was issued. CMS does not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(iii) *Conduct of reconsideration.* In conducting the reconsideration, the CMS reconsideration official reviews the calculations that were used to determine the final settlement amount and any additional evidence timely submitted by the MA organization.

(iv) *Reconsideration decision.* The CMS reconsideration official informs the MA organization of its decision on the reconsideration in writing.

(v) *Effect of reconsideration decision.* The decision of the CMS reconsideration official is final and binding unless a timely request for an informal hearing is filed in accordance with paragraph (a)(2) of this section.

(2) *Informal hearing.* An MA organization dissatisfied with CMS' reconsideration decision made under paragraph (a)(1) of this section is entitled to an informal hearing as provided for under paragraphs (a)(2)(i) through (a)(2)(iv) of this section.

(i) *Manner and timing of request.* A request for an informal hearing must be made in writing and filed with CMS within 15 calendar days of the date of CMS' reconsideration decision.

(ii) *Content of request.* The request for an informal hearing must include a copy of the reconsideration decision and must specify the findings or issues in the decision with which the MA organization disagrees and the reasons for its disagreement.

(iii) *Informal hearing procedures.* The informal hearing is conducted in accordance with the following:

(A) The CMS Hearing Officer provides written notice of the time and place of the informal hearing at least 30 days before the scheduled date.

(B) The CMS reconsideration official provides a copy of the record that was before CMS when CMS made its decision to the hearing officer.

(C) The hearing officer review is conducted by a CMS hearing officer who neither receives testimony nor accepts any new evidence. The CMS hearing officer is limited to the review of the record that was before CMS when CMS made its decision.

(iv) *Decision of the CMS hearing officer.* The CMS hearing officer decides the case and sends a written decision to the MA organization explaining the basis for the decision.

(v) *Effect of hearing officer's decision.* The hearing officer's decision is final and binding, unless the decision is reversed or modified by the CMS Administrator in accordance with paragraph (a)(3) of this section.

(3) *Review by the Administrator.* The Administrator's review is conducted in the following manner:

(i) *Manner and timing of request.* An MA organization that has received a hearing officer's decision may request review by the Administrator within 15 calendar days of the date of issuance of the hearing officer's decision under paragraph (a)(2)(iv) of this section. An MA organization may submit written arguments to the Administrator for review.

(ii) *Discretionary review.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing officer's determination in accordance with paragraph (a)(3)(iii) of this section or to decline to review the hearing officer's decision within 30 calendar days of receiving the request for review. If the Administrator declines to review the hearing officer's decision, the hearing officer's decision is final and binding.

(iii) *Administrator's review.* If the Administrator elects to review the hearing officer's decision, the Administrator reviews the hearing officer's decision, as well as any information included in the record of the hearing officer's decision and any written argument submitted by the MA organization, and determine whether to uphold, reverse, or modify the hearing officer's decision.

(iv) *Effect of Administrator's decision.* The Administrator's decision is final and binding.

(b) *Matters subject to appeal and burden of proof.* (1) The MA organization's appeal is limited to CMS' calculation of the final settlement amount. CMS does not consider information submitted for the purposes of retroactively adjusting a prior reconciliation.

(2) The MA organization bears the burden of proof by providing evidence demonstrating that CMS' calculation of the final settlement amount is incorrect.

(c) *Stay of financial transaction until appeals are exhausted.* If an MA organization requests review of the final settlement amount, the financial transaction associated with the issuance or payment of the final settlement amount is stayed until all appeals are

exhausted. Once all levels of appeal are exhausted or the MA organization fails to request further review within the applicable 15-calendar-day timeframe, CMS communicates with the MA organization to complete the financial transaction associated with the issuance or payment of the final settlement amount, as appropriate.

(d) *Continued compliance with other law required.* Nothing in this section limits an MA organization's responsibility to comply with any other applicable statute or regulation.

[89 FR 30825, Apr. 23, 2024]

§ 422.530 Plan crosswalks.

(a) *General rules*—(1) *Definition of crosswalk.* A crosswalk is the movement of enrollees from one plan (or plan benefit package (PBP)) to another plan (or PBP) under a contract between the MA organization and CMS. To crosswalk enrollees from one PBP to another is to change the enrollment from the first PBP to the second.

(2) *Prohibitions.* Except as described in paragraph (c) of this section, crosswalks are prohibited between different contracts or different plan types (for example, HMO to PPO).

(3) *Compliance with renewal/non-renewal rules.* The MA organization must comply with renewal and non-renewal rules in §§ 422.505 and 422.506 in order to complete plan crosswalks.

(4) *Eligibility.* Enrollees must be eligible for enrollment under §§ 422.50 through 422.54 in order to be moved from one PBP to another PBP.

(5) *Types of MA plans.* For purposes of crosswalk policy in this section, CMS considers the following plans as different plan types:

- (i) Health maintenance organizations coordinated care plans.
- (ii) Provider-sponsored organizations coordinated care plans.
- (iii) Regional or local preferred provider organizations coordinated care plans.
- (iv) Special needs plans.
- (v) Private Fee-for-service plans.
- (vi) MSA plans.

(b) *Allowable crosswalk types*—(1) *All MA plans.* An MA organization may perform a crosswalk in the following circumstances:

(i) *Renewal.* A plan in the following contract year that links to a current contract year plan and retains the entire service area from the current contract year. The following contract year plan must retain the same plan ID as the current contract year plan.

(ii) *Consolidated renewal.* A plan in the following contract year that combines 2 or more complete current contract year plans of the same plan type but not including when a current PBP is split among more than one PBP for the following contract year. The plan ID for the following contract year must be the same as one of the current contract year plan IDs.

(iii) *Renewal with a service area expansion (SAE).* A plan in the following contract year that links to a current contract year plan and retains all of its plan service area from the current contract year, but also adds one or more new counties. The following year contract plan must retain the same plan ID as the current contract year plan.

(iv) *Renewal with a service area reduction (SAR).* (A) A plan in the following contract year that links to a current contract year plan and only retains a portion of its plan service area. The following contract year plan must retain the same plan ID as the current contract year plan. The crosswalk is limited to the enrollees in the remaining service area.

(B) While the MA organization may not affirmatively crosswalk enrollees in the locations that will no longer be part of the service area, the MA organization may offer those affected enrollees in the reduced portion of the service area a continuation in accordance with § 422.74(b)(3)(ii), provided that there are no other MA plan options in the reduced service area.

(C) If the MA organization offers another PBP in the locations that will no longer be part of the service area, current enrollees in the locations that will no longer be part of the service area must be disenrolled and the MA organization must send a non-renewal notice that includes notification of a special enrollment period under § 422.62 and, for applicable enrollees, Medigap guaranteed issue rights.

(D) The MA organization may offer current enrollees in the locations that

will no longer be part of the service area the option of enrolling in the other plan(s) the MA organization offers in the location that is no longer part of the service area, however, no specific plan information for the following contract year may be shared with any beneficiaries prior to the plan marketing period for the next contract year, consistent with 42 CFR 422.2263 and 423.2263.

(2) *Special needs plans (SNPs)*. In addition to those described in paragraph (b)(1) of this section, SNPs may also perform the following types of crosswalks:

(i) *Chronic SNPs (C-SNPs)*. (A) Renewing C-SNP with one chronic condition that transitions eligible enrollees into another C-SNP with a grouping that contains that same chronic condition.

(B) Non-renewing C-SNP with one chronic condition that transitions eligible enrollees into another C-SNP with a grouping that contains that same chronic condition.

(C) Non-renewing C-SNP with a grouping that is transitioning eligible enrollees into a different grouping C-SNP if the new grouping contains at least one condition that the prior C-SNP contained.

(ii) *Institutional SNP*. (A) Renewing Institutional SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

(B) Renewing Institutional Equivalent SNP that transitions enrollees to an Institutional/Institutional Equivalent SNP.

(C) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional SNP.

(D) Renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to an Institutional Equivalent SNP.

(E) Non-renewing Institutional/Institutional Equivalent SNP that transitions eligible enrollees to another Institutional/Institutional Equivalent SNP.

(c) *Exceptions*. In order to perform a crosswalk that is not specified in paragraph (b) of this section, an MA organization must request an exception. Crosswalk exceptions are prohibited between different plan types. CMS re-

views exception requests and may permit a crosswalk exception in the following circumstances:

(1) When a non-network or partial network Private Fee-For-Service (PFFS) plan changes to either a partial network or to a full network PFFS plan, enrollees may be moved to the new plan when CMS determines it is in the interest of beneficiaries, considering whether the risks to enrollees are such that they would be better served by remaining in the plan, whether there are other suitable managed care plans available, and whether the enrollees are particularly medically vulnerable, such as institutionalized enrollees. Crosswalks from a network based PFFS plan to a non-network or partial network PFFS plan will not be permitted.

(2) When MA contracts offered by two different MA organizations that share the same parent organization are consolidated such that the separate contracts are consolidated under one surviving contract, the enrollees from the consolidating contracts may be crosswalked to an MA plan under the surviving contract.

(3) When a renewing D-SNP with a multi-state service area reduces its service area or, in the case of a D-SNP in an MA regional plan contract, non-renews and creates state-specific local preferred provider organization plans in its place to accommodate state contracting efforts in the service area, enrollees who are no longer in the service area may be moved into one or more new or renewing D-SNPs, offered under the same parent organization (even if the D-SNPs are offered by two different MA organizations), and for which the enrollees are eligible, as CMS determines is necessary to accommodate changes to the contracts between the state and D-SNP under § 422.107. For this crosswalk exception, CMS will permit enrollees to be moved between different contracts.

(4) When—

(i) A renewing D-SNP has another new or renewing D-SNP, and the two D-SNPs are offered to different populations, enrollees who are no longer eligible for their current D-SNP may be moved into the other new or renewing