

(2) [Reserved]

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Subpart E—Relationships With Providers

SOURCE: 63 FR 35085, June 26, 1998, unless otherwise noted.

§ 422.200 Basis and scope.

This subpart is based on sections 1852(a)(1), (a)(2), (b)(2), (c)(2)(D), (j), and (k) of the Act; section 1859(b)(2)(A) of the Act; and the general authority under 1856(b) of the Act requiring the establishment of standards. It sets forth the requirements and standards for the MA organization's relationships with providers including physicians, other health care professionals, institutional providers and suppliers, under contracts or arrangements or deemed contracts under MA private fee-for-service plans. This subpart also contains some requirements that apply to noncontracting providers.

§ 422.202 Participation procedures.

(a) *Notice and appeal rights.* An MA organization that operates a coordinated care plan or network MSA plan must provide for the participation of individual physicians, and the management and members of groups of physicians, through reasonable procedures that include the following:

(1) Written notice of rules of participation including terms of payment, credentialing, and other rules directly related to participation decisions.

(2) Written notice of material changes in participation rules before the changes are put into effect.

(3) Written notice of participation decisions that are adverse to physicians.

(4) A process for appealing adverse participation procedures, including the right of physicians to present information and their views on the decision. In the case of termination or suspension of a provider contract by the MA organization, this process must conform to the rules in § 422.202(d).

(b) *Consultation.* The MA organization must establish a formal mechanism to

consult with the physicians who have agreed to provide services under the MA plan offered by the organization, regarding the organization's medical policy, quality improvement programs and medical management procedures and ensure that the following standards are met:

(1) Practice guidelines and utilization management guidelines—

(i) Are based on current evidence in widely used treatment guidelines or clinical literature;

(ii) Consider the needs of the enrolled population;

(iii) Are developed in consultation with contracting physicians; and

(iv) Are reviewed and updated periodically.

(2) The guidelines are communicated to providers and, as appropriate, to enrollees.

(3) Decisions with respect to utilization management, enrollee education, coverage of services, and other areas in which the guidelines apply are consistent with the guidelines.

(c) *Subcontracted groups.* An MA organization that operates an MA plan through subcontracted physician groups must provide that the participation procedures in this section apply equally to physicians within those subcontracted groups.

(d) *Suspension or termination of contract.* An MA organization that operates a coordinated care plan or network MSA plan providing benefits through contracting providers must meet the following requirements:

(1) *Notice to physician.* An MA organization that suspends or terminates an agreement under which the physician provides services to MA plan enrollees must give the affected individual written notice of the following:

(i) The reasons for the action, including, if relevant, the standards and profiling data used to evaluate the physician and the numbers and mix of physicians needed by the MA organization.

(ii) The affected physician's right to appeal the action and the process and timing for requesting a hearing.

(2) *Composition of hearing panel.* The MA organization must ensure that the majority of the hearing panel members are peers of the affected physician.

(3) *Notice to licensing or disciplinary bodies.* An MA organization that suspends or terminates a contract with a physician because of deficiencies in the quality of care must give written notice of that action to licensing or disciplinary bodies or to other appropriate authorities.

(4) *Timeframes.* An MA organization and a contracting provider must provide at least 60 days written notice to each other before terminating the contract without cause.

[64 FR 7981, Feb. 17, 1999, as amended at 65 FR 40324, June 29, 2000; 68 FR 50857, Aug. 22, 2003; 70 FR 4724, Jan. 28, 2005; 88 FR 22334, Apr. 12, 2023]

§ 422.204 Provider selection and credentialing.

(a) *General rule.* An MA organization must have written policies and procedures for the selection and evaluation of providers. These policies must conform with the credential and recredentialing requirements set forth in paragraph (b) of this section and with the antidiscrimination provisions set forth in § 422.205.

(b) *Basic requirements.* An MA organization must follow a documented process with respect to providers and suppliers who have signed contracts or participation agreements that—

(1) For providers (other than physicians and other health care professionals) requires determination, and redetermination at specified intervals, that each provider is—

(i) Licensed to operate in the State, and in compliance with any other applicable State or Federal requirements; and

(ii) Reviewed and approved by an accrediting body, or meets the standards established by the organization itself;

(2) For physicians and other health care professionals, including members of physician groups, covers—

(i) Initial credentialing that includes written application, verification of licensure or certification from primary sources, disciplinary status, eligibility for payment under Medicare, and site visits as appropriate. The application must be signed and dated and include an attestation by the applicant of the correctness and completeness of the ap-

plication and other information submitted in support of the application;

(ii) Recredentialing at least every 3 years that updates information obtained during initial credentialing, considers performance indicators such as those collected through quality improvement programs, utilization management systems, handling of grievances and appeals, enrollee satisfaction surveys, and other plan activities, and that includes an attestation of the correctness and completeness of the new information; and

(iii) A process for consulting with contracting health care professionals with respect to criteria for credentialing and recredentialing.

(3) Specifies that basic benefits must be provided through, or payments must be made to, providers and suppliers that meet applicable requirements of title XVIII and part A of title XI of the Act. In the case of providers meeting the definition of “provider of services” in section 1861(u) of the Act, basic benefits may only be provided through these providers if they have a provider agreement with CMS permitting them to provide services under original Medicare.

(4) Ensures compliance with the requirements at § 422.752(a)(8) that prohibit employment or contracts with individuals (or with an entity that employs or contracts with such an individual) excluded from participation under Medicare and with the requirements at § 422.220 regarding physicians and practitioners who opt out of Medicare.

(c) An MA organization must follow a documented process that ensures compliance with the preclusion list provisions in § 422.222.

[65 FR 40324, June 29, 2000, as amended at 66 FR 47413, Sept. 12, 2001; 70 FR 4724, Jan. 28, 2005; 81 FR 80556, Nov. 15, 2016; 83 FR 16731, Apr. 16, 2018]

§ 422.205 Provider antidiscrimination rules.

(a) *General rule.* Consistent with the requirements of this section, the policies and procedures concerning provider selection and credentialing established under § 422.204, and with the requirement under § 422.100(c) that all Medicare-covered services be available

to MA plan enrollees, an MA organization may select the practitioners that participate in its plan provider networks. In selecting these practitioners, an MA organization may not discriminate, in terms of participation, reimbursement, or indemnification, against any health care professional who is acting within the scope of his or her license or certification under State law, solely on the basis of the license or certification. If an MA organization declines to include a given provider or group of providers in its network, it must furnish written notice to the affected provider(s) of the reason for the decision.

(b) *Construction.* The prohibition in paragraph (a)(1) of this section does not preclude any of the following by the MA organization:

(1) Refusal to grant participation to health care professionals in excess of the number necessary to meet the needs of the plan's enrollees (except for MA private-fee-for-service plans, which may not refuse to contract on this basis).

(2) Use of different reimbursement amounts for different specialties or for different practitioners in the same specialty.

(3) Implementation of measures designed to maintain quality and control costs consistent with its responsibilities.

[65 FR 40324, June 29, 2000]

§ 422.206 Interference with health care professionals' advice to enrollees prohibited.

(a) *General rule.* (1) An MA organization may not prohibit or otherwise restrict a health care professional, acting within the lawful scope of practice, from advising, or advocating on behalf of, an individual who is a patient and enrolled under an MA plan about—

(i) The patient's health status, medical care, or treatment options (including any alternative treatments that may be self-administered), including the provision of sufficient information to the individual to provide an opportunity to decide among all relevant treatment options;

(ii) The risks, benefits, and consequences of treatment or non-treatment; or

(iii) The opportunity for the individual to refuse treatment and to express preferences about future treatment decisions.

(2) Health care professionals must provide information regarding treatment options in a culturally-competent manner, including the option of no treatment. Health care professionals must ensure that individuals with disabilities have effective communications with participants throughout the health system in making decisions regarding treatment options.

(b) *Conscience protection.* The general rule in paragraph (a) of this section does not require the MA plan to cover, furnish, or pay for a particular counseling or referral service if the MA organization that offers the plan—

(1) Objects to the provision of that service on moral or religious grounds; and

(2) Through appropriate written means, makes available information on these policies as follows:

(i) To CMS, with its application for a Medicare contract, within 10 days of submitting its bid proposal or, for policy changes, in accordance with all applicable requirements under subpart V of this part.

(ii) To prospective enrollees, before or during enrollment.

(iii) With respect to current enrollees, the organization is eligible for the exception provided in paragraph (b)(1) of this section if it provides notice of such change within 90 days after adopting the policy at issue; however, under § 422.111(d), notice of such a change must be given in advance.

(c) *Construction.* Nothing in paragraph (b) of this section may be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974.

(d) *Sanctions.* An MA organization that violates the prohibition of paragraph (a) of this section or the conditions in paragraph (b) of this section is subject to intermediate sanctions under subpart O of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 52026, Sept. 1, 2005; 83 FR 16731, Apr. 16, 2018]

§ 422.208 Physician incentive plans: requirements and limitations.

(a) *Definitions.* In this subpart, the following definitions apply:

Bonus means a payment made to a physician or physician group beyond any salary, fee-for-service payments, capitation, or returned withhold.

Capitation means a set dollar payment per patient per unit of time (usually per month) paid to a physician or physician group to cover a specified set of services and administrative costs without regard to the actual number of services provided. The services covered may include the physician's own services, referral services, or all medical services.

Combined Stop-Loss Insurance Deductible Table (Table PIP-1) means the table described and developed using the methodology in paragraph (f)(2)(iv) of this section.

Global capitation means a specific type of "capitation" that includes both professional and institutional services. Services covered by global capitation may also include prescription drug benefits and supplemental benefits as well as basic benefits (as those terms are defined in § 422.100(c)). For purposes of Tables PIP-1 and PIP-2 global capitation includes all Parts A and B services except hospice.

Net benefit premium means the total amount of stop-loss claims (90 percent of claims above the deductible) for that panel size divided by the panel size. It is determined for each panel size and shown in Table PIP-1, described in paragraph (f)(2)(iv) of this section. It is then used in Table PIP-2, described in paragraph (f)(2)(vi) of this section, to identify all separate institutional and separate professional deductible combinations that meet the stop-loss requirements for multi-specialty physician groups participating in PIPs.

Non-Risk Patient Equivalents (NPE) means the estimate of annual claims for physician rendered services for non-risk patients served by the physician or physician group divided by what the PMPY capitation for physician rendered services would be if the beneficiary were part of the risk arrangement. Both Medicare and non-Medicare patients are included in this calculation.

Physician group means a partnership, association, corporation, individual practice association, or other group of physicians that distributes income from the practice among members. An individual practice association is defined as a physician group for this section only if it is composed of individual physicians and has no subcontracts with physician groups.

Physician incentive plan means any compensation arrangement to pay a physician or physician group that may directly or indirectly have the effect of reducing or limiting the services provided to any plan enrollee.

Potential payments means the maximum payments possible to physicians or physician groups including payments for services they furnish directly, and additional payments based on use and costs of referral services, such as withholds, bonuses, capitation, or any other compensation to the physician or physician group. Bonuses and other compensation that are not based on use of referrals, such as quality of care furnished, patient satisfaction or committee participation, are not considered payments in the determination of substantial financial risk.

Referral services means any specialty, inpatient, outpatient, or laboratory services that a physician or physician group orders or arranges, but does not furnish directly.

Risk threshold means the maximum risk, if the risk is based on referral services, to which a physician or physician group may be exposed under a physician incentive plan without being at substantial financial risk. This is set at 25 percent risk.

Separate Stop-Loss Insurance Deductible Table (Table PIP-2) means the table described and developed using the methodology in paragraph (f)(2)(vi) of this section.

Substantial financial risk, for purposes of this section, means risk for referral services that exceeds the risk threshold.

Withhold means a percentage of payments or set dollar amounts deducted from a physician's service fee, capitation, or salary payment, and that may or may not be returned to the physician, depending on specific predetermined factors.

(b) *Applicability.* The requirements in this section apply to an MA organization and any of its subcontracting arrangements that utilize a physician incentive plan in their payment arrangements with individual physicians or physician groups. Subcontracting arrangements may include an intermediate entity, which includes but is not limited to, an individual practice association that contracts with one or more physician groups or any other organized group such as those specified in § 422.4.

(c) *Basic requirements.* Any physician incentive plan operated by an MA organization must meet the following requirements:

(1) The MA organization makes no specific payment, directly or indirectly, to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to any particular enrollee. Indirect payments may include offerings of monetary value (such as stock options or waivers of debt) measured in the present or future.

(2) If the physician incentive plan places a physician or physician group at substantial financial risk (as determined under paragraph (d) of this section) for services that the physician or physician group does not furnish itself, the MA organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with paragraph (f) of this section.

(3) For all physician incentive plans, the MA organization provides to CMS the information specified in § 422.210.

(d) *Determination of substantial financial risk*—(1) *Basis.* Substantial financial risk occurs when risk is based on the use or costs of referral services, and that risk exceeds the risk threshold. Payments based on other factors, such as quality of care furnished, are not considered in this determination.

(2) *Risk threshold.* The risk threshold is 25 percent of potential payments.

(3) *Arrangements that cause substantial financial risk.* The following incentive arrangements cause substantial financial risk within the meaning of this section, if the physician's or physician group's patient panel size is not great-

er than 25,000 patients, as shown in the table at paragraph (f)(2)(iii) of this section:

(i) Withholds greater than 25 percent of potential payments.

(ii) Withholds less than 25 percent of potential payments if the physician or physician group is potentially liable for amounts exceeding 25 percent of potential payments.

(iii) Bonuses that are greater than 33 percent of potential payments minus the bonus.

(iv) Withholds plus bonuses if the withholds plus bonuses equal more than 25 percent of potential payments. The threshold bonus percentage for a particular withhold percentage may be calculated using the formula—Withhold % = $-0.75 (\text{Bonus \%}) + 25\%$.

(v) Capitation arrangements, if—

(A) The difference between the maximum potential payments and the minimum potential payments is more than 25 percent of the maximum potential payments;

(B) The maximum and minimum potential payments are not clearly explained in the contract with the physician or physician group.

(vi) Any other incentive arrangements that have the potential to hold a physician or physician group liable for more than 25 percent of potential payments.

(e) *Prohibition for private MA fee-for-service plans.* An MA fee-for-service plan may not operate a physician incentive plan.

(f) *Stop-loss protection requirements*—

(1) *Basic rule.* The MA organization must assure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection in accordance with the following requirements:

(2) *Specific requirements.* (i) Aggregate stop-loss protection must cover 90 percent of the costs of referral services that exceed 25 percent of potential payments.

(ii) For per-patient stop-loss protection if the stop-loss protection provided is on a per-patient basis, the stop-loss limit (deductible) per patient must be determined based on the size

of the patient panel and may be a combined policy or consist of separate policies for professional services and institutional services. In determining patient panel size, the patients may be pooled in accordance with paragraph (g) of this section.

(iii)(A) Stop-loss protection must cover at least 90 percent of costs of referral services above the deductible or an actuarial equivalent amount of the costs of referral services that exceed the per-patient deductible limit. The single combined deductible for the required stop-loss protection for the various panel sizes for contract years beginning on or after January 1, 2019 is determined using the Combined Stop-Loss Insurance Deductible Table (Table PIP-1). For panel sizes not shown on Table PIP-1 and for values not shown on Table PIP-2, linear interpolation (between the table values) may be used to identify the maximum deductible(s) for the required stop-loss coverage. Tables PIP-1 and PIP-2 apply to only multi-specialty physician groups in global capitation arrangements with per-patient stop-loss insurance. For all other physician incentive plan arrangements, the MA organization must assure that the physician or physician group entering into the physician incentive plan arrangement is covered by actuarially equivalent stop-loss protection that meets the requirements of this regulation.

(B) Using Table PIP-1, the deductible is identified for the panel size that is the number of risk patients plus non-risk patient equivalents. Non-risk patient equivalents may add a maximum of \$100,000 to the deductible. The deductible for the stop-loss insurance required to be provided for the physician or physician group is then based on the lesser of:

(1) The deductible for the risk patient panel size plus \$100,000; and

(2) The deductible for the panel size that is the total of the number of risk patients plus non-risk patient equivalents.

(iv) Table 1 is developed and updated by CMS using the methodology in this paragraph. CMS publishes Table PIP-1 in guidance (such as an attachment to the Rate Announcement issued under section 1853(b) of the Act) in advance of

the bid due date for the upcoming year if CMS determines that an update would be prudent for that year.

(A) The stop-loss tables are calculated using claims data for a statistically valid sample of beneficiaries enrolled in Fee-for-Service Medicare Parts A and B from the most available recent year. The sample includes only claims for beneficiaries eligible for both Part A and Part B for whom Medicare is the primary insurer and excludes hospice claims. The estimate of medical group income is derived from payments for all Part A and Part B services (excluding hospice) in the sampled claims data (to emulate a multi-specialty practice). The central limit theorem is used to obtain the distribution of claim means for a multi-specialty group of any given panel size. The distribution of claim means is used to obtain, with 98 percent confidence, the point at which a multi-specialty group of a given panel size would, through referral services, lose no more than 25 percent of potential payments. This point is the deductible in Table PIP-1 for the given panel size.

(B) The 'net benefit premium' (NBP) column in Table PIP-1 is not used for computation of combined insurance but is used to determine the separate deductibles for professional services and institutional services in the *Separate Stop-Loss Insurance Deductible Table* (Table PIP-2).

(C) The NBP is computed by dividing the total amount of stop loss claims (90 percent of claims above the deductible) for that panel size by the panel size.

(v)(A) Insurance using separate deductibles for professional and institutional claims is permissible so long as the separate deductibles for institutional services and professional services are determined using Table 2 as described in paragraph (f)(2)(vi)(B) of this section. Table PIP-2 is developed and updated by CMS using the methodology in paragraph (f)(2)(vi). CMS publishes Table PIP-2 in guidance (such as an attachment to the Rate Announcement issued under section 1853(b) of the Act) in advance of the bid due date for the upcoming year if CMS determines that an update would be prudent for that year.

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(B) The maximum deductibles for each category of services (institutional and professional claims) are identified by using the net benefit premium (NBP) determined in Table PIP-1 as the starting point in Table PIP-2. Any combination of institutional and professional attachment points for which the NBP in Table PIP-2 is greater than the NBP determined in Table PIP-1 is permissible. Interpolation may be used to find the NBP values in Table PIP-2 that are closest to the NBP identified in Table PIP-1.

(vi) Table PIP-2 is developed using a methodology similar to that for Table PIP-1.

(A) Claims data are obtained as described in paragraph (f)(2)(iv)(A).

(B) Professional and institutional claims are defined and categorized based on industry standards and based on payments for Part A and Part B services.

(C) The central limit theorem is used to obtain the distribution of claim means and deductibles are obtained at the 98 percent confidence level.

(3) *Special insurance.* If there is a different type of stop-loss policy obtained by the physician group, it must be actuarially equivalent to the coverage shown in Tables PIP-1 and PIP-2. Actuarially equivalent deductibles are acceptable if the insurance is actuarially certified by an attesting actuary who fulfills all of the following requirements:

(i) Develops the deductibles to be actuarially equivalent to those coverages in the Tables.

(ii) Makes the computations in accordance with generally accepted actuarial principles and practices.

(iii) Meets the qualification standards established by the American Academy of Actuaries and follow the practice standards established by the Actuarial Standards Board.

(g) *Pooling of patients.* Any entity that meets the pooling conditions of this section may pool commercial, Medicare, and Medicaid enrollees or the enrollees of several MA organizations with which a physician or physician group has contracts. The conditions for pooling are as follows:

(1) It is otherwise consistent with the relevant contracts governing the com-

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pensation arrangements for the physician or physician group.

(2) The physician or physician group is at risk for referral services with respect to each of the categories of patients being pooled.

(3) The terms of the compensation arrangements permit the physician or physician group to spread the risk across the categories of patients being pooled.

(4) The distribution of payments to physicians from the risk pool is not calculated separately by patient category.

(5) The terms of the risk borne by the physician or physician group are comparable for all categories of patients being pooled.

(h) *Sanctions.* An MA organization that fails to comply with the requirements of this section is subject to intermediate sanctions under subpart O of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 4724, Jan. 28, 2005; 70 FR 52026, Sept. 1, 2005; 83 FR 16731, Apr. 16, 2018; 83 FR 27914, June 15, 2018]

§ 422.210 Assurances to CMS.

(a) Assurances to CMS. Each organization will provide assurance satisfactory to the Secretary that the requirements of § 422.208 are met.

(b) Disclosure to Medicare Beneficiaries. Each MA organization must provide the following information to any Medicare beneficiary who requests it:

(1) Whether the MA organization uses a physician incentive plan that affects the use of referral services.

(2) The type of incentive arrangement.

(3) Whether stop-loss protection is provided.

[70 FR 52026, Sept. 1, 2005]

§ 422.212 Limitations on provider indemnification.

An MA organization may not contract or otherwise provide, directly or indirectly, for any of the following individuals, organizations, or entities to indemnify the organization against any civil liability for damage caused to an enrollee as a result of the MA organization's denial of medically necessary care:

(a) A physician or health care professional.

(b) Provider of services.

(c) Other entity providing health care services.

(d) Group of such professionals, providers, or entities.

§ 422.214 Special rules for services furnished by noncontract providers.

(a) *Services furnished by non-section 1861(u) providers.* (1) Any provider (other than a provider of services as defined in section 1861(u) of the Act) that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts that the provider could collect if the beneficiary were enrolled in original Medicare.

(2) Any statutory provisions (including penalty provisions) that apply to payment for services furnished to a beneficiary not enrolled in an MA plan also apply to the payment described in paragraph (a)(1) of this section.

(b) *Services furnished by section 1861(u) providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA coordinated care plan, an MSA plan, or an MA private fee-for-service plan must accept, as payment in full, the amounts (less any payments under §§ 412.105(g) and 413.76 of this chapter) that it could collect if the beneficiary were enrolled in original Medicare. (Section 412.105(g) concerns indirect medical education payment to hospitals for managed care enrollees. Section 413.76 concerns calculating payment for direct medical education costs.)

(c) *Deemed request for Medicare payment rate.* A noncontract section 1861(u) of the Act provider of services that furnishes services to MA enrollees and submits the same information that it would submit for payment under Original Medicare is deemed to be seeking to be paid the amount it would be paid under Original Medicare unless the provider expressly notifies the MA organi-

zation in writing that it is billing an amount less than such amount.

(d) *Regional PPO payments in non-network areas.* An MA Regional PPO must pay non-contract providers the Original Medicare payment rate in those portions of its service area where it is providing access to services by non-network means under § 422.111(b)(3)(ii) of this part.

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 4724, Jan. 28, 2005; 70 FR 47490, Aug. 12, 2005; 76 FR 21564, Apr. 15, 2011]

§ 422.216 Special rules for MA private fee-for-service plans.

(a) *Payment to providers—(1) Payment rate.* (i) The MA organization must establish payment rates for plan covered items and services that apply to deemed providers. The MA organization may vary payment rates for providers in accordance with § 422.4(a)(3).

(ii) Providers must be reimbursed on a fee-for-service basis.

(iii) The MA organization must make information on its payment rates available to providers that furnish services that may be covered under the MA private fee-for-service plan.

(2) *Noncontract providers.* The organization pays for services of noncontract providers in accordance with § 422.100(b)(2).

(3) *Services furnished by providers of service.* Any provider of services as defined in section 1861(u) of the Act that does not have in effect a contract establishing payment amounts for services furnished to a beneficiary enrolled in an MA private fee-for-service plan must receive, and accept as payment in full, at least the amount (less any payments under §§ 412.105(g) and 413.76 of this chapter) that it could collect if the beneficiary were enrolled in original Medicare.

(b) *Charges to enrollees—(1) Contract providers* (i) Contract providers and “deemed” contract providers may charge enrollees no more than the cost-sharing and, subject to the limit in paragraph (b)(1)(ii) of this section, balance billing amounts that are permitted under the plan, and these amounts must be the same for “deemed” contract providers as for

those that have signed contracts in effect, unless access requirements with respect to a particular category of health care providers are met solely through § 422.114(a)(2)(ii) and the MA organization imposes higher beneficiary copayments as permitted under § 422.114(c).

(ii) The organization may permit balance billing no greater than 15 percent of the payment rate established under paragraph (a)(1) of this section.

(iii) The MA organization must specify the amount of cost-sharing and balance billing in its contracts with providers and these amounts must be the same for “deemed” contract providers as for those that have signed contracts in effect, unless access requirements with respect to a particular category of health care providers are met solely through § 422.114(a)(2)(ii) and the MA organization imposes higher beneficiary copayments as permitted under § 422.114(c).

(iv) The MA organization is subject to intermediate sanctions under § 422.752(a)(7), under the rules in subpart O of this part, if it fails to enforce the limit specified in paragraph (b)(1)(i) of this section.

(2) *Noncontract providers.* A noncontract provider may not collect from an enrollee more than the cost-sharing established by the MA private fee-for-service plan as specified in § 422.256(b)(3), unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter.

(c) *Enforcement of limit—(1) Contract providers.* An MA organization that offers an MA fee-for-service plan must enforce the limit specified in paragraph (b)(1) of this section.

(2) *Noncontract providers.* An MA organization that offers an MA private fee-for-service plan must monitor the amount collected by noncontract providers to ensure that those amounts do not exceed the amounts permitted to be collected under paragraph (b)(2) of this section, unless the provider has opted out of Medicare as described in part 405, subpart D of this chapter. The MA organization must develop and document violations specified in instructions and must forward documented cases to CMS.

(d) *Information on enrollee liability—(1) General information.* An MA organization that offers an MA private fee-for-service plan must provide to plan enrollees, an appropriate explanation of benefits consistent with the requirements of § 422.111(b)(12).

(2) *Advance notice for hospital services.* In its terms and conditions of payment to hospitals, the MA organization must require the hospital, if it imposes balance billing, to provide to the enrollee, before furnishing any services for which balance billing could amount to not less than \$500—

(i) Notice that balance billing is permitted for those services;

(ii) A good faith estimate of the likely amount of balance billing, based on the enrollees presenting condition; and

(iii) The amount of any deductible, coinsurance, and copayment that may be due in addition to the balance billing amount.

(e) *Coverage determinations.* The MA organization must make coverage determinations in accordance with subpart M of this part.

(f) *Rules describing deemed contract providers.* Any provider furnishing health services, except for emergency services furnished in a hospital pursuant to § 489.24 of this chapter, to an enrollee in an MA private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, is treated as having a contract in effect and is subject to the limitations of this section that apply to contract providers if the following conditions are met:

(1) The services are covered under the plan and are furnished—

(i) To an enrollee of an MA fee-for-service plan; and

(ii) Provided by a provider including a provider of services (as defined in section 1861(u) of the Act) that does not have in effect a signed contract with the MA organization.

(2) Before furnishing the services, the provider—

(i) Was informed of the individual’s enrollment in the plan; and

(ii) Was informed (or given a reasonable opportunity to obtain information) about the terms and conditions of

payment under the plan, including the information described in § 422.202(a)(1).

(3) The information was provided in a manner that was reasonably designed to effect informed agreement and met the requirements of paragraphs (g) and (h) of this section.

(g) *Enrollment information.* Enrollment information was provided by one of the following methods or a similar method:

(1) Presentation of an enrollment card or other document attesting to enrollment.

(2) Notice of enrollment from CMS, a Medicare intermediary or carrier, or the MA organization itself.

(h) *Information on payment terms and conditions.* Information on payment terms and conditions was made available through either of the following methods:

(1) The MA organization used postal service, electronic mail, FAX, or telephone to communicate the information to one of the following:

(i) The provider.

(ii) The employer or billing agent of the provider.

(iii) A partnership of which the provider is a member.

(iv) Any party to which the provider makes assignment or reassigns benefits.

(2) The MA organization has in effect a procedure under which—

(i) Any provider furnishing services to an enrollee in an MA private fee-for-service plan, and who has not previously entered into a contract or agreement to furnish services under the plan, can receive instructions on how to request the payment information;

(ii) The organization responds to the request before the entity furnishes the service; and

(iii) The information the organization provides includes the following:

(A) Billing procedures.

(B) The amount the organization will pay towards the service.

(C) The amount the provider is permitted to collect from the enrollee.

(D) The information described in § 422.202(a)(1).

(3) Announcements in newspapers, journals, or magazines or on radio or television are not considered commu-

nication of the terms and conditions of payment.

(i) *Provider credential requirements.* Contracts with providers must provide that, in order to be paid to provide services to plan enrollees, providers must meet the requirements specified in §§ 422.204(b)(1)(i) and (b)(3).

[63 FR 35085, June 26, 1998, as amended at 65 FR 40325, June 29, 2000; 70 FR 52056, Sept. 1, 2005; 70 FR 47490, Aug. 12, 2005; 70 FR 76197, Dec. 23, 2005; 73 FR 54250, Sept. 18, 2008; 77 FR 22167, Apr. 12, 2012]

§ 422.220 Exclusion of payment for basic benefits furnished under a private contract.

(a) Unless otherwise authorized in paragraph (b) or (c) of this section, an MA organization may not pay, directly or indirectly, on any basis, for basic benefits furnished to a Medicare enrollee by a physician (as defined in paragraphs (1), (2), (3), and (4) of section 1861(r) of the Act) or other practitioner (as defined in section 1842(b)(18)(C) of the Act) who has filed with the Medicare contractor an affidavit promising to furnish Medicare-covered services to Medicare beneficiaries only through private contracts under section 1802(b) of the Act with the beneficiaries.

(b) An MA organization must pay for emergency or urgently needed services furnished by a physician or practitioner described in paragraph (a) of this section who has not signed a private contract with the beneficiary.

(c) An MA organization may make payment to a physician or practitioner described in paragraph (a) of this section for services that are not basic benefits but are provided to a beneficiary as a supplemental benefit consistent with § 422.102.

[86 FR 6098, Jan. 19, 2021]

§ 422.222 Preclusion list for contracted and non-contracted individuals and entities.

(a)(1)(i) Except as provided in paragraph (a)(1)(ii) of this section, an MA organization must not make payment for a health care item, service, or drug that is furnished, ordered, or prescribed by an individual or entity that is included on the preclusion list, defined in § 422.2.

(ii) With respect to MA providers that have been added to an updated preclusion list but are not currently excluded by the OIG, the MA organization must do all of the following:

(A) No later than 30 days after the posting of this updated preclusion list, must provide an advance written notice to any beneficiary who has received or been prescribed an MA service, item, or drug from or by the individual or entity added to the preclusion list in this update.

(B)(1) Subject to paragraph (a)(1)(ii)(B)(2) of this section, must ensure that reasonable efforts are made to notify the individual or entity described in paragraph (a)(1)(ii) of this section of a beneficiary who was sent a notice under paragraph (a)(1)(ii)(A) of this section.

(2) Paragraph (a)(1)(ii)(B)(1) of this section applies only upon receipt of a claim from a precluded provider in Medicare Part C when—

(i) The MA organization has enough information on file to either copy the provider on the notification previously sent to the beneficiary or send a new notice informing the provider that they may not see plan beneficiaries due to their preclusion status; and

(ii) The claim is received after the claim denial or reject date in the preclusion file.

(C) Must not deny payment for a service, item, or drug furnished, ordered, or prescribed by the newly added individual or entity, solely on the ground that they have been included in the updated preclusion list, in the 60-day period after the date it sent the notice described in paragraph (a)(1)(ii)(A) of this section.

(2)(i) CMS sends written notice to the individual or entity via letter of their inclusion on the preclusion list. The notice must contain the reason for the inclusion and inform the individual or entity of their appeal rights. An individual or entity may appeal their inclusion on the preclusion list, defined in § 422.2, in accordance with part 498 of this chapter.

(ii) If the individual's or entity's inclusion on the preclusion list is based on a contemporaneous Medicare revocation under § 424.535 of this chapter:

(A) The notice described in paragraph (a)(2)(i) of this section must also include notice of the revocation, the reason(s) for the revocation, and a description of the individual's or entity's appeal rights concerning the revocation.

(B) The appeals of the individual's or entity's inclusion on the preclusion list and the individual's or entity's revocation must be filed jointly by the individual or entity and, as applicable, considered jointly under part 498 of this chapter.

(3)(i) Except as provided in paragraph (a)(3)(ii) of this section, an individual or entity will only be included on the preclusion list after the expiration of either of the following:

(A) If the individual or entity does not file a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list upon the expiration of the 60-day period in which the individual or entity may request a reconsideration; or

(B) If the individual or entity files a reconsideration request under § 498.5(n)(1) of this chapter, the individual or entity will be added to the preclusion list effective on the date on which CMS, if applicable, denies the individual's or entity's reconsideration.

(ii) An OIG excluded individual or entity is added to the preclusion list effective on the date of the exclusion.

(4) Payment denials based upon an individual's or entity's inclusion on the preclusion list are not appealable by beneficiaries.

(5)(i) Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is revoked under § 424.535 of this chapter will be included on the preclusion list for the same length of time as the individual's or entity's reenrollment bar.

(ii) Except as provided in paragraphs (a)(5)(iii) and (iv) of this section, an individual or entity that is not enrolled in Medicare will be included on the preclusion list for the same length of time as the reenrollment bar that CMS could have imposed on the individual or entity had they been enrolled and then revoked.

(iii) Except as provided in paragraph (a)(5)(iv) of this section, an individual or entity, regardless of whether they

are or were enrolled in Medicare, that is included on the preclusion list because of a felony conviction will remain on the preclusion list for a 10-year period, beginning on the date of the felony conviction, unless CMS determines that a shorter length of time is warranted. Factors that CMS considers in making such a determination are as follows:—

(A) The severity of the offense.

(B) When the offense occurred.

(C) Any other information that CMS deems relevant to its determination.

(iv) In cases where an individual or entity is excluded by the OIG, the individual or entity must remain on the preclusion list until the expiration of the CMS-imposed preclusion list period or reinstatement by the OIG, whichever occurs later.

(6) CMS has the discretion not to include a particular individual or entity on (or if warranted, remove the individual or entity from) the preclusion list should it determine that exceptional circumstances exist regarding beneficiary access to MA items, services, or drugs. In making a determination as to whether such circumstances exist, CMS takes into account:

(i) The degree to which beneficiary access to MA items, services, or drugs would be impaired; and

(ii) Any other evidence that CMS deems relevant to its determination.

(b) An MA organization that does not comply with paragraph (a) of this section may be subject to sanctions under § 422.750 and termination under § 422.510.

[83 FR 16733, Apr. 16, 2018, as amended at 84 FR 15831, Apr. 16, 2019]

§ 422.224 Payment to individuals and entities excluded by the OIG or included on the preclusion list.

(a) An MA organization may not pay, directly or indirectly, on any basis, for items or services furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG) or is included on the preclusion list, defined in § 422.2.

(b) If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or an individual or entity that is included on the preclusion list, defined in § 422.2, the MA organization

must notify the enrollee and the excluded individual or entity or the individual or entity included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.

[83 FR 16733, Apr. 16, 2018]

Subpart F—Submission of Bids, Premiums, and Related Information and Plan Approval

SOURCE: 70 FR 4725, Jan. 28, 2005, unless otherwise noted.

§ 422.250 Basis and scope.

This subpart is based largely on section 1854 of the Act, but also includes provisions from sections 1853 and 1858 of the Act, and is also based on section 1106 of the Act. It sets forth the requirements for the Medicare Advantage bidding payment methodology, including CMS' calculation of benchmarks, submission of plan bids by Medicare Advantage (MA) organizations, establishment of beneficiary premiums and rebates through comparison of plan bids and benchmarks, negotiation and approval of bids by CMS, and the release of MA bid submission data.

[81 FR 80556, Nov. 15, 2016]

§ 422.252 Terminology.

Annual MA capitation rate means a county payment rate for an MA local area (county) for a calendar year. The terms “per capita rate” and “capitation rate” are used interchangeably to refer to the annual MA capitation rate.

Low enrollment contract means a contract that could not undertake Healthcare Effectiveness Data and Information Set (HEDIS) and Health Outcome Survey (HOS) data collections because of a lack of a sufficient number of enrollees to reliably measure the performance of the health plan.

MA local area means a payment area consisting of county or equivalent area specified by CMS.

MA monthly basic beneficiary premium means the premium amount (if any) an MA plan (except an MSA plan) charges