

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 § 422.80 (concerning approval of marketing materials and election forms) and with § 422.111.

(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]

§ 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.

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.

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 greater 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 (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 finan-

cial 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) Stop-loss protection must cover 90 percent of the costs of referral services that exceed the per patient deductible limit. The per-patient stop-loss deductible limits are as follows:

Panel size	Single combined deductible	Separate institutional deductible	Separate professional deductible
1–1,000	\$6,000	\$10,000	\$3,000
1,001–5,000	30,000	40,000	10,000
5,001–8,000	40,000	60,000	15,000
8,001–10,000	75,000	100,000	20,000
10,001–25,000	150,000	200,000	25,000
>25,000	(¹)	(¹)	(¹)

¹ None.

(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 compensation 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]

§ 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