

§ 417.476 Waived conditions.

If CMS waives any of the qualifying conditions required under subpart J of this part, the contract must specify the following information for each waived condition:

- (a) The specific terms of the waiver.
- (b) The expiration date of the waiver.
- (c) Any other information required by CMS.

[60 FR 45680, Sept. 1, 1995]

§ 417.478 Requirements of other laws and regulations.

The contract must provide that the HMO or CMP agrees to comply with—

- (a) The requirements for QIO review of services furnished to Medicare enrollees as set forth in subchapter D of this chapter;
- (b) Sections 1318(a) and (c) of the PHS Act, which pertain to disclosure of certain financial information;
- (c) Section 1301(c)(8) of the PHS Act, which relates to liability arrangements to protect enrollees of the HMO or CMP; and
- (d) The reporting requirements in § 417.126(a), which pertain to the monitoring of an HMO's or CMP's continued compliance.

[50 FR 1346, Jan. 10, 1985; 50 FR 20570, May 17, 1985, as amended at 56 FR 8853, Mar. 1, 1991; 58 FR 38079, 38082, July 15, 1993]

§ 417.479 Requirements for physician incentive plans.

(a) The contract must specify that an HMO or CMP may operate a physician incentive plan only if—

- (1) No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to an individual enrollee; and

(2) The stop-loss protection, enrollee survey, and disclosure requirements of this section are met.

(b) *Applicability.* The requirements in this section apply to physician incentive plans between HMOs and CMP and individual physicians or physician groups with which they contract to provide medical services to enrollees. The requirements in this section also apply to subcontracting arrangements as specified in § 417.479(i). These re-

quirements apply only to physician incentive plans that base compensation (in whole or in part) on the use or cost of services furnished to Medicare beneficiaries or Medicaid beneficiaries.

(c) *Definitions.* For purposes of this section:

Bonus means a payment an HMO or CMP makes 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) that an organization pays 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.

Payments means any amounts the HMO or CMP pays physicians or physician groups for services they furnish directly, plus amounts paid for administration and amounts paid (in whole or in part) based on use and costs of referral services (such as withhold amounts, bonuses based on referral levels, and any other compensation to the physician or physician group to influence the use of referral services). Bonuses and other compensation that are not based on referral levels (such as bonuses based solely on quality of care furnished, patient satisfaction, and participation on committees) are not considered payments for purposes of this section.

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

Physician incentive plan means any compensation arrangement between an HMO or CMP and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished to Medicare beneficiaries or Medicaid beneficiaries enrolled in the HMO or CMP.

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.

Withhold means a percentage of payments or set dollar amounts that an HMO or CMP deducts 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.

(d) *Prohibited physician payments.* No specific payment of any kind may be made directly or indirectly under the incentive plan to a physician or physician group as an inducement to reduce or limit covered medically necessary services covered under the HMO's or CMP's contract furnished to an individual enrollee. Indirect payments include offerings of monetary value (such as stock options or waivers of debt) measured in the present or future.

(e) *General rule: Determination of substantial financial risk.* Substantial financial risk occurs when the incentive arrangements place the physician or physician group at risk for amounts beyond the risk threshold, if the risk is based on the use or costs of referral services. Amounts at risk based solely on factors other than a physician's or physician group's referral levels do not contribute to the determination of substantial financial risk. The risk threshold is 25 percent.

(f) *Arrangements that cause substantial financial risk.* For purposes of this paragraph, *potential payments* means the maximum anticipated total payments (based on the most recent year's utilization and experience and any current or anticipated factors that may affect payment amounts) that could be received if use or costs of referral services were low enough. The following physician incentive plans cause substantial financial risk if risk is based (in whole or in part) on use or costs of referral services and the patient panel size is not greater than 25,000 patients:

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

(2) 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.

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

(4) 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%.

(5) Capitation, arrangements, if—

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

(ii) The maximum and minimum potential payments are not clearly explained in the physician's or physician group's contract.

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

(g) *Requirements for physician incentive plans that place physicians at substantial financial risk.* HMOs and CMPs that operate incentive plans that place physicians or physician groups at substantial financial risk must do the following:

(1) Conduct enrollee surveys. These surveys must—

(i) Include either all current Medicare/Medicaid enrollees in the HMO or CMP and those who have disenrolled (other than because of loss of eligibility in Medicaid or relocation outside the HMO's or CMP's service area) in the past 12 months, or a sample of these same enrollees and disenrollees;

(ii) Be designed, implemented, and analyzed in accordance with commonly accepted principles of survey design and statistical analysis;

(iii) Address enrollees/disenrollees satisfaction with the quality of the services provided and their degree of access to the services; and

(iv) Be conducted no later than 1 year after the effective date of the Medicare contract and at least annually thereafter.

(2) Ensure 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:

(i) If aggregate stop-loss protection is provided, it must cover 90 percent of the costs of referral services (beyond allocated amounts) that exceed 25 percent of potential payments.

(ii) If the stop-loss protection provided is based on a per-patient limit, the stop-loss limit per patient must be determined based on the size of the patient panel and may be a single combined limit or consist of separate limits for professional services and institutional services. In determining patient panel size, the patients may be pooled in accordance with paragraph (h)(2) of this section. Stop-loss protection must cover 90 percent of the costs of referral services that exceed the per patient limit. The per-patient stop-loss limit is as follows:

| Panel size | Single combined limit | Separate institutional limit | Separate professional limit |
|---------------------|-----------------------|------------------------------|-----------------------------|
| 1-1000 | \$6,000 | \$10,000 | \$3,000 |
| 1,001-5000 | 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 | none | none | none |

(h) *Disclosure and other requirements for organizations with physician incentive plans*—(1) *Disclosure to CMS.* Each health maintenance organization or competitive medical plan must provide to CMS information concerning its physician incentive plans as requested.

(2) *Pooling of patients.* Pooling of patients is permitted only if—

(i) It is otherwise consistent with the relevant contracts governing the compensation arrangements for the physician or physician group;

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

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

(iv) The distribution of payments to physicians from the risk pool is not

calculated separately by patient category; and

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

(3) *Disclosure to Medicare beneficiaries.* Each health maintenance organization or competitive medical plan must provide the following information to any Medicare beneficiary who requests it:

(i) Whether the prepaid plan uses a physician incentive plan that affects the use of referral services.

(ii) The type of incentive arrangement.

(iii) Whether stop-loss protection is provided.

(iv) If the prepaid plan was required to conduct a survey, a summary of the survey results.

(i) *Requirements related to subcontracting arrangements*—(1) *Physician groups.* An HMO or CMP that contracts with a physician group that places the individual physician members at substantial financial risk for services they do not furnish must do the following:

(i) Disclose to CMS any incentive plan between the physician group and its individual physicians that bases compensation to the physician on the use or cost of services furnished to Medicare beneficiaries or Medicaid beneficiaries. The disclosure must include the information specified in paragraphs (h)(1)(i) through (h)(1)(vii) of this section and be made at the times specified in paragraph (h)(2) of this section.

(ii) Provide adequate stop-loss protection to the individual physicians.

(iii) Conduct enrollee surveys as specified in paragraph (g)(1) of this section.

(2) *Intermediate entities.* An HMO or CMP that contracts with an entity (other than a physician group) for the provision of services to Medicare beneficiaries must do the following:

(i) Disclose to CMS any incentive plan between the entity and a physician or physician group that bases compensation to the physician or physician group on the use or cost of services furnished to Medicare beneficiaries or Medicaid beneficiaries. The disclosure must include the information required to be disclosed under paragraphs

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(h)(1)(i) through (h)(1)(vii) of this section and be made at the times specified in paragraph (h)(2) of this section.

(ii) If the physician incentive plan puts a physician or physician group at substantial financial risk for the cost of services the physician or physician group does not furnish—

(A) Meet the stop-loss protection requirements of this subpart; and

(B) Conduct enrollee surveys as specified in paragraph (g)(1) of this section.

(3) For purposes of paragraph (i)(2) of this section, an entity includes, but is not limited to, an individual practice association that contracts with one or more physician groups and a physician hospital organization.

(j) *Sanctions against the HMO or CMP.* CMS may apply intermediate sanctions, or the Office of Inspector General may apply civil money penalties described at § 417.500, if CMS determines that an HMO or CMP fails to comply with the requirements of this section.

[61 FR 13446, Mar. 27, 1996; 61 FR 46385, Sept. 3, 1996, as amended at 61 FR 69049, Dec. 31, 1996; 68 FR 50855, Aug. 22, 2003]

§ 417.480 Maintenance of records: Cost HMOs and CMPs.

A reasonable cost contract must provide that the HMO or CMP agrees to maintain books, records, documents, and other evidence of accounting procedures and practices that—

(a) Are sufficient to—

(1) Ensure an audit trail; and

(2) Properly reflect all direct and indirect costs claimed to have been incurred under the contract; and

(b) Include at least records of the following:

(1) Ownership, HMO or CMP, and operation of the HMO's or CMP's financial, medical, and other recordkeeping systems.

(2) Financial statements for the current contract period and three prior periods.

(3) Federal income tax or information returns for the current contract period and three prior periods.

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

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

(6) Franchise, marketing, and management agreements.

(7) Schedules of charges for the HMO's or CMP's fee-for-service patients.

(8) Matters pertaining to costs of operations.

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

(10) Cash flow statements.

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

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45680, Sept. 1, 1995]

§ 417.481 Maintenance of records: Risk HMOs and CMPs.

A risk contract must provide that the HMO or CMP agrees to maintain and make available to CMS upon request, books, records, documents, and other evidence of accounting procedures and practices that—

(a) Are sufficient to—

(1) Establish component rates of the ACR for determining additional and supplementary benefits; and

(2) Determine the rates utilized in setting premiums for State insurance agency purposes; and

(b) Include at least any records or financial reports filed with other Federal agencies or State authorities.

[50 FR 1346, Jan. 10, 1985, as amended at 58 FR 38082, July 15, 1993; 60 FR 45680, Sept. 1, 1995]

§ 417.482 Access to facilities and records.

The contract must provide that the HMO or CMP agrees to the following:

(a) HHS may evaluate, through inspection or other means, the quality, appropriateness, and timeliness of services furnished under the contract to its Medicare enrollees.

(b) HHS may evaluate, through inspection or other means, the facilities of the HMO or CMP when there is reasonable evidence of some need for that inspection.

(c) HHS, the Comptroller General, or their designees may audit or inspect any books and records of the HMO or CMP or its transferee that pertain to any aspect of services performed, reconciliation of benefit liabilities, and