residues of the herbicide 2,4-D (2,4-dichlorophenoxyacetic acid) resulting from the preplant use of 2,4-D ester or amine in or on the raw agricultural commodity as follows:

Commodity	Parts per million
Soybeans	0.1

[FR Doc. 96–7449 Filed 3–26–96; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 417 and 434

Office of Inspector General

42 CFR Part 1003

[OMC–010–FC]

RIN 0938–AF74

Medicare and Medicaid Programs; Requirements for Physician Incentive Plans in Prepaid Health Care Organizations

AGENCY: Health Care Financing Administration (HCFA), HHS. Office of Inspector General (OIG), HHS.

ACTION: Final rule with comment period.

SUMMARY: This final rule amends the regulations governing Federally-qualified health maintenance organizations and competitive medical plans contracting with the Medicare program, and certain health maintenance organizations and health insuring organizations contracting with the Medicaid program. It implements requirements in sections 4204(a) and 4731 of the Omnibus Budget Reconciliation Act of 1990 that concern physician incentive plans.

The provisions of this final rule will also have an effect on certain entities subject to the physician referral rules in section 1877 of the Social Security Act (the Act) as amended by the Omnibus Budget Reconciliation Act of 1993 (OBRA '93). Section 1877 provides that, if a physician (or an immediate family member of the physician) has a financial relationship with certain entities (that is, has an ownership or investment interest in the entity or a compensation arrangement with the entity), the physician may not make a referral to the entity for the furnishing of certain health services for which payment otherwise may be made under the Medicare program. Additionally, effective December 31, 1994, section 1903(s) of the Act provides for denial of Federal financial participation payment under the Medicaid program to a State for expenditures for certain health services furnished to an individual on the basis of a physician referral that would result in denial of payment under the Medicare program if Medicare covered the services in the same manner as they are covered under the State plan.

Among other amendments, section 13562 of OBRA '93 sets forth an exception to the physician referral prohibition that, in effect, incorporates the provisions of this final rule. That is, it provides that, under certain circumstances, compensation received under a personal services arrangement that meets the physician incentive plan requirements established by the Secretary does not trigger the ban on referrals. Thus, the provisions of this final rule have implications for entities that would not have been affected at the time we published the proposed rule (December 14, 1992). (The proposed rule applied to only prepaid health plans that contract with Medicare or Medicaid under section 1876 or 1903(m) of the Act, respectively.) OBRA '93 applies the requirements to any prepaid health care organization that bills Medicare or Medicaid. The additional organizations that may be affected include preferred provider organizations, health maintenance organizations that do not contract with Medicare or Medicaid and are not Federally qualified, prepaid health plans that contract with Medicaid, and some States that contract with managed care organizations under the Medicaid program (including those that operate under a section 1115 waiver).

DATES: *Effective dates.* These regulations are effective on April 26, 1996.

Comment dates. To be considered, comments must be mailed or delivered to the appropriate address, as provided below and must be received by 5 p.m. on May 28, 1996.

Compliance dates. Affected organizations with contracts or agreements on March 27, 1996 must comply with (1) the applicable disclosure requirements at § 417.479(h)(1)(i) through (h)(1)(v) or with § 434.70(a)(3) of this rule by May 28, 1996 or by the renewal date of the contract or agreement, whichever is later, and (2) the survey requirement at § 417.479(g)(1)(iv) and the disclosure requirement at § 417.479(h)(1)(vi) by March 27, 1997. Affected organizations must comply with all other requirements by May 28, 1996.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: OMC–010–FC, P.O. Box 26688, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, or

Room C5–09–26, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code OMC–010–FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Medicare: Tony Hausner, (410) 786–1093. Medicaid: Beth Sullivan, (410) 786–4596. Office of Inspector General: Joel Schaer, (202) 619–0089.

SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

Prepaid health care organizations, such as health maintenance organizations (HMOs), competitive medical plans (CMPs), and health insuring organizations (HIOs), are entities that provide enrollees with comprehensive, coordinated health care in a cost-efficient manner. The goal of prepaid health care delivery is to control health care costs through preventive care and case management and provide enrollees with affordable, coordinated, quality health care services. Titles XVIII and XIX of the Social Security Act (the Act) authorize contracts with prepaid health care organizations (hereinafter referred to as ''organizations'' or ''prepaid plans'') for the provision of covered health services to Medicare beneficiaries and Medicaid recipients, respectively. Such organizations may contract under either a risk-based or cost-reimbursed contract.

B. Medicare

Section 1876 of the Act authorizes the Secretary to enter into contracts with eligible organizations (HMOs that have been Federally qualified under section 1310(d) of the Public Health Service Act and CMPs that meet the requirements of section 1876(b)(2) of the Act) to provide Medicare-covered services to beneficiaries and specifies the requirements the organizations must meet. Section 1876 of the Act also provides for Medicare payment at predetermined rates to eligible organizations that have entered into risk-based contracts under Medicare or for Medicare payment of reasonable costs to eligible organizations that have entered into cost-reimbursed contracts under Medicare. Implementing Federal regulations for the organization and operation of Medicare prepaid health care organizations, contract requirements, and conditions for payment are located at 42 CFR 417.400 through 417.694.

Risk-based organizations are paid a prospectively-determined per capita monthly payment for each Medicare beneficiary enrolled in the organization. This capitated payment is the projected actuarial equivalence of 95 percent of what Medicare would have paid if the beneficiaries had received services from fee-for-service providers or suppliers. Organizations paid on a risk basis are liable for any difference between the Medicare prepaid amounts and the actual costs they incur in furnishing services, and they are therefore ''at risk.''

Cost-reimbursed organizations are paid monthly interim per capita payments that are based on a budget. Later, a retrospective cost settlement occurs to reflect the reasonable costs actually incurred by the organization for the covered services it furnished to its Medicare enrollees.

C. Medicaid

Section 1903(m) of the Act specifies requirements that must be met for States to receive Federal financial participation (FFP) for their contracts with organizations (HMOs or HIOs) to furnish, either directly or through arrangements, specific arrays of services on a risk basis. Federal implementing regulations for these contract requirements and conditions for payment are located at 42 CFR part 434.

States determine the per capita monthly rates that are to be paid to risk-based organizations. FFP is available for these payments at the matching rate applicable in the State as long as HCFA determines that: (1) The HMO or HIO rates are actuarially sound; (2) the rates do not exceed the cost of providing the same scope of services, to an actuarially equivalent nonenrolled population group, on a fee-for-service basis; and (3) the contract meets the additional requirements at 42 CFR part 434 (''Contracts'') and 45 CFR part 74 (''Administration of Grants'').

II. Legislative History

Section 9313(c) of the Omnibus Budget Reconciliation Act of 1986 (OBRA '86), Public Law 99–509, prohibited, effective April 1, 1989, hospitals and prepaid health care organizations with Medicare or Medicaid risk contracts from knowingly making incentive payments to a physician as an inducement to reduce or limit services to Medicare beneficiaries or Medicaid recipients. Under the OBRA '86 provisions, parties who knowingly made or accepted these payments would have been subject to specified civil money penalties. Additionally, the provisions required that the Secretary report on incentive arrangements in HMOs and CMPs. Section 4016 of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87), Public Law 100–203, extended the original implementation date for the OBRA '86 physician incentive provisions to April 1, 1991. Subsequently, sections 4204(a) and 4731 of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), Public Law 101–508, repealed, effective November 5, 1990, the prohibition of physician incentive plans in prepaid health care organizations and enacted requirements, effective January 1, 1992, for regulating these plans.

Specifically, section 4204(a)(1) of OBRA '90 added paragraph (8) to section 1876(i) of the Act to specify that each Medicare contract with a prepaid health care organization must stipulate that the organization must meet the following requirements if it operates a physician incentive plan:

- That it not operate a physician incentive plan that directly or indirectly makes specific payments to a physician or physician group as an inducement to limit or reduce medically necessary services to a specific individual enrolled with the organization.
- That it disclose to us its physician incentive plan arrangements in detail that is sufficient to allow us to determine whether the arrangements comply with Departmental regulations.
- That, if a physician incentive plan places a physician or physician group at ''substantial financial risk'' (as defined by the Secretary) for services not provided directly, the prepaid health care organization: (1) Provide the physician or physician group with adequate and appropriate stop-loss protections (under standards determined by the Secretary) and (2) conduct surveys of currently and previously enrolled members to assess the degree of access to services and the satisfaction with the quality of services.

Section 4204(a)(2) of OBRA '90 amended section 1876(i)(6)(A)(vi) of the Act to add violations of the above requirements to the list of violations that could subject a prepaid health care organization to intermediate sanctions and civil money penalties.

Section 4731 of OBRA '90 enacted similar provisions for the Medicaid program by amending sections 1903(m)(2)(A) and 1903(m)(5)(A) of the Act.

As noted earlier (in the ''Summary'' section), subsequent to the December 1992 publication of the proposed rule, the Omnibus Budget Reconciliation Act of 1993 (OBRA '93), Public Law 103–66, was enacted. Section 13562 of OBRA '93 amended section 1877 of the Act, which prohibits physician referrals to entities with which the physician (or an immediate family member) has a financial relationship (which can consist of either (1) an ownership or investment interest or (2) a compensation arrangement). OBRA '93 provides an exception to the section 1877 physician referral prohibition that incorporates the physician incentive plan rules implemented in this final rule. Under this exception, compliance with these physician incentive rules is one of several conditions that must be satisfied if a personal services compensation arrangement involves compensation that varies based on the volume or value of referrals.

This exception affects managed care organizations that were not specified in the December 1992 proposed rule on physician incentive plans. The proposed rule applied to only prepaid plans that contract with Medicare or Medicaid under section 1876 or 1903(m) of the Act, respectively. The OBRA '93 physician referral provisions, however, apply to any entity with an incentive plan that bills Medicare or Medicaid. The additional organizations that may be affected include preferred provider organizations, HMOs that do not contract with Medicare or Medicaid and are not Federally qualified, and prepaid health plans'' (PHPs) that contract with Medicaid. (PHPs are organizations that are exempt from section 1903(m) of the Act.) Some States that contract with managed care organizations under the Medicaid program (including those that operate under a section 1115 waiver)

may also be affected. We believe that most prepaid health care organizations will not be affected by these provisions since they apply only if (1) the physician incentive plan includes services not furnished by the physician group, and (2) there is a compensation arrangement between the physician group and the entity furnishing the services.

III. Opportunity for Public Comment

Because there may be entities that were not affected by the proposed rule at the time it was published but are now affected, we are publishing this rule as a final rule with a 60-day comment period so that these newly-affected entities have an opportunity to comment. Note also, we will incorporate the OBRA '93 amendments to section 1877 of the Act into a final rule with comment covering the physician referral prohibition as it relates to referrals for clinical laboratory services. We will also publish a proposed rule to interpret or clarify these OBRA '93 amendments as they relate to referrals for all of the health services designated in section 1877 of the Act, including clinical laboratory services. Once these rules are published, entities will have had several opportunities to comment on the interaction between the physician referral prohibition in section 1877 and the physician incentive rules.

We are also providing the 60-day comment period because we are interested in receiving comments on the changes from the proposed rule. For example, we are particularly interested in receiving comments on the thresholds we have set for determining substantial financial risk and for determining per-patient stop loss limits.

Because of the large number of items of correspondence we normally receive on a rule, we are not able to acknowledge or respond to them individually. We will, however, consider all comments that we receive by the date specified in the **DATES** section of this preamble and, if we publish a subsequent document, we will respond to the comments in that document.

IV. Discussion of Physician Incentive Plans

Effective utilization control that identifies both underutilization and overutilization is essential for the efficient operation of prepaid health care organizations. A prepaid health care organization needs to minimize overutilization of services not only to prevent unnecessary spending, but also to reduce the risk of unnecessary and intrusive procedures. Nonetheless, a prepaid health care organization also needs to ensure that all medically necessary services are furnished both to protect patient health and to avoid the need for more costly care later. Medicare and Medicaid require both cost-reimbursed and risk organizations to have internal quality assurance programs, external quality review or medical audits, and other mechanisms to ensure proper delivery of health care services. Medicare and Medicaid contracts also are subject to periodic monitoring for compliance. In addition, sections 1876(i)(6) and 1903(m)(5) of the Act provide for intermediate sanctions and civil money penalties that may be imposed if an HMO or CMP fails substantially to provide medically necessary services. (Regulations implementing this authority were published on July 15, 1994 (59 FR 36072).

One mechanism many prepaid health care organizations use to encourage proper utilization is a financial incentive as part of a physician incentive plan. OBRA '90 defines a physician incentive plan as any compensation arrangement between an eligible organization and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled in the organization.

A review and analysis of physician incentive plans in a sample of HMOs was conducted and presented in the Department's 1990 report to the Congress, ''Incentive Arrangements Offered by Health Maintenance Organizations and Competitive Medical Plans to Physicians.'' The results showed a wide variety of incentive plans. There were differences in the types of incentive payments, the distribution of incentives, the basis for determining the incentive payments, and the parties or entities the incentives affected.

Physicians in prepaid health care organizations generally receive fee-for-service payments, salary, or capitation payments (a set dollar amount per patient) for the services they furnish. Financial incentives may be used with the various types of physician payments to encourage appropriate levels of referral services. Referral services are any specialty, inpatient, outpatient, or laboratory services that a physician arranges for but does not provide directly. Prepaid health care organizations may hold physicians or physician groups at risk for all or a portion of the cost of referral services so that they have a financial incentive to arrange for the furnishing of only medically necessary services. If the physician or physician group successfully controls the levels of referral services, the physician or group may receive additional compensation (an incentive payment) from the prepaid health care organization. The incentive payment may take the form of unused capitation, a returned withhold, or a bonus payment. Each of these methods is described below.

A capitation payment is a set dollar amount per patient per month that a prepaid health care organization pays to a physician or a physician group to cover a specified set of services, without regard to the actual number of services furnished to each person. The capitation may cover the physician's own services, referral services, or all medical services and/or administrative costs. If patient costs exceed the capitation amount, the physician or physician group must absorb these additional costs. If costs are below the capitation, the physician or physician group may keep the additional money.

Withholds are percentages of payments or set dollar amounts that a prepaid health care organization deducts from each physician's or physician group's payment (salary, fees, or capitation). The amount withheld is set aside in pools to pay for specialty referral services and inpatient hospital services. If referral costs exceed a prepaid health care organization's budget, part or all of the withhold may be forfeited depending on the terms of the physician's contract. If referral costs do not exceed the ceiling, part or all of the withhold may be returned to a physician or a physician group. Some plans limit the amount of the risk to the withhold; others hold the physician or physician group liable for amounts beyond the amount withheld.

Bonuses are payments prepaid health care organizations make to a physician or a physician group beyond the physician's set salary, fee-for-service payments, or capitation. Bonuses may be based on a physician's or physician group's level of referral services or may be based on the overall performance of the organization.

If the physician or physician group has excessive referrals (as defined by the prepaid health care organization), it may not receive any incentive funds. In addition, the prepaid health care organization may hold the physician or physician group liable for referral costs that exceed a specified threshold. The prepaid health care organization may also increase the physician's or physician group's withhold or make other changes in its incentive arrangements.

Many physician incentive plans incorporate stop-loss protection to limit the liability of the physician or physician group. Most often, the stop-loss protection limits a physician's maximum liability per patient to a specific dollar amount.

Other variables may affect the amount of risk or the effect of financial incentives on physicians; for example, whether incentive payments are calculated according to each individual physician's performance or according to a physician group's performance; the size of the physician group; the length of time over which performance is evaluated; the number of enrollees; and the amount of total income at risk. In addition, the relative health status of the patients involved affects the level of risk. If because of their health status the patients served require more services than the average enrollee, the risk increases. Conversely, if they are healthier than the average enrollee, the risk may be lower.

V. Provisions of the Proposed Regulations

On December 14, 1992, we published a proposed rule (57 FR 59024) that set forth our proposal for implementing the requirements of sections 1876(i) and 1903(m) of the Act as amended, respectively, by sections 4204(a) and 4731 of OBRA '90. Sections 1876(i)(8) and 1903(m)(2)(A)(x) of the Act require that physician incentive plans be regulated, and sections 1876(i)(6)(A) and 1903(m)(5)(A) provide penalties for violation of the regulation. To implement these provisions for Medicare, we proposed to impose new contract requirements pertaining to physician incentive plans. For Medicaid, we proposed new requirements for the granting of FFP for State Medicaid agency contracts with HMOs and HIOs. The requirements address—

- The scope of the regulation;
- Disclosure requirements;
- Criteria for the determination of substantial financial risk;
- Requirements for physician incentive plans that place physicians at substantial financial risk;
- Prohibition on certain physician payments; and
- Enforcement.

Each proposed requirement is summarized individually below. Readers who desire more specifics are referred to the proposed rule.

A. Scope

Because sections 4204(a)(2) and 4731 of OBRA '90 amended sections that govern Medicare and Medicaid contracts, but did not amend title XIII of the Public Health Service Act, which governs all Federally-qualified HMOs, we proposed to apply these requirements to only physician incentive plans that base incentive payments (in whole or in part) on services provided to Medicare beneficiaries or Medicaid recipients. Nonetheless, because relevant statutory language uses the term ''individuals enrolled with the organization,'' which could be interpreted as all of an organization's enrollees, not just Medicare or Medicaid enrollees, we specifically sought comments regarding the proposed scope of the regulations.

B. Disclosure

We proposed that an HMO, CMP, or HIO disclose to HCFA (for Medicare) or to the State Medicaid agency (for Medicaid) information on physician incentive plans that affect Medicare beneficiaries or Medicaid recipients that is sufficient for us or the States to determine whether the organization is in compliance with our requirements. We also proposed when submittal of the information would be required.

C. Substantial Financial Risk

We proposed that a physician or physician group is considered to be at substantial financial risk if more than a specified percentage (the risk threshold) of the prepaid health care organization's total potential payments to the physician or physician group is at risk and the risk is based on the costs of services the physician or physician group does not provide (for example, referrals to specialists or the cost of inpatient care).

For purposes of determining substantial financial risk, we proposed to define payments as any amounts the organization pays physicians or physician groups for services they provide, plus amounts paid for administration and controlling levels or costs of referral services. We proposed that payments do not include bonuses or other forms of compensation that are not based on referral levels (such as bonuses based solely on the quality of care provided, patient satisfaction, and participation on committees).

Under our proposal, the risk threshold that determines substantial financial risk would depend on the frequency with which the health plan assesses or distributes incentive payments. We proposed that, for prepaid health care organizations that assess or distribute incentive payments no more often than annually, the risk threshold is 25 percent. The risk threshold we proposed for prepaid health care organizations that assess or distribute incentive payments more often than annually was 15 percent.

Often, prepaid health care organizations use more than one type of compensation arrangement. If more than one type of arrangement is used, we proposed to consider all the different risk arrangements placed on physicians or physician groups to determine whether they collectively exceeded either of the thresholds.

D. Requirements for Physician Incentive Plans That Place Physicians at Substantial Financial Risk

1. Enrollee Surveys

We proposed that HMOs, CMPs, and HIOs that place their physicians or physician groups at substantial financial risk must conduct enrollee surveys at least annually. We proposed that the surveys must—

- Either survey all current Medicare/Medicaid enrollees in the organization and those who have disenrolled (due to other than loss of eligibility in Medicaid) in the past 12 months, or survey a statistically valid sample of these same enrollees and disenrollees;
- Be designed, conducted, and results analyzed in accordance with commonly accepted principles of survey design and statistical analysis; and
- Address enrollees'/disenrollees' satisfaction with the quality of the services furnished and their degree of access to the services.

2. Stop-loss Protection

We proposed two levels of stop-loss protection depending on the incentive plan's risk threshold. If the risk threshold is 25 percent, the stop-loss protection must protect physicians and physician groups from losses greater than 30 percent of the payments for services they furnish, plus payments for administrative costs and controlling levels of referral services. If the risk threshold is 15 percent, the stop-loss protection must protect physicians and physician groups from losses greater than 20 percent of payments.

We proposed that the organization may provide the stop-loss protection directly or purchase it, or the physician or physician group may purchase it.

E. Prohibited Physician Payments

We proposed language reflecting section 1876(i)(8)(A)(i) of the Act, which provides that physician incentive plans may operate only if no specific payment is made directly or indirectly under the plan as an inducement to reduce or limit medically necessary services furnished to a specific enrollee. We

proposed that indirect payments include offerings of monetary value (such as stock options or waivers of debt) measured in the present or future.

F. Enforcement

We proposed that noncompliance with the proposed requirements discussed above could result in civil money penalties, intermediate sanctions, and/or contract termination (for Medicare) or withholding of FFP (for Medicaid). The civil money penalties would be limited to $25,000 for each determination of noncompliance. Under the intermediate sanctions provision, HCFA could (for Medicare) suspend the enrollment of individuals into noncompliant plans and HCFA (for Medicare) or the State (for Medicaid) could suspend payment for new enrollees until it is satisfied that the basis for the determination is not likely to recur. The process for applying civil money penalties and intermediate sanctions would be the same process as that proposed in the July 22, 1991, proposed rule on civil money penalties and intermediate sanctions (56 FR 33404).

VI. Analysis of and Responses to Public Comments

We received 41 timely comments on the December 1992 proposed rule. (Comments related to the provisions that were proposed in the July 1991 proposed rule on civil money penalties and intermediate sanctions and that were merely republished in the December 1992 proposed rule were not considered timely.) Commenters included prepaid plans, State agencies, national and local associations of managed care providers, physician associations, consumer advocacy groups, and an insurance industry trade association. This section of the preamble contains a summary of the comments and our responses.

Note: This final rule changes the CFR designation of a number of the proposed provisions. To aid the reader, we have provided in section VI. of this preamble, a crosswalk between the proposed provisions and the provisions of this final rule.

Scope of Regulation

Comment: Many commenters agreed with our position that the proposed rule should apply to only Medicare and Medicaid risk contracts. In contrast, one commenter believed protection should be extended to plans governed by title XIII of the Public Health Service Act but conceded that the scope of the authorizing legislation is not clear on this point. This commenter recommended that we seek congressional clarification of the intent of the statute.

Response: As indicated in the preamble to the proposed regulation (hereinafter referred to as the ''proposed preamble''), the original legislation amended only titles XVIII and XIX of the Act. Subsequent legislation, however, applies to all physicians that furnish services under the Medicare or Medicaid program.

Comment: One commenter suggested that we apply the proposed requirements only if there is a greater risk for Medicare and Medicaid contracts than for commercial contracts.

Response: The legislation requires us to develop these regulations for Medicare and Medicaid prepaid plans but not for commercial plans. It does not provide us with flexibility to make this determination. Thus, we will examine only incentive plans between a prepaid plan and a physician or physician group that apply to Medicare and Medicaid enrollees. We will not examine the incentive plans as they relate to commercial enrollees, even if the commercial enrollees are in addition to Medicare and Medicaid enrollees. The only exception to this is if the plan uses the pooling methods described later in this preamble.

Comment: One commenter suggested that the Department of Health and Human Services should evaluate the feasibility of applying these regulations to accountable health plans or other health care delivery systems that may be created under health care reform.

Response: This suggestion does not fall within the scope of this rulemaking, which implements enacted legislation in regulations.

Comment: Some commenters stated that there are no published studies that link quality problems to physician incentive plans. They suggest, therefore, that the regulation be dropped. In addition, some commenters suggested that we are only responding to pressures from press reports. Furthermore, some commenters believed this rule would not improve quality of care and that it would only add to the cost of care.

One commenter believed that the proposed rule is too restrictive. The commenter stated that it would make far more sense to monitor the health outcomes of enrollees to ensure that they are receiving quality health care services than to micromanage the administrative arrangements within these health organizations.

Response: We reject these recommendations for the following reasons:

- OBRA '90 requires us to issue these regulations.
- While we acknowledged in the proposed preamble that no link between quality problems and incentive plans has been established, the issue has not been sufficiently examined. In the report to the Congress entitled ''Incentive Arrangements Offered by Health Maintenance Organizations and Competitive Medical Plans to Physicians'' (hereinafter referred to as the ''Report''), no study is cited that directly tests the link. Instead the Report cites studies that show no differences in quality between prepaid plans and fee-for-service arrangements. From this evidence, the Report infers that incentive plans do not affect quality. It should be noted that studies to date have used limited outcome measures.

Furthermore, the OBRA '90 provisions that require these regulations were enacted after the submission of the Report, confirming legislative intent subsequent to the Report.

- HCFA is sponsoring quality assurance reform initiatives in both Medicare and Medicaid that will begin to develop outcome measures for HMOs. HCFA's first efforts contain some outcome measures. Future projects will develop even more of these measures. The state of the art in outcome measures is still in the early stages and, thus, at this time, they cannot serve as a reliable measure of potential underutilization.

While there is no guarantee that these requirements will result in improvements in the quality of care, the Congress was concerned with ensuring that underuse of necessary services does not occur. We are all concerned with ensuring adequate protection of beneficiaries and recipients so that they have access to all necessary and appropriate care. As indicated in both the proposed preamble and later in this document, we anticipate most prepaid plans will not incur significant additional costs because most of them already meet the requirements that are specified in this regulation.

Comment: A major organization suggested that we examine incentive plans only if quality problems are detected.

Response: We rejected this recommendation for the following reasons:

- The legislation does not provide for an exception if there is an absence of quality problems.
- As indicated in the Report, there are limitations in the quality studies and methodologies used to detect quality problems.

Prohibited Arrangements

Comment: One commenter recommended that we revise proposed

§ 417.479(c) (''Prohibited physician payments'') to clarify that medically necessary services means medically necessary *covered* services.

Response: In this final rule, we have revised proposed § 417.479(c) (now designated as § 417.479(d)) to include all medically necessary services covered by the prepaid plan contract. We have included all services covered in the contract since some plans contain services in their Medicare and Medicaid contracts that are in addition to those covered under the regular Medicare or Medicaid program. Furthermore, as established under title XIX of the Act, if a plan contracts to provide early and periodic screening and diagnosis and treatment services, the plan is responsible for any medically necessary Medicaid covered services, regardless of whether these services are covered under the State plan.

Disclosure

Comment: Several commenters, including major organizations, requested that we require disclosure of the incentive plans to all enrollees at the time of enrollment. They believed that disclosure is necessary to protect patients and physicians.

In contrast, several commenters, also including major organizations, stated that incentive plans are proprietary information and, as such, should be exempt from disclosure under the Freedom of Information Act (FOIA).

Response: We agree that disclosure of the incentive plans to patients can aid them in ensuring that they receive needed services. This information in the hands of Medicare beneficiaries and Medicaid recipients will also help physicians to counter pressure from the prepaid plans to reduce services. At the same time, we want to protect the proprietary aspects of the information. To effectively balance these conflicting goals, this final rule adds new §§ 417.479(h)(3) and 434.70(a)(4) to require that prepaid plans provide a summary of three items of information to Medicare beneficiaries and Medicaid recipients, respectively, when they request it. The three items are identified in the next response. As the prepaid plans' experience with physician incentive plans and disclosure increases, we encourage them to voluntarily share summaries of the incentive plans with all enrollees. We have not asked that more information be provided for the following reasons:

- We do not want to put an undue burden on the prepaid plans.
- We do not require fee-for-service physicians to provide a notice that they have incentives to provide excessive services.
- Certain information in the incentive plans is proprietary information and is exempt from disclosure under the FOIA.

Comment: One commenter recommends we clarify what constitutes ''sufficient information'' for disclosure purposes.

Response: This final rule revises proposed §§ 417.479(h) and 434.70(a) to provide for two types of disclosure. Disclosure to HCFA and the States requires that prepaid plans submit information that describes (1) whether services not furnished by the physician or physician group are covered by the incentive arrangement (if only the services furnished by the physician or physician group are covered by the incentive plan, there is no need for disclosure of other aspects of the plan); (2) the type of incentive arrangement, for example, withhold, bonus, capitation; (3) the percent of the withhold or bonus, if any; (4) the amount and type of stop-loss protection; (5) the panel size and, if enrollees are pooled according to the principles discussed later, the method of pooling used; (6) in the case of capitated physicians or physician groups, capitation payments paid to primary care physicians for the most recent year broken down by percent for primary care services, referral services to specialists, hospital services, and other types of provider (for example, nursing homes and home health agencies) services; and (7) in the case of those prepaid plans that are required to conduct beneficiary surveys, the survey results. We are requesting the information described in item 6 so that we can determine whether additional standards are necessary in the future.

Disclosure to Medicare beneficiaries and Medicaid recipients requires that only a summary of the above information be made available if requested by the beneficiary. This information will indicate, 1) whether the prepaid plan uses a physician incentive plan that affects the use of referral services, 2) the type of incentive arrangement, 3) and whether stop-loss protection is provided. In addition, those prepaid plans that must conduct enrollee surveys must provide a summary of the survey results to those beneficiaries and recipients who request it.

Comment: One commenter stated that disclosure should not be needed *each* time there is any change in the incentive plan. A second commenter stated that we should require disclosure only initially and when changes occur relative to rules.

Response: We agree with these recommendations. Therefore, we have revised proposed § 417.479(h)(3) and proposed § 434.70(a)(2)(ii) to specify that an organization must provide information concerning any of the following changes in its incentive plan: A change as to the type of incentive plan; a change in the amounts of risk or stop-loss protection; or expansion of the risk formula to cover services not provided by the physician group which the formula had not included previously. We also specify that this information must be provided to HCFA at least 45 days (rather than the proposed 30 days) before the change takes effect. This latter change is made to make this rule consistent with existing § 417.428, which requires that HMOs and CMPs submit to HCFA all marketing information 45 days in advance of distribution. (Proposed § 417.479(h)(3) is now § 417.479(h)(2)(C)(ii).)

Comment: One commenter recommended that the due date for submission of the required information by organizations that have a contract with us be extended from 30 days after publication of the final rule to 60 days after publication. The commenter stated that 30 days is not sufficient for organizations to become aware of the rule, study its details, analyze their incentive plans, and formulate disclosures that meet the rule's requirements.

One commenter believed there should be a phase-in period for organizations to comply with the regulations. The commenter suggested that the phase-in period be the remainder of the term of the organization's existing provider contract.

Response: We agree that organizations should be given more than 30 days to comply with the provisions of this rule. Since 60 days for compliance is a standard time period used in many of our regulations, particularly in the Medicaid program, we have extended the time period in which organizations must comply with this rule to at least 60 days from the date of publication. Further, we now require that organizations with existing contracts with us comply with most of the disclosure requirements by the date of the contract renewal or at least 60 days from the date of publication of this final rule, whichever is later. We now require compliance with the disclosure requirement related to capitation data within 1 year from the date of publication of this rule. (See **DATES** section of this rule.)

Comment: One commenter believed that subcontracting poses an

impediment to an HMO's ability to comply with the disclosure requirement. The commenter stated that subcontracting will result in numerous contracts being subject to disclosure, particularly in the case of larger HMOs. This commenter also pointed out that the proposed rule does not address the extent to which subcontractors will be compelled to disclose information concerning incentive arrangements. The commenter stated that HMOs need to know the extent of the disclosure obligation of the HMO where subcontracting has resulted in incentive arrangements currently unknown to the HMO.

This same commenter believed that our estimate of 4 hours per organization to meet disclosure requirements is a serious underestimation given the complexity of current industry contracting practices. The commenter did not offer an alternate estimate.

Response: Under this final rule, if the prepaid plan contracts with a physician group that puts its individual physician members at substantial financial risk for services not provided, the prepaid plan must disclose to us (or in the case of Medicaid, to the State agency) any physician incentive plans between the physician group and its individual physicians that base compensation on the use or cost of services furnished to beneficiaries or recipients.

Additionally, if a prepaid plan contracts with an ''intermediate entity'' that, in turn, subcontracts with individual physicians or a physician group, the prepaid plan, under all circumstances, must disclose to us (or the State agency) any physician incentive plans between the intermediate entity and the individual physician or physician group that base compensation on the use or cost of services furnished to beneficiaries. This information is necessary to ensure that physicians are not placed at substantial financial risk for services not provided.

For purposes of this requirement, we define intermediate entities as organizations or individuals who contract with the prepaid plan and, in turn, subcontract with one or more physician groups. Thus, for example, an individual practice association (IPA) is an intermediate entity if it subcontracts with one or more physician groups. (It is simply a physician group when it is composed of a set of individual physicians and has no subcontracts with physician groups.) A physician hospital organization is also an example of an intermediate entity.

The information to be disclosed for each of the situations described above includes the following:

- Whether services not furnished by the physician or physician group are covered by the incentive plan. If only the services furnished by the physician or physician group are covered by the incentive plan, disclosure of other aspects of the plan need not be made.
- The type of incentive arrangement; for example, withhold, bonus, capitation.
- If the incentive plan involves a withhold or bonus, the percent of the withhold or bonus.
- The amount and type of stop-loss protection.
- The panel size and, if patients are pooled according to one of the permitted methods, which method is used.
- In the case of capitated physicians or physician group, capitation payments paid to primary care physicians for the most recent year broken down by percent for primary care services, referral services to specialists, and hospital and other types of provider services.
- In the case of those prepaid plans that are required to conduct beneficiary surveys, the survey results.

In subcontracting relations, if, under any circumstances, a physician group and/or individual physicians are put at substantial financial risk, the prepaid plan must conduct the beneficiary survey required by this rule and provide adequate stop-loss protection to the physician group and/or individual physicians. We have taken this position because recent investigations by HCFA of HMOs in a number of States has led us to conclude that, in subcontracting situations, some physicians have been put at substantial financial risk without adequate examination of the effect this has on the quality of care furnished to the enrollees.

We have set forth the above requirements in this final rule by adding a new paragraph (i) to § 417.479 (for Medicare) and revising proposed § 434.70(a) (for Medicaid). We have also revised the proposed definition of ''physician group'' at § 417.479(b) to clarify that an IPA is a physician group only if it is composed of individual physicians and has no subcontracts with physician groups.

We believe these additional requirements will increase the burden on prepaid health plans by an additional 4 hours, resulting in a total of 8 hours per organization to meet the disclosure requirements. The organization can either submit copies of its incentive plans or submit information that addresses the required items listed in § 417.479(h)(1).

We would welcome comments on our estimate of the burden imposed by the above requirements. We are particularly interested in receiving empirical data supporting any estimates the commenter may offer.

Comment: One commenter believed the disclosure requirements are excessively burdensome. This commenter noted that, as stated in the preamble of the proposed rule, the justification for these disclosure requirements is that, if the information is only disclosed during site visits, an organization could change its physician incentive plan shortly after the site visit, and we would not know of the new arrangement for 2 years. The commenter pointed out that there are many items of information that we review at site visits that could be changed shortly thereafter without our knowledge; for example, HMO marketing material, provider contracts, and quality assurance plans. The commenter pointed out that these are reviewed during site visits and not re-reviewed during the 2-year cycle. The commenter stated that the proposed rule offered no explanation for different treatment for incentive plans, and, therefore, the requirements are not based on an acceptable justification.

Response: Section 1876(i)(8)(A)(iii) of the Act requires that we obtain sufficient information to determine if substantial financial risk occurs, adequate stop-loss protection is provided, etc. As indicated in an earlier response, we have limited the amount of information prepaid plans are required to submit to HCFA and the States to information on just a few key items. As prescribed by legislation, marketing materials are submitted to us every year. Further, as a change from the proposed rule, we are requiring that we be notified of only significant changes in the incentive plan, rather than each change, thereby reducing the burden of this requirement.

Comment: One commenter suggested that HCFA use a simple disclosure form that can quickly be completed by HMO personnel and reviewed promptly by HCFA.

Response: HCFA will consider the feasibility of a form and, if it decides to adopt the recommendation, in accordance with the Paperwork Reduction Act of 1995, will publish a document in the Federal Register soliciting public comments on a proposed form.

Comment: One commenter recommended that disclosure not be required if the HMO essentially admits substantial financial risk by agreeing to comply with enrollee survey and stop-loss requirements.

Response: The statute requires that organizations disclose their incentive plan arrangements.

Comment: One commenter asked what timeframes an organization may anticipate for HCFA's review of its incentive arrangements.

Response: Timeframes for the review of incentive plans will be addressed in a forthcoming manual issuance. At this time, we anticipate that the average review time will be 60 days.

Implementation

Comment: One commenter recommended that the final rules provide an explicit mechanism for dealing with disputes arising from and during the determination of whether physicians are at substantial financial risk.

Response: We agree with the commenter that there should be procedures for these disputes. Details on the dispute procedures will be addressed in a forthcoming manual issuance.

Referral service

Comment: We proposed to define ''referral services'' as any specialty, inpatient, outpatient, or laboratory services that a physician or physician group orders or arranges, but does not provide directly. One commenter believed that this definition is ambiguous. The commenter questioned whether we intended to distinguish between the services provided by the prepaid plan's physician employees and services provided by independent contract physicians. The commenter believed that absent knowing our position on this issue, the terms ''provide directly'' in the definition is ambiguous. The commenter believed we should clarify that services provided by specialist physicians through a contract with the physician group would not constitute referral services. In addition, the commenter believed that ''referral services'' should be limited to services that a physician is not licensed to provide, such as hospital services.

Response: We disagree that the definition is ambiguous. We believe the problem the commenter had with this definition is related to the understanding of another term used in the definition, that is, the meaning of ''physician group.'' We assume that what the commenter is really asking is ''If a physician group contracts for services of a specialist, is the contract physician considered a member of the physician group?'' We see this as the real issue because, if the contract physician is a member of the physician group, then services furnished by that physician would be services furnished directly by the group. Thus, the services would not be referral services.

We proposed to define ''physician group'' as a partnership, association, corporation, individual practice association, or other group that distributes income from the practice among members according to a prearranged plan unrelated to the members' referral levels. (For reasons that will be discussed later in this preamble, this final rule adopts a revised version of that definition. That is, we have deleted from the definition the phrase ''according to a prearranged plan unrelated to the members' referral levels''. We also no longer include an individual practice association in the definition.) According to this definition, a contract physician is not a member of the physician group.

We disagree with the comment that referral services should be limited to services that a physician is not licensed to provide. The legislation requires the Secretary to determine if the plan places the physicians at substantial financial risk for services not provided by the physician group. Thus, referrals to specialists who are not part of the group practice are considered referral services in the determinations of risk. It is these services that the legislation intended to address. Prepaid plans generally use primary care physicians as gatekeepers. These models encourage the primary care physician gatekeeper to not use specialist services if he or she can perform the services. We support these models. The legislation, however, is designed to prevent restrictions on necessary specialist care.

Substantial Financial Risk

Comment: Several commenters believed the definition of ''substantial financial risk'' is overly restrictive. They believed it fails to fulfill the goal of only identifying outliers because it fails to address the variables that affect risk. One commenter suggested that it be redrafted or, if HCFA is unwilling to redraft the definition, that organizations be given the choice of either complying with the regulation as written or demonstrating to HCFA that their incentive plan does not put physicians at substantial financial risk.

A number of commenters recommended, more specifically, that HCFA include the size of patient and physician pools (panels) in the risk formula threshold as, in their view, required by the legislation. On the other hand, one commenter stated that attempting to incorporate patient panel size as a risk factor would prove unduly complex and less workable than the approach contained in the proposed rule.

Response: We have reconsidered this issue and, in this final rule, we take panel size into account in determining adequate stop-loss requirements (See § 417.479(g)(2)(ii).) Analyses by Rossiter and Adamache (1990) (Health Care Financing Review, vol. 12, pp. 19–30) show that there is no significant variation in costs from year to year for counties with populations greater than 25,000. Based on these analyses, we have determined that physician groups with more than 25,000 patients are able to adequately spread risk and, therefore, are not at substantial financial risk, even if 100 percent of the physician group's income is at risk for referral services. This does not apply to panels of more than 25,000 patients as a result of pooling. (See § 417.479(f).) Pooling of patients is discussed later in this preamble.

As stated, our decision to set the threshold at 25,000 was based on the analyses done by Rossiter and Adamache. We would welcome information as to whether there are data that would support another threshold.

With regard to the suggestion that we allow organizations the choice of either complying with the regulation as written or demonstrating that their incentive plan does not put physicians at substantial financial risk, we would be interested in receiving comments on how we might implement such an exception process.

The remainder of this response applies to panels of less than 25,000 patients. As stated in the proposed preamble, the size of the patient or physician pool can have several theoretical effects on substantial financial risk. Furthermore, there is no empirical evidence that could guide us on the effects of these and other factors. We requested information in this regard in the proposed preamble. Nonetheless, while commenters suggested that size is a factor, none of the commenters provided information on the exact relationship between size and risk. Therefore, we have no basis for specifying this relationship. Finally, the legislation discusses panel size only in regard to stop-loss protection and not in regard to substantial financial risk.

Comment: One major organization stated that, under the proposed rule, prepaid plans that assess and/or distribute incentive payments more often than annually are subject to lower risk thresholds. It maintains that there are problems with this requirement as follows:

First, it contends that the term ''assess'' as used in this regard is not

clear. It might, the organization suggests, be interpreted to bar plans from communication with physicians as to their progress in meeting annual goals. The organization stated that it disagrees with any interpretation of this requirement that might prevent plans that distribute incentive payments annually from working with their physicians on their mutual cost containment goals on a more frequent basis.

Second, the proposed regulation does not achieve its goal of using an outlier approach in this area. Many organizations that use withhold and distribute, or assess, incentive payments more often than once a year exceed the 15 percent risk threshold. These organizations, however, fall within the 25 percent threshold set for plans distributing or assessing payments annually or less often.

Another commenter stated that the frequency of the assessment or distribution should not affect the level or risk necessary to qualify as substantial financial risk.

Response: The term ''assess'' is meant to refer to imposing a charge. It is not used in the meaning of an evaluation or appraisal of progress toward a goal.

We agree that a 15 percent threshold is not an outlier, since the median withhold is between 10 and 20 percent. Also, there is no evidence that making assessments or distributions more often than annually affects the amount of risk placed on physicians. While our rationale in the proposed rule was based upon reasonable assumptions as to the impact of more frequent assessments or distributions, we now agree that the 15 percent threshold is inconsistent with our intent to use an outlier approach. Therefore, we have eliminated making a distinction on the basis of the frequency of the assessment or distribution. We establish the 25 percent threshold in all cases. The 25 percent threshold is an outlier since it exceeds the median withhold of 10 to 20 percent. Proposed § 417.479 has been revised to reflect the elimination of the distinction.

Comment: One commenter stated that the proposed threshold for combination of withholds and bonuses does not identify only outliers. The commenter also stated that, in practice, physician performance will be either in the bonus area *or* in the withhold area; therefore, to limit the amount of financial risk that a physician will ultimately accept, it is not necessary to limit the combination. The commenter also pointed out that there is no evidence that upward variations on physician payments (bonuses) have the same potential to cause underutilization as downward variations (withholds).

Response: If organizations do not use a combination of withholds and bonuses, there is no problem with setting the same limit for the combinations as for withholds and bonuses individually. Since it is possible for plans to use combinations of withholds and bonuses, it is necessary to set a limit on the combination. As indicated in the proposed preamble, to avoid putting physicians at substantial financial risk, we determined it necessary to use the same threshold for the combination.

With regard to the last comment, we are not aware of any data on the effect of bonuses as opposed to withholds on physician behavior. We would, therefore, appreciate receiving any information in this regard.

Comment: Several commenters recommended that we lower the threshold.

Response: The proposed preamble had an extensive discussion of this issue. As we stated, because of the limited information available on this issue, the only logical approach is to use an outlier formula. Given this decision, the threshold of 25 percent that we proposed is consistent with the data that showed that the median withhold was between 10 to 20 percent. It is also consistent with the concept of substantial financial risk, which implies a greater than average risk. As indicated, the threshold is based on withhold data. Averaging in the organizations with capitation arrangements, which are the majority of organizations, and treating them as equal to 100 percent withhold would raise the threshold rather than lower it. We decided not to raise the threshold because that would not make a difference to the capitation arrangements. This would be so because, if capitation were considered equal to 100 percent withhold, all plans using capitation would be placing their physicians at substantial financial risk (unless the threshold were set at 100 percent). Furthermore, as indicated in the proposed preamble, the 25 percent withhold figure is within the range of discounts that physician groups frequently provide to various insurers. Physicians also lose similar amounts to bad debts.

Comment: One commenter suggested that we include the risk arrangements between the physician groups and their individual physicians, because the prepaid plan may use this strategy to circumvent the process. The commenter maintained that the statute does not specifically exclude these arrangements from scrutiny. The commenter pointed out that the statute defines an incentive plan as ''any compensation arrangement between an eligible organization and a physician that may directly *or indirectly* have the effect of reducing * * *'' [Emphasis added.] The commenter believed that the use of the words ''or indirectly'' indicates that the types of compensation arrangements should be looked at broadly.

Response: As stated in an earlier response, we are requiring a prepaid health plan that contracts with an intermediate entity to disclose information about the physician incentive plans that the entity has with physician groups or physicians. This will prevent a prepaid plan from creating intermediate entities merely to evade the requirements of this rule.

Furthermore, if the physician group subcontract with its physicians places the latter at substantial financial risk, the prepaid health plan must disclose the incentive arrangements. In order to minimize the burden on prepaid plans, we are not requiring disclosure of every incentive arrangement between physician groups and individual physicians, only of those under which the physicians are placed at significant financial risk.

In regard to the phrase ''indirectly have the effect of reducing or limiting services,'' this phrase applies only to the arrangement between the plan and physician group. It does not apply to the relationship between the physician group and its individual physicians. ''Indirect'' as used in the statute refers to methods of compensation to the physician groups that are not strictly monetary, but can be considered the equivalent. Examples would include providing stocks, waivers of debt, or equipment.

The commenter has raised the issue of physician groups that have incentive arrangements with their individual physicians. As we examined this issue, we noted that the definition of ''physician group'' in proposed § 417.479(b) technically would exclude such a physician group, since it would *not* be a group that ''distributes income from practice among members according to a * * * plan *unrelated to the members' referral levels*.'' (Emphasis added.) It was not intended that any physician group fall outside the scope of our definition, and thus technically outside the scope of these regulations. We, accordingly, are deleting ''according to a prearranged plan unrelated to the member's referral levels'' from the definition of ''physician group.'' It is also for this reason that we did not adopt any existing definitions of a physician group

or group practice that may similarly have contained provisions that would exclude a group Congress intended to reach in this rule (for example, the existing definition of ''medical group'' at 42 CFR 417.1 or ''group practice'' in section 1877 of the Act.

We are also taking this opportunity to point out that, although we define a ''physician incentive plan'' as ''any compensation arrangement between an *organization* 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 recipients enrolled in the organization'' [emphasis added], this definition also encompasses a compensation arrangement between an *entity* with which the organization contracts and physicians/physician groups and a compensation arrangement between a *physician group* and its individual physicians. This is because, although not a direct relationship, a linkage between the organization and the physician group or individual physicians has been established through the entity or physician group with which the organization contracts.

Comment: One commenter suggested that we not apply substantial financial risk to individual practice association (IPA) and direct contracting models. The commenter stated that there would be no loss if a few providers drop out.

Response: While the organization may not feel a loss, the enrollees may be concerned about the loss. Furthermore, this may be an indication that the incentive plans are having an undesired effect. The legislation requires us to apply these regulations to all prepaid plans. There is no justification for treating IPA and direct contracting models differently. If anything, since these models frequently involve contracts with individual physicians, these physicians are less in a position to spread risk and may be at even greater risk than other models.

Comment: Several commenters, including a major organization, raised the concern that they do not know the total payments and patient loads until the end of the year. They suggested that we substitute total potential payments, based on the most recent year's utilization and experience, in the substantial financial risk and stop-loss formulas.

Response: We agree that this option is acceptable, unless the organization has information that suggests a significantly different situation; for example, the addition of a major new contract. Appropriate revisions have been made to proposed § 417.479 to clarify this.

Comment: A major organization suggested that we substitute an actuarially derived threshold instead of an outlier approach.

Response: We reviewed this recommendation with several actuaries, including staff from HCFA's Office of the Actuary. We concluded that it is not feasible to make such an analysis. Actuaries can perform analyses for certain kinds of losses, such as loss of life or loss of income. However, the determination of what is a substantial loss of income to a physician or physician group is more of a subjective or policy decision than a measurable amount.

The actuaries also indicated that they could not perform such an analysis because there are no empirical data to indicate how physicians respond to different levels of financial risk.

Actuaries have supplied us with recommendations as to stop-loss protection, discussed later in this preamble. The recommendations result in different stop-loss requirements for different panel sizes. Also, as discussed earlier, we have determined that physicians or physician groups serving panels of over 25,000 patients are not at substantial financial risk. We are, however, interested in receiving current data on how physicians respond to different levels of financial risk.

Comment: One commenter raised a concern that the Internal Revenue Service (IRS) is developing policy on withholds that defines them as discounts that would not be tax-exempt.

Response: We have held discussions with the IRS to coordinate consistent policies and will continue to work with them.

Comment: One organization commented that the threshold should only apply to the aggregate group of physicians and not to individual physicians. It stated that its incentive plan is within the specified limits for physician groups, but will exceed the limits for individual physicians whose behavior exceeds certain norms.

Response: The legislation is concerned with whether a plan puts physicians or physician groups at substantial financial risk. Thus, the threshold policy applies to contracts between an organization and individual physicians, but only if the contract is specifically between the organization and an individual physician. As indicated earlier, we have not interpreted the legislation to apply to subcontracts between the physician group and its individual physicians.

Comment: A major organization asked if a contract for primary care services outside the service area equals referral services.

Response: Primary care services outside the service area are not ''referral services.'' The prepaid plan, however, must ensure that all necessary services are available and accessible within the service area.

Comment: A major organization commented that the proposed regulation poses a problem for staff model HMOs in medically underserved areas (MUAs). The commenter stated that, because the salaries of many physicians in community health centers (CHCs) are low (because they are often working under a Federal student loan repayment program), the formula we use to determine the risk threshold results in a threshold that is artificially low for these HMO programs. The commenter added that, to impose additional administrative obligations on these community programs, because of their bonus payment arrangements for salaried physicians, would divert time, energy, and resources away from their mission of providing health services in MUAs.

Response: We share the concerns raised by this commenter. The low salaries do create an artificially lower threshold, and the centers have much more limited administrative resources. Nevertheless, these circumstances result in even greater pressures on these physicians to contain costs. With lower salaries, the physicians are more sensitive to factors that can affect their income. Therefore, it is even more appropriate to have the policies in this regulation apply to these centers. Unfortunately, we have not been able to develop a different policy for these centers. Note, however, that if an HMO contracts with a CHC, then, as indicated in an earlier response, these regulations would not apply to contracts between the centers and their physicians because they are subcontracts.

Capitation Arrangements With Physicians

Comment: Several commenters, including a major organization, stated that the threshold should not apply to capitation. Their argument was that the thresholds were based on withhold data and, further, that it is difficult to separate services furnished by the physicians from referral services. The commenters also claimed that we did not specify that the capitation applies only to referral services.

The commenters raised the concern that the capitation payments may include payments for services furnished directly by the physician group. Thus, they point out, we are limiting the

amount of risk a physician can accept for his or her own services. The commenters stated that to do so is beyond the mandate of the statute, which is intended to apply only to services not provided by the physician group.

Response: We gave this issue a great deal of thought. We decided, however, to continue with our proposed policy of applying a 25 percent threshold. To exempt capitation from the threshold could place physicians who are compensated in this manner at substantial financial risk, without subjecting the prepaid plans to the requirement either to set limits to the risk in the form of maximums and minimums, or provide adequate stop-loss protection and conduct beneficiary surveys as required by the statute. Furthermore, the commenters are incorrect; the proposed and final rules are concerned with referral services. If the incentive plan applies only to the services furnished by the physician group, these rules do not apply. The legislation specifies that we address services not furnished by the physician group. If the incentive plan applies to all services or just referral services, these rules apply.

The commenters are correct on these two points: our policy does affect services that the physician group directly provides if we are dealing with capitation for all services; and services furnished directly by the physician group or physician are not covered by the statute. However, when the capitation covers all services, we are not able to separate those service furnished directly from the referral services. And, since the referral services are our primary concern, we need to be inclusive rather than exclusive.

Comment: One commenter recommended that we not require the maximum and minimum formula for capitation arrangements if the organization can show that a 25 percent differential had not occurred in the past.

Response: While there is merit to this recommendation, we have decided to reject it. The legislation requires that organizations that place their physicians at substantial financial risk, as determined by the Secretary, provide stop-loss protection and conduct enrollee surveys. Thus, the formula is necessary for us to determine if substantial financial risk exists. Also, past behavior is no guarantee of future behavior. Thus, physicians could still feel the pressure if they are placed at substantial financial risk, regardless of past payments.

Comment: One commenter believed the rule should distinguish between a monthly capitation payment to a physician group that includes an amount for referral services, and an incentive plan assessment or payment.

Response: The applicability of the provisions of this rule depends upon the specific arrangements in the incentive plan. As stated earlier, if the incentive plan applies only to services directly furnished by the physician or physician group and does not cover referral services, the regulations do not apply. If the capitation includes payment for referral services, the provisions of § 417.479(f)(5) apply. If the organization capitates its physicians only for services they directly furnish and uses withholds or bonuses (or a combination of withholds and bonuses) as incentives to control referrals, the requirements of § 417.479(f)(5) concerning capitation do not apply. In this case, however, if the withholds or bonuses or combination of withholds and bonuses exceed the 25 percent risk threshold, the stop-loss and survey requirements of this rule apply.

Comment: One commenter suggested that, if a physician group achieves a patient population of approximately 250 members from a single capitated HMO, there is no longer a need for the risk protection.

Response: There is no evidence that supports this number. As indicated later in this preamble, we have set an exception for the stop-loss requirements that is based on panel size.

Comment: A number of commenters stated that the proposed rules, as they relate to capitated payment arrangements, do not accommodate common, longstanding contractual arrangements and should be withdrawn to permit additional study.

Response: The Group Health Association of America (GHAA) has supplied us with updated data as of the Winter 1993–94. Furthermore, Mathematica has published data from 1995. We took these data into account as we revisited our decisions regarding specific risk thresholds and issues concerning capitation and stop-loss protection. These data support the approach we have taken in this final rule. If more recent data exists, we would appreciate receiving it.

Comment: Several commenters stated that they capitate their physicians but also provide adequate stop-loss protection. They believed that these physicians are not at risk, because of the stop-loss protection.

Response: We agree in principle with this view. If an HMO has stop-loss protection in place that ensures that no more than 25 percent of a physician's or physician group's income is at risk, we would determine that the plan does not involve substantial financial risk.

Stop-Loss

Comment: A commenter recommended that we put physicians at risk beyond the stop-loss limit. The commenter believed that setting an absolute limit on the amount of risk that physicians can accept (that is, requiring stop-loss protection to cover the cost of referrals in excess of 30 percent of payments) obstructs an organization's ability to control physician behavior beyond that point. The commenter suggested that the stop-loss requirement be constructed to allow for continued, but limited, risk sharing. The commenter recommended that the organization be allowed to hold physicians or physician groups responsible for 20 percent of the cost of referrals beyond the point at which the stop-loss protection begins. The commenter stated that it does not believe the statute requires an absolute limit on the amount of risk, but instead only ''adequate and appropriate'' stop-loss protection.

Response: The approach suggested by this commenter is consistent with the policy used by a number of HMOs. The practice of requiring physicians to continue to share in the risk beyond a stop-loss limit makes the physicians sensitive to the need to avoid furnishing unnecessary services. Therefore, this final rule allows for continued, but limited, risk sharing beyond the point at which the stop-loss protection begins.

For those prepaid plans that provide an aggregate stop-loss policy, we are setting the required stop-loss limit at 25 percent. The prepaid plan will bear 90 percent of the losses beyond this level and the physicians will bear 10 percent of the losses. (See § 417.479(g)(2)(i).) Because we are adding a 90/10 ratio to the potential loss level, we believe it is necessary to reduce the proposed 30 percent stop-loss limit to 25 percent to compensate for the added element of risk sharing. Furthermore, the 25 percent level is consistent with the threshold we established for substantial financial risk.

The 90/10 split also applies to those plans that provide per patient stop-loss protection.

Comment: Several commenters, including major organizations, stated that aggregate stop-loss policies are not currently used and would be difficult to obtain. They recommended that patient, dollar, and/or specific disease protections be substituted.

Response: We have decided to allow plans to provide either aggregate or per-patient limit stop-loss policies. (See

§ 417.479(g)(2).) The amount of the per patient policy required to be considered adequate and appropriate will vary with the patient panel size and will be discussed later in this preamble. We reached this decision on the following basis.

We agree that some organizations might have trouble purchasing aggregate stop-loss policies or that it may be expensive to switch from a per patient limit to an aggregate policy. Since most organizations do not have such policies, this aggregate policy requirement would, at the least, cause a significant change in policy, which could be very difficult or expensive to implement. Furthermore, actuarial analyses indicate that aggregate coverage is unlikely to be needed.

On the other hand, there are some organizations that do provide aggregate stop-loss protection. Requiring them to switch to a per-patient limit would also be expensive. There are advantages and disadvantages to both aggregate and per-patient stop-loss coverage. Aggregate policies provide greater overall protection, while per-patient policies provide better protection at the individual patient level.

Both of these options provide reasonable protection for physicians and their patients. By providing an option, we have eliminated the burden organizations might face to switch policies.

We considered the recommendation to include specific disease protections. We reviewed the Department's preliminary plans for implementing the Medicare Catastrophic Coverage Act of 1988 (Public Law 100–203), major provisions of which were repealed before being implemented. The Department had not planned to specify any specific diseases as catastrophic and instead planned to use specific dollar levels to define ''catastrophic'' expenses.

Comment: Several commenters stated that the prepaid plans should not be required to pay for the cost of stop-loss protection. They believed they should be allowed to charge the physicians a reasonable premium for stop-loss protection.

Response: Section 1876(i)(8)(ii) of the Act reads, in relevant part, as follows:

(ii) If the plan places a physician or physician group at substantial financial risk * * * the organization—(I) provides stop-loss protection for the physician or group * * *.

In the case where the physician or physician group decides to purchase its own stop-loss protection, we interpret ''provides'' to mean that the organization either pays for the premium or reduces the level at which the stop-loss protection applies by the cost of the stop-loss. We also rejected the proposal of allowing HMOs to make available stop-loss protection rather than paying for it. Making available is not consistent with providing.

Thus, we provide, in § 417.479(g)(2)(iii), that the prepaid plan may either (1) Provide the stop-loss protection directly, (2) purchase the stop-loss protection, or (3) if the physician or physician group purchases the protection, pay the portion of the premium that covers its enrollees or reduce the level at which the stop-loss protection applies by the cost of the stop-loss. We are interested in any comments on this provision and alternative proposals.

Comment: Several commenters suggested that we establish a case-by-case exceptions process for stop-loss requirements.

Response: As stated previously for substantial financial risk, such a process would be administratively burdensome. Further, it would be difficult to make judgments.

Comment: One commenter, a major organization, disputed our statement that there is little information available regarding the impact of various factors on physician behavior.

Several commenters believed we should take patient panel size into account and exclude large panels from this requirement. Other commenters suggested that we have a higher stop-loss requirement, for example, $200,000 per patient, for larger panels. They noted that the legislation instructed us to take panel size into account for stop-loss protection. The commenters argued that, with a sufficiently large patient panel (generally a clinic), the physicians are able to spread the risk across all the patients.

In addition, several commenters pointed out that a number of physician groups have contracts with many different HMOs, particularly IPA models, and have the equivalent of a large panel spread out among the HMOs. The commenters recommended that HMOs that contract with these groups be exempt from the stop-loss requirements.

Response: Analyses by several actuarial firms and data from several HMOs support the position that having a large panel does reduce the level of risk. The data is also consistent with the findings of Rossiter and Adamache (1990) discussed previously. Based on these analyses, we have determined the limits specified in the following table (Table 1) for different panel sizes and have revised proposed § 417.479(g)(2) accordingly. Providing a higher stop-loss requirement (a higher stop-loss level is a lower level of protection) is consistent with the legislation, which specified that we take panel size into account.

TABLE 1.—STOP LOSS LIMITS PER PATIENT PANEL SIZE

Number of patients	Stop-loss limits per patient
Less than 1,000	$10,000
1,000 to 10,000	$30,000
10,000 to 25,001	$200,000
Greater than 25,000 (unpooled)	None
Greater than 25,000 (as a result of pooling).	$200,000

There are two ways physician groups can pool patients to meet the panel size requirements specified in the table: (1) Including commercial, Medicare, and/or Medicaid enrollees in the calculation of panel size, and (2) Pooling together, by the organization, of several physician groups into a single panel. Each method may lead to a panel size large enough to reduce the financial risk. These methods may be used to pool patients, provided they are consistent with the relevant contract between the physician or physician group and the prepaid plan. (For instance, if there are separate contracts for commercial, Medicare, and/or Medicaid enrollees, then, absent contractual provisions to the contrary, pooling would be precluded).

We consider physician groups whose panels are greater than 25,000 patients without pooling of patients as not at substantial financial risk. Thus, the organization would be exempt from stop-loss protection and beneficiary survey requirements.

For those groups whose panel size is greater than 25,000 patients as a result of pooling, the organization is required to provide stop-loss protection at the same level that is required if the panel size is between 10,000 to 25,000 patients ($200,000 per patient). This policy is adopted so that plans will not use pools to circumvent the stop-loss requirements. Furthermore, physicians may be at higher risk for panels that are pooled than panels that are not pooled since the former may experience greater variability in costs than the latter.

We have not established an increasing scale for the aggregate stop-loss option, except that those panels over 25,000 patients without pooling do not need aggregate stop-loss coverage. The scale does not need to increase because, since a percentage formula is used, the dollar

amount represented by the threshold rises as the panel size increases.

We are willing to consider policy alternatives that are supported by empirical data. We are interested in receiving public comments in this regard.

Surveys

Comment: Several commenters believed a survey of enrollee satisfaction should be required of all prepaid plans, not just those where there is substantial financial risk.

Response: While most prepaid plans do conduct surveys, there is no legislative requirement to do so except as prescribed by this regulation.

Comment: One commenter, a major organization, stated that the proposed rule is silent about what HCFA must do with the survey results. This organization proposed that the regulations explicitly require HCFA to (1) Annually review the results as they are filed, (2) share the complete results with the appropriate PRO, (3) take appropriate action if the results indicate a problem; and (4) ensure public access to the survey results by requiring that they be published and disseminated to interested parties by the PRO, the organization, or HCFA.

Response: We partially addressed this comment earlier in this preamble. The survey results will be submitted to plan managers in HCFA's central and regional offices. They will review the results in conjunction with PRO results, disenrollment data, reconsiderations, and related information, as part of ongoing compliance monitoring activities. As HCFA develops performance measures and report cards over the next several years, it will consider the best way to make the survey results available to consumers and providers.

Comment: One commenter suggested that disenrollees that move be excluded from the surveys.

Response: We agree with this recommendation since it may be very hard to locate these beneficiaries. Therefore, we have revised proposed § 417.479(g) accordingly.

Comment: One commenter, a major organization, requested that we specify that surveys do not need to be done more often than annually.

Response: This final rule, at § 417.479(g)(1)(iv), revises the requirement to specify that the survey must be conducted no later than 1 year from the effective date of the incentive plan, and at least every 2 years thereafter. As noted in the **DATES** section of this preamble, compliance with § 417.479(g)(1)(iv) is not required until 1 year after the effective date of this rule.

Medicaid

Comment: One commenter asked whether States have the option to prohibit incentive plans that place providers at a substantial financial risk. The commenter believed this option would eliminate the need to obtain and monitor stop-loss requirements and a member survey.

Response: Nothing in OBRA '90 prohibits States from placing more restrictive requirements under State law on the physician incentive plans of their HMO and HIO contractors. As a result, States do have the option of under State law prohibiting altogether incentive plans that place providers at substantial financial risk, regardless of any stop-loss arrangements and member satisfaction surveys used by the contractor. We point out, however, that the sanctions and penalties provided for under this final rule would apply only with respect to violations of the Federal requirements in this rule.

Comment: One commenter asked whether, if annual member surveys are already required under quality assurance standards, an additional member survey is necessary for those plans placing providers at substantial financial risk.

Response: No additional survey is required, as long as the survey conducted under the quality assurance standards meets the requirements specified at § 417.479(g) of this rule.

Comment: One commenter stated that sufficient time must be allowed for States to incorporate the new provisions in program rules and existing provider agreements.

Response: We agree with this comment. As a result, as stated in the **DATES** section of this preamble, the compliance date for most provisions is 60 days after publication of this final rule. This time period is the standard commonly used for implementation under Medicaid.

Comment: One commenter stated that incentive plans for physicians serving Medicaid recipients need to address access to primary and preventive services and quality of care services. The commenter stated that these plans must include incentives based on specific health outcomes, timely access to primary care, and enrollee satisfaction based on specific health outcomes.

Response: OBRA '90: (1) Prohibits certain physician incentive arrangements and (2) specifies two requirements to be met if other types of arrangements that place physicians at substantial financial risk are used. The statute does not go beyond these prohibitions and requirements to mandate the use of any particular type of incentive arrangements, including those described by the commenter. Accordingly, the rule does not include any requirements that certain types of incentives be used.

Comment: One State agency stated that incentive plans for physicians serving Medicaid must limit the payment of any incentives to once annually. The commenter believed this would decrease the possibility that physicians will cut back on services or refuse to treat individual patients because of fear of financial losses.

Response: OBRA '90 prohibited only one type of incentive arrangement: those that make specific payments, ''directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services provided with respect to a specific individual enrolled with the organization.'' All other types of incentive arrangements are allowed, including those that place physicians at ''substantial financial risk.'' (Those that place physicians at substantial financial risk must meet certain requirements for the provision of stop-loss protection for physicians and periodic enrollee satisfaction surveys.) The statute makes no provision, including the one recommended by the commenter, for banning other types of incentive plans. We cannot impose the restrictions on the incentive program that were recommended by the commenter. As noted above, however, OBRA '90 would not prohibit a State from imposing such a restriction under State law.

Comment: One commenter recommended that the reporting and other requirements for physician incentive plans be limited to only those HMOs, CMPs, or HIOs that institute percentage risk levels that are greater for the Medicaid and Medicare populations than for their commercial contracts.

Response: With respect to Medicaid, OBRA '90 amended section 1903(m)(2)(A) of the Act to condition a State's receipt of FFP for expenditures in prepaid capitation or other risk-based reimbursement contracts upon a contractor's adherence to the requirements for physician incentive plans also described in OBRA '90. The statute does not authorize the Secretary to exempt certain plans or State Medicaid contracts from compliance with these reporting and other requirements. Therefore, we cannot change the regulation as the commenter has proposed.

Comment: One commenter stated that the definitions of ''substantial risk,'' ''withhold,'' and ''bonus'' are too inflexible to meet the special needs related to the Medicaid program. Citing monthly eligibility variation and differences in payments based on varying Medicaid eligibility categories as examples of variables that can affect payment to a provider in any given period, the commenter questioned how, if incentive payments are based on end of year results and a percent sharing arrangement, a plan can know in advance if its providers will be at substantial risk.

Response: The maximum potential (as opposed to the actual) amount of withhold or bonus lost or awarded, respectively, determines whether a prepaid plan has placed a physician or physician group at substantial financial risk. If the plan places the practitioner at risk of losing more than 25 percent of his/her potential earnings, then the plan has placed the physician or physician group at substantial financial risk. The actual amount of withhold returned or not returned or bonus awarded or not awarded at the end of the assessment and disbursement period is not the determinant of substantial financial risk because money returned or awarded after care has already been delivered does not serve as an inducement. It is the promise of potential earnings (or the prospect of loss thereof) that serves as the inducement. Therefore, a prepaid plan does not need to know its end of year results in order to determine if it is placing its physicians and physician groups at substantial financial risk.

The minimum and maximum potential earnings, including the portions that are the result of incentive arrangements, should be known both to the plan and the physician or physician group under contract at the beginning of each risk assessment period. As a result, the regulation states that capitation arrangements in which the maximum and minimum possible payments are not clearly explained in the physician's or physician group's contract constitute substantial financial risk.

Comment: One commenter stated that the rules are not very clear on defining a number of terms. As examples, the commenter asked the following questions:

- What does ''risk based on the levels or costs of referral services'' mean? Are the ''levels or costs'' applied to an individual capitated physician, physician group, or organization?
- What if the amount allocated to cover referral services is placed in a pool account for debiting patient costs and the amount from these services that might be paid as part of the incentive plan depends on the performance of the larger pool formed by a number of separate physicians and these physicians pool accounts?
- What if the ''capitation'' amount actually paid to a physician is meant to cover that physician's services and involves a 15 percent withhold?

Response: In response to the first question, the term ''referral services'' is defined in § 417.479(c) of the regulation. In addition, the word ''level'' has been changed to ''use'' for greater clarity.

In response to the first two questions, it is important to note that, in general, the regulation does not attempt to address how a prepaid plan chooses to design or implement its physician incentive plan. Rather, it attempts to regulate one of the final products, that is, the maximum financial risk to which a physician or physician group may be exposed for referral services. Plans may use a variety of incentive arrangements, including those identified by the commenter, in structuring their physician incentive plans. However, prepaid plans should be able to determine or establish, as part of their physician incentive plans, the maximum financial risk, when the risk is based on referral services, to which a physician or physician group may be exposed under the physician incentive plan. If a plan is unable, based on the structure and operation of its incentive plan, to determine the amount of the financial risk, then, according to § 417.479(f)(5)(ii), we would determine that the plan places physicians or physician groups at ''substantial financial risk'' and the plan would be required to implement stop-loss protection and conduct enrollee surveys. As indicated previously, we have decided to allow a plan to pool patients for different physician groups.

In response to the third question, the threshold for withhold arrangements is established in § 417.479(f) of this final rule. This section would apply only if the withhold is based in part or in its entirety on utilization or costs of referral services. If the return of the withhold is based solely on the physicians' own services, then, under § 417.479(f) of this final rule, these regulations would not apply.

Comment: One commenter stated that the proposed rule does not allow for the differences found in HIOs, specifically that they have mandatory enrollment in a specific area, may be at-risk for retroactively eligible individuals, and may be responsible for an ongoing category of special members who are not capitated to a particular physician. The commenter noted that the cost of services to this population affects the incentive plan (withhold payment and surplus sharing). The commenter also specifically noted that the HIOs in California which are Medicaid only were not specifically addressed in the proposed rule.

Response: The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA '85) generally subjected HIOs which were operational on or after January 1, 1986, to the same requirements as other organizations contracting with Medicaid agencies on a risk basis to provide or arrange for comprehensive services (HMOs). (Certain exceptions to this are allowed under the law.) Therefore, this proposed rule did not reiterate the fact that HIOs subject to the same requirements for HMOs are also subject to these requirements for physician financial incentive plans.

Further, OBRA '90 did not contain any provisions calling for the differential treatment of HIOs. Because of this, and the historical interest of the Congress in subjecting HIOs to the same standards as HMOs, we did not identify the need for differential treatment of HIOs in this regulation.

Comment: One commenter stated that the proposal on enrollee surveys excludes only those Medicaid enrollees who have disenrolled because of a loss of Medicaid eligibility. The commenter recommended we consider excluding those who disenroll from a prepaid plan because they moved from the plan's service area.

Response: As stated earlier, we agree that individuals who have disenrolled from the plan because they have moved outside of a plan's service area may be omitted from the plan's enrollee survey. The regulations text at § 417.479(g)(1) has been appropriately modified.

Comment: One commenter stated that, in addition to an enrollee survey, monitoring of the complaint/appeals process for the plan and the State's Medicaid fair hearing process would be another check on the quality of care and the denial of needed service.

Response: OBRA '90 does not address monitoring the complaint/appeals process for the plan and the State Medicaid fair hearing process in the State. However, monitoring the plan's complaint hearing process is the responsibility of the State Medicaid agency as part of its routine monitoring of its managed care contractors. In addition, HCFA routinely monitors a State's fair hearing process as part of the monitoring of each State's Medicaid plan. As a result, these areas are not included in these regulations.

Miscellaneous

Comment: One commenter recommended that we clarify the definition of ''medically necessary services'' as it applies in the prohibition on specific payment as an inducement to reduce or limit medically necessary services to a specific enrollee.

Response: We are preparing a final rule entitled ''Medicare Program: Criteria and Procedures for Making Medical Services Coverage Decisions that Relate to Health Care Technology.'' This rule will specify the definition of medically necessary services that will apply for purposes of the prohibition in question. (The rule will be in response to a notice we published in the Federal Register on April 29, 1987, at 52 FR 15559, that requested comments on procedures for medical services coverage decisions.)

Comment: One commenter stated that managed care plans should be specifically directed to provide for effective physician participation in the development of incentive plans and other elements of the organization's management.

Response: Physicians have the opportunity for input before they sign a contract with the organization. Physicians have the opportunity to negotiate all aspects of the contract. Since the contract specifies the nature of the incentive arrangements, the physicians have an opportunity for input through the negotiation process.

Comment: Some commenters recommended that patients be allowed direct access to specialists and/or that the prepaid plan explain, as part of the enrollment contract, that patients have limited access to specialists.

Response: HCFA supports the practice of HMOs using gatekeepers to limit patients from direct access to specialists. HMOs have found this to be an effective way to limit inappropriate utilization and expenditures. HMOs are required to explain this practice as part of the enrollment.

Comment: Several commenters suggested that there be an appeals process for physicians and patients.

Response: HCFA requires prepaid plans to provide an appeals process for enrollees. For physicians, there are several arrangements. All physicians have an opportunity to informally appeal decisions through the plan's medical review board and through the contract negotiation process. In addition, for Medicare risk contractors, unaffiliated physicians can represent a Medicare beneficiary in an appeal to the prepaid plan. In the case of a cost contract, the physician can represent a beneficiary in an appeal to whichever entity (prepaid plan, carrier, or intermediary) made the determination.

VII. Provisions of the Final Regulations

The proposed rule is adopted, with the changes listed below. Many of these changes are discussed in section V. of this preamble. If the change is not discussed in section V, the reason for the change is given below.

Changes to Proposed § 417.479

- We add a new paragraph (a); and designated proposed paragraph (a) as paragraph (b). New paragraph § 417.479(a) is added to reflect the requirement at section 1876(i)(8) of the Act that each contract between HCFA and an eligible organization contain provisions related to physician incentive plans. This new paragraph also makes it clear why this provision is placed in part 417, subpart L (Medicare Contract Requirements).
- We designate paragraph (b) as paragraph (c) and revise the definition of ''physician group'' so that it no longer inadvertently excludes physician groups that pay their physicians using a methodology under which the amount of payment is affected by referrals. We also clarify, in that definition, that an IPA is a physician group only if it is composed of individual physicians and has no subcontracts with physician groups.
- We designate proposed (c) as paragraph (d). We also revise this paragraph to remove language that, because of the addition of new paragraph (a), became redundant. Also, in response to a comment, we change ''to reduce or limit medically necessary services'' to ''to reduce or limit medically necessary services covered under the organization's contract''.
- Proposed paragraph (d) is designated as paragraph (e). Additionally, the difference in risk threshold based on the frequency of distribution or assessment of incentive payments is removed.
- Proposed paragraph (e) is designated as paragraph (f) and is revised to—

  + Provide a definition of ''potential payments'' and clarify that it is these payments that are used in the calculation of the level of risk.

  + Provide that substantial financial risk does not exist if, without pooling, the patient panel size is 25,000 patients or more.
- Proposed paragraph (g) is revised to—

  + Specify that individuals who disenroll from a prepaid plan because they relocate outside the plan's service area need not be included in the enrollee survey.

  + Provide that, in the case of aggregate stop-loss protection, the protection must cover 90 percent of the costs of referral services (beyond allocated amounts) that exceed 25 percent of potential payments.

  + Establish, in the case of stop-loss protection based on a per-patient limit, requirements as to the amount of stop-loss protection that are based on patient panel size.
- Proposed paragraph (h) is revised to-

  + Specify the items of information that must be disclosed to HCFA and to Medicare beneficiaries and, in accordance with § 434.70(a)(3) and (a)(4), to the State Medicaid agency or recipient, respectively.

  + Include methods that may be used in the calculation of panel size.

  + Specify those types of changes in the incentive plan that must be reported to HCFA and require that this information be submitted to HCFA 45 days before implementing the changes.

  + Remove proposed paragraph (h)(5). The proposed paragraph addressed when organizations with existing contracts must comply with the disclosure requirements. Because that provision would become quickly irrelevant, we have decided to address this issue in the **DATES** section of this final rule, rather than by incorporation into the CFR.

  + Require that organizations provide Medicare beneficiaries a summary of the disclosure information, if they request it.
- We designate proposed § 417.479(i) as § 417.479(j). We add a new § 417.479(i) to specify requirements related to subcontracting arrangements.

Changes to Proposed § 434.70

- Proposed paragraph (a)(2) is revised to—

  + Require compliance with §§ 417.479(d) through (g) and the requirements related to subcontracts set forth at § 417.479(i) if the subcontract is for the provision of services to Medicaid recipients.

  + Specify the items of information that must be disclosed to the State agency.

  + Require that the organization provide certain information concerning the physician incentive plan to any Medicaid recipient who requests it.

  + Remove proposed paragraph (a)(2)(iv). The proposed paragraph addressed when organizations with existing contracts (agreements) must comply with the disclosure requirements. Because that provision

would quickly become irrelevant, we have decided to address this issue in the **DATES** section of this final rule, rather than by incorporation into the CFR.

Crosswalk Between Proposed Rule and This Final Rule

Note that those provisions related to civil money penalties and intermediate sanctions that were included in the July 22, 1991, proposed rule and that were merely republished in the December 1992 proposed rule on physician incentive plans are not included in this final rule or in the following crosswalk.

Proposed	This rule
	§ 417.479(a)—new contents.
§ 417.479(a)	§ 417.479(b).
§ 417.479(b)	§ 417.479(c).
§ 417.479(c)	§ 417.479(d).
§ 417.479(d)	§ 417.479(e).
§ 417.479(e)	§ 417.479(f).
§ 417.479(f)	Content deleted.
§ 417.479(g)	§ 417.479(g).
§ 417.479(h)	§ 417.479(h).
	§ 417.479(i)—new contents.
§ 417.479(i)	§ 417.479(j).
§ 417.495(a)(7)	§ 417.500(a)(9).
§ 434.44(a)	§ 434.44(a).
	§ 434.70(a)(3) and (a)(4)—added.
§ 1003.100(b)(vi)	§ 1003.100(b)(vi).
§ 1003.101 (definitions).	§ 1003.101—only definition of ''physician incentive plan'' added by this rule.
§ 1003.103(e)(iv) through (e)(vi).	§ 1003.103(e)(iv) through (e)(vi).
§ 1003.106(a)(4)(vii)	§ 1003.106(a)(4)(vii).

VIII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the Federal Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements:

The information collection requirements in § 417.479(g)(1) (and § 434.70(a)(3) for Medicaid) concern organizations that operate incentive plans that place physicians or physician groups at substantial financial risk and require them to conduct annual enrollee surveys that include either all current Medicare/Medicaid enrollees in the organization and those who have disenrolled (other than because of loss of eligibility in Medicaid or relocation outside the organization's service area) in the past 12 months, or a sample of these same enrollees and disenrollees. These surveys must be designed, implemented, and analyzed in accordance with commonly accepted principles of survey design and statistical analysis. They must address enrollees/disenrollees satisfaction with the quality of services furnished and their degree of access to the services. We estimate that 200 organizations will conduct the surveys each year. We estimate that a total of approximately 90,000 enrollees will respond to the survey.

The information collection requirements in §§ 417.479(h)(1) and (h)(2), 417.479(i), and 434.70(a)(3) specify that disclosure concerning physician incentive plans must be made to HCFA or to the State, as appropriate. The requirements apply to physician incentive plans between eligible organizations and individual physicians or physician groups with whom they contract to furnish medical services to enrollees. The requirements apply only to physician incentive plans that base compensation on the use or cost of services furnished to Medicare beneficiaries or Medicaid recipients.

The disclosure must contain the following information:

(1) Whether services not furnished by the physician or physician group are covered by the incentive plan. (If not, disclosure of other aspects of the plan need not be made.)

(2) The type of incentive arrangement.

(3) If the incentive plan involves a withhold or bonus, the percent of the withhold or bonus.

(4) The amount and type of stop-loss protection.

(5) The patient panel size and, if patients are pooled, the pooling method used.

(6) In the case of capitated physicians or physician groups, capitation payments paid to primary care physicians for the most recent year broken down by percent for primary care services, referral services to specialists, and hospital and other types of provider services.

(7) In the case of prepaid plans that must conduct beneficiary/recipient surveys, the survey results.

An organization must provide the information upon application for a contract; upon application for a service area expansion; at least 45 days before implementing certain changes in its incentive plan, and within 30 days of a request by HCFA or the State. The respondents that will provide the information are HMOs, CMPs, HIOs, and certain subcontractor entities that contract with the Medicare program or States and have physician incentive plans. We estimate that approximately 600 organizations will submit the information.

Sections 417.479(h)(3) and 434.70(a)(4) require that the following information be provided to any Medicare beneficiary or Medicaid recipient, respectively, who requests it: Whether the plan uses a physician incentive plan that affects the use of referral services; if so, the type of incentive arrangement; whether stop-loss protection is provided; and, if a survey is required, a summary of the survey results. The respondents who will provide this information will be HMOs, CMPs, HIOs, that contract with the Medicare program or States and have physician incentive plans. We estimate that approximately 300 organizations will provide this information to a total of approximately 1,500 Medicare beneficiaries and 1,500 Medicaid recipients.

The table below indicates the annual number of responses for each regulation section in this final rule containing information collection requirements, the average burden per response in minutes or hours, and the total annual burden hours.

CFR section	Annual No. of responses	Annual frequency	Average burden per response	Annual burden hours
417.479(g)(1)	90,000	1	10 minutes	15,000
417.479(h) (1) and (2) and 417.479(I)	600	1	1 hour	600

CFR section	Annual No. of responses	Annual frequency	Average burden per response	Annual burden hours
417.479(h)(3)	1,500	1	10 minutes	250
434.70(a)(4)	1,500	1	10 minutes	250

We have submitted a copy of this final rule with comment period to OMB for its review of the above information requirements. A document will be published in the Federal Register when OMB approval is obtained.

If you comment on these information collection and recordkeeping requirements, please mail your comments to the following address: Health Care Financing Administration, Office of Financial and Human Resources, Management Planning and Analysis Staff, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850.

IX. Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all HMOs, CMPs, and HIOs are considered to be small entities.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

This final rule with comment period will amend the regulations governing prepaid health care organizations with Medicare or Medicaid risk contracts. Sections 4204(a) and 4731 of OBRA 1990 repealed the prohibition of physician incentive plans in prepaid health care organizations and enacted requirements, effective January 1, 1992, for regulating these plans.

One of the requirements imposed was that each Medicare contract with a prepaid health care organization stipulate that, if a physician incentive plan places a physician or physician group at ''substantial financial risk'' for services not provided directly, the prepaid health plan organization must: (1) Provide the physician or physician group with adequate and appropriate stop-loss protection, and (2) conduct surveys of currently and previously enrolled members to assess the degree of access to services and the satisfaction with the quality of services.

We received one comment that dealt with the impact statement in the proposed rule published in the Federal Register on December 14, 1992 (57 FR 59034). The commenter believed that the proposed rule would have a substantial impact on prepaid health care organizations. The commenter stated that it would be required to make significant changes to limit physician group participation in incentive programs. The commenter also believed the proposed rule would limit its ability to control costs and also result in higher administrative expenses. We believe most plans already meet a majority of our requirements, as indicated by the survey data collected by GHAA and Mathematica discussed in the preamble. We strongly believe that if physicians are at substantial financial risk, organizations must provide stop-loss protection to ensure that essential health care services are received by Medicare beneficiaries and Medicaid enrollees.

All of the approximately 600 HMOs, CMPs, and HIOs could be affected by the revised incentive plan disclosure requirements. We believe, however, that few incentive plans will require changes to comply with the regulations. In addition, since we expect that most current incentive plans already comply with the regulations, we believe that we will rarely need to impose intermediate sanctions or civil money penalties on prepaid health plan organizations that fail to provide covered medically necessary services. Further, we expect few additional surveys of currently and previously enrolled members will be necessary to assess the degree of access to services and the satisfaction with the quality of services. Thus, we believe that additional costs will be incurred by only a small number of organizations.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and the Secretary certifies, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals. We will, however, publish a regulatory flexibility analysis and regulatory impact analysis if we receive comments and data that would enable us to do so.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Health maintenance organization (HMO), Medicare, Reporting and recordkeeping requirements.

42 CFR Part 434

Grant programs—Health, Health maintenance organization (HMO), Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 1003

Administrative practice and procedure, Fraud, Grant programs—Health, Health facilities, Health profession, Maternal and child health, Medicaid, Medicare, Penalties.

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

I. Chapter IV of title 42 is amended as set forth below:

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

A. Part 417 is amended as follows:

1. The authority citation for part 417 is revised to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. A new § 417.479 is added to read as follows:

§ 417.479 Requirements for physician incentive plans.

(a) The contract must specify that an organization 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 eligible organizations and individual physicians or physician groups with whom they contract to provide medical services to enrollees. These requirements 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 recipients.

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

Bonus means a payment an organization 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 organization 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 subpart.

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 organization 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 recipients enrolled in the organization.

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 organization 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 organization'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 or is greater than 25,000 patients only as a result of pooling patients using a method set forth in paragraph (h)(1)(v) of this section:

(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 possible payments and minimum possible payments is more than 25 percent of the maximum possible payments; or

(ii) The maximum and minimum possible 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.* Organizations 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 organization and those who have disenrolled (other than because of loss of eligibility in Medicaid or relocation outside the organization'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 incentive plan, and at least every 2 years 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. In determining patient panel size, the patients may be pooled using one of the methods set forth in paragraph (h)(1)(v) of this section if pooling is consistent with the relevant contract between the physician or physician group and the organization. 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:

(A) Less than 1,000 patients—$10,000.

(B) 1,000 to 10,000 patients—$30,000.

(C) 10,000 to 25,001 patients—$200,000.

(D) Greater than 25,000 patients—

(*1*) Without pooling patients—none; and

(*2*) As a result of pooling patients—$200,000.

(iii) The organization may provide the stop-loss protection directly or purchase the stop-loss protection, or the physician or physician group may purchase the stop-loss protection. If the physician or physician group purchases the stop-loss protection, the organization must pay the portion of the premium that covers its enrollees or reduce the level at which the stop-loss protection applies by the cost of the stop-loss.

(h) *Disclosure requirements for organizations with physician incentive plans*—(1) *Disclosure to HCFA.* Each organization must provide to HCFA information concerning its physician incentive plans as required or requested. The disclosure must contain the following information in detail sufficient to enable HCFA to determine whether the incentive plan complies with the requirements specified in this section:

(i) Whether services not furnished by the physician or physician group are covered by the incentive plan. If only the services furnished by the physician or physician group are covered by the incentive plan, disclosure of other aspects of the plan need not be made.

(ii) The type of incentive arrangement; for example, withhold, bonus, capitation.

(iii) If the incentive plan involves a withhold or bonus, the percent of the withhold or bonus.

(iv) The amount and type of stop-loss protection.

(v) The panel size and, if patients are pooled according to one of the following permitted methods, the method used:

(A) Including commercial, Medicare, and/or Medicaid patients in the calculation of the panel size.

(B) Pooling together, by the organization, of several physician groups into a single panel.

(vi) In the case of capitated physicians or physician groups, capitation payments paid to primary care physicians for the most recent year broken down by percent for primary care services, referral services to specialists, and hospital and other types of provider (for example, nursing home and home health agency) services.

(vii) In the case of those prepaid plans that are required to conduct beneficiary surveys, the survey results.

(2) *When disclosure must be made to HCFA.* (i) An organization must provide the information required by paragraph (h)(1) of this section to HCFA—

(A) Upon application for a contract;

(B) Upon application for a service area expansion; and

(C) Within 30 days of a request by HCFA.

(ii) An organization must notify HCFA at least 45 days before implementing any of the following changes in its incentive plan:

(A) A change as to the type of incentive plan.

(B) A change in the amounts of risk or stop-loss protection.

(C) Expansion of the risk formula to cover services not furnished by the physician group that the formula had not included previously.

(3) *Disclosure to Medicare beneficiaries.* An organization 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 organization 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 HCFA 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 recipients. 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 organization 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 HCFA 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 recipients. The disclosure must include the information required to be disclosed under 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) 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 organization.* HCFA may apply intermediate sanctions, or the Office of Inspector General may apply civil money penalties described at § 417.500, if HCFA determines that an eligible organization fails to comply with the requirements of this section.

3. In § 417.500, the introductory text of paragraph (a) is republished, and a new paragraph (a)(9) is added to read as follows:

§ 417.500 Sanctions against HMOs and CMPs.

(a) *Basis for imposition of sanctions.* HCFA may impose the intermediate sanctions specified in paragraph (d) of this section, as an alternative to termination, if HCFA determines that an HMO or CMP does one or more of the following:

* * * * *

(9) Fails to comply with the requirements of §§ 417.479(d) through (i) relating to physician incentive plans.

* * * * *

PART 434—CONTRACTS

B. Part 434 is amended as follows:

1. The authority citation for part 434 continues to read as follows:

Authority: Secs. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 434.44, the introductory text of paragraph (a) is republished, and paragraph (a)(1) is revised to read as follows:

§ 434.44 Special rules for certain health insuring organizations.

(a) A health insuring organization that first enrolls patients on or after January 1, 1986, and arranges with other providers (through subcontract, or through other arrangements) for the delivery of services (as described in §§ 434.21(b)) to Medicaid enrollees on a prepaid capitation risk basis is—

(1) Subject to the general requirements set forth in § 434.20(d) concerning services that may be covered and § 434.20(e) which sets forth the requirements for all contracts, the additional requirements set forth in §§ 434.21 through 434.38 and the Medicaid agency responsibilities specified in subpart E of this part; and

* * * * *

3. In § 434.67, the introductory text of paragraph (a) is republished, and a new paragraph (a)(5) is added to read as follows:

§ 434.67 Sanctions against HMOs with risk comprehensive contracts.

(a) Basis for imposition of sanctions. The agency may recommend that the intermediate sanction specified in paragraph (e) of this section be imposed if the agency determines that an HMO with a risk comprehensive contract does one or more of the following:

* * * * *

(5) Fails to comply with the requirements of §§ 417.479(d) through (g) of this chapter relating to physician incentive plans, or fails to submit to the State Medicaid agency its physician incentive plans as required or requested in § 434.70.

* * * * *

4. Section 434.70 is revised to read as follows:

§ 434.70 Condition for FFP.

(a) FFP is available in expenditures for payments to contractors only for the periods that—

(1) The contract—

(i) Meets the requirements of this part;

(ii) Meets the appropriate requirements of 45 CFR part 74; and

(iii) Is in effect;

(2) The HMO or HIO complies with the physician incentive plan requirements specified in §§ 417.479(d) through (g) of this chapter and the requirements related to subcontracts set forth at § 417.479(i) of this chapter if the subcontract is for the provision of services to Medicaid recipients;

(3) The HMO or HIO (or, in accordance with § 417.479(i) of this chapter, the subcontracting entity) has supplied the information on its physician incentive plan listed in §§ 417.479(h)(1) of this chapter to the State Medicaid agency. The information must contain detail sufficient to enable the State to determine whether the plan complies with the requirements of §§ 417.479(d) through (g) of this chapter. The HMO or HIO must supply this information to the State Medicaid agencies as follows:

(i) Upon application for a contract.

(ii) At least 45 days before implementing any of the following changes in its incentive plan:

(A) A change as to the type of incentive plan.

(B) A change in the amounts of risk or stop-loss protection.

(C) Expansion of the risk formula to cover services not furnished by the physician group that the formula had not included previously.

(iii) Within 30 days of a request by the State or HCFA; and

(4) The HMO or HIO has provided the information on physician incentive plans listed in § 417.479(h)(3) of this chapter to any Medicaid recipient who requests it.

(b) HCFA may withhold FFP for any period during which—

(1) The State fails to meet the State plan requirements of this part;

(2) Either party to a contract substantially fails to carry out the terms of the contract; or

(3) The State fails to obtain from each HMO or HIO contractor proof that it meets the requirements for physician incentive plans specified in §§ 417.479(d) through (g) and (i) of this chapter.

CHAPTER V—OFFICE OF INSPECTOR GENERAL—HEALTH CARE, DEPARTMENT OF HEALTH AND HUMAN SERVICES

II. 42 CFR part 1003 is amended as set forth below:

PART 1003—CIVIL MONEY PENALTIES, ASSESSMENTS AND EXCLUSIONS

1. The authority citation for part 1003 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7a, 1320b–10, 1395mm, 1395ss(d), 1395u(j), 1395u(k), 1396b(m), 11131(c) and 11137(b)(2).

2. In § 1003.100, paragraph (b)(1) introductory text is revised and paragraph (b)(1)(vii) is revised to read as follows:

§ 1003.100 Basis and purpose.

* * * * *

(b) *Purpose.* * * *

(1) Provides for the imposition of civil money penalties and, as applicable, assessments against persons who—

* * * * *

(vii) Substantially fail to provide an enrollee with required medically necessary items and services, or who engage in certain marketing, enrollment, reporting, claims payment, employment or contracting abuses, or that do not meet the requirements for physician incentive plans for Medicare specified in §§ 417.479 (d) through (i) of this title;

* * * * *

3. Section 1003.101 is amended by adding, in alphabetical order, a definition for the term ''Physician incentive plan'' to read as follows:

§ 1003.101 Definitions.

* * * * *

Physician incentive plan means any compensation arrangement between a contracting organization and a physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to enrollees in the organization.

* * * * *

4. In § 1003.103, paragraph (f)(1) introductory text is republished, paragraphs (f)(1)(iv) and (f)(1)(v) are revised, and a new paragraph (f)(1)(vi) is added, to read as follows:

§ 1003.103 Amount of penalty.

* * * * *

(f)(1) The OIG may, in addition to or in lieu of other remedies available under law, impose a penalty of up to $25,000 for each determination by HCFA that a contracting organization has—

* * * * *

(iv) Misrepresented or falsified information furnished to an individual or any other entity under section 1876 or section 1903(m) of the Act;

(v) Failed to comply with the requirements of section 1876(g)(6)(A) of the Act, regarding prompt payment of claims; or

(vi) Failed to comply with the requirements of §§ 417.479 (d) through (i) of this title for Medicare, and §§ 417.479 (d) through (g) and (i) of this title for Medicaid, regarding certain prohibited incentive payments to physicians.

* * * * *

5. In § 1003.106, paragraph (a)(5) introductory text is republished; paragraphs (a)(5)(vii) and (a)(5)(viii) are redesignated as paragraphs (a)(5)(viii) and (a)(5)(ix), respectively; and a new paragraph (a)(5)(vii) is added to read as follows:

§ 1003.106 Determinations regarding the amount of the penalty and assessment.

(a) * * *

(5) In determining the appropriate amount of any penalty in accordance with § 1003.103(f), the OIG will consider, as appropriate—

* * * * *

(vii) The extent to which the failure to provide medically necessary services could be attributed to a prohibited inducement to reduce or limit services under a physician incentive plan and the harm to the enrollee which resulted or could have resulted from such failure. It would be considered an aggravating factor if the contracting organization knowingly or routinely engaged in any prohibited practice which acted as an inducement to reduce or limit medically necessary services provided with respect to a specific enrollee in the organization;

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.733—Medicare—Hospital Insurance Program; No. 93.774—Medicare Supplementary Medical Insurance Program; No. 93.778—Medical Assistance Program)

Dated: April 20, 1995.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: May 19, 1995.

June G. Brown,

Inspector General, Department of Health and Human Services.

Dated: November 2, 1995.

Donna E. Shalala,

Secretary.

[FR Doc. 96–7228 Filed 3–25–96; 8:45 am]

BILLING CODE 4120–01–P

UTAH RECLAMATION MITIGATION AND CONSERVATION COMMISSION

43 CFR Part 10001

Operating Procedures

AGENCY: Utah Reclamation Mitigation and Conservation Commission.

ACTION: Final rule.

SUMMARY: This part establishes the final rule that describes the operating procedures of the agency established by the Central Utah Project Completion Act. The rule meets the requirement of the Administrative Procedure Act that directs each agency to publish its organizational structure and functions in the Federal Register for the guidance of the public.

EFFECTIVE DATE: February 5, 1996.

FOR FURTHER INFORMATION CONTACT: Michael C. Weland, Executive Director, Utah Reclamation Mitigation and Conservation Commission, 111 East Broadway, Suite 310, Salt Lake City, Utah, 84111. Telephone (801) 524–3146.

SUPPLEMENTARY INFORMATION: The final rule was adopted by the Utah Reclamation Mitigation and Conservation Commission in public session February 5, 1996.

List of Subjects in 43 CFR Part 10001

Administrative practice and procedures, Organization and functions (Government Agencies).

Chapter III of title 43 of the Code of Federal Regulations is amended to add new part as follows:

PART 10001—OPERATING PROCEDURES

Sec.
10001.1 Commissioners.
10001.2 Meetings.

Authority: Sec. 301, Pub. L. 102–575, 106 Stat 4625.

§10001.1 Commissioners.

(a) Three members of the Commission shall constitute a quorum.

(b) The affirmative vote of at least three members of the Commission in attendance at a meeting at which a quorum is present, on any matter within their duties and responsibilities, shall constitute the Commission's action, except as otherwise provided herein.

(1) The Commission may not take action on a matter not appearing on the published agenda for a particular meeting except upon the unanimous vote of the members present.

(2) Any proposed Commission action must be moved by a Commission member and seconded by another member before a vote may be taken by the Commission. Other questions of procedure will be decided by reference to generally accepted principles of parliamentary procedure, as determined by the Chairman or the Chairman's designee.

(3) A member who is present at a meeting of the Commission at which action on any matter is taken shall be presumed to have assented to the action taken unless that member's abstention or dissent shall have been entered into the minutes of the meeting or unless that member shall file a written dissent to such action with the Chairman before the adjournment of the meeting. A written dissent shall not apply to a member who voted in favor of such action.

(4) In a case where a member is recused due to a conflict in a particular matter, the member shall not be present during, nor take any part in, the proceedings on that matter and shall not be counted as having voted.

(5) No member of the Commission may appoint another individual, including another member, by proxy or otherwise, to assume his or her responsibilities or vote on his or her behalf as a member of the Commission.

(c) There shall be one office of Chairman of the Commission to be held by a member of the Commission.

(1) The Chairman shall be elected by an affirmative vote by at least three members of the Commission and shall hold office for one year, commencing immediately upon election, or until resignation from the office or the Commission.

(2) The Chairman shall be the presiding officer of the Commission and shall perform the following duties and responsibilities:

(i) Preside at all meetings of the Commission;

(ii) Vote on all matters requiring Commission action;

(iii) Execute all contracts, agreements, resolutions, and other documents approved and authorized by the Commission, except as otherwise delegated by the Commission;

(iv) Preside at ceremonial activities sponsored by the Commission and represent the Commission at other ceremonial activities upon invitation;

(v) Appoint any other member of the Commission to serve as Acting Chairman in the absence of the Chairman and Vice-Chairman; and

(vi) Serve as spokesperson for the Commission, unless otherwise directed by the Commission. When the Chairman or any other member of the Commission speaks as an individual member of the Commission, the Chairman or member shall state when he or she is representing his or her own views and not the consensus of the Commission as a whole.

(3) A member may not serve as Chairman for more than four consecutive full one-year terms.

(4) Whenever a vacancy occurs in the office of Chairman, the members shall at their next meeting elect a successor to fill the vacancy for the unexpired term.

(d) The Commission may, upon an affirmative vote by at least three members, elect one of its members to serve as Vice-Chairman.

(1) The Vice-Chairman, whenever such office may from time to time be established, shall perform all of the duties of the Chairman of the Commission when the Chairman is unable for any reason to act or when for any reason there is a vacancy in the office of Chairman.