regulatory flexibility analysis that describes the impact of a proposed or final rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant adverse economic impact on a substantial number of small entities. Today's rule is deregulatory in nature. The effect of today's final rule is to remove obsolete guidelines which are mandatory only for Federal facilities. Therefore, I certify that today's rule will not have a significant economic impact on a substantial number of small entities. As a result, no Regulatory Flexibility Analysis is needed.

VI. Submission To Congress And The General Accounting Office

Under 5 U.S.C. 801(a)(1)(A) as added by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 244

Environmental Protection, Beverages, Government property, Recycling.

40 CFR Part 245

Government property, Recycling.

Dated: December 20, 1996.

Carol M. Browner,

Administrator.

For the reasons set forth in the preamble and under the authority of 42 U.S.C. sections 6907, 6912, 6961, and 6964, Title 40, Chapter I of the Code of Federal Regulations is amended as follows:

PART 244—[REMOVED]

1. Part 244 is removed.

PART 245—[REMOVED]

2. Part 245 is removed.

[FR Doc. 96–32967 Filed 12–30–96; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 401 and 405

[BPD–869–CN]

Medicare Program; Waiver of Recovery of Overpayments

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Correction notice.

SUMMARY: On September 19, 1996, we published a final rule (61 FR 49269), which duplicated in HCFA's regulations the content of two sections of the Social Security Administration's (SSA) regulations concerning waiver of recovery of overpayments. Since SSA was restructuring its regulations to apply only to the Federal Old-Age, Survivors and Disability Insurance Program, we established the content of these sections in 42 CFR part 405 to preserve the content of the SSA regulations that are applicable to the Medicare Program. This notice corrects an error in the authority citation in that document.

EFFECTIVE DATE: These regulations are effective on October 21, 1996.

FOR FURTHER INFORMATION CONTACT: David Walczak, (410) 786–4475.

SUPPLEMENTARY INFORMATION: On September 19, 1996, we published a final rule (61 FR 49269) concerning waiver of recovery of overpayments. This notice corrects an error in the authority citation in that document.

On page 49271, in column one, under part 405, amendment 1, the authority citation for part 405, ''Authority: Secs. 1102, 1862, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395y, and 1895hh).'' is corrected to read, ''Authority: Secs. 1102, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a), unless otherwise noted.''

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 19, 1996.

Michael W. Carleton,

Acting Deputy Assistant Secretary for Information Resources Management.

[FR Doc. 96–33090 Filed 12–30–96; 8:45 am]

BILLING CODE 4120–01–P

42 CFR Parts 417 and 434

[OMC–010–F]

RIN 0938–AF74

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

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations established by a March 27, 1996, final rule with comment period. The regulations govern physician incentive plans operated by 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.

As explained in the March 27 rule, 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.

DATES: *Effective date.* These regulations are effective on January 1, 1997.

FOR FURTHER INFORMATION CONTACT: Beth Sullivan, (410) 786–4596.

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. Payment under these contracts may either be made on a risk capitation basis, under which a fixed amount is paid per Medicare enrollee per month, or on a reasonable cost basis, under which costs are reimbursed retrospectively. Implementing Federal regulations for the organization and operation of Medicare HMOs and CMPs, contract requirements, and conditions for payment are located at 42 CFR 417.400 through 417.694.

The amount paid to risk HMOs/CMPs 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 contracts with organizations (HMOs, and certain 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 the contracts comply with detailed requirements in section 1903(m)(2)(A) and 42 CFR part 434.

II. Legislative and Regulatory 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.

Section 13562 of OBRA '93 amended section 1877 of the Act, which prohibits physicians from referring Medicare patients to an entity for the furnishing of certain designated health services if the physician (or an immediate family member) has a financial relationship with that entity. A financial relationship can consist of either an ownership or investment interest in the entity or a compensation arrangement with the entity. 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 physician's or family member's personal services compensation arrangement with an entity involves compensation that varies based on the volume or value of referrals. OBRA '93 also extended the provisions in section 1877 to Medicaid.

In the December 14, 1992 issue of Federal Register, we published, in conjunction with the Office of Inspector General, our proposal for implementing the requirements in sections 4204(a) and 4731 of OBRA '90 (57 FR 59024). On March 27, 1996, again in conjunction with the Office of Inspector General, we published, at 61 FR 13430, a final rule with comment period that set forth in regulations incentive plan requirements that govern Federally-qualified HMOs and CMPs contracting with the Medicare program and certain HMOs and HIOs contracting with the Medicaid program. On September 3, 1996, we published, at 61 FR 46384, a final rule correction that clarified and changed some of the dates by which prepaid health plans had to comply with the requirements of the March 27 rule. Readers who desire additional background information are referred to the above cited Federal Register documents.

III. Provisions of the March 27, 1996 Rule

This section contains a brief summary of the provisions of the March 27, 1966 rule. If we received public comments on a particular provision, a fuller description of the provision is given in section IV of this preamble (Analysis of and Responses to Public Comments), and we indicate that in this section. Note that we do not describe below those provisions of the March 27, 1996 rule that amended 42 CFR Part 1003 (Civil Money Penalties, Assessments

and Exclusions) since they are not the subject of this revised final rule.

The requirements for physician incentive plans are set forth in § 417.479. Paragraph (a) of that section specifies that the contract between HCFA and an HMO or CMP must specify that the HMO or CMP may operate a physician incentive plan only if: (1) No specific payment is made directly or indirectly under the plan to a physician or physician group as an inducement to reduce or limit medically necessary services furnished to an individual enrollee, and (2) the stop-loss protection, enrollee survey, and disclosure requirements of § 417.479 are met.

Section 417.479(b) provides that the physician incentive plan requirements apply to physician incentive plans between HMOs/CMPs and individual physicians or physician groups with whom the HMOs or CMPs contract to provide medical services to enrollees. It further provides that the 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.

Section 417.479(c) defines the following terms for purposes of § 417.479: Bonus, capitation, payment, physician group, physician incentive plan, referral services, risk threshold, and withhold.

Section 417.479(d) prohibits payment of any kind made directly or indirectly under the incentive plan as an inducement to reduce or limit medically necessary services covered under the HMO's or CMP's contract that are furnished to an individual enrollee.

Section 417.479(e) sets forth a general rule for determining when substantial financial risk occurs. (See section IV.)

Section 417.479(g) mandates that, if an HMO or CMP operates an incentive plan that places physicians or physician groups at substantial financial risk, it must conduct enrollee surveys that meet specified requirements and ensure that all physicians and physician groups at substantial financial risk have either aggregate or per-patient stop-loss protection that meets specified requirements. (See section IV.)

Section 417.479(h) requires that organizations with physician incentive plans disclose information about those plans to us and to any Medicare beneficiary who requests it. (See section IV.)

Section 417.479(i) sets forth requirements related to subcontracting arrangements. (See section IV.)

Section 417.479(j) specifies that we may apply intermediate sanctions, or the Office of Inspector General may apply civil money penalties, if we determine that an HMO or CMP fails to comply with the physician incentive plan requirements. In addition, failure to comply with the physician incentive plan requirements was added to the list of bases for imposition of sanctions at § 417.500.

The March 27, 1996 final rule also amended the Medicaid rules at § 434.70 (Conditions for Federal financial participation (FFP)) to specify that FFP is available in expenditures for payments to an HMO or HIO only if it complies with the physician incentive plan requirements. The final rule also incorporated these requirements into §§ 434.44 (Special rules for certain HIOs) and 434.67 (Sanctions against HMOs with risk comprehensive contracts).

IV. Analysis of and Responses to Public Comments

We received 38 timely items of correspondence on the March 27, 1996 final rule with comment period. Commenters included prepaid plans, national and local associations of managed care providers, physician associations, a State medical association, and consumer advocacy groups. This section of the preamble contains a summary of the comments and our responses. Note that a national association that indicated that it represents approximately 1,000 health plans and identified below as ''a major association'' submitted comments. Although some of the comments below are attributed only to the major association, individual health plans also made some of these same comments.

Applicability

Comment: A commenter asked whether the regulations apply to enrollees who are enrolled through the prepaid plan's commercial line of business if the enrollees are also Medicare beneficiaries. For example, if an individual who is over 65 but is actively working is covered by the prepaid plan's commercial product through his or her employer, would the physician incentive arrangement between the prepaid plan and the physician(s) treating that individual under the commercial product be subject to the regulations?

Response: Yes, the regulations apply to these plans. The employer's plan is the first payer, and the Medicare capitation payment is adjusted downward, but the enrollee is still a Medicare beneficiary.

Comment: One commenter stated that the regulation defines ''physician group'' as a corporation or other group that ''*distributes income* from the practice among *members*.'' [Emphasis added by commenter.] The commenter stated that community health centers (CHCs) are clearly not included within this definition. As a result, the commenter is unable to ascertain whether plans contracting with CHCs will be required to provide to CHCs the stop-loss protection described in the regulation. The commenter recommends that the definition of ''physician group'' be changed as regards distribution of income and membership so as to include CHCs. The commenter pointed out the following: CHCs are by definition public or private nonprofit entities. As tax-exempt entities, they cannot ''distribute'' income like a for-profit entity does. CHC physicians are not ''members'' of the corporation. Usually they are employees or, in some instances, contractors.

Response: We disagree that the definition needs to be revised. We believe the commenter has misinterpreted the definition as describing profit sharing among the members of a for-profit entity. The term ''income'' does not equate to ''profits.'' The definition does include CHCs.

Disclosure

We received several comments concerning the disclosure requirements in the March 27 rule. Specifically, § 417.479(h)(1) requires each HMO or CMP with a physician incentive plan to provide us with information concerning its physician incentive plans as required or requested by us. The disclosure must contain the following information in detail sufficient to enable us to determine whether the incentive plan complies with the requirements of § 417.479:

- 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 plan, disclosure of other aspects of the plan need not be made.
- The type of incentive arrangement.
- 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, the pooling method used.
- In the case of a capitated physician or physician group, capitation 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 an HMO or CMP that is required to conduct beneficiary surveys, the survey results.

Section 417.479(h)(2) requires an HMO or CMP to provide the above information to us (1) upon application for a contract; (2) upon application for a service area expansion; and (3) within 30 days of a request by us. This section also requires an HMO or CMP to notify us at least 45 days before implementing a change in 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 furnished by the physician group that the formula had not included previously.

Section 417.479(h)(3) of the March 27 rule requires an HMO or CMP to provide the following information to any Medicare beneficiary who requests it:

• Whether it uses a physician incentive plan that affects the use of referral services.

• The type of incentive arrangement.

• Whether stop-loss protection is provided.

• If it was required to conduct a beneficiary survey, a summary of the survey results.

Section 417.479(i) requires a prepaid plan that contracts with a physician group that places the individual physician members at substantial financial risk for services they do not furnish to disclose to us 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 § 417.479 (h)(1)(i) through (h)(1)(vii) and be made at the times specified in § 417.479(h)(2).

Section 434.70(a) provides that Federal financial participation is available in expenditures for payment to HMOs or HIOs only for periods that the HMO or HIO has (1) supplied the information listed in § 417.479(h)(1) to the State Medicaid agency; and (2) supplied the information on physician incentive plans listed in § 417.479(h)(3) to any Medicaid recipient who requests it. The timeframes for disclosure to the State Medicaid agency are the same as those for Medicare.

Comment: One commenter suggested that health plans be permitted to deem themselves to have transferred substantial financial risk without having to describe to us the specific incentive arrangements and analyses of each arrangement. The commenter also questioned our authority for requiring disclosure of incentive arrangements and believed that disclosure presents an enormous administrative burden. The commenter asked: If an HMO agrees to provide stop-loss and to conduct surveys, must it still disclose the information to HCFA as required by the regulation?

Response: Yes, under the statute and the regulation, health plans must disclose this information. This information serves many purposes. For example, it will be used to monitor compliance, evaluate the impact of the regulation, and ensure the delivery of high quality health care. In addition, this information will be useful to beneficiaries in ensuring that they get needed care. Section 1876(i)(8) of the Act requires the HMO or CMP provide the Secretary with descriptive information regarding the plan that is sufficient to permit the Secretary to determine whether the plan is in compliance with the physician incentive plan requirements. Congress clearly intended health plans to disclose information about the nature of physician incentive compensation arrangements and the extent to which physicians are being placed at substantial risk by the arrangements.

In preparing both the March 27 regulation and these amendments and clarifications, we have tried to limit the information being reported to only that which is essential for us to carry out this explicit statutory responsibility to ensure that plans are in compliance. We are not requiring extensive detail about the compensation arrangements being used, but rather are seeking information about the general nature and scope of these arrangements.

Comment: One commenter believed that the information to be disclosed to us under the regulation is proprietary and should be protected under the Freedom of Information Act (FOIA). The commenter stated that we should adopt the same policy we use for disclosure of a risk contractor's adjusted community rating (ACR). The commenter believed that the physician incentive information merits comparable treatment.

Response: To the degree that physician incentive information constitutes ''trade secrets or commercial or financial information obtained from a person [that is] privileged or confidential,'' the information will be protected from release under exemption (b)(4) of the FOIA (5 U.S.C. 552(b)(4).) In accordance with 45 CFR 5.65 (c) and (d), the submitter of such information may designate all or part of the information as confidential and exempt from disclosure at the time the information is submitted to the government. Also, the Freedom of Information and Privacy Office, HCFA, upon receipt of a FOIA request for the information, will ask that the involved submitter specify what it believes to be confidential commercial or financial information. In both situations, we will follow procedures set forth at 45 CFR 5.65(d), with the initial disclosure decisions independently made by our Freedom of Information Officer. The information specified as available to a beneficiary upon request will be available under FOIA. For instance, whether or not the incentive plan covers referral services, the type of incentive arrangement (for example, withhold or capitation), and whether adequate stop-loss protection is in place would be available under FOIA.

Comment: One commenter did not believe that disclosure requirements would pose an undue burden on plans, because ''plans routinely provide information to patients at the time of enrollment.'' The commenter stresses the time that notice is provided as well as the substance of what is provided. The commenter believed that all financial information should be provided at enrollment (and annually thereafter), but also notes that plans should report information regarding the scope of benefits and procedures for review of grievances. The commenter stated that one of its internal publications includes a statement on incentive plans, asserting that these plans ''should be disclosed to the patient upon enrollment and at least annually thereafter.'' The commenter elaborated on that assertion by stating, ''[we] strongly support disclosure to patients of physician incentive plans affecting Medicare and Medicaid patients'' and ''strongly support disclosure by all managed care plans to patients of information regarding the scope of benefits and procedures for review of grievances.''

The commenter also stated the disclosures are necessary to serve as notice to patients that incentives exist. The commenter went on to state that it believes the information is necessary in place of outcomes measures until such measures are widely accepted and available.

In contrast, a major association of health plans asked that we give plans broad discretion to decide how this information will be presented.

Another commenter contended that section 1876(i)(8) of the Act does not give us the authority to require that a prepaid plan release information about its incentive plans to Medicare beneficiaries and Medicaid recipients, and that there is no such grant of authority in parallel medical provisions. The commenter added that, even if it

were to assume that a general authority conferred upon us allows us to impose this obligation, the regulation goes far beyond what the commenter believes to be reasonable. The commenter noted that, under the regulation, every beneficiary or recipient in the country, regardless of location and regardless of the relationship to the prepaid plan, may obtain information about the incentive plan. The commenter recommended that only enrollees of the prepaid plan or beneficiaries or recipients who file an application to join the plan should be entitled to obtain the information. The commenter also recommended that the information be limited to the following: (1) Whether the physician has an arrangement with the prepaid plan that has the potential to compensate him or her for controlling the services he or she provides; (2) that the amount of risk is limited because of stop-loss protection; and (3) the results of any enrollee survey will be provided, upon request, including information about quality of care.

Response: Some of the information may be confidential and will be protected by FOIA. Nonetheless, we intend to require plans to publish in the evidence of coverage (EOC) notices that beneficiaries can request summary information on the HMO's physician incentive plans. These EOC notices are available at enrollment. We will provide further guidance on this in the future.

On the question of our legal authority to require disclosure to beneficiaries, we believe that in requiring disclosure of information on physician incentive plans, Congress intended that this information be used in the best interests of the beneficiary. While the statute refers only to disclosure of this information to the Secretary, this information is clearly of interest to beneficiaries as well. Requiring plan disclosure directly is simply more efficient than having the Secretary provide this information to beneficiaries, which the Secretary clearly has legal authority to do.

We do not agree that this information should be made available only to an enrollee or applicant for enrollment in a managed care plan. This information is potentially very important and useful to a beneficiary in deciding whether to select managed care rather than fee-for-service care and which of the available managed care plans to select.

Comment: A major association of health plans stated that we should make available to the public all the information on incentive plans that we and the States receive. The commenter did not explain why the information should be made public, but just noted that there is ''no valid reason to keep this information from the public'' and that publication would allow health policy researchers to better understand the relationship between specific risk arrangements and access and quality of care provided to enrollees.

Response: We plan to publish aggregate information on physician incentive plans obtained under the regulation; therefore, the information will be public. Publication of additional information, beyond that specified in the regulation, however, would be a substantial administrative task and would not advance the purposes of the law.

Comment: One commenter stated that requiring the HMO or CMP to collect information about incentive plans operated by physician groups or subcontractors is not the most efficient or effective means of collecting the necessary information. The commenter suggested that we collect the information directly from the physician groups and subcontractors. This commenter believed we should allow a physician group to attest that it has no physician incentive plan or no physician incentive plan related to use of referral services for Medicare or Medicaid enrollees and that HMOs should be allowed to rely upon that attestation.

Response: The HMO/CMP is responsible for ensuring that the requirements of this regulation are met if a physician group or individual physicians are placed at substantial financial risk by a subcontractor or physician group. Requiring that the HMO or CMP collect the information ensures that it is aware of all arrangements subject to the regulations. In addition, since lines of communication between the physician group or subcontractor and the prepaid plan are already in place, the HMO or CMP is the most efficient conduit for the disclosure of information. We will allow physician groups to make attestations and will provide further guidance on this item. We will also develop a disclosure form that will describe the minimum amount of information that the prepaid plan must obtain from physician groups.

Substantial Financial Risk

We received significant comments on our definition of ''substantial financial risk.'' Section 417.479(e) provides that substantial financial risk occurs when an incentive arrangement places a physician or physician group at risk for amounts beyond the risk threshold (25 percent), 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.

Section 417.479(f) provides that physician incentive plans with any of the following features place physicians at substantial financial risk if the 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:

- Withholds greater than 25 percent of potential payments.
- 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.
- Bonuses greater than 33 percent of potential payments minus the bonus.
- 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%.
- Capitation arrangements if—

+ The difference between the maximum possible payments and minimum possible payments is more than 25 percent of the maximum possible payments; or

+ The maximum and minimum possible payments are not clearly explained in the physician's or physician group's contract.

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

Section 417.479(f) defines ''potential payments'' as 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.

Comment: A major association contended that the methodology for determining substantial financial risk is flawed because a substantial number of affected prepaid plans will be viewed as transferring substantial financial risk and be subject to the stop-loss and enrollee survey requirements. The association pointed out that we stated in the proposed rule that the original choice of a 25 percent threshold for substantial financial risk was based on the assumption that only ''outlier'' risk levels would be considered ''substantial.'' The association contends

that our methodology in fact covers ''mainstream'' arrangements, and thus implicitly suggests that they are outliers. The association believes that the proportion of outliers in a given population should be quite small (typically in the range of 5 percent) and that a methodology that purports to only identify outliers is invalid to the extent it includes a proportion of the population beyond that represented by the extreme. The association has concluded, based on extensive communications with its membership and its work group, that application of the methodology in the March 27 rule will result in the inclusion of substantial numbers of what it contends to be ''mainstream'' incentive arrangements as involving substantial financial risk. The association stated that, based upon information from its member organizations, a large number of plans combine capitation or withholds with bonuses, and the result is that the risk level exceeds 25 percent.

The association reminded us that, in the preamble of the proposed rule, we stated that 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, but that if new information regarding the influence of various elements of physician incentive plans becomes available, we will evaluate it to determine if the approach in our proposed regulations should be reconsidered. The association contended that a reevaluation of this structure is clearly necessary at this time and that the regulations need to be modified to address five areas: (1) The association believes that the risk threshold should be refined to allow for the transfer of a larger portion of risk for referral services; (2) the association believes that the regulation needs a mechanism to estimate the amount of risk transferred if a precise calculation cannot be made; (3) the association recommends that maximum and minimum thresholds be calculated based on standards that are more ''realistic'' in its view; (4) the association would like more latitude in the pooling rules to allow large physician groups that spread risk across large total numbers of health plan patients to be exempt from the requirements; and (5) the association suggests that a good cause exemption be available to allow for the approval of physician incentive plans that, for policy reasons, should not be considered as transferring substantial financial risk, although the circumstances were not envisioned when the regulations were drafted.

To achieve the above objectives, the association presented a number of recommendations. These recommendations and our response to each of them follow, but first we respond to the above comment that many plans would be identified as outliers.

Response: At the time we were developing these regulations in proposed form, it was our understanding that most physician incentive plans created financial incentives to reduce unnecessary referrals through the use of bonuses or withholds or some combination of the two. On the assumption that a specific amount of payment was ''at risk'' (whether an amount withheld when referrals are high or a bonus paid if they are low), we had to come up with a threshold beyond which risk would be considered ''substantial.'' As the commenting association correctly notes, we used an outlier approach to determine what level of risk would be considered ''substantial'' under this methodology. This resulted in a figure of 25 percent of potential payments. It is our view that 25 percent represents a significant amount of income to lose. This may be in addition to discounts that physicians may give to various patients or prepaid plans. Many consumer and physician groups, in fact, believe that 25 percent is too high. We now recognize that an increasing number of plans use capitation arrangements under which referral service costs must be covered with capitation amounts, and that these plans will be determined to be at substantial financial risk if the maximum and minimum potential payments are not clearly explained in the physician's or physician group's contract. Raising the risk threshold to a higher level will not affect these plans since they would still be deemed to involve substantial financial risk and trigger stop-loss insurance requirements. However, in most of these cases, the physicians already have stop-loss protection comparable to the requirements of this regulation. With regard to suggestions to lower the threshold, here, again, changing the threshold would not affect these plans. We thus believe that the 25 percent threshold should remain in place.

Recommendation: The association recommended that an exception to the 25 percent risk threshold be created for certain bonus arrangements. This exception would permit prepaid plans to supplement their incentive programs by offering an opportunity for a bonus, in addition to capitation payments or withholds, or an opportunity for an additional bonus where a bonus is already in place. The supplemental bonus could not exceed 15 percent of the ''payments.''

Response: Under the March 27, 1996 rule, any combination of incentive arrangements that exceeds the 25 percent threshold, whether labeled a bonus or withhold, puts the physician or physician group at substantial financial risk. We adopted this policy towards bonuses because (1) if the same amount of money is at risk based on referral levels, it should not matter whether this money is labeled a withhold or a bonus, and (2) we did not want plans to avoid these rules merely by ''re-labeling'' withholds or other arrangements as bonuses. The incentive arrangement described in this comment would exceed the 25 percent threshold for substantial financial risk as we interpret this term and, accordingly, should not be permitted in our view.

Recommendation: The association recommended that a prepaid plan that capitates physicians or physician groups be permitted to estimate the portion of the capitation allocated to referral services for purposes of determining whether there is substantial financial risk. This is because it is the association's belief that many large prepaid plans do not have, and cannot obtain, this information. The association believes that the regulatory requirement that contracts specify the allocation between services provided by the physician or physician group and the amount allocated for referral services (provided outside the physician group or the physician's practice) has two objectives: (1) To provide a basis for the calculation of risk transference to determine whether substantial financial risk is transferred; and (2) to apprise the physician or physician group of the portion of its capitation ''at risk.'' The association contends that we could achieve the first of these two objectives by allowing the prepaid plan to estimate the expected portion of referrals through the use of historical data or actuarial tables. The prepaid plan could be required to certify that its decision was made in good faith based on the best available data. In accepting this proposal, the association contends that we would be meeting our responsibilities under E.O. 12866 to find an alternative regulatory approach that imposes the least burden on society while still achieving its objective.

The association questioned whether the second objective it has presumed, to apprise the physician or physician group of the portion of its capitation ''at

risk,'' is meaningful today since physicians are far more aware of the implications of risk assumption than they once were.

As an alternative approach, the association suggested that the physician/physician group put in the contract the estimated portion of services that would not be provided by the physician or physician group. The association stated that, although this amount may change over time, it would not support revisions to the contract to reflect changes made within the discretion of the individual physician or physician group. The association notes that this alternative approach would not be the most desirable because it would require the burdensome step of recontracting with large numbers of physicians.

Response: As indicated in the March 27, 1996 rule, prepaid plans have the option of specifying in the contract maximum and minimum payment amounts. As long as the difference between these amounts does not exceed 25 percent of the maximum amount, the physician or physician group is not at substantial financial risk. Without specifying these limits, physicians who are capitated for all services are potentially at risk of losing 100 percent of their income. Given this potential loss, they may feel the pressure to reduce necessary services.

Prepaid plans have the opportunity to include a provision in their contract with a physician group that would require the physician group to specify the level of potential risk for referral services. Relying on historical or actuarial data may not be reflective of risk in current contracts. While it may be true that physicians today are more aware of the implications of risk assumption, there is no evidence that the ability to manage this risk has substantially changed. Further, while physician groups may want the flexibility to change risk sharing arrangements on an ad hoc basis, we have to question the impact of these changes on patient care decisions.

Recommendation: The association recommends that the regulation be amended to allow for the pooling of the total prepaid enrollment from the prepaid plan and across prepaid plans for purposes of determining substantial financial risk. The regulation exempts from the requirements of the regulations physicians or physician groups who provide services to 25,000 Medicare or Medicaid enrollees of the prepaid plan. The association maintains that this approach, which does not allow for the pooling of patients, is unnecessarily and inappropriately rigid and conservative. The association stated that it believed the 25,000 patient exemption is permitted because physician groups with a patient base this large can assume the risk for referral services greater than the risk threshold without the need for stop-loss coverage. As the number of enrollees under the responsibility of the physician group increases, so does the ability of the physician group to assume that risk. The association believed that this risk is reduced regardless of whether the patients are Medicare, Medicaid, or commercial. Similarly, this risk is reduced regardless of whether the patients are the enrollees of a single prepaid plan or the enrollees of several prepaid plans. Thus, for purposes of qualifying for the substantial financial risk exemption, a prepaid plan should be allowed to consider the total number of prepaid enrollees served by a physician group. These pooled enrollees should, in the association's view, include all enrollees of that prepaid plan and enrollees of other prepaid plans that have selected the physician or physician group, provided that the physician or physician group is at risk for the provision of services to those enrollees.

Response: In the preamble, we provided evidence from analyses by Rossiter and Adamache (1990) (Health Care Financing Review, vol. 12, prepaid plan. 19–30) that supported the decision that physician groups with more than 25,000 patients are able to adequately spread risk and are so unlikely to lose money that we could determine them to not be at substantial financial risk.

We have decided to allow pooling of Medicare, Medicaid, and commercial members for purposes of determining substantial financial risk because this kind of pooling is consistent with the rationale for permitting pooling (that is, the spreading of risk). The physician group may also pool patients across more than one managed care plan with which it has a contract. Note, however, that, as revised by this final rule, § 417.479(h)(1)(v) allows for pooling of patients for purposes of determining substantial financial risk and meeting various stop-loss requirements. This section then specifies that pooling is permitted only if: (1) Pooling is otherwise consistent with the relevant contracts governing the compensation arrangements for the physician or physician group; (2) the physician or physician group is at risk for referral services with respect to each of the categories of patients being pooled; (3) the terms of the compensation arrangements permit the physician or physician group to spread the risk across the categories of patients being pooled; (4) the distribution of payments to physicians from the risk pool is not calculated separately by patient category; and (5) the terms of the risk borne by the physician or physician group are comparable for all categories of patients being pooled.

In general, the purpose of these conditions is to ensure that all patients included in the risk pool are being treated under comparable payment arrangements; that is, the risk or reward to the physician or physician group would be the same for referring services for any individual patient in the pool. The patient categories refer to Medicare, Medicaid, and commercial members. The type of incentive arrangements, such as withholds and capitation would usually be the same throughout the pool to be considered comparable. Pools over the 25 percent risk threshold can be combined with those arrangements below the 25 percent risk threshold. The pool represents the total dollars on which the payout is made to the doctor or the stop-loss threshold is assessed.

This final rule, however, eliminates the arrangement that allows the HMO, CMP, or HIO to pool across physician groups to reduce the stop-loss requirements. We believe physician behavior is influenced by the number of patients using the physician group, rather than total enrollment in the HMO, CMP, or HIO. A physician group that has a small number of patients does not spread its risk throughout the prepaid plan, but only within its group. Allowing pooling across groups does not provide patients enough protection.

Recommendation: The association recommended that the regulations apply a ''reasonableness test'' in calculating compensation under a physician incentive plan. The association noted that plans often use formulas to calculate the amount of the withhold to be returned or the bonus to be distributed. These formulas allow for distributions of a certain percentage of savings to the physician or physician group when utilization or costs are less than projected. These arrangements often do not cap the upside potential gain from a bonus although natural limits may exist because there is no expectation that the scenario in which no services are provided will occur. The physicians and physician groups understand these de facto limits, and it would be unnecessarily burdensome to require prepaid plans to amend thousands of contracts to insert bonus limits in their contracts. The regulations should be amended to confirm that prepaid plans may use an amount for purposes of determining the maximum

payment that is realistic rather than the theoretical highest payment level. The same standard should be applied in calculating minimum levels.

Response: We believe that past behavior is no guarantee of future behavior. Physicians could still feel the pressure if they are placed at substantial financial risk, regardless of past payments. Therefore, the incentive plan contracts must contain these limits explicitly.

Recommendation: The association recommends that the regulation should allow for a ''good cause'' exemption from the requirements of the regulation in the event that substantial financial risk is transferred. The association argued that in an ever-changing health care delivery system, the regulation should provide for flexibility to adapt to unanticipated circumstances. The association notes that our regulations frequently allow for good cause exemptions from requirements, and it contends that circumstances may arise in the future that merit an exemption from the regulatory requirements. According to the association, inclusion of a good cause exemption would give us the flexibility to approve appropriate physician incentive plans without the need to amend our regulations. An example of one instance in which a good cause exemption may be appropriate is if the prepaid plan can demonstrate that the physician group is assured of receiving compensation on an encounter basis comparable to or at a certain percentage of the resource-based relative value scale fee schedule amount.

The association stated that it is currently exploring functional ways in which a good cause exemption could be designed and appropriately implemented.

Response: We have no legal authority to permit plans to fail to comply with the rules in section 1876(i)(8) for ''good cause.'' Moreover, even if we did, we do not know of any systematic basis for providing a good cause exemption to this regulation. The example cited by the commenter can be written into the contract to ensure that the physician receives a certain percentage of the fee schedule amount. However, the issue is not guaranteeing a minimum level of income. Rather it is setting parameters so that decisions are not made because of a concern with unforseen circumstances, such as adverse selection, bad incentive plan design, etc. Our goal is to protect beneficiaries in these circumstances.

Comment: A group that advocates on behalf of individuals with disabilities recommended that we consider alternative methods to determine the appropriate levels of stop-loss insurance for those involved in the care of persons or communities who are at high risk for unexpected, adverse medical events (For example, urban providers with a high patient load of pregnant women with histories of substance abuse). The group stated that these providers may have difficulties determining an accurate estimate of expected expenditures based on a previous year's per-patient costs. The group suggested that other methods to determine substantial financial risk may include:

(1) The use of several years of longitudinal data to determine a realistic substantial risk level (in order to adjust for the periodicity of certain illnesses); or

(2) The use of retrospective analyses to determine the incidence of unexpected events within the provider's pool, with adjustments made to correct for current levels of expected ''substantial risk'' related to the likelihood of these previous events.

This group further recommended that we examine alternative methods of determining substantial risk for providers who are likely to care for ''medically needy'' eligibles. The association gave the following example, a preferred provider organization (PPO) medical specialist provider may care for a substantial number of persons with life-threatening illness, such as cancer, Alzheimer's or AIDS. If patients switch from private to public health insurance while under the care of the medical provider (due to ''spending down'' into poverty), the provider's determination of ''substantial risk'' may be underestimated. In this case, the PPO medical specialist may be subject to various levels of financial incentives (through both private and public funded health plans) without having to demonstrate adequate quality of care or financial liability provisions.

Response: The goal of the substantial financial risk analysis is to determine whether stop-loss protection is needed. The stop-loss protection is designed to provide protection if the physician group experiences patients with a greater than average risk. Thus, there is no need to set a different substantial financial risk threshold for high risk cases. The stop-loss protection addresses this concern.

Comment: A commenter recommended that we consider lowering the threshold at which plans are required to provide stop-loss coverage for CHCs. The commenter suggested that we consider whether it is appropriate to compare risks to CHCs with risks to other kinds of primary care providers. The commenter pointed out that CHCs provide services almost exclusively to Medicaid/Medicare beneficiaries and impoverished uninsured patients. Thus, CHCs essentially have no capacity to generate revenues to offset losses sustained on referrals under a capitated rate. In addition, the commenter suggested that the schedule reducing the amount of protection required should be modified so that it decreases more slowly as a CHC's patient panel increases. The commenter said such a change is justified because CHCs may incur even greater risk as their capitated patient enrollment increases because the CHC's patients are likely to be in poorer health than the average patient.

Response: We are giving additional consideration to the impact of the current risk threshold on physician incentive plans with CHCs. During the implementation of this regulation, we will collect data on the impact of the 25 percent threshold on CHCs, and consider whether some form of relief may be appropriate. We are concerned, however, that lowering the threshold as the commenter suggests would require a substantial number of these centers to provide stop-loss protection to their physicians that they may not be able to afford.

Comment: A commenter asked whether ancillary services are considered referral services.

Response: For purposes of § 411.479, if the physician group performs the ancillary services then the services are not referral services. If the physician group refers patients to other providers of services for the ancillary services, then the services are referral services.

Comment: A commenter pointed out that a response in the March 27 final rule at 61 FR 13438, column 2, states that, if the HMO uses a combination of withhold and/or bonus arrangements, these arrangements will be aggregated for purposes of determining whether the physician is placed at substantial financial risk. The commenter adds that, in column 3 of that page, however, the response states that we are not requiring disclosure of every incentive arrangement between a physician group and its physicians, only those under which the physician is placed at substantial financial risk. A prepaid plan wanted to know how it could be expected to know that in the aggregate the arrangements created substantial financial risk if the physician group is not required to disclose the individual arrangements.

Response: The above comment reflects a misconception. The quote from the third column addresses what

information must be disclosed by the prepaid plan to us, not what information the physician group must disclose to the prepaid plan. It is incumbent upon the prepaid plan to obtain from the physician group all the information that it needs to determine whether individual physicians are placed at substantial financial risk. This can be a subject addressed as part of the contract negotiations between the prepaid plan and the physician group.

Comment: A commenter stated that the methodology used to determine substantial financial risk has consequences that they believe we never intended. For example, certain bonus arrangements could be construed as transferring substantial financial risk. The commenter described a program under which bonuses that are added to a base capitation are aimed at rewarding the primary care physician (PCP) for high quality care, full service capacity, long office hours, accepting all new patients, and cost-effectiveness. The commenter offered the following illustration: a PCP might get $10.50 per member/per month (PMPM) as capitation, $1.50 PMPM for scoring well on member surveys and office record reviews, $1.00 PMPM for being open to new patients, and $1.50 PMPM for having average utilization. The total compensation would then be $14.50 PMPM. The commenter stated it does not believe that these quality performance and service bonuses are the ''substantial financial risk'' with which we are concerned. The commenter stated that there is no downside risk here, but there is the ability to add to income for good performance. If the intent is to include these bonus arrangements, the commenter wanted to know whether the relevant amount was the maximum attainable bonus or the average bonus paid to all PCPs in the network. The commenter also pointed out that, in applying our methodology to calculate substantial financial risk, a physician who is paid a higher quality office component than a second physician (both with the same utilization), would be found to have assumed a greater financial risk than the second, even though the first physician's revenues were greater.

Response: While we are supportive of a quality bonus payment, there is very limited experience with its use, and whether a physician will actually receive it is speculative. We will revisit the issue when more information is available on the nature, extent, and experience with quality bonuses.

Subcontracting

A number of commenters, including a major association, made the same comment on the provisions of section 417.479(i), which requires that the disclosure, stop-loss protection, and survey requirements of § 417.479 be satisfied when an HMO or CMP contracts with a physician group that places the individual physician members at substantial financial risk for services they do not furnish. The major association's comment, which was the most comprehensive, is presented below.

Comment: One major association challenged our legal authority to reach arrangements between a contracting physician group and its individual physicians (or between an ''intermediate entity'' and physicians or a physician group). The association pointed out that section 1876(i)(8)(B) of the Act defines a physician incentive plan as—

> any compensation arrangement *between* an eligible organization and physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided with respect to individuals enrolled with the organization. [Emphasis added by the association.]

The association argued that, regardless of the policy considerations that favor extending the reach of these rules to subcontracts (for example, the possibility that failure to do so could create a ''loophole'' that could be abused), doing so was inconsistent with the ''plain meaning'' of this statute. The association accordingly contended that our interpretation was legally impermissible, regardless of the policy considerations in its favor.

The association also argued that expanding the scope of the regulation to cover other incentive plans without a new opportunity for notice and comment violated the Administrative Procedure Act (APA). The association pointed out that the APA requires that there be a general notice of proposed rulemaking published in the Federal Register that includes, among other things, the terms or substance of a proposed rule or a description of the subjects and issues involved. The association included the following quotation from a decision by the Court of Appeals for the District of Columbia Circuit discussing a standard that the court applied for determining whether the APA requirement has been met:

> Statutory duty to submit proposed rule for comment does not include obligation to provide new opportunities for comments whenever final rule differs from proposed rule; rather, an agency adopting final rules that differ from proposed rules is required to renotice when changes are so major that original notice did not adequately frame subjects for discussion. (*Air Transport Association of America* v. *C.A.B.*, 732 F.2d 219 (D.C. Cir. 1984))

The association argued that revising the proposed rule to extend its provisions to subcontractor arrangements was a sufficiently ''major'' change that a new notice and opportunity for comment was required under the above standard.

Finally, the association contended that support for its position could be found in language from earlier legislation directing HHS to study incentive arrangements. This language referred to ''incentive arrangements offered by health maintenance organizations and competitive medical plans to physicians.''

Response: We believe that in referring both to individual ''physician[s]'' and to ''physician group[s],'' Congress intended to cover all incentive arrangements that could provide incentives for a physician treating an HMO enrollee to reduce or limit services; both those affecting only an individual physician and those affecting a group of physicians as a whole. A letter from the original author of this legislation confirms that this was his intent in drafting this language.

As noted above, the association attempts to place significance on the use of the word ''between'' in the definition of physician incentive plan in section 1876(i)(8)(B) (quoted above). The association reads this as limiting the scope of the definition of physician incentive plan to arrangements in a contract directly between a prepaid plan and a physician or physician group. In fact, however, an individual physician who serves a prepaid plan's enrollees as a member of a physician group does have a relationship with that prepaid plan, albeit an indirect one. There is an indirect but clear link ''between'' that physician and the prepaid plan whose enrollees the physician treats. The only difference is that instead of a single direct contract between the physician and the prepaid plan, the physician has a contract with the group, and the group in turn contracts with the prepaid plan.

Even though this is a two or more step arrangement rather than a single direct contract, there nonetheless is a physician incentive plan involving the prepaid plan's enrollees that exists ''between'' the physician providing services to a prepaid plan's enrollees and the prepaid plan that is accountable for these services. There is simply an added layer of organization and legal arrangements ''between'' the physician and the prepaid plan. During our review

of applications for Medicare contracts, we currently review the plan's contracting arrangements to ensure that subcontracts actually signed by the physician at the ''retail'' end of the prepaid plan's health care delivery network inform physicians of their responsibility to carry out the prepaid plan's obligations under section 1876. This longstanding practice is fully consistent with our view that an individual physician contract with a physician group is part of the total arrangement ''between'' that physician and the prepaid plan that is accountable for the services the physician is providing to the plan's members. For instance, we hold the plan accountable for the quality of care delivered by all components subcontracting with the plan including the care delivered by the physicians.

For all of the above reasons, we believe that it is fully consistent with the words of the statute to reach all incentive arrangements that exist ''between'' doctors providing the care and a prepaid plan accountable for that care, whether they are contained in a physician's contract with a physician group or other intermediate entity, or in the contract the group or entity has with the prepaid plan. (With respect to the association's reliance on language in past legislation, we do not believe that it has any relevance in interpreting section 1876(i)(8). Indeed, it is inconsistent with the language in section 1876(i)(8), since it references only arrangements with a physician, and not those with a physician group.)

In addition to being consistent with the words of the statute, we believe that our interpretation is consistent with the purpose of the statute, which is to protect Medicare beneficiaries enrolled in prepaid plans from the possible effects of financial incentives to deny or limit medically necessary care. It is irrelevant to this statutory objective whether incentives are contained in the prepaid plan's contract with a physician group, or in the group's contract with the physician. It is fully consistent with the intent and purpose of section 1876(i)(8) to reach any plan that could contain the incentives Congress wanted to address. As suggested above, it also would make no sense to establish a regulatory scheme that could be circumvented simply by erecting a ''protective shield'' between the prepaid plan and individual physicians in the form of an intermediate entity or physician group structure. The possibility of such a ''loophole'' permitting plans to circumvent these regulations was a major factor in our decision to extend the reach of these regulations to subcontractors.

We also disagree with the association that the change we made in the final rule violated the APA under the standards of the *Air Transport Association* case cited by the association. Indeed, we believe that this type of revision is precisely the kind the court had in mind when it wrote that there is no ''obligation to provide new opportunities for comments whenever a final rule differs from a proposed rule.'' We believe that it is clear that this is *not* a change ''so major that original notice did not adequately frame [the] subject [ ] for discussion.'' Clearly the ''original notice'' *did* ''frame'' this as a ''subject [ ] for discussion,'' since commenters in fact commented on this question. A second notice thus was not required under the *Air Transport* decision.

In any event, even if a second opportunity to comment had been required under the *Air Transport* standard, any such requirement has now been satisfied through the notice and comment process culminating in this revised rule.

Stop-loss

We received several comments on the stop-loss requirements in the March 27 rule. Section 417.479(g)(2) requires that HMOs or CMPs that operate incentive plans that place physicians or physician groups at substantial financial risk ensure that these physicians or physician groups have either aggregate or per-patient stop-loss protection in accordance with the following requirements:

- 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.
- 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 approved methods (discussed below) if pooling is consistent with the relevant contract between the physician or physician group and the prepaid plan. 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:
- Less than 1,000 patients—$10,000.
- 1,000 to 10,000 patients—$30,000.
- 10,000 to 25,001 patients—$200,000.
- Greater than 25,000 patients:

+ Without pooling patients—none; and

+ As a result of pooling patients—$200,000.

Section 417.479(h)(1)(v) provides that, for purposes of determining panel size, patients may be pooled according to one of the following methods:

- Including commercial, Medicare, and/or Medicaid patients in the calculation of the panel size.
- Pooling together, by the HMO or CMP, of several physician groups into a single panel.

Section 417.479(g)(2)(iii) provides that the HMO or CMP may provide the stop-loss protection directly or purchase it, or the physician or physician group may purchase the stop-loss protection. This section also provides that, if the physician or physician group purchases the stop-loss protection, the HMO or CMP 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 that protection.

Comment: A major association stated that enormous confusion exists among its membership as to the meaning and application of the stop-loss provisions. The association urged us to reevaluate not only the substantive requirements, but the manner in which we expressed the information and to explain more clearly our intentions. The association's comments on this issue fall into two categories: (1) The obligation for payment of the stop-loss coverage and (2) the substantive requirements for stop-loss. In making its comments, the association also offered recommendations for amendments to the regulations. We summarize the association's comments and recommendations below:

Comment 1. The association believed that the responsibility of paying for the stop-loss protection should be a negotiable issue between the HMO or CMP and its physician group or physician. The association argued that the language used in section 1876(i)(8) of the Act requiring HMOs or CMPs to provide stop-loss can be reasonably interpreted to impose an obligation that the stop-loss coverage be made available to the physician or physician group.

The association also maintained that public policy supports allowing the financial responsibility for stop-loss coverage to be determined between the parties and not mandated by us. The association noted that a common element in a capitation arrangement between an organization and a physician group is a requirement that stop-loss be obtained to protect the physician group from undue risk. This stop-loss could be purchased by the prepaid plan or by the physician group.

The association stated that typically, these arrangements provide that the physician group, and not the prepaid plan, has the responsibility to pay for the stop-loss coverage. Another option the association noted would be to give the physician group the option either of purchasing the stop-loss coverage made available by the prepaid plan or purchasing the stop-loss coverage itself. The association pointed out that in all cases, the cost of the stop-loss coverage is an element of the compensation (the capitation would be reduced if the prepaid plan pays for the stop-loss coverage and would be higher if the physician group does).

The association stated that stop-loss coverage at the levels required by the regulations is very expensive to obtain and that requiring prepaid plans to bear that cost would result in an enormous financial burden shifted from physician groups to prepaid plans. To avoid this, and consistent with the discussion above, the association recommended that we allow the prepaid plan and the physician group or physician to negotiate the financial responsibility for the stop-loss coverage.

Response: After further analysis, and for the reasons set forth in the above comment, we are amending the regulation to require only that the HMO or CMP provide us proof that the physician groups have adequate stop-loss protection in place. We believe this is consistent with the primary goal of the regulation of ensuring that if the physicians are at substantial risk, they have adequate stop-loss protection. In addition, we have further information that physician groups may have access to more affordable stop-loss as a result of their participation in a number of HMOs or CMPs.

Comment 2. The association recommended that we revise the regulations to reflect what it believes to be more appropriate stop-loss levels, to account for existing stop-loss arrangements, and to provide an appropriate means of applying the stop-loss requirements to bonus and withhold arrangements. The association believed that the stop-loss limits are inappropriately low. It stated that a $10,000 limit might be appropriate for a panel size less than 250 patients, but is not reasonable for a 1,000 patient panel. The association stated that one of its members projects that the cost of stop-loss over $10,000 for hospital services for a Medicare enrollment would be about 20 percent of the total medical cost; this could be about $80 to $100 per member per month depending on geographic area. Therefore, the association believed that it is incumbent upon us to reevaluate the stop-loss limits and to replace the existing limits with ones that are more appropriate and less costly to obtain.

In addition, the association maintained that the stop-loss requirements fail to identify how prepaid plans can analyze stop-loss coverage that is already being provided to the physicians or physician groups to determine whether it meets the regulatory standard. The association stated that while it assumes we would allow prepaid plans to obtain ''credit'' for stop-loss coverage that already exists, it may be exceedingly difficult to compare the coverage. For example, existing stop-loss coverage may have a lower attachment point (that is, deductible), but higher coinsurance amounts or vice versa. Some stop-loss coverage may vary by disease. Also, some coverage may vary depending on whether the cost is related to inpatient care or specialty care. Some prepaid plans apply individual and aggregate stop-loss simultaneously. Some stop-loss limits are linked to utilization levels and not cost levels. Some physician groups decline the coverage offered by the prepaid plan because it may be less costly to obtain the coverage for all their patients rather than only those who are enrollees of a single prepaid plan. In light of this, the association recommended that we do the following:

- Reevaluate the stop-loss limits in light of actuarial input on the appropriate need for stop-loss coverage and its cost.
- Allow a prepaid plan to retain the services of an actuary who would assign an actuarial value to the stop-loss coverage currently being provided to the physician or physician group. Allow the prepaid plan to meet the stop-loss requirements by providing (that is, making available) the difference between the actuarial value of the requirement and the value of the stop-loss currently being provided to the physician or physician group. The prepaid plan, in consultation with its actuary, could convert this difference into an actuarial equivalent in order that the new coverage be consistent with the nature of the stop-loss coverage already provided to the physician or physician group. The association stated that this recommendation is intended to accomplish two objectives: (1) The prepaid plan would obtain credit for stop-loss coverage already provided to the physician or physician group; (2) the prepaid plan would have more flexibility in determining how the requirement was met; for example, if it wished, the prepaid plan could meet the requirement by building on the structure of its existing stop-loss coverage.

A second issue raised by the association concerns the applicability of the stop-loss requirements to withhold and bonus arrangements. When physicians or physician groups are at risk for referral services under a capitation arrangement, stop-loss coverage would protect the physician group or physician from excessive costs. In contrast, when an organization uses withholds or bonuses as its incentive arrangements, no large potential economic loss would occur at which the stop-loss would attach. The association recommended that we rethink the application of the stop-loss requirements to withhold and bonus situations. It also argued that we should amend our regulation to allow for adjustments in the stop-loss attachment points to account for inflation; that is, as health care costs increase, the limits need to be raised accordingly. Otherwise, the stop-loss coverage provided by the prepaid plan would become unduly and inappropriately comprehensive.

Response: Based on actuarial analyses and consultation with experts knowledgeable about current stop-loss insurance practices, this final rule makes a number of changes to the stop-loss provision. Because many of the stop-loss arrangements currently in place differentiate between professional services and hospital or other institutional services, we are revising § 417.478(g)(2)(ii) to permit prepaid plans and physician groups to choose either a single combined limit or separate limits for professional services and institutional services. We are also revising the categories of patient panel size to increase the number of categories and smooth out the gradation of attachment points. This final rule establishes the following limits:

Panel Size	Single Combined Limit	Separate Institutional Limit	Separate Professional Limit
1–1000	*$6,000	*$10,000	*$3,000
1,001–5000	30,000	40,000	10,000
5,001–8,000	40,000	60,000	15,000
8,001–10,000	75,000	100,000	20,000
10,001–25,000	150,000	200,000	25,000
> 25,000	none	none	none

The asterisks indicate that, at this level, stop-loss insurance is impractical. The premiums would be prohibitively expensive. Plans and physician groups clearly should not be putting physicians at financial risk for panel sizes this small. It is our understanding that doing so is not common. For completeness, however, we do show what the limits would be in these circumstances.

In regard to the comments on bonuses and withholds, we specifically indicated that when bonuses and withholds put physicians at substantial financial risk, the physicians need to have stop-loss protection. The legislation and regulation require that all forms of incentive arrangements that put physicians at substantial financial risk have stop-loss protection. Even though current stop-loss policies may not cover bonuses and withholds, this is the requirement of this regulation. Thus, if current policies do not cover these arrangements, the prepaid plans, physician groups, and/or the reinsurance companies must arrange for protection against losses that can occur due to withholds or the potential loss of bonus payments.

With regard to the suggestion that we account for inflation, we will be periodically reviewing the requirements of this regulation in light of new or more complete information about compensation arrangements and their impact on patients. We will consider this and other recommendations again in the future.

Comment: A commenter asked how frequently panel size can be updated and how soon this increased panel size can be reflected in higher stop-loss limits for the group. The commenter also asked whether an HMO that increases enrollment in a physician panel and correspondingly raises its stop-loss limits must refile its physician incentive arrangement with us.

Response: There is no limitation on the frequency with which panel size can be updated.

Comment: One commenter noted that the stop-loss protection required by this regulation would cover only 90 percent of the costs of referral services that exceed 25 percent of potential payments. The commenter believed that the financial incentive to reduce or withhold referral services to Medicare patients could, in this situation, be overwhelming. The commenter said this would be particularly true in situations in which the physician treated an atypical mix of patients requiring referrals for specialty care.

Response: We adopted our position based upon comments on the proposed rule. As indicated in the preamble to the March 27, 1996 final rule, this policy is currently used by many prepaid plans and has worked well to ensure that physicians are sensitive to avoid the furnishing of unnecessary services. Recent information from prepaid plans and actuaries confirms that this 90/10 standard is consistent with actual practices and policies. We set the ratio at the high end of the continuum of ratios used in the industry since they range from 90/10 to 75/25. Thus, we have allowed for limited risk sharing beyond the stop-loss limits. Further, as indicated in the preamble to the March 1996 rule, we made changes in the stop-loss limits to adjust for the incorporation of this additional risk sharing.

Comment: A major organization representing physicians believed that we should require a reduced, but still substantial, amount of stop-loss for plans with enrollment in excess of 25,000 patients.

Response: As stated earlier, evidence from analyses by Rossiter and Adamache supports the decision that physician groups with more than 25,000 patients are able to adequately spread risk. Therefore we concluded that they are not at substantial financial risk. The commenter did not provide any data or rationale that would lead us to a different conclusion. Note also that the change made by this final rule discussed earlier that eliminates pooling by the prepaid plan across physician groups to achieve the 25,000 base should alleviate the commenter's concern.

Survey

We received a single comment on the enrollee survey provisions in the rule. Section 417.479(g)(1) requires that HMOs or CMPs that operate incentive plans that place physicians or physician groups at substantial financial risk conduct enrollee surveys. These surveys must—

- Include either all current Medicare/Medicaid enrollees of the HMO or CMP and those who have disenrolled (other than because of loss of eligibility in Medicaid or relocation outside the HMO's or CMP's service area) in the past 12 months, or a sample of these same enrollees and disenrollees.
- Be designed, implemented, and analyzed in accordance with commonly accepted principles of survey design and statistical analysis.
- Address enrollees/disenrollees satisfaction with the quality of the services provided and their degree of access to the services.
- Be conducted no later than 1 year after the effective date of the incentive plan, and at least every 2 years thereafter.

Comment: A major organization suggested that we require health plans to use a standardized survey questionnaire designed by HCFA; require health plans to oversample disenrollees and persons with chronic conditions or high cost illnesses; provide detailed instructions to plans on survey design; and publish a comparison report card of all survey results.

Response: The final rule did not specify that the plans conduct a separate survey for this regulation because most plans already administer surveys that meet the requirements of this regulation. We do, however, recognize the value of having a standardized survey instrument and have developed one, as part of our effort to measure and improve quality of care, that can be used to satisfy the requirements of this regulation.

We have, in concert with the Agency for Health Care Policy and Research through the latter's CAHPS process

(Consumer Assessments of Health Plans Study), sponsored the development of a Medicare-specific consumer satisfaction instrument, so that the unique health care concerns of the senior population are adequately addressed. CAHPS is a 5-year project whose purpose is to develop a set of standardized consumer satisfaction instruments usable across all populations; subpopulation specific modules are being developed not only for the Medicare population, but also for Medicaid, the chronically ill and disabled, and children.

We have notified plans of our intention to require all Medicare contracting plans that have had a Medicare contract for at least 1 year as of January 1, 1997 to participate in this CAHPS survey. The CAHPS Medicare survey will be administered by an independent third-party contractor to the Government, secured through an open, competitive bidding process. The primary purpose of the survey is to provide information to consumers that will enable them to make plan-to-plan comparisons and thereby to make better-informed health plan choices. Key results of the survey will be published in a comparability chart that contains cost and benefit information on all Medicare contracting plans.

We will consider participation by a plan in the CAHPS survey as satisfying the requirements of this regulation, subject to the following two additional considerations. First, the current version of CAHPS does not contain a module addressed to disenrollees. Efforts are underway to develop such a module, which may be available by 1998. For 1997, we are preparing guidelines to managed care plans on how to satisfy the requirement to survey disenrollees. That guidance will be available in the spring of 1997.

Second, as noted above, under the requirements of our quality initiative, plans that received their initial Medicare contract after January 1, 1996, are not required to participate in the CAHPS survey until calendar year 1998. There will likely be plans, however, that received their first contract after January 1, 1996, that will be required to meet the enrollee and disenrollee survey requirements of this regulation in calendar year 1997. Those plans may wish to use the CAHPS survey to meet this requirement.

We have issued an operational policy letter explaining this requirement in more detail (See OPL number 96.045, December 3, 1996).

Oversampling for the chronically ill and disabled, dually eligible, and various racial and ethnic groups is a complex issue. Strategies for doing so are being seriously considered. We will be forwarding additional guidance to managed care plans.

It should also be noted that the CAHPS survey collects information at the level of the managed care plans, without distinguishing among patients of various physician groups within the plan. Ideally, the survey required under this regulation, however, should do so. We will accept the CAHPS survey as satisfying this regulation at this time, while we continue to evaluate additional measures that might be taken to collect information by physician group.

Finally, we will not require that the Medicaid version of the CAHPS survey be administered by HMOs with Medicaid contracts. However, we are willing to assist States that wish to require administration of the CAHPS Medicaid survey.

Other Comments

We received other comments that were not specifically directed to the provisions of the regulation. Since these comments do not directly address the regulations, we are not responding to them in this preamble.

We also want to clarify an inconsistency that occurred in the preamble to the March 27, 1996 final rule. While the regulation text was accurate in specifying that subcontracts were covered by the regulations, we were inconsistent in different sections of the preamble. In the first column at 61 FR 13439, we indicated that subcontracts are covered, while in the second and third column of the same page we indicated that they were not covered. The statements in the second and third column were incorrect.

V. Provisions of this Final Rule

This final rule reflects the March 27, 1996 final rule with comment period, with changes. Many of the substantive change listed below have been discussed in section IV of this preamble. Those that have not are explained below.

- Section 417.479(b) is revised to clarify that the physician incentive plan requirements also apply to subcontracting arrangements.
- Section 417.479(f), which describes arrangements that cause substantial financial risk, is revised to permit pooling by physician groups of patients across prepaid plans. A technical change is also made to change ''possible payments'' wherever it appears to ''potential payments''. This latter change reflects the fact that ''potential payments'' is the term defined in the paragraph's introductory text.
- In § 417.479(g), which sets forth the requirements that HMOs and CMPs that place physicians or physician groups at substantial financial risk must meet, the following changes are made:

+ Paragraph (g)(1) is revised to require that the enrollee survey be conducted no later than 1 year after the effective date of the Medicare contract and at least annually thereafter.

+ Paragraph (g)(2)(ii) is revised to establish new stop-loss limits based either on a single combined limit or on separate limits for professional services and institutional services.

+ Paragraph (g)(2)(iii) is removed to eliminate the requirement that the HMO or CMP pay for the stop-loss protection.

- In § 417.479(h), which concerns disclosure requirements, the following changes are made:

+ Paragraph (h)(1)(iv) is revised to specify that the HMO or CMP must provide us with proof that the physician or physician group has adequate stop-loss protection, including the amount and type of stop-loss protection.

+ Existing paragraph (h)(1)(v) is removed to eliminate, as an approved method of pooling, pooling together, by the organization, of several physician groups into a single panel. A new paragraph (h)(1)(v) is added to permit pooling, by a physician group, of patients across prepaid plans. New paragraph (h)(1)(v) also specifies the conditions under which pooling is permitted.

+ Paragraph (h)(2) is revised to change when the HMO or CMP must provide the required information. The current regulation requires this to be done upon application for a contract, upon application for a service area expansion, within 30 days of a request by us, and at least 45 days before implementing certain changes in the incentive plan. We have changed this to make it an annual requirement. This first submission must be done prior to approval of a new contract, with subsequent submissions prior to each renewal of the contract. This change is intended to simplify the requirement and reduce the reporting burden on the prepaid plans.

In addition we now specify, in paragraph (h)(2)(ii), that an HMO or CMP must provide the capitation data for the previous calendar year to us by April 1 of each year. This change is being made to eliminate confusion about the reporting period and ensure consistency.

- In § 434.70, which concerns conditions for FFP, paragraph (a)(3) is revised to—

+ Eliminate the requirement that the HMO or HIO must disclose certain

information within 30 days of a request by the State or HCFA.

+ To specify that an HMO or HIO must provide the capitation data for the previous calendar year to the State Medicaid agency by April 1 of each year.

+ Eliminate the requirement that the HMO or HIO submit the required information at least 45 days before implementing certain changes in its incentive plan.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies 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. This final rule contains information collections that are subject to review by OMB under the Paperwork Reduction Act of 1995. The title, description, and respondent description of the information collections are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and collecting and reviewing the collection of information.

We are, however, requesting an emergency review of these regulations. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to OMB the following requirement for emergency review. We are requesting an emergency review because the collection of this information is needed prior to the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320, to ensure compliance with the physician incentive regulation necessary to implement congressional intent with respect to incentive arrangements between managed care entities and their contracting providers. We cannot reasonably comply with the normal clearance procedures because public harm is likely to result due to the delay in reporting and monitoring of these incentives. If emergency clearance is not provided, we will be forced to postpone the collection of these data for 12 months due to the timing of contract cycles.

We are requesting that OMB provide a 5-day public comment period with a 2-day OMB review period and a 180-day approval. During this 180-day period, we will publish a separate Federal Register notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. Then we will submit the requirements for OMB review and an extension of this emergency approval.

Type of Information Request: New collection.

Title of Information Collection: Incentive Arrangement Disclosure Form and Supporting Regulations 42 CFR 417.479 (g)(1), 417.479(h)(1) and (h)(2), 417.479(i), and 434.70(a)(3).

Form Number: HCFA–R–201.

Use: Incentive Arrangement Form and supporting regulations will be used to monitor physician incentive plans.

Frequency: Annually.

Affected Public: Nonprofit and for profit HMOs, CMPs, and HIOs.

Number of Respondents: 450.

Total Annual Responses: 450.

Total Annual Hours Requested: 45,000.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office at (410) 786–1326.

The sections in these final regulations that contain information collection requirements are:. §§ 417.479 (h)(1) and (h)(2), 417.479(i), 434.70(a)(3), and 417.479(g)(1), (and § 434.70(a)(3) for Medicaid) of this document. However, the information collection requirements referenced in §§ 417.479(g)(1) and 434.70(a)(3) of this final rule, described below, are currently pending approval by OMB (under the title ''HEDIS 3.0 (Health Plan Data and Information Set) and supporting regulations 42 CFR 417.470 and 42 CFR 417.126'').

The information collection requirements at existing §§ 417.479(h)(1) and (h)(2), 417.479(i), and 434.70(a)(3) were established by the March 27, 1996 final rule with comment period. These sections of the regulations specify that disclosure concerning physician incentive plans must be made to us or the State, as appropriate. The requirements apply to physician incentive plans between prepaid plans 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. Under the existing regulations, a prepaid plan 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 us or the State. This rule would amend the regulations by removing the requirements that disclosure be made upon application for a service area expansion, within 30 days of a request by us or the State, and at least 45 days before implementing certain changes in the incentive plan. It would add that disclosure must be made prior to the approval of a new contract or agreement and annually thereafter. These changes should reduce the reporting burden on prepaid plans. At the time we published the March 1996 rule, we estimated that approximately 600 entities will submit the information. We estimated the burden as 8 hours per response. As discussed in section IV above, we received numerous comments stating that we greatly underestimated the burden associated with complying with the disclosure requirements and suggesting alternative approaches. We now estimate that approximately 450 prepaid plans will disclose information. We estimate that the burden per response will be 100 hours, for an annual total burden of 45,000 hours. This estimate includes time spent by subcontractors in furnishing information to the prepaid plan.

Existing § 417.479(g)(1) (and § 434.70(a)(3) for Medicaid) concern prepaid plans that operate physician incentive plans that place physicians or physician groups at substantial financial risk and require them to conduct enrollee surveys that include either all current Medicare/Medicaid enrollees in the prepaid plan and those who have disenrolled (other than because of loss of eligibility in Medicaid or relocation outside the prepaid plan's) in the past 12 months, or a sample of these same enrollees and disenrollees. These surveys are required to be conducted annually.

The information collection and recordkeeping requirements, referenced in § 417.479 (h)(1) and (h)(2), 417.479(g)(1), 417.479(i), and 434.70(a)(3) of these regulations are not effective until they have been approved by OMB. The agency has submitted a copy of this final rule with comment period to OMB for its review of these information collections. A notice will be published in the Federal Register when approval is obtained. Interested persons are invited to send comments regarding this burden or any other aspect of these collections of information, including any of the following subjects: (1) The necessity and utility of the information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection

techniques or other forms of information technology to minimize the information collection burden.

Comments on these information collections should be mailed directly to the following address:

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, HCFA Desk Officer.

In addition, comments may be faxed to: Allison Herron Eydt at (202) 395–6974.

A copy of the comments may be mailed to the following address: Health Care Financing Administration, Office of Financial and Human Resources, Management Analysis and Planning Staff, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850.

We will also be undertaking an overall evaluation of all of the reporting and disclosure requirements in this regulation within the next year, to assess the value of the information compared with the burden of reporting. All of the disclosure and reporting requirements, and any related forms, will continue to be subject to review under the Paperwork Reduction Act.

VII. 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, we consider all HMOs, CMPs, and HIOs to be small entities.

In addition, section 1102(b) 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), we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

In the preamble to the March 27, 1996 rule, which provided an opportunity for comments, we stated that we had decided not to prepare a regulatory flexibility analysis because we believed that few incentive plans will require changes to comply with the regulations. A major association of health plans, which submitted comments on behalf of its membership, strongly disagreed with this position.

The association maintained that the regulations, as adopted, will result in substantial administrative and financial burdens on a large number of organizations. The association requested that, in light of the information it was providing to us in its other comments, we reconsider our decision not to prepare a regulatory impact analysis.

A number of commenters believed that, in estimating a burden of 8 hours per response, we had grossly underestimated the time and financial resources that need to be expended to comply with the disclosure requirements. These commenters stated that this problem may be alleviated to some extent if the prepaid plans were allowed to agree that all or some of their physician incentive programs resulted in substantial financial risk without having to disclose to us the detailed information specified in the Regulations. One commenter added that the regulations, in essence, require prepaid plans to act as information gathering conduits for information related to physician group and/or subcontractor incentive plans. The commenter stated that this is not the most efficient or effective means and that a preferable approach is for us to solicit the information directly from the physician group or subcontractor. The commenter recommended that we adopt a uniform and standardized calculation and attestation form that prepaid plans could use to solicit the information.

Another commenter stated that the stop-loss limits are inappropriately low and, because of this, the cost of stop-loss coverage is very high. The commenter maintains that this rule results in substantial financial burdens on a large number of prepaid plans.

The suggestions offered by the commenters have been addressed in section IV above. With regard to our assessment of the impact of the March 27, 1966 rule, we have reviewed our assessment. In this review, we used information developed by a major accounting firm at the request of a major association, which was shared with us.

Based on survey data from Mathematica (1995), approximately one-third of prepaid plans capitate their physicians for all services. This means that, of approximately 300 Medicare prepaid plans, about 100 plans will capitate for all services. Of approximately 300 Medicaid HMOs and HIOs, approximately one-half will have Medicare contracts and, thus, do not add to the total. Of the remaining 150 Medicaid plans, many will be relatively new Medicaid plans. Most new Medicaid plans do not capitate their physicians for all services. Therefore, we estimate that there will be a total of 25 Medicaid prepaid plans in addition to the 100 Medicare plans that capitate for all services. These 125 plans will have to provide stop-loss insurance. Very few plans that use bonuses or withholds will exceed the substantial risk threshold.

Of the 125 plans that will need to provide stop-loss insurance, most of these plans already have such coverage. Taking into account the changes made by this final rule, we estimate that approximately 44 prepaid plans (35 percent) will need to increase their stop-loss coverage. The cost of this additional coverage is estimated at approximately $65 million. Since the affected entities are large, $65 million represents a very small percentage of their gross annual income. In addition, we expect that some of the $65 million will be offset by monies received from the insurers because of the increased coverage.

With regard to the financial burden associated with complying with the disclosure requirements, we continue to estimate that approximately 450 plans will need to comply with the disclosure requirements. We now estimate the burden to be 100 hours per response, at a cost of $20 per hour. This includes the burden on the physician groups and subcontractors in furnishing information to the prepaid plan. Thus, we estimate the total impact of the disclosure requirements at $900,000 per year.

This rule changes the frequency of the survey requirements (from biennially to annually), we believe that this imposes very little additional burden on prepaid plans since most plans already conduct annual surveys. In addition, as discussed in section V of the preamble, this rule changes when disclosure must be made to HCFA or the State Medicaid agency. While this rule adds that disclosure must be made upon the contract or agreement renewal or anniversary date, it removes other circumstances under which disclosure must be made. We believe the overall effect of these changes as to when disclosure must be made is to reduce the reporting burden on the affected prepaid plans.

We are not preparing analyses of this final rule 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 economic impact on the operations of a substantial number of small rural hospitals.

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

VIII. Waiver of Delayed Effective Date

We ordinarily provide for final rules to be effective no sooner than 30 days after the date of publication unless we find good cause to waive the delay.

This final rule amends existing regulations that set forth the requirements that certain managed care organizations must meet in order to contract with the Medicare and/or Medicaid program. A number of the changes made by this final rule either reduce the burden associated with the regulations or recognize existing industry practices. Since many managed care Medicare and Medicaid contracts renew on January 1, if this final rule does not become effective until after that date, the benefits that result from the changes made by this rule will not be realized until 1998. Therefore, we find that it would be against the public interest to delay the effective date of this final rule.

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 continues to read as follows:

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

2. In § 417.479, paragraph (g) introductory text and paragraph (g)(1) introductory text are republished; paragraph (g)(2)(iii) is removed; paragraph (b), paragraph (f) introductory text, paragraphs (f)(5), (g)(1)(iv), (g)(2)(ii), (h)(1)(iv), (h)(1)(v), and (h)(2) are revised to read as follows:

§ 417.479 Requirements for physician incentive plans.

* * * * *

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

* * * * *

(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:

* * * * *

(5) Capitation, arrangements, if—

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

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

* * * * *

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

(1) Conduct enrollee surveys. These surveys must—

* * * * *

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

(2) * * *

(ii) If the stop-loss protection provided is based on a per-patient limit, the stop-loss limit per patient must be determined based on the size of the patient panel and may be a single combined limit or consist of separate limits for professional services and institutional services. In determining patient panel size, the patients may be pooled in accordance with paragraph (h)(1)(v) of this section. Stop-loss protection must cover 90 percent of the costs of referral services that exceed the per patient limit. The per-patient stop-loss limit is as follows:

Panel size	Single combined limit	Separate institutional limit	Separate professional limit
1–1000	$6,000	$10,000	$3,000
1,001–5000	30,000	40,000	10,000
5,001–8,000	40,000	60,000	15,000
8,001–10,000	75,000	100,000	20,000
10,001–25,000	150,000	200,000	25,000
> 25,000	none	none	none

* * * * *

(h) * * *

(1) * * *

(iv) Proof that the physician or physician group has adequate stop-loss protection, including the amount and type of stop-loss protection.

(v) The panel size and, if patients are pooled, the method used. Pooling is permitted only if: it is otherwise consistent with the relevant contracts governing the compensation arrangements for the physician or physician group; the physician or physician group is at risk for referral services with respect to each of the categories of patients being pooled; the terms of the compensation arrangements permit the physician or physician group to spread the risk across the categories of patients being pooled; the distribution of payments to physicians from the risk pool is not calculated separately by patient category; and the terms of the risk borne by the physician or physician group are comparable for all categories of patients being pooled. If these conditions are met, the physician or physician group may use either or both of the following methods to pool patients:

(A) Pooling any combination of commercial, Medicare, or Medicaid patients enrolled in a specific HMO or CMP in the calculation of the panel size.

(B) Pooling together, by a physician group that contracts with more than one HMO, CMP, health insuring organization (as defined in § 434.2 of

this chapter), or prepaid health plan (as defined in § 434.2 of this chapter) the patients of each of those entities.

* * * * *

(2) *When disclosure must be made to HCFA.* (i) HCFA will not approve an HMO's or CMP's application for a contract unless the HMO or CMP has provided to it the information required by paragraphs (h)(1)(i) through (h)(1)(v) of this section. In addition, an HMO or CMP must provide this information to HCFA upon the effective date of its contract renewal.

(ii) An HMO or CMP must provide the capitation data required under paragraph (h)(1)(vi) for the previous calendar year to HCFA by April 1 of each year.

* * * * *

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, paragraph (a)(1) is revised to read as follows:

§ 434.44 Special rules for certain health insuring organizations.

(a) * * *

(1) Subject to the general requirements set forth in § 434.20(d) concerning services that may be covered; § 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 § 434.70, paragraph (a) introductory text is republished, and paragraph (a)(3) 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—

* * * * *

(3) The HMO, 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 the information required under §§ 417.479 (h)(l)(i) through (h)(1)(v) of this chapter to the State Medicaid agency as follows:

(i) Prior to approval of its contract or agreement.

(ii) Upon the contract or agreements anniversary or renewal effective date.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; Program No. 93.774, Medicare—Supplementary Medical Insurance Program; and Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: December 17, 1996.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: December 20, 1996.

Donna E. Shalala,

Secretary.

[FR Doc. 96–33330 Filed 12–30–96; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 960129018–6018–01; I.D. 122396A]

Fisheries of the Exclusive Economic Zone Off Alaska; Groundfish of the Gulf of Alaska; Pacific Cod for Processing by the Inshore Component in the Western and Central Regulatory Areas

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Directed fishing opening.

SUMMARY: MFS is opening directed fishing for Pacific cod for vessels catching Pacific cod for processing by the inshore component in the Western and Central Regulatory Areas of Gulf of Alaska (GOA). This action is necessary to fully utilize the total allowable catch (TAC) of Pacific cod for the inshore component in the Western and Central Regulatory Areas of the GOA.

EFFECTIVE DATE: 1200 hrs, Alaska local time (A.l.t.), January 1, 1997, until 2400 hrs, A.l.t., December 31, 1997.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907–586-7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the GOA exclusive economic zone is managed by NMFS according to the Fishery Management Plan for Groundfish of the GOA (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at subpart H of 50 CFR part 600 and 50 CFR part 679.

In accordance with § 679.20 (c)(2)(i), the interim TAC of Pacific cod for vessels catching Pacific cod for processing by the inshore component in the Western and Central Regulatory Areas was established by the Interim 1997 Harvest Specifications for Groundfish (61 FR 64299, December 4, 1996) as 3,393 metric tons (mt) and 7,722 mt, respectively.

Vessels catching Pacific cod for processing by the inshore component in the Western and Central Regulatory Areas were prohibited from directed fishing for Pacific cod under § 679.20 (d)(1)(iii) in order to reserve amounts anticipated to be needed for incidental catch in other fisheries (61 FR 64299, December 4, 1996). NMFS has determined that sufficient TAC is available to allow a directed fishery. Therefore, NMFS is terminating the previous closure and is opening directed fishing for Pacific cod for processing by the inshore component in the Western and Central Regulatory Areas.

Classification

This action is taken under 50 CFR 679.20 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: December 24, 1996.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

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