

List of Subjects in 41 CFR Part 101-20

Concessions, Federal buildings and facilities, Government property management.

For the reasons set forth in the preamble, 41 CFR part 101-20 is amended as follows:

PART 101-20—MANAGEMENT OF BUILDINGS AND GROUNDS

1. The authority citation for Part 101-20 continues to read as follows:

Authority: Sec. 205(c), 63 Stat. 390 (40 U.S.C. 486(c))

Subpart 101-20.2—Vending Facility Program for Blind Persons

2. Section 101-20.109 is amended by adding paragraph (d) to read as follows:

§ 101-20.109 Concessions.

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(d) Public Law 104-52, Section 636, prohibits the sale of tobacco products in vending machines in Government-owned and leased space under the custody and control of GSA. The Administrator of GSA or the head of an Agency may designate areas not subject to the prohibition, if the area prohibits minors and reports are made to the appropriate committees of Congress.

2. Section 101-20.204 is amended by revising paragraph (c)(3) to read as follows:

§ 101-20.204 Terms of permit.

* * * * *

(c) * * *

(3) Articles sold at vending facilities operated by blind licensees may consist of newspapers, periodicals, publications, confections, tobacco products, foods, beverages, chances for any lottery authorized by State law and conducted by an agency of a State within such State, and other articles or services as are determined by the State licensing agency, in consultation with GSA to be suitable for a particular location. Such articles and services may be dispensed automatically or manually and may be prepared on or off the premises. Public Law 104-52, Section 636, prohibits the sale of tobacco products in vending machines in Government-owned and leased space under the custody and control of GSA.

3. Section 101-20.309 is revised to read as follows:

§ 101-20.309 Posting and distributing materials.

(a) Public Law 104-52, Section 636, prohibits the distribution of free samples of tobacco products in or around Federal buildings.

(b) Posting or affixing materials, such as pamphlets, handbills, or flyers, on bulletin boards or elsewhere on GSA-controlled property is prohibited, except as authorized in § 101-20.308 or when these displays are conducted as part of authorized Government activities. Distribution of materials, such as pamphlets, handbills, or flyers is prohibited, except in the public areas of the property as defined in § 101-20.003(z), unless conducted as part of authorized Government activities. Any person or organization proposing to distribute materials in a public area under this section shall first obtain a permit from the building manager under Subpart 101-20.4 and shall conduct distribution in accordance with the provisions of Subpart 101-20.4. Failure to comply with those provisions is a violation of these regulations.

Dated: January 5, 1996.

Roger W. Johnson,

Administrator of General Services.

[FR Doc. 96-1088 Filed 1-24-96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Office of Inspector General****42 CFR Part 1001**

RIN 0991-AA69

Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Protecting Health Plans

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Final rule.

SUMMARY: In accordance with section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, this final rule sets forth various standards and guidelines for safe harbor provisions designed to protect certain health care plans, such as health maintenance organizations and preferred provider organizations, under the Medicare and State health care programs' anti-kickback statute. These safe harbor provisions were originally published in the Federal Register on November 5, 1992 in interim final form. In response to the various public comments received, this final rule revises and clarifies various aspects of that earlier rulemaking.

EFFECTIVE DATE: This rule is effective on January 25, 1996.

FOR FURTHER INFORMATION CONTACT: Linda Grabel or Tom Hoffman, Office of the General Counsel, (202) 619-0335

Joel Schaer, Office of Inspector General, (202) 619-3270.

Please send comments regarding the paperwork reduction and information collection requirements discussed in section IV.B. of this preamble in writing to: Joel Schaer, Regulations Officer, Office of Inspector General, Room 5550 Cohen Building, 330 Independence Avenue SW., Washington, D.C. 20201.

SUPPLEMENTARY INFORMATION:**I. Background**

On November 5, 1992, we published an interim final rule with comment period establishing two new safe harbors, and amending one existing safe harbor, to provide protection for certain health care plans, such as health maintenance organizations (HMOs) and preferred provider organizations (PPOs) (57 FR 52723). The first new safe harbor provision, set forth in § 1001.952(l), protects certain incentives to enrollees (including waiver of coinsurance and deductible amounts) paid by health care plans. The second new provision, set forth in § 1001.952(m), protects certain negotiated price reduction agreements between health care plans and contract health care providers. In addition, the existing safe harbor addressing the waiver of beneficiary coinsurance and deductible amounts, codified in § 1001.952(k), was amended to protect certain agreements entered into between hospitals and Medicare SELECT insurers.

These safe harbors set forth various standards and guidelines that, if met, allow specific business arrangements and payment practices of certain health care plans *not* to be treated as criminal offenses under section 1128B(b) of the Social Security Act (the Act) and *not* to serve as a basis for a program exclusion under section 1128(b)(7) of the Act. As with the other safe harbor provisions codified in § 1001.95 of the regulations, these new safe harbors placed no affirmative obligation on any individual or entity.

Although the regulations were issued in final form and became effective on their date of publication, we indicated in the preamble of that November 5, 1992 document that we were allowing a 60-day public comment period during which time interested parties could submit comments and concerns regarding these safe harbors. An additional 60-day extension to the public comment period was published in the Federal Register on January 7, 1993 (58 FR 2989).

II. Summary of the Interim Final Rule

A. Section 1001.952(l)—Increased Coverage, Reduced Cost-Sharing Amounts, or Reduced Premium Amounts Offered by Health Plan

As indicated above, a new safe harbor, set forth in § 1001.952(l), was created to protect certain incentives to enrollees (including increased benefits and waiver of deductible and coinsurance amounts) offered by health plans. This safe harbor contained two parts designed to protect incentives offered by health care plans under contract with the Health Care Financing Administration (HCFA) or a State health care program.

The first part of this safe harbor protected risk-based health plans, like HMOs, competitive medical plans (CMPs) and prepaid health plans (PHPs), under contract with HCFA or a State health care program; and operating (i) in accordance with section 1876(g) or 1903(m) of the Act, (ii) under a Federal statutory demonstration authority, or (iii) under other Federal statutory or regulatory authority. Under this part, the only standard for such health plans was that the health care plan could not discriminate in the offering of these incentives, but must offer the same incentives to all enrollees unless otherwise specifically approved by HCFA or a State health care program.

The second part of this safe harbor protected incentives offered to enrollees by HMOs, CMPs, PHPs and health care prepaid plans (HCPPs) that are under contract with HCFA or a State health care program, and that are paid on a reasonable cost or similar basis. For these plans to be under the safe harbor, two standards had to be met—(1) the same incentives must be offered to all enrollees for all covered services, and (2) the health plan may not claim the cost of these incentives as bad debts or otherwise shift the burden of these incentives onto Medicare, the State health care programs, other payers or individuals.

B. Section 1001.952(m)—Price Reductions Offered to Health Plans

The safe harbor in § 1001.952(m) was created to protect certain negotiated price reduction agreements between health care plans and contract health care providers, and was set forth in three parts. The first two parts were designed to protect risk-based and cost-reimbursed health care plans that operate in accordance with a contract or agreement with HCFA or a State health care program; the third part established additional standards to protect health plans that do not have contracts or

agreements with HCFA or State health care programs. In order to comply with this price reduction safe harbor, three fundamental prerequisites were to be met in all cases—(1) the protected remuneration was the contract health care provider's reduction of its usual charges for the services; (2) the terms of the agreement between the parties must be in writing; and (3) the agreement must be for the sole purpose of having the contract health care provider furnish enrollees items or services that are covered by the health plan, Medicare or the State health care program.

The first part of this safe harbor (§ 1001.952(m)(1)(i)) protected risk-based HMOs, CMPs and PHPs under contract with HCFA or a State health care program; and operating (i) in accordance with section 1876(g) or 1903(m) of the Act, (ii) under a Federal demonstration authority, or (iii) under other Federal statutory or regulatory authority. In addition to the three prerequisites mentioned above, in order to be covered under the safe harbor risk-based contract health plans under this part could not separately bill Medicare, Medicaid or another State health care program for items and services furnished under the agreement with the health plan (except as specifically authorized by HCFA or the State health care program), and could not otherwise shift the burden of the agreement onto Medicare, Medicaid, other payers or individuals.

The second part (§ 1001.952(m)(1)(ii)) protected health care plans that have executed a contract or agreement with HCFA or a State health care program to have payment made on a reasonable cost or similar basis. In addition to the three prerequisites, price reduction agreements with contract health care providers under this safe harbor were protected if (1) the term of the agreement was not less than one year; (2) the agreement specified in advance the covered items and services that the contract health care provider will furnish to enrollees and the methodology for computing the payment to the contract health care provider; (3) the health plan fully and accurately reported to HCFA or the State health care program the amount it paid the contract health care provider in accordance with the agreement; and (4) the contract health care provider could not claim payment in any form unless specifically authorized by HCFA or the State health care program.

Lastly, the third part of this safe harbor (§ 1001.952(m)(1)(iii)) protected reductions offered by contract health care providers to all other health plans when six standards, in addition to the

three prerequisites, were met. The six standards set forth required (1) the term of the price reduction agreement not be less than one year; (2) the agreement specify in advance the covered items and services, which party is to file claims or requests for payment with Medicare, Medicaid and other State health care programs, and the schedule of fees that contract provider will be paid; (3) the schedule remain in effect throughout the term of the agreement (unless a fee update is specifically authorized by HCFA or a State health care program); (4) the party submitting claims for items or services under the agreement not claim or request payment for amounts in excess of the fee schedule; (5) full and accurate reporting of costs be made by the health plan or the contract health care provider; and (6) a prohibition on the party that is not responsible under the agreement for seeking reimbursement from Medicare, Medicaid and any other State health care program from claiming payment or otherwise shifting the burden of the price reduction onto Medicare, Medicaid, other payers or individuals.

C. Section 1001.952(k)—Waiver of Beneficiary Coinsurance and Deductible Amounts

The existing safe harbor in § 1001.952(k), the waiver of coinsurance and deductible amounts, was also amended to protect certain agreements entered into between hospitals and Medicare SELECT insurers. Medicare SELECT is a type of supplemental policy under which reduced benefits may be paid for the use of an out-of-network health care provider. Under this amended safe harbor, waivers or reductions of inpatient hospital coinsurance and deductibles by a hospital in accordance with an agreement with a Medicare SELECT insurer were protected by amending the third of the existing 3 standards set forth in § 1001.952(k)(1). The prior standard required that the reduction or waiver not result from an agreement between a hospital and a third-party payer. The amended standard exempted agreements that are part of a contract between a hospital and a Medicare SELECT insurer for furnishing items or services to Medicare SELECT beneficiaries when (1) the insurer issued a Medicare SELECT insurance policy under the terms of section 1882(t)(1) of the Act, and (2) the waiver of coinsurance or deductible amounts provided under the agreement were limited to beneficiaries covered by the insurer's Medicare SELECT policy. The other requirements of the existing safe

harbor still apply to such waivers or reductions.

III. Response to Comments and Summary of Revisions

As a result of our request for comments, we received a total of 42 timely-filed public comments from various health care associations, health care plans and medical groups, professional and business organizations, and insurance companies on how best to protect HMOs, PPOs and other managed care plans. The comments included both general and broad concerns about the impact of the regulations, and specific comments on those areas and the safe harbor provisions about which we invited public input. The following is a summary of the issues raised through that public comment process, our response to those various comments, and a summary of the specific revisions and clarifications being made to these regulations.

A. General Comments

Comment: Commenters generally objected that the safe harbors would inhibit or “chill” existing activities in which managed care plans engage and thereby jeopardize numerous arrangements. They specifically asserted that should HMOs and PPOs not receive safe harbor protection, vast networks of providers would be at risk and would therefore refuse to enter into discount arrangements with such entities.

Response: The commenters have misconstrued the effect of the safe harbor provisions. The interim final rule did not expand the zone of illegal conduct under the anti-kickback statute. Legally and logically, the safe harbors can only make the zone of illegal conduct smaller. As indicated above, compliance with the safe harbors is completely voluntary. If a practice or arrangement does not fall within a safe harbor, it has precisely the same legal risk that it had before the safe harbor was promulgated. The safe harbors are designed to provide a means through which plans and providers can be assured that their arrangements are immune from potential criminal and administrative sanctions under the anti-kickback statute.

Comment: Several commenters wrote that the regulations do not address numerous activities that managed care entities engage in, and thus imply that such activities could be considered unlawful or would be subject to heightened scrutiny.

Response: Commenters should not infer that because a safe harbor provision does not specifically refer to

a particular arrangement or activity, it is unlawful. Nor should they interpret that lack of a safe harbor to mean that these activities will be subjected to heightened scrutiny. Moreover, the safe harbors do not create affirmative obligations on individuals or entities since compliance with these safe harbors is purely voluntary. The failure to comply with a safe harbor means only that the practice or arrangement does not have the absolute assurance of protection from anti-kickback liability.

Comment: Certain commenters argued that the statute does not apply to particular arrangements. For instance, one commenter claimed that a hospital's agreement with a managed care plan to forego a deductible or coinsurance does not violate the statute because “payment” is made to a third party payer. Other commenters contended that since the statute confers exempt status on health plans for all discounted transactions, a safe harbor for price reduction agreements is unnecessary. Some commenters further indicated that the statute does not apply to the enrollment of persons in a health plan. These commenters opined that the regulations erroneously indicate that HMOs, especially independent practitioner association models, are “providers” in a position to refer patients.

Response: We believe that the anti-kickback statute is broad enough to potentially cover each of these types of arrangements. The statute prohibits any remuneration which is in return for, or which is designed to induce, the flow of Medicare and Medicaid program-related business. Therefore, it could cover a hospital's agreement to forego or reduce coinsurance or deductibles in exchange for increased program-related business. It does not matter that the payment is made to a third party rather than the beneficiary.

The current discount statutory exception and the discount safe harbor are generally not applicable to the discounts involved in managed care plans. The statutory exception covers discounts obtained by buyers which are to be reported to the programs by such buyers with costs and charges reduced appropriately to reflect the discounts. In managed care plans, the provider is the “seller” who provides a discount to the plan/patient “buyer.” Where the provider/seller submits a claim to the program, the statutory requirements have not been met and therefore, the discount is not exempted. The discount safe harbor (which encompasses all conduct under the statutory discount exception) also requires that the discount be offered to Medicare and

Medicaid. In the case of managed care contracts with providers, the discount is offered only to the managed care plan. Since the discounted fees are not offered to Medicare or Medicaid, the arrangement does not fall within the parameters of the safe harbor. An additional safe harbor is therefore necessary to protect discounts between managed care plans and providers.

Enrollment in a health plan falls within the scope of the anti-kickback statute where such enrollment involves Medicare or Medicaid beneficiaries and results from various incentives offered to these individuals by the managed care plan. The incentives offered to beneficiaries constitute remuneration with the meaning of the statute. Once enrolled, the plan is entitled to receive Medicare or Medicaid reimbursement for the services directly provided to program beneficiaries. Alternatively, the plan steers enrollees to certain providers who furnish reimbursable services. The incentives offered to program beneficiaries can be in return for obtaining reimbursable program business and, therefore, are covered by the statute.

Moreover, one does not have to be a “provider” or make an actual “referral” to be covered by the anti-kickback statute. The statute covers any persons who offer, pay, solicit, or receive any unlawful remuneration. The scope of prohibited conduct includes not only that which is intended to induce referrals, but also that which is intended to induce the purchasing, leasing, ordering or arranging for any good, facility, service or item paid for by Medicare or Medicaid. Accordingly, the statute covers recommendations on which providers to use, and would include the preferred or approved provider lists of HMOs or PPOs, especially where such providers have agreed to discount their fees in return for such designations.

Comment: Some commenters wanted the OIG to obtain industry input before finalizing these safe harbor regulations.

Response: The interim final rule originally provided for a 60-day public comment period. The OIG subsequently agreed to extend the comment period an additional 60 days. Consequently, we do not believe that further public comment is necessary before the regulations are revised to take into account the public comments received.

Comment: One commenter requested that the OIG provide a mechanism by which members of the public could seek advance rulings on whether practices violate the anti-kickback statute or fall within the safe harbor regulations.

Response: As we explained in the July 29, 1991 final safe harbor provisions, we understand and appreciate the desire for legal security in parties' business relations. However, we are unable to provide a mechanism responding to individual requests for advisory opinions about the legality of a particular business arrangement under the statute for several reasons. The Department of Justice (DOJ) has exclusive authority to enforce all criminal laws of the United States such as the anti-kickback statute. (See 28 U.S.C. 516, 519 and 547.) Any advisory opinions that we would issue would not be binding on DOJ and could serve to impede the prosecution of a particular case. Moreover, the statute requires proof of knowing and willful intent, which is generally impossible to evaluate on the basis of written submissions from interested requestors.

Comment: Certain commenters wrote that the OIG should publish a new safe harbor exempting managed care entities from the 60/40 investor and revenue provisions of the small entity safe harbor on investment interests.

Response: These issues lie beyond the scope of this rulemaking and would require separate notice and public comment in order to be adopted. The OIG will consider whether circumstances warrant the future revision of that safe harbor for managed care entities.

Comment: Some commenters addressed the issue of independent agents and brokers in the managed care arena. They asserted that the OIG should revise the existing safe harbor on personal or management services or create an additional safe harbor to protect an HMO's or PPO's use of independent agents and brokers. They believed that independent broker representatives have been the most effective marketing tool for Medicare coverage products. These commenters stated that HMOs or PPOs cannot meet the personal services safe harbor because they cannot establish the aggregate compensation element in advance of a transaction.

Response: This issue is beyond the scope of the interim final rule and would require separate notice and public comment in order to be adopted. In addition, we disagree that the OIG should protect independent agents or brokers used by HMOs or PPOs. Widespread abusive practices have occurred in several States involving independent contractors who misrepresent the nature of a plan's coverage in attempting to enroll individuals. As discussed in the

preamble to the July 29, 1991 final safe harbor regulations, we are unpersuaded that such contractors would be subject to adequate supervision or control unless they become employees. We recognize that various personal services arrangements are not covered by these regulations but reiterate that the OIG must reasonably protect the Medicare and State health care programs from abuse.

Comment: Some commenters requested that the OIG seek to amend the anti-kickback statute to clarify its parameters and provide ample scope to managed care entities for their contracting and pricing practices.

Response: The OIG clearly lacks authority in these regulations to amend the anti-kickback statute, which only Congress may do. Therefore, the commenters' suggestion falls outside the scope of this rulemaking. The OIG will, however, continue to consider from time to time whether additional safe harbors are appropriate or whether other specific managed care contracting or pricing practices should be protected.

Comment: One commenter stated that the revised final rule should clearly prohibit providers from balance billing Medicare patients any amounts which exceed either Federal or State law. The commenter noted that currently Federal law permits providers generally to balance bill their patients up to 115 percent of the Medicare allowable amount and that some States do not allow any balance billing whatsoever.

Response: The commenter raises an issue which is beyond the purview of these managed care safe harbor regulations. Neither the new safe harbors nor the amended Medicare SELECT provision addresses the balance billing practices of providers. As the commenter indicates, Federal law precludes providers from charging beneficiaries more than 15 percent above the fee schedule or other allowable charge. The Medicare statute includes a specific remedy for violations of the limitations on balance billing. Moreover, some States like New York absolutely ban balance billing and have mechanisms to enforce those requirements. Therefore, we believe that both Federal and State law already adequately regulate balance billing practices.

B. Comments Applicable to the Two New Safe Harbors

1. The Definition of "Health Plan"

Comment: The vast majority of commenters objected to the scope of the definition of health plan used in the regulations as being too narrow and

requested that it be broadened. Commenters specifically requested that the definition should be expanded to include ERISA plans, employer self-funded plans, union welfare funds, non-premium or uninsured HMOs, exclusive provider organizations (EPOs), physician/hospital organizations (PHOs), and PPOs which serve as intermediaries between providers and plans or between providers and employers.

Response: We agree that the definition of health plan should be broadened and have revised the definition to include two additional categories of entities. We had not intended to exclude ERISA plans or other company or union sponsored health plans, and we had specifically mentioned these types of plans as legitimate health plans in the preamble to the interim final rule. As we discussed in that preamble, our primary concern in requiring a health plan to charge a premium and in requiring State regulation of that premium was to exclude phony insurance plans from protection. We still believe it is necessary for the definition to exclude such phony insurance plans because if such plans were not excluded, we would have lost a major tool to combat them and, if they were immunized from liability under the anti-kickback statute, we would have only limited ability to take effective action against these types of abusive arrangements. For example, the requirement is necessary to prevent entities from establishing "insurance plans" that charge only minimal premiums, such as \$1.00, that are unrelated to the cost or level of services provided. Often, such plans are merely an attempt to legitimize an unlawful waiver of coinsurance or deductibles. The requirement is also necessary to prevent the creation and use of "shell" entities, which would qualify as a health plan and would, in turn, subcontract all of its responsibilities to other entities or insurance companies. We believe the revisions we have made to the definition of health plan will allow a wide variety of legitimate managed care health plans to qualify for protection.

The revised definition maintains the requirement that the entity furnish or arrange for the furnishing of items or services to enrollees of the plan through contracts or agreements with health care providers, or furnish insurance coverage for the provision of such items or services. However, we have broadened the definition to provide that the entity must furnish or arrange for the provision of items or services to enrollees in exchange for either a

premium or a fee. The fee is designed to cover those situations where a premium is not charged, such as where an employer negotiates directly with providers the fees it will pay for the provision of health care services. It would also cover situations where an entity establishes a network of providers and markets that network to an employer or an insurance company, in return for a fee for administering the plan. The fee must reflect the fair market value of administering the plan or the network.

Additionally, in order to qualify as a health plan, the entity must fall within one of four categories. The entity must (1) operate in accordance with a contract, agreement, or statutory demonstration authority approved by HCFA or a State health care program; (2) charge a premium and have its premium structure regulated under a State insurance statute or a State enabling statute governing HMOs or PPOs; (3) be an employer or a union welfare fund whose enrollees are current or retired employees or union members, respectively; or (4) be licensed in the State, be under contract with an employer, a union welfare fund, or a health insurance company, which meets the requirements of (2) or (3), and be paid a fee for the administration of the plan. The first two categories were included in the original definition of health plan. The third category is designed to cover ERISA plans, or other employer or union plans which are self-insured or self-funded and which contract directly with health care providers or insurance companies. In order to exclude bogus or sham entities, we have required that the enrollees of such plans be limited to current or retired employees or current union members, and their families. By union welfare funds, we mean those funds which are operated by bona fide labor organizations. The fourth category is designed to cover entities such as PPOs that act as intermediaries between contract health care providers and employers, union welfare funds or insurance companies. Again, to exclude entities that are not bona fide intermediaries, we have required that the entity be furnishing or arranging for services under contract with a bona fide insurance company, employer, or union welfare fund.

We elected to broaden the definition of health plan by referring to categories of entities based on how they operate or arrange for services rather than by specifically naming different types of common managed care entities, such as HMOs, PPOs, EPOs, or PHOs. We believe this is a preferable approach

because there are no single or commonly recognized definitions of each of these types of entities. Any definition we might choose to use would likely be viewed as arbitrary and would likely exclude some otherwise legitimate arrangements. We believe that the majority of legitimate managed care entities will be able to fit into one of the four categories contained in the definition.

We would also point out that the broadening of the definition of health plan to cover preferred provider organizations which act as intermediaries does not provide automatic safe harbor protection for the arrangement between the organization and the insurance company, employer, or union welfare fund. It only enables such organizations to qualify as a health plan for purposes of negotiating protected price reduction agreements with contract health care providers. In order for the PPO's intermediary arrangement to qualify for safe harbor protection, it must meet the requirements of the personal services and management contracts safe harbor in § 1001.952(d).

Comment: A number of commenters argued that legitimate managed care health plans can be identified through the accreditation process by AAPI or NCQA or by requiring non-accredited entities to meet the requirements of those bodies. They believed that the definition of health plan should be revised to include all managed care plans and that the safe harbor should require accreditation or that entities meet the standards for such accreditation.

Response: We do not believe that it is appropriate to require health plans to seek accreditation from private companies or require them to comply with the standards developed by such private companies. We would have no way to determine compliance with those standards if an entity did not seek accreditation. Moreover, accreditation is not a widespread practice and the standards used by such companies are not universally recognized or accepted as minimum standards that should be required for all managed care plans. Finally, we are not aware of any evidence that health plans or entities that do not meet these accreditation standards are abusive or illegitimate, nor do we have any evidence that accredited plans are less likely than other managed care plan to engage in practices that may violate the anti-kickback statute. Therefore, we have declined to require or incorporate accreditation as a part of the definition

of a health plan or as a requirement of a safe harbor.

Comment: Some commenters believed that the OIG should pursue "sham" arrangements via "selective enforcement" of Fraud Alert standards rather than through limiting the definition of a health plan.

Response: We disagree that the OIG should allow any managed care entity to qualify as a health plan because the OIG can effectively pursue sham transactions through the selective enforcement of the Fraud Alert standards. First, the Fraud Alerts issued by the OIG do not establish standards which can be enforced. The standards that exist are established by the anti-kickback statute or other federal statutes and regulations. The Fraud Alerts only set forth practices that have been identified as abusive or that may be potentially abusive depending on the circumstances and the intent of the parties. The Fraud Alerts are intended to provide guidance to the public on how they can avoid violations of the statute. Second, the purpose of the safe harbor regulations is both to identify practices or arrangements that fall within the broad scope of the anti-kickback statute but that are not abusive, and to immunize those practices or arrangements from criminal or civil liability. Our intent in establishing these safe harbors is to include only those practices or arrangements that we are confident are not abusive. Accordingly, we believe it is appropriate to limit the definition of health plans to exclude sham managed care plans or phony insurance plans to ensure that such plans do not qualify for protection under a safe harbor.

2. Shifting the Burden

Comment: The commenters universally objected to the interim final rule's prohibition against plans "shifting the burden" of increased coverage, reduced cost-sharing or price reductions onto other payers. Most commenters asserted that this standard was unclear and imposed a burdensome requirement on health plans that the government should not be imposing. They argued that without the ability to shift the revenue loss from incentives or discounts across their entire customer base, health plans would be unable to offer incentives and providers would be unwilling or unable to offer discounts.

Response: We continue to believe that enrollee incentives and provider price reductions should be economically sensible, i.e., they should not be driven by a motive to shift costs to the government or other payers. A health plan should not be offering incentives or provider discounts unless they believe

the cost of those incentives or discounts can be recovered through lower operating costs resulting from increased volume, economies of scale or other efficiencies. We also believe that practices should be protected only if they do not cause harm to the Medicare and Medicaid programs. Accordingly, we are only willing to protect incentives and price reductions that do not result in increased costs to the programs. In order to ensure that result, we believe it is necessary to include a requirement which prohibits cost shifting to the Medicare and Medicaid programs. We recognize that the prohibition as originally drafted went beyond what was necessary to protect these Federal programs. We have therefore narrowed the scope of the prohibition against cost shifting to the Medicare and State health care programs and have clarified the circumstances when cost shifting is considered to have occurred, i.e. when an arrangement or agreement results in increased payments being claimed from the Medicare or State health care programs.

Comment: Some commenters requested that the OIG set standards establishing when cost shifting has occurred. They complained that plans and providers have no way to tell if they are in compliance with this requirement.

Response: We do not believe it would be possible to provide a complete or exhaustive list of situations where cost shifting has occurred. We believe that plans and providers make judgments that they expect to forego income to maintain market share, or that they expect to recover lost income resulting from incentives to enrollees or discounts to plans. These plans and providers make judgments whether those means involve allocating increased costs to other customers or payers. Certainly, in any case where a plan or provider raises its costs or fees to others or reduces the services it provides to others as a result of an incentive or a discount, prohibited cost shifting has occurred. Claiming certain costs, such as waivers of coinsurance or deductibles, as bad debt would also constitute impermissible cost shifting.

C. Provision-by-Provision Analysis of Safe Harbors

1. Waiver of Part A Deductible and Coinsurance Amounts in Accordance With an Agreement Between a Hospital and a Medicare SELECT Insurer

Comment: Several commenters objected to the expansion of this safe harbor provision being limited to Medicare SELECT plans for a variety of

different reasons. These included the fact that Medicare SELECT is only available in 15 States; that other Medigap plans or preferred provider plans provide no greater risk of abuse than do Medicare SELECT plans; that Medicare SELECT was not intended to be the exclusive mechanism for allowing new and innovative Medigap benefits; and that preferred provider plans that existed prior to the enactment of Medicare SELECT and that now have frozen enrollments due to the standardization of Medigap policies should be allowed to continue to arrange for waivers through agreements with hospitals.

Response: We believe that it continues to be appropriate to limit the amendment of the safe harbor on inpatient hospital waivers of coinsurance and deductibles to Medicare SELECT. As we noted in the preamble to the interim final rule, the Medicare SELECT program is a demonstration project, authorized in only 15 States, and scheduled to operate only from January 1, 1992 until the end of 1994. In order to provide any protection during the demonstration period, it was necessary to publish the safe harbor promptly and in final form. Since we had not previously received comments on this issue from managed care entities, we did not believe a broad waiver was appropriate without subjecting the proposal to notice and comment. Therefore, a limited waiver was included in order to permit the demonstration projects to enter into agreements with hospitals for the waiver of inpatient deductibles and coinsurance amounts without fear of prosecution under the anti-kickback statute. We also believe that the amendment was appropriately limited to Medicare SELECT because the demonstration project included an evaluation and report that would enable the OIG to determine whether the amendment had any undesirable effects. We believe that such evaluation will also provide a factual basis for the OIG to decide whether the amendment should be continued or expanded to other similar types of arrangements.

The demonstration project is still in progress and no final report has yet been issued evaluating the different Medicare SELECT plans that are operating in the 15 States participating in the demonstration project. However, we have reviewed some of the preliminary results of the evaluation. While the data indicate that most beneficiaries who purchase a Medicare SELECT policy pay a lower premium than they would pay for the same package of benefits under a regular supplemental policy, in most

cases the lower premiums are the result of the waiver of inpatient hospital deductibles and coinsurance by hospitals rather than the result of reduced utilization or improved management of care. The amendment to the safe harbor permitting agreements between hospitals and Medicare SELECT insurers for the waiver of these cost sharing obligations seems to be the variable that enables Medicare SELECT insurers to reduce claims and thereby offer lower premiums to beneficiaries.

The evaluation of service utilization by beneficiaries with Medicare SELECT policies is expected to take several months to complete. We expect that this part of the evaluation will provide information as to whether the amendment has affected costs to the Medicare program or other payers, or whether it promotes or helps to control overutilization or inappropriate utilization of inpatient hospital or other services. Additionally, it will provide information on whether the Medicare SELECT program is fulfilling the legislative intent of establishing a "managed care" Medicare supplement alternative. Specifically, the intent of Medicare SELECT was to give beneficiaries some of the benefits of a managed care plan enrollment, that is, case management, a primary care physician and cost effective care; it was not intended to be a mere discounting arrangement between hospitals and insurers.

Accordingly, we believe it is appropriate to reserve the option of expanding, revising or rescinding the amendment until we have had an opportunity to consider the complete results of the Medicare SELECT evaluation report.

We do not see any basis for providing safe harbor protection to non-SELECT plans which offer preferred provider provisions merely because such plans predate the enactment of the Medicare SELECT program or because their enrollment is frozen as the result of the new standardized Medigap program rules. The mere existence of a practice or arrangement is not a sufficient basis to exempt that practice or arrangement from the reach of the anti-kickback statute. Our position is that we will not provide safe harbor protection for any practice or arrangement unless we are confident the practice or arrangement is not abusive. We do not currently have any evidence to show that the waivers negotiated by these plans are not abusive or harmful to the programs. The fact that enrollment in these plans is frozen does not make the waivers any less potentially abusive or any less risky. The enactment of Medicare

SELECT and the standardization of Medigap benefits and policies did nothing to affect or change the legal status of routine waivers of coinsurance or deductibles. Consequently, they do not provide any justification for an extension of the existing safe harbor.

We believe that the Medicare SELECT demonstration project is also distinguishable from other preferred provider arrangements on other grounds. First, section 1882(t) of the Social Security Act establishes certain minimum standards that Medicare SELECT plans must meet. These standards include a provider network to provide all services with sufficient access, full benefits for emergency care, an ongoing quality assurance program, and provisions to ensure that beneficiaries are fully informed about the benefits and restrictions of the plan. Medicare SELECT plans are also subject to the imposition of civil monetary penalties for the failure to meet certain requirements, including the failure to provide medically necessary services within the provider network. No other Medigap plans or preferred provider plans are subject to these standards or penalties. Finally, the Medicare SELECT program is subject to ongoing evaluation and expires at the end of 1994. We believe the requirements imposed on Medicare SELECT plans and the time-limited nature of the demonstration provide substantially more protection and less risk to both the Medicare program and Medicare beneficiaries than do other plans.

Contrary to one commenter's belief, we do not view the Medicare SELECT program to be the exclusive vehicle for providing new or innovative Medigap benefit packages. Since it is an existing program, we considered whether it was appropriate to provide any safe harbor protection. To the extent that a State approves a new or innovative Medigap benefit package, we would similarly consider whether any additional safe harbor protection was necessary or appropriate. While States may have the authority to approve the sale of certain non-standardized benefit packages, they do not have the authority to exempt any such benefit packages from the prohibitions of the anti-kickback statute. As we were unwilling to provide a blanket exemption for the Medicare SELECT program, we are unwilling to commit in advance to a blanket exemption for any State-approved innovative benefit package. The approval of additional benefits as part of a Medigap policy would not necessarily implicate the anti-kickback statute and therefore no automatic protection would be necessary. However, the

arrangements that insurers may enter into in order to be able to furnish those benefits economically or without additional premium costs could be violative of the anti-kickback statute.

Comment: Some commenters believed that this safe harbor should allow inpatient waivers for agreements with third party payers for all managed care entities. Other commenters requested that safe harbor protection be extended to entities having risk or cost contracts with HCFA.

Response: We disagree. At the present time, we do not believe there is sufficient evidence to demonstrate that waivers that result from agreements between hospitals and third party payers, such as insurers or health plans, are not abusive. We believe there are significant differences between waivers of deductibles and coinsurance offered by hospitals directly to beneficiaries and those negotiated between hospitals and health plans. When we promulgated the original safe harbor provision, we noted that there is a limited risk of abuse because of various factors. First, the Medicare program is not directly harmed since hospitals receive a predetermined amount under the prospective payment system for each admission regardless of their costs or charges. Second, hospital admissions are subject to peer review and there is a relatively fixed level of patient demand for hospital services. Third, physicians, rather than patients, make the decision whether admission is medically indicated and their practice patterns and admitting privileges also affect the decision as to which hospital will be selected. Therefore, we believed that a waiver of inpatient beneficiary fees would not be likely to increase utilization significantly, especially if hospitals could not discriminate on the basis of length of stay or type of diagnosis.

These limiting factors do not exist where waivers result from agreements between hospitals and insurers or plans. In contrast to the effect of a waiver given to a beneficiary which affects only a single admission, health plans or insurers have the capacity to direct the flow of large numbers of admissions to specific hospitals by designating them as preferred or exclusive providers in return for an agreement to waive coinsurance and deductibles. Where this flow results from the hospital's agreement to waive inpatient beneficiary fees or to reduce its charges, or both, the practice can be abusive and anti-competitive. Hospital reimbursement rates differ and the designation of certain hospitals as preferred or exclusive providers in a

particular geographic area could result in a direct increase in the amounts paid by the Medicare program for inpatient hospital costs. Thus, while the plan or insurer would save money, the Medicare program would not. Similarly, a health plan or insurer's designation of certain hospitals could result in substantial decreases in the number of admissions to other area hospitals and might eventually result in the closure of some facilities, thus lessening competition. Reduced competition could lead to increased charges by the remaining hospitals. Additionally, the waiver of beneficiary fees or reduced charges that the hospital has agreed to in order to obtain the health plan or insurer's business may ultimately be passed along to the Medicare program or other payers. Finally, we are concerned about the possibility of overutilization or inappropriate use of services that may result from a waiver of beneficiary fees. Where Medicare is the primary payer, a hospital's waiver of inpatient deductible and coinsurance amounts results in the insurer or health plan having no financial liability. Since the plan or insurer has no financial stake, it may be less concerned about guarding against the overutilization or inappropriate utilization of services.

We have made, however, a minor change to the regulation to clarify the meaning of "third party payer." There has been some question as to whether that term would include PPOs that serve as intermediaries between health care providers and insurers or employers, but who are not responsible for the payment of claims for services provided to beneficiaries. We have revised the regulation to indicate that a third party payer includes any entity that meets the definition of a health plan set forth in § 1001.952(l)(2) of the regulation. With the limited exception for Medicare SELECT, it is our intent, as discussed in the preamble to the July 29, 1991 final safe harbor regulations, to protect only those waivers that are given by hospitals directly to beneficiaries. We did not intend to protect any waivers that resulted from contractual agreements entered into by hospitals.

Comment: A number of commenters, including some who are Medicare SELECT insurers, raised objections to the effect that even where Medicare SELECT is in place, the safe harbor does not permit waiver of coinsurance for a large number of services that are essential to cost-efficient managed care networks (e.g., hospital outpatient services, ambulatory surgical centers, physician services) because it is limited to inpatient hospital services. They urged that the safe harbor be expanded

to cover services reimbursed under Part B of Medicare.

Response: We do not believe that safe harbor protection is appropriate for routine waivers of coinsurance and deductibles for outpatient services covered under the Medicare Part B program. We also do not believe that such waivers are necessary or essential to the efficient or cost-effective operation of managed care plans. Managed care plans are free to seek discounts or price reductions from providers that lower the costs of providing services, as long as those reductions are reflected as a lowering of the provider's total charge for the service. We have expressly provided protection for this type of discount in the safe harbor on price reductions offered to health plans.

As we indicated in the preamble to the interim final rule, routine waivers of coinsurance and deductibles are an area of significant abuse in the Medicare program. Such waivers result in the submission of false claims to the Medicare program because providers misstate their charges on claims submitted to the program. For example, if a provider's usual charge is \$100 and he or she routinely waives the 20 percent coinsurance, then the provider's actual charge for providing the service is really only \$80, the amount he or she expects to receive as payment for the service. If the provider submits a claim to the Medicare program for \$100, he or she has misrepresented the actual charge and the Medicare program will reimburse the provider a higher than appropriate amount. If the Medicare program reimburses the provider \$80, then the program will have paid for the entire cost of providing the service, rather than the 80 percent authorized by law. In this single instance, the program would have overpaid the provider by \$16 (the difference between \$80 and \$64, which is 80 percent of the provider's actual fee of \$80). Thus, the waiver of coinsurance results in substantially higher costs to the Medicare program. Similar problems may arise with cost-based health care providers. We would also note that the Secretary's authority to grant safe harbor protection extends only to violations of the anti-kickback statute. The Secretary has no authority to provide protection from criminal, civil, or administrative liability arising from the submission of false claims to the Medicare program.

We also believe that the routine waiver of coinsurance and deductibles may result in overutilization or inappropriate utilization of services. Cost sharing is an essential element of the Medicare program. To the extent

that beneficiaries have a financial stake in the cost of services, they have a direct interest in seeking the most efficient and economical providers and are deterred from seeking unnecessary services. As a result, Medicare program expenditures are lower. Where Medicare beneficiaries have no financial stake because a provider has waived their coinsurance amount, they are less likely to be concerned over whether the charge for the service is \$10 or \$100, and are less likely to question the medical necessity of the item or service provided or ordered. Similarly, where a health plan (or insurer) is responsible for paying a Medicare beneficiary's coinsurance or deductible amounts, it is concerned about the cost or necessity of the services provided to their enrollees. However, where a health plan negotiates a waiver of Medicare coinsurance or deductible amounts with providers, it no longer has a financial stake because there are no costs it incurs for the services provided by that provider to Medicare beneficiaries. Once again, the Medicare program ends up paying for the full cost of care.

We have no evidence to indicate that Medicare SELECT plans are significantly different from other Medigap plans or other types of managed care health plans in this respect, or that they will adequately protect the Medicare program from higher costs or inappropriate expenditures. Section 1882(t) of the Act does not provide any specific safeguards against the abuses that occur from the waiver of Medicare Part B coinsurance or deductibles. Thus, we continue to decline to provide any expanded protection for Medicare SELECT plans.

Comment: One commenter indicated that the False Claims Act and other laws, but not this rule, should address situations where waivers of coinsurance and deductibles might result in inaccurate charges billed to Medicare program.

Response: We disagree that abuses arising from the waiver of coinsurance and deductibles should be addressed through the use of the False Claims Act and other laws and regulations. One of the primary purposes of the anti-kickback statute is to protect the Medicare program from higher costs and overutilization that occur when financial incentives are offered or given in order to obtain Medicare program business. Thus, the anti-kickback statute is an appropriate mechanism to deal with higher program costs resulting from inaccurate charges and claims submitted to the Medicare program.

Moreover, the purpose of the safe harbor regulations is to exempt from

criminal or civil liability those practices which, although they violate the anti-kickback statute, are not harmful to the Medicare or State health care programs. As discussed above, routine waivers of Medicare Part B coinsurance and deductible amounts are harmful and abusive because they regularly lead to false claims and increased costs and because they encourage overutilization or inappropriate utilization of services. Thus, safe harbor protection is unwarranted and inappropriate.

Finally, another purpose of the safe harbor regulations is to provide standards which providers and other persons or entities can comply with and be assured that they will not be subject to criminal or civil prosecution or exclusion from program participation. We actively encourage providers to come into compliance with applicable safe harbor provisions. It would be unfair and misleading, if not an abuse of discretion, for us to provide an exception under the anti-kickback statute for certain behavior when compliance with that exception would subject providers and plans or insurers to the very same criminal, civil, and administrative sanctions under the False Claims Act or other provisions. The mission of the OIG is to prevent fraud and abuse, not to encourage it.

Comment: One commenter indicated that the OIG should, at a minimum, publish a new Federal Register notice that lists examples of coinsurance waiver arrangements that may not qualify for safe harbor protection, but "probably would not be pursued criminally or civilly by the OIG."

Response: We do not believe that there are any specific types of situations involving a routine waiver of coinsurance or deductibles that we would decline to pursue as a general rule. Thus, we believe that publication of a new Federal Register notice is not necessary. In the OIG Fraud Alert on this subject, we have indicated that waivers were only appropriate on a case-by-case basis in consideration of a patient's financial hardship or where a good faith effort to collect has been made. We have not changed our position.

2. Incentives to All Enrollees

Comment: Some commenters maintained that a literal reading of the enrollee incentive safe harbor would necessitate uniformity among all products, thereby eliminating any incentive. The commenters encouraged the OIG to eliminate the provision or restrict it to all enrollees of a particular product.

Response: The purpose of the requirement that incentives be provided to all enrollees was to restrict the ability of health plans to target particular Medicare or Medicaid beneficiaries or groups of such beneficiaries and induce them to enroll in the plan by providing incentives. We were concerned that plans would target healthy beneficiaries by offering them increased services or reductions in cost sharing and attempt to avoid older or sicker beneficiaries or those with expensive or chronic health conditions requiring a high utilization of services by offering only the same services available through a fee-for-service plan. Accordingly, we are reluctant to eliminate this requirement from the safe harbor. We are also reluctant to limit the regulation to a product-specific approach because we are concerned that the same type of abuses could occur where health plans offered several different products.

Comment: A number of commenters urged the OIG to restrict the scope of "enrollee" only to members of the Medicare or State health care programs. They believed that the inclusion of all enrollees was unwarranted and exceeded the scope of the Medicare and Medicaid Patient Program Protection Act (MMPPPA) of 1987.

Response: Although we do not agree that the scope of the provision exceeded our authority under MMPPPA, we believe that these concerns can be adequately addressed by limiting the provision to all enrollees who are also beneficiaries of the Medicare and State health care programs. Accordingly, we have revised the safe harbor on incentives to enrollees to require that incentives offered by health plans be offered to all Medicare or State health care program enrollees of the plan. We believe that this limitation will adequately safeguard against the possibility that health plans may improperly favor certain healthy beneficiaries or use incentives to improperly encourage utilization when the item or service is furnished.

3. Incentives by Non-Contract Health Plans

Comment: Several commenters believed that safe harbor protection should be given to any managed care plan that offers a higher level of benefits or services obtained from a contract provider. They believed that protection should be given for all incentives by managed care plans, including those providing Medicare supplemental coverage. Other commenters indicated that coinsurance waivers and other financial incentives to encourage the use of a preferred provider panel were

historically legitimate managed care incentives that do not cause harm to Medicare or Medicaid and should therefore be recognized.

Response: We remain unpersuaded at this time that safe harbor protection is appropriate for health plans that are not under contract with HCFA or a Medicaid State agency. Unlike contract plans that are limited to a few types of arrangements, non-contract plans consist of widely varying arrangements and widely differing scopes of benefits. These plans are subject to little oversight. Most of the commenters who requested a broadening of the safe harbor failed to provide any discussion of precisely how the Medicare and Medicaid programs would or could be protected against abuses if all managed care plans were permitted to offer any kind of incentives free of anti-kickback liability. Nor did they provide any substantive evidence that the majority of the existing managed care plans have effective mechanisms and controls that would adequately protect the Medicare and Medicaid programs against higher costs or overutilization. Finally, the commenters did not suggest any standards we could impose which would eliminate plans that do not have in effect adequate mechanisms to protect the Medicare or Medicaid programs from abuse.

Moreover, we believe that the fact that the Medicare and Medicaid programs reimburse services provided to enrollees of non-contract plans on a fee-for-service basis makes these situations subject to the same potential abuses and risks as exist with incentives offered by non-managed care plans or providers. Where a health care provider who is part of a preferred provider network treats a beneficiary and will be paid for each service that he or she provides on a fee-for-service basis by Medicare or Medicaid, that provider has no built-in incentive not to overutilize. To the extent that the provider has agreed to accept reduced fees for the treatment of plan enrollees, he or she may have a direct incentive to increase the number of services to make up for the reduction in fees. Similarly, if the beneficiary has reduced or no cost sharing obligations, the beneficiary faces no disincentive to overutilization. The plan does not prevent reimbursement for these unnecessary services because the claims are directly submitted to and paid by Medicare or Medicaid. Finally, where managed care providers agree to accept Medicare payment as payment in full, the burden of the reduced cost sharing incentives offered to beneficiaries comes at the expense of the Medicare program, because the program will end up paying

100 percent of the provider's fee. Thus, these incentives can cause harm to the Medicare and Medicaid programs.

Comment: Some commenters argued that incentives by non-contract plans should be allowed because most managed care plans adequately monitor for overutilization, and that many non-contract plans are monitored either as Federally-qualified HMOs or as a result of accreditation by independent organizations. They also argued that Medicare and Medicaid patients cannot be carved out of a managed care plan's incentive programs, and that a loss of administrative efficiencies could result if plans need to handle program beneficiaries differently than others covered under group plans.

Response: We do not believe that existing utilization review mechanisms are sufficient to protect the Medicare and Medicaid programs against abuses associated with self-referral. One major problem is that there are no widely accepted definitions or standards governing utilization review. This presents a major barrier to drafting a safe harbor with clear, well-defined standards. Additionally, most utilization review activity is focused on expensive procedures or on patterns of care, and therefore does not address individual physician decisions on diagnostic or other treatment services, where many self-referral abuses occur. Utilization review is also designed to identify and address medical care that falls outside of accepted medical parameters or norms. Most of the problems we have observed in the area of self-referral involve physician treatment decisions that are within the range of accepted parameters or norms, but where financial incentives may improperly influence or affect physician judgments. Accordingly, we are not at all confident that utilization review will cure or prevent self-referral problems that the anti-kickback statute was intended to address. Therefore, it would be unwise to adopt utilization review mechanisms as an appropriate standard for safe harbor protection.

Where Medicare or Medicaid are responsible for paying for a portion of the care rendered to enrollees of a managed care plan, the plan must already have some procedures that are different from those used where the plan is solely responsible for the cost of care. For example, separate claims must be submitted to those programs either before or after claims are submitted to the managed care health plan. We believe that managed care plans can handle potential differences between Medicare's and the plan's coinsurance amounts in ways that are efficient and

economical as well as in compliance with the requirements of Federal law.

Comment: One commenter specifically urged that safe harbor protection should be limited to plans under contract with HCFA or a State agency, arguing that if it is broadened it will result in unfair competitive practices and illegal waivers of coinsurance and deductibles. A second commenter agreed, but believed an exception should be made for situations where dual coverage exists and the second plan adopts a non-duplication of benefits or preservation of deductibles and coinsurance posture.

Response: We share the concerns of the commenters that expansion of the safe harbor provision could result in abusive or illegal practices. As we indicated in an earlier response, we remain concerned that because services provided to enrollees of non-contract plans are reimbursed on a fee-for-service basis, the plans would pose the same risks to the Medicare and Medicaid programs as typical fee-for-service plans. In the case of contract plans, the reimbursement formulae take into account the cost sharing obligations of beneficiaries that the Medicare or Medicaid programs may require, so there is no problem with illegal waivers of coinsurance or deductibles. We also believe that the rules applicable to contract plans and the oversight provided by HCFA or a State Medicaid agency should be sufficient to prevent anti-competitive or other abusive practices from occurring in contract plans.

We do not believe that a special safe harbor provision is necessary or warranted at this time to deal with dual coverage situations. Dual coverage is where a person is covered by more than one health insurance policy. An example would be where a husband and wife are both employed and each is covered by an employer policy that includes family members. We do not believe that dual coverage (to be distinguished from Medicare supplemental or Medigap coverage) is a problem that affects significant numbers of Medicare or Medicaid beneficiaries. Companies are expressly prohibited by law from selling Medicare beneficiaries health insurance coverage that duplicates any existing coverage that they may have. Medicaid is a payer of last resort and will not pay for services covered by other health insurance or plans.

4. Price Reduction Agreements

Comment: One commenter questioned why the price reduction safe harbor applicable to plans not under contract

with HCFA or a Medicaid State agency was drafted on a fee-for-service concept.

Response: The safe harbor was drafted in this manner because that is how the Medicare and Medicaid programs almost exclusively pay for services furnished to program beneficiaries by non-contract managed care health plans or by providers who are affiliated with non-contract plans. Such plans and providers are reimbursed for each separate covered service provided to Medicare or Medicaid beneficiaries on the basis of fee schedules or allowable charges. Capitated payment arrangements and reasonable cost-related reimbursement are only directly allowed in plans which are under contract. We have dealt with those types of arrangements in the first two parts of the price reduction safe harbor dealing with plans under contract with HCFA or a Medicaid State agency. Therefore, we did not believe it was necessary or appropriate to provide for safe harbor protection for other types of payment mechanisms in the price reduction safe harbor for non-contract plans.

Comment: Many commenters objected to the fact that this safe harbor exempted only remuneration in the form of a reduction in the provider's usual charge for the service, thereby not protecting capitation agreements, bonuses, and withhold arrangements. These commenters believed that the safe harbor should protect all HMO or PPO compensation arrangements, including risk incentive pools and volume rebates, so long as they were not linked to referrals of Medicare or Medicaid patients.

Response: We have reconsidered our position that we did not need to address capitated arrangements in the safe harbor for price reductions in non-contract health plans. Although the Medicare and Medicaid programs may pay for services on a fee-for-service basis, some health plans contract with individual health care providers for the provision of services using a variety of different mechanisms, including capitation. Since the amount paid to a provider under a capitated arrangement may represent a reduction in the amount he or she would otherwise receive for treating a particular patient and the provider agrees to accept such payment amount in return for an agreed upon or anticipated flow of patients, the anti-kickback statute may be implicated. Therefore, we believe that some protection for these arrangements may be warranted.

Our experience has indicated that the most common risks that the anti-kickback statute is directed toward preventing are not present in the case of

at-risk, capitated payment mechanisms. Where a provider is paid a fixed amount for all the services provided to a patient, there is no incentive for overutilization. If anything, there is an incentive to underutilize. Accordingly, the Medicare and Medicaid programs face little risk of overutilization or the increased costs that accompany such overutilization where services are provided by a provider who is paid solely on an at-risk or capitated basis. For these reasons, we believe it would be appropriate for us to provide safe harbor protection for such arrangements.

Accordingly, we have revised the price reduction safe harbor to add a new category of price reduction agreement applicable to capitated payment arrangements to providers. In order to qualify for safe harbor protection, both the health plan and the contract health care provider must comply with five standards. First, the term of the agreement must be for not less than one year. Second, the agreement must specify the covered items or services that will be furnished to enrollees of the plan and the total amount per enrollee that the provider will be paid for such covered items or services, including any copayments to be paid by enrollees. The amount the provider will be paid per enrollee may be expressed in a per month or other time period basis. Third, the payment amount set forth in the agreement must remain in effect throughout the term of the agreement. Fourth, the health plan and the provider must fully and accurately report to the Medicare and State health care programs upon request, the terms of the agreement and the amounts paid in accordance with the agreement. Finally, the provider must not claim or request payment in any form from the Department, a State health care program or an enrollee (other than specified copayment amounts) for covered items or services. Similarly, the health plan must not pay the provider in excess of the amounts provided by the agreement for the provision of covered items or services.

For the most part, the conditions applicable to this new category of price reduction agreement are the same or comparable to those applicable to fee-for-service arrangements. We believe these conditions are necessary to prevent plans or providers from manipulating the terms of the agreed upon arrangement and adjusting the level of reimbursement or the scope of covered services for improper or illegal purposes. We believe that providers and plans should take steps to ensure that they have sufficient information concerning the costs of providing

services and the frequency and types of services that will be required for the plan's enrollees before they enter into these types of arrangements. We believe that the restrictions on seeking or paying additional amounts for covered services and the requirements for disclosure are necessary to ensure that the Medicare and Medicaid programs are not being charged excessive or inappropriate amounts.

We have declined to provide specific safe harbor protection to withhold pools, risk incentive pools, or other types of incentive programs offered by non-contract managed care plans. One problem we have with these types of arrangements is that there are no uniform standards or definitions applicable to each of these different types of mechanisms. Each health plan sets its own standards or risk pools and determines the amounts that will be paid or withheld. Because these types of arrangements vary so widely in amounts and scope, and because there are no commonly accepted minimum standards as to what criteria an incentive plan should include, we do not believe that it would be feasible for us to set adequate or appropriate minimum standards for a safe harbor. Moreover, because these types of payment mechanisms offer additional remuneration to providers that is related to the volume or value of services provided, their use is particularly vulnerable to abuse. They can be used to manipulate provider payment levels and can be used to inappropriately affect the flow of Medicare and Medicaid reimbursable business. We are not confident that we could create a safe harbor where we would be reasonably certain that any individual incentive plan qualifying for protection would be non-abusive.

We also believe that withhold arrangements present additional problems. We are concerned that in some cases providers subject to a withhold may be submitting false claims to the Medicare and Medicaid programs. If the provider does not ultimately receive the withheld amount or does not have a reasonable expectation of receiving it, and includes the full amount of the potential fee on the claim form, he or she has misrepresented the amount of his or her fee and stands to be overpaid by the Medicare or Medicaid programs. For example, if a provider's agreed upon fee is \$100 but the health plan has a 20 percent withhold in place, he or she is only assured of receiving \$80 in payment for the services provided. If that provider submits a claim to the Medicare program for \$100 and is paid \$80, that

provider will have received full payment from the Medicare program unless he or she also receives the withheld amount. The net effect is the same as an express waiver of coinsurance.

In some cases involving withholds, there is little likelihood that the payment amounts withheld will actually be made to providers. We are unwilling to protect any practice that may result in the submission of false or improper claims to the programs.

Comment: Some commenters objected to the fact that this safe harbor provision does not recognize compensation based on reasonable and customary allowances, such as a discount from usual charges.

Response: We believe that reasonable and customary or usual charges have no fixed meaning and are subject to change at the provider's discretion and, therefore, subject to manipulation and abuse. We believe it is necessary to have a fixed and identifiable list of charges and services in order to be able to determine compliance with the terms of the safe harbor. If the provider had a list of his or her reasonable and customary or usual charges that was incorporated as a part of the agreement with the health plan, and the agreement specified that the agreed upon payment rate would be 80 percent of the charges on the list, we believe that would be acceptable under the terms of the safe harbor because the price for each service would be a fixed and readily ascertainable amount. Of course, it would be the reduced amount that is the provider's charge for services to the plan's enrollees, not the reasonable and customary or usual charge, and that reduced amount would be required to be submitted on any claims or requests for payment to the Medicare or Medicaid programs for services rendered to plan enrollees.

Comment: Some commenters objected to the prohibition against submitting a claim in excess of the fee schedule because it prohibits plans or intermediaries that operate by negotiating discounts with providers and marking up the fees to the purchaser. This is the PPO's mechanism for defraying its costs. They indicated that such arrangements should be allowed because fees are still less than what the purchaser would otherwise pay. Specifically, commenters stated that the safe harbor should cover fees to providers that are a percentage of charges billed by the contracting provider and are attributable to the PPO's marketing services to third party payers.

Response: We believe any arrangements that set fees based on the volume or value of services provided to patients are subject to abuse and therefore, we decline blanket protection for them. We have seen instances where such payments are really only thinly disguised attempts to pay for referrals. Moreover, there is also no guarantee that the marked-up charges submitted to the Medicare and Medicaid programs would be any lower than the provider's usual charges to the programs. Thus, there is no guarantee that the programs will benefit from allowing such arrangements. We believe that there are enough other options a PPO can employ to cover its administrative or marketing costs. The PPO can include such costs in the premiums charged to plan enrollees or in fees charged to insurers or employers where the PPO administers the plan for such entities. The PPO is also free to enter into separate contracts with providers for management services. Of course, in order to qualify for safe harbor protection, such contracts would have to meet the terms of the safe harbor on management or personal services contracts. We also wish to emphasize that by not protecting such payment mechanisms under the safe harbor, we do not prohibit them, as the commenters believe. The failure to fall within a safe harbor means only that they are subject to the anti-kickback statute in precisely the same manner that they were prior to the issuance of the safe harbor.

Comment: Some commenters opposed the regulation's "sole purpose" requirement as being inconsistent with the structures of managed care plans. These commenters argued that providers qualifying for the safe harbors should be allowed to contribute activities such as pre-enrollment screening, utilization review and quality assurance services.

Response: Our intent in creating the safe harbor for price reduction agreements was to protect only those discounts given by contract health care providers for the items and services they furnish to enrollees. In order to ensure that we can determine whether the discounts given by providers comply with all of the requirements of the safe harbor, it is necessary to have a separate agreement that covers only the discounted arrangements that fall within the scope of the safe harbor. We have not prohibited managed care entities from entering into separate agreements with providers for other activities such as utilization review, pre-enrollment screening or even marketing activities. However, contracts for such activities will be scrutinized separately

and will only be afforded safe harbor protection if they meet the requirements of the existing management and personal services safe harbor.

We are unwilling to expand the price reduction safe harbor to cover these activities because, as we noted in the preamble to the interim final rule, we have observed that some HMOs have abused their contractual relationships with medical groups where individuals in the groups have conducted abusive or illegal activities on behalf of the HMO. For instance, various contract health plans have engaged in pre-enrollment screening in order to deny or discourage relatively sick beneficiaries from enrolling. Such activities in at least one case resulted in a criminal conviction. Additionally, it is easy to manipulate agreements for the provision of utilization review services and other activities to make payments to reward providers for certain actions or to provide additional reimbursement to certain providers in violation of the anti-kickback statute. For these reasons, we believe the standards of the management and personal services safe harbor should continue to be applied to personal services contracts between managed care entities and contract health care providers.

Comment: A number of commenters wanted the OIG to protect volume-sensitive fee schedules, subject to "possible pricing adjustments," if the schedule is stated in the contract and not increased during its term. These commenters would like to render higher payment to providers who service a greater number of managed care patients to ensure access to care.

Response: We decline to protect volume-sensitive fee schedules. We have found that volume-sensitive reimbursement levels are often extremely abusive. These types of schedules offer increased incentives for providers to overutilize, since the payments they receive will be higher if they provide more services to more patients. We are not sure what one of the commenters meant specifically by the term "possible pricing adjustments," but we are concerned that any such adjustments could create a referral-driven mechanism that would not serve the interests of the programs. We believe that other mechanisms exist through which health plans may ensure that providers give adequate coverage to patients or through which plans could reimburse providers who agree to treat a larger number of plan enrollees. For example, plans could require that providers agree to treat minimum numbers of enrollees and set the amount of compensation based on that number.

Alternatively, providers could agree to treat all plan enrollees who need services up to a certain number, with higher reimbursement levels for larger numbers of patients.

Comment: Several commenters took exception to the one-year term minimum requirement, contending that it excludes common contract terms, such as reciprocal termination clauses and inhibits plans, that may need to contract with a particular provider for less than one year. Other commenters argued that the requirement unduly restricts HMOs and does not allow for alterations based on changed circumstances. These commenters asserted that a change during the contract year in the percentage of fee schedule an HMO will pay is not a means of inducing referrals of patients enrolled in a plan.

Response: We have found that reciprocal termination clauses can result in parties engaging in "sham" contracts whereby they terminate the contract and renegotiate terms to gain more favorable financial positions. Alternatively, they may terminate contracts in order to enter into contracts with more favorable financial terms with other providers. These renegotiations may affect the flow of Medicare or Medicaid reimbursable business. We believe it is necessary for the contracts to have a fixed term of at least one year in order to avoid such manipulations. We have adopted a one-year term for all of the safe harbor provisions involving contracts. The commenters have not demonstrated any reasons why managed care contracts necessitate a different length. Accordingly, if parties alter contractual terms based on purportedly changed circumstances, that alteration will not enjoy safe harbor protection. Termination "for cause" clauses drafted in compliance with Internal Revenue Service or other legal or regulatory requirements should not jeopardize safe harbor status if the purpose of the termination clause is to comply with these requirements and not to facilitate renegotiation of contract terms. If a contract is terminated in accordance with a legally enforceable termination clause, the failure to renew the contract would indicate that the termination was effectuated for a legitimate business purpose. As to other types of termination clauses, the OIG will examine such conduct on a case-by-case basis to assess whether it is abusive and harmful.

We acknowledge that health care providers may enter into short-term service contracts for legitimate business reasons and not because of referral opportunities. However, we cannot

ensure that only legitimate short-term contracts will be covered if we delete the one-year requirement. We would also note that the one-year term does not refer to the length of time that services will be necessarily provided, but rather to the length of time within which the fees for the services covered by the agreement may not be changed. So long as the contract terms are not altered within a one-year period, an agreement that is performed in less than one year will meet the one-year requirement in the safe harbor provision.

Comment: Some commenters requested that the price reductions allowed under the safe harbor should be limited to a specific amount, e.g., a Medicare-approved rate or a percentage. They claimed that this restriction is necessary to prevent providers from accepting below-cost prices and increasing prices for non-managed care Medicare patients and others.

Response: We understand that providers negotiate discounted prices with health plans in order to increase the number of patients in their practices. Providers may expect that they can make up for the reductions in their charges by providing services to a greater number of patients. Generally, providers may anticipate a certain number of new patients as a result of entering into a contract with a managed care plan. However, the commenters raise a valid concern that the price reductions given, if great enough, may shift the burden of the price reduction to others by resulting in increased prices for non-managed care Medicare patients. We have specifically addressed that concern in the safe harbor by including a prohibition against cost-shifting onto the Medicare or State health care programs. Therefore, we are not convinced that setting limitations on the amount of a discount a provider may offer is necessary to prevent abuse. We also believe that the wide variations in providers' rates and costs make identifying a fixed "below-cost" point virtually impossible. We would have to assess a provider's entire billing practice to determine whether, in a given case, services were offered at rates below actual cost.

Comment: A number of commenters contended that managed care plans cannot reasonably ensure that its contract providers are not submitting claims which violate the contract's terms or claims that exceed the fee schedule. According to these commenters, Medicare should recoup the amounts erroneously paid to the provider rather than deprive both the provider and the plan of safe harbor protection.

Response: We believe it is appropriate to condition the granting of safe harbor protection on compliance by both plans and providers. Managed care health plans have an ongoing relationship with contract health care providers that includes monitoring and utilization review of the services provided to plan enrollees. This relationship is different from the usual relationship between buyers and sellers. Because of this special, ongoing relationship, health plans have a greater ability to monitor and ensure compliance with the requirements of the safe harbor regarding the submission of claims to the Medicare or Medicaid programs. Unless plans are held accountable in some way for the propriety of claims submitted to the programs, they will have no interest in ensuring the accuracy of those claims.

We also believe that health plans have available to them several ways to monitor or ensure compliance. For example, plans may require that the plan submit all claims to the Medicare or Medicaid programs. Alternatively, as part of their contracts with providers, plans have the ability to require providers to furnish copies of claims submitted to the programs for plan enrollees or to allow a review of their billing records. Plans can include as a contract term the requirement to submit program claims according to the agreed upon fee schedule and provide for termination of the contract for non-compliance. We would also expect plans to report to the Medicare or Medicaid programs any contract-related violations of which they become aware so the programs can take appropriate steps to deal with the improper billing, including recovery of any overpayments made to the provider. We would consider the actions taken by the health plan in deciding whether any action was warranted under the anti-kickback statute.

Comment: Several commenters wrote that the price reduction safe harbor imposes unnecessary and impractical standards regarding advance disclosure of covered fees and services, fee schedules and cost shifting that will impede negotiations and increase costs. These commenters urged the OIG to permit other methods of describing covered items or services, such as incorporation by reference of benefit summaries.

Response: We are uncertain how the requirement that the agreement spell out the agreed-upon fees will result in an increase in costs or will impede negotiations between health plans and providers. This safe harbor merely requires that the agreement specify in

writing what the parties have already agreed upon, i.e., the items and services that will be furnished to plan enrollees and the prices that the provider will charge for them. We have no objections if the parties wish to reference the covered items and services and the schedule of fees for those services in an attachment to the contract. However, those attachments must clearly indicate the specific amounts that will be paid to the provider for each of the covered items and services he or she furnishes to plan enrollees in order to comply with the safe harbor. General summaries of plan benefit coverage and references to percentages of usual charges will not suffice. We reserve the right to closely scrutinize these attachments to ensure that the parties have adequately identified these items or services. We believe it is important for both the providers and the plans to know what the contract covers and the amounts they are entitled to bill the plan, the Medicare and Medicaid programs and the program beneficiaries.

Comment: One commenter objected to the safe harbor requirements on the grounds that managed care contracts with providers rarely establish fees for services covered by others nor do they specify billing procedures for services not billable to the managed care plan.

Response: We believe that the commenter has misconstrued the safe harbor's requirements. The safe harbor does not broaden the scope of managed care plans' coverage to services covered by other plans nor does it require a price reduction agreement between a managed care plan and a provider to establish fees for services provided by others or for services not billable to the plan. The agreement need only identify those services that the provider will be paid for by the plan and only those services that are covered by the plan and provided to plan enrollees.

IV. Additional Information

A. Regulatory Impact Statement

The Office of Management and Budget (OMB) has reviewed this revised final rule in accordance with the provisions of Executive Order 12866. As indicated in the original safe harbor provisions published on July 29, 1991 and the interim final rule for these safe harbors published on November 5, 1992, the safe harbor provisions set forth in this rulemaking are designed to permit individuals and entities to freely engage in business practices and arrangements that encourage competition, innovation and economy. In doing so, these regulations impose no requirements on any party. Health care providers and

others may voluntarily seek to comply with these provisions so that they have the assurance that their business practices are not subject to any enforcement action under the anti-kickback statute. As such, we believe that the economic impact of these regulations is minimal and have no effect on the economy or on Federal or State expenditures.

In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (5 U.S.C. 601-612). We believe that the majority of health care providers and practitioners do not engage in illegal remuneration schemes, and that the aggregate economic impact of this provision should, in effect, be minimal, affecting only those who have chosen to engage in prohibited payment schemes in violation of the statutory intent. As indicated above, this revised final rule serves to clarify various aspects of the safe harbor provisions originally published on November 5, 1992 to enable entities to more easily immunize themselves from potential criminal and administrative sanctions, and to eliminate potential barriers to the provision of coordinated health care under the Medicare and State health care programs. As a result, we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a number of small business entities, and we have, therefore, not prepared a regulatory flexibility analysis.

B. Paperwork Reduction Act

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 OMB for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comments on the following issues:

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

As a result, we are soliciting public comment on the information collection requirements being set forth in sections

1001.952(m)(1) (ii), (iii) and (iv) of these regulations.

Under the safe harbor for price reductions offered to health plans, if a health plan is an HMO, competitive medical plan, health care prepayment plan, prepaid health plan or other health plan that has executed a contract or agreement with HCFA or a State health care program to receive payment for enrollees on a reasonable cost or similar basis, the health plan and the contract health care provider must comply with four standards. One of those standards is that the plan must fully and accurately report the amount it has paid the contract health care provider under the agreement for the covered items and services furnished to enrollees on the applicable cost report or other claim form filed with the Department or the State health care program (§ 1001.952(m)(1)(ii)).

Similarly, if a health plan is not described in section 1001.952(m)(1) (i) and (ii) of the regulations, and the contract health care provider is not paid on an at-risk, capitated basis, both the plan and contract provider must, among the six standards set forth, fully and accurately report any cost report filed with Medicare or a State health care program the fee schedule amounts charged in accordance with the agreement (§ 1001.952(m)(1)(iii)).

In addition, under sections 1001.952(m)(1) (iii) and (iv), both the health plan and the provider, upon request, must report to the Medicare or State health care program the terms of the agreement and amounts paid in accordance with the agreement.

We estimate that the current burden associated with the submitting the data would be minimal, i.e., less than one hour per request. Specifically, we anticipate that any data request will not involve the creation of any new documents or the calculation of new figures by entities. Rather, we would be seeking only copies of those agreements that have already been executed by entities and those amounts paid to individual providers that are already maintained for general business and tax purposes. Since most plans maintain such information on electronic data bases and have these contracts on file, we believe such requests can be produced and provided in less than one hour's time. Further, we believe that only a very small number of plans and providers—less than 3 percent of the nation's health care plans and contract providers—would be potentially impacted by this request. Accordingly, we estimate that the total number of requests will be no more than 10 to 12 per year since they will be made only

where there is a question of whether a specific plan or provider has violated the statute and claims immunity based on these safe harbor regulations. Based on an estimate of less than one dozen requests per year, the estimated total burden on these entities will be under 20 hours.

This information collection and recordkeeping requirement is not effective until it has been approved by OMB. A notice will be published in the Federal Register when approval is obtained. As indicated in the **INFORMATION CONTACT** section at the beginning of this preamble, organizations and individuals wishing to submit comments on this information collection and recordkeeping requirement should direct them to the Office of Inspector General, Office of Management and Policy, Room 5550, Cohen Building, Washington, D.C. 20201, Attention: Joel Schaer, Regulations Officer.

C. Department of Justice Review

In accordance with the provisions of Public Law 100-93, these regulations have been developed in consultation with the Department of Justice.

List of Subjects in 42 CFR Part 1001

Administrative practice and procedure, Fraud, Health facilities, Health professions, Medicare.

TITLE 42—PUBLIC HEALTH

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

42 CFR Part 1001 is amended as set forth below:

PART 1001—PROGRAM INTEGRITY—MEDICARE AND STATE HEALTH CARE PROGRAMS

1. The authority citation for part 1001 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7, 1320a-7b, 1395u(j), 1395u(k), 1395y(e), and 1395hh.

2. Section 1001.952 is amended by republishing the introductory text of both paragraph (k) and (k)(1) and revising paragraphs (k)(1)(iii), (l), and (m) to read as follows:

§ 1001.952 Exceptions.

* * * * *

(k) *Waiver of beneficiary coinsurance and deductible amounts.* As used in section 1128B of the Act, "remuneration" does not include any reduction or waiver of a Medicare or a State health care program beneficiary's obligation to pay coinsurance or deductible amounts as long as all of the

standards are met within either of the following two categories of health care providers:

(1) If the coinsurance or deductible amounts are owed to a hospital for inpatient hospital services for which Medicare pays under the prospective payment system, the hospital must comply with all of the following three standards—

* * * * *

(iii) The hospital's offer to reduce or waive the coinsurance or deductible amounts must not be made as part of a price reduction agreement between a hospital and a third-party payer (including a health plan as defined in paragraph (l)(2) of this section), unless the agreement is part of a contract for the furnishing of items or services to a beneficiary of a Medicare supplemental policy issued under the terms of section 1882(t)(1) of the Act.

* * * * *

(l) *Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans.* (1) As used in section 1128B of the Act, "remuneration" does not include the additional coverage of any item or service offered by a health plan to an enrollee or the reduction of some or all of the enrollee's obligation to pay the health plan or a contract health care provider for cost-sharing amounts (such as coinsurance, deductible, or copayment amounts) or for premium amounts attributable to items or services covered by the health plan, the Medicare program, or a State health care program, as long as the health plan complies with all of the standards within one of the following two categories of health plans:

(i) If the health plan is a risk-based health maintenance organization, competitive medical plan, prepaid health plan, or other health plan under contract with HCFA or a State health care program and operating in accordance with section 1876(g) or 1903(m) of the Act, under a Federal statutory demonstration authority, or under other Federal statutory or regulatory authority, it must offer the same increased coverage or reduced cost-sharing or premium amounts to all Medicare or State health care program enrollees covered by the contract unless otherwise approved by HCFA or by a State health care program.

(ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan or other health plan that has executed a contract or agreement with HCFA or with a State health care program to receive payment

for enrollees on a reasonable cost or similar basis, it must comply with both of the following two standards—

(A) The health plan must offer the same increased coverage or reduced cost-sharing or premium amounts to all Medicare or State health care program enrollees covered by the contract or agreement unless otherwise approved by HCFA or by a State health care program; and

(B) The health plan must not claim the costs of the increased coverage or the reduced cost-sharing or premium amounts as a bad debt for payment purposes under Medicare or a State health care program or otherwise shift the burden of the increased coverage or reduced cost-sharing or premium amounts to the extent that increased payments are claimed from Medicare or a State health care program.

(2) For purposes of paragraph (1) of this section, the terms—

Contract health care provider means an individual or entity under contract with a health plan to furnish items or services to enrollees who are covered by the health plan, Medicare, or a State health care program.

Enrollee means an individual who has entered into a contractual relationship with a health plan (or on whose behalf an employer, or other private or governmental entity has entered into such a relationship) under which the individual is entitled to receive specified health care items and services, or insurance coverage for such items and services, in return for payment of a premium or a fee.

Health plan means an entity that furnishes or arranges under agreement with contract health care providers for the furnishing of items or services to enrollees, or furnishes insurance coverage for the provision of such items and services, in exchange for a premium or a fee, where such entity:

(i) Operates in accordance with a contract, agreement or statutory demonstration authority approved by HCFA or a State health care program;

(ii) Charges a premium and its premium structure is regulated under a State insurance statute or a State enabling statute governing health maintenance organizations or preferred provider organizations;

(iii) Is an employer, if the enrollees of the plan are current or retired employees, or is a union welfare fund, if the enrollees of the plan are union members; or

(iv) Is licensed in the State, is under contract with an employer, union welfare fund, or a company furnishing health insurance coverage as described in conditions (ii) and (iii) of this

definition, and is paid a fee for the administration of the plan which reflects the fair market value of those services.

(m) *Price reductions offered to health plans.* (1) As used in section 1128B of the Act, "remuneration" does not include a reduction in price a contract health care provider offers to a health plan in accordance with the terms of a written agreement between the contract health care provider and the health plan for the sole purpose of furnishing to enrollees items or services that are covered by the health plan, Medicare, or a State health care program, as long as both the health plan and contract health care provider comply with all of the applicable standards within one of the following four categories of health plans:

(i) If the health plan is a risk-based health maintenance organization, competitive medical plan, or prepaid health plan under contract with HCFA or a State agency and operating in accordance with section 1876(g) or 1903(m) of the Act, under a Federal statutory demonstration authority, or under other Federal statutory or regulatory authority, the contract health care provider must not claim payment in any form from the Department or the State agency for items or services furnished in accordance with the agreement except as approved by HCFA or the State health care program, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(ii) If the health plan is a health maintenance organization, competitive medical plan, health care prepayment plan, prepaid health plan, or other health plan that has executed a contract or agreement with HCFA or a State health care program to receive payment for enrollees on a reasonable cost or similar basis, the health plan and contract health care provider must comply with all of the following four standards—

(A) The term of the agreement between the health plan and the contract health care provider must be for not less than one year;

(B) The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, and the methodology for computing the payment to the contract health care provider;

(C) The health plan must fully and accurately report, on the applicable cost report or other claim form filed with the Department or the State health care

program, the amount it has paid the contract health care provider under the agreement for the covered items and services furnished to enrollees; and

(D) The contract health care provider must not claim payment in any form from the Department or the State health care program for items or services furnished in accordance with the agreement except as approved by HCFA or the State health care program, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(iii) If the health plan is not described in paragraphs (m)(1)(i) or (m)(1)(ii) of this section and the contract health care provider is not paid on an at-risk, capitated basis, both the health plan and contract health care provider must comply with all of the following six standards—

(A) The term of the agreement between the health plan and the contract health care provider must be for not less than one year;

(B) The agreement between the health plan and the contract health care provider must specify in advance the covered items and services to be furnished to enrollees, which party is to file claims or requests for payment with Medicare or the State health care program for such items and services, and the schedule of fees the contract health care provider will charge for furnishing such items and services to enrollees;

(C) The fee schedule contained in the agreement between the health plan and the contract health care provider must remain in effect throughout the term of the agreement, unless a fee increase results directly from a payment update authorized by Medicare or the State health care program;

(D) The party submitting claims or requests for payment from Medicare or the State health care program for items and services furnished in accordance with the agreement must not claim or request payment for amounts in excess of the fee schedule;

(E) The contract health care provider and the health plan must fully and accurately report on any cost report filed with Medicare or a State health care program the fee schedule amounts charged in accordance with the agreement and, upon request, will report to the Medicare or a State health care program the terms of the agreement and the amounts paid in accordance with the agreement; and

(F) The party to the agreement, which does not have the responsibility under the agreement for filing claims or requests for payment, must not claim or

request payment in any form from the Department or the State health care program for items or services furnished in accordance with the agreement, or otherwise shift the burden of such an agreement to the extent that increased payments are claimed from Medicare or a State health care program.

(iv) If the health plan is not described in paragraphs (m)(1)(i) or (m)(1)(ii) of this section, and the contract health care provider is paid on an at-risk, capitated basis, both the health plan and contract health care provider must comply with all of the following five standards—

(A) The term of the agreement between the health plan and the contract health provider must be for not less than one year;

(B) The agreement between the health plan and the contract health provider must specify in advance the covered items and services to be furnished to enrollees and the total amount per enrollee (which may be expressed in a per month or other time period basis) the contract health care provider will be paid by the health plan for furnishing such items and services to enrollees and must set forth any copayments, if any, to be paid by enrollees to the contract health care provider for covered services;

(C) The payment amount contained in the agreement between the health care plan and the contract health care provider must remain in effect throughout the term of the agreement;

(D) The contract health care provider and the health plan must fully and accurately report to the Medicare and State health care program upon request, the terms of the agreement and the amounts paid in accordance with the agreement; and

(E) The contract health care provider must not claim or request payment in any form from the Department, a State health care program or an enrollee (other than copayment amounts described in paragraph (m)(2)(iv)(B) of this section) and the health plan must not pay the contract care provider in excess of the amounts described in paragraph (m)(2)(iv)(B) of this section for items and services covered by the agreement.

(2) For purposes of this paragraph, the terms *contract health care provider*, *enrollee*, and *health plan* have the same meaning as in paragraph (l)(2) of this section.

Dated: June 21, 1995.

June Gibbs Brown,
Inspector General.

Approved: September 12, 1995.
Donna E. Shalala,
Secretary, Department of Health and Human Services.

[FR Doc. 96-1073 Filed 1-24-96; 8:45 am]

BILLING CODE 4150-04-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Chapter II

[WO-420-1820-00-24 1A]

RIN 1004-AC47

Table of Public Land Orders; Removal

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule; removal.

SUMMARY: This administrative final rule removes the Appendix to 43 CFR chapter II which constitutes a Table of Public Land Orders (PLOs), 1942-Present.

EFFECTIVE DATE: February 26, 1996.

FOR FURTHER INFORMATION CONTACT: Matthew Reed, 202-452-5069.

SUPPLEMENTARY INFORMATION: The Bureau of Land Management (BLM) is not statutorily required to include this Appendix in the CFR. The material contained in the Appendix is an unindexed, strictly chronological list of PLOs from 1942 until 1995. The Table includes only a PLO number, a signature date, a brief subject heading describing effect, and a Federal Register citation for each PLO. The Table is organized neither geographically nor by subject classification. In sum, the Table is of extremely limited utility as a reference tool for persons attempting to determine the status of any particular tract of the public lands. The public may obtain the relevant information contained in the Appendix more efficiently by contacting the BLM State Office managing the subject lands. The master title plat for each jurisdiction will reveal the impact of any and all PLOs affecting the public lands within the jurisdiction. Additionally, the BLM will maintain the Table electronically on the Bureau's Internet Homepage.

The 1996 edition of title 43 of the CFR will be the last to include the Appendix. This edition may be retained for future reference. Additionally, one may consult the annual Federal Register index to locate Public Land Orders issued within any subsequent given

year. As the Appendix currently comprises nearly 200 pages of printed text in Title 43 of the CFR, removal of the Appendix will produce significant cost and printed space savings for the BLM without depriving the public of its sole or best source of information concerning the PLOs. In light of the foregoing analysis, the BLM has determined for good cause that notice and public procedure on this rule are unnecessary and contrary to the public interest. The principal author of this final rule is Matthew Reed, Regulatory Management Team, BLM.

This rule is an administrative action and not a major rule for the purposes of E.O. 12291. Accordingly, neither an environmental impact analysis nor a regulatory flexibility analysis is required. This rule does not contain information collection requirements that require approval by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*

List of Subjects for 43 CFR Chapter II

Public land orders.

For the reasons stated in the preamble and under the authority of 43 USC 1740, the Appendix to chapter II of subtitle B of title 43 of the Code of Federal Regulations is removed in its entirety.

Appendix to Chapter II of Subtitle B [Removed]

Removed in its entirety.

Dated: December 18, 1995.

Bob Armstrong,

Assistant Secretary of the Interior.

[FR Doc. 96-1183 Filed 1-24-96; 8:45 am]

BILLING CODE 4310-84-P

43 CFR Public Land Order 7179

[CA-940-5700-00; CACA 32220]

Withdrawal of National Forest System Land for a University of California-Berkeley Seismic Observatory; California

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order withdraws 45 acres of National Forest System land from mining for a period of 20 years to protect the seismic integrity of a University of California-Berkeley seismic observatory. The land has been and will remain open to mineral leasing.

EFFECTIVE DATE: January 25, 1996.

FOR FURTHER INFORMATION CONTACT: Duane Marti, BLM California State Office (CA-931), 2800 Cottage Way,