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

Thursday, November 5, 1992 (57 FR 52723)

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

ACTION: Interim final rule with request for comment.

SUMMARY: In accordance with section 14 of the Medicare and Medicaid Patient and Program Protection Act of 1987, this interim final rule establishes two new safe harbors and amends one existing safe harbor to provide protection for certain health care plans, such as health maintenance organizations and preferred provider organizations. The first new provision protects certain incentives to enrollees (including waiver of coinsurance and deductible amounts) paid by health care plans. The second new provision protects certain negotiated price reduction agreements between health care plans and contract health care providers. Finally, an existing safe harbor has been amended to protect certain agreements entered into between hospitals and Medicare SELECT insurers. These safe harbors specifically set forth various standards and guidelines that, if met, will result in the particular arrangement being protected from criminal prosecution or civil sanctions under the anti-kickback provisions of the statute.

DATES: Effective date: This rule is effective on November 5, 1992. Comment period: Although this rule is final, we will consider comments on this regulatory revision delivered to the address provided below by 5 p.m., January 4, 1993. Comments are available for public inspection on November 19, 1992.

ADDRESSES: Address comments to: Office of Inspector General, Department of Health and Human Services, Attention: LRR-28-FC, room 5246, 330 Independence Avenue, SW., Washington, DC 20201. If you prefer, you may deliver your comments to Room 5551, 330 Independence Avenue, SW., Washington, DC. In commenting, please refer to file code LRR-28-FC. Comments are available for public inspection in room 5551, 330 Independence Avenue, SW., Washington, DC on Monday through Friday of each week from 9 a.m. to 5 p.m., (202) 619-3270.

FOR FURTHER INFORMATION CONTACT:

Linda Grabel or D. McCarty Thornton, Office of the General Counsel, (202) 619-0335.

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

For paperwork reduction and information collection requirements write to: Allison Eydt, Office of Management and Budget, New Executive Office Building, room 3001, 725 17th Street, NW., Washington, DC 20503.

SUPPLEMENTARY INFORMATION:

I. Background

Section 14 of Public Law 100-93 requires the promulgation of regulations specifying those payment practices that will not be subject to criminal prosecution under section 1128B(b) of the Social Security Act (the Act), 42 U.S.C. 1320a-7b(b), and that will not provide a basis for exclusion from Medicare or the State health care programs under section 1128(b)(7) of the Act. 42 U.S.C. 1320a-7(b)(7). State health care programs are the Medicaid program, the Maternal and Child Health Services Block Grant program, and the Social Services Block Grant program.

Proposed regulations designed to implement section 14 of Public Law 100-93 were developed by the Office of Inspector General (OIG) and published in the Federal Register on January 23, 1989 (54 FR 3088). The regulations set forth various proposed business and payment practices, or "safe harbors," that would not be treated as criminal offenses under section 1128B(b) of the Act and would not serve as a basis for a program exclusion under section 1128(b)(7) of the Act.

In that proposed rulemaking, we did not specifically delineate a safe harbor provision for a variety of arrangements grouped under the generic headings of "managed care" plans for "preferred provider organizations" (PPOs) because we believed that one or more of the other proposed safe harbors would protect relationships in managed care and PPO networks. However, we did invite public comments on the question of adding additional safe harbors that would provide further protections to health maintenance organizations (HMOs), PPOs and other managed care plans. Although we received a number of responsive comments, we did not publish a specific safe harbor in this area in the final rule published on July 29, 1991 (56 FR 35952). As was true then, we could publish the two new safe harbors related to managed care in final form without an opportunity for further public comment. In addition, as discussed in section III.C. of this preamble, we find that good cause exists to publish the amendment regarding Medicare SELECT without a prior comment period. Therefore, further public comment is not required before publication of this rule. However, we will accept public comments submitted within 60 days of the publication of this interim final rule.

These interim final regulations will be effective upon publication. We find that good cause exists for an immediate effective date due to the nature of these safe harbor regulations. This rule places no affirmative obligation on any individual or entity. Indeed, by expanding safe harbor protection, this rule exempts certain conduct from potential criminal and administrative sanctions. We find that the benefit conferred on the public by this rule's publication provides good cause for it to be effective upon publication.

We wish to emphasize that nothing in this final regulation changes reimbursement rules promulgated by the Health Care Financing Administration (HCFA) or a State health care program. If a provider chooses to engage in one course of conduct in order to comply with these safe harbor provisions, such action may very well have reimbursement implications. However, such reimbursement is governed exclusively by HCFA or State regulations, and not by this rulemaking.

II. Summary of Comments Received

As a result of our request for comments in the proposed rulemaking published on January 23, 1989, we received numerous responses on how best to protect HMOs, PPOs and other managed care plans. The following is a summary of the various issues raised through that public comment process. In the following section, we will discuss our responses to the comments we received.

Two commenters requested safe harbor protection for HMOs that waive the beneficiary's obligation to pay coinsurance and deductible amounts. They believed that this was a common practice among HMOs. In addition, a few commenters pointed out that some PPOs negotiate agreements with contract health care providers for those providers not to change the health plan or enrollee for some or all of the coinsurance and deductible amounts they are owed for furnishing services to enrollees. Under such an agreement, when the contract provider bills the Medicare program directly (and not the health plan) and agrees to waive all coinsurance and deductibles, the commenters typically phrased the agreement as one "to accept Medicare payment as payment in full." One commenter specifically objected to this practice.

Several commenters requested the OIG to protect a variety of arrangements between HMOs, PPOs, competitive medical plans (CMPs) as defined in 42 CFR part 417, managed care plans, and other health plans on the one hand, and medical groups and other health care providers who furnish items and services to the health plans at a reduced price on the other hand. A few of these commenters indicated that benefits can be achieved when a health care provider offers discounts to these organizations.

III. Provisions of the Interim Final Rule

In this section, we discuss our responses to the comments indicated above, and set forth the provisions of this interim final rule.

Many program beneficiaries are now served by a wide variety of managed care plans, such as various models of HMOs, CMPs, and health care prepayment plans (HCPPs) as defined in 42 CFR part 417, and prepaid health plans (PHPs) as defined in 42 CFR part 434, as well as PPOs, and we agree that additional safe harbor protection is warranted. We are promulgating two safe harbor provisions to protect the essential activities of prepaid health plans ("health plans"). The first provision protects the various marketing incentives that health plans offer to attract "enrollees" through increased benefits coverage, reduced cost- sharing amounts (coinsurance, deductibles, or copayments), or reduced premiums. The second provision protects the contractual relationships between health plans and "contract health care providers" for the furnishing of covered items and services at reduced prices. Before discussing the specific features of these two safe harbor provisions, we will discuss our specific use of the terms "health plan," "contract health care provider," and "enrollee," all of which are defined in § 1001.952(1)(2).

Definition of Terms

Health Plan

For an entity to be classified as a "health plan", it must either (1) furnish, or arrange under agreement with contract health care providers for the furnishing of, items or services to enrollees or, (2) as with some PPOs, furnish health insurance coverage for the provision of such items or services. In either case, it must charge a premium (with exceptions noted below) for these covered benefits. Such premiums may be paid by a variety of sources, including HCFA, a State agency, an employer, or the enrollee. In addition, the health plan must either be operating under a contract or agreement with HCFA or a State health care program, or be subject to State regulation of its premium structure.

Where the health plans do not operate in accordance with a contract or agreement with HCFA or State health care program, we require the regulation of the premium structures because of our experience with phony insurance plans created by providers where for a $1 "premium" all Medicare coinsurance and deductibles are covered. The premium structure of these "insurance plans" is not based on a bona fide assessment of the liability risk of providing health benefits to enrollees. Therefore, such health plans are not legitimate forms of health insurance or prepaid health care, and we consider them to be unlawful

routine copayment waiver programs.

Such health plans with regulated premium structures must operate under the oversight to State insurance laws or a State enabling statute governing HMOs or PPOs. Many such health plans may be federally qualified HMOs under 42 U.S.C. 300e or may operate under the Employee Retirement Income Security Act of 1974. Such health plans also may exist in a variety of other forms. They may be established as provider-based plans, or be independent of providers (such as union-sponsored plans or company plans). In addition, they may be Medicare supplemental (Medigap) policies, such as a Medicare SELECT plan issued under the terms of section 1881(t)(1) of the Act.

Contract Health Care Provider

Under these safer harbor provisions, the term "contract health care provider" means an individual or entity under contract with a health plan to furnish to the health plan's enrollees items or services that are covered by the health plan, Medicare, or a State health care program. Although such health care providers may have contractual relationships with health plans to perform a variety of other functions, such as marketing or peer review, the term "contract health care provider" under these two safe harbor provisions is limited to contractual relations for the furnishing of covered items and services.

Enrollee

The third defined term for these two safe harbor provisions is "enrollee," meaning 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.

Set forth below is a discussion of the specific features of these two safe harbor provisions, and the amendments to existing § 1001.952(k) involving the protection of certain waivers of Medicare copayments for inpatient hospital services under Medicare SELECT.

A. Increased Coverage, Reduced Cost-sharing Amounts, or Reduced Premium Amounts Offered by Health Plans

The first of these safe harbor provisions protecting health plans deals with the relationship of health plans to enrollees. Although the anti-kickback statute is generally not implicated when a health plan offers a premium to a Medicare or State health care program beneficiary to provide an insurance package, the statute is implicated when discounts on premiums or other incentives are offered.

Health plans offer a variety of incentives to attract beneficiaries to enroll. Under these incentives a health plan may increase covered benefits, reduce or eliminate the beneficiary's obligation to pay cost-sharing amounts (such as coinsurance, deductibles, and copayments), or reduce or eliminate the beneficiary's obligation to pay the premium amounts attributable to the costs of furnishing the covered benefits. The first new safer harbor covers health plans operating pursuant to a contract or agreement with HCFA or a State health care program and is divided into two parts. The first part of the safe harbor (§ 1001.952(l)(1)(i)) protects HMOs, PHPs, CMPs and other health plan under risk contract, and the second part of the safe harbor (§ 1001.952(l)(1)(i)) protects HMOs, CMPs, PHPs, HCPPs and other health plans paid on a reasonable cost or similar basis. Before discussing the standards contained in these two parts of the safe harbors, we will briefly discuss the types of incentives these health plans offer enrollees and why we believe safe harbor protection is appropriate.

In some cases, incentives to enrollees are either mandated under the Social Security Act or are provided with the approval of HCFA. For example, under section 1876 of the Act and implementing regulations, beneficiaries who enroll in HMOs and CMPs are financially responsible for paying the Medicare coinsurance and deductible amounts. Further, section 1876 permits HMOs and CMPs to charge beneficiaries monthly premiums to cover such coinsurance and deductible amounts. HCFA must approve the premiums that are charged, and it regularly permits health plans to waive these premiums. Further, under certain conditions, section 1876 mandates HMOs and CMPs to offer additional benefits or reduce beneficiary cost-sharing amounts. The decision regarding the mix between additional benefits and reduced cost-sharing amounts, however, is left up to the discretion of the health plan.

The routine waiver of a beneficiary's obligation to pay coinsurance and deductible amounts by a prepaid health plan is clearly distinguishable from such routine waiver by other health care providers, such as hospital outpatient departments, physicians, or durable medical equipment suppliers. Two principal characteristics distinguish a health plan's routine waiver of cost-sharing amounts from that of other health care providers. First, a health plan's routine waiver program is inextricably intertwined with the offering of a comprehensive package of covered benefits, and is not offered for the purchase of an individual item or service. Quite often, in the case of prepaid plans, the routine waiver of cost-sharing amounts is made in the form of a waiver of the beneficiary's premium and may also be combined with the offering of increased covered benefits. Thus, the routine waiver of cost-sharing amounts is generally not an incentive to use a particular item or service at the time it is furnished.

Second, although cost-sharing requirements can serve to control utilization, HMOs and other health plans under contract with HCFA or a State health care program have built-in incentives to control unnecessary utilization, or have their utilization and costs monitored by HCFA or the State health care program. Thus, the issue of potential overutilization (with increased costs to the Medicare and Medicaid programs) is adequately dealt with without report to imposing the obligation on beneficiaries to pay coinsurance and deductible amounts.

As discussed above, both parts of this safe harbor protect health plans that are acting in accordance with a contract or agreement with HCFA or a State health care program. As stated above, the first part of this safe harbor protects incentives offered by risk-based contract health plans, such as HMOs, CMPs and PHPs, 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 only standard for such health plans is that the health plan may 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. This standard will minimize the possibility for the health plan to improperly favor certain healthy beneficiaries or to use incentives to improperly encourage utilization at the time the item or service is furnished.

The second part of the safe harbor protects incentives offered to enrollees by HMOs, CMPs, PHPs and 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, two standards must be met. One, the same incentives must be offered to all enrollees for all covered services. And two, the health plan may not claim the cost of these incentives as bad debts or otherwise shift the burden of these incentives onto Medicare, Medicaid, other payors, or individuals. We impose this second standard because the incentives a health plan offers to its enrollees should make economic sense for the health plan, and should not be motivated by a desire to shift costs. In addition, it is noted that claiming such costs as Medicare bad debts is not authorized under 42 CFR 413.80 and 417.536 of the Medicare regulations. And where such a claim is presented unlawfully, an entity may be subject to civil or criminal prosecution.

This new safe harbor does not protect incentives to enrollees offered by health plans that do not have a

contractual relationship with HCFA or a State health care program. (Note: As indicated above, we are amending existing § 1001.952(k) to protect certain waivers of Medicare copayments for inpatient hospital services under Medicare SELECT. See section III.C. of this preamble below.) An example of some of the incentives we are not protecting is an agreement between a PPO and a contract health care provider whereby that provider agrees not to charge the health plan or enrollee all or part of the coinsurance and deductible amounts. When the contract provider bills the program directly (and not the health plan) and agrees to waive all coinsurance and deductibles, the agreement typically is characterized as an agreement to "accept Medicare payment as payment in full." Although such waiver programs may be offered in conjunction with a package of health care benefits and thus have some features similar to the other waiver programs we are protecting in this safe harbor provision, we are not convinced that the Medicare and Medicaid programs are properly protected against overutilization. As discussed above, when a health plan under contract with HCFA or a State health care program waives cost-sharing amounts, utilization and costs are controlled or monitored. This is not necessarily the case with HMOs and PPOs or their providers that bill the Medicare and Medicaid programs on a fee-for-service basis.

For this reason, we are soliciting comments on whether safe harbor protection should be afforded health plans, which do not have a contract or agreement with HCFA or a State health care program, to waive cost-sharing amounts as part of their agreements with contract providers.

B. Price Reductions Offered to Health Plans

This second safe harbor provision for health plans protects the price reductions offered to them by contract health care providers pursuant to an agreement to furnish or arrange for the furnishing of covered items and services. Typically, health care providers will contract with health plans and agree to furnish items and services to enrollees of the health plan at a discount from the provider's usual fee in return for obtaining a large volume of patients.

As with the safe harbor provision discussed above protecting incentives to enrollees, this safe harbor provision is divided into two separate parts for risk-based and cost-reimbursed health plans that operate in accordance with a contract or agreement with HCFA or a State health care program. In addition, this price reduction safe harbor provision contains a third part protecting other health plans that do not have contracts or agreements with HCFA or State health care programs where additional standards are met.

Before discussing the standards to be met in each of these three price reduction safe harbors, we will discuss three definitional prerequisites in § 1001.952(m)(1). The first prerequisite is that the protected remuneration is the contract health care provider's reduction of its usual charges for the services. This safe harbor does not cover reductions which are applicable only to a specific part or portion of the health care provider's charge, such as coinsurance and deductibles, but only applies to reductions in the total amount charged by the health care provider as its usual fee. Furthermore, we are only protecting the remuneration which represents the price reduction offered by the contract health care provider to make clear that any other forms of remuneration offered or paid by a contract health care provider to a health plan are not protected under this safe harbor provision. Indeed, we will closely review any forms of other such remuneration to ensure that improper payments are not employed to induce the health plan to issue a contract or otherwise steer patients to the person paying the remuneration.

The second prerequisite is that the terms of the agreement between the parties must be in writing. This prerequisite is intended to assist the Department in understanding the intent of the parties. Obviously, if need be, we will look behind the contract to determine if the real intent of the parties is not fully disclosed in the written agreement.

The third prerequisite is that the agreement must be for the sole purpose of having the contract health care provider furnish to enrollees items or services that are covered by the health plan, Medicare, or Medicaid. In other words, this provision does not protect contracts between health plans and contract health care providers for these providers to furnish services other than covered benefits. For example, many contract health care providers furnish peer review, marketing services, or pre-enrollment screening. We note that health plans with HCFA contracts under section 1876 of the Act are not permitted to engage in such pre-enrollment screening as a means of denying or discouraging relatively sick beneficiaries from enrolling (sections 1876(c)(3) and (i)(6) of the Act). For the remuneration attributable to the furnishing of other than covered services to be protected, it must comply with the personal service/management contracts safe harbor (§ 1001.952(d)) as set forth in the safe harbor regulations published in the Federal Register on July 29, 1991 (56 FR 35952). And as with all safe harbor provisions, where two parties engage in a multi-faceted payment arrangement where protection is sought from more than one safe harbor, separate justifications must be clearly set forth for each provision for which protection is sought.

We are imposing this third prerequisite because of our experience with some HMOs that have abused their contractual relationships with medical groups where individuals in the groups have engaged in abusive or illegal activities on behalf of the HMO, for example, by conducting pre-enrollment screening. In at least one case such activities have resulted in a criminal conviction. We intend to use our authorities aggressively to monitor closely and penalize where appropriate any abusive relationships between health plans and contract health care providers to assure the medically necessary services of a high quality are available and accessible to all enrollees.

We now discuss the standards in each of the three parts of the price reduction safe harbor. The first part of this safe harbor (§ 1001.952(m)(1)(i)) protects risk-based HMOs, PHPs and CMPs 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. Risk-based contract health plans must meet the three fundamental prerequisites discussed above. Additionally, except as specifically authorized by HCFA or the State health care program, contract health care providers may not separately bill Medicare, Medicaid or another State health care program for items or services furnished under the agreement with the health plan. Nor may the contract health care provider otherwise shift the burden of the agreement onto Medicare, Medicaid, other payors, or individuals.

The second part of the price reduction safe harbor (§ 1001.952(m)(1)(ii)) protects health 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. Price reduction agreements with contract health care providers will be protected as long as four standards are met. One, the term of the agreement may not be for less than one year. Two, the agreement must specify 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. Three, the health plan must fully and accurately report to HCFA or the State health care program the amount it has paid the contract health care provider pursuant to the agreement. And four, the contract health care provider may not claim payment in any form unless specifically authorized by HCFA or the State health care program, or otherwise shift the burden of such an agreement onto Medicare, Medicaid, other payors, or individuals for the costs of furnishing the items and services. Any claim for reimbursement made directly to Medicare, Medicaid or other State health care program for items or services for which payment was made by the health plan would constitute an unlawful false claim.

The third part of the price reduction safe harbor (§ 1001.952(m)(1)(iii)) protects price reductions offered by contract health care providers to all other health plans where six standards are met. One, the term of

the price reduction agreement may not be for less than one year. Two, the agreement must specify in advance the covered items and services, which party is to file claims or requests for payment with Medicare, Medicaid and the other State health care programs, and the schedule of fees that contract provider will be paid. In other words, to meet this second standard, although it does not matter whether the health plan or the contract health care provider bills Medicare, Medicaid or another State health care program, the parties must agree to a set fee schedule. Three, unless a fee update is specifically authorized by Medicare or a State health care program, the fee schedule must remain in effect throughout the term of the agreement. Four, the party submitting claims for items or services furnished under the agreement may not claim or request payment for amounts in excess of the fee schedule. This fourth standard should not be misconstrued as a "lowest charge" provision in that it does not restrict the contract provider from claiming or requesting payment in amounts in excess of this fee schedule when it negotiates a different fee schedule with another health plan or when it is furnishing items or services directly to enrollees on a fee-for-service basis. Five, full and accurate reporting of costs must be made by the health plan or the contract health care provider. And six, to help assure that false claims are not filed, we prohibit the party which 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 payors, or individuals.

C. Waiver of Part A Deductible and Coinsurance Amounts Pursuant to an Agreement Between a Hospital and a Medicare SELECT Insurer

The Department has designated 15 States in which State insurance regulators may approve the issuance of Medicare supplemental (Medigap) insurance policies that restrict Medigap benefits to services provided through a network of providers if the standards in section 1882(t)(1) of the Act are met. (See Pub. L. 101-508, section 4358.) Under this authority, known as Medicare SELECT, approved insurers may contract with health care provider entities to furnish items or services to policyholders. Subject to the approval of the State insurance commissioner, the Medicare SELECT insurer may pay less than full Medigap benefits for services obtained outside this provider network.

In return for becoming a preferred provider under the Medicare SELECT plan, the provider would presumably be willing to accept less payment for its treatment of Medicare SELECT beneficiaries. The Medicare SELECT insurer, in turn, should be able to provide health care to its beneficiaries at a lower price. The beneficiary will, in theory, relinquish some freedom of choice in selecting health care providers in return for lower Medigap insurance premiums.

The arrangements between Medicare SELECT insurers and provider entities might implicate the anti-kickback statute. The provider may offer or pay remuneration (in the form of reducing its charges) to induce the referral of Medicare patients by the insurer to the provider. Likewise, the insurer may solicit or receive remuneration from the provider in return for the insurer's referral of Medicare beneficiaries. We believe that some potential arrangements between Medicare SELECT insurers and providers should be granted safe harbor protection while other potential arrangements could be abusive and do not deserve protection.

We have identified two types of arrangements between Medicare SELECT insurers and providers that may implicate the statute but deserve safe harbor protection. First, payments between Medicare SELECT insurers and health care providers may be protected under the newly established safe harbor for price reductions offered to health plans (§ 1001.952(m)). Second, waivers or reduction of inpatient hospital coinsurance and deductible by a hospital pursuant to an agreement with a Medicare SELECT insurer will be protected under the amendment to the safe harbor set forth below.

On July 29, 1991, the Department published final regulations which, among other provisions, included a

safe harbor for the reduction or waiver of coinsurance or deductible amounts for inpatient hospital services paid for under the prospective payment system (§ 1001.952(k)(1)). To receive safe harbor protection, three standards must be met: (1) The hospital may not claim the waived amount as bad debt or otherwise shift the cost of the waiver; (2) the hospital may not discriminate in offering reductions or waivers based on the patient's reason for admission; and (3) the reduction or waiver may not result from an agreement between the hospital and a third-party payor. The Department concluded that waivers of coinsurance and deductibles for inpatient hospital services that comply with these standards will not increase costs to the Medicare program, shift costs to other payors, or increase patient demand for inpatient hospital services.

We are amending this existing safe harbor to accommodate the waiver or reduction of inpatient hospital coinsurance or deductible amounts made pursuant to a contract between the hospital and a Medicare SELECT insurer. Specifically, the third standard in this safe harbor will now exempt agreements that are part of a contract between a hospital and a Medicare SELECT insurer for the furnishing of items or services to Medicare SELECT beneficiaries. To qualify for protection under this safe harbor, the insurer must have issued a Medicare SELECT insurance policy under the terms of section 1882(t)(1) of the Act. In other words, the Medicare SELECT policy must meet all of the requirements of section 1882(t)(1), and must be approved by a State insurance commissioner for use in one of the 15 States designated by the Secretary. Furthermore, to be protected by this safe harbor, the waiver of coinsurance or deductible amounts provided for under the agreement must be limited to beneficiaries covered by the insurer's Medicare SELECT policy.

The other requirements of the safe harbor still apply to such waivers or reductions. We believe that this amendment will allow Medicare SELECT insurers to enter into advantageous contracts with hospitals, while continuing to ensure that hospital waivers do not increase costs to Medicare or other payors, or promote over utilization. The evaluation of Medicare SELECT to be completed in 1994 (see Pub. L. 101-508, section 4358(d)) will enable us to determine whether this amendment has had any of these undesirable effects.

In contrast, we will provide safe harbor protection for other types of arrangements between Medicare SELECT insurers and providers that may implicate the anti-kickback statute. For example, we continue to consider routine waivers of coinsurance and deductibles under Part B of Medicare to be an area of potential abuse. Any provider that routinely waives coinsurance and deductible under Part B is subject to criminal liability and civil and administrative sanctions under Federal false claims and false statements statutes as well as the anti-kickback statute. (See OIG's Special Fraud Alert on Routine Waiver of Copayments or Deductibles Under Medicare Part B.) Section 1882(t) of the Act does not provide any safeguards against the abuse of Part B waivers. Therefore, we will not grant any safe harbor protection for the waiver or reduction of Part B coinsurance or deductibles by Medicare SELECT providers.

We find good cause to publish this amendment in interim final form with a comment period rather than as a proposed rule. We find that the delay that would result from soliciting public comment prior to publications would be impracticable, unnecessary and contrary to the public interest. Medicare SELECT only applies to Medicare supplemental (Medigap) insurers who meet specific statutory criteria in one of 15 States designated by the Secretary during the three year period commencing on January 1, 1992. Because the Medicare SELECT program has already started and is only authorized to continue to the end of 1994, the amendment must be published promptly in final form in order to have its intended effect, that is, to protect certain transactions involving Medicare SELECT providers. Furthermore, the amendment is quite limited in scope since it merely broadens one standard in an existing safe harbor to accommodate certain actions taken in accordance with agreements between hospitals and Medicare SELECT insurers. Finally, the amendment by expanding a safe harbor, places no affirmative obligations on any individuals or entities. Rather, the amendment expands a safe harbor to enable some entities to

more easily immunize themselves from potential criminal and administrative sanctions.

IV. Additional Information

A. Regulatory Impact Statement

Executive Order 12291 requires us to prepare and publish a final regulatory impact analysis for any regulation that meets one of the Executive Order criteria for a "major rule," that is, that which would be likely to result in (1) an annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individuals, industries, Federal, State, or local government agencies or geographic regions; or, (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In addition, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (5 U.S.C. 601-612), unless the Secretary certifies that a final regulation would not have a significant economic impact on a substantial number of small entities.

In the proposed rule published on January 23, 1989, we indicated that this provision was designed to specify business and payment practices that would not be considered a kickback for purposes of criminal or civil remedies, and served to clarify departmental policy as to the legality of various commercial arrangements. We stated that the great 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 interim final rulemaking serves to further expand the safe harbor provisions 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.

Consistent with the intent of the statute, this regulation has been designed to permit individuals and entities to freely engage in business practices and arrangements that encourage competition, innovation and economy. Compliance with these provisions may require that certain individuals and entities change their business practices or arrangements. It is impossible to predict how many individuals and entities will be affected by this regulation. We believe, however, that the number will be insignificant.

For this reason, we have determined that a regulatory impact analysis is not required. Further, 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. Information Collection Requirements

Sections 1001.952(m)(1)(ii) and 1001.952(m)(1)(iii) of this rule contain information collection requirements which are subject to Office of Management and Budget review under the Paperwork Reduction Act of 1980. These sections are currently approved under OMB control number 0938-0165 (HCFA-276). Comments on these requirements may be forwarded to the individual whose name appears in the address section of this preamble.

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.

D. Response to Comments

Because of the large number of comments we normally receive on regulations, we cannot acknowledge or respond to them individually. However, we will consider all comments received timely and the appropriateness of revising this interim final rule.

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 revising paragraph (k)(1)(iii) and republishing the introductory text of the section, paragraph (k) introductory text and paragraph (k)(1) introductory text, and adding new paragraphs (l) and (m) to read as follows:

§ 1001.952 Exceptions.

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

* * * * *

(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) This 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 payor, 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 the 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 contact 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 enrollees 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 enrollees 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 onto Medicare, a State health care program, other payors, or individuals.

(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.

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, where such entity either operates in accordance with a contract, agreement or statutory demonstration authority approved by HCFA or a State health care program, or has its premium structure regulated under a State insurance statute or a State enabling statute governing health maintenance organizations or preferred provider organizations.

(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 three categories of health plans:

(i) If the health plan is a 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 onto Medicare, a State health care program, other payors, or individuals.

(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 onto Medicare, a State health care program, other payors, or individuals.

(iii) If the health plan is not described in paragraphs (m)(1)(i) or (m)(1)(ii) of this section, 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

(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 of the State health care program for items or services furnished in accordance with the agreement, or otherwise shift the burden of such an agreement onto Medicare, a state health care program, other payors, or individuals.

(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: August 12, 1992.

Bryan B. Mitchell,

Principal Deputy Inspector General.

Approved: October 6, 1992.

Louis W. Sullivan,

Secretary.

(FR Doc. 92-26802 Filed 11-4-92; 8:45 am)

BILLING CODE 4150-04-M