MEMORANDUM

TO: HEALTH CARE CLIENTS

DATE: September 6, 2002

RE: OIG Issues Special Advisory Bulletin on “Offering Gifts and Other Inducements to Beneficiaries”

I. INTRODUCTION

On August 30, 2002, the Office of Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”) issued a Special Advisory Bulletin (the “Bulletin”) providing guidance on the OIG’s interpretation of a statute which prohibits anyone from furnishing remuneration which they know (or should know) is likely to influence a Medicare or Medicaid beneficiary’s selection of a particular provider, practitioner, or supplier.¹

The Bulletin appears to be part of the OIG’s recently announced efforts to use the civil monetary penalty (“CMP”) statutes in its arsenal to combat fraud and abuse in addition to the anti-kickback statute,² the Stark Law,³ and the False Claims Act.⁴

In the Bulletin, the OIG confirms its position that providers may not offer any gifts or “free” services to beneficiaries that exceed $10 per item (with a $50 annual limit) unless the incentives fit within a statutory or regulatory exception, or are the subject of a favorable advisory opinion.

¹ The text of the Bulletin is available on the OIG web site at http://oig.hhs.gov/fraud/fraudalerts.html#2, or you can obtain it from our office. It also was published in the Federal Register on August 30, 2002 (67 Fed. Reg. 55,855).

² 42 U.S.C. § 1320a-7b(b).


opinion. Nevertheless, the OIG officially acknowledges for the first time that incentives offered by drug manufacturers in connection with product selection generally are exempt from the statutory prohibition unless the manufacturers own or operate, directly or indirectly, other entities that file Medicare or Medicaid claims.

In addition, the OIG notes that it may solicit public comment on the possibility of creating regulatory “safe harbors” for certain complimentary local transportation and for free goods and services provided in connection with government-sponsored clinical trials. The agency also indicates that it is reviewing its pending proposal to allow certain dialysis providers to purchase Medicare supplemental insurance for financially-needy beneficiaries in light of the principles established in the Bulletin.

We have summarized some of the more significant aspects of the Bulletin below.

II. BACKGROUND

Section 1128A(a)(5) of the Social Security Act (“the Act”) imposes CMPs of up to $10,000 on a provider, practitioner, or supplier of Medicare or Medicaid payable items or services for offering or transferring to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary’s selection of a particular Medicare or Medicaid provider. 42 U.S.C. § 1320a-7a(5). Under this law, “remuneration” includes waivers of copayments and deductible amounts (or any part thereof) and transfers of items or services for free or for other than fair market value.

The definition of “remuneration” contains the following five specific exceptions:

(1) Non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts (but not paying the premiums for a beneficiary’s Medicare Part B or supplemental insurance);

(2) Properly disclosed differentials in a health insurance plan’s copayments or deductibles which meet certain conditions (e.g., lower plan copayments for using preferred providers, mail order pharmacies, or generic drugs, but not waivers of Medicare or Medicaid copayments);

(3) Incentives to promote the delivery of preventive care as defined in regulations (i.e., items and services that (i) are covered by Medicare or Medicaid and (ii) are either pre-natal or post-natal well-baby services or are services described in the Guide to Clinical Preventive Services published by the U.S. Preventive Services Task Force. Such incentives may not be in the form of cash or cash equivalents and may not be disproportionate to the value of the preventive care provided);
(4) Any practice permitted under an anti-kickback statute safe harbor at 42 C.F.R. § 1001.952 (e.g., warranties; discounts; employee compensation; waivers of certain beneficiary coinsurance and deductible amounts; and increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans); and

(5) Waivers of copayment amounts in excess of the minimum copayment amounts under the Medicare hospital outpatient fee schedule.

The legislative history of the provision also expressed the intent of Congress that inexpensive gifts of nominal value be permitted. The OIG has interpreted “inexpensive” to mean a retail value of no more than $10 per item or $50 in the aggregate, per patient on an annual basis. These amounts may be adjusted subsequently for inflation.

III. OIG ANALYSIS

The OIG raises the possibility that incentives provided to beneficiaries can raise both quality and cost concerns as well as potential anti-competitive issues. According to the OIG, providers may offset costs attributable to giveaways by providing unnecessary services or by substituting cheaper or lower-quality services. Such incentives also favor large providers with the financial resources to fund such activities over smaller providers and businesses.

A. Elements of the Prohibition

The Bulletin contains definitions and interpretations of key concepts within the prohibition on beneficiary remuneration. Section 1128A(a)(5) of the Act bars the offering of remuneration to Medicare or Medicaid beneficiaries where the person offering the remuneration “knows or should know” that the “remuneration” is likely to influence the beneficiary to order or receive items or services from a particular provider. The OIG notes that the term “remuneration” has been broadly interpreted to include “anything of value” in the context of various health care fraud and abuse statutes, and affirms this broad definition in connection with the beneficiary inducement prohibition. The “should know” standard is met if a provider acts with deliberate ignorance or reckless disregard; no proof of specific intent is required.

The “inducement” element encompasses any offer of valuable goods and services as part of a marketing or promotional activity, regardless of whether or not the marketing or promotional activity is active or passive. The OIG notes that even if a provider does not directly advertise or promote the benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of disseminating information, such as “word of mouth” promotion.
by practitioners or patient support groups. The OIG further considers providing free goods or services to existing customers who have an ongoing relationship with a provider as conduct that is likely to influence those customers’ future purchases. Thus, the practice, common in other industries, of rewarding customers for their loyalty can violate the law in the health care context under certain circumstances.

With respect to the beneficiaries covered by the provision, the OIG states that inducements may not be offered to Medicare and Medicaid beneficiaries, regardless of the beneficiary’s medical condition. The OIG notes that some specialty providers offer valuable gifts to beneficiaries with specific chronic conditions. However, the OIG states that there is no meaningful basis under the statute for creating an exemption based on a beneficiary’s medical condition or the condition’s severity, particularly since providers have more incentive to offer gifts to chronically ill beneficiaries because they are likely to generate substantially more business. Moreover, the prohibition applies regardless of whether the incentive provides therapeutic as well as financial benefits to the beneficiary. Similarly, the OIG finds no statutory basis for an exemption based on the financial need of a category of patients, since Congress expressly included the Medicaid program within the prohibition and created only a narrow exception for non-routine waivers of copayments and deductibles based on individual financial need.

Finally, the OIG discusses the application of the provision to providers, practitioners, and suppliers. The OIG has interpreted this element to exclude health plans that offer incentives to Medicare and Medicaid beneficiaries to enroll in a plan, although incentives provided to influence an already enrolled beneficiary to select a particular provider, practitioner, or supplier within the plan are subject to the statutory proscription (other than copayment differentials that are part of a health plan design). In an important clarification, the OIG states that it does not consider drug manufacturers to be “providers, practitioners, or suppliers” for the limited purposes of section 1128A(a)(5), unless they also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs.

B. OIG Principles for Applying the Inducement Prohibition

In addition, the OIG states that it will apply the inducement prohibition according to the following four principles:

? Medicare or Medicaid providers may offer beneficiaries inexpensive gifts (other than cash or cash equivalents) or services without violating the statute (i.e., items
with a retail value of no more than $10 individually and no more than $50 in the aggregate annually per patient).

Providers may offer beneficiaries more expensive items or services that fit within one of the five statutory exceptions: (1) waivers of cost-sharing amounts based on financial need; (2) properly disclosed copayment differentials in health plans; (3) incentives to promote the delivery of certain preventive care services; (4) any practice permitted under the federal anti-kickback statute pursuant to 42 C.F.R. § 1001.952; or (5) waivers of hospital outpatient copayments in excess of the minimum copayment amounts.

The OIG is considering two additional regulatory exceptions to the prohibition (see below).

The OIG will continue to accept requests for advisory opinions related to the prohibition on inducements to beneficiaries, although favorable opinions will likely be limited to situations involving practices that are very close to an existing statutory or regulatory exception.

C. Providing Benefits Through Independent Entities

Under the OIG’s interpretation of the statute, an important exception permits valuable services or other remuneration to be furnished to financially needy beneficiaries by an independent entity, even if the benefits are funded by providers, as long as (i) the independent entity makes an independent determination of need; and (ii) the beneficiary’s receipt of the remuneration does not depend, directly or indirectly, on the beneficiary’s use of any particular provider. In this regard, the OIG cites previous advisory opinions including one approving the American Kidney Fund’s program to assist needy end stage renal disease patients with funds donated by dialysis providers, which included paying for the patients’ supplemental medical insurance premiums.

IV. ADDITIONAL REGULATORY CONSIDERATIONS

While the OIG is authorized to create additional exceptions to the remuneration prohibition under section 1128A(a)(5), the OIG indicates that additional exceptions will likely be few in number and narrow in scope because: (i) any exception will create the activity that the statute prohibits -- namely, competing for business by providing remuneration to Medicare and Medicaid beneficiaries, triggering ever more valuable offers; and (ii) there is no principled basis under the statute for distinguishing between the kinds of goods or services offered or the types of beneficiaries to whom the goods or services are offered.
Nevertheless, the OIG is considering soliciting public comment on the possibility of providing “safe harbor” exceptions under section 1128A(a)(5) for two kinds of arrangements:

**Complimentary local transportation** – This new exception would protect complimentary local transportation of greater than nominal value offered to beneficiaries residing in the provider’s primary catchment area. The exception would not cover luxury or specialized transportation, including limousines or ambulances (but would permit vans specially outfitted to transport wheelchairs). The proposed exception may include transportation to the office or facility of a provider other than the donor. However, the OIG emphasizes that even if such arrangements ultimately are excepted from the beneficiary inducement prohibition, they may implicate the anti-kickback statute by conferring a benefit on a provider that is a potential referral source for the party providing the transportation.

**Government-sponsored clinical trials** – The OIG may propose an exception for free goods and services (possibly including waivers of copayments) in connection with certain clinical trials. However, this proposed exception apparently would be limited to only those clinical trials that are principally sponsored by a component of HHS.

The OIG also notes that its pending proposal to permit certain dialysis providers to purchase Medicare supplemental insurance for financially needy persons, originally proposed several years ago, is currently under review in light of the principles established in the Bulletin. Finally, while the OIG indicates that it does not currently expect to propose additional regulatory exceptions related to unadvertised waivers of copayments and deductibles, the agency recognizes that such waivers occur in a variety of circumstances, and do not necessarily present a significant risk of fraud and abuse. Providers are encouraged to bring such situations to the OIG’s attention through the advisory opinion process.

V. **CONCLUSION**

The Bulletin demonstrates the OIG’s determination to use the range of legal tools at its disposal for fraud and abuse enforcement. Thus, providers may well see more government enforcement actions under the OIG’s CMP powers in addition to use of the anti-kickback statute, the Stark Law, and the False Claims Act. Moreover, the Bulletin indicates the government’s renewed interest in incentives offered by providers, practitioners, and suppliers to attract and retain Medicare and Medicaid beneficiaries as customers.

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Any individual or organization currently offering gifts or other incentives to Medicare or Medicaid beneficiaries should carefully review them in light of the guidelines in the Bulletin to evaluate whether or not existing practices may present risks. This review should occur as quickly as possible since the OIG has stated that it will consider whether providers terminate prohibited programs expeditiously in exercising its enforcement discretion. Appropriate policies should also be developed as part of an entity’s compliance program to ensure that any incentives offered in the future are consistent with the guidelines in the Bulletin.

It is important recognize that the various exceptions discussed in the Bulletin do authorize a limited range of incentives. Nevertheless, the OIG has signaled that any such benefits furnished to Medicare or Medicaid beneficiaries should be carefully tailored. Further, where there is any uncertainty, the OIG has strongly encouraged providers to submit requests for advisory opinions. Finally, since beneficiary inducements may potentially implicate other fraud and abuse statutes under certain circumstances, providers and other affected individuals and organizations should ensure that their operations comply with all the applicable standards set forth in federal and state law.

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Please do not hesitate to contact Linda Baumann (202/414-9488), Robert Wanerman (202/414-9242), Carol Loepere (202/414-9216), Thomas Greeson (703/641-4242), or any member of the Reed Smith health care group with whom you work if you would like additional information or if you have any questions.

The contents of this Memorandum are for informational purposes only, and do not constitute legal advice.