

DATES: Submit written comments on the collection of information by September 30, 2002.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1471.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed

collection of information to OMB for review and clearance.

Focus Groups as Used by the Food and Drug Administration—New Collection

FDA will collect and use information gathered through the focus group vehicle. This information will be used to develop programmatic proposals, and as such, compliments other important research findings to develop these proposals. Focus groups do provide an important role in gathering information because they allow for a more in-depth understanding of consumers' attitudes, beliefs, motivations, and feelings than do quantitative studies.

Also, information from these focus groups will be used to develop policy and redirect resources, when necessary, to our constituents. If this information is

not collected, a vital link in information gathering by FDA to develop policy and programmatic proposals will be missed causing further delays in policy and program development.

In the **Federal Register** of May 24, 2002 (67 FR 36613), the agency requested comments on the proposed collection of information. FDA received four comments, but they did not pertain to the information collection though one heartily supported the use of focus groups as an instrument to help FDA better understand how well respondents comprehend health issues.

FDA estimates the burden for completing the forms for this collection of information as follows:

The total annual estimated burden imposed by this collection of information is 2,884 hours annually.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Center	Subject	No. of Focus Groups per Study	No. of Focus Group Sessions Conducted Annually	Number of Participants per Group	Hours of Duration for Each Group (includes screening)	Total Hours
Center for Biologics Evaluation and Research.	May use focus groups when appropriate.	1	5	9	1.58	71
Center for Drug Evaluation and Research.	Varies (e.g., direct-to-consumer Rx drug promotion, physician labeling of Rx drugs, medication guides, over-the-counter drug labeling, risk communication).	10	100	9	1.58	1,422
Center for Devices and Radiological Health.	Varies (e.g., FDA Seal of Approval, patient labeling, tampons, on-line sales of medical products, latex gloves).	5	25	9	2.08	468
Center for Food Safety and Applied Nutrition.	Varies (e.g., food safety, nutrition, dietary supplements, and consumer education).	8	32	9	1.58	455
Center for Veterinary Medicine.	Varies (e.g., food safety, labeling, cosmetic safety and labeling).	5	25	9	2.08	468
Total		29	187		1.99	3,352

¹There are no capital costs or operating and maintenance costs associated with this collection.

Annually, FDA projects about 29 focus group studies using 187 focus groups lasting an average of 1.99 hours each. We have allowed burden for unplanned focus groups to be completed so as not to restrict the agency's ability to gather information on public sentiment for its proposals in its regulatory as well as other programs.

Dated: August 26, 2002.
Margaret M. Dotzel,
Associate Commissioner for Policy.
 [FR Doc. 02-22284 Filed 8-29-02; 8:45 am]
BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries

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

ACTION: Notice.

SUMMARY: The OIG periodically develops and issues guidance, including Special Fraud Alerts and Special Advisory Bulletins, to alert and inform the industry about potential problems or areas of special interest. This **Federal Register** notice sets forth the recently issued OIG Special Advisory Bulletin addressing the offering of gifts and other inducements to Medicare and Medicaid beneficiaries.

FOR FURTHER INFORMATION CONTACT: Vicki Robinson or Joel Schaer, Office of Counsel to the Inspector General, (202) 619-0335.

SUPPLEMENTARY INFORMATION:**I. Background**

We are issuing this Special Advisory Bulletin to help the industry better understand the prohibition on furnishing inducements to Medicare and Medicaid beneficiaries at section 1128A(a)(5) of the Social Security Act. Specifically, the Special Advisory Bulletin addresses the offering of gifts and other inducements to beneficiaries to influence their choice of a Medicare or Medicaid provider, practitioner, or supplier.

II. Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries (August 2002)*Introduction*

Under section 1128A(a)(5) of the Social Security Act (the Act), enacted as part of Health Insurance Portability and Accountability Act of 1996 (HIPAA), a person who offers or transfers 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 provider, practitioner, or supplier of Medicare or Medicaid payable items or services may be liable for civil money penalties (CMPs) of up to \$10,000 for each wrongful act. For purposes of section 1128A(a)(5) of the Act, the statute defines "remuneration" to include, without limitation, 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. (See section 1128A(i)(6) of the Act.) The statute and implementing regulations contain a limited number of exceptions. (See section 1128A(i)(6) of the Act; 42 CFR 1003.101.)

Offering valuable gifts to beneficiaries to influence their choice of a Medicare or Medicaid provider¹ raises quality

and cost concerns. Providers may have an economic incentive to offset the additional costs attributable to the giveaway by providing unnecessary services or by substituting cheaper or lower quality services. The use of giveaways to attract business also favors large providers with greater financial resources for such activities, disadvantaging smaller providers and businesses.

The Office of Inspector General (OIG) is responsible for enforcing section 1128A(a)(5) through administrative remedies. Given the broad language of the prohibition and the number of marketing practices potentially affected, this Bulletin is intended to alert the health care industry as to the scope of acceptable practices. To that end, this Bulletin provides bright-line guidance that will protect the Medicare and Medicaid programs, encourage compliance, and level the playing field among providers. In particular, the OIG will apply the prohibition according to the following principles:

- *First*, the OIG has interpreted the prohibition to permit Medicare or Medicaid providers to offer beneficiaries inexpensive gifts (other than cash or cash equivalents) or services without violating the statute. For enforcement purposes, inexpensive gifts or services are those that have a retail value of no more than \$10 individually, and no more than \$50 in the aggregate annually per patient.

- *Second*, providers may offer beneficiaries more expensive items or services that fit within one of the five statutory exceptions: waivers of cost-sharing amounts based on financial need; properly disclosed copayment differentials in health plans; incentives to promote the delivery of certain preventive care services; any practice permitted under the federal anti-kickback statute pursuant to 42 CFR 1001.952; or waivers of hospital outpatient copayments in excess of the minimum copayment amounts.

- *Third*, the OIG is considering several additional regulatory exceptions. The OIG may solicit public comments on additional exceptions for complimentary local transportation and for free goods in connection with participation in certain clinical studies.

- *Fourth*, the OIG will continue to entertain requests for advisory opinions related to the prohibition on inducements to beneficiaries. However, as discussed below, given the difficulty in drawing principled distinctions between categories of beneficiaries or types of inducements, favorable opinions have been, and are expected to be, limited to situations involving

conduct that is very close to an existing statutory or regulatory exception.

In sum, unless a provider's practices fit within an exception (as implemented by regulations) or are the subject of a favorable advisory opinion covering a provider's own activity, any gifts or free services to beneficiaries should not exceed the \$10 per item and \$50 annual limits.²

In addition, valuable services or other remuneration can be furnished to financially needy beneficiaries by an independent entity, such as a patient advocacy group, even if the benefits are funded by providers, so long as the independent entity makes an independent determination of need and the beneficiary's receipt of the remuneration does not depend, directly or indirectly, on the beneficiary's use of any particular provider. An example of such an arrangement is the American Kidney Fund's program to assist needy patients with end stage renal disease with funds donated by dialysis providers, including paying for their supplemental medical insurance premiums. (See, e.g., OIG Advisory Opinion No. 97-1 and No. 02-1.)

Elements of the Prohibition

Remuneration. Section 1128A(a)(5) of the Act prohibits the offering or transfer of "remuneration". The term "remuneration" has a well-established meaning in the context of various health care fraud and abuse statutes. Generally, it has been interpreted broadly to include "anything of value." The definition of "remuneration" for purposes of section 1128A(a)(5)—which includes waivers of coinsurance and deductible amounts, and transfers of items or services for free or for other than fair market value—affirms this broad reading. (See section 1128A(i)(6).) The use of the term "remuneration" implicitly recognizes that virtually any good or service has a monetary value.³

The definition of "remuneration" in section 1128A(i)(6) contains five specific exceptions:

- *Non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts.* Paying the premiums for a beneficiary's Medicare Part B or supplemental insurance is *not* protected by this exception.

- *Properly disclosed differentials in a health insurance plan's copayments or*

² The OIG will review these limits periodically and may adjust them for inflation if appropriate.

³ Some services, such as companionship provided by volunteers, have psychological, rather than monetary value. (See, e.g., OIG Advisory Opinion No. 00-3.)

¹ For convenience, in this Special Advisory Bulletin, the term "provider" includes practitioners and suppliers, as defined in 42 CFR 400.202.

deductibles. This exception covers incentives that are part of a health plan design, such as lower plan copayments for using preferred providers, mail order pharmacies, or generic drugs. Waivers of Medicare or Medicaid copayments are not protected by this exception.

- *Incentives to promote the delivery of preventive care.* Preventive care is defined in 42 CFR 1003.101 to mean 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 (available online at <http://odphp.osphs.dhhs.gov/pubs/guidecps>). 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. (See 42 CFR 1003.101; 65 FR 24400 and 24409.)

- *Any practice permitted under an anti-kickback statute safe harbor* at 42 CFR 1001.952.⁴

- *Waivers of copayment amounts in excess of the minimum copayment amounts under the Medicare hospital outpatient fee schedule.* (See section 1128A(i)(6) of the Act; 42 CFR 1003.101.)

In addition, in the Conference Committee report accompanying the enactment of section 1128A(a)(5), Congress expressed its intent that inexpensive gifts of nominal value be permitted. (See Joint Explanatory Statement of the Committee of Conference, section 231 of HIPAA, Public Law 104–191.) Accordingly, the OIG interprets the prohibition to exclude offers of inexpensive items or services, and no specific exception for such items or services is required. (See 65 FR 24400 and 24410.) 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. *Id.* at 24411.

Inducement. 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 “should know” standard is met if a provider acts with deliberate ignorance or reckless

disregard. No proof of specific intent is required. (See 42 CFR 1003.101.)

The “inducement” element of the offense is met by any offer of valuable (*i.e.*, not inexpensive) goods and services as part of a marketing or promotional activity, regardless of whether the marketing or promotional activity is active or passive. For example, even if a provider does not directly advertise or promote the availability of a benefit to beneficiaries, there may be indirect marketing or promotional efforts or informal channels of information dissemination, such as “word of mouth” promotion by practitioners or patient support groups. In addition, the OIG considers the provision of free goods or services to existing customers who have an ongoing relationship with a provider likely to influence those customers’ future purchases.

Beneficiaries. Section 1128A(a)(5) of the Act bars inducements offered to Medicare and Medicaid beneficiaries, regardless of the beneficiary’s medical condition. The OIG is aware that some specialty providers offer valuable gifts to beneficiaries with specific chronic conditions. In many cases, these complimentary goods or services have therapeutic, as well as financial, benefits for patients. While the OIG is mindful of the hardships that chronic medical conditions can cause for beneficiaries, there is no meaningful basis under the statute for exempting valuable gifts based on a beneficiary’s medical condition or the condition’s severity. Moreover, providers have a greater incentive to offer gifts to chronically ill beneficiaries who are likely to generate substantially more business than other beneficiaries.

Similarly, there is no meaningful statutory basis for a broad exemption based on the financial need of a category of patients. The statute specifically applies the prohibition to the Medicaid program—a program that is available only to financially needy persons. The inclusion of Medicaid within the prohibition demonstrates Congress’ conclusion that categorical financial need is not a sufficient basis for permitting valuable gifts. This conclusion is supported by the statute’s specific exception for non-routine waivers of copayments and deductibles based on individual financial need. If Congress intended a broad exception for financially needy persons, it is unlikely that it would have expressly included the Medicaid program within the prohibition and then created such a narrow exception.

Provider, Practitioner, or Supplier. Section 1128A(a)(5) of the Act applies to

incentives to select particular providers, practitioners, or suppliers. As noted in the regulations, the OIG has interpreted this element to exclude health plans that offer incentives to Medicare and Medicaid beneficiaries to enroll in a plan. (See 65 FR 24400 and 24407.) However, 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). *Id.* In addition, the OIG does not believe that drug manufacturers are “providers, practitioners, or suppliers” for the limited purposes of section 1128A(a)(5), unless the drug manufacturers 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.

Additional Regulatory Considerations

Congress has authorized the OIG to create regulatory exceptions to section 1128A(a)(5) of the Act and to issue advisory opinions to protect acceptable arrangements. (See sections 1128A(i)(6)(B) and 1128D(b)(2)(A) of the Act.) While the OIG has considered numerous arrangements involving the provision of various free goods and services to beneficiaries, for the following reasons the OIG has concluded that any additional exceptions will likely be few in number and narrow in scope:

- Any exception will create the activity that the statute prohibits—namely, competing for business by giving remuneration to Medicare and Medicaid beneficiaries. Moreover, competition will not only result in providers matching a competitor’s offer, but inevitably will trigger ever more valuable offers.

- Since virtually all free goods and services have a corresponding monetary value, 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. Attempting to draw such distinctions would necessarily result in arbitrary standards and would undermine the entire prohibition. Congress has provided no further statutory guidance on the bases for distinguishing and evaluating potential exceptions.

Despite these serious concerns, the OIG is considering soliciting public comment on the possibility of regulatory “safe harbor” exceptions under section

⁴ For example, anti-kickback statute safe harbors exist for 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. See 42 CFR 1001.952(g), (h), (i), and (k).

1128A(a)(5) for two kinds of arrangements:

- *Complimentary local transportation.* The OIG is considering proposing a new exception for complimentary local transportation offered to beneficiaries residing in the provider's primary catchment area. The proposal would permit some complimentary local transportation of greater than nominal value. However, 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, such arrangements may implicate the anti-kickback statute insofar as they confer 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 a new exception for free goods and services (possibly including waivers of copayments) in connection with certain clinical trials that are principally sponsored by the National Institutes of Health or another component of the Department of Health and Human Services.

The OIG is reviewing its pending proposal (65 FR 25460) to permit certain dialysis providers to purchase Medicare supplemental insurance for financially needy persons in the light of the principles established in this Bulletin.

While the OIG does not expect at this time to propose any additional regulatory exceptions related to unadvertised waivers of copayments and deductibles, the OIG recognizes that such waivers occur in a wide variety of circumstances, some of which do not present a significant risk of fraud and abuse. The OIG encourages the industry to bring these situations to our attention through the advisory opinion process. Instructions for requesting an OIG advisory opinion are available on the OIG Web site at <http://oig.hhs.gov/advopn/index.htm>.

Finally, the OIG reiterates that nothing in section 1128A(a)(5) prevents an independent entity, such as a patient advocacy group, from providing free or other valuable services or remuneration to financially needy beneficiaries, even if the benefits are funded by providers, so long as the independent entity makes an independent determination of need and the beneficiary's receipt of the remuneration does not depend, directly or indirectly, on the beneficiary's use of any particular provider. The OIG has approved several such arrangements

through the advisory opinion process, including the American Kidney Fund's program to assist needy patients with end stage renal disease with funds donated by dialysis providers. (See, e.g., OIG Advisory Opinion No. 97-1 and No. 02-1.)

Conclusion

Congress has broadly prohibited offering remuneration to Medicare and Medicaid beneficiaries, subject to limited, well-defined exceptions. To the extent that providers have programs in place that do not meet any exception, the OIG, in exercising its enforcement discretion, will take into consideration whether the providers terminate prohibited programs expeditiously following publication of this Bulletin.

The Office of Inspector General (OIG) was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse, and waste in the Department's programs and to promote efficiency and economy in departmental operations. The OIG carries out this mission through a nationwide program of audits, investigations, and inspections.

The Fraud and Abuse Control Program, established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), authorized the OIG to provide guidance to the health care industry to prevent fraud and abuse and to promote the highest level of ethical and lawful conduct. To further these goals, the OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by the OIG.

Dated: August 8, 2002.

Janet Rehnquist,

Inspector General.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR 4736-N-12]

Notice of Proposed Information Collection for Public Comment—Lease Requirements, Recordkeeping

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* October 29, 2002.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control number and should be sent to: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4249, Washington, DC 20410-5000.

FOR FURTHER INFORMATION CONTACT: Mildred M. Hamman, (202) 708-3642, extension 4128. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated collection techniques or other forms of information technology; e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Lease Requirements—24 CFR 966.4, Recordkeeping.

OMB Control Number: 2577-0006.

Description of the need for the information and proposed use: HUD regulations 24 CFR 966.4 prescribe the provisions that shall be incorporated in leases by public housing agencies (PHAs) for dwelling units assisted under the U.S. Housing Act of 1937 in projects owned by or leased to PHAs to the tenants. This recordkeeping requirement imposed upon PHAs by HUD regulations and associated information incidental to PHAs' day-to-day operations as landlords of rental housing. If these minimal requirements were not imposed, the Federal Government would have no assurance that PHAs were adopting leases consistent with the law and regulations