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

†There 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 Schaefer, 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(j)(6) of the Act: 42 CFR 1003.101.)

Offering valuable gifts to beneficiaries to influence their choice of a Medicare or Medicaid provider 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 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. 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. The definition of “remuneration” in section 1128A(j)(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

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

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

• Some services, such as companionship provided by volunteers, have psychological, rather than monetary value. (See, e.g., OIG Advisory Opinion No. 00–3.)
deductibles. This exception covers incentives that are part of a health plan design, such as lower plan copayments, reduced cost-sharing amounts, 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.oshs.dhhs.gov/pubs/guides/). 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 or 1001.957.** Incentives to promote the delivery of preventive care are not protected by this exception.

- **Waivers of copayment amounts in excess of the minimum copayment amounts under the Medicare hospital outpatient fee schedule.** (See section 1128A(1)(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 HPAA, 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 inducements offered to Medicare and Medicaid beneficiaries, regardless of 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(1)(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

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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).
and the beneficiary
an independent determination of need
so long as the independent entity makes
advocacy group, from providing free or
an independent entity, such as a patient
opn/index.htm.

Instructions for requesting an OIG
abuse. The OIG encourages the industry
circumstances, some of which do not
such waivers occur in a wide variety of
and deductibles, the OIG recognizes that
exception for free goods and services
trials.

Finally, the OIG reiterates that
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.

[FR Doc. 02–22124 Filed 8–29–02; 8:45 am]
BILLING CODE 4152–01–P

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.