Lexington-Fayette Urban County Government
DEPARTMENT OF LAW

Jim Gray
Mayor

Janet M. Graham
Commissioner

TO: Commissioner Chris Ford
Councilmember Peggy Henson

FROM: Department of Law

DATE: April 23, 2015

RE: Emergency Medical Transport Assistance Program

This memorandum is in response to your request for a legal opinion regarding the authority to operate a Medical Transport Assistance Program through the Department of Social Services' Division of Adult and Tenant Services.

Background

In the fall of 2014, Councilmember Henson inquired into what assistance could be provided to Lexington-Fayette County citizens, especially senior citizens that are unable or find it difficult to pay the fees associated with emergency ambulance transportation. Originally, it was suggested that the Division of Fire and Emergency Service ("Fire") waive fees for LFUCG provided trips for all senior citizens who reside in Lexington-Fayette County. Fire requested a legal opinion from the Law Department; the Law Department advised that such a waiver would violate the Federal anti-kickback statute of the Social Security Act. The Law Department's research showed that any waiver or reduction of fees could not be based on patient-specific factors, in this case – age and residency, rather it must be a uniform waiver or reduction of fees.

Based on the above, the Department of Social Services, through its' Division of Adult and Tenant Services (the "Division"), suggested the creation of a program to potentially address the problem. The Division sought to create an Ambulance Fee Assistance Program (the "Program"). The Program would be similar to other assistance programs currently administered by the Division. Specifically, the Program would be designed to pay for all of the remaining out-of-pocket fees, i.e. co-pays and deductibles, associated with an emergency ambulance transport for certain low-income Lexington-Fayette County residents. In order to qualify for Program assistance, an applicant would submit a form requesting reimbursement for out-of-pocket fees to the Division. LFUCG would pay for all of the out-of-pocket fees up to twice in a 12-month period if the applicant

met the Program criteria: (1) he or she is a resident of Lexington-Fayette County; and (2) his or her income is at or below 150% of the Poverty Guidelines.

Taking into consideration the full program details, the Law Department elected to request an opinion from United States Department of Health and Human Services' Office of Inspector General ("OIG"). Specifically, the request was: 1) whether a payment from one governmental entity to another would be considered a waiver; and 2) if so, would this waiver violate the Federal anti-kickback statute.

Conclusion

Based on the facts submitted, the OIG responded to our request with the following legal guidance:

1) OIG Advisory Opinion No. 12-16 (November 5, 2012) (attachment A)
2) US Department Health and Human Services, OIG Special Advisory Bulletin entitled *Offering Gifts and Other Inducements to Beneficiaries (August 2002)*. (attachment B)

After careful review of the provided guidance, the Program is legally permitted but must be administered within the prescribed waiver exceptions provided by 42 CFR 1001.952. Specifically, the Division must do the following:

1) Notify potential clients of the availability of assistance after services are rendered, the availability of potential assistance must not be advertised or be offered as an inducement to receive services;
2) Make a good faith review of potential clients' financial need; and
3) Make all determinations of financial assistance based on objective criteria.

In review of both the above articles, in conjunction with the description of the Program to be created by the Division, it is the Law Department's opinion that the Program does not violate the Federal anti-kickback statute.

If you have any questions, please let me know.

Melissa Moore Murphy, Attorney Senior

cc: Jim Gray, Mayor
Sally Hamilton, CAO

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: October 26, 2012

Posted: November 5, 2012

[Name and address redacted]

Re: OIG Advisory Opinion No. 12-16

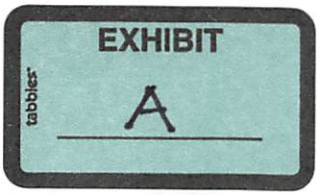
Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding a proposal to waive cost-sharing amounts on a non-routine, unadvertised basis for insured patients, including Federal health care program beneficiaries, based on individualized determinations of financial need (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or under the exclusion authority at section 1128(b)(7) of the Act, or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would not constitute



grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of Inspector General ("OIG") would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] (the "Requestor") is a not-for-profit corporation that provides emergency-only ambulance services throughout the [city redacted] metropolitan area. It is a volunteer ambulance organization founded to address the special needs of observant Jewish communities, but which provides care to all patients who request its services. Knowledge of the Requestor's services is generally spread through word of mouth in the communities it serves. The Requestor currently relies on charitable donations to meet its operating costs and does not charge patients for its services. Due to recent economic constraints, however, the Requestor seeks to accept reimbursement from third-party payors, including Medicare and Medicaid.

Under the Proposed Arrangement, the Requestor would continue its historical, charitable practice of treating and transporting uninsured patients free of charge. For insured patients, the Requestor[1] would bill all third-party payors, including Medicare and Medicaid, as well as any applicable supplemental or secondary insurance, for emergency transport services rendered. The Requestor would not routinely waive coinsurance or deductible amounts. However, the Requestor would waive or reduce coinsurance or deductible amounts, if it determines in good faith that the transported patient is in financial need. The Requestor would make all financial eligibility determinations using objective criteria. Any decision to reduce or waive a patient's cost-sharing obligations

[1] For ease of reference, our use of the term "Requestor" throughout this opinion may also include any billing agent used by the Requestor, as applicable. We have not been asked to opine on, and we are not opining on, the relationship between the Requestor and any billing agent used by the Requestor.

would be made on a case-by-case basis and would be based only on the patient's specific financial situation.

Under the Proposed Arrangement, the Requestor would not advertise waivers of cost-sharing amounts for its emergency transport services. The Requestor would inform an insured patient of a potential waiver only after the Requestor has finished rendering services to the patient, and the patient indicates that he or she is unable to pay.

In shifting from a business model relying entirely on charitable contributions to fund all operations to one that accepts reimbursement from all third-party payors, including Medicare and Medicaid, the Requestor certifies that it would comply with all Federal fraud and abuse laws, as well as applicable Medicare and Medicaid coverage rules for emergency ambulance transports.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

Section 1128A(a)(5) of the Act (the "CMP") provides for the imposition of civil

monetary penalties against any person who offers or transfers remuneration to a Medicare or state health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of section 1128A(a)(5) as including "the waiver of coinsurance and deductible amounts (or any part thereof)." The CMP contains certain exceptions from the definition of remuneration. Waivers of cost-sharing amounts are excepted if:

> (i) the waiver is not offered as part of any advertisement or solicitation;
> (ii) the person [making the waiver] does not routinely waive coinsurance or deductible amounts; and
> (iii) the person [making the waiver]—
>
> > (I) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or
> > (II) fails to collect coinsurance or deductible amounts after making reasonable collection efforts.

Section 1128A(i)(6) of the Act. Subsections (i), (ii), and at least one prong of subsection (iii) must be satisfied for the exception to apply.

B. Analysis

The Proposed Arrangement implicates the CMP and the anti-kickback statute because the Requestor would waive cost-sharing amounts for emergency ambulance transports for certain patients, including Federal health care program beneficiaries. However, if the Requestor's Proposed Arrangement satisfies all of the criteria of the CMP's exception for waivers of cost-sharing amounts, it would not involve prohibited remuneration within the meaning of section 1128A(a)(5) of the Act. For the following reasons, we conclude that it satisfies all of the criteria.

First, the Requestor certified that it would not offer the waiver as part of any advertisement or solicitation under the Proposed Arrangement. The Requestor would inform a patient of the waiver only after the Requestor has finished rendering services to the patient, and the patient indicates that he or she is unable to pay. Second, waivers of cost-sharing amounts under the Proposed Arrangement would not be made routinely; rather, they would be contingent on the insured patient's inability to pay amounts owed, which the Requestor would determine on a case-by-case basis. Third, the Requestor would make all financial eligibility determinations using objective criteria. Patients would not be eligible for cost-sharing waivers unless they meet the Requestor's financial

need eligibility criteria. The Requestor has certified that it would make these individualized determinations of financial need in good faith.

Accordingly, the Proposed Arrangement satisfies all of the criteria of the exception for waivers of cost-sharing amounts and would not constitute prohibited remuneration under Section 1128A(a)(5) of the Act. In light of the same safeguards set forth above, we also conclude that we would not subject the Requestor to administrative sanctions under the anti-kickback statute in connection with the remuneration provided to financially-needy, insured patients under the Proposed Arrangement.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law,

section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [name redacted] with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [name redacted] with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General

OFFICE OF INSPECTOR GENERAL

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 provider[1] 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

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

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

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

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 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.)

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

- 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

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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).

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 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 website at http://oig.hhs.gov/fraud/advisoryopinions.html

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.