State of Maryland
Department of Health and Mental Hygiene
Office of Health Services
Long-Term Care and Community Support Services

Provider Solicitation Addendum 2016

Comprehensive Case Management and Supports
Planning Services for Medicaid Long-Term Services and Supports

January 1, 2015 - December 31, 2015
Option #1: January 1, 2016 to December 31, 2016
Option #2: January 1, 2017 to December 31, 2017

Provider Solicitation Addendum 2016

Contents

Community Options Programs Policy Guidance
Inclusive for case management and supports planning services for the Home and Community Based Options Waiver, Community First Choice, Increased Community Services, and Community Personal Assistance Services programs

This guidance provides clarification of the 15-minute billing unit for supports planning and case management services covered under the community options programs.

Reimbursement for supports planning and case management services is for a distinct service event. Supports planning and case management services must be billed in increments of 15-minutes, referred to as a 15-minute unit. Minutes of service and units are to be totaled by day by service.

A provider may not bill for a service of less than 8 minutes if it is the only service provided that day. For multiple units of the same service on the same day, total the actual minutes and round up to the nearest 15 minute increment. If the total minutes end in a seven or less, round down to the nearest 15 minute increment.

Do not round up each service episode to the nearest 15 minute increment before totaling the units per day per service. Three separate case management services for the same participant of 7 minutes, equaling 21 total timed minutes, must be billed as one 15-minute unit of service. Three separate case management services for the same participant of 8 minutes each, equaling 24 total minutes, must be billed as 2 units. Please see the chart below for additional examples of accurate billing of daily total minutes as 15-minute units of service.

Units	Minutes of Service
1	Greater than or equal to 8 minutes, but less than 23 minutes (8-22 min)
2	Greater than or equal to 23 minutes, but less than 38 minutes (23-37 min)
3	Greater than or equal to 38 minutes, but less than 53 minutes (38-52 min)
4	Greater than or equal to 53 minutes, but less than 68 minutes (53-67 min)
5	Greater than or equal to 68 minutes, but less than 83 minutes (68-82 min)
6	Greater than or equal to 83 minutes, but less than 98 minutes (83-97 min)
7	Greater than or equal to 98 minutes, but less than 113 minutes (98-112 min)
8	Greater than or equal to 113 minutes, but less than 128 minutes (113-127 min)

The actual minutes billed for any one supports planner in a work day may not exceed seven hours (420 minutes; 28 units) or 7/8ths of the work hours of that supports planner, whichever is less. Supports planners who work a non-traditional schedule must provide written notification of their schedule to the Department for approval to bill up to 7/8th of their workday. Written approval of the alternate schedule is required prior to billing greater than 7 hours per day.

Providers must maintain records which fully demonstrate the extent, nature and medical necessity of services provided to Medicaid recipients. The records must support the fee charged or payment sought for the services and items, and demonstrate compliance with all applicable

requirements. These records of case management activities shall be maintained in the waiver tracking system.

Not all activities performed by the provider are considered billable activities. The following section outlines billable versus non-billable activities. Billable supports planning activities shall be based on the applicant/participant's waiver plan of service and necessary for participation in the waiver program. Examples of billable activities include but are not limited to face-to-face contacts with the applicant/participant, development of the waiver plan of service, and collateral contact made to persons on behalf of the applicant/participant or that relate directly to the management of the applicant/participant's services.

Some examples of non-billable activities include, but are not limited to activities that are not allowable under the Federal definition of case management, such as time spent by the provider solely for the purpose of transporting participants. Other examples of non-billable activities include:

- Supports planning and case management services of less than eight minutes duration;
- Telephone contact with the Department or its designated agent for the purpose of requesting or reviewing authorization;
- Time spent engaged in activities required by a credentialing, certification or oversight entity such as gathering and submitting care plan or service data or other information;
- Completion of billing documentation;
- Individual or group supervision, routine case reviews and rounds, ad hoc consultation with supervisors and discussion or consultation among team members;
- Time spent in staff training, clinical supervision or case reviews including for the purpose of treatment planning, unless the participant is present;
- Travel time;
- Attempted contacts or leaving messages; and
- Services provided by individuals who do not meet the definition of and minimum qualifications for a case manager.

Medicaid Community Options

Course 12

Billing for your Time

8/14/15

How do supports planners get paid?

- Supports planning agencies are paid for the time they spend actively helping and supporting their participants.
- All time must be documented in the LTSSMaryland system.
- Each activity must include:
  - Length of time/duration of activity;
  - Actions taken;
  - Outcomes; and
  - Planned follow-up.

What activities are covered?

- There are 21 covered activities/tasks for you to select.

Annual Redetermination Paperwork	Documentation
Community Application Assistance	Educate Participant on HCBS
Coordinate Emergency Back-Up Provider	Housing Applications
Coordinate Money Follows the Person (MFP) Flex Funds	Housing Assessment
Coordinate Non-Medicaid Resources	Identify Service Provider
Coordinate Transition	Institutional Re-Application
Coordinate Waiver Transition Funds	Plan of Service (POS) Development
Coordination with Local Health Department (LHD)	Reportable Events
Coordination with the Eligibility Determinations Division (EDD)	Train Participant on In-Home Supports Assurance System (ISAS)
Coordination with Nurse Monitor	Waiver Eligibility Coordination
Discharge Meeting	

Sample Activity Category	Sample Activity Description
Housing Application	Completed applications for two rental properties; spoke to property manager at one location regarding additional requirements; followed-up with obtaining birth certificate
Coordinate Non-Medicaid Resources	Followed-up with various faith-based resources to include food pantry and options for transportation; spoke with local community association to inquire about potential resources
Community Application Assistance	Obtained signatures and supplemental documentation for application; sent consent for waiver services to DEWS
Annual Redetermination Paperwork	Met with participant to complete ELP, reviewed recommendations in medical assessment and POS from last year to discuss needed changes
Coordinate Transition	Made arrangements for delivery of necessary medical supplies; spoke with new provider to confirm start date and time; uploaded receipts for needed household items
Identify Service Provider	Talked with participant by phone regarding potential back-up providers; forwarded referral and requested information to personal care agency
Plan of Service Development	Met with participant and talked about self-direction options and training opportunities; discussed plan for reducing costs; identified resources for independent providers; obtained signatures on POS
Train Participant on ISAS	Spoke by phone with participant to make appointment to deliver OTP
Educate Participant on HCBS	Met with participant and mother to discuss waiver and CFC; emailed follow-up information regarding self-direction

What activities are not covered?

- Direct delivery of an underlying medical, educational, social or other service to which an eligible individual has been referred;
- Time spent transporting participants;
- Contact with the Department or its designated agent for the purpose of requesting or reviewing authorization;
- Time spent engaged in activities required by a credentialing, certification or oversight entity such as gathering and submitting care plan, service data or other information;

What activities are not covered? (cont.)

- Activities of less than 8 minutes;
- Billing functions and/or completing billing documentation;
- Attempted contacts or leaving messages;
- Travel time; and
- Staff training, individual or group supervision, routine case reviews, ad hoc consultation with supervisors or among team members.

How is my time added up?

- Payments are made in 15-minute increments.
  - Every 15-minutes is a "unit" and is paid a specific rate
    - To get to units, time is rounded up or down to the closest 15 minutes
  - All time spent with/for a participant in a given day is added up to determine how many units are paid.
- All time spent with a participant in a given day is added up.
  - For instance, you spent
    - 10 minutes in the morning on a phone call with the participant,
    - 60 minutes in the afternoon at the participant's house, and
    - 30 minutes in the evening writing up a plan of service for the participant.
    - 10 minutes + 60 minutes + 30 minutes = 100 minutes
- Once added up, a claim is created and a certain number of units are billed.
  - Units are matched to the duration of activities.

Daily activity duration and units billed

UNITS	DURATION
1	Greater than or equal to 8 minutes but less than 23 minutes
2	Greater than or equal to 23 minutes but less than 38 minutes
3	Greater than or equal to 38 minutes but less than 53 minutes
4	Greater than or equal to 53 minutes but less than 68 minutes
5	Greater than or equal to 68 minutes but less than 83 minutes
6	Greater than or equal to 83 minutes but less than 98 minutes
7	Greater than or equal to 98 minutes but less than 113 minutes
8	Greater than or equal to 113 minutes but less than 128 minutes
9	Greater than or equal to 128 minutes but less than 143 minutes
10	Greater than or equal to 143 minutes but less than 158 minutes

Billing Limitations

- A supports planner may only bill for up to 7 hours in a work day.
- A person may only receive up to 7 hours per day of supports planning.

Types of Supports Planning Activities (for billing purposes)

- All billing happens through the LTSSMaryland system.
- Each activity/task is linked to one of three activity types:
  - Administrative
    - Participants are not yet enrolled.
    - Billing will not occur until the participant has a Community MA span.
    - E.g., Plan of Service development, transition assistance, identifying providers.
  - Comprehensive
    - Participants are not yet enrolled.
    - Billing will not occur until the participant has a Community MA span.
    - E.g., housing assistance, application assistance
  - Ongoing
    - Participant is enrolled and billing will process automatically.
    - Similar activities to Administrative however the participant is enrolled.

Reports for Tracking Agency Claims

- Dashboard reports allow Support Planning agency administrators and staff to view entered activities and projected billing amounts during designated time periods.
- Activity summary reports permit agency staff to review data entered by specific supports planners for a designated time period and includes information regarding the number of individuals served, total activity time entered, and average time spent working per participant.
- Activity reports highlight specific information by activity category for a designated time period.
- Claims reports provide detailed information related to submitted claims to include activity date, procedure code, units billed, billed amount and claim status.

DHMH Conflict Free Case Management Guidance
7.10.15

It is not allowable for any supports planner to take any gift or incentive of any kind from another provider.

DHMH will rigorously investigate allegations and take the action necessary to protect the integrity of the programs.

If you have knowledge of this behavior we urge you to report it immediately.

If an agency provider approaches you with an offer or if you are aware of the exchange of gifts or other incentives, you have several avenues through which to report this behavior. You may report to the program, to the state, and to the Federal authorities. Please see the contact information below.

Taking gifts or financial incentives is prohibited for the following reasons.

1. Violates conflict-free case management standards
2. Interferes with the right of the participant to free choice of provider
3. Negates the person-centered planning process
4. Conflicts with the principles of self-direction and participant choice and control
5. Ethical issue

Regulatory and policy prohibitions exist at both the state and Federal level.

1. State and Federal Medicaid rules regarding freedom of choice of provider

10.09.36.03 Conditions for Participation.
A. To participate in the Program, the provider shall comply with the following criteria:

(10) Place no restriction on a recipient's right to select health care providers of the recipient's choice,

2. Balancing Incentive Program conflict-free case management

One of the three structural change requirements Balancing Incentive States must implement is a conflict-free case management system. "Conflict of interest" is defined for the Balancing Incentive Program as a "real or seeming incompatibility between one's private interests and one's public or fiduciary duties." This definition is echoed in the Community First Choice regulations under 10.09.84.02. B(10). The BIP cites the following examples of conflicts of interest.

- Incentives for either over- or under-utilization of services.
- Interest in retaining the individual as a client rather than promoting independence. Agents may also be reluctant to suggest providers outside their agency because the agency may lose revenue.
- Issues that focus on the convenience of the agent or service provider rather than being person-centered.

Supports planning services are required to comply with the BIP conflict-free case management standards.

BIP Resources

http://www.balancingincentiveprogram.org/resources/what-design-elements-does-conflict-free-case-management-system-include

http://www.medicaid.gov/medicaid-chip-program-information/by-topics/long-term-services-and-supports/balancing/downloads/bip-manual.pdf

3. CFC regulations regarding conflict, person-centered planning, and self-direction

10.09.84.01 Purpose

B. Community First Choice is designed as a system of personal assistance that:
(1) Supports participants' ability to direct their own services;

10.09.84.02.B Definitions
(10) "Conflict of interest" means a real or seeming incompatibility between one's private interests and one's public or fiduciary duties.
(26) "Person-centered" means that the plan reflects what is important to the individual, what is important for his or her health and welfare, and is developed with input from the individual and the individual's representative when applicable.

(29) "Plan of service" means the written person-centered support plan developed by the applicant or participant with support from the supports planner and the individual's representative, when applicable.

(38) "Supports planner" means an individual who coordinates services, including:
(a) Supporting development of a person-centered plan of service;

10.09.84.05 Conditions for Provider Participation — General Requirements.
A. To participate as a provider of a service covered under this chapter, a provider:
(1) Shall meet all of the conditions for participation as a Maryland Medical Assistance Program provider as set forth in COMAR 10.09.36

10.09.84.15 Covered Services — Supports Planning.
B. Supports planning services shall:
(3) Support the participant to self-direct services; and
(4) Allow participants to exercise as much control as desired to select, train, supervise, schedule, determine duties, and dismiss the personal assistance provider.
C. Supports planning services include time spent by a qualified provider conducting any of the following activities:
(1) Assisting the participant in developing a person-centered plan of service in consultation with the applicant or participant and any individual requested by the participant.

(6) Providing guidance and support to help individuals self-direct their services

Report Fraud and Abuse

Medicaid Fraud Control Unit of the Office of the Maryland Attorney General
410-576-6521 or 1-888-743-0023
MedicaidFraud@oag.state.md.us

DHMH Office of the Inspector General
(866) 770-7175
http://dhmh.maryland.gov/oig/SitePages/reportfraud.aspx

Federal - 1-800-HHS-TIPS (1-800-447-8477)
Office of Inspector General - Report Fraud

Main line at DHMH for CFC – 410-767-1739

You may also report directly to your SPA liaison or call April Wiley at 410-767-1483.

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.)

[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

[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.