



*[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.]*

Date Issued: September 30, 2002

Date Posted: October 7, 2002

[Name and address of requestor redacted]

**Re: OIG Advisory Opinion No. 02-14**

Dear [name redacted]:

We are writing in response to your request for an advisory opinion concerning a proposed program to provide free safety equipment to hemophilia patients, as well as free electronic pagers to the parents of pediatric hemophilia patients (the "Program"). Specifically, you have inquired whether the Program would constitute grounds for the imposition of sanctions under the civil monetary penalty ("CMP") provision for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Social Security Act (the "Act"), as well as under the CMP and exclusion authorities at sections 1128A(a)(7) and 1128(b)(7) of the Act, respectively, as these sections relate to the commission of acts described in the anti-kickback statute, section 1128B(b) of the Act.

You have certified that all of the information provided in your request letter, including all supplementary information, is true and correct, and constitutes a complete description of the material facts regarding the Program. You have also certified that, upon our approval, you will undertake to effectuate the Program.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken any 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 the Program may potentially generate prohibited remuneration under the CMP for inducements to beneficiaries and, if the requisite intent to induce or reward referrals of Federal health care program business were present, under the anti-kickback statute. Because the Program as submitted does not impose the value limits necessary to qualify for the exceptions discussed below, we will not protect the Program. However, the OIG would not impose administrative sanctions on [name of requestor redacted] for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Act nor for violations of the anti-kickback statute 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), provided that the retail value of benefits provided are limited to \$10 per item and no more than \$50 per patient in the aggregate annually, as discussed below.

## **I. FACTUAL BACKGROUND**

This opinion concerns the provision of free goods by an infusion therapy company to hemophilia patients. Hemophilia is a bleeding disorder resulting from a flaw in the body's blood clotting system. Due to the potentially life threatening risk of bleeding episodes and hemorrhages, hemophilia patients must avoid injuries that could cause bleeding. Moreover, these patients must have prompt access to emergency medical care if a bleeding episode occurs.

[Name of requestor redacted] (the "Requestor") is a for-profit provider of infusion therapy and related services outside of the hospital. Its patients are covered by private insurers and Federal health care programs, including Medicaid and Medicare. The Requestor estimates that approximately ten percent (10%) of its hemophilia supplies business involves patients covered by various state Medicaid programs, and approximately one percent (1%) involves Medicare beneficiaries (usually qualifying under Medicare's disability eligibility provisions). In 1999, the Requestor established a division that focuses on providing products and services to persons with hemophilia.

Under the Program, the Requestor would provide certain personal safety equipment free of charge to any hemophilia patient who requests the equipment, without regard to his or her payor status. Patients could select from among the following items: safety

helmets; knee pads; medical information alert bracelets; tourniquets; cold packs for joints; emergency contact folders; and a carrying case for medications.

In addition to the free safety equipment for those patients who request it, the Requestor proposes to furnish electronic pagers to the parents of pediatric hemophilia patients without charge. The pagers would enable those supervising the child (i.e., school, day care, etc.) to contact the child's parent in the event of an emergency bleeding episode.

The Requestor estimates that the retail value of the pager and pager service (if procured directly by an individual patient) would be between \$5 and \$15 per month, depending on the type of pager and the pager's geographic service area. The Requestor would pay both the cost of the pager and the monthly service charge, but would instruct pager recipients that the pager should be used only in connection with its intended patient safety purposes and that improper use would result in the immediate forfeiture of the device. At the termination of the Requestor's provision of goods or services to the patient, the Requestor would retrieve the pager.

## II. LEGAL ANALYSIS

### A. Law

The provision of free equipment and pagers to patients covered by Medicare and Medicaid implicates section 1128A(a)(5) of the Act, which prohibits a person from offering or transferring remuneration to a beneficiary that such person knows or should know is likely to influence the beneficiary to order items or services from a particular provider, practitioner, or supplier for which payment may be made by Medicare or Medicaid. For purposes of section 1128A(a)(5), "remuneration" includes transfers of items or services for free or for other than fair market value. See section 1128A(i)(6) of the Act. Where a party commits an act described in section 1128A(a)(5) of the Act, the OIG may initiate administrative proceedings to impose CMPs on such party.

Section 1128A(a)(5) contains an exception that protects incentives given to individuals to promote the delivery of preventive care. The exception recognizes that "it may be prudent to allow providers to encourage individuals to obtain covered preventive care services. Benefits from appropriate preventive care include, among other things: healthier patient populations, lower health care costs, and reduced morbidity and mortality." 65 Fed Reg 24400, 24408 (April 26, 2000). The exception, however, only protects incentives given to asymptomatic persons to receive preventive health care

services that are covered by Medicare or Medicaid. In this case, the incentives are offered in connection with ongoing treatment of a clinical illness, not a covered preventive service.

No other statutory exception is applicable to the Program. However, the OIG has interpreted section 1128A(a)(5) as not applying to the provision of goods or services valued at less than \$10 per item and \$50 per patient in the aggregate on an annual basis. See Revised OIG CMPs, 65 Fed. Reg. 24400, 24410 (April 26, 2000); see also, Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries (“SAB”), 67 Fed. Reg. 55855 (August 30, 2002). This position is based upon the intent of Congress as expressed in the Committee reports accompanying the enactment of Section 1128A. See Joint Explanatory Statement of the Committee of Conference, section 231 of HIPAA, Public Law 104-191.

In addition to the CMP at section 1128A(a)(5), the Program may violate the anti-kickback statute, section 1128B(b) of the Act. The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by Federal health care programs. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services paid for 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.

## **B. Analysis**

The Program clearly comes within the statutory prohibition against improper inducements to beneficiaries and does not fit within the statutory exceptions. While not lavish, the value of the full package of safety equipment would exceed the threshold level of \$10 per item and \$50 in the aggregate on an annual basis. The same can be said of a single year of pager use.

While we are mindful of the hardships that chronic medical conditions can cause for beneficiaries, as well as the beneficial aspects of the offered goods in question, there is no reliable and consistent basis for distinguishing between goods or services offered or the types of beneficiaries that should and should not be excepted from the general

prohibition. Virtually all free goods and services are reducible to a monetary value. Attempting to draw subjective distinctions in such circumstances undermines the entire prohibition.

There are valid reasons for Congress' determination to restrict the availability of "giveaways" in connection with Medicare and Medicaid providers. First, such programs can corrupt the decision-making process. Second, there is potential harm to competing providers and suppliers, because use of giveaways creates an uneven playing field, steering business to big companies with "deep pockets" that can afford the cost of the free goods or services, and disadvantaging smaller and less well-capitalized providers or suppliers. Third, these practices could negatively affect the quality of care given to beneficiaries. As providers and suppliers race to the bottom by offering increasingly valuable goods or services, the incentive to cheat on the quality of the Medicare item or service increases proportionately. See, generally, the SAB.

We are sympathetic to the difficulties faced by the beneficiaries of the Requestor's Program. However, if we permit the Requestor to offer the Program without qualification, then competing providers must match the offer or lose business. Moreover, providers have a greater incentive to offer gifts to chronically ill beneficiaries who are likely to generate substantially more business than other beneficiaries. Notwithstanding, to the extent that benefits are limited to equipment not exceeding \$10 per item, \$50 in value in the aggregate, per beneficiary, on an annual basis, the Program would not implicate section 1128A(a)(5).

The pager benefit, on the other hand, would clearly exceed nominal value on an annual basis. With a retail value between \$5 and \$15 per month, the pagers could not be provided within the limits of nominal value for any significant period of time. At a minimum, the pager benefit would quickly limit the Requestor's ability to provide the equipment benefit to the same patients within the limits of nominal value during the same year. The pager benefit does not fit into any exception to the prohibition against improper inducements to beneficiaries.

### **III. CONCLUSION**

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Program may potentially generate prohibited remuneration under Section 1128A(a)(5) and, if the requisite intent to induce or reward referrals of Federal health care program business were present, under the anti-kickback

statute. Because the Program as submitted does not impose the value limits necessary to qualify for the exceptions discussed above, we will not protect the Program. However, the OIG would not impose administrative sanctions on [name of requestor redacted] for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Act, nor for violations of the anti-kickback statute 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), provided that the benefits provided under the Program to any particular beneficiary do not exceed the value limits discussed above.

#### **IV. LIMITATIONS**

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name of requestor 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 in any matter involving an entity or individual that is not a requestor of this opinion.
- 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 Program, including, without limitation, the physician self-referral law, section 1877 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 or programs, even those that 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 the Requestor with respect to any action that is part of the Program 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 Program 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 the Requestor with respect to any action 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,

/s/

D. McCarty Thornton  
Chief Counsel to the Inspector General