



[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: June 1, 2011

Posted: June 8, 2011

[Name and address redacted]

Re: OIG Advisory Opinion No. 11-07

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding the expansion of your vaccine reminder program to include entities that insure and treat patients covered by a fee-for-service Federal health care program (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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 Arrangement does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the 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”) will 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 Arrangement. This opinion is limited to the 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 publicly-traded pharmaceutical manufacturer and the ultimate parent entity of the manufacturer of the vaccines [vaccine redacted] and [vaccine redacted] (the “Manufacturer”). The Manufacturer introduced [vaccine redacted] (the “Original Vaccine”) in 2000. Until February 2010, the Original Vaccine was the only vaccine approved by the Food and Drug Administration (“FDA”) for the active immunization of infants and toddlers against infection caused by pneumococcal bacteria.

In February 2010, the Manufacturer introduced [vaccine redacted] (the “Expanded Vaccine”). The Expanded Vaccine protects against the same strains of bacteria found in the Original Vaccine, plus six additional strains. Like the Original Vaccine, the Expanded Vaccine is administered in four doses to children under the age of fifteen months. The Requestor has certified that, except where contra-indicated, the Expanded Vaccine is universally recommended: under the current standard of care, children under the age of fifteen months should receive the recommended course of vaccination with the Expanded Vaccine, and children ages fifteen months to five years who previously received four doses of the Original Vaccine should receive one supplemental dose of the Expanded Vaccine (the “Catch-up Dose”).¹ In September 2010, the Requestor

¹ See Advisory Committee on Immunization Practices to the Department of Health & Human Services Centers for Disease Control and Prevention “Recommended

discontinued the sale of the Original Vaccine in the United States. The Expanded Vaccine is currently the only available pneumococcal conjugate vaccine that is FDA-approved for use in children ages six weeks to five years.

The Requestor sponsors a vaccine reminder program (the “Program”).² Under the Program, the Requestor arranges for the delivery of postcard and telephone reminders to the parents or guardians of children who either: (1) have begun, but have not yet completed, a prescribed course of pneumococcal vaccinations in accordance with the recommended course of vaccination, or (2) have previously been administered four doses of the Original Vaccine and are eligible for, but have not yet received, a Catch-up Dose (collectively, “Eligible Children”). Until mid-February 2011, the Requestor limited participation in the Program to health insurers and health care entities that: (1) agreed to use the Program exclusively with respect to members and patients who were not covered by a fee-for-service Federal health care program, or (2) satisfied certain other objective criteria. Under the Arrangement, the Requestor expanded the Program, effective mid-February 2011, to include health insurers and health care entities that insure and treat patients covered by a fee-for-service Federal health care program.

The Requestor informs health insurers and health care entities of, and allows them to participate in, the Program without regard to the number of children who have been, or will be, vaccinated through the auspices of the health insurer or health care entity. The telephone and postcard reminder services provided under the Program are paid for by the Requestor and provided free of charge to the health insurers and health care entities that wish to participate in the Program (collectively, the “Participating Entities”). Program services are provided in one of two ways: (1) by an external third party, [name redacted] (the “Contractor”), or (2) by the Requestor.

To receive Program services provided by the Contractor, a Participating Entity must be able to filter and electronically transfer to the Contractor data pertaining exclusively to Eligible Children. The Contractor provides the Program services pursuant to a three-way agreement (the “Agreement”) between and among the Requestor, the Contractor, and the

Immunization Schedule for Persons Aged 0-6 Years (United States, 2010),” available at <http://www.ahrq.gov/clinic/pocketgd1011/gcp10aptab1.htm>.

² The Program was initiated in 2005 with respect to the Original Vaccine and was modified in 2010 to include the Expanded Vaccine.

Participating Entity.³ Participating Entities that qualify for and elect to receive Program services from the Contractor may choose from one of three service options: (1) automated telephone services, (2) postcard services, or (3) combined telephone and postcard services. Under each of the service options, the Contractor contacts the parents or guardians of Eligible Children in the manner selected by the Participating Entity.

Under the Agreement, if a Participating Entity does not have its own opt-out telephone line, the Contractor must maintain a telephone line that allows recipients of telephone reminders to opt-out of future communications, and must ensure that only patients who have not opted-out receive the reminders. For postcard reminders, Participating Entities are required to ensure that they have excluded from the mailing list provided to the Contractor any parents or guardians of Eligible Children who have opted-out of communications from the Participating Entity. At the request of a Participating Entity, the Contractor will personalize the postcard reminders with either the Participating Entity's corporate logo or other corporate branding.⁴ The Contractor coordinates the design, proofing, and printing of the customized logo, affixes it to the Requestor-approved postcard, and warehouses the printed cards for delivery based on the Participating Entity's schedule.

The Requestor does not allow Participating Entities that lack the requisite electronic data-filtering capabilities or that are unwilling or unable to work with a third party vendor the opportunity to receive Program services from the Contractor. Under the Arrangement, the Requestor offers its own, postage-paid, postcard-only service to such Participating Entities. Under the Requestor's postcard-only service, the Requestor provides the postcard reminders directly to the Participating Entity, pursuant to a contract between the Requestor and the Participating Entity, for the Participating Entity to distribute to the parents and guardians of Eligible Children. The contract requires the Participating Entity to include its return address on the postcards so that it is clear to the recipient that the postcards were distributed by the Participating Entity, and not by the Requestor.

Program reminder messages—whether provided by the Requestor or the Contractor—do not mention any specific product. Neither the postcards nor the automated telephone calls direct the patient or the patient's parent or guardian to any particular health care entity, nor do they refer to any specific recommended course of vaccination. With

³ The Requestor certified that the Agreement incorporates business associate provisions that enable Participating Entities to provide protected health information to the Contractor in accordance with applicable privacy laws.

⁴ The Requestor certified that Participating Entities may not further customize or otherwise alter the Requestor-approved messages contained on the postcard.

respect to reminders in connection with children for whom a prescribed course of pneumococcal vaccinations has been initiated and who have missed a recommended dose, the Program provides a message stating: “Records show that your child may have missed a vaccine shot. Please contact your child’s doctor or health clinic to find out if you need to schedule an appointment.” With respect to reminders for the Catch-up Dose, the Program provides a message that states: “Records show that your child may not have received a recommended vaccine that is included in a recently updated shot schedule. Please contact your child’s doctor or health clinic to find out if you need to schedule an appointment.” All reminder messages state that the Requestor has provided financial support for the communication and that no patient-specific information has been or will be provided to the Requestor. Reminder messages provided by the Contractor also state that the Participating Entity is the source of the communication; reminder messages sent pursuant to the Requestor’s postcard-only service convey this information by means of the Participating Entity’s return address, which the Participating Entity is required by contract to include.

According to the Requestor, vaccine reminder programs improve adherence to immunization schedules generally, and, in one case, compared with no intervention, a reminder program that coupled a mailing with a follow-up telephone reminder was correlated with a 61% increase in recommended immunizations in children who had been behind on these immunizations.

II. LEGAL ANALYSIS

A. Law

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 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. 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 gives something of value 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 “transfers of items or services for free or for other than fair market value.” The OIG has previously taken the position that “incentives that are only nominal in value are not prohibited by the statute,” and has interpreted “nominal value to be no more than \$10 per item, or \$50 in the aggregate on an annual basis.” 65 Fed. Reg. 24400, 24410-24411 (Apr. 26, 2000) (preamble to the final rule on the CMP).

B. Analysis

Under the Arrangement, the Requestor provides, or arranges for the provision of, services that potentially benefit both the parents and guardians of Eligible Children and the Participating Entities. Thus, we must examine two aspects of the Arrangement: (1) whether the Program reminder messages constitute remuneration to the recipient parents and guardians to induce or influence those parents and guardians to select a particular drug; and (2) whether the Program reminder services constitute remuneration to the Participating Entities to induce them to prescribe, or to arrange for or recommend the prescribing of, the Requestor’s drugs. We address each issue in turn.

1. Parents and Guardians of Eligible Children

The anti-kickback statute is not implicated if remuneration is not offered, paid, solicited, or received. Similarly, the CMP is not implicated if remuneration is not offered or transferred to a Federal health care program beneficiary. Therefore, a threshold question is whether the Program reminder messages constitute remuneration to the recipient parents and guardians under either statute. We conclude they do not.

The Program reminder messages provided under the Arrangement serve only to inform the parents and guardians of Eligible Children that their children might have missed a vaccine shot, or might not have received a recommended vaccine that is included in a recently updated shot schedule. The reminder messages do not offer the recipients any incentives, such as coupons or offers of free items, to request the Expanded Vaccine or to make an appointment. Although the Program reminder services may result in some inchoate psychic value to the parents and guardians of Eligible Children, they provide no actual or expected economic or other actionable benefit. Accordingly, neither the anti-kickback statute nor the CMP is implicated as between the Requestor and the parents or guardians.

2. Participating Entities

The OIG’s position on the provision of free or below-market goods or services to actual or potential referral sources is longstanding and clear: such arrangements are suspect and may violate the anti-kickback statute, depending on the circumstances. For example, in 2005, the OIG issued its Supplemental Compliance Program Guidance for Hospitals, which explained that “[t]he general rule of thumb is that any remuneration flowing between hospitals and physicians should be at fair market value Arrangements under which hospitals . . . provide physicians with items or services for free or less than fair market value . . . [or] relieve physicians of financial obligations they would otherwise incur . . . pose significant risk.” 70 Fed. Reg. 4858, 4866 (Jan. 31, 2005). In particular, the OIG consistently has distinguished between free items and services that are integrally related to the offering provider or supplier’s services and those that are not. For instance, we have stated that a free computer provided to a physician by a laboratory would have no independent value to the physician if the computer could be used only, for example, to print out test results produced by the laboratory. In contrast, a free personal computer that the physician could use for a variety of purposes would have independent value and could constitute an illegal inducement. 56 Fed. Reg. 35952, 35978 (July 29, 1991) (preamble to the 1991 safe harbor regulations).

The Program reminder services could have independent value to the Participating Entities because they could replace actions the Participating Entities might otherwise take, and consequently defray expenses the Participating Entities might otherwise incur, to recommend to the parents and guardians of Eligible Children that they consult with their children’s physicians about the children’s vaccination status. The Program reminder services could confer an additional financial benefit in cases where the Participating Entity is a physician or physician group, as the messages are intended to encourage the recipients to schedule an appointment with their children’s health care practitioners, who likely will be reimbursed for administering the vaccine, and possibly for an associated office visit. However, for the following reasons, we conclude that the Arrangement

presents a sufficiently low risk of fraud and abuse and therefore will not impose administrative sanctions on the Requestor in connection with the Arrangement.

First, the Arrangement is narrowly tailored and operates transparently. Program reminder messages are sent only to the parents and guardians of Eligible Children—*i.e.*, children who either have begun, but not yet completed, a course of pneumococcal vaccinations in accordance with the recommended course of vaccination, or have previously been administered four doses of the Original Vaccine and are eligible for, but have not yet received, a Catch-up Dose—and include a disclosure that the Requestor provided financial support for the communication. The Requestor has little opportunity to influence referrals, because the only recipients of the Program reminder messages are the parents and guardians of children who already have been prescribed and received at least one dose of the Requestor’s vaccine.

Second, the Arrangement does not target any particular referral sources. The Program services are made available on an equal basis to all health insurers and health care entities without regard to any health insurer’s or health care entity’s overall volume or value of expected or past referrals to the Requestor’s products.

Third, the Arrangement is unlikely to result in overutilization. The Requestor certified that administration of the Expanded Vaccine is the standard of care and is universally recommended except where contra-indicated. Thus, the Arrangement is unlikely to induce a health care practitioner to prescribe and administer a vaccine that the practitioner would not otherwise have furnished in the absence of the inducement.

Fourth, the Arrangement is unlikely to result in unfair competition or a decrease in patient freedom of choice. The Program reminder messages do not recommend a specific vaccine or course of vaccination; the messages therefore increase the likelihood that all necessary vaccinations will be administered.

Finally, the Program increases the quality of health care services by helping health insurers and health care entities remind the parents and guardians of Eligible Children that their children might need to finish a course of previously prescribed vaccinations.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement does not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) while the 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 will 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 Arrangement. This opinion is limited to the 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 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 Arrangement, 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, 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 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

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 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,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General