



*[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:** February 15, 2008

**Posted:** February 22, 2008

[Name and address redacted]

**Re: OIG Advisory Opinion No. 08-05**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding your pharmaceutical company's proposal to place in certain physicians' offices electronic kiosks that offer patients free disease state screening questionnaires (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (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, or under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act.

You have certified that all of the information provided in your request, including all supplementary letters, 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 generate prohibited

remuneration under the anti-kickback statute, and, thus 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; and (ii) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act.

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 letter 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 pharmaceutical and healthcare company that develops, manufactures, and markets pharmaceuticals for a number of diseases and conditions, including [diseases redacted] (collectively, the four “Disease States”). Requestor’s products are reimbursable under Federal health care programs, including Medicare and Medicaid.

At present, Requestor places in physicians’ waiting rooms informational pamphlets on different disease states for use by patients. These pamphlets may include questionnaires, which Requestor states can help patients determine if they should talk to their physician about a particular disease or condition.

Under the Proposed Arrangement, Requestor would place freestanding kiosks that offer interactive questionnaires in the waiting rooms of certain physicians (the “Participating Physicians”). Each kiosk would have a touch screen, keyboard, printer, and software that would enable it to display interactive questionnaires about the four Disease States. Requestor asserts that the kiosks would help patients determine whether they should discuss symptoms of any of the four Disease States with a physician. Patients’ use of the kiosks would be voluntary.

The questionnaires would consist of several questions on each of the four Disease States that the Participating Physicians’ patients would be able to answer using the keyboard. Once a patient had answered all questions, the patient could generate a printout that would contain the screening questions along with the patient’s responses, and choose to share the printout with his or her physician. Neither the kiosks nor the printouts would contain

conclusions that the patient has a particular condition or requires a particular therapy, nor would they contain any messages directed to the patient's physician. Rather, all of the questionnaires would advise patient users to talk to their doctor about the screening results. The questionnaires would not mention Requestor's drug products or contain any advertisements or incentives for using the kiosks, such as coupons or offers of free items. Patients would not need to enter their names, and the questionnaires would include a screen with a privacy statement notifying patients that Requestor and companies working with Requestor would obtain aggregate data from the kiosks, but no individual identifying information.<sup>1</sup>

Neither the interactive questionnaires nor the kiosk itself would mention any drug names. According to Requestor, the kiosk would carry a small image of Requestor's logo with wording similar to "brought to you by [name redacted]" to disclose that the kiosk and its information are not coming from the physician in whose office the kiosk is located. The questionnaires and the printouts would include a footer at the bottom of the screen and page that displays Requestor's logo and a copyright notice.

Participating Physicians would neither pay Requestor, nor receive payment from Requestor, for hosting the kiosks.<sup>2</sup> Requestor would offer to place a kiosk in the waiting room of primary care physicians whom Requestor expects would treat a large number of patients with the four Disease States, including Federal health care program beneficiaries. Requestor would identify potential Participating Physicians based on whether they historically have prescribed drugs in therapeutic classes that are commonly used to treat the four Disease States, but Participating Physicians need not have prescribed any of Requestor's products. Participating Physicians would not be required to prescribe Requestor's drugs in return for the kiosks.

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<sup>1</sup> The kiosks would save certain information on the machine: the number of participants for each questionnaire; the number of patients completing the questionnaire and obtaining a result advising them to talk to their physician; the number of patients who print out the results of their questionnaires; the number of patients who quit the questionnaire early and, if so, the question at which they quit; and the average time spent completing the questionnaire. The kiosks would route this information to a centralized server that would only be accessible by Requestor or by employees of a company hired by Requestor to collect and store the information in a computer database. Requestor's sales representatives would not have access to the database. Requestor has certified that the Proposed Arrangement would comply with all applicable privacy laws.

<sup>2</sup> Participating Physicians would be responsible for paying for the electricity to power the kiosks.

Kiosks would be installed in a Participating Physician's waiting room for up to a one year term, but a Participating Physician could choose to have Requestor remove it at any time. At all times, the kiosk would remain the property of Requestor. After the one year term, the kiosk could remain at the location for an additional period of time, or Requestor could remove the kiosk.

## 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.), 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 provides for the imposition of civil monetary penalties against any person who gives something of value to a Medicare or 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 Medicaid. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs.

## **B. Analysis**

The Proposed Arrangement presents two possible kickback scenarios: (1) a potential kickback from Requestor to the patient users of the kiosks to induce them to self-refer to Requestor's drugs, and (2) a potential kickback from Requestor to the Participating Physicians to induce them to prescribe Requestor's drugs. We address each scenario in turn.

### **1. Patient Use of the Kiosks**

It is axiomatic that there cannot be a violation of the anti-kickback statute without an offer, solicitation, or transfer of remuneration between parties. As such, the threshold question regarding patients' use of Requestor's kiosks is whether the kiosks would have remunerative value to the patients who would use them. Requestor has certified that the kiosks would provide only a printout reprising the questionnaire and each patient's answers. The questionnaires would not offer patients incentives for using the kiosks, such as coupons or offers of free items. Accordingly, we believe that the Proposed Arrangement would not provide anything of value to patients and therefore the anti-kickback statute is not implicated as between the Requestor and patient users of the kiosks.<sup>3</sup>

Our conclusion that the kiosks are not remuneration to patients for purposes of the anti-kickback statute does not mean that the Proposed Arrangement does not pose other risks to patients and Federal health care programs. It is apparent to us that the kiosks are contrivances designed to elicit patient inquiries regarding the four Disease States for which Requestor's drugs are indicated. Like their paper brochure analogues, which are commonly found in physician offices, the kiosks are a type of "direct to consumer" advertising. Direct to consumer advertising is often used by pharmaceutical manufacturers to generate additional utilization of their products by encouraging consumers to initiate discussions with their physicians about the advertised product or the symptoms for which it is indicated. Such sales techniques increase the risk of overutilization, as well as the risk of increased costs to patients who are influenced to choose name-brand drugs instead of less costly generic equivalents. They may also implicate Federal or state consumer protection laws, Food and Drug Administration regulations, or Federal Trade Commission regulations.<sup>4</sup>

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<sup>3</sup> The Proposed Arrangement may result in some inchoate psychic value to patients, but that value would not implicate the anti-kickback statute. For the same reasons set forth above, we also conclude that the Proposed Arrangement would not generate remuneration for purposes of section 1128A(a)(5) of the Act.

<sup>4</sup> We offer no opinion on whether the Proposed Arrangement implicates or violates these authorities, as they are beyond the scope of our advisory opinion process.

Finally, our conclusion that the kiosks are not remuneration for purposes of the anti-kickback statute as to patients would likely be different if the kiosks were used to communicate offers of remuneration to patients, such as coupons, gifts, or services.

## **2. Participating Physicians**

We further conclude that the Proposed Arrangement, as represented by Requestor, would not generate prohibited remuneration for the Participating Physicians. Under the Proposed Arrangement, the kiosks would remain the property of Requestor. The Participating Physicians would host the kiosks, but would not receive space rental or utilities fees or other compensation in connection with the Proposed Arrangement. It seems unlikely that the kiosk-generated questionnaires would save any appreciable amount of physician or staff time. We believe the kiosks, as described above, would not enhance the attractiveness of the Participating Physicians' office practices to prospective patients such that they would be likely to select a Participating Physician because he or she offered a kiosk in the waiting room.

The limited purpose kiosks – which amount to little more than high-tech interactive brochures – have no independent value to the Participating Physicians. As such, they stand in contrast to, for instance, multi-functional computers or fax machines furnished by a laboratory supplier, which have independent value to physicians apart from the transmission of lab results because they can be used for a variety of purposes. We have stated that the provision of such types of free goods, depending on the circumstances, may constitute an illegal inducement.<sup>5</sup> Although the printouts may encourage patients to speak to their physicians about their symptoms, this result would be akin to whatever residual benefit might accrue to physicians on account of low-tech paper brochures or direct-to-consumer commercials.

Finally, the Proposed Arrangement contains safeguards to protect patient privacy. Requestor has certified that the Proposed Arrangement would comply with all applicable privacy laws. Neither individual patient information nor data related to prescriptions that Participating Physicians may ultimately write under the Proposed Arrangement would be conveyed to the Requestor or its affiliates via the kiosks. Patients would receive a privacy notification stating that Requestor and companies working with Requestor would obtain aggregate data from the kiosks, but no individual identifying information.

In sum, based on the totality of facts and circumstances, we conclude that the Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute. For the same reasons, we also conclude that the Proposed Arrangement would not be

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<sup>5</sup> See 56 Fed. Reg. 35978 (July 29, 1991) (preamble to the 1991 safe harbor regulations).

subject to sanction under section 1128A(a)(5) of the Act.<sup>6</sup>

### **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 generate prohibited remuneration under the anti-kickback statute, and, thus 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; and (ii) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act.

### **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 Proposed 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.

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<sup>6</sup> A pharmaceutical manufacturer is not “a particular provider, practitioner, or supplier” for the limited purposes of section 1128A(a)(5) of the Act, unless it owns or operates entities that file claims for payment with the Medicare or Medicaid programs. However, an offer of remuneration by a pharmaceutical manufacturer to a beneficiary to influence the beneficiary to select a particular physician would implicate the statute. Here, as explained above, we find no suspect remuneration to beneficiaries.

- 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 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/

Lewis Morris  
Chief Counsel to the Inspector General