[*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: August 21, 2007

Posted: August 28, 2007

[Name and Address Redacted]

Re: OIG Advisory Opinion No. 07-09

Dear [name redacted]:

We are writing in response to your request for an advisory opinion regarding [name redacted's] reward program under which certain of its members receive an annual reward based on the amount spent on purchases, including pharmaceutical purchases (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes 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.

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 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, but that 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 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] ("Requestor") operates membership warehouse clubs ("Warehouses") that sell nationally branded and private label products in a wide range of merchandise categories. Many of Requestor's Warehouses also have retail pharmacies, which sell items reimbursable by Federal health care programs, and offer certain professional services.[1] Requestor's members are individuals and businesses that pay $50 each year in exchange for the ability to purchase goods and services at Requestor's Warehouses. Requestor also offers a premium membership, which offers additional benefits to individuals and businesses that pay an annual fee of $100 (the "Premium Members").

The Arrangement is one of the additional benefits offered to Premium Members. Under the Arrangement, each Premium Member receives an annual reward of [percent redacted (less than 5%)] of the amount the Premium Member spent that year on purchases of most items at the Warehouses.[2] The maximum reward a Premium Member can receive under the Arrangement is $500 per year, which would require spending [dollar amount redacted] at the Warehouses. Rewards are calculated only on amounts actually paid by the Premium Member and not on amounts received from third parties. This means that, for pharmacy or other covered purchases, a Premium Member's reward amount is

[1] Requestor employs licensed audiologists at 211of the Warehouses; they receive an hourly wage and do not have any compensation based on unit sales. Requestor leases space to Doctors of Optometry who staff eye centers at 356 of the Warehouses; the lease rates do not take into account or otherwise vary with the volume or value of business generated for Requestor by the optometrist. No physicians (i.e., licensed Doctors of Medicine) do business or provide services at the Warehouses. We have not been asked to opine on, and we offer no opinion regarding, any of the arrangements between Requestor and audiologists and Doctors of Optometry.

[2] In compliance with applicable laws and regulations, rewards for Premium Members in the United States are not calculated (i) on purchases of tobacco-related products, Requestor's Cash Cards, postage stamps, and alcoholic beverages in certain states; (ii) on membership fees and purchases such as services, travel, auto buying program, purchases at Requestor's gas stations and food vendors; (iii) on miscellaneous fees, deposits and taxes, including sales tax; (iv) where prohibited by legal or regulatory restrictions; (v) on purchases made by anyone other than the Premium Member account's primary cardholders; or (vi) on certain other categories as determined from time to time at Requestor's discretion.

calculated only on his or her cost-sharing amount or other out-of-pocket expense (collectively "Cost-Sharing Amounts"). Insurance plan and other third-party payments for drugs or other covered items purchased at Requestor's pharmacies are not included in calculating a Premium Member's reward amount. The Arrangement has been in place since 2000 (i.e., before the advent of the Medicare Part D benefit).

The reward is provided in the form of a certificate that is mailed with the Premium Member's annual membership renewal notice, which can result in a significant delay between a qualifying expenditure and the Premium Member's receipt of the reward. The reward certificate may be used toward the purchase of all merchandise at the Warehouses except excluded items.[3] If the reward certificate is used to purchase an item costing less than the dollar value on the certificate, the Premium Member receives cash for the remaining dollar value.

II. LEGAL ANALYSIS

A. Law

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 beneficiary of Medicare or a state health care program, including Medicaid, that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a state health care program, including Medicaid. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of section 1128A(a)(5) as including "the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value."

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

[3] The reward certificate may not be used (i) toward the purchase of alcohol or tobacco-related products; (ii) toward purchases that are not recorded through Requestor's front-end registers (e.g., at Requestor's gas stations or food vendors, or via the Requestor's website); (iii) to purchases of services (e.g., travel); (iv) where prohibited by legal or regulatory restrictions; (v) on certain other categories as determined from time to time at Requestor's discretion.

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.

B. Analysis

With respect to Medicare beneficiaries, the Arrangement, under which Premium Members earn awards, including awards based on their pharmaceutical Cost-Sharing Amounts, potentially implicates the CMP prohibiting beneficiary inducements, as well as the anti-kickback statute. However, for the reasons set forth below, we conclude that the Arrangement presents a minimal risk of Federal health care program abuse, and we would not seek to impose administrative sanctions in connection with the statutes discussed above.

1. The CMP

We begin with the application of the CMP to the facts presented. The threshold question is whether the reward of [percent redacted (less than 5%)] of the amount a Premium Member spends that year on purchases, including Part D pharmaceutical Cost-Sharing Amounts, constitutes remuneration to the Premium Member who receives it. We treat the reward, which potentially can be worth between $10 and $500 (if a Premium Member spends between [dollar amounts redacted] at the Warehouses in a year), as remuneration.

The next question under the CMP is whether the Arrangement is likely to influence Premium Members to select Requestor as their provider of items or services payable by Medicare or Medicaid. On the facts presented, we believe this is unlikely. First, we look for a direct tie between the annual reward and the purchase of prescription drugs or other Federally payable items or services. The Arrangement does not tie the annual reward to the purchase of prescription drugs or other Federally payable items or services, and the [percent redacted (less than 5%)] reward formula does not vary based on the

types of products purchased. Premium Members need not buy any prescription drugs to earn their reward, and the availability of the reward is not jeopardized by a Premium Member's decision to obtain prescription drugs or other covered products from another provider. Requestors likely fashioned the annual reward – a program that predated Part D – to influence overall shopping at the Warehouses, and its application to Medicare payable products appears incidental.

Second, in the absence of a direct tie, we look for indicia that the annual reward indirectly influences Premium Members to purchase prescription drugs or other Federally payable items or services at the Warehouses. The [percent redacted (less than 5%)] annual reward is unlikely to drive beneficiaries' Federal business to Requestor because the availability of Federally reimbursable products at the Warehouses presents a relatively small opportunity for Premium Members to accrue the annual reward. This is particularly true in a consumer environment that offers an array of merchandise categories as encyclopedic as the Warehouses, where pharmacies likely play a small role in attracting customers.

Finally, Requestor's method of distributing the reward (i.e., once a year, two months after the end of the year upon which the reward is calculated) mitigates the influence that an instant discount at the time of sale could have on Premium Members' decisions to choose the Warehouses as their provider of Federally payable items or services. Accordingly, we conclude that it is not probable that the Arrangement would influence beneficiaries to select the Warehouses as their provider of pharmaceuticals or other covered items or services.

Having determined that the Arrangement is unlikely to influence beneficiaries to select the Warehouses as their provider of items or services payable by Medicare or Medicaid, we do not reach the third issue under the CMP (i.e., whether the Requestor knows or should know that the Arrangement would be likely to influence beneficiaries' selection of the Warehouses for future items or services). For the reasons noted above, we would not impose sanctions on Requestor under the CMP.

2. The Anti-kickback Statute

For the reasons set forth above, and for the reasons discussed below, we also conclude that the Arrangement poses a minimal risk of Federal health care program or patient fraud or abuse, and would therefore not impose administrative sanctions on Requestor arising in connection with the anti-kickback statute.

First, the Arrangement presents a low risk of steering beneficiaries to the Warehouses to purchase pharmaceuticals or other Federally payable items or services. Beneficiaries who decide to become Premium Members need not buy any prescription drugs or other covered items to earn or maximize their reward, and the availability of the reward is not

jeopardized by a Premium Member's decision to obtain prescription drugs or other covered items from another provider. The reward may be used toward the purchase of nearly all merchandise sold by Requestor, so it does not obligate Premium Members to redeem their rewards for Federally reimbursable products.

Second, the Arrangement appears unlikely to encourage overutilization or otherwise increase costs to Federal health care programs. The relatively minimal, indirect [percent redacted (less than 5%)] annual "discount" on a beneficiary's Cost-Sharing Amount should not vitiate a primary object of the Cost-Sharing Amount, i.e., to foster prudent purchasing.[4] Moreover, beneficiaries still have to pay 100% of the Cost-Sharing Amount up front and will not receive any "discount" until the next calendar year. The annual reward is based on overall purchases of a wide array of consumer goods and is capped at $500 per year; these features reduce the likelihood that the reward will increase costs to Federal health care programs. In addition, the Arrangement – a [percent redacted (less than 5%)] annual reward to Premium Members – includes no features suggesting any inducement to prescribers of Federal health care program items.[5]

Third, while we cannot determine a party's intent, we note that the Arrangement has been in place since 2000, before the existence of the Medicare Part D benefit. Moreover, the Arrangement does not target Federal health care program beneficiaries. These facts, together, suggest that Requestor is not operating the Arrangement to induce beneficiaries to self-refer their Federal program business to Requestor.

Finally, we note that the annual reward more closely resembles an across-the-board price reduction than a kickback scheme. We have long regarded certain across-the-board price reductions as presenting an inducement that is so diffuse that it does not appear intended to encourage a particular buyer to purchase or order a particular good or service payable under Medicare or Medicaid. Such is the case here. See Final Rule: OIG Anti-Kickback Provisions, 56 F.R. 35952, 35977 (July 29, 1991).

For the foregoing reasons, we conclude that the Arrangement poses a minimal risk of Federal health care program or patient fraud or abuse, and would therefore not impose sanctions on Requestor in connection with the anti-kickback statute.

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[4] Discounts applied only to a beneficiary's cost-sharing amount, but not to the Medicare portion of the charge, can implicate the anti-kickback statute as well as the CMP (and do not qualify under the discount safe harbor at 42 CFR 1001.952(h)). However, on the facts presented here, the fact that the annual reward *qua* discount does not inure to the Medicare program does not change the low risk nature of the Arrangement.

[5] We express no opinion regarding any arrangement between Requestor and health care providers or suppliers offering services at the Warehouses.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that 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 letter 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General