DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

[*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 20, 2016

Posted: June 27, 2016

[Name and address redacted]

Re: OIG Advisory Opinion No. 16-07

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a savings card program under which individuals who have prescription drug coverage under Medicare Part D receive discounts on a drug that is statutorily excluded from coverage (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 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, although 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] ("Requestor") markets and distributes [drug name redacted] (the "Drug"), a prescription drug that has been approved by the U.S. Food and Drug Administration for the treatment of erectile dysfunction ("ED"). Requestor states that the Drug is covered by many private insurance plans and also is available under some Federal health care programs, including state Medicaid programs and TRICARE; however, the Drug is statutorily excluded from coverage under Medicare Part D.[1]

Under the Arrangement, individuals who have prescription drug coverage through Medicare Part D ("Part D Beneficiaries") may use a savings card issued by Requestor (the "Card") to receive discounts when they fill their Drug prescriptions, subject to a minimum number of tablets dispensed.[2] To receive a discount under the Arrangement, Part D Beneficiaries must present the Card to their pharmacists along with their Drug prescriptions. The Card allows Part D Beneficiaries to receive discounts on out-of-pocket costs greater than $15, up to a maximum benefit of $75 per prescription, on up to 12 Drug prescriptions.

The Card must be activated online or by telephone before it may be used. To activate the Card, individuals must answer several questions to determine if they are eligible to participate in the Arrangement and, if an individual uses Medicare Part D for prescription drug coverage, the individual must agree not to submit claims for the Drug to their Medicare Part D plan. Requestor, through its affiliate, entered into an agreement with [name redacted] ("Vendor") to implement the Arrangement. Vendor processes pharmacy claims and relies on claims data to detect, in real time, attempted Card use by individuals who are ineligible to participate in the Arrangement. Requestor certified that individuals filling prescriptions for the Drug that are paid for, in whole or in part, by Federal or State

[1] See section 1860D-2(e)(2)(A) of the Act.

[2] While individuals enrolled in commercial insurance plans also use the Card, this opinion is limited to use of the Card by Part D Beneficiaries.

health care programs other than Medicare Part D are not eligible to participate in the Arrangement.[3] Individuals who are enrolled in Medicare Part D may participate in the Arrangement because the Drug is statutorily excluded from coverage under Medicare Part D and such individuals are, in effect, cash-paying customers when filling their Drug prescriptions.

Prescriptions for the Drug may be filled at any pharmacy. Requestor developed and distributes written materials to pharmacies with detailed processing instructions for the Arrangement for different types of coverage. Under the Arrangement, when an individual with commercial insurance fills a prescription for the Drug at a pharmacy, the pharmacy first submits a claim to the individual's primary payor, often leaving the individual responsible for various out-of-pocket costs (e.g., copayments, coinsurance). The pharmacy then submits a secondary transaction to Vendor as a claims processor. Vendor processes this transaction in accordance with Requestor's policies and procedures and further reduces the individual's out-of-pocket costs based on these rules.[4, 5] The individual is responsible for any additional out-of-pocket costs not covered by commercial insurance or the Arrangement.

Requestor's written materials direct pharmacies to process Part D Beneficiaries as cash-paying customers. When a pharmacy submits a cash transaction to Vendor, Vendor processes the transaction as though Requestor were the payor. The Part D Beneficiary is then responsible for any additional out-of-pocket costs that are not covered by the Arrangement.[6] By accepting the Card when dispensing a prescription for the Drug to a Part D Beneficiary, the pharmacist certifies that he or she has not submitted and will not submit a claim for reimbursement for the prescription to any State or Federal health care program or other governmental program.

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[3] We have not been asked to opine on, and we offer no opinion regarding, this aspect of the Arrangement, including the steps taken by Requestor or Vendor to exclude such individuals from the Arrangement.

[4] Vendor compensates the pharmacy for the amount of the discount and invoices Requestor on a monthly basis for the aggregate amount of discounts for which it compensated pharmacies.

[5] Requestor states that Vendor's contractual obligations require it to process claims submitted using the Card consistent with the Card's terms and conditions, and that Vendor has represented to Requestor that it, Vendor, conducts audits of its claims editing processes to ensure compliance with those terms and conditions.

[6] Requestor certified that Part D Beneficiaries are informed when activating the Card that out-of-pocket expenses incurred using the Card cannot be applied towards Medicare Part D true out-of-pocket (TrOOP) expenses.

Requestor certified that it does not, and will not, use or arrange to use the Arrangement as a vehicle to market other products it manufactures, markets, or distributes to Federal health care program beneficiaries. Requestor further certified that it is not pursuing, and has no plans to pursue, any additional indications for the Drug, and that no clinical barriers prevent Part D Beneficiaries from switching from the Drug to any other medication approved for the treatment of ED.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully 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. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); 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.[7]

[7] 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 program 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. Generally speaking, pharmaceutical manufacturers are not "providers, practitioners, or suppliers" for the limited purposes of section 1128A(a)(5), unless they also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or

B. Analysis

Under the Arrangement, Requestor offers and provides coupons, in the form of the Card, to Part D Beneficiaries to defray the cost of the Drug. As we observed in our Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons (Sept. 2014), (the "Bulletin") available at: http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf, copayment coupons constitute remuneration that is offered to consumers to induce the purchase of specific items. When the item in question is one for which payment may be made, in whole or in part, under a Federal health care program (including Medicare Part D), the anti-kickback statute is implicated.

Copayment coupons may induce the purchase of federally payable items in two ways. First, as described in the Bulletin, copayment coupons may induce the purchase of the specific items that are the subject of the coupons by reducing or eliminating Federal health care program beneficiaries' out-of-pocket costs for those items. Second, copayment coupons may induce the Federal health care program beneficiaries who receive them to purchase other federally payable products manufactured, marketed, or distributed by the manufacturer that issued the coupon. We address each manner of inducement in turn and, for a combination of the following reasons, conclude that the Arrangement presents no more than a minimal risk of fraud and abuse under the anti-kickback statute.

First, the Arrangement does not induce the purchase of a specific item for which payment may be made by Medicare Part D. Although the Card reduces Part D Beneficiaries' out-of-pocket costs for the Drug, and therefore induces its purchase, Requestor operates the Arrangement entirely outside of the Medicare Part D benefit. Requestor takes measures to ensure that claims for the Drug are not submitted to Medicare Part D plans by contractually requiring the Vendor to use claims data to detect attempted Card use by ineligible individuals, by requiring Part D Beneficiaries to agree not to submit such claims, and by instructing the pharmacies that fill the Part D Beneficiaries' prescriptions to treat them as cash-paying customers. These measures are not infallible, and normally might be insufficient to allow us to conclude that the Card cannot be used to purchase an

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other entities that file claims for payment under the Medicare or Medicaid programs. Requestor certified that it does not 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. The Arrangement is not expected to steer beneficiaries to any particular pharmacy or any other particular provider, practitioner, or supplier. Thus, in these circumstances, section 1128A(a)(5) is not implicated by the Arrangement.

item for which payment may be made by Medicare Part D.[8] However, the unique circumstances presented by the Arrangement allow us to conclude that the Drug is not payable by Medicare Part D, because the Drug is statutorily excluded from coverage. Consequently, even if an ineligible individual used the Card, or a Part D Beneficiary, or a pharmacy filling a Part D Beneficiary's prescription, submitted a claim to a Medicare Part D plan for the Drug, the claim would be denied. This statutory exclusion serves as an effective backstop that prevents Requestor's coupon program from inducing the purchase of a drug payable by Medicare Part D.

Second, we believe that the risk the Arrangement induces Part D Beneficiaries to purchase other federally payable products manufactured, marketed, or distributed by Requestor is low, because Requestor certified that it does not, and will not, use or arrange to use the Arrangement as a vehicle to market other products it manufactures, markets, or distributes to Federal health care program beneficiaries.

For the combination of reasons set forth above, we conclude that the Arrangement presents no more than a minimal risk of fraud and abuse under the anti-kickback statute. We stress, however, that this advisory opinion is limited to whether the Arrangement presents no more than a minimal risk of fraud and abuse under the anti-kickback statute. We express no opinion as to whether the Arrangement complies with any other Federal or state laws.

III. CONCLUSION

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

[8] A recent OIG study found that the types of safeguards Requestor uses may not prevent all copayment coupons from being used for drugs paid for by Medicare Part D. See Manufacturer Safeguards May Not Prevent Copayment Coupon Use for Part D Drugs, OEI-05-12-00540, September 2014.

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 by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- 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 (or that provision's application to the Medicaid program at section 1903(s) 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 that is part of the Arrangement 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General