



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: December 12, 2019

Posted: December 17, 2019

[Name and address redacted]

Re: OIG Advisory Opinion No. 19-06

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a supermarket's proposal to expand its current loyalty program to allow customers to earn rewards points on out-of-pocket costs paid in connection with pharmacy purchases (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute 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 Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Proposed 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”) 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. 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 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”) operates over 200 supermarkets in [states redacted] under various names. All of the supermarkets sell groceries and other incidentals, and approximately half of the stores operate in-store, full-service pharmacies. Requestor currently offers a loyalty program under which customers earn one reward point (“Point”) per dollar spent on purchases, subject to certain exclusions¹ (“Qualifying Purchases”). In particular, customers may not earn Points on any out-of-pocket costs for pharmacy items or immunizations (“Pharmacy Products”). Customers may redeem Points as dollars off future purchases at Requestor’s stores but cannot redeem Points for cash or Pharmacy Products. The Points expire on the last day of the month 90 days after the applicable purchase date. For example, Points awarded for a purchase made on January 21st would expire on April 30th.

¹ In addition to the exclusions that are the subject of this opinion, Requestor’s terms and conditions provide a list of other non-qualifying purchases, including, but not limited to, alcohol, lottery tickets, tobacco, postage stamps, and gift cards. See [Program name redacted] Terms & Conditions, [https://www. \[name redacted\].com/\[program name redacted\]-terms-conditions](https://www.[name redacted].com/[program name redacted]-terms-conditions) (last visited November 7, 2019).

Under the Proposed Arrangement, Requestor would expand the loyalty program such that out-of-pocket costs for Pharmacy Products, including Pharmacy Products covered by Federal health care programs, would be Qualifying Purchases. The Proposed Arrangement would not, however, expand the loyalty program to permit customers to redeem Points on out-of-pocket costs in connection with Pharmacy Products. Requestor certified that the loyalty program under the Proposed Arrangement would be available on equal terms to all members of the public. In addition, just like the current program,² customers would earn one Point per dollar spent, and Points earned on out-of-pocket expenditures on Pharmacy Products would be subject to the same restrictions as Points earned on other Qualifying Purchases. For example, Points earned on Pharmacy Products would be subject to the same expiration policy as Points earned on other Qualifying Purchases and would not be redeemable for cash or the purchase of Pharmacy Products. In addition, while the aggregate number of Points a customer could earn on Qualifying Purchases would not be limited, Requestor certified that it would limit the number of Points any customer could earn on Pharmacy Products to 6,750 Points per calendar year,³ which is the equivalent of \$75 off purchases in Requestor's stores.

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. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v.

² Requestor noted that it sometimes runs promotions that allow for multipliers (e.g., double Points for certain products). Requestor would not offer multipliers on out-of-pocket expenditures on Pharmacy Products.

³ Requestor certified that it is able to track when Points are earned on Pharmacy Products and that the software would not award a person more than 6,750 Points for the purchase of Pharmacy Products in a calendar year.

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 \$100,000, imprisonment up to ten 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 “Beneficiary Inducement CMP”) provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration 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 for the order or receipt 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 the Beneficiary Inducement CMP as including “transfers of items or services for free or for other than fair market value.” The definition of “remuneration” includes a number of exceptions, including an exception for certain retailer rewards, as discussed in more detail in section II.B, below.

In addition, the OIG has taken the position that incentives that are only nominal in value are not prohibited by the statute and currently interprets “nominal in value” to mean no more than \$15 per item or \$75 in the aggregate on an annual basis.⁴

⁴ See, e.g., Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88,368, 88,394 (Dec. 7, 2016); “Office of Inspector General Policy Statement Regarding Gifts of Nominal Value To Medicare and Medicaid Beneficiaries,” available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf>. We note that, despite Requestor’s proposal to limit the number of Points a customer can earn on Pharmacy Products, the amount of Points a customer could earn in a year on Qualifying Purchases in the aggregate could exceed \$75 in value and thus would not be “nominal in value.”

B. Analysis

The Proposed Arrangement, under which Requestor would expand an existing loyalty program to permit customers to earn Points on Pharmacy Products, including any cost-sharing amounts paid in connection with items covered by Federal health care programs, would implicate both the Beneficiary Inducement CMP and the anti-kickback statute. However, the Proposed Arrangement would satisfy the terms of the exception to the definition of remuneration related to retailer rewards and, for the combination of the reasons described below, would pose a low risk of fraud and abuse under the anti-kickback statute.

1. The CMP

The Proposed Arrangement would implicate the Beneficiary Inducement CMP because the Points earned by purchasing Pharmacy Products—which could result in discounts on other purchases at Requestor’s stores—could induce a beneficiary to select Requestor as his or her supplier for federally reimbursable items or services. However, section 1128A(i)(6)(G) of the Act includes an exception for certain retailer rewards programs. Under this exception, retailer rewards do not constitute “remuneration” under the Beneficiary Inducement CMP if: (1) the rewards consist of coupons, rebates, or other rewards from a retailer; (2) the rewards are offered or transferred on equal terms available to the general public, regardless of health insurance status; and (3) the offer or transfer of the rewards is not tied to the provision of other items or services reimbursed in whole or in part by the Medicare or Medicaid programs.⁵ The rewards under the Proposed Arrangement would meet all of these criteria.

First, Requestor operates supermarkets with in-store pharmacies that sell items directly to the public. On the basis of such sales, Requestor would allow customers to earn rewards—in the form of Points—for their Qualifying Purchases. Thus, the rewards would consist of coupons, rebates, or other rewards from a retailer, as required by the first prong of the exception.

Second, the expansion of the loyalty program to allow customers to earn Points on out-of-pocket costs for Pharmacy Products would be offered on equal terms to all customers at Requestor’s supermarkets. That is, any customer could earn Points on their out-of-pocket expenditures on Pharmacy Products, and those Points would be subject to the same limits and restrictions on redemption, regardless of health insurance status.

Third, the offer or transfer of the rewards under the Proposed Arrangement would not be tied to the provision of other items or services reimbursable in whole or in part by the

⁵ See also paragraph (7) under the definition of “remuneration” in 42 C.F.R. § 1003.110.

Medicare or Medicaid programs. In fact, Federal health care program beneficiaries could not redeem Points on Pharmacy Products (nor could they redeem such Points for cash); thus, there would be no tie to federally reimbursable items on the “redeeming” side of the transaction. Furthermore, we find no tie to the provision of other items or services reimbursed in whole or in part by the Medicare or Medicaid programs on the “earning” side of the rewards transaction. Although the Proposed Arrangement would allow Federal health care program beneficiaries the opportunity to include out-of-pocket costs in connection with Pharmacy Products with the rest of their Qualifying Purchases to earn Points, the purchase of Pharmacy Products would not be required, nor would Points earned on Pharmacy Purchases be subject to any increased reward value as compared to any other Qualifying Purchase (i.e., any item not reimbursable by Federal health care programs) in Requestor’s stores.

2. Anti-kickback Statute

The Proposed Arrangement also would implicate the anti-kickback statute because allowing customers to earn Points by purchasing Pharmacy Products, which can be redeemed in the form of discounts on other purchases at Requestor’s stores, is remuneration that could induce a beneficiary to purchase federally reimbursable items or services from Requestor. Although the Proposed Arrangement would meet an exception to the definition of “remuneration” for purposes of the Beneficiary Inducement CMP, no parallel exception exists under the anti-kickback statute. Therefore, we analyze the particular facts and circumstances of the Proposed Arrangement, and for the following reasons, in combination with the factors set forth above, we conclude that the Proposed Arrangement would pose a minimal risk of fraud and abuse under the anti-kickback statute.

First, the risk that the Proposed Arrangement would steer beneficiaries to Requestor’s supermarkets to purchase federally reimbursable items or services is low. Requestor’s stores are general supermarkets, selling a broad range of groceries and other non-federally reimbursable items. Customers would not be required to purchase any prescription items or immunizations to earn Points, and there would be no specific incentive (i.e., no “bonus” Points) for transferring prescriptions to Requestor’s pharmacies. The Proposed Arrangement simply would allow all of a Federal health care program beneficiary’s out-of-pocket expenditures on Pharmacy Products to be counted equally towards earning Points.

Second, the Proposed Arrangement would be unlikely to result in overutilization or otherwise increase costs to Federal health care programs. Any out-of-pocket costs on Pharmacy Products that would count towards a customer’s rewards would result from prescription drugs already prescribed or recommended immunizations. Moreover, the Proposed Arrangement would not involve a waiver or reduction in any cost-sharing amounts; only the amount actually paid out-of-pocket by a customer would count towards

earning Points, and the customer could not redeem Points on Pharmacy Products (including items or services reimbursable by Federal health care programs).

For the foregoing reasons, we conclude that the Proposed Arrangement would pose a minimal risk of fraud and abuse under the anti-kickback statute and would meet an exception to the definition of remuneration for purposes of the Beneficiary Inducement CMP, and thus, we would not impose administrative sanctions on Requestor under those statutes in connection with the Proposed Arrangement.

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 constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Proposed 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 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. 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 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 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 Proposed

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 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 that is part of the Proposed 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,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs