



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, unless otherwise approved by the requestor(s).]

Issued: January 13, 2022

Posted: January 19, 2022

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 22-01

Dear [Names redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request for an advisory opinion on behalf of [names redacted] (collectively, “Requestors”) regarding the proposed expansion of discount programs for low-income individuals (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the “Act”), as that section relates to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the “Beneficiary Inducements CMP”); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

Requestors have certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Proposed Arrangement, and we have relied solely on the facts and information Requestors provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestors. This opinion is limited to the relevant facts presented to us by Requestors in connection with the Proposed Arrangement. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG would not impose administrative sanctions on Requestors in connection with the Proposed Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and

(ii) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Beneficiary Inducements CMP, the OIG would not impose administrative sanctions on Requestors in connection with the Proposed Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

This opinion may not be relied on by any person¹ other than Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] (“Retailer”) operates a web-based marketplace that sells a wide variety of consumer goods and services to the general public. Retailer’s customers may enroll in [name redacted], which is a membership program (the “Membership Program”) that confers various benefits to members, including free shipping or free expedited shipping for certain goods, video and music streaming services, digital photo storage, and other benefits. The Membership Program is available to the general public for a monthly or annual fee.

[Name redacted] (“Pharmacy”), a wholly owned subsidiary of Retailer, is a pharmacy licensed in [locations redacted]. Pharmacy, through subsidiary entities, currently is enrolled as a pharmacy provider in Medicare Part B and with Medicaid programs in approximately 23 states.² Pharmacy also has entered into participating pharmacy agreements with a number of commercial insurers and pharmacy benefit managers, including those that administer pharmacy benefits for Medicare Part D sponsors, Medicare Advantage plans, and Medicaid managed care organizations. Pharmacy certified that, as part of these relationships, it is in-network with most major Medicare Part D plans.

Individuals enrolled in the Membership Program receive certain benefits with respect to items ordered from Pharmacy. For example, although Pharmacy offers free shipping on all orders, Membership Program members receive free expedited shipping on orders from Pharmacy, which amounts to 2-day shipping rather than Pharmacy’s standard shipping speed of 4-5 days. Membership Program members also are eligible for a prescription savings benefit, which offers discounts on certain brand-name and generic prescription medications to customers who pay out of pocket and purchase such medications from either Pharmacy or other participating pharmacies. Third-party payors, including Federal health care programs, cannot be billed for drugs purchased under the prescription savings benefit, although payors can be billed for covered drugs purchased from Pharmacy that are not eligible for the prescription savings benefit.

¹ We use “person” herein to include persons, as referenced in the Federal anti-kickback statute and Beneficiary Inducements CMP, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

² Pharmacy intends to expand and enroll in additional state Medicaid programs.

A. Overview of Current Discount Programs

Retailer offers two discount programs to low-income individuals: (i) a discount on the monthly fee for the Membership Program, whereby individuals who qualify pay a reduced monthly fee of slightly less than half of the fee charged to the general public (the “Membership Program Discount”); and (ii) discounts on certain food and other grocery items (the “Grocery Discount”). These two programs are collectively referenced herein as the “Discount Programs.” The Grocery Discount is available at no charge to eligible customers regardless of whether they are enrolled in the Membership Program. The Grocery Discount does not apply to items or services sold by Pharmacy. According to Requestors, the Discount Programs were designed to provide lower-income individuals with access to the items and services available in its online and physical stores, including access to discounted food and other grocery items.

Currently, individuals are eligible for the Discount Programs if they can show proof that they are receiving benefits under one or more of the following programs: (i) Supplemental Security Income; (ii) Direct Express Debit Card; (iii) Economic Impact Payment Debit Card; (iv) National School Lunch Program; (v) Low Income Home Energy Assistance; (vi) Tribal assistance; and (vii) State and Federal assistance programs for low-income individuals that utilize an Electronic Benefits Transfer card (such as Temporary Assistance for Needy Families; Women, Infants, and Children; and Supplemental Nutrition Assistance Program). Retailer selected these programs, which all serve low-income individuals, as a straightforward method to identify low-income individuals and verify eligibility for the Discount Programs.

Retailer offers the Discount Programs uniformly to eligible individuals without regard to an individual’s purchasing history, if any, with Retailer or Pharmacy. Eligibility also is not based on an individual’s anticipated future purchases from Retailer or Pharmacy. The Membership Program Discount is advertised to the general public via Retailer’s websites and through advertisements on third-party websites and social media. Retailer advertises the Grocery Discount through a variety of national marketing channels, such as television, online, and direct mail.

B. The Proposed Arrangement

Under the Proposed Arrangement, Retailer proposes to add an additional category of eligibility for the Discount Programs: enrollment in Medicaid.³ Requestors certified that individuals’ Medicaid enrollment information received for the purpose of determining eligibility for the

³ Retailer previously used Medicaid enrollment as a basis for eligibility for the Membership Program Discount beginning in 2018 and the Grocery Discount beginning in 2020, but Retailer suspended the use of Medicaid enrollment to enroll new individuals in both Discount Programs pending the issuance of a favorable advisory opinion. Although at present Retailer is not enrolling any new individuals into the Discount Programs based on Medicaid enrollment, individuals who previously qualified for either or both programs based on Medicaid enrollment may remain enrolled in such programs and continue to receive benefits. This advisory opinion addresses only the Proposed Arrangement and does not extend to Requestors’ past enrollment of individuals in the Discount Programs based on Medicaid enrollment.

Discount Programs would be used solely for that purpose. Requestors also certified that they do not and would not track utilization of Pharmacy by individual customers who qualify for either Discount Program based on Medicaid enrollment. The availability of the Discount Programs to Medicaid beneficiaries would not be based on a beneficiary's actual or anticipated purchases from Retailer or Pharmacy. Requestors certified that marketing for the Discount Programs would not be targeted toward Medicaid beneficiaries, although advertisements would specifically state that Medicaid cardholders would qualify for the Discount Programs.

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program.⁴ The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.⁵ For purposes of the Federal 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 is to induce referrals for items or services reimbursable by a Federal health care program.⁶ Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to 10 years, or both. Conviction also will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

2. Beneficiary Inducements CMP

The Beneficiary Inducements 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 beneficiary that the person knows or should know is likely to influence the

⁴ Section 1128B(b) of the Act.

⁵ Id.

⁶ E.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); 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).

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. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value."

The definition of "remuneration" in 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 Inducements CMP if: (i) the rewards consist of coupons, rebates, or other rewards from a retailer; (ii) the rewards are offered or transferred on equal terms available to the general public, regardless of health insurance status; and (iii) 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.⁷

B. Analysis

Retailer currently offers discounts to qualifying low-income individuals in two forms: the Membership Program Discount (including access to free expedited shipping on drugs purchased from Pharmacy and discounts on certain drugs not billed to payors) and the Grocery Discount. Under the Proposed Arrangement, Retailer would expand eligibility for the Discount Programs to individuals who show proof of Medicaid enrollment.⁸ The remuneration Pharmacy would offer and provide to Medicaid beneficiaries who are not otherwise eligible for the Discount Programs under current eligibility categories could induce those beneficiaries to select Pharmacy for the purchase of future drugs, including drugs reimbursable by Medicaid. For example, the availability of free expedited shipping could induce Medicaid beneficiaries to order drugs reimbursable by Medicaid from Pharmacy. Accordingly, the Proposed Arrangement would implicate the Federal anti-kickback statute and the Beneficiary Inducements CMP.

The Proposed Arrangement would not meet any safe harbors to the Federal anti-kickback statute. With respect to the Beneficiary Inducements CMP, the Proposed Arrangement would not meet all conditions of the retailer rewards exception. In particular, the Discount Programs under the Proposed Arrangement would not be offered on equal terms available to the general public, regardless of health insurance status. Rather, it would be available only to individuals who are enrolled in one of a number of programs, including Medicaid. No other exception to the Beneficiary Inducements CMP is applicable to the Proposed Arrangement.

We conclude, nevertheless, that, for the reasons set forth below, the Proposed Arrangement would present a minimal risk of fraud and abuse under the Federal anti-kickback statute, and we

⁷ See also 42 C.F.R. § 1003.110 (paragraph (7) under the definition of "remuneration").

⁸ This opinion is limited to the Proposed Arrangement, which involves expansion of the Discount Programs to Medicaid beneficiaries based on their Medicaid enrollment. This opinion does not opine on remuneration offered to Federal health care program beneficiaries who qualify for the Discount Programs via other eligibility criteria.

would not impose sanctions under the Beneficiary Inducements CMP in connection with the Proposed Arrangement.

First, the nexus between the Discount Programs and a Medicaid beneficiary's potential ordering of drugs from Pharmacy is attenuated. The Discount Programs offer a wide range of benefits, most of which are unrelated to the purchase of prescription drugs. The Grocery Benefit, in particular, is wholly unrelated to Pharmacy purchases. The Membership Program Discount is a discount on the typical monthly fee for the Membership Program, which includes access to free expedited shipping of all drugs ordered from Pharmacy—not just Medicaid-reimbursable drugs. The Membership Program's shipping-related benefits—including free shipping or free expedited shipping—are also available across Retailer's broad array of consumer items. Furthermore, free expedited shipping is just one of many benefits Requestors offer under the Membership Program, which also include video and music streaming and photo storage.

Second, Requestors have certified that the eligibility process is born out of a desire for convenience—both for individuals and for Retailer. The Proposed Arrangement would use Medicaid enrollment as one of multiple proxies for financial need, not as part of an effort to provide remuneration only to Medicaid beneficiaries, and Requestors have certified that they do not and would not track utilization of Pharmacy by individual customers who qualify for the Discount Programs based on Medicaid enrollment. Accordingly, the Proposed Arrangement is distinguishable from suspect arrangements that involve remuneration specifically targeted at Federal health care program beneficiaries.

Third, the Proposed Arrangement is unlikely to result in inappropriate utilization or overutilization of items or services reimbursable by Federal health care programs or an increase in costs to Federal health care programs. Even if a Medicaid beneficiary would be more likely to purchase drugs from Pharmacy in order to take advantage of the free expedited shipping offered to Membership Program members, there is no indication that the free expedited shipping—or any of the other benefits provided under the Discount Programs—would induce beneficiaries to order prescription drugs they would not otherwise purchase. In addition, although the prescription savings benefit offers discounts on certain drugs to Membership Program members, it would not induce overutilization or inappropriate utilization of drugs reimbursable by a Federal health care program because it applies only when customers pay out of pocket.

Fourth, the Proposed Arrangement does not pose a risk to patient safety or raise any quality of care concerns. Rather, the Discount Programs have the potential to provide meaningful assistance to low-income individuals, especially through the Grocery Discount, which could reduce barriers for low-income individuals to obtain affordable food.

Lastly, although the Proposed Arrangement—in particular the availability of free expedited shipping—may factor into a Medicaid beneficiary's decision to purchase drugs from Pharmacy instead of a pharmacy that does not offer this convenience measure, other important factors, including price, location, availability, and medication management considerations, also could inform that decision. Accordingly, the Proposed Arrangement does not present a heightened concern with respect to steering beneficiaries to a particular pharmacy.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG would not impose administrative sanctions on Requestors in connection with the Proposed Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute; and (ii) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Beneficiary Inducements CMP, the OIG would not impose administrative sanctions on Requestors in connection with the Proposed Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Proposed Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.
- This advisory opinion is issued only to Requestors. This advisory opinion has no application to, and cannot be relied upon by, any other person.
- This advisory opinion may not be introduced into evidence by a person other than Requestors to prove that the person did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion 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.
- We express no opinion herein regarding the liability of any person 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 Requestors 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 Requestors 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