

PUBLICATION

Pharmacy Chain's Benefit Program Gets OIG Approval in Advisory Opinion 17-05

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The OIG approved a retail pharmacy chain's proposal to expand its benefit program, which allows participating federal health care program beneficiaries to receive discounts and other benefits when purchasing certain products and walk-in clinic services in its retail stores. In Advisory Opinion 17-05, issued August 30, 2017, the OIG analyzed the benefit program under the civil monetary penalty prohibition against inducements to beneficiaries (beneficiary inducement CMP) and the Anti-Kickback Statute (AKS). The OIG concluded that the program would not constitute grounds for the imposition of a CMP or, absent the requisite intent, sanctions under the AKS.

The Proposed Arrangement

The benefit program is currently available only to non-federal health care program beneficiaries, but the pharmacy chain proposes to allow federal health care program beneficiaries to participate. The benefit program, which provides discounts to enrollees who pay an annual fee, has several key components:

- First, members receive discounts on certain items for which they pay entirely out of pocket – generic drugs, certain other prescription drugs listed on the program formulary, pet prescriptions, immunizations, and certain devices and related supplies.
- Second, members are eligible for a ten percent discount on clinic services for which the member pays entirely out of pocket. Such services would include physicals, immunizations, and health screenings and tests.
- Third, members earn a ten percent credit toward future purchases when they purchase the pharmacy chain's branded products and in-store photo finishing. These credits cannot be used to purchase alcohol, prescriptions, clinic services, immunizations, pre-paid cards or gift certificates, postage stamps, or tobacco products or to cover cost-sharing amounts. They can, however, be used to purchase over-the-counter drugs which, OIG notes, could be purchased using pre-loaded debit cards issued by certain Medicare and Medicaid managed care plans.
- No additional credits, bonuses, discounts, rebates or rewards are offered for transferring prescriptions to any of the chain's retail pharmacies or for receiving services at its clinics. At present, members are also eligible for guaranteed savings in the form of a credit if the total savings achieved over the course of a year do not exceed the annual fee for the program, but the pharmacy chain indicated that this feature will be eliminated by the end of 2017.

Individuals over age 18 may enroll in the program either online or in-store and must pay a fee and provide certain demographic information, but no information is provided or requested regarding insurance status. The terms and conditions of the benefit program require members to be financially responsible for all items and services purchased through the program, although no mechanism exists to prevent a member from submitting a claim to a federal health care program for benefit program services. Medicare Part D beneficiaries may, under the terms of the program, submit claims for prescriptions filled and paid for out-of-pocket during the coverage gap and that such claims would count towards the beneficiary's true out-of-pocket (TrOOP) cost calculation.

OIG Analysis

The OIG first addresses the likelihood that the benefit program would provide remuneration that could induce beneficiaries to select the pharmacy chain for services paid for by federal health care programs. It concludes that the benefit program does not constitute *remuneration* under the beneficiary inducement CMP because it qualifies as "coupons, rebates, or other rewards from a retailer" that are excepted from the definition of *remuneration* under the beneficiary inducement statute (42 U.S.C. § 1320a-7a(i)(6)(G)) and the related regulations finalized in December 2016 (42 C.F.R. § 1003.110).

The OIG made several key determinations with respect to the exception for "coupons, rebates, or other rewards from a retailer." First, the pharmacy chain is a retailer because it sells items directly to the public, that the benefit program's discounts constitute a coupon, and that its credits and savings constitute a rebate, thus satisfying the first prong of the statutory exception to the definition of *remuneration* for "coupons, rebates, and other rewards." Second, the program would be available on equal terms to all individuals over the age of 18 who pay the membership fee, satisfying the second prong of the exception. Third, the discount would not be tied to the provision of any other items or services reimbursed by a federal health care program.

In assessing the program under the third prong of the statutory exception, the OIG notes that, while the program could not ensure that a beneficiary would not submit a claim for services rendered under the benefit program, it believes such claims would be "unlikely" because a "rational economic actor" would only utilize the benefit program to purchase items and services that would cost less than they would cost if purchased using a federal health care program benefit. The OIG also acknowledges that claims could be submitted to Medicare Part D plans that would count towards TrOOP costs during the coverage gap, but notes that beneficiaries would be solely responsible for the costs of the drugs. Such expenditures would eventually lead to a beneficiary qualifying for catastrophic coverage under Medicare Part D, but the OIG identifies this as "a function of the Medicare Part D benefit structure" rather than the benefit program that "does not result in the type of problematic conduct" that the beneficiary inducement CMP was designed to address. Finally, the OIG concludes that, while in certain limited circumstances, the credits accrued under the program could be used to pay for the pharmacy chain's branded items and services reimbursable under Medicare and Medicaid managed care programs that cover over-the-counter medications, the program is structured in a way that does not differentiate or give preference to items and services that could be paid for by federal health care programs and those that could not.

With regard to the Anti-Kickback Statute, the OIG determined that it would not impose administrative sanctions in connection with the program, despite the absence of an exception for such retailer coupon and rebate programs under the Anti-Kickback Statute. First, the OIG notes that the program would not necessarily steer beneficiaries to the pharmacy chain's retail stores or clinics to purchase federally reimbursable services because the retail stores offer a broad range of inventory through which members of the program could accrue credits without purchasing any health care-related items or services. The OIG further noted the absence of specific incentives to encourage members to transfer prescriptions to the pharmacy chain's pharmacies. The program "simply would allow federal health care program beneficiaries access to the ... program's discounts and rebates." Second, the OIG notes that the program would not encourage overutilization or increase costs because an individual would only purchase prescription drugs for which a prescription had already been obtained, claims for items purchased under the program would not be submitted to federal health care programs by the pharmacy chain and program benefits could not be used to waive or reduce any cost-sharing amounts.

Baker Donelson Comments

Advisory Opinion 17-05 is the first to apply the "coupons, rebates, and other rewards" exception to the definition of *remuneration* under the beneficiary inducement CMP since the promulgation of the related regulations in December 2016. While, as with all advisory opinions, the OIG's determination cannot be directly extrapolated to other proposed arrangements, this opinion gives some helpful insight into how the OIG views

the exception as a general matter. It also seems to suggest that arrangements that satisfy the exception to the beneficiary inducement CMP are unlikely to be found to violate the Anti-Kickback Statute, despite the absence of an exception for such retailer coupon and rebate programs under the Anti-Kickback Statute.