PUBLICATION

Discount Drug Program Passes OIG Scrutiny [Ober|Kaler]

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On July 28th, 2014, the Department of Health and Human Services, Office of Inspector General (OIG) released favorable advisory opinion 14-05, concluding that a pharmaceutical manufacturer's direct-to-patient discounted, cash product sales program did not violate the federal antikickback statute (AKS) or the civil monetary prohibition on inducements to beneficiaries (CMP).

Factual Overview

A pharmaceutical manufacturer (Manufacturer) sought approval from the OIG to sell one of its brand name prescription drugs (Discount Drug) directly to patients with a valid prescription, at a discounted price, irrespective of the patient's insurer. While eligible for Part D coverage, the Discount Drug is not covered by a large majority of Part D plans (PDPs) due to the availability of generic equivalents. Moreover, where covered, the Discount Drug is placed on PDP non-formulary tiers with restrictions on coverage and reimbursement.

Enrollment

To enroll, participants must provide a valid prescription for the Discount Drug, identify their insurance (if any), and agree to allow the Manufacture to share information with third parties, as needed, to facilitate the administration of the Discount Drug Program.

Those patients with Medicare Part D insurance must further agree to (1) allow the Manufacturer to send a written notice to their PDP regarding their participation; (2) obtain the product only through the Discount Drug program for the applicable Part D coverage year; (3) not submit any claim for reimbursement for the Discount Drug to any third-party payor; and (4) not include the amounts paid for the Discount Drug in any submission for true out-of-pocket (TROOP) expenses calculations under the PDP.

At the end of each Part D coverage year, the Manufacturer automatically re-enrolls program participants for the next coverage year, unless a participant affirmatively opts out. In the event the Discount Drug Program terminated or participants affirmatively sought to opt out of it, the Manufacturer certified that participants would face no clinical barriers to switching from the product to the product's generic equivalents.

Once enrolled, communications between all participants and the Manufacturer are limited to the Discount Drug Program and its related diseases states. Communications do not extend to other products offered by the Manufacturer.

Online Retail Pharmacy

All participants must purchase the Discount Drug from the Manufacturer's dispensing agent, an online retail pharmacy vendor (Pharmacy). The price of the Discount Drug is at a fixed cash price set by the Manufacturer (which is “substantially lower” than the Manufacturer's whole sale acquisition cost), and is paid by all participants to the Pharmacy. The Pharmacy then collects participant payments and sends the full amount to the Manufacturer.

Communications between participants, participants' physicians, and the Pharmacy are, like that between participants and the Manufacturer, limited. Communications pertain only to order notifications, shipment notifications, and email reminders.

Service Arrangement Agreement

In exchange for the services provided by the Pharmacy, the Manufacturer pays the Pharmacy both a flat monthly fee for operational expenses, and a flat per-transaction fee for each Discount Drug ordered. The Manufacturer also pays a flat, one-time fee for the Pharmacy's start-up costs related to its Discount Drug services. The Pharmacy is prohibited from filing any claim for payment under any federal health care program, and instead must process all participants as cash-paying customers.

The Manufacturer certified that its fee arrangement with the Pharmacy is the product of an arms-length negotiation, that all fees reflect fair market value for the services provided, and that the arrangement does not take into account the volume or value of referrals or other business generated between the parties.

In addition to the above payment terms, the service arrangement between the Manufacturer and the Pharmacy requires the Pharmacy to: (1) segregate all Discount Drugs supplied by the Manufacturer to the Pharmacy for sale; (2) comply with all applicable laws; (3) refrain from offering any inducement to a health care provider to prescribe, or switch participants to, drugs sold by the Manufacturer; and (4) allow the Manufacturer to audit the Pharmacy to confirm compliance with the terms of the agreement.

OIG's Analysis

Civil Monetary Penalties Law

In the Drug Discount Program, participants receive remuneration from the Pharmacy (on behalf of the Manufacturer) via a discount on the price of the Discount Drug. Notwithstanding the discount, and the CMP risk that it presents, the OIG concluded it was unlikely to induce participants to select the Pharmacy to supply other products payable by Medicare or Medicaid because: (1) participants are not required to purchase any items other than the Discount Drug from the Pharmacy; and (2) the Manufacturer certified that it would permit only limited, well defined communications with participants to ensure that the discount does not serve as a vehicle to market other federally reimbursable products that it manufactures.

More specifically, the OIG highlighted the Manufacturer's participant communication policies, which strictly limit Manufacturer and Pharmacy communications with participants to matters concerning or related to the Discount Drug Program. The marketing of other products is expressly prohibited.

Federal Antikickback Statute

Despite finding both the personal service arrangement safe harbor and discount safe harbor inapplicable (due to the per-transaction fee structure and the fact that no claim for payment would be filed with a federal health care program, respectively), the OIG nonetheless determined the arrangement posed a minimal risk under the AKS.

In its analysis, the OIG first highlighted the remuneration provided to participants via a discount on the price of the Discount Drug. However, because the Manufacturer certified that (1) it (and the Pharmacy) would not use the Discount Drug Program as a means to market other federally reimbursable products; (2) in the event the Discount Drug Program terminated, most PDP plans would not cover the Discount Drug; and (3) that no clinical barriers prevent participants from switching to the Discount Drug's generic equivalent, the OIG determined that it was unlikely the purpose of the Discount Drug program was to induce participants to later purchase the Discount Drug with the assistance of federal health care programs.

Secondly, the OIG noted that the remuneration provided from the Manufacturer to the Pharmacy may induce the Pharmacy to arrange for or recommend the purchase of the Manufacturer's other products payable by a federal health care program. However, the OIG's concerns were again addressed by the Drug Discount Program safeguards: (1) all fees in the arrangement between the Pharmacy and the Manufacturer were consistent with fair-market value in an arms-length transaction; (2) all per-fee transactions took into account only those services necessary to dispense the Discount Drug; and (3) both the Manufacturer and the Pharmacy agreed not to offer, promote, or market any of their products or services other than the Discount Drug and the services required to dispense the Discount Drug, in contrast to other problematic carve-out arrangements.

OIG Caveats

Upon concluding that the Discount Drug Program did not run afoul of the AKS or CMP, the OIG noted several unique aspects of the arrangement at issue, stating that it "may have reached a different conclusion" in the event the Discount Drug had no generic equivalents, was covered by more plan formularies, and/or was more generously covered by some PDP plan formularies.

Ober|Kaler Comments

Interestingly, the OIG was unwilling to rely solely on the fact that the arrangement operated outside of the federal health care programs, with no claims filed by the participants or the Pharmacy with any federal health care program. The OIG considered whether the arrangement might have other indirect effects on federal health care programs. Based on a number of factors, the OIG concluded that the arrangement contained sufficient safeguards. Given the particular nature of the arrangement, as highlighted by the OIG's caveats, it seems unlikely that this advisory opinion will have broad applicability.