OIG RELEASES ADVISORY OPINION ON PHARMACEUTICAL DIRECT-TO-PATIENT SALES PROGRAM

EXECUTIVE SUMMARY

On July 28, 2014, the Department of Health and Human Services Office of Inspector General ("OIG") released Advisory Opinion No. 14-05 ("AO 14-05"), addressing one of OIG's favorite foci, federal health care program "carve out" arrangements. AO 14-05 was issued in response to a pharmaceutical manufacturer's ("Company") request for review of its direct-to-patient product sales program ("Arrangement") that allows patients to purchase the Company's brand name prescription drug ("Product") at a significantly reduced price from an online retail pharmacy ("Pharmacy") outside any applicable prescription drug insurance benefit program. The Company specifically requested guidance concerning whether it would be subject to sanctions under the civil monetary penalty provision prohibiting inducements to Medicare beneficiaries ("CMPL") or under the civil monetary penalty provisions applicable to violations of the Federal Anti-Kickback Statute ("AKS"). OIG found that although the Arrangement potentially generates prohibited remuneration under the AKS if the requisite intent to induce or reward referrals payable by a federal health care program were present, it would not impose sanctions. Likewise, OIG would not impose sanctions under the CMPL. A description of the Arrangement and a detailed analysis is set forth below.

THE ARRANGEMENT

The Company manufactures and sells the Product. The Product is technically eligible for coverage under Medicare Part D, but according to the Company: (i) it is not included on most third-party payor formularies due to the availability of generic equivalents (Medicare Part D coverage is immaterial if the particular prescription drug plan elected by a Medicare Part D beneficiary does not include the Product on its formulary); (ii) for those payors that do include the Product, it is placed on non-preferred formulary tiers; and (iii) there are other coverage- and reimbursement-related restrictions imposed on the Product. Thus, for all intents and purposes, individuals wishing to use the Product pursuant to physician orders have very limited access to the Product at a cost that is reasonable.As the Product is not readily available at retail pharmacies or through insurance, the Arrangement allows any patient, insured or uninsured, with a valid prescription ("Participant") to purchase the Product directly from the Pharmacy at a reduced rate. Participants must enroll in the Arrangement via phone, email or mail and are subject to a number of restrictions. For example, they must identify their prescription drug insurance information and permit the Company to share it with third-party payors and CMS, so, for example, payors can perform utilization review and quality insurance functions. With respect to Participants who are Medicare Part D beneficiaries, these Part D Participants must agree to obtain the Product only through the Arrangement for the entire Part D coverage year, must never submit any claim for reimbursement for the Product to any third-party payor (including federal health care programs) nor include any out-of-pocket costs related to purchase of the Product in any submission for true-out-of-pocket ("TrOOP") calculations under a Part D prescription drug plan. The Participant may switch to a generic version of the Product if the Company discontinues the Arrangement. Through these measures, the Arrangement is structured to avoid any payments/subsidies by federal health care programs.The Arrangement operates entirely outside all federal and state health care programs and is set forth under a written agreement between the Company and the Pharmacy. Under this agreement, the Pharmacy is prohibited from: (i) filing any claims for payment with any federal health care program or commercial payor for any Product sold to Participants - all Product-related sales to Participants are for a fixed cash price; (ii) offering any inducement to any health care provider to prescribe or switch Participants to drugs sold by the Company including the Product; and (iii) marketing or promoting any of the *other* products or services the Pharmacy offers to Participants. The Company pays the Pharmacy a combination of certain fixed monthly fees for services such as operating a toll-free customer service number related to the Product and fixed "per transaction" or "per occurrence" fees for Participant enrollment, dispensing, shipping, etc. All fees are set at fair market value pursuant to a third-party appraisal.

ANALYSIS

*The AKS and Remuneration Provided to Beneficiaries*The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce or reward referrals or purchases of items or services reimbursable by a federal health care program.OIG believes the AKS could be implicated in this Arrangement because the Company provides remuneration to patients in the form of a discount on its Product, which could potentially induce patients who are federal health care program beneficiaries to purchase *other* products manufactured by the Company for which payment *may* be made by the federal health care program. In addition, to the extent the discount

induces Participants to "switch" to the Product, and the Arrangement eventually is terminated, the Participant may wish to continue to use the Product and use his/her Medicare Part D benefit or another federal health care program prescription drug benefit to pay for the Product, resulting in increased costs to the federal fisc. Notwithstanding both of these concerns, OIG deemed the overall risk under the AKS to be low for two major reasons:

1. The Company certified that neither it nor the Pharmacy would use the Arrangement to market any other federally reimbursable products.
2. Most Medicare Part D beneficiaries do not have coverage for the Product because their prescription drug plans either offer generically equivalent products or the Product is on a non-preferred formulary tier. Therefore, in OIG's estimation, it seems unlikely *the purpose* of the Arrangement is to induce future (i.e., post-Arrangement termination) purchase of the Product on the federal health care program's dime.

*The AKS and Remuneration Provided to the Pharmacy*Next, OIG was concerned that the remuneration provided by the Company to the Pharmacy could influence the Pharmacy to arrange for or recommend the purchase of the Company's other products for which payment may be made by federal health care programs.Here, again, OIG determined the risks to be low:

1. All fees paid under the Arrangement were set at fair market value in an arms-length transaction, not taking into account the volume or value of any referrals or other business generated between the parties. Further, the per-transaction fees were paid only for items and services necessary for dispensing the Product and were not fees intended for the marketing for other items or services unrelated to the Product.
2. There was no evidence that the remuneration paid by the Company to the Pharmacy was intended to influence the Pharmacy to arrange for or recommend the purchase of the Company's other products. Both the Company and the Pharmacy agreed not to market to Participants items and services other than the Product. The Pharmacy also agreed not to offer inducements to health care providers to prescribe the Product or the Company's other products. Finally, the Pharmacy agreed to allow the Company to audit the Pharmacy to confirm compliance with the Company-Pharmacy agreement.

*The CMPL*The CMPL imposes penalties against any person who offers or transfers remuneration to a Medicare or state health care 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 a state health care program.OIG was concerned that the Pharmacy's Product discount could influence Participant beneficiaries to select the Pharmacy to provide other (non-Product) items payable by Medicare or a state health care program. However, it determined that the Arrangement was low-risk under the CMPL and therefore would not impose any penalties for the following reasons:

1. Participants are not required to buy items other than the Product from the Pharmacy.
2. The Company certified it would not use the Arrangement to market its other federally reimbursable products and also would not allow the Pharmacy to influence or market its other federally reimbursable products to the Participants.
3. The communication to Participants is limited to information on the Product or general advertising to the public.

PRACTICAL TAKEAWAYS

Drug manufacturers, pharmacies and other providers considering similar federal health care program "carve-out" discount arrangements should carefully review AO 14-05 for the numerous fraud and abuse protections built into the arrangement. While OIG is concerned with ensuring that Medicare beneficiaries have access to care (in this case access to a drug that is generally not covered by Medicare Part D), it is equally concerned that the federal health care programs and the Medicare trust fund are protected.AO 14-05 may be found here.If you have any questions, please contact:

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Special thanks to Patrick C. Walsh, Law Clerk, for his contribution to this article.Please visit the Hall Render Blog at

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