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Client Alert

FDA & Life Sciences Practice Group

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OIG Issues Advisory Opinion Regarding Pharmaceutical Manufacturers' Program to Provide Free Limited Drugs to Beneficiaries When Insurance Coverage Is Delayed

On August 12, 2015, the Department of Health and Human Services Office of Inspector General (OIG) posted Advisory Opinion No. 15-11, finding that a program to supply a limited amount of free cancer drugs to federal health care program beneficiaries who experience certain insurance approval determination delays does not warrant enforcement under either the Anti-Kickback Statute ("AKS") or the beneficiary inducement provisions of the Civil Monetary Penalties Statute ("Beneficiary Inducement CMP Statute").[1] The OIG determined that, although providing free drugs to beneficiaries in general "could potentially generate prohibited remuneration," the unique circumstances of the particular program implemented by the manufacturers in this case presented a "low risk of fraud and abuse." Although the OIG's determination is limited to the specific facts and requestors in this case, the advisory opinion provides pharmaceutical manufacturers with important factors to help assess the potential risks associated with developing and implementing free drug programs during new product launches when patients are faced with delays in securing coverage.

Overview of the Free Supply Program

The request for an advisory opinion was submitted by two pharmaceutical manufacturers that co-promote an oral dosage form of a cancer (antineoplastic) drug ("Drug") distributed only through specialty pharmacies. The manufacturers certified that patient response time to the Drug is rapid (first response is generally under two months), and that while other on-label treatments for the cancer treated by the Drug exist, most of these therapies have boxed warnings. Moreover, there is no clinical barrier to switching from the Drug to one of these other therapies at any time.

The manufacturers created a "Free Supply Program" for the Drug, administered by a specialty pharmacy licensed in all 50 states that only fulfills prescription orders pursuant to special programs (and not to the general public outside of those programs). To be eligible for the Free Supply Program, a patient must: (1) be a new patient; (2) have already received a prescription for the Drug; (3) have an on-label diagnosis; (4) be insured by a third-party payer; and (5) have experienced a delay in coverage determination of at least five business days. If a patient meets

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these criteria, his or her prescriber or pharmacy can request the specialty pharmacy to dispense one free 30-day supply of the Drug (the prescriber must issue a new prescription for the sole purpose of dispensing the Drug under the Free Supply Program). If the coverage delay continues, or the patient's insurer denies coverage sometime after the initial five-business-day period and the patient is diligently pursuing an appeal, the patient may be eligible for one 30-day refill of the Drug (for a total of 60 days of product). No additional refills are available under the Free Supply Program.

The Requestors also represented that no patient, pharmacy, or third-party payer is billed by any party for drug dispensed under the Free Supply Program. For Medicare Part D beneficiaries, the specialty pharmacy notifies applicable Part D sponsors that the Drug is being provided to their enrollees outside the Part D benefit, that no part of the Drug's costs should count toward the patient's true out-of-pocket ("TrOOP") costs, and that no claim should be submitted to the Part D plan sponsor for the free Drug. Receipt of the free Drug is not contingent on any future purchases of the Drug or other products of the requesting manufacturers. Moreover, Part D beneficiaries who are prescribed the Drug and decide to continue with the therapy after receiving free product under the Free Supply Program are subject to substantial cost-sharing amounts. It is also important to note that any subsequent prescription of the Drug cannot be filled by the specialty pharmacy administering the Free Supply Program, because it does not service the public outside special programs. In other words, the patient must choose his or her own (different) specialty pharmacy to continue to use the Drug. The manufacturers do not market the Free Supply Program directly to consumers, other than including information about the Free Supply Program on the manufacturers' websites. Information about the Free Supply Program is also provided to health care providers.

The manufacturers certified that, since the Free Supply Program was implemented, only 0.0008 percent of all shipments of the Drug have been shipped to patients under the Free Supply Program (approximately one-third of which went to Medicare or Medicaid beneficiaries). Because Part D sponsors must include all or substantially all antineoplastic drugs on their Part D plan formularies,[2] and are required to notify enrollees of a coverage determination within 72 hours of receiving the request,[3] the manufacturers do not anticipate that the Free Supply Program will be utilized by a significant number of Part D beneficiaries.

OIG Concludes that the Narrowly-Defined Free Supply Program for the Drug Does Not Warrant Enforcement Under the AKS

The AKS 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.[4] Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a federal health care program, the AKS is violated. The OIG determined that the Free Supply Program presents a "low risk" under the AKS for the following reasons:

(1) There is limited risk of overutilization presented by the Free Supply Program because the Drug is an antineoplastic drug indicated for treatment of particular types of cancer, and the Free Supply Program only applies to on-label uses of the Drug. Moreover, patients are eligible for no more than two free 30-day supplies of the Drug, and, if prescribed after that time, the patient would be subject to standard substantial cost-sharing amounts to obtain the Drug (absent qualifying for a patient assistance program).

(2) The Free Supply Program is distinguishable from "seeding" programs in which a manufacturer might seek to induce a patient onto a product by offering free or reduced cost product because the Free Supply Program is not actively marketed to patients and represents only a small fraction of the product's sales. Only 0.0008 percent of shipments of the Drug have been made pursuant to the Free Supply Program, which indicates that patients and prescribers assume that insurance will cover the Drug, and therefore patients will be subject to subsequent cost-

sharing. The Program is only available in the rare cases where insurance approval is delayed, and providing free Drug product is unlikely to influence patients or prescribers to choose the drug over alternative therapies (which are limited and contain boxed-warnings).

(3) Prescribers receive no financial benefit under the Free Supply Program because the Drug is dispensed directly by the specialty pharmacy to the patient.

(4) The Free Supply Program would not induce patients to select the specialty pharmacy for the Drug in the future, because the specialty pharmacy does not service the public outside special client programs. Similarly, the Program is unlikely to induce a federal health care program beneficiary to obtain future prescriptions (for different drugs) from the specialty pharmacy because, again, the specialty pharmacy only dispenses drugs in connection with certain client programs and does not dispense to the general public outside of those programs.

(5) The Free Supply Program entails no cost to federal health care programs, as no patient, pharmacy or third-party payer is billed for the free Drug product. Moreover, the specialty pharmacy notifies Part D plan sponsors if their enrollees receive free drug product, including that it is providing the Drug outside of the Part D benefit, that no parts of the costs of the Drug should be counted toward the enrollee's TrOOP, and that no claim should be submitted to the Part D plan sponsor for the free Drug.

For these reasons, the OIG determined that the Free Supply Program presents a low risk of fraud and abuse and does not warrant enforcement under the AKS. The OIG noted, however, that its conclusions with respect to the AKS were based on the particular facts of this case, and that its conclusions may change if the Free Supply Program is used as a marketing tool for the product or the manufacturer, or is used at a greater rate than would be expected based on typical insurance approval rates. Thus, the OIG expects that the manufacturers will continue to monitor utilization of the Free Supply Program.

The Free Supply Program Does Not Warrant Enforcement Under the Beneficiary Inducement CMP Statute

The Beneficiary Inducement CMP Statute prohibits a person from offering or transferring remuneration to a federal health care program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service reimbursable by a federal health care program.[5] The parties offering remuneration in this case are pharmaceutical manufacturers, which OIG does not consider to be "providers, practitioners, or suppliers" for purposes of the Beneficiary Inducement CMP Statute. The specialty pharmacy, however, is a "supplier" under the statute. The OIG concluded that because the specialty pharmacy does not bill third-party payers under the Free Supply Program, and also does not dispense drugs to the general public, beneficiaries could not select the specialty pharmacy as a supplier for Drug refills payable by federal health care programs. Therefore, because it is unlikely that the Free Supply Program would influence a beneficiary to select the specialty pharmacy to supply other products reimbursable by federal health care programs, the OIG determined that it would not subject the manufacturers to sanctions under the Beneficiary Inducement CMP Statute.

Implications for Pharmaceutical Manufacturers

It is important to recognize that Advisory Opinion No. 15-11 is limited to the specific (narrow) facts and circumstances of the Free Supply Program at issue, as well as the unique qualities of the Drug, which has a rapid response time. As such, significant caution is warranted by manufacturers seeking to offer free drugs to patients.

That said, the advisory opinion offers insight into what OIG would view as important for structuring programs that are low risk for the provision of free drugs when launching new drug products where third-party payer

reimbursement is uncertain or delayed. Notably, OIG seemed to prioritize the fact that timing was of the essence for the Drug in the present case. Other key factors that could impact the potential risk associated with such programs—and which manufacturers should carefully consider—include (1) the risk of overutilization of the drug by federal health care program beneficiaries; (2) whether there is any financial benefit to prescribers of the drug; (3) whether the program uses a pharmacy or other supplier that offers services to beneficiaries outside the particular program; (4) whether the manufacturer markets the program (and if so, how); (5) whether federal health care programs are billed for the free drug; and (6) the degree to which the manufacturer will oversee and monitor the use of the free product. Any free drug program that a manufacturer might develop or that currently exists should be closely analyzed in consideration of Advisory Opinion No. 15-11 to help assess potential risks under the AKS and Beneficiary Inducement CMP Statute.

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King & Spalding LLP regularly monitors and analyzes advisory opinions and other guidance from the OIG related to pharmaceutical manufacturer compliance in reimbursement programs. We also have substantial experience assisting manufacturers with developing beneficiary assistance programs and other initiatives in consideration of OIG guidance and our experience working closely with the Agency. Should you have questions or need additional information or assistance, please contact us.

[1] OIG Advisory Opinion No. 15-11 (August 5, 2015) (a*vailable at*: http://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-11.pdf).
[2] Medicare Prescription Drug Benefit Manual, Chapter 6, section 30.2.5.
[3] Medicare Prescription Drug Benefit Manual, Chapter 18, section 40.2.
[4] Section 1128B(b) of the Social Security Act.
[5] Section 1128A(a)(5) of the Social Security Act.