



August 17, 2015

## **OIG ISSUES ADVISORY OPINION REGARDING FREE DRUG SUPPLY PROGRAM**

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On August 12, 2015, the Office of Inspector General (“OIG”) posted [Advisory Opinion No. 15-11](#) relating to a free specialty drug supply program that allows eligible patients to receive a 30-day supply of drugs without cost in certain circumstances (the “Program”). Pursuant to the Program, patients receive a free 30-day supply (and possibly a free 30-day refill) of a particular specialty drug (the “Drug”) in the event of an insurance approval delay at least five (5) business days long. The OIG declined to impose administrative sanctions in connection with the Program.

The Program involves an antineoplastic drug approved under the FDA’s Breakthrough Therapy Designation, which expedites the development of drugs that are intended to treat serious or life-threatening diseases or conditions and that show early clinical evidence of substantial improvement in such diseases or conditions. 21 U.S.C. § 356. The Drug has a rapid response time and patients may switch to an alternative therapy without significant delay, if that becomes necessary. (In any event, only limited alternatives to taking the Drug exist and most of them have boxed warnings under the FDA regulations. 21 C.F.R. § 201.57(c)(1).)

The pharmaceutical manufacturers requesting OIG’s guidance in this case run the Program with a vendor and a pharmacy that dispenses drugs solely for client programs and not to the general public (the “Pharmacy”). The Program is available to new, insured patients with an on-label diagnosis who have a prescription for the Drug and who experience an insurance approval delay of at least five (5) business days. If a pharmacy to which a prescriber or eligible patient forwards the Drug fails to receive a coverage determination within the five (5) business day period, the pharmacy or prescriber may submit a request to the Pharmacy to dispense a free 30-day supply of the Drug. The Pharmacy receives a fair market value dispensing fee and the patient obtains subsequent prescriptions from the specialty pharmacy of his or her choice. If the delay persists or coverage is denied and an appeal is pending, the patient may receive one (1) free 30-day refill under the Program. No patient, pharmacy or payor is billed for the free Drugs.

The OIG determined that the arrangement has a low risk of overutilization since (i) the patient is not eligible for more than one (1) free 30-day supply of the Drug and possibly one (1) free 30-day refill; (ii) the arrangement is unlikely to influence patients or prescribers to utilize the Drug over any of the alternatives; (iii) the arrangement provides no financial incentives to prescribers; (iv) Program beneficiaries are not likely to be induced to obtain Federally payable prescriptions from the Pharmacy in the future; and (v) Federal health care programs are not responsible for any Program costs.

The OIG concluded that although the Program could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent was present, it has a low risk of fraud and abuse and it fails to warrant the imposition of administrative sanctions.

For more information on OIG Advisory Opinion No. 15-11 or related issues, please feel free to contact any member of the firm's Pharmaceutical Industry and Pharmacy practice group or Health Care Law practice group for further discussion.

**DISCLAIMER:** This Client Alert is designed to keep you aware of recent developments in the law. It is not intended to be legal advice, which can only be given after the attorney understands the facts of a particular matter and the goals of the client. If someone you know would like to receive this Client Alert, please send a message to Deborah A. Cmielewski, Esq., a partner in Schenck, Price, Smith & King's Health Care Practice Group as well as the Pharmaceutical Industry and Pharmacy Practice Group at [dac@spsk.com](mailto:dac@spsk.com).

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