
Patient Support Services and False Claims Act Risks

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What are Patient Support Services?

- Typically equated with Patient Assistance Programs (“PAPs”), which provide financial assistance to patients:
 - assistance with copayments,
 - coinsurance, deductibles, and
 - other health-related expenses.
- PAPs are administered through independent charitable organizations or foundations set up by pharmaceutical companies.

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What are Patient Support Services?

- But patient support services can also include non-financial assistance:
 - One-on-one education;
 - Mentoring programs;
 - Community building; and
 - Tools to manage diseases and navigate finances

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Patient Support Services and the Anti-Kickback Statute (“AKS”)

- The AKS is a broad criminal statute that prohibits one person from “knowingly and willfully” giving (or offering to give) “**remuneration**” to another person if the payment is intended to “**induce**” the recipient to:
 - (1) “refer” an individual to a person for the furnishing, or arranging for the furnishing, of any item or service for which payment may be made, in whole or in part, under a Federal health care program (i.e., a “covered item or service”);
 - (2) “purchase,” “order,” or “lease” any covered item or service;
 - (3) “arrange for” the purchase, order, or lease of any covered item or service; or
 - (4) “recommend” the purchase, order, or lease of any covered item or service.

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Patient Support Services and the Anti-Kickback Statute (“AKS”)

- The AKS prohibits:
 - Drug manufacturers from providing something of value to doctors to recommend or prescribe their products.
 - Drug manufacturers from using “conduits” to make prohibited payments.

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What constitutes a kickback under the AKS?

- Free nurse services?
- White coat marketing?
- Reimbursement support services?
- These are benefits to doctors, but do these payments implicate the AKS?

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Case Study: DOJ moved to dismiss 11 *qui tam* lawsuits in December 2018

- Corporate relators filed FCA lawsuits alleging that **nurse services, white coat marketing** and **reimbursement support services** violated the AKS.

- *U.S. ex rel. SAPF, LLC, v. Amgen, Inc.*, No. 16-cv-5203 (E.D. Pa.)
- *U.S. ex rel. SMSPF, LLC v. EMD Serono, Inc.*, No. 16-cv-5594 (E.D. Pa.)
- *U.S. ex rel. SMSF, LLC v. Biogen, Inc.*, No. 1:16-cv-11379-IT (D. Mass.)
- *U.S. ex rel. NHCA-TEV, LLC v. Teva Pharms.*, No. 17-cv-2040 (E.D. Pa.)
- *U.S. ex rel. SCEF, LLC v. Astra Zeneca PLC*, No. 17-cv-1328 (W.D. Wash.)
- *U.S. ex rel. Miller, v. AbbVie, Inc.*, No. 3:16-cv-2111 (N.D. Tex.)
- *U.S. ex rel. Carle, v. Otsuka Holdings Co.*, No. 17-cv-966 (N.D. Ill.)
- *U.S. ex rel. CIMZNHCA v. UCB, Inc.*, No. 3:17-cv-00765 (S.D. Ill.)
- *U.S. ex rel. Health Choice Group, LLC. v. Bayer Corp., et al.*, No. 5:17-cv-126 (E.D. Tex.)
- *U.S. ex rel. Health Choice Alliance, LLC v. Eli Lilly & Co.*, No. 5:17-cv-123 (E.D. Tex.)
- *U.S. ex rel. Health Choice Advocates, LLC v. Gilead, et al.*, No. 5:17-cv-121 (E.D. Tex.)

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Case Study: DOJ moved to dismiss 11 *qui tam* lawsuits in December 2018

- The DOJ moved to dismiss all 11 lawsuits across the country arguing the claims lacked merit and wasted “scarce government resources.”
 - Allegations “conflict with important policy and enforcement prerogatives of the federal government’s healthcare programs.”
 - The “**provision of educational materials or informational programs to patients**, without more, does not constitute ‘remuneration.’”
- The DOJ seemingly protects services “**providing patients with greater access to product education and support**”

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But may companies provide non-financial patient support services without risk?

- Safe from the DOJ?
- Free from the risk of relator *qui tams*?
 - District courts dismissed 8 of the lawsuits; 2 lawsuits pending hearings on the motions to dismiss
 - But the Southern District of Illinois denied the DOJ's Motion to Dismiss
 - Adopted the "rational relation" test
 - The complaint alleged a "classic violation" of the AKS
 - The DOJ failed to conduct a "minimally adequate investigation"
 - The DOJ may have been motivated by animus for the relators
- Permissible support services or "classic violation" of the AKS?

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Traditional Patient Assistance Programs

- PAPs provide financial assistance to patients in a variety of forms
- PAPs may be administered through independent charitable organizations or by foundations established by pharmaceuticals.
 - often set up as 501(c)(3) nonprofits or charities.
- PAPs can be structured in many different ways:
 - 1) Reimbursement
 - 2) Direct discounts at the pharmacy
 - 3) Free product/product donation

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Recent Enforcement Developments

- In recent years, DOJ has significantly increased focus on pharmaceutical companies' contributions to copay assistance charities.
- Manufacturers have also recently entered into settlements with DOJ to resolve allegations that their donations to patient assistance organizations violated the AKS by defraying patients' co-payment obligations for drugs offered by the manufacturers

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Recent Trends: OIG Rescission and DOJ Enforcement

- November 2017: HHS-OIG rescinded its previous, favorable advisory opinion for Caring Voice Coalition ("CVC")
- OIG asserted that:
 - CVC failed "to fully, completely, and accurately disclose all relevant and material facts to OIG"
 - OIG alleged the charity **"allowed donors to directly or indirectly influence the identification or delineation of [its] disease categories"**
 - OIG alleged the charity gave patient-specific data to one or more donors, enabling donors to **"correlate the amount and frequency of their donations with the number of subsidized prescriptions or orders for their products"**
- Impact of the OIG's rescission?
 - CVC announced it would "not open financial assistance for any disease fund in 2018," and ultimately ceased operations on May 1, 2019.

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CVC Settlements: Actelion Pharmaceuticals

- In connection with the rescission of CVC's advisory opinion, the DOJ announced multiple settlements with pharmaceutical companies
- In December 2018, the DOJ announced a settlement with Actelion for \$360 million to resolve FCA liability in connection with donations to CVC for a pulmonary arterial hypertension fund.
- The government alleged that Actelion:
 - **Routinely obtained data from CVC** detailing how much the foundation had spent for patients on four of Actelion's pulmonary arterial hypertension drugs
 - Used information from the PAP to decide how much to donate and confirm that its contributions were sufficient to **cover the copays of only Actelion's drugs**
 - Had a policy of **excluding Medicare patients** from its free drug program

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CVC Settlements: Jazz Pharmaceuticals

- In April 2019, the DOJ announced a settlement with Jazz Pharmaceuticals in which Jazz agreed to pay \$57 million in order to resolve FCA liability relating to donations to CVC.
- The government alleged that Jazz:
 - **Approached CVC to create a narcolepsy fund** to assist patients with copays associated with Jazz's drug, Xyrem.
 - Acted as the **sole donor** to the fund.
 - Changed the eligibility for its program to in effect **disqualify Medicare patients**.
 - **Increased the list price** for Xyrem by approximately 150% over the relevant time period.
- As part of the settlement, Jazz entered into a five-year corporate integrity agreement ("CIA") with HHS-OIG.

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PAP-Risks Associated with the Anti-Kickback Statute

- HHS-OIG indicated that **directly subsidizing co-payments for patients** enrolled in government healthcare programs presents AKS risk.
- But the HHS-OIG has openly recognized “**the importance of ensuring that financially needy beneficiaries . . . receive medically necessary drugs**, and OIG supports efforts of charitable organizations and others to assist financially needy beneficiaries”
- HHS-OIG suggests a potential safeguard to resolve this conflict: **manufacturers can effectively contribute to the safety net by making cash donations to bona fide, independent charities.**

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OIG’s Special Advisory Bulletins on PAPs

- **OIG’s 2005 Special Advisory Bulletin (“SAB”):** “cash donations to independent, *bona fide* charitable assistance programs” presented “few, if any” AKS concerns.
- **OIG’s 2014 SAB:** praises independent charity PAPs and **cautions against limitations in drug choice** offered by a PAP such as by:
 - Narrowly defining the disease fund or limiting the drug choice which may end up primarily or exclusively funding the products of its donors.
 - Defining patient eligibility for PAP assistance with reference to the cost of a particular drug.
 - Providing donors with information that would permit donors to correlate their donations with the volume of their products supported by the PAP.
- The SABs emphasize that the OIG conducts an **individualized evaluation of all of the relevant facts and circumstances**, including the parties’ intent, to assess AKS liability.

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OIG's Special Advisory Bulletins on PAPs (cont.)

- Key areas of focus for designing a compliant program:
 - Neither the donor nor any affiliate “exerts any direct or indirect influence or control over the PAP”;
 - The PAP awards assistance “in a truly independent manner that severs any link between the donor’s funding and the beneficiary”;
 - The PAP awards assistance “without regard to the pharmaceutical manufacturer’s interests and without regard to the beneficiary’s choice of product, practitioner, supplier, or Part D drug plan”;
 - The PAP provides assistance “based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner”; and
 - The manufacturer “does not solicit or receive data from the PAP that would allow it to link its donations, in frequency or amount, to the number of subsidized prescriptions for its products”

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CVC Settlements: Lundbeck LLC

- April 2019: DOJ announced a settlement with Lundbeck for \$52 million to resolve FCA liability relating to donations to CVC.
- The government alleged that Lundbeck:
 - Was the **sole donor** to a Huntington’s Disease fund at CVC
 - Manufactured and marketed a drug, Xenazine, indicated **only** for treatment of chorea associated with Huntington’s Disease
 - Referred patients with conditions **other than Huntington’s Disease to CVC** for assistance with copays associated with Xenazine
 - Made **unrestricted** donations to CVC for a general fund, to be used for **non-Huntington’s Disease patients** prescribed Xenazine
 - **Excluded Medicare and CHAMPVA beneficiaries** from its free drug program
- Lundbeck entered into a five-year corporate integrity agreement (“CIA”) with HHS-OIG.

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Case Study: Alexion Pharmaceuticals

- April 2019: Alexion Pharmaceuticals agreed to pay **\$13 million** to resolve allegations that Alexion provided financial assistance to patients taking Soliris (costing up to \$500,000 per patient annually) through a PAP.
- Specifically, DOJ alleged that Alexion:
 - **Approached the foundation to create a fund** to financially assist to Soliris patients.
 - Discussed **coverage parameters** for the fund
 - Acted as the **sole donor** to the fund.
 - Tried to make financial assistance to patients **contingent on the patient taking Soliris**.
 - **Excluded Medicare patients** from its in-house free drug program.
- Alexion was not required to enter a corporate integrity agreement because it made "sweeping and fundamental organizational changes following the bad conduct."

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Questions?

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