Helping Hands?
Current Issues with Co-pay Cards, Coupons and Patient Assistance Programs

Seth H. Lundy
King & Spalding LLP
Washington, DC
(202) 626-2924
slundy@kslaw.com
Overview of Presentation

• What are Co-pay Card and PAPs?
  — The common thread between Patient Assistance Programs (PAPs), Co-pay cards and Coupons

• Government Scrutiny
  — Tension between helping patients and increasing sales or market share (of government program patients)
  — Why are these forms of assistance getting more attention now?
  — Recent government issuances, developments and compliance issues with
    — Charity PAPs
    — Co-pay Cards and Coupons

• Practical Considerations
What are Co-pay Cards and Coupons?

- Co-pay cards and Coupons
  - Any form of direct support offered by manufacturers to insured patients to reduce or eliminate out-of-pocket expenses for prescription drugs
  - Common forms of support: coupons (print or electronic), debit cards, direct reimbursements
  - Usually offered without regard to ability to pay
  - Most manufacturers exclude federal (and some state) health care program beneficiaries
What are PAPs?

- PAPs
  - Patient assistance in the form of free product or reimbursements for co-pays or deductibles for indigent patients or patients who cannot otherwise afford their medications
  - Focus on uninsured or underinsured patients who cannot afford their prescribed medications
  - Two types of PAPs:
    - Manufacturer-Run PAPs
    - Third-Party Charity PAPs Based on Manufacturer Funded Donations/Grants
• Natural Tension – Commercial vs. Charity
  — Co-pay programs and PAPs are generally commercially-driven activities
    — Developed, supported and funded by sales and marketing
    — One purpose is to sell product, gain market share, encourage patient loyalty
  — Co-pay programs and particularly PAPs are intended to expand access to patients and allow patients to afford expensive lifesaving products
    — Often involve charitable donations
    — Patient ability to pay is a key factor
    — Address unmet patient needs

• Legal Implications
  — Inducement to beneficiaries under federal Anti-Kickback Statute (AKS)
  — Interference with private payor-patient contact
  — Appearance of anticompetitive, exclusionary conduct that violates federal antitrust laws
PAPs: Benefits of Charitable Support

• OIG Guidance

“We accept that the majority of donors who make contributions to tax-exempt organizations and the majority of tax-exempt entities that solicit or accept donations – including donors and recipients with ongoing business relationships with one another – are motivated by _bona fide_ charitable purposes and a desire to benefit their communities. . . . A business relationship between a donor and recipient does not make a tax-deductible donation automatically suspect under the AKS. On the other hand, a donation made for the purpose of inducing the recipient to refer Federally payable business to the donor would violate the Anti-Kickback Statute, regardless of whether the donation was direct or passed through an intermediary.”

- OIG Advisory Opinion 10-19 at 6–7
Government Scrutiny

• Legal Implications
  — While the charitable/beneficial component of the programs are recognized and encouraged, the commercial aspects of these programs create legal risk:
    — Potential for illegal inducement to beneficiaries under the federal Anti-Kickback Statute or similar state laws
    — Potential for illegal inducements to prescribing physicians
    — Possible tortious interference with private payor-patient contacts
    — Appearance of anticompetitive, exclusionary conduct that violates federal antitrust laws
Patient Assistance in the Spotlight

• October 22, 2013 Article on Seeking Alpha Financial Website

— Focuses on arrangement between a major independent, charitable patient assistance foundation and a pharmaceutical company donor to the charity PAP

— Raises questions about patient assistance generally

— Characterizes donations as a way to increase sales for manufacturers

— Calls into question existing OIG guidance as a “loophole” protecting improper payments

— Note that the author had an undisclosed financial position at stake in trying to sell short the donor’s stock
Patient Assistance in the Spotlight

• Seeking Alpha Article (Cont’d)
  – Key issues raised: PAP allegedly used as a conduit for payments from manufacturers to their own patients that is otherwise prohibited by the Anti-Kickback Statute
    – Foundation is a very sizable charity receiving millions of dollars in annual donations
    – “Co-pay assistance donation dollars are largely solicited from pharmaceutical and biotech companies whose expensive drugs are then purchased with those same donations.”
  – 80% of the donations came from just two pharma companies
  – Questioned whether the foundation is sufficiently transparent as a charity (i.e., at its donors and how donations are spent)
  – Degree of independence of the foundation and board
    – Focus on related services and consulting agreements of directors and managers
  – Co-operation of an Assistance Fund and a pharmacy
  – Propensity of single-drug funds
    – Ability to direct donations toward coverage for a donor’s products
Patient Assistance in the Spotlight

• Seeking Alpha Article was picked up on and followed by several major news outlets, including:
  
  — New York Times:

  Shake-Up at Big Co-Pay Fund Raises Scrutiny on Similar Charities

  By ANDREW POLLACK
  Published: December 18, 2013

  — Barron’s:

  Too Close for Comfort?

  By BILL ALPERT | MORE ARTICLES BY AUTHOR

  Drug company Questcor is both a donor and a beneficiary of a fast-growing medical charity. That could give investors aches and pains.

• These and other articles raise similar concerns in the mainstream media
Updated Guidance: 2014 OIG Supplemental Special Advisory Bulletin (SAB)

- Issued May 21, 2014 and published in the May 30, 2014 Federal Register
- Updates the OIG’s November 7, 2005 SAB
- Response to public criticism of charitable PAPs published in SeekingAlpha, New York Times, Barron’s, etc.
- Reiterates positions from the 2005 SAB, but narrows it
- Takes positions that are contrary to Advisory Opinions already provided by OIG
  - Disallows certain assistance programs that were previously approved, such as those focusing on only high-cost specialty pharmaceuticals
  - Mandates the inclusion of biosimilars and generics
  - Limits the way that charitable disease funds can be structured to try to limit the channeling of pharma company donations towards their own patient bases
Key Differences Between the 2005 SAB and the 2014 SAB

2014 Supplemental SAB and supplemental guidance:

- The foundation must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries’ drug choices.
- Foundations may not artificially define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of a donor’s particular products.
- Disease funds may not be defined by reference to specific symptoms, severity of symptoms, method of administration of drugs, stages of a particular disease, type of drug treatment, or any other way of narrowing the definition of widely recognized disease states.
- OIG is unlikely to approve any disease fund that covers only one drug (whereas previously such funds could be operated in “rare circumstances”).
- Disease funds must not be limited to high-cost or specialty drugs.
- Patient assistance must be available for all products, including generic or bioequivalent drugs, covered by Medicare when prescribed for the treatment of the disease states covered by the fund (includes biosimilars and generics).
Post 2014 SAB Actions by OIG

• Simultaneous to the issuance of the 2014 SAB, OIG sent letters to all patient assistance foundations that had previously received favorable OIG Advisory Opinions.

• OIG will require new certifications from all such foundations in order to continue the favorable Advisory Opinion.

• Certifications will need to be aligned with the updated 2014 SAB requirements, which may require changes to operations.

• Failure to make a certification does not mean that the foundation is operating in violation of the law, but would prevent the foundation from having an approved Advisory Opinion.

• OIG is seeking similar (if not the same) certifications from all foundations and wants the entire industry to comply with the same requirements.

• For purposes of the certifications, OIG is reconsidering some of its new guidance, such as “stage of a disease”
Key Developments

- All patient assistance foundations with favorable OIG Advisory Opinions are in current dialogue with OIG regarding the new certifications.
- As long as the dialogue remains open, the current Advisory Opinions remain in effect.
- There is no time table for this process.
- OIG has indicated that its primary concerns and focus are on the manufacturers that provide the donations, rather than the foundations that administer them.
- New Advisory Opinions are likely forthcoming soon.
Keys for Compliance

- Have an independent, bona fide charitable organization interposed between the manufacturer and patients in a manner that effectively insulates beneficiary decision-making from information attributing funding or benefit to any manufacturer so that any donation is (1) unlikely to influence selection of provider, practitioner, supplier, product, insurance plan and (2) sufficient diffused among products of multiple manufacturers

- The independent charity should have:
  - A truly independent Board of Directors overseeing all policy-making functions, including determinations of eligibility requirements, disease funds served, and program requirements
  - No conflicts of interest in the way of other financial relationships with the donor/manufacturer
  - A structure to ensure that no donor or donor affiliate may exert in/direct control over the organization and its programs (organization has absolute, independent, and autonomous discretion as to use of contributions)
  - Policies to ensure that assistance based on reasonable, verifiable, uniform measure of financial need applied in consistent manner on a first-come-first-served basis
  - Policies in place to ensure that donors are not be provided with any data that would allow donor to correlate amount or frequency of donations with frequency of use of that donor’s products or to determine other donors or donor amounts
  - Disease funds that are defined in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products

- In other words, the charity must be able to assert that it is without influence from any manufacturer’s commercial operations or interests

- Manufacturers must take care not to create inferences of influence or connections with the charity
Co-pay Cards and Coupons

— Parallel to the PAP developments, related issues have been developing with regard to co-pay cards and coupons

— Co-pay cards and coupons are a common business response by manufacturers (typically branded) to respond competitively to efforts by insurance companies to steer their enrollees to certain drugs they deem to be “less expensive” to control healthcare costs by the use of drug formularies

— Arrangements can potentially raise antitrust and unfair trade practice issues
Co-pay Cards/PAPs – Antitrust

- Antitrust arguments by insurance companies and generic drug companies
  - Co-pay cards and PAPs are mechanisms deployed by branded drug companies to prevent/impede generic entry by paying consumers not to buy generic drugs
  - Subsidies are offered when faced with generic drug competition
  - These actions demonstrate that branded drug manufacturers are not interested in competing on the merits but rather to impede the success of lower cost generic alternatives
Co-pay Cards/PAPs – Litigation Results

— To date, recent efforts by private plaintiffs to stop conduct through civil litigation have not been successful.

— No evidence of any interest by the FTC or the Antitrust Division of DOJ.

— Even if the FTC lacks interest, private lawsuits and the information that becomes publicly available from them interests other federal agencies, such as OIG.
Co-pay Cards/Coupons - Fraud and Abuse

• Private antitrust litigation and facts learned from those failed cases increased OIG interest

• Anti-Kickback Statute (AKS)
  — Provision of co-pay assistance is remuneration
  — Certain drugs covered by Part D
  — No safe harbor
  — Intent?

• OIG has long recognized that co-payment card likely implicate the AKS
  — Notes that cost-sharing (patient co-pay) is important
    — Prudent prescribing by physicians
    — Price competition in marketplace
Recent OIG Issuances

• Two concurrent reports September 19, 2014
• Item from two previous work plans

— OIG Special Advisory Bulletin
  — Pharmaceutical Manufacturer Co-payment Coupons

— OIG Report
  — Manufacturer Safeguards May Not Prevent Co-payment Coupon Use for Part D Drugs
OIG Special Advisory Bulletin (SAB)

— Restates legal risks presented by co-pay coupons under the AKS

— Coupons induce beneficiaries to purchase a drug payable by a federal healthcare program - Medicare Part D

— Carve-outs have not effectively prevented use

— Manufacturers responsible for operating coupon programs in compliance with law

— Manufacturers who fail to “take steps to ensure” that co-pay coupons do not induce the purchase of drugs may be subject to sanctions

— Also “failure to take such steps may be evidence of intent to induce the purchase of drugs paid for by [federal healthcare] programs, in violation of the anti-kickback” statute
OIG Report

- Issued with SAB
- Surveyed 30 manufacturers of the top 100 Part D brand-name drugs with coupons and highest Medicare expenditures
- Assessed effectiveness of safeguards that manufacturers have to ensure that Medicare Part D beneficiaries do not use co-pay coupons
- Key finding:
  - Many of the measures that manufacturers currently undertake to prevent federal beneficiaries from using co-pay coupons are imperfect
The report discussed three findings and potential of safeguards:  
— (1) coupon notices to beneficiaries and pharmacies;  
— (2) claim edits used in pharmacy claim processing; and  
— (3) inability for others to identify coupons
OIG Report

• Coupon Notices
  — All surveyed manufacturers provide carve-out notices to beneficiaries, pharmacists, or both
  — Notices state that co-pay coupons may not be used to purchase drugs paid for by FHCPs
  — OIG findings on patient notice:
    — Patients notices are often difficult to detect – on back of the coupon, on separate printout pages, and/or in small font
    — Patients could manipulate eligibility to obtain coupons (e.g., identify private insurance)
• Coupon Notices:

— OIG Findings on pharmacy notices:

  — Manufacturers did not always provide pharmacists with clear eligibility notices
  — Small fonts used and notices included in other instructions
  — Notice sent via an “alert” had questionable effectiveness -- pharmacists exhibit “alert fatigue” given the volume of warnings they receive

— In sum:

  — OIG concluded that the beneficiary and pharmacy notices they reviewed do not “necessarily stop coupons from being processed to purchase drugs paid for by Federal healthcare programs.”
OIG Report

- **Claims edits:**
  - Most manufacturers have edits in the pharmacy claims transaction system to prevent the use of coupons for drugs paid by Part D
  - Effectiveness of edits imperfect in preventing Part D beneficiaries from using coupons
    - lack of access to data; proxies for Part D enrolment status used instead
    - Implementation errors in claims processing edits (no auditing to verify correct use)
• Inability for others to identify coupons:
  — Coupons not transparent to entities other than manufacturers
  — Impedes other entities, including Part D plans, from preventing the use of coupons for drugs paid for by Part D
  — Overall difficult for Part D plans and others to determine how often federal beneficiaries have used coupons with drug purchases
OIG Report

• Report asks manufacturers to engage CMS and industry stakeholders to:
  – Find ways to make coupon processing transparent
  – Improve reliability of pharmacy claims edits

• Examples
  – CMS could consider options to facilitate verification of Part D enrollment status before a coupon is proceed
  – Explore possibility of making changes to Part D program to facilitate Part D enrolment verification
OIG Report and SAB: What to Do?

- Review coupon program structure and administration
- Goal: ensure that federal beneficiaries meet co-payment obligations
- Safeguards to consider:
  - More prominent notices to beneficiaries and pharmacies
  - Maintaining consistent eligibility questions across all coupon formats and preventing circumvention;
  - Obtaining certifications from beneficiaries/pharmacists that recipient is not a federal healthcare program beneficiary
Conclusions and Common Threads

- Broad public concerns about patients being able to afford the cost of their (branded) medications
- Broad public and private concerns about various forms of assistance being used to push patients towards higher cost medications
- Both the media and the government are closely watching
- There is a rebuttable presumption that patient assistance is permissible
- Manufacturers must take steps to avoid allowing that presumption to be rebutted
  - Patient assistance generally should be divorced from sales/marketing
  - All forms of assistance must adhere to federal healthcare program requirements
  - Internal (and external) communications and structures should align to the above
Questions?