

The logo for Hogan Lovells, consisting of the name "Hogan Lovells" in a black serif font, positioned to the left of a large, stylized graphic. The graphic is composed of several overlapping, angular shapes in shades of white and lime green, creating a sense of depth and movement. The shapes are arranged in a way that suggests a large, downward-pointing arrow or a stylized letter 'H'.

Current Issues in Patient and Product Support

October 20, 2016

How Did a Perennial Issue Become the “Hot Topic?”

1. Reimbursement Support
2. Patient Assistance Programs
3. Donations to Charitable Foundations
4. Copay Coupons

It is an Election Year

“It is time to deal with skyrocketing out-of-pocket costs and runaway prescription drug prices that are going up...”



“We don’t negotiate the price of the drugs so we’re spending perhaps \$300 to 350 billion more buying drugs from our drug companies...”

The Media Has Made a Connection

- Public scrutiny of patient and product support programs related to high-cost drugs
 - “Drug Coupons: Helping a Few at the Expense of Everyone,” New York Times (October 12, 2016)
 - “Drug coupons may save you money, but they’re keeping prices high. Here’s how.” Washington Post (June 23, 2016)
 - “How Big Pharma Uses Charity Programs to Cover for Drug Price Hikes,” Bloomberg News (May 19, 2016)
 - “Drug Companies’ Patient-Assistance Programs—Helping Patients or Profits?,” New England Journal Of Medicine (July 10, 2014)

And the Government is Pursuing that Connection

- Government scrutiny of patient and product support programs related to high-cost drugs
 - Recent Congressional investigations: Valeant, Turig, Mylan, naloxone manufacturers, among others
 - October 2015 Warner Chilcott settlement
 - Beginning in late 2015, Boston USAO sent subpoenas to over a dozen manufacturers seeking information about their relationships with independent charitable foundations
 - Investigation likely expanding to other patient support activities and hub services
 - HHS-OIG activity
 - Supplemental Special Advisory Bulletin on Independent Charity Patient Assistance Programs (2014)
 - Modified advisory opinions to independent charitable foundations
 - Special Advisory Bulletin on co-pay coupons (2014)
 - August 2016 GAO report on copay coupons for physician-administered (Part B) drugs

Reimbursement Support Compliance Risks

- Could be viewed by government as “remuneration” having **independent value** to a customer
 - Substitute for activities that are part of the customer’s cost of doing business
 - “Free” consulting services for which customers otherwise would pay
- Food, Drug and Cosmetic Act (FDCA) promotional violations
 - Supporting unapproved uses by seeking reimbursement for them
- HIPAA Privacy Rule
 - Disclosure of PHI pursuant to statutorily defined purpose or based on valid patient authorization

OIG Guidance on Reimbursement Support

- **Special Advisory Bulletin on the Practices of Business Consultants (2001):**
 - Abusive practices include suggesting the use of inappropriate billing codes in order to elevate reimbursement, describing methods to avoid detection, adopting a patently unreasonable interpretation of a reimbursement law, regulation, or rule to justify substantially increased reimbursement
- **OIG Compliance Program Guidance for Pharmaceutical Manufacturers (2003):**
 - “[L]imited reimbursement support services in connection with [a manufacturer’s] own products” have “no independent value” and standing alone may not implicate the anti-kickback statute
 - However, when such support is provided “in tandem with another service or program that confers a benefit on a referring provider...the arrangement would raise kickback concerns.”
- **OIG Advisory Opinions: 00-10; 06-16; 08-12**

The Latest Salvo: Warner Chilcott

- In October 2015, Warner Chilcott Sales US pled guilty to a felony health care fraud charge and agreed to pay \$23M in criminal penalties and \$102M in civil penalties
- The global settlement covered two main types of conduct—
 - Promotional payments and gifts to speakers
 - Prior authorization services provided to physicians
 - Sales reps filling out prior authorization requests using “canned” language
 - Unauthorized access to medical records
 - Reps calling insurers and claiming they worked for the physician
- Hub activities part of the Boston USAO investigation of copay charity donations

Patient Assistance via Independent Foundations

- In 2014, OIG issues updated Special Advisory Bulletin re-emphasizing need to sever link between donors and assistance provided by foundations
 - Identifies two types of arrangements that will draw its scrutiny
 - Disease funds **limited to a subset of available products**, rather than all approved products for the treatment of the disease state
 - Disease funds that **cover only one product or the products of a single manufacturer** that is a significant donor to the fund
- Recent advisory and modified advisory opinions clarify OIG's expectations
- Boston USAO investigation

OIG Guidance on Copay Charity Donations

- Grants for patient assistance to *bona fide* independent charity/foundations permissible as long as the foundation—
 - Is **truly independent** and **not influenced** or controlled by manufacturer donors
 - Awards assistance in an independent manner that severs any link between donor funding and the beneficiary
 - Provides assistance without regard to the interests of any donor or the applicant's choice of product, provider, etc.
 - Develops financial eligibility criteria based on “reasonable, verifiable and uniform measure of financial need that is applied in a consistent manner”
- Charities may **provide limited information to donors**, such as aggregate data on the number of applicants and the number of patients receiving assistance
 - Actions by donors to correlate funding with support or their own products implicates the AKS

OIG Advisory Opinion 15-11: Free Drug Program Implications

- Accepts limited “quick start” program that includes federal program beneficiaries
- Exceptional circumstances
 - Second-line cancer drug with breakthrough therapy designation by FDA
 - Alternative treatments have serious side effects and black box warning
- Limited scope and considerable program safeguards, including—
 - Initial prescription, for on-label diagnosis
 - Patient has experienced 5 business day delay in obtaining insurance coverage determination
 - **No active marketing to patients**
 - Very low-volume use of program (0.0008%)
- *“Our conclusions with respect to the anti-kickback statute are based on the particular facts of this Arrangement. **We might reach different conclusion on different facts, such as if the Arrangement were used as a marketing tool or if the Arrangement appeared to be used at a greater rate than would be expected based on typical insurance approval rates.**”*

Copay Coupons: Regulatory Challenges

- Exclusion of FHCP beneficiaries
 - September 2014 OIG report and Special Advisory Bulletin: Warns manufacturers they bear ultimate responsibility to structure and administer coupon programs in compliance with law
 - **Failure to take appropriate steps** to ensure that copay coupons do not induce the purchase of drugs through FHCPs **may be evidence of intent to induce within the meaning of the AKS**
- After HHS confirms ACA exchanges are not FHCPs – and thus not subject to the AKS – CMS discourages cost sharing assistance from “commercial entities” to ACA exchange patients and encourages plans to reject third party payments

GAO Study on Impact of Coupon Use on Part B Spending

- August 26, 2016 GAO issued a report on coupon programs for privately insured patients and their potential impact on Medicare Part B drug spending
 - Report analyzed data on 18 of the 50 highest expenditure drugs under Part B for 2013
 - 19% of patients who used drugs also used a copay coupon, and realized just over \$2,000 in annual savings
 - Part B ASP-based drug reimbursement methodology does not account for direct discounts/rebates to patients
 - GAO found that the ASP for the drugs with coupons exceeds the “effective market price” by **0.7%** on average (~\$69M more in Part B spending in 2013)
 - GAO notes growing use of coupons may make Part B rates “less suitable over time”
 - Recommends Congress consider giving CMS authority to **collect data on drug discount programs** and report on implications to Part B payments



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