

The Anti-Kickback Statute and Marketing

April 2013

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Overview

- The AKS statute and regulations don't tell the whole story
  - Additional Guidance: OIG Opinions & Case Law
  - Very fact-intensive scrutiny
- Recent trends: Internet-based marketing

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Beyond The Statute & Regulations

- Additional guidance/compliance strategies comes from OIG Advisory Opinions & OIG compliance guidance, case law, industry guidance (e.g. Phrma Code)
- OIG oversees fraud, waste, and abuse of federally funded health care programs (e.g. Medicare, Medicaid)
  - Providers submit business arrangements to OIG
    - Analysis of the particular facts presented
    - Opinions apply only to those facts but they provide general guidance for industry

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## OIG Advisory Opinions - Overview

- OIG focuses on services “particularly susceptible” to overutilization (e.g. DME). OIG Advisory Opinion No. 10-14
- OIG focuses on marketing activities involving personal contact with beneficiaries (especially when targeted at elderly, Medicaid patients, & other vulnerable patients). OIG Advisory Opinion No. 08-20
  - door-to-door marketing
  - telephone solicitations
  - direct mailings
  - in-person sales pitches or ‘information’ sessions

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## Relevant OIG Opinions

- “Per-click” or commission-based compensation
  - Marketing \$ awarded based on successful orders of items / services
  - OIG Advisory Opinion No. 98-1 – “percentage based compensation arrangements are potentially abusive ...because they provide financial incentives that may encourage overutilization of items and services and may increase program costs”

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## Relevant OIG Opinions (cont'd)

- Per-click compensation was suspect because:
  - % arrangement created financial incentive, increasing risk of abusive marketing and billing practices
  - Marketing firm had direct contact with physicians and patients
  - No safe guards against fraud and abuse

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## Relevant OIG Opinions (cont'd)

- OIG Advisory Opinion No. 98-10 – if percentage-based compensation doesn't fit into a safe harbor, look for 6 suspect characteristics
  - 1. Compensation based on a % of sales
  - 2. Direct billing of a federal program by the seller for item/service sold by agent/marketer
  - 3. Direct contact b/w the sales agents and referring physicians

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## Relevant OIG Opinions (cont'd)

- 4. Direct contact b/w sales agents and beneficiaries
- 5. Use of sales agents who are health care professionals or in similar position to exert undue influence on purchasers/patients
- 6. Marketing of items/services separately reimbursable by a federal program
  - i.e., services where reimbursement not "bundled" w/ other services

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## Relevant OIG Opinions (cont'd)

- Gift cards for utilizing services
  - OIG Advisory Opinion No. 12-21– FQHC would give grocery gift cards to patients for receiving health screening
    - Letter sent to enrollees offering \$20 gift card in return for going for screening
    - Letters sent regardless of health status
    - Center would not engage in additional promotion or marketing of arrangement

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## Relevant OIG Opinions (cont'd)

- OIG approved
  - Would not lead to higher reimbursements
    - “Medicaid would not change the capitated payments made to the managed care plans based on the nature or number of services the Health Center provides to the Eligible Enrollees”
  - “[A]pparent purpose of engaging beneficiaries and educating them ... so as to improve health outcomes and make best use of resources in connection with capitated managed care plans”

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## Walgreens Settlement

- On April 20, 2012, DOJ announced that Walgreens agreed to pay \$7.9 million to settle allegations of violations of AKS, the CMP Law, and False Claims Act
- Offered gift cards and discounts to encourage customers to transfer their business to the pharmacy.
- Walgreens intended to “carved-out” or prohibited employees from honoring discounts for federal health care program business,
- But in reality, Walgreens:
  - distributed advertisements about discounts and gifts cards to all customers (i.e. mailed to 6.1 million AARP members),
  - encouraged employees to honor the program even when federal health care programs were involved,
  - actually honored the programs when federal health care programs were involved despite disclaimers to contrary.

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## Recent Case Law

- Judicial guidance is sparse
- However, cases tend to show courts will not consider mitigating factors like OIG
  - Will often find that an agreement violates AKS if it does not explicitly fall into a safe harbor
  - Some courts hold OIG opinions only persuasive
    - Not entitled to deference and not binding. See *U.S. ex rel Perales v. St. Margaret's Hospital* (C.D. Ill. 2003)

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## Recent Case Law (cont'd)

- *Zimmer v. Nu Tech Medical* (N.D. Ind. 1999) – percentage-based payment for marketing and distributing orthopedic products violated AKS
  - Fees based on % of receivables from insurance companies
  - Nu Tech was to receive remuneration from Zimmer in return for “arranging for” the purchasing of Zimmer’s products

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## Recent Case Law (cont'd)

- *U.S. v. Miles* (5th Cir 2004) – HHA paid PR firm to distribute info to physicians
  - Physicians would contact firm, who in turn would provide patient info to HHA
  - Firm was paid \$300 for each patient who became a client of HHA
- No AKS violation b/c no evidence that firm had influence on physicians in choosing which agency to refer to
  - Firm was not the relevant decision maker

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## Recent Case Law (cont'd)

- *U.S. v. Polin* (7th Cir 1999)– pacemaker monitoring service paid \$ to a sales rep based on the # of patients rep signed up for service
  - Sales rep in charge of which service provider to contact when patient needed service
    - Thus improperly received remuneration from the monitoring service
  - Note: this runs counter to *Miles*

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## Recent Case Law (cont'd)

- *Medical Development Network v. Professional Respiratory Care* (Fla. Dist. Ct. App. 1996)
  - AKS violated when DME supplier paid marketing firm % of sales from clients contacted by the marketer
- *U.S. v. Robinson*, 11-20645, 2013 WL 57901 (5th Cir. Jan. 4, 2013)
  - bone fide employee safe harbor not met b/c no evidence of regular paychecks, training, or regular office hours
  - Lack of sufficient control over manner and means of work

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## Internet Advertising

- Health care providers are increasingly turning to the internet to market their services
  - Internet Coupon sites
  - Online Ad Hosting Sites
  - Per-Click Advertising arrangements
  - Pay-Per Call / Email Advertising from a Referral Site

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## Internet Coupon Sites

- Groupon / "daily deal" sites offer targeted coupons to customers based on geographic location
- Providers use sites to offer discounts on elective cosmetic procedures (e.g., teeth whitening)
  - These services typically not reimbursable by federal program
  - But more recently offering traditional health care services, (i.e., "check-ups" and physicals from clinics)

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## Internet Coupon sites (cont'd)

- Provider contracts with deal site to offer discounted “comprehensive physicals”
  - Contracts typically stipulate that for every coupon sold, site keeps % of \$ and remits remainder to the physician
- Regardless of invocation of AKS liability, providers must be wary of:
  - State anti-kickback laws (broader than federal h/c programs)
  - State “fee-splitting” laws – prohibition on splitting fees for professional services in exchange for referrals

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## Internet Coupon Sites (cont'd)

- AMA guidance: coupons unethical
- Most state licensing boards prohibit
- OIG concerned prepaid coupons can lead to medically unnecessary services
  - Physicians hesitant to not provide a service if patient had already paid
- Note: some sites have changed fee structure to flat fee, where all \$ from coupons go directly to provider
  - However, does not address OIG’s issue with medically unnecessary treatments

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## Online Ad Hosting Sites

- Online site hosting advertising and coupons but don’t charge fee based on value of coupon
- OIG Advisory Opinion No. 12-02 – providers buy membership to site allowing them to post coupons for services
  - Advertisers also could buy banner ads and pop-ups
  - Coupons and ads directed at patients through zip-code search
  - Site owned by physician but his name would not appear on the site and any providers he refers to would not be allowed to use site

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## Online Ad Hosting Sites (cont'd)

- OIG approved
  - Unlikely physician-owner would refer to any provider who might contract with site
  - Fee set in advance, FMV, and did not take into account value/volume
  - Terms of use of site required advertisers and providers to comply w/ AKS discount safe harbor
  - Lower risk of overutilization b/c end user would not pay \$ for coupon

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## Per-Click Advertising Arrangements

- Provider pays fee to advertiser every time visitor clicks ad for provider
  - Providers pays only when person / potential patient shows interest in services
- OIG Advisory Opinion 02-12 – enrollees in MCO given access to site, operated by a third party, providing drug and behavior compliance programs
  - Company would sell banner ads on the site to providers that participated in the MCO network

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## Per-Click Advertising Arrangements (cont'd)

- Provider would pay per-click fee for every member directed to its website through an ad
- OIG approved
  - Advertising would be clearly marked as such
  - Fee would not fluctuate based on the value or quantity of any subsequent sales transaction

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**Pay Per Call / Email Advertising From A Referral Site**

- Sites charge providers to be listed on the site
- Fee may also be charged for each lead generated through the site
- OIG Advisory Opinion 08-19 – site collected zip-code info from potential patients and directed them to chiropractors
  - Chiropractors paid fee to subscribe to site
    - Set in advance, FMV, and did not take into account whether patients actually utilized services.
  - Fees also paid for each call and email routed through site to chiropractor

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**Pay Per Call / Email Advertising From A Referral Site (cont'd)**

- OIG approved
  - “Minimal risk” of abuse:
    - Site itself not owned by health care providers
    - Marketing did not target federal program beneficiaries
    - Patients not steered to particular subscriber
    - Fees were uniform and did not take into account the value of any subsequent services
    - Patients did not pay to use site

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**Summary**

- Try to fit into a AKS safe harbor
- Stick to the basics -- fair market value, fixed (not variable) comp; not tied to volume or value of federal h/c program business
- Be wary of trying to “carve-out” federal h/c program business
- Personal contact w/ beneficiaries = strong OIG scrutiny
- Be careful with certain providers – e.g., DME
- Marketer shouldn't be relevant decision maker
- Internet: be wary of encouraging overutilization
- Incorporate safe guards

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## Additional Concerns

- Besides AKS, there are other federal and state laws and regulations controlling marketing
  - State fee-splitting & anti-kickback laws
  - FTC regulations control “content” of ads
    - e.g. “Hospital X is the best in the US”
- Professional Codes – e.g., AMA Code of Medical Ethics (unethical for providers to engage in false or deceptive advertising)

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Questions

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