
The Anti-Kickback Statute and Marketing

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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

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

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

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”

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

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

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

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

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”

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.

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)

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

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

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*

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

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

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)

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

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

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

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

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

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

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

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

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

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)

Questions

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