

# You Can't Do What? Legal Guidance for Marketing

Nebraska Healthcare Marketers  
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# Topics

1. Offering marketing inducements to patients
2. Offering or accepting inducements among referral sources
3. Special HIPAA issues in marketing
4. Social media and marketing
5. Risk management issues - did you mean to say that?

# “Marketing”

- All efforts to build an identity in your service area
- Efforts to create demand for goods and services
- Efforts to distinguish your brand, services and results
- Efforts to communicate your story

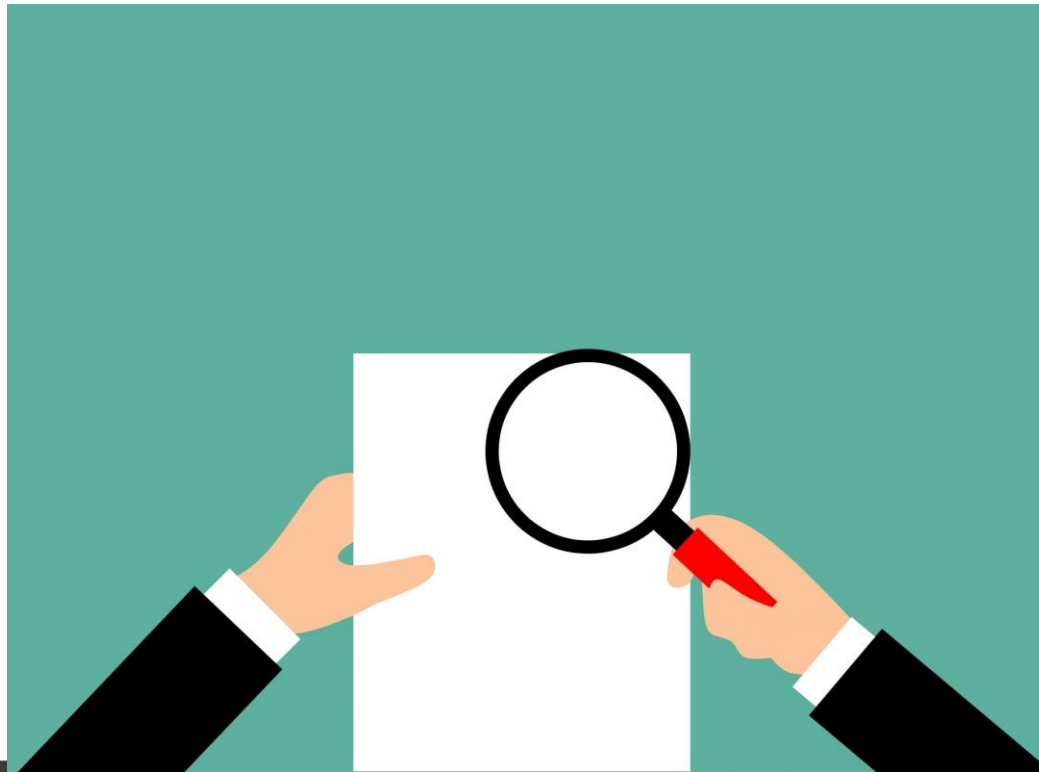
# CMP LAW & PROHIBITION ON BENEFICIARY INDUCEMENTS

# Examples

- 55Plus Club, Silver Circle Club, etc.
- Free Diagnostic Screening Exams
- Health Fairs
- Free Transportation
- Advertised discounts or co-pay waivers
- Newsletters, birthday cards
- Free community education

# Analysis

When multiple benefits are grouped each activity must be analyzed individually-- (55 Plus Club)



# Legal Backdrop

- Civil Monetary Penalty Law (42 USC § 1128A(a)(5))
- Special Advisory Bulletin: *Offering Gifts and Other Inducements to Beneficiaries*, August 2002
  - Updated December 2016
- Numerous OIG Advisory Opinions  
[www.oig.hhs.gov](http://www.oig.hhs.gov)
- Section 6402 of the ACA with some relaxing for screening activities

# CMP: Prohibition Against Beneficiary Inducement

- Civil Monetary Penalty law's prohibition against beneficiary inducement prohibits
  - “offers or transfers to a Medicare or Medicaid beneficiary [of] any remuneration that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services”
- CMPs up to \$10,000 for each wrongful act



# CMP: Prohibition Against Beneficiary Inducement

- The prohibition is limited to Medicare/Medicaid beneficiaries, but be aware of MSP issues
- What about private pay?
  - “Insurance only” billing – insurance companies have taken the position that their obligation is also reduced
  - Managed care contracts may include an affirmation obligation to collect co-pays or deductible amounts
  - Commercial insurers now have program integrity units

# CMP: Permissible Activities

- *Special Advisory Bulletin*
- Sets out principles for application of the prohibitions
  - Medicare/Medicaid beneficiaries may be offered inexpensive gifts (no cash or cash equivalents) or services without violating the statute
    - \$15/75 “Bright Line” rule
    - Tracking is necessary

# CMP: Permissible Activities

- Special Advisory Bulletin (cont'd)
  - More expensive item or service may be offered if within one of five exceptions in the statute:
    - Properly disclosed co-payment differences in health plans
    - Incentives to promote the delivery of certain preventive care/services
    - Any practice permitted under the federal AKS under 42 CFR 1001.952 (safe harbors) or
    - Waivers of hospital outpatient co-pays in excess of minimum co-pay amounts under the Medicare hospital outpatient fee schedule
    - Waivers of cost-sharing amounts based on financial need

# CMP: Permissible Activities

- Special Advisory Bulletin (cont'd)
  - Preventive care: items/services that:
    - Are covered by Medicare **or** Medicaid and are pre-natal or post-natal well baby services or are services described in the current annual edition *Guide to Clinical Preventive Services*  
<https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/clinicians-providers/guidelines-recommendations/guide/cpsguide.pdf>
    - Services may not be in the form of cash or cash equivalents and
  - May not be disproportionate to the value of the preventive care provided

# OIG Advisory Opinions

- Only binding on the parties
- Seek interpretation of how CMP law will be applied to facts
- Anti-kickback statute issues combined for analysis
- Set forth favorable and unfavorable factors
- Arrangements outside of safe harbors seek to maximize favorable facts and minimize unfavorable facts

# Patient Screenings

- Why screening?
  - Free screening can funnel patients for higher priced covered services
  - But screening can have huge health benefits and reduce costs
- AO-01-14: Waiver of co-pay and deductible for certain screening
- AO-04-04: Free vision screening for infants meeting conditions for preventive services
- AO-09-11: Free blood pressure screenings

# Patient Screenings

- Factors in OIG analysis
  - Benefits often flow to uninsured or those who would not otherwise receive it
  - No patient selection based on coverage
  - Free screening not tied to other covered services – sometimes even direct disclosure
  - On balance a public benefit from early detection with little risk
  - Not seen as a marketing initiative – see and structured as mission outreach

# Promotes Access/Low Risk of Harm

- ACA § 6402: Excludes from definition of “remuneration”
  - “[a]ny other remuneration that promotes access to care and poses a low risk of harm to patients and federal health care programs”
- Excludes offer of items/services for below FMV if:
  - Consist of coupons, rebates or rewards from retailer
  - They are offered or transferred on equal terms offered to the public, regardless of health insurance status; and
  - Not tied to provision of other services reimbursed under Medicare or Medicaid



# Promotes Access/Low Risk of Harm

- ACA exception to “remuneration” for “any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs”

# Promotes Access/Low Risk of Harm

- “Care” = items and services that are payable by Medicare or a State health care program
- “Promotes Access” = improves beneficiary’s ability to obtain items and services payable by Medicare or a State health care program”
  - Does not protect rewards for accessing care
  - But could include something that helps a patient comply with a treatment plan

# Promotes Access/Low Risk of Harm

- (1) Be unlikely to interfere with, or skew, clinical decision making
- (2) Be unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization
- (3) Not raise patient safety or quality of care concerns

# ACA

- ACA also excludes offer or transfer of items/services for below FMV if:
  - Not offered as part of an advertisement or solicitation
  - Not tied to provision of other services reimbursed under Medicare or Medicaid
  - There is a reasonable connection between the items and services and the medical care of the individual; and
  - Provided only after “determining in good faith that the individual is in financial need”

# HHH & DME

- Why HHA and DME?
  - Areas of high abuse; but can be critical part of effective discharge planning

# HHH & DME: Good Idea/Bad Idea?

Free safety equipment/pagers  
to hemophilia patients

Free pre-operative in-home  
safety assessment

Free oxygen for patients until  
they qualify for Medicare  
oxygen coverage

Free pre-operative educational  
video on home safety/recovery

Free in-home congestive heart  
failure assessment

Free medical alert  
pagers/monitoring to home  
health patients

# HHHA & DME

- Sec. 1834(a)(17)(A) of SSA
  - Prohibits DME suppliers from making unsolicited beneficiary calls
    - OK if written permission
    - OK if involves a prior item furnished
    - OK if supplier has furnished 1 or more covered items in past 15 months
  - Special Fraud Alert 2003/2010: *Telemarketing by DME Suppliers* – We're watching!

# HHH & DME

- OIG Factors:
  - Look to \$15/\$75 (but not always enough)
  - CMS: telehealth technology (e.g., in-home monitor)  
OK to promote efficiency/quality of care
  - Intrinsic value to the individual patient – what the patient believes is value
  - Is the service widely available from other sources?
  - Will beneficiary select a supplier based on a familiar relationship?
  - Is it marketing or treatment?



# Other Programs

- AO-08-07: \$10 gift cards to hospital patients who experienced poor service
  - Excessive wait time, cancelled appointment, loss of personal items, etc.
  - OIG: arrangement would not constitute “remuneration” – cards not cash/cash equivalents
  - Value not more than \$10 per item/\$50 aggregate per year
  - Redeemable at vendors that do not sell items/services paid by federal health care programs
  - Not redeemable for cash/services provided by hospital

# ANTI-KICKBACK STATUTE

# AKS Analysis

- Anti-Kickback Statute (42 USC § 1128(b)(B))
  - Unlawful to offer or pay (or solicit or receive) any *remuneration* intended to induce a person to refer, recommend or arrange for the purchase of items or services payable under Medicare, Medicaid or a federal health care program.
  - Violation is a felony punishable by a fine up to \$25,000 or imprisonment for not more than five years, or both

# AKS Analysis

- Intent based
- “One purpose” test
- Broad definition of “*remuneration*”
- OIG has published safe harbors
  - Fit a safe harbor if feasible (if not, why not?)
  - Most arrangements do not fit safe harbor
  - Analyze them under the sum of authorities
  - Does the deal make commercial sense without factoring in anticipated referrals?

# Common Relationships & Violations

- Inducement to one in a position to refer, recommend or arrange - Examples
  - Hospitals and physicians
  - Diagnostic centers and physicians
  - Pharmacies and physicians
  - Drug and device mfgs and physicians
  - Drug and device suppliers and physicians
  - Downstream vendors and hospitals

# Marketing Examples

- Free/discounted goods or services in connection with sales
- Price discounts
- Bogus consulting or service contracts
- Bogus research studies and payments
- < FMV rent or charges for referral sources
- Anything of value between referral sources as a “marketing” strategy needs analysis

# OIG Advisory Opinion

- AO-06-16: DME manufacturer offering inducements to DME suppliers
  - Payment or reimbursement of DME advertising expenses
  - Free reimbursement consulting service including claims submission and coding assistance
  - Offered selectively based on volume of orders placed
- Conclusion – arrangement raised anti-kickback concerns

# Identifying Problem Relationships

- Spotting problem deals offered by others is easy
- Spotting our own problem deals can be harder
  - The Christmas fruit basket
  - Free CME to community or outreach physicians
  - Pagers, phones, in-office technology as convenience
  - Free EHR services
  - Participation in beneficial ventures
  - Preferred access to services
- Many outreach activities ok – but spot, stop and analyze first



# AKS Safe Harbors

- Personal services and management contracts
- Referral services
- Warranties
- Discounts
- Price reductions offered to group health plans
- Referral arrangements for specialty services
- Price reductions offered to eligible MCOs
- Price reductions to MCOs by providers at substantial financial risk

# Patient Transportation: Safe Harbor

**Eligible Entity** → Any individual or entity except those that primarily supply health care items (e.g., DME suppliers or pharmaceutical companies)

**Established patients** → Individual has either (a) selected and initiated contact with the provider or services, or (b) has had previous appointments with provider

**Purpose of Transportation** → Must be for the purpose to receive medically necessary services (i.e., no rides to the grocery store, movie theater, or shopping center)

**Modes of Transportation** → Cannot be luxury vehicles, or ambulance-level transportation

# Patient Transportation: Safe Harbor

**Marketing** → Not publicly marketed or advertised; cannot advertise health care services inside the vehicle; it is okay to include name of your facility on outside of vehicle

**Local transportation** → Limited to 25 miles for urban areas and 50 miles in rural areas; measured "as the crow flies"; urban area is one defined as one within an MSA; a rural area defined as non-urban

**No Cost Shifting** → Cannot transfer any costs to a federal health care program

**Shuttle Services** → (1) No luxury/ambulance, (2) Not marketed, (3) limited to same distance requirements for urban/rural areas, (4) Can not shift costs to federal health care programs

# Patient Transportation: Safe Harbor

- Local transportation
  - Eligible entity
  - Established patients
  - Purpose of transportation
  - Need for transportation
  - **Modes of transportation**
  - Marketing
  - “Local” transportation
  - Shuttle transportation
- Effective date January 6, 2017



# STARK LAW

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# Stark Law

- The Stark Law (aka "Ethics in Patient Referral Act") adds technical requirements for physician financial relationships
  - Technical, not intent-based
  - Anything that is *remuneration* for A/K will trigger a financial relationship for Stark
  - List of technical exceptions – relationships must fit an exception
  - If *remuneration* – fit an exception!

# Stark Law

- Remuneration – examples may include:
  - Billing or transcription services for docs
  - Pre-certification performed by hospital
  - Private film storage on hospital PACS
  - Free pick-up and delivery of samples;
  - Off-site training for new hospital technology
  - Info on website for physicians
  - Marketing assistance
- Activity may be ok, but identify and analyze
- Medical staff incidental benefits
- Non-monetary compensation
- Employed or private practice?

# Stark Law: Good Idea/Bad Idea

Listing hospital's non-employed physicians on the hospital's website

Tweet or Facebook post about a new physician hired by the hospital

Another Tweet or Facebook post about a physician's expanded hours on weekends

Promotion for physician's private practice on hospital's website

Joint advertisement promoting both hospital's services and private physician practice's services

Mailer to existing patients of the hospital announcing a new surgeon's start date



# Risk Management

- Misrepresentation of endorsements, affiliations and relationships
  - Many contracts include a prohibition against unilateral use of the other party's name
- Are you conferring benefit (*remuneration*) on physicians by including descriptions of them in your advertising?
  - Whose products and services are you marketing?
  - Who pays?

# HIPAA & MARKETING

# HIPAA Privacy Rule

- HIPAA is comprised of both a privacy and security rule
  - Focus is on the HIPAA Privacy Rule
- Issues include:
  - Using PHI to market to your patients
  - Furnishing PHI to others for their marketing
  - Using PHI in joint marketing
  - Improper disclosure of PHI in marketing

# HIPAA Privacy Rule

- HIPAA Privacy Rule controls access, *use* and disclosure of PHI
  - Internal use needs its own exception
  - Not just a disclosure issue
- Privacy Rule requires an authorization for a use or disclosure of PHI, unless an exception applies
- Analysis of marketing and “marketing-like” activities under HIPAA is quite complex

# Authorization

- No authorization required to use PHI for:
  - Treatment
  - Payment
  - Health care operations (HCOps)
- “Marketing” is none of the above
- Marketing requires authorization
- Issue is to design marketing-like activities so they fall under treatment or HCOps, not marketing

# Defining "Marketing"

- HIPAA defines "marketing" as:
  - "[A] communication about a product or service that encourages recipients of the communications to purchase or use the product or service," (45 CFR § 164.501)
- General rule: If it is marketing, you (most likely) need prior authorization
- Except for:
  - Refill reminders
  - Treatment of an individual\*
  - Case management or care coordination\*
  - \* = unless you receive direct or indirect payment for the communications

# Is an Authorization Needed? Yes or No

Entity provides free package of formula and diapers to new mothers after leaving maternity ward

Hospital communicates via mailer with recent cardiac patients about an unaffiliated cardiac facility providing discounted EKGs

Physician practice sends a refill reminder to a patient

Hospital sends a postcard appointment reminder one week prior to patient's appointment

Provider discusses new product with patient during a face-to-face visit

A telemarketer has approached you about contacting recent orthopedic patients

# Takeaways

- Ask: Is an authorization required?
- Review HIPAA privacy rule's definition of "marketing"
- Visit OCR's HIPAA website for "marketing" and review the FAQs
- Still uncertain? Contact Privacy Officer, Compliance Officer, or legal counsel
- Remember, this evaluation can be complex



# MARKETING & SOCIAL MEDIA

# Social Media

- Social media = interactive electronic communication and display
  - Typically viewed by others
  - Typically generates two-way dialogue
- Use growing dramatically
- Offer tremendous marketing potential
- Carry significant but manageable risks

# Social Media Compliance Challenges

- Can a hospital-sponsored social media account create a hospital-patient relationship?
- What is a hospital's responsibility for volunteered PHI?
- What is hospital's responsibility for quality of advice?
- What is hospital's responsibility for follow through?

# Social Media Compliance Challenges

- Can a physician-sponsored SNS create a physician-patient relationship?
- Can physician interaction on hospital's SNS create a physician-patient relationship?
- Is there physician risk for abandonment?
- Is there physician risk for malpractice?

# Social Media Compliance Challenges

- If a hospital “advertises” on a physician’s social media, is that *remuneration* under Stark?
- What about drug and device companies advertising on physician's social media?
  - “Remuneration” for anti-kickback?
  - Part of Health Reform transparency and does it trigger the annual report?
  - Must vendors track amounts in order to report?

# Social Media Compliance Challenges

- What about pharmaceutical and device companies advertising on physician's social media?
  - “Remuneration” for anti-kickback?
  - “Remuneration” for reporting under ACA?

# MARKETING & RISK MANAGEMENT

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# Risk Management

- You said it – now back it up!
- Public entitled to rely on your statements
- Professional ethics principles against promises, guarantees and excessive puffery
- What you say is the standard against which your conduct will be measured at trial



# Risk Management

- Have you misappropriated another's identity without permission?
  - Use of likeness without permission for commercial purposes
  - There is a recognized right of an individual to protect his/her name, likeness, image, signature, photograph, voice and other distinctive characteristics from non-authorized commercial use by others

# Risk Management

- Neb. Rev. Stat. § 20-202 prohibiting exploitation of a natural person's identity for commercial purposes
  - Protects natural persons, not corporations
  - Consent
- Use of materials contrary to protected copyright, trademark, service mark or other restrictions.

# Questions?

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