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Tomi Hagan, MSN, RN, CHC

Manager, Compliance

Brenda Manning, JD, CHC, CHPC

Privacy and Compliance Consultant

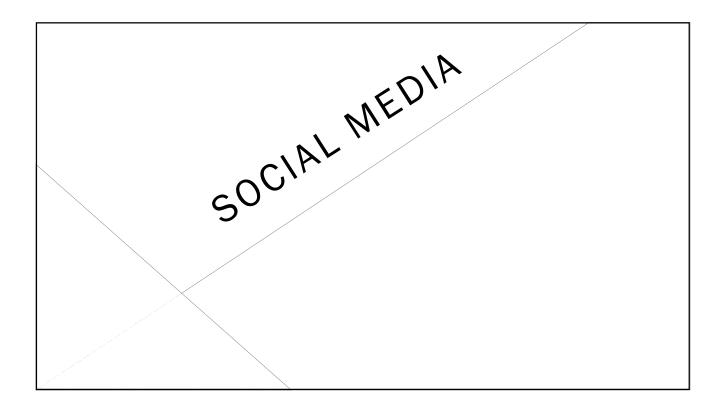
HCCA Compliance Institute

Aria, Las Vegas

April 17, 2018

Describe the role Anti-Kickback Statute and Stark Law in marketing to and for physicians Review inducement considerations for marketing to patients Apply HIPAA regulations to health care marketing Consider how the Culture of Compliance impacts marketing

Reasonable Factual Avoid hyperbole



SOCIAL MEDIA



9/1 S. adults e online 75% 72% of them are active on social media online for h

of U.S. internet users looked online for health info in 2013

A Hospital Leadership Guide to Digital & Social Media Engagement. American Hospital Association. May 2015.

WHO IS USING SOCIAL MEDIA?

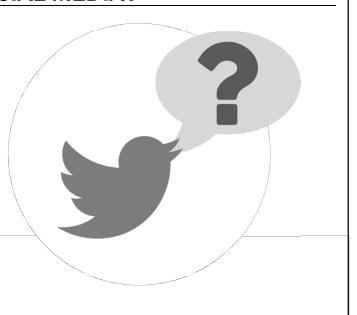


WHY SHOULD WE USE SOCIAL MEDIA?

Wide reach

Inexpensive

Effective marketing tool



WHAT ARE SOME PITFALLS?

Difficult to control

- Negative comments and reviews by public
- Employees personal accounts
- Patient/provider or employee connection



WHAT ARE SOME PITFALLS?

Photography

- PHI in the background
- Using photos without permission
- Policies difficult to enforce



BEST PRACTICES

Policies and procedures

Education and training

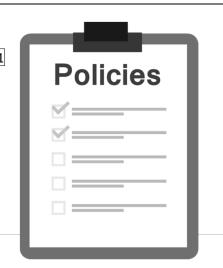
Staff as "Brand Ambassadors"

Monitoring and auditing

Automated reputation management

Administrative control

Official accounts



1 Brenda Manning, 3/5/2018

PHYSICIANS



ANTI-KICKBACK STATUTE

Any intent to induce the referral or purchase of items or services for which payment may be made in whole or in part by a federal healthcare program may implicate the Anti-Kickback Statute



ANTI-KICKBACK STATUTE

If even 1 purpose of an arrangement is to induce or reward referrals, AKS applies

Actual knowledge of AKS or specific intent to commit a violation no longer required per PPACA



AKS SAFE HARBORS

Possible safe harbors for marketing to or for physician:

- Employment
- Personal Services and Management
- Recruitment



PHYSICIAN SELF-REFERRAL (STARK LAW)

When physician or their family member has relationship with entity:

- Physicians cannot refer patients for "designated health services"
- Unless an exception applies
- Entity cannot bill Medicaid or Medicare

POTENTIAL STARK EXCEPTIONS

- Bona fide employment relationship
- Physician recruitment
- Non-monetary compensation under \$407/year
- Medical staff incidental benefits under \$34/occurrence



HIGH RISK ACTIVITIES

Marketing for physicians

Entertainment

Gifts

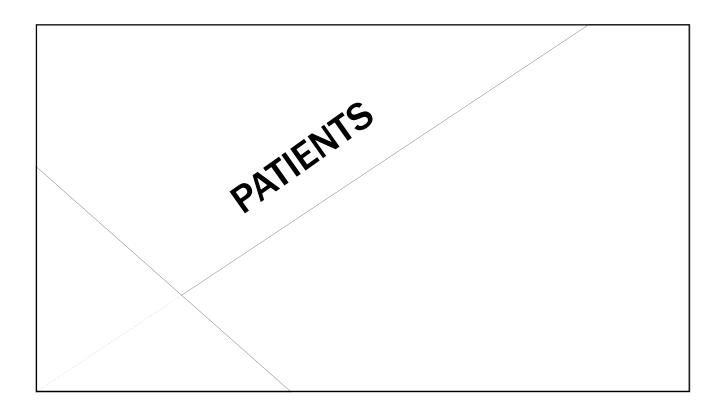
Free equipment/supplies

Recruitment

 Stark Exceptions and AKS Safe Harbors apply, but must meet specific criteria



Exception/Safe Harbors No marketing activity tied to referrals Promoting services provided at hospital vs. marketing physician private practice Legal analysis of individual situations



INDUCEMENTS

OIG Final Regulation & Advisory Opinion (December 2016)

- ACA permits "certain remuneration that poses a low risk of harm that promotes access to care."
- Final regulation establishes more safe harbors in the AKS
- Incorporates ACA mandated exceptions to the definition of remuneration

ACA EXCEPTIONS TO REMUNERATION

Access to Care Exception

Providing free child care may assist a patient by removing a financial barrier allowing the patient to attend a smoking cessation class.

Free movie tickets would not.

LOW RISK OF HARM STANDARD

Low Risk of Harm - if unlikely to:

- 1. Interfere with or skew clinical decision making
- Increase costs to federal healthcare programs or cause over utilization
- 3. Not raise patient safety of quality of care concerns

ACA REMUNERATION EXCEPTION

Financial Need Based Exception

- 1) Item or service is not advertised or solicited
- Not tied to the provision of other services reimbursed by Medicaid or Medicare
- 3) Reasonable connection between the item/service and the individual's medical condition
- 4) Individualized determination of financial need

ACA REMUNERATION EXCEPTIONS

Retail Rewards Programs

- Offered or transferred on equal terms available to the general public regardless of insurance status
- Not tied to the provision of other items or services reimbursed under a federal health care program.

Waiver of copays for covered Part D generic drugs

WHAT DOES OIG ALLOW?

- Gifts of nominal value allowed
- \$15/\$75 aggregate per patient
- No cash or cash equivalents
 - Gift card allowed if can be redeemed at a specific store such as a gas card



BEST PRACTICES FOR PATIENT ENGAGEMENT PROGRAMS

- ✓ Review the safe harbors
- ✓ If no safe harbor, review the Anti-kickback, Civil Monetary Penalty Statutes & State law.
- ✓ Review payer contracts (e.g. waiving copays may violate terms)

HOW DO WE AVOID INDUCEMENT RISK?

Compliance/legal analysis of marketing initiatives

- Health Fair
 - Be careful of giveaways need to meet \$ limit or preventive exception
- Free Screening
 - o Cannot be tied to provision of services by the hospital

Refer to current *Guide to Clinical Preventive* Services to identify exceptions

HIPAA

WHAT IS MARKETING?

A communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

Dear Patient,

We would like to tell you about this amazing new product from XYZ Company...

HISTORY OF MARKETING: HIPAA PRIVACY RULE

1999

- - Face-to-face communications
 - Promotional items / gifts of nominal value (e.g., calendar, pen, toothbrush)



PRE-HITECH EXCLUSIONS FROM MARKETING

"Marketing" does not include communications:

- Describing a health-related product or service provided by or included in the covered entity's plan of benefits
- 2) Made for the treatment of the individual
- 3) For case management, care coordination or to direct or recommend alternative treatments

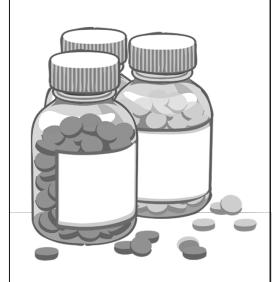
TIGHTENING UP UNDER HITECH

2009

The exclusions on the previous slide, are now prohibited without an authorization *if* the covered entity receives direct or indirect payment in exchange for making the communications.

HITECH PERMITS SUBSIDIZED COMMUNICATIONS

- Without authorization
- To provide refill reminders or otherwise communicate about a drug or biologic
 - Currently being prescribed for the individual
 - But only if the amount paid to the covered entity is reasonable in amount (e.g., printing / postage)



HIPAA OMNIBUS (MEGA RULE) – FURTHER TIGHTENING

2013

Excludes the following from marketing, but only if the CE does NOT receive financial remuneration:

1) Communications for treatment of an individual by a healthcare provider, including case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, healthcare providers, or settings of care to the individual

HIPAA OMNIBUS (MEGA RULE) – FURTHER TIGHTENING

2) Communications to describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: the entities participating in a healthcare provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits; or

HIPAA OMNIBUS (MEGA RULE) – FURTHER TIGHTENING

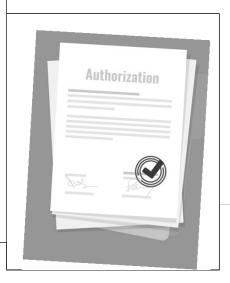
3) Communications for case management or care coordination, contacting of individuals with information about treatment alternatives, and related functions to the extent these activities do not fall within the definition of treatment

AUTHORIZATION

Required for subsidized communications

Must state that financial remuneration is involved

Required element in Notice of Privacy Practices



AUTHORIZATION

Required

 A communication from a hospital informing former patients about a cardiac facility, that is not part of the hospital, that can provide a baseline EKG for \$39, when the communication is not for the purpose of providing treatment advice

Not Required

 A hospital uses its patient list to announce the arrival of a new specialty group (e.g., orthopedic) or the acquisition of new equipment (e.g., x-ray machine or magnetic resonance image machine) through a general mailing or publication

CASE STUDY

A hospital is excited to announce their new surgeon who specializes in a bariatric procedure!

A local newspaper publishes an article about the availability of the surgery, along with photo of the physician performing the surgery, with the abdomen of a draped patient visible.



HIPAA VIOLATION? BREACH?

Did you obtain patient authorization?

If not, does the story content point to a patient?

- # of these types of surgeries performed
- Geographic area
- Other HIPAA identifiers



DE-IDENTIFICATION OF PHI: 18 PATIENT IDENTIFIERS

- 1) Names
- 2) Geographic subdivision smaller than state
- 3) Dates
- 4) Telephone numbers
- 5) Fax numbers
- 6) Email addresses
- 7) SSNs
- 8) MRN's
- 9) Health plan numbers

- 10) Account numbers
- 11)License numbers
- 12) Vehicle identifiers
- 13) Device Identifiers
- 14)Web URLS
- 15)IP addresses
- 16) Biometrics
- 17) Full face photos
- 18)Any other unique identifier

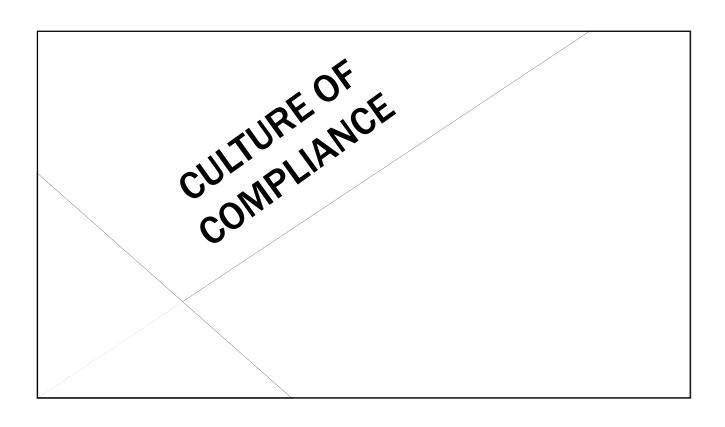
FOUR FACTOR BREACH ANALYSIS

- The nature and extent of the PHI involved, including the types of identifiers and the likelihood of reidentification;
- The unauthorized person who used the PHI or to whom the disclosure was made;
- 3) Whether the PHI was actually acquired or viewed; and
- 4) The extent to which the risk to the PHI has been mitigated.

BEST PRACTICES

- Obtain patient authorization for marketing
- Have an opt out process
- De-identify PHI used in stories or obtain consent
- Be cognizant of other laws
 - CAN-SPAM Act, AKS, State Law







A CULTURE OF COMPLIANCE PERMEATES THE ORGANIZATION 7 Required Elements of an Effective Compliance Program Compliance Officer & Oversight Code of Conduct & Policies/Procedures Education & Training Culture of Compliance 4 Reporting & Communication Monitoring & Auditing 6 Response & Corrective Action Enforcement & Discipline

VIEWING MARKETING THROUGH THE 7 ELEMENTS LENS 1) **Oversight** 1) Responsibility 2) Policies & Procedures 2) Clear guidance 3) Education & Training 3) Awareness 4) Reporting & Communication 4) Mechanism for concerns 5) Monitoring & Auditing Diligence 5) **Response & Corrective** 6) 6) Addressing reported Action concerns and issues 7) Enforcement & Discipline

7)

Laws/Regs and P&P

Questions