OBJECTIVES

- Identify best practices related to social media marketing
- 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
GENERAL GUIDELINES

Reasonable
Factual
Avoid hyperbole

SOCIAL MEDIA
**SOCIAL MEDIA**

9/1 of U.S. adults are online

75% of them are active on social media

72% of U.S. internet users looked online for health info in 2013

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**WHO IS USING SOCIAL MEDIA?**

Patients
Families
Physicians
Employees
Competitors

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
PHYSICIANS

KNOW THE RULES
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
KEYS TO STARK/AKS COMPLIANCE

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
2. Increase costs to federal healthcare programs or cause over utilization
3. Not raise patient safety of quality of care concerns

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**ACA REMUNERATION EXCEPTION**

*Financial Need Based Exception*

1) Item or service is not advertised or solicited
2) 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
  - Cannot be tied to provision of services by the hospital

Refer to current Guide to Clinical Preventive Services to identify exceptions
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
- Authorization required for use or disclosure of PHI
  - Exceptions:
    - 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:
1) 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**

<table>
<thead>
<tr>
<th>2013</th>
<th>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</th>
</tr>
</thead>
</table>

| 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 |

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

<table>
<thead>
<tr>
<th>Required</th>
<th>Not Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 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</td>
<td>• 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</td>
</tr>
</tbody>
</table>

### 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

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**DE-IDENTIFICATION OF PHI: 18 PATIENT IDENTIFIERS**

<table>
<thead>
<tr>
<th>1) Names</th>
<th>10) Account numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>2) Geographic subdivision</td>
<td>11) License numbers</td>
</tr>
<tr>
<td>smaller than state</td>
<td>12) Vehicle identifiers</td>
</tr>
<tr>
<td>3) Dates</td>
<td>13) Device Identifiers</td>
</tr>
<tr>
<td>4) Telephone numbers</td>
<td>14) Web URLs</td>
</tr>
<tr>
<td>5) Fax numbers</td>
<td>15) IP addresses</td>
</tr>
<tr>
<td>6) Email addresses</td>
<td>16) Biometrics</td>
</tr>
<tr>
<td>7) SSNs</td>
<td>17) Full face photos</td>
</tr>
<tr>
<td>8) MRN’s</td>
<td>18) Any other unique</td>
</tr>
<tr>
<td>9) Health plan numbers</td>
<td>identifier</td>
</tr>
</tbody>
</table>
FOUR FACTOR BREACH ANALYSIS

1) The nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification;
2) 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
DOES THE CULTURE OF COMPLIANCE AFFECT THE MARKETING PROGRAM?

YES
A CULTURE OF COMPLIANCE PERMEATES THE ORGANIZATION

7 Required Elements of an Effective Compliance Program

1) Compliance Officer & Oversight
2) Code of Conduct & Policies/Procedures
3) Education & Training
4) Reporting & Communication
5) Monitoring & Auditing
6) Response & Corrective Action
7) Enforcement & Discipline

VIEWING MARKETING THROUGH THE 7 ELEMENTS LENS

1) Oversight
2) Policies & Procedures
3) Education & Training
4) Reporting & Communication
5) Monitoring & Auditing
6) Response & Corrective Action
7) Enforcement & Discipline

1) Responsibility
2) Clear guidance
3) Awareness
4) Mechanism for concerns
5) Diligence
6) Addressing reported concerns and issues
7) Laws/Regs and P&P
Questions