Financial Disclosure

- Associate in the West Palm Beach, FL office for the law firm of Broad and Cassel
Maze of Laws and Regulations

- Federal Trade Commission Act ("FTC")
- Food and Drug Cosmetic Act ("FDA")
- Health Insurance Portability and Accountability Act of 1996 ("HIPAA")
- Federal Anti–kickback Statute ("AKS")
- Federal STARK Laws ("STARK")
- CAN-SPAM
- State Laws
  - Fee Splitting laws
  - Consumer Protection laws
  - "Mini" STARK, HIPAA and AKS laws
  - Professional Rules and Regulations

Navigating the Minefield

Consequences for failure to Comply

- Professional discipline · Loss of licensure
- Loss of reputation
- Fines
- Lawsuits
- Jail time

Marketing...what is it?

Generally, the regulations govern the overall practices of a medical provider

- Advertisements (in any media)
  (Any Form of Self Promotion)
  Social Media
  - Blogs
  - Webpages
- Patient Consultations
- Patient Reward Programs and Discounts
- Lead Generation
- Employee Bonus Programs
FTC - General Overview

Federal Trade Commission Act allows the FTC to prevent deceptive and unfair acts or practices.

An act is Deceptive if it is likely to mislead patients and affects the patient’s behavior or decisions about a product or service.

An act is Unfair if the injury it causes is substantial, not outweighed by benefits, and not reasonably avoidable.

FTC - Medical Marketing

Substantiation

All marketing claims regarding health, safety, or performance must be substantiated. Claims must be backed by scientific data supporting such claims.

"Competent and Reliable Scientific Evidence"

FTC and FDA Overlap

The Food and Drug Cosmetic Act gives authority to the FDA to oversee the safety of food, drugs, medical devices and cosmetics.

- The FDA and FTC operate under a liaison agreement under which:
  - the FTC possesses primary enforcement responsibility for claims made in advertising.
  - while the FDA has primary enforcement responsibility for claims made in labeling and packaging.
FTC and FDA Overlap

FTC
Disclosure of Product and Pricing

FDA
Disclosure of Risks and Side Effects

CLEAR AND CONSPICUOUS
- Prominent
- Placement
- Presentation
- Proximity

FDA and FTC
Examples of marketing pitfalls for Refractive Surgery Centers:

Promise of Outcome Results
Claims of Safety
Comparison Claims
Testimonials
Risks and Side Effects

HIPAA and Marketing
HIPAA protects the privacy of individually identifiable patient information and provides for the electronic and physical security of patient medical information.

Privacy Rule sets the standards for:
- How PHI should be controlled,
- What information is PHI,
- Who is authorized to access, use, or disclose PHI, and
- What processes must be in place to control the access, use, and disclosure.

The Security Rule sets the standards for:
- Basic security safeguards to protect electronic PHI, and
- Who has access to electronic health information and how to protect it from accidental or intentional disclosure.

The standards include administrative, technical, and physical safeguards.
What is Marketing under HIPAA

1) Any “communication about a product or service that encourages recipients of the communication to purchase or use the product or service”
2) The sale of PHI to a third party

Generally marketing requires consent
- Examples:
  - Any marketing of third party services by the healthcare provider to its patients.
  - Any marketing by a third party using PHI (regardless of how PHI was obtained).

What is NOT Marketing under HIPAA

3 exceptions to Marketing rule

Communications made:
- by a provider regarding its own products or services
- for the treatment of the individual, or
- for case management/care coordination for the individual
  - to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual

Examples of Marketing Programs that may implicate HIPAA

- Social Media Campaigns
- Groupon Advertisements
- Lead Generation Agreements
Federal Anti–Kickback Law

Anti–Kickback Statute 42 U.S.C. § 1320a–7(b)

- Prohibits the knowing and willful payment of “remuneration” to induce or reward patient referrals or the generation of business involving any item or service payable by the Federal health care programs.
  - “Remuneration” includes anything of value.
  - Focus on intent of the parties.
  - Intent can be on one or both sides.
  - If even one purpose of an arrangement is to induce or reward making or arranging for referrals, the arrangement is tainted.
  - Penalties of up to $50,000 per kickback.

- There are over 30 “safe harbors” under the Anti–Kickback Law, each with detailed compliance requirements.

Examples of Marketing Programs that may implicate the AKS

- Patient Referral Programs
- Optometrist Referral Programs
- Pay–per–Click Lead Agreements
- Percentage Based Marketing Agreements

Federal STARK Law

Prohibits physicians from referring patients to receive “designated health services” payable by Medicare or Medicaid from entities with which the physician or an “immediate family member” has a “financial relationship,” unless an exception applies.

- Immediate Family Members include:
  - Husband or wife,
  - Birth or adoptive parent,
  - Child,
  - Sibling,
  - Step-parent, step-child, step-brother, or step-sister,
  - Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law,
  - Grandparent or grandchild, and
  - Spouse of a grandparent or grandchild.

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STARK Law DHS

"Designated Health Services" include:
- clinical laboratory services;
- physical therapy, occupational therapy, and outpatient speech-language pathology services;
- radiology and certain other imaging services such as ultrasound A and B scans;
- radiation therapy services and supplies;
- durable medical equipment and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services not independent ASC services.

STARK Law Financial Interest

"Financial Interest" is defined as:
- direct ownership interest,
- indirect ownership interest,
- investment interest, or
- compensation arrangement.

Untangling the chain of indirect financial interest and compensation agreements can be confusing! When in doubt seek legal guidance.

Marketing Programs that may implement STARK

1. Are you a DHS Entity? (e.g., hospital, multi-specialty group)
2. As a result of the marketing activity/arrangement, does a referring physician receive something of value from a DHS entity?

Marketing to DHS entity e.g., IDTF, radiology practice, hospital, multi-specialty group/marketing/partnering/collaborating efforts focusing on referring physicians.

- Practice/hospital providing entertainment or other benefit (e.g., lunches, etc.) to a referring physician
- Joint marketing agreement between non-employed physician and hospital
- Transportation offered to referring doctor’s patients
Marketing Programs that do NOT implicate STARK

Marketing to:
- Patients
- Non-Physician referral sources
- Stark defines "physician" as MD, DO, DPM, a doctor of dental medicine, a doctor of optometry, or a chiropractor
- Marketing for non-DHS entity business

CAN-SPAM Act

The CAN-SPAM Act sets the rules for commercial email, establishes requirements for commercial messages, and gives recipients the right to have you stop emailing them.
- Applies to "any electronic mail message the primary purpose of which is the commercial advertisement or promotion of a commercial product or service"
  - Specific "To," "From," and "Subject" Requirements
  - Notification of Advertisement
  - Location
  - Opt-Out
- The "seller" is liable for acts violations of marketing companies
- Penalties of up to $16,000 per occurrence

State Laws

Fee Splitting Laws
- Most states have enacted fee splitting laws that prohibit the division of physician fees
  - Statute
  - Medical Board/ Optometry Board Rules
  - Case Law
Penalties range from professional discipline to fines, to possible criminal charges and vary from state to state
State Laws

**Consumer Protection Laws**
- Most states have enacted mini FTC laws that protect citizens from false advertising
  - May impose more stringent limitations on advertising the FDA and FTC,
  - Often include a "private right of action," and
  - Often include "attorneys fees" provisions.

State Laws

**State Mini HIPAA, STARK and AKS Laws**
- Several states have implemented laws similar to federal laws
  - May impose more stringent limitations than federal counterparts,
  - May be more broadly applied,
    - Not limited to federal payers
    - Not limited to DHS (or broader definition of DHS)
    - Not limited to "covered entities" for privacy concerns
  - May include elective procedures and impose liability on non-physicians and non-medical entities.

Social Media

Several components of regulation over Social Media
- HIPAA
- FDA/FTC
- State Laws
Social Media

Challenges with Social Media Advertising Compliance
- Character Restrictions
- Interactive Nature
- Control

Social Media FDA Guidance

Character Spacing and Disclosure of Benefits vs. Risks and Side Effects??

DEAL WITH IT!
- Regardless of space restriction if you claim a benefit— you must disclose the risk
  - Can include a link to a more detailed risk information
  - Most severe risk should be disclosed in ad directly
- Benefit information must be accurate

If you can’t conform with disclosure requirements within the spacing limits— don’t use this form of media

Social Media FDA Guidance

Examples

Twitter
Nofocus for mild to moderate memory loss; may cause seizures in patients with a seizure 377 disorder www.nofocus.com/risk [77/7/40]

Google
Handout [9/9]
www.handout.com [27/38]
For severe headcount from traumatic brain injury [47/70]
Periodic (1/1/12) Earning [3/2/2]
Life-threatening drop in heart rate [19/27] Important safety information [18/35]
A Word about Daily Deals

Voucher System, patient "pre-pays" for the service at a discount.

Areas of Concern:
- Fee for Voucher Company typically a percentage of total fee for services
- Typically requires a "verification" the patient received medical services
- Several state medical boards have issued advisory opinions

Questions ????

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