

Marketing Traps for Healthcare Providers



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Overview

- Fraud and abuse laws
 - Stark
 - Anti-kickback statute
 - Civil monetary penalties laws
 - State laws
- HIPAA
- Telemarketing
- False and deceptive marketing
 - Medical practices acts
 - Consumer protection laws
- Marketing limits for certain providers
- Suggestions



Preliminaries

- **Written materials**
 - .ppt slides
 - *OIG Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse*
 - *OIG Supplemental Compliance Program Guidance for Hospitals*
 - *OIG Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries*
 - Client Alerts re fraud and abuse issues.
- **Written materials are available per the webinar instructions or contact me at kcstanger@hollandhart.com.**
- **The program will be recorded and available for download at www.hhhealthlawblog.com.**
- **Submit questions per chat function or contact me at kcstanger@hollandhart.com.**

Preliminaries

- This is an overview of some relevant laws relevant to providers.
 - Additional state or federal laws may apply.
- Application may depend on specific facts.
 - govt v. private payors
 - Type of provider
- Law is fluid and often ill-defined in a certain situation.

Fraud and Abuse Laws



Fraud and Abuse Laws

DANGER

Marketing techniques that are acceptable in other industries may be illegal in the healthcare industry!

Fraud and Abuse Laws

- Federal fraud and abuse laws
 - Anti-Kickback Statute (“AKS”)
 - Ethics in Patient Referrals Act (“Stark”)
 - Civil Monetary Penalties Law (“CMPL”)

Apply if govt programs involved (e.g., Medicare, Medicaid, etc.).

- Patient is govt program beneficiary.
- Item or services payable by govt program.

- State fraud and abuse laws
 - Anti-Kickback Laws
 - Self-Referral Laws
 - Fee Splitting
 - Patient Brokering
 - Others

May apply to:

- Govt programs.
- Private payors.

** Check your state law.*

Ethics in Patient Referrals Act ("Stark") (42 USC 1395nn)

- *Applies if marketing physicians or their family members or giving them anything of value.*
- If a physician (or their family member) has a financial relationship with an entity:
 - The physician may not refer patients to that entity for designated health services, and
 - The entity may not bill Medicare for such designated health services

unless arrangement is structured to fit within a regulatory safe harbor.

(42 CFR 411.353)

Stark

- **Penalties**
 - No payment for services provided per improper referral.
 - Repayment of payments improperly received within 60 days.
 - Civil penalties.
 - \$15,000 per claim submitted
 - \$100,000 per scheme
- (42 CFR 411.353, 1001.102(a)(5), and 1001.103(b))
- May also constitute Anti-Kickback Statute violation.
 - May trigger False Claims Act.

Stark

- Possible safe harbors for marketing:
 - Employment contract with physician or family member
 - Contractor agreement with physician or family member
 - Contract for items or services provided to physician
 - Incidental medical staff benefits
 - Non-monetary compensation < \$300
 - Recruitment of physician
 - Professional courtesy
 - Others?
- Must satisfy certain conditions for each.

Anti-Kickback Statute

- *Applies if marketing govt program beneficiaries or business.*
- Cannot knowingly and willfully offer, pay, solicit or receive remuneration to induce referrals for items or services covered by govt program unless transaction fits within a regulatory safe harbor.

(42 USC 1320a-7b(b))

- Anti-Kickback Statute applies if one purpose of the remuneration is to induce referrals even if there are other legitimate purposes.

(*U.S. v. Greber*, 760 F.2d 68 (3d Cir. 1985)).

Anti-Kickback Statute

- “The [Anti-Kickback Statute] on its face prohibits the offering or acceptance of remuneration, inter alia, for the purposes of “arranging for or recommending the purchasing, leasing, or ordering of any [...] service or item” payable under Medicare or Medicaid. Thus, we believe that many marketing and advertising activities may involve at least technical violations of the statute.” (OIG Adv. Op. 10-23).

Anti-Kickback Statute

- **Penalties**
 - 5 years in prison
 - \$25,000 criminal fine
 - \$50,000 administrative penalty
 - 3x damages
 - Exclusion from Medicare/Medicaid

(42 USC 1320a-7b(b); 42 CFR 1003.102)
- **OIG Self-Disclosure Protocol: minimum \$50,000 settlement.**
- **Anti-Kickback violation = False Claims Act violation**
 - Lower standard of proof
 - Subject to False Claims Act penalties
 - Subject to qui tam suit.
 - Obligated to repay govt.

(42 USC 1320a-7a(a)(7))

Anti-Kickback Statute

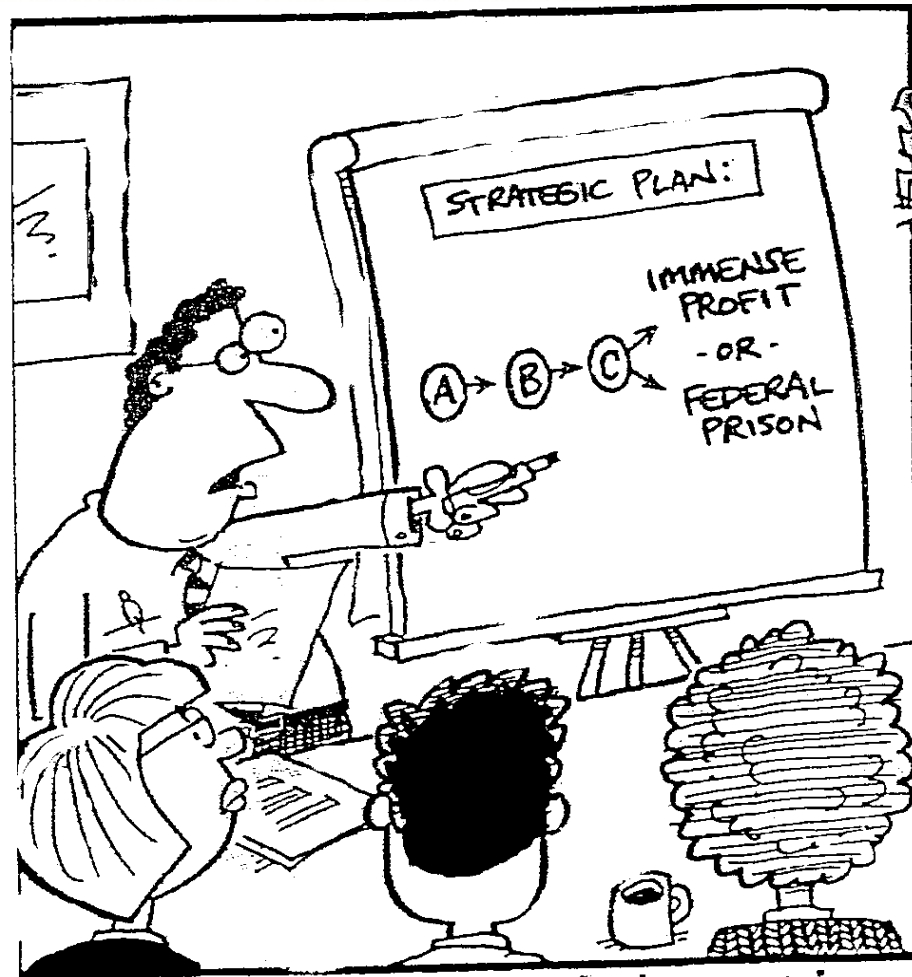
- Possible safe harbors for Anti-Kickback Statute:
 - Employment
 - Independent contractor
 - Recruitment
 - Referral services
 - Discounts
 - Others...(42 CFR 1001.952)
- Must satisfy all conditions for safe harbor.
- May obtain advisory opinion from OIG.
 - Prior advisory opinions may provide guidance.
 - Published at <https://oig.hhs.gov/compliance/advisory-opinions/>.

Civil Monetary Penalties Law

- *Like AKS, applies if marketing govt program beneficiaries or business.*
- Prohibits certain specified conduct, including:
 - Offering, soliciting, giving or receiving remuneration to induce referrals (i.e., kickbacks).
 - Offering inducements to program beneficiaries if know or should know that remuneration is likely to influence beneficiary to order or receive items or services payable by federal or state programs from a particular provider.

(42 USC 1320a-7a; 42 CFR 1003.102)

Applying Fraud and Abuse Laws



"Stay with me now, people, because in step C, things get a bit delicate."

Free or Discounted Items or Services to **Patients**

- Free items to induce purchase of other items or services (e.g., free diapers or other supplies, gift cards, etc.).
- Free services to induce referrals for other items (e.g., free massage, lawn or home care, etc.)
- Discounted items to induce purchase of other items.
- Rebates.
- Thank you gifts.
- “Insurance only” billing.
- Free transportation.
- Others....

May constitute:

- *Kickbacks in exchange for receiving or referring services.*
- *Inducements for patient services.*

Free or Discounted Items or Services to **Patients**

- **Govt program beneficiaries:** may offer—
 - Item or service of low value, i.e.,
 - Each item or service is less than \$10, and
 - Aggregate is less than \$50 per patient per year.
 - (OIG Bulletin, *Offering Gifts to Beneficiaries* (8/02); 66 FR 24410)
 - Incentives to promote certain types of preventative care.
 - Remuneration that promotes access to care and poses a low risk of harm to patients and govt programs.
 - Retailer coupons, rebates or rewards offered to public.
 - (42 USC 1320a-7a(i); 42 CFR 1003.101)
- **Private pay situations.**
 - Check state laws.
 - Beware “carve outs” for federal programs.

“Insurance Only” Billing

- **Govt program beneficiaries**

- Generally cannot waive copays or deductibles unless:

- Good faith determination of financial need or unsuccessful collection efforts.
- Not part of any advertisement or solicitation.
- Not routine.

(42 USC 1320a-7a(i)(6); 42 CFR 1003.101; *see also* Adv. Op. 12-16).

- May waive copays if satisfy AKS safe harbor for hospital inpatient paid under PPS. (42 CFR 1001.952(k)).

- **Private insurance**

- Managed care contracts typically prohibit waiving copays or deductibles.
- Check state laws.

Prompt Pay Discounts

- **Govt program beneficiaries**
 - **OIG has approved prompt pay discounts for govt beneficiaries if:**
 - Amount of discount relates to avoided collection costs.
 - Offered to all patients for all services without regard to patient's reason for admission, length of stay, or DRG.
 - Not advertised so as to solicit business.
 - Notified private payors of program.
 - Costs not passed to Medicare, Medicaid or other payors.
- (56 FR 35952; Adv. Op. 08-3)
- **Private pay business**
 - May affect “usual and customary” charges.
 - Check insurance contracts.
 - Check state laws.

Free Tests or Screening

- **Govt program beneficiaries**

- **OIG has approved free screening services or tests (e.g., free blood pressure check by hospital) where:**

- **Not conditioned on the use of any items or services from any particular provider.**
- **Patient not directed to any particular provider.**
- **Patient not offered any special discounts or follow-up services.**
- **If test shows abnormal results, visitor is advised to see his or her own health care professional.**

(Adv. Op. 09-11)

- **Private pay patients**

- **Check state law**

Free Transportation

- **Govt program business**

- OIG has approved free transportation programs where, among other things:

- Program open to all eligible patients; not selectively limited to targeted beneficiary populations.
- Type of transportation is reasonable (i.e., no limousine).
- Travel is local to physicians' offices.
- Public transportation and parking is limited.
- Cost of program would not be claimed on cost report or shifted to a federal program.

(Adv. Op. 11-02; *see also* OIG Bulletin, *Gifts to Beneficiaries*)

- **Private pay business**

- Check state laws.

Drawing for a Prize

- **Govt program business**
 - Maybe okay if value of chance to win is nominal (e.g., value of prize \div number of participants).
 - More suspect if have to purchase care for chance to win.
 - No guarantees.
- **Private pay business**
 - Check state laws, including:
 - Sweepstakes
 - Raffle rules
 - Lotteries

Freebies to Providers or Other Referral Sources

- “Refer a friend” offers (e.g., free gift card, free x-box, discounted service, etc.)
- Thank you gifts.
- Support or subsidies.
- Free use of hospital space, equipment or personnel.
- Professional courtesies.
- Paying more than FMV for services.
- Paying for services that are not needed.
- Others....

May constitute:

- *Kickbacks in exchange for receiving or referring services.*
- *Inducements for patient services.*

Freebies to Providers or Other Referral Sources

- **Referral source for govt program business**
 - Stark applies if involves physician or family member unless fit within safe harbor. (See 42 CFR 411.357)
 - AKS and CMPL apply if “one purpose” is to induce referrals unless fit within safe harbor. (See 42 CFR 1001.952)
 - Applies to giver or receiver.
- **Referral source for private pay business**
 - OIG has cautioned that carving out govt programs from specific program may not protect the parties if there are other referrals for federal programs between parties.
 - May violate state laws.

Subsidizing Other Provider's Marketing Expenses

- **Referral source for govt program business**
 - “Are you marketing their practice or yours?”
 - Stark applies if and to extent marketing non-employed physician's practice; possible safe harbors include:
 - Non-monetary compensation < \$300+/year.
 - Recruitment safe harbor.
(42 CFR 411.357)
 - AKS and CMPL apply if “one purpose” is to induce referrals from the subsidized practitioners.
- **Referral source for private pay business**
 - May implicate AKS and CMPL if improper intent.
 - Check state laws.

Subsidizing Other Provider's Marketing Expenses

Adv. Op. 06-16

- DME supplier wanted to provide free advertising or reimburse clients for advertising expenses.
- OIG refused to approve arrangement. “By subsidizing advertising expenses..., [the DME supplier] would provide valuable services to the selected [clients], sparing them costs they would otherwise incur to promote and operate their businesses.... The proposed arrangement poses all the risks associated with kickbacks. There is a substantial risk of driving overutilization and increasing program costs.... The proposed arrangement would give [clients] an incentive to steer patients to the [DME supplier's] products, even if products from other manufacturers were less expensive or more appropriate.”

Listing Non-Employed Providers on Hospital's Website

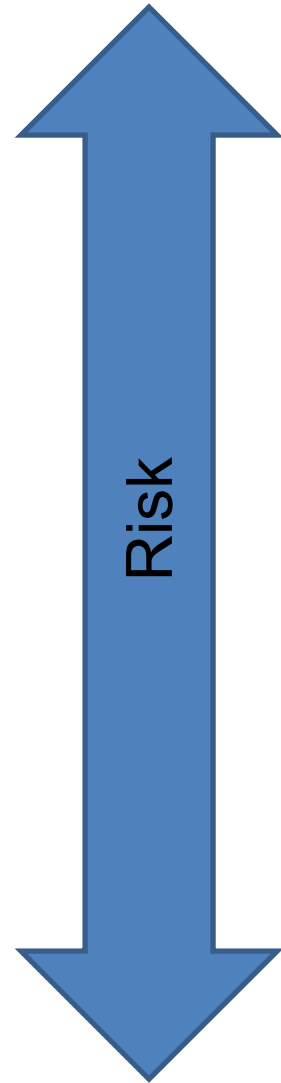
- **Physician is referral sources for govt program business**
 - Stark applies to listing physicians who refer business.
 - Simple listing of medical staff on hospital's website is an "incidental benefit" excepted from Stark.
 - Advertising or promoting a physician's private practice on a hospital website is not an excepted incidental benefit, so hospital would need to fit within another Stark exception or charge fair market value for advertising.

(69 FR 16113)

Joint Marketing with Other Providers

- **Referral source for govt program business**
 - Stark applies if marketing non-employed physician's private practice; possible safe harbors include:
 - Payments by a physician at fair market value.
 - Non-monetary compensation < \$300+/year.
 - Recruitment safe harbor.
 - AKS and CMPL apply if “one purpose” is to induce referrals from the other practitioners.
- **Referral source for private pay business**
 - May implicate AKS and CMPL if improper intent.
 - Check state laws.

Joint Marketing with Other Providers



- Marketing physician's private practice?
 - Does the joint marketing...
 - Focus on hospital service or physician's practice?
 - Contain physician's private contact info?
 - Contain info about physician's private practice?
 - Promote physician's services away from hospital?
- Marketing hospital's practice?

Joint Marketing with Other Providers

- Make sure each party pays their fair share.
 - Relative advertising time benefiting that party.
 - Relative advertising space benefiting that party.
 - Relative focus of the advertisement.
- Make sure arrangement is documented appropriately.
 - Practitioner agrees to reimburse or pay the hospital (or other provider) for respective share.
 - Parties each contract separately with marketing company.

Paying for Leads

- Some entities will generate and sell leads to providers.
 - *When does a “lead” become a “referral”?*
- **Govt program business**
 - Adv. Op. 08-19. OIG approved arrangement whereby website sold leads to chiropractors because:
 - Arrangement did not target govt beneficiaries.
 - Arrangement did not actively steer patients to particular provider.
 - Fees paid did not depend on whether the lead became a patient.
 - No health info was collected by the lead generator (e.g., age, illness, products currently used, insurance coverage, etc.)
 - Lead generator did not “qualify” the lead.
- Caution: beware HIPAA.

Paying Independent Contractors Based on Commission

- **Govt beneficiaries or programs.**

- To fit within AKS safe harbor, compensation must:
 - Be set in advance
 - Not based on the volume or value of referrals.

(42 CFR 1001.952(d))

- OIG: “We are aware of many examples of abusive practices by sales personnel who are paid as independent contractors.... We believe that if individuals and entities desire to pay a salesperson on the basis of the amount of business they generate, then to be exempt from civil or criminal prosecution, they should make these salespersons employees where they can and should exert appropriate supervision for the individual’s acts.” (54 FR 3093).

- **Private pay business.**

- Check state law.

“White Coat” Marketing



“White Coat” Marketing

- **Govt program beneficiaries or business.**
 - OIG has expressed concern over advertising through which a trusted healthcare provider recommends a product or service.
 - Lower risk where marketing is:
 - Not by healthcare professionals.
 - Accurate.
 - Not deceptive.
 - Passive.
 - Provided in general broadcast media, not targeted to the particular patient.

(OIG Adv. Op. 02-12)
- **Private pay business.**
 - Beware deceptive advertising.

“White Coat” Marketing

“[M]any ... advertising and marketing activities do not warrant prosecution in part because (1) they are passive in nature, i.e., the activities do not involve direct contact with program beneficiaries, or (2) the individual or entity involved in these promotions is not involved in the delivery of health care. Such individuals are not in a position of public trust in the same manner as physicians or other health care professionals who recommend or order products and services for their patients.” (OIG Ad. Op. 10-23)

Fraud and Abuse Laws: Summary

- Do not advertise or use the following as part of a marketing program, especially for govt programs.
 - Waivers of copays and deductibles or “insurance only” billing.
 - Prompt pay discounts.
 - Charity care or write offs due to financial need.
 - Free or discounted items if intend to rely on exception for services that promote access to care and pose low risk of fraud.
 - Beware offering freebies to patients or referral sources.
 - Beware receiving freebies from vendors.
 - Beware paying contractors based on referrals.
- * Are you giving or receiving freebies to induce referrals?*



Advisory Opinions

- OIG may issue advisory opinions.
- Listed on OIG fraud and abuse website, www.oig.hhs.gov/fraud.
- Not binding on anyone other than participants to the opinion.
- But you are probably fairly safe if you act consistently with favorable advisory opinion.

Related

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certain privileged, confidential, or financial
e specified by the requestor.

Health Insurance Portability and Accountability Act (“HIPAA”)



HIPAA

- Generally cannot use or disclose protected health information (“PHI”) without the patient’s written, HIPAA-compliant authorization unless exception applies.
 - Applies to internal use as well as external disclosures, including marketing your own patients.
 - Applies to any individually identifiable health info, including but not limited to:
 - Names, addresses, phone numbers, account numbers, URLs, and IP addresses;
 - Photos, images, or videos; and
 - Any info that may reasonably identify the individual.

(45 CFR 160.103 and 164.500 et seq.)

HIPAA: Civil Penalties

Conduct	Penalty
Did not know and should not have known of violation	<ul style="list-style-type: none">• \$100 to \$50,000 per violation• Up to \$1.5 million per type per year• No penalty if correct w/in 30 days• OCR may waive or reduce penalty
Violation due to reasonable cause	<ul style="list-style-type: none">• \$1000 to \$50,000 per violation• Up to \$1.5 million per type per year• No penalty if correct w/in 30 days• OCR may waive or reduce penalty
Willful neglect, but correct w/in 30 days	<ul style="list-style-type: none">• \$10,000 to \$50,000 per violation• Up to \$1.5 million per type per year• Penalty is mandatory
Willful neglect, but do not correct w/in 30 days	<ul style="list-style-type: none">• At least \$50,000 per violation• Up to \$1.5 million per type per year• Penalty is mandatory

HIPAA: Criminal Penalties

- Applies if employees or other individuals obtain or disclose protected health info from covered entity without authorization.

Conduct	Penalty
Knowingly obtain info in violation of the law	<ul style="list-style-type: none">• \$50,000 fine• 1 year in prison
Committed under false pretenses	<ul style="list-style-type: none">• 100,000 fine• 5 years in prison
Intent to sell, transfer, or use for commercial gain, personal gain, or malicious harm	<ul style="list-style-type: none">• \$250,000 fine• 10 years in prison

HIPAA: Treatment or Healthcare Operations

- May use or disclose PHI without patient's authorization for purposes of:
 - Treatment, including provision, coordination, management, or referral of care.
 - Healthcare operations, including contacting patients with info about treatment alternatives and related functions that do not involve treatment.

unless you have agreed otherwise with the patient.

 - Don't agree to other restrictions!

(45 CFR 164.501, .506 and .522)

HIPAA: Marketing

- Covered entity must obtain an authorization for any use or disclosure of PHI for “marketing”.
 - “Marketing” means a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.
- If marketing involves financial remuneration to the covered entity from a third party, the authorization must state that such remuneration is involved.
 - “Financial remuneration” means direct or indirect payment by the third party whose product or service is being described.

(45 CFR 164.501 and .508(a)(3); 78 FR 5592-97)

HIPAA: Marketing

- “Marketing” does not include a communication made:
 - To provide refill reminders or communicate about a drug that is currently being prescribed for the individual.
 - Any financial remuneration must be reasonably related to the cost of making the communication.
 - For the following treatment and health care operations purposes unless the covered entity receives financial remuneration for the communication:
 - Treatment, including case management, care coordination, or recommend treatment alternatives; or
 - To describe health related product or service provided by the covered entity.

(45 CFR 164.501 and 508(a)(3))

HIPAA: Marketing

- No authorization is required for the following marketing communications even if financial remuneration is received for making the communication for the following:

- Face-to-face communication made by a covered entity to an individual.

- Not via telephone, e-mail, text, fax, mail, etc.

- A promotional gift of nominal value provided by the covered entity.

(45 CFR 164.508(a)(3)(i); 78 FR 5596-97)

- No authorization is required for communications:

- Promoting health in general, not a product or service.

- About government-sponsored programs.

(78 FR 5597)

HIPAA: Treatment v. Marketing

Treatment or Operations

- ✓ **Does not require authorization.**
- Communicating for purposes of treatment.
- Communicating about your own products or services.

unless remuneration given for the communication.

- Face-to-face communication.
- Promotional gift of nominal value.

Marketing

- ✓ **Requires authorization.**
- Communicating about another entity's product unless for treatment and no remuneration given.
- Communicating about your own product or service if remuneration is given for communication.

HIPAA: Fundraising

- Subject to certain conditions, a covered entity may disclose the following PHI to a business associate or institutionally related foundation for purpose of raising funds for its own benefit without an authorization:
 - Name, address, contact info, age, gender and birth date;
 - Dates of healthcare provided to the individual;
 - Department of service information;
 - Treating physician;
 - Outcome information; and
 - Health insurance status.
- May only disclose the minimum necessary.

(45 CFR 164.514(f)(1); 78 FR 5618-22)

HIPAA: Fundraising

- **To use PHI for fundraising, covered entity:**
 - **Must include statement notifying individual of fundraising in covered entity's notice of privacy practices.**
 - **With each fundraising communication, must provide clear and conspicuous opportunity to opt out of fundraising.**
 - **Method for opting out cannot cause undue burden or more than nominal cost (e.g., toll-free number, e-mail).**
 - **May not condition treatment or payment on participation in fundraising.**
 - **May not make fundraising communications to individuals who opt out.**
 - **May notify individuals of method to opt back in.**

(45 CFR 164.512(f)(1))

HIPAA: Sale of PHI

- Covered entity or business associate may not sell PHI unless
 - They obtain individual’s prior written authorization, and
 - Authorization discloses that the covered entity will receive remuneration in exchange for PHI.

(45 CFR 164.502(a)(5)(ii) and .508(a)(4); 78 FR 5603-5609)

- “Sale of PHI” means disclosure of PHI by a covered entity or business associate if they receive directly or indirectly any remuneration, financial or otherwise, from or on behalf of the recipient of the PHI in exchange for the PHI.

(45 CFR 164.502(a)(5)(ii)(B)(1))

HIPAA: Business Associates

- If covered entity contracts with outside entity (“business associate”) to help with marketing efforts involving PHI, parties must execute a business associate agreement (“BAA”).
 - BAA requires business associate to comply with certain HIPAA requirements.
 - BAA may include additional requirements.
- Business associate must execute BAA with any subcontractors that the business associate uses.
- Business associates and subcontractors must comply with relevant HIPAA requirements regardless of whether a BAA is executed.

(45 CFR 164.502 and .504).

HIPAA: Security

- Covered entities and business associates must implement specified safeguards to protect e-PHI.
 - Administrative safeguards
 - Physical safeguards
 - Technical safeguards, including “a mechanism to encrypt [e-PHI] whenever deemed appropriate.”

(45 CFR 164.308-.312)

- *Are your e-mails or texts to client compliant with HIPAA security rule?*

HIPAA: E-mails or Texts

- Does the HIPAA Privacy Rule permit health care providers to use e-mail to discuss health issues and treatment with their patients?
- **Answer:** Yes. The Privacy Rule allows covered health care providers to communicate electronically, such as through e-mail, with their patients, provided they apply reasonable safeguards when doing so. See 45 CFR § 164.530(c). For example, certain precautions may need to be taken when using e-mail to avoid unintentional disclosures, such as checking the e-mail address for accuracy before sending, or sending an e-mail alert to the patient for address confirmation prior to sending the message. Further, while the Privacy Rule does not prohibit the use of unencrypted e-mail for treatment-related communications between health care providers and patients, other safeguards should be applied to reasonably protect privacy, such as limiting the amount or type of info disclosed through the unencrypted e-mail. In addition, covered entities will want to ensure that any transmission of electronic protected health information is in compliance with the HIPAA Security Rule requirements at 45 CFR Part 164, Subpart C.

(OCR HIPAA Privacy FAQ dated 12/15/08)

HIPAA: E-mails or Texts

- Does the Security Rule allow for sending electronic PHI (e-PHI) in an e-mail or over the Internet?
- **Answer:** The Security Rule does not expressly prohibit the use of e-mail for sending e-PHI. However, the standards for access control (45 CFR § 164.312(a)), integrity (45 CFR § 164.312(c)(1)), and transmission security (45 CFR § 164.312(e)(1)) require covered entities to implement policies and procedures to restrict access to, protect the integrity of, and guard against unauthorized access to e-PHI. The standard for transmission security (§ 164.312(e)) also includes addressable specifications for integrity controls and encryption. This means that the covered entity must assess its use of open networks, identify the available and appropriate means to protect e-PHI as it is transmitted, select a solution, and document the decision. The Security Rule allows for e-PHI to be sent over an electronic open network as long as it is adequately protected.

(OCR FAQ [undated])

HIPAA: E-mails or Texts

- Omnibus Rule commentary states that covered entity or business associate may communicate via unsecured e-mail so long as they warn patient of risks and patient elects to communicate via unsecured e-mail to text.

(78 FR 5634)

- Probable net effect:
 - If disclosing PHI in e-mail:
 - Ensure patient agrees to communicate via e-mail or text, and
 - Notify patient of security risks.
 - If not disclosing PHI in e-mail:
 - Apply reasonable safeguards.
 - But no guarantees...

E-Mails or Text

- Remember other laws affecting e-mail or text marketing, e.g.,
 - Controlling the Assault of Non-Solicited Pornography and Marketing Act (“CAN-SPAM”)
 - Affects content
 - Affects manner in which e-mail sent
 - Requires unsubscribe options(15 USC 7701 et seq.)
 - Telephone Consumer Protection Act (“TCPA”)
 - Discussed below
 - State laws

Responding to Negative Reviews



Just because the patient discloses info does not mean that you can!



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Policing Patient Privacy



Stung by Yelp Reviews, Health Providers Spill Patient Secrets

The vast majority of reviews on Yelp are positive. But in trying to respond to critical ones, some doctors, dentists and chiropractors appear to be violating the federal patient privacy law known as HIPAA.

by [Charles Ornstein](#)
ProPublica, May 27, 2016, 11 a.m.

58 Comments



This is part of an ongoing investigation

[Policing Patient Privacy](#)

ProPublica is exploring how patient privacy violations are affecting patients and the medical care they receive.



4 Stages to a Heart Attack



Responding to Negative Reviews

- Do NOT disclose protected health info in online response.
 - HIPAA prohibits unauthorized use or disclosure of protected health info, including:
 - Fact that a person is or was a patient.
 - Info that could reasonably identify the patient.
 - There is no HIPAA exception for responding to a patient complaint online.
 - Patient does not waive HIPAA privacy rights by posting info online.

Responding to Negative Reviews

- Options for responding:
 - Ignore it.
 - Encourage and emphasize positive reviews.
 - Contact patient to resolve concerns or obtain consent to respond.
 - Respond generically.
 - Do not confirm or deny that complainant was a patient, or include any info about the patient or patient encounter.
 - May explain policies or practices without reference to patient.
 - Contact online company to request removal of complaint.
 - If review is defamatory, may threaten lawsuit.

Telemarketing



Telemarketing

- **Telephone Consumer Protection Act (“TCPA”)**
 - Generally prohibits prerecorded calls to a residence or prerecorded or autodialed calls to a wireless number without recipient’s prior express consent.
 - Exempts prerecorded healthcare related calls to residential and likely wireless numbers.
 - Such calls are subject to HIPAA
(47 USC 227; 47 CFR 64.1200 et seq.; FCC Order 12-21).
 - Does not apply to autodialed or prerecorded non-telemarketing calls, e.g., non-profit organizations, political purposes, or other non-commercial purposes.

Telemarketing

- **Telemarketing Consumer Fraud and Abuse Prevention Act and FCC Telemarketing Sales Rules.**
 - Prohibits deceptive and abusive telemarketing practices, including pre-recorded calls without recipient's prior written consent.
(15 USC 6101 et seq.; 16 CFR 310.1 et seq.)
- **Anti-Solicitation Statute**
 - Applies to DMEPOS (discussed below)
(42 USC 1395m(a)(17); 42 CFR 424.57).
- **Additional state laws may apply.**

False or Deceptive Advertising



False or Deceptive Advertising: Medical Practice Acts

- State medical practice acts often prohibit items such as:
 - Misrepresenting or omitting material facts.
 - Creating unjustified expectations of favorable results, including use of photos, models, or guaranteed results.
 - Promoting items that are not necessary or medically indicated.
 - Representing that an incurable condition may be cured.
 - Abusing or exploiting the trust of a patient.
 - Making a false or misleading statement concerning the person's skill or efficacy of the treatment.
 - Representing superior skill if not supported by reliable data.
 - Making a scientific claim that cannot be supported by reliable data.
 - Representing self as specialist or certified if that is not the case.
 - Advertising in any other unethical or unprofessional manner.
 - Misrepresenting fees or charges.
- *See also* AMA CEJA Ethics E-5.02

False or Deceptive Advertising: Medical Practice Acts

- Violation of state medical practices act may result in:
 - Adverse licensure action.
 - Civil fines or penalties.
 - Injunction or other equitable relief.
 - Adverse credentialing actions.
 - Adverse publicity and professional embarrassment.
- Violation of medical practices act may also give rise to action by patients, e.g.,
 - Malpractice claim.
 - Breach of contract claim.
 - Fraud.

False or Deceptive Advertising: Consumer Protection Acts

- **Federal Trade Commission Act**
 - Prohibits false, deceptive or misleading advertising.
- **Most states prohibit actions such as:**
 - Representing that goods or services have approval, characteristics, uses, benefits or qualities that they do not have.
 - Representing that a person has approval, status, or affiliation that he or she does not have.
 - Representing that goods or services are of a particular standard, quality if they are of another.
 - Engaging in any other unconscionable, false, misleading or deceptive act or practice.

False or Deceptive Advertising: Consumer Protection Acts

- **Violations of consumer protection laws**
 - **Criminal fines or penalties.**
 - **Civil fines or penalties.**
 - **Injunction or other equitable relief.**
 - **Adverse publicity and professional embarrassment.**
- **Violations may trigger medical practices act investigation.**
- **Beware advertising that may cross state boundaries and implicate other state's laws.**

False or Deceptive Advertising: Testimonials and Endorsements

- May be prohibited by state law.
- FTC has issued guides concerning the use of endorsements and testimonials in advertising.

(16 CFR part 255)

- “[T]estimonials of patients as to the physician’s skills or the quality of the physician’s professional services tend to be deceptive when they do not reflect the results that patients with conditions comparable to the testimoniant’s condition generally receive. Objective claims regarding experience, competence, and the quality of physicians and the services they provide may be made only if they are factually supportable. Similarly, generalized statements of satisfaction with a physician’s services may be made if they are representative of the experiences of that of physician’s patients.”

(AMA CEJA Ethics E-5.02)

Marketing Limitations for Certain Providers or Suppliers



Medicare Plans

- **Certain plans must comply with Medicare Marketing Guidelines.**
 - Medicare advantage plans (MA or MA-PD)
 - Prescription drug plans (Part D plans)
 - Section 1876 cost plans
 - **Guidelines apply to providers who contract with plans, e.g., providers may not:**
 - Accept enrollment applications
 - Steer beneficiaries to plan based on financial interest
 - Mail marketing materials for plan.
 - Offer inducements to beneficiaries, including free screening.
- (42 CFR 422.268, 423.2268; Medicare Marketing Guidelines)
- **See Medicare plans' websites.**

DMEPOS

- **Suppliers of durable medical equipment, prosthetics, orthotics, and supplies (“DMEPOS”)**
 - **May not directly market Medicare beneficiaries through telephone unless:**
 - **beneficiary gave written permission for contact;**
 - **contact is for a covered item that the supplier has already furnished; or**
 - **supplier has furnished at least one covered item the beneficiary during the prior 15 months.**
 - **No payment for items ordered per improper solicitation.**
 - **May be excluded for pattern of violations.**

(42 USC 1395m(a)(17); 42 CFR 424.57; *Special Fraud Alert, Telemarketing by DMEPOS* (2003) and (2010))

Others?

- **Additional laws may apply to certain providers, e.g.,**
 - Medical device manufacturers
 - Pharmaceutical manufacturers or distributors
 - Others?
- **Additional agencies may issue applicable regulations, e.g.,**
 - FDA
 - FTC
 - FCC
 - USDA
 - CMS
 - State agencies or licensing boards
 - Others?

To Do



To Do

- Review existing arrangements.
 - Marketing programs to patients.
 - Beware inducements or freebies to patients, especially govt beneficiaries.
 - Do not advertise waiver of copays, indigency discounts, etc.
 - Arrangements with vendors and referral sources, including providers.
 - Beware free or discounted items or services, i.e., less than FMV.
 - Ensure financial arrangements with physicians and other referral sources fit within applicable safe harbor.
 - Written agreement for services.
 - Not based on volume or value of referrals.
 - Beware paying commissions to marketers.

To Do

- Ensure your compliance plan addresses marketing issues.
- Train your marketing department on compliance issues.
 - Fraud and abuse laws.
 - HIPAA.
 - Telemarketing.
 - Deceptive advertising.
 - Other?

Document training.

- Require review of marketing programs by compliance officer, attorney, or other person who understands the rules.
- Require immediate reports of violations.

To Do

- **Protect patient info.**
 - **Execute business associate agreements with marketing contractors if you share patient info.**
 - **Do not use patient photos, quotes, or other identifying info without a valid authorization and media release.**
 - **Do not talk about specific patients at all without authorization, even if you try to remove identifying info.**
 - **Beware remuneration from third parties in exchange for marketing products or services.**
 - **Implement appropriate safeguards for e-mail or other communications via internet.**
 - **Monitor social media.**

To Do

- **In advertising:**
 - **Ensure your statements are accurate and supportable.**
 - **Do not overpromise or guarantee results.**
 - **Include appropriate disclaimers, e.g., “results may vary.”**
 - **Beware using photos, endorsements, and/or testimonials.**
 - **Avoid high pressure, direct contact, “white coat” marketing.**
 - **Be very careful in making comparison with competitors.**
 - **Don’t claim expertise that you don’t have or overstate your credentials.**

Additional Resources



https://oig.hhs.gov/compliance/

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https://oig.hhs.gov/compliance/

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Accountable Care Organizations

The Affordable Care Act contains several provisions that support the development of Accountable Care Organizations to manage and coordinate care for beneficiaries.

Read More >>

Advisory Opinions

The OIG issues advisory opinions about the application of OIG's fraud and abuse authorities to the requesting party's existing or proposed business arrangement.

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I'm looking for

Let's start by choosing a topic

Select One

- Accountable Care Organizations
- Advisory Opinions
- Compliance 101 and Provider Education
- Compliance Guidance
- Corporate Integrity Agreements
- Open Letters
- RAT-STATS

OIG Website

- **Compliance 101 series**
- **OIG Compliance Program Guidance**
 - **OIG Supplemental Compliance Program Guidance for Hospitals, 70 FR at 4863-69**
 - **OIG Compliance Program Guidance for Physicians**
- **Advisory Opinions**
- **Special Fraud Alerts**
- **Fraud Bulletins**
- **Letters**
- **Other materials**

Questions?



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