THE INS, OUTS AND LEGAL CONSIDERATIONS OF REFERRAL AND MARKETING ARRANGEMENTS

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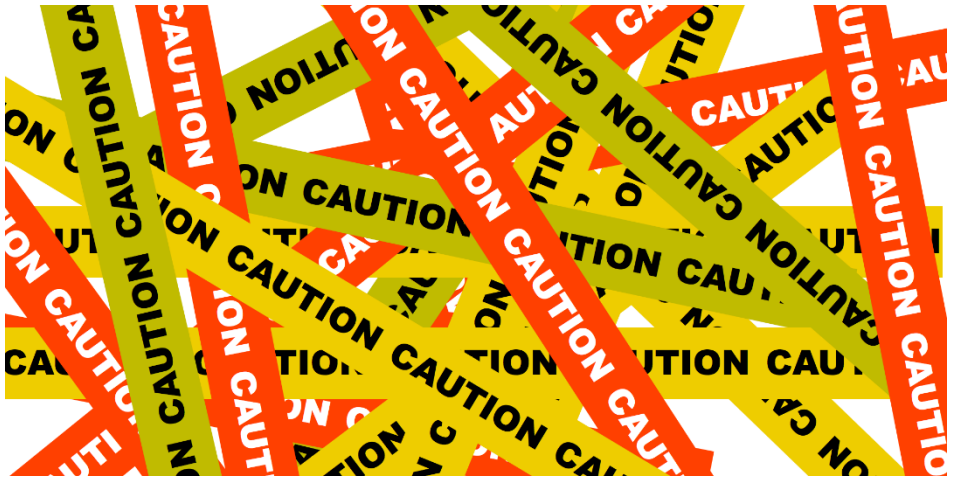
Agenda

- Recent Enforcement Actions
- Applicable Federal and State Laws
  - Federal Anti-Kickback Statute
  - Beneficiary Inducement & Civil Monetary Penalties Law
  - Minnesota Anti-kickback Statute
  - Fee-Splitting Laws
- Safe Harbors
- Hypotheticals
- Tips to Consider

Why are “referral arrangements” suspect?

- To protect patients from referrals that are not in their best interest
- To reduce risk of low quality service
- To manage the cost of the health care industry
- To prevent corruption



If you're not careful… (Recent Enforcement Actions)

- October 17, 2017
  - A CEO excluded from participation in all Federal health care programs due to violations of the AKS
    - His company paid physicians based on the volume of referrals made to his company to induce those physicians to order tests from the laboratory
    - Entered into a marketing arrangement with the laboratory that took into account the volume or value of referrals with the intention of inducing the referrals of tests
    - Entered into marketing arrangements with individual marketers that took into account the volume or value of referrals with the intention of inducing referrals of tests
- September 27, 2017
  - A pain management practice with multiple locations in Arizona entered into a $186,210.20 settlement agreement with OIG after allegations of improper remuneration, which resulted in prohibited referrals.

More Enforcement Actions

- August 31, 2016
  - A health care provider agreed to pay $5,008,732.14 for allegedly violating the Civil Monetary Penalties Law provisions applicable to physician self-referrals and kickbacks.
- May 31, 2016
  - A doctor agreed to be excluded from participation in all Federal health care programs for five years due to violations of the AKS
  - Examples
    - Dr. Oppenheimer directly considered the volume and/or value of referrals between his laboratory and the physician practice when determining whether to make a donation and the size of the donation.
    - He improperly considered the volume of Medicare business when he considered making a donation.
    - He occasionally withheld agreed-upon donation payments until a certain number of cases/referrals were received.

Federal Laws and Guidance

- Anti-Kickback Statute (AKS)
  - 42 U.S.C. § 1320a-7b
  - Prohibits transactions that are meant to induce or reward referrals for items or services that are reimbursed by federal health care programs
- Civil Monetary Penalty Law (CMP)
  - Beneficiary inducement provisions
  - 42 U.S.C. § 1320a-7a
  - Prohibits any person from offering remuneration to Medicare or Medicaid beneficiaries that the offeror knows or should know are likely to influence the selection of providers, practitioners, or suppliers
- Office of Inspector General (OIG)
  - Offers advisory opinions to health providers on whether their actions violate AKS or CMP
  - Only binding to requestor of opinion, but could still be good guidance
  - Issues wide range of guidance (Special Fraud Alerts, Special Advisory Bulletins, Compliance Guidance, Training Materials, etc.).

Minnesota Laws

- Minn. Stat. § 62J.23 (Minnesota's Anti-Kickback Statute)
  - Applies federal AKS to "all persons in the state", regardless of whether person participates in "state health care program"
- Minn. Stats § 147.091 Subd. 1(p) § 148.941 Subd. 2(11) (Minnesota's Fee-Splitting Statutes)
  - Prohibits fee-splitting activities
  - Examples
    - Paying or receiving remunerations for a referral of clients
    - Dividing client fees with another individual or entity
    - Referring an individual or entity to a health care provider for financial interest
- Corporate practice of medicine
- Professional licensure laws (e.g., Minn. Stats. Ch. 147, 148, etc.).

Let’s Dive a Little Deeper

Anti-Kickback Statute (AKS)

- Purpose: To prevent corruption in federal health care program beneficiary referrals, to prevent increased health care costs, and to prevent poor quality services.
- Penalties
  - Criminal Penalties
    - Maximum fine of $100,000; or
    - Imprisonment up to 10 years; or
    - Both
  - Possible CMP penalties
    - Up to $100,000 per kickback; and
    - 3x the amount of the remuneration
  - Exclusion from Federal health care programs
  - Violation of the False Claims Act (***triple damages and fines of about $22,000 per claim!***)

“One Purpose Test”

- OIG—AKS applies if one purpose of the remuneration is to induce or reward referrals, even if it is not the primary purpose of the arrangement
- Remuneration is anything of value
  - Examples: Money, rebates, free services, computers, tickets, jewelry, etc.

Safe Harbors for the AKS

- Certain exceptions (called “safe harbors”) may be available to ensure AKS compliance
- Examples:
  - Personal Services and Management
  - Bona Fide Employee
  - Discounts
  - Referral Services
- Why not meet a safe harbor?
- If safe harbor cannot be met, facts and circumstances analysis is required

Personal Services and Management Contracts (42 CFR 1001.952(d))

- 7 standards that must be met—
  - Parties must sign a written agreement.
  - The agreement must specifically cover all the services provided by the agent.
  - The agreement must specify the schedule of part-time services, if applicable.
  - The agreement must be for at least a year.
  - The aggregate compensation over term is consistent with fair market value and is not based off any referrals.
  - The services cannot involve any counseling or promotion of an arrangement that violates state or federal law.
  - The services agreed upon must be reasonable to accomplish commercially reasonable business purposes.

Bona Fide Employee (42 CFR 1001.952(i))

- “Remuneration” does not include any amount paid by an employer to a bona fide employee for employment in furnishing services for which payment may be made under federal health care programs
- This safe harbor does not apply to independent contractors

Discounts (42 CFR 1001.952(h))

- Discount allowed if buyers, sellers, and offerors of discounts comply with certain requirements
- Requirements include:
  - Discount must be disclosed to buyer at the time of the initial sale of the good or service and the buyer must provide (upon request) information provided by the seller
  - Seller must report discounts, inform the buyer of its obligations to report such discounts, and refrain from actions that would impede the buyer from meetings its obligations
  - Offeror of discount must inform the buyer of its obligations to report discounts and refrain from actions that would impede the buyer from meetings its obligations

Referral Services (42 C.F.R. § 1001.952(f))

- Protects payments between a referral service and participant in that service…
- Standards that must be met:
  - The referral service does not exclude any individual or entity who meets the qualifications for participation
  - Any payment to the referral service is only based on the cost of operating the referral service and is not based on the volume or value of referrals
  - The referral service cannot impose any requirements on the way the participant provides services to a referred person, except requirements for charge rates

Referral Services (42 C.F.R. § 1001.952(f))

- The referral service must make five disclosures to each person seeking a referral:
  - How the referral service selects participants that it makes referrals to
  - Whether the referral service is paid a fee
  - How it refers a particular participant to a potential client
  - The nature of the relationship between the referral service and the participants
  - Any restrictions that would exclude an individual or entity from continuing as a participant

Civil Monetary Penalty Law (CMP)

- Prohibits any person from offering remuneration to Medicare or Medicaid beneficiaries that the offeror *knows or should know* are likely to influence the selection of providers, practitioners, or suppliers.
- Remuneration
  - "transfers of items or services for free or for other than fair market value" §1128A(i)(6)
- Penalties
  - Up to fines of $50,000 per act
  - 3x the amount of the remuneration

Exceptions from the CMP

- Certain exceptions may apply that would prevent a health provider from violations of the CMP
- Examples
  - Remuneration that Promotes Access to Care and Poses a Low Risk of Harm
  - Financial Need-Based Exception
  - Local Transportation
  - Shuttle Services

Remuneration that Promotes Access to Care and Poses a Low Risk of Harm

- Shields remuneration that promotes "access to care and poses a low risk of harm to patients and Federal health care programs".
- No financial maximum amount for remuneration that qualifies for this safe harbor.
- Explanation of terms
  - "Promote access" - if an arrangement "improves a particular beneficiary's ability to obtain" care
    - Does not include arrangements that reward patients
  - "Care" – broad definition: any items or services provided to a Medicare or Medicaid beneficiary and that are payable by Medicare or Medicaid
  - "Low Risk of Harm" - low risk of harm if the items or services: (1) are unlikely to interfere with, or skew, clinical decision-making; (2) are unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) do not raise patient safety or quality of care concerns.

Examples from the CMP Exception

- Permissible Actions
  - Offering free child care to a patient who is attending a smoking-cessation program
  - Giving diabetic patients a subscription to a web-based food and activity tracker to help the patients better manage their disease and lifestyles
- Impermissible Actions
  - Giving a patient movie tickets in return for attending a counseling session
  - Surgeon giving out general purpose debit cards to patients who chose her as their surgeon
    - These actions do not help the patient receive access to care.

Financial Need-Based Exception

- Individuals or entities are allowed to offer or transfer items or services (excluding cash or cash equivalents such as checks or debit cards) for free or less than fair market value to Medicare and Medicaid beneficiaries if
  - (1) there is a good faith determination of the individual's financial need,
  - (2) the items or services are not advertised,
  - (3) the offer is not tied to the provision of other items or services reimbursed by Medicare or Medicaid, and
  - (4) there is a "reasonable connection" between the items or services being offered and the medical needs of the individual.

Local Transportation Exception

- Local transportation can be offered to federally funded patients if
  - The availability is uniform and consist
  - It is not air, luxury, or ambulance-level transportation
  - Not publicly marketed
  - Within 25 miles of the provider/supplier, or 50 miles in a “rural” area
  - Transportation must be for the purpose of obtaining medically necessary items or services
  - The provider offering the transportation pays the cost, and does not delegate it to another entity, federal program, other patients, etc.
  - Individual is an “established patient”
    - Defined as: “any person who has selected and initiated contact to schedule an appointment or who has previously attended an appointment with the provider/supplier in question”

Shuttle Services Exception

- Must follow the requirements for general transportation, but:
  - Not limited to only established patients for the purpose of seeking medically necessary items or services (family, employees, etc. can use it); and
  - It does not have to be operated uniformly or consistently

OIG Advisory Opinions

- Referral services arrangement for senior housing (Adv. Op. 14-01)
  - Placement agency paid for referring new residents to 2 senior communities
  - Communities provided both housing and geriatric services, including medication management and daily living activities
  - Almost all residents were self-pay or had commercial insurance coverage
  - Senior communities did not provide any services reimbursable by Medicare
  - One community provides services covered by Elderly Waiver program, but placement agency prohibited from referring eligible individuals
  - Fee calculated on percentage of community's initial gross collections from new resident

Adv. Op. 14-01

- Could not meet safe harbor
- OIG approved anyway, because—
  - Fee Structure
    - Fee takes into account only the initial rent and services provided by the senior community.
    - Fee calculation does not include any charges to Federal health care programs.
  - Contract Terms
    - Contract between the senior community and placement agency prohibited placement and acceptance of potential residents who rely on govt. programs for payment of amounts owed to the senior community
  - Govt. Programs Carve Out
    - The placement agency refers potential residents for housing/services that are not payable by Federal health care programs.
    - The senior communities do not provide services reimbursed by Medicare, and residents do not have access to services that are reimbursable by Federal health care programs.
  - Referrals and intent
    - The parent organization certified that it does not track referrals or common residents among its subsidiaries, nor does it limit residents' choice of providers, practitioners, or suppliers of services in order to steer them to affiliated providers.

State Laws

Minnesota's Anti-Kickback Statute (M.S.A. § 62J.23)

- Applies federal AKS to "persons" in MN regardless of "state" insurance
- Does it apply to services paid out-of-pocket?
- Are there safe harbors?
- Penalties
  - $1,000 or 110 percent of the estimated financial benefit, whichever is greater

Minnesota's Fee-Splitting Statutes

- Health providers cannot engage in fee splitting
  - M.S.A. § 147.091 Subd. 1(p) pertains to physicians
  - M.S.A. § 148.941 Subd. 2(11) pertains to chiropractors
- Fee splitting includes, but is not limited to:
  - Taking a commission, rebate, or remuneration for the referral of clients
  - Dividing client fees with another individual or entity
  - Referring an individual or entity to a health care provider in which the referring licensee or applicant has a significant financial interest, unless the financial interest was already disclosed to the client
  - Recommending a product, service, or device for commercial purposes, unless the profit interest was already disclosed
- Penalties
  - License could be revoked, suspended, or not renewed
  - Practice of psychology could be limited
  - Up to $7,500 penalty per violation

Corporate Practice of Medicine (CPM)

- CPM prohibits “non-professional” businesses from engaging in practice of medicine directly or indirectly through employment of licensed professionals
  - No room for “middleman” between provider and patient
- Can apply beyond just “medicine”
- Are there exceptions?
- How is it enforced?

What About?

- Arrangements that do not trigger AKS/CMP or MN law
- Arrangements that qualify for advisory opinions
  - Meeting advisory opinion v. consistent with advisory opinion v. obtaining advisory opinion
- Offering educational materials without trying to influence a patient's decision
- Non-cash gifts that are less than $15 each or $75 maximum in the aggregate on an annual, per patient basis

What About?

- The Stark Law
- Actions that fall within a safe harbor or exception under the AKS or CMP
  - Referral Services Safe Harbor
  - Personal Services and Management Safe Harbor
    - Using independent contractors through this safe harbor
  - Bona Fide Employee Safe Harbor
    - Using W-2 employees to market business
  - Promotes Access to Care Exception under CMP

What About?

- Any payment to the referral service “intended” to generate Medicare/Medicaid referrals, but also to get their legitimate expertise on a particular issue
  - Does it matter if the payment is for the “expertise” and not the referrals?
- “Swapping” arrangements
  - You refer patients to me for XYZ and I’ll refer to you for ABC?
- 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.

What About?

- Rewarding patients for receiving care or for choosing a certain provider
  - Movie tickets, food baskets, general purpose debt cards, etc.
- Remuneration to the resident, not someone who refers other residents
  - Waivers of copay and deductibles
  - Transfers of items or services for free or less than fair market value
- Paying independent marketing companies on a referral or percentage basis

What About?

- Distinguishing advertising from “referring”?
- How much marketing is too much marketing?
- Gifts
  - Gifts cards, rewards, etc. for persons who refer business.
- "Refer a friend" programs
- Splitting fees with third parties in exchange for referring business
- Arrangements that do not trigger “fee splitting” and do not involve state insurance?

What About?

- Marketing personnel who work directly for your company
  - Employees paid based on leads they generate
  - Independent contractors paid based on leads they generate
- New “resident specials”
  - Offering discount/specials for up-front move in costs
  - Are services reimbursable by federal health care programs?
  - Does resident require other services reimbursable by federal health care programs?

What About?

- Placement fees not calculated on basis of charges of Federal health care programs
- Situations that do not clearly fall within a safe harbor or exception
  - If there are enough risk reduction factors, then a provider might be safe
  - Example: Advisory Opinion No. 11–16
    - Hospital's program that provides transportation, lodging, and meal assistance to certain patients and their family members was approved
    - Enough factors to protect against risk of fraud and abuse
      - Requester is a nonprofit that is reimbursed for less than 25% of the costs it expends for federally funded beneficiaries
      - Services not marketed to prospective patients, families, or referring patients

Hypothetical 1—is this ok?

- Hospital operates post-discharge referral service
- Lists SNF, HHA, assisted living providers
- Once post-discharge provider selected, hospital sends info to referral service which forwarded to provider
- Providers pay 1 time implementation fee and monthly service fee
- Hospitals discharged on first-come, first serve basis which means post-acute providers submitting electronic requests get preference

Hypothetical 2—is this ok?

- Assisted Living facilities contract with placement agency to refer patients to AL facilities.
- Agency and AL do not accept govt. patients and inform customers of same at outset of relationship.
- Participant ALs are affiliated with entities that do offer services covered by govt. programs (e.g., SNF, HHAs).
- Referral fee is fixed for AL with a bonus if patient selects SNF, HHA at later date

Hypothetical 3—is this ok?

- Web-based placement service (“Doc for Grandma.com”) holds itself as making recommendations “in grandma’s best interests”
- Purports to offer review and consults by “qualified providers, just like Dr. Westby would do”
- Website branded with medical lingo like “doc”, “M.D.”
- Facilities do not accept Medicare/Medicaid and Doc for Grandma.com clearly says no govt. patients allowed
- Facilities pay Doc for Grandma.com a fixed fee of $1000 per month, regardless of volume

Hypothetical 4—is this ok?

- LTC facility wants to market itself as a high quality provider for senior living and offer Best Buy gift cards to people who take tours
- Facility does not want to get into trouble, so offers cards not to residents (or potential residents) but to family members

Risk Reduction Tips

- The importance of intent
- Arrangements that have a low risk of improper utilization
- No link between a placement fee calculation and charges to federal/state health care program
- Prohibiting placement and acceptance of potential residents who rely on federal/state funds
- Refraining from actively marketing an arrangement
- Thinking about how a remuneration might influence a beneficiary under both the AKS and CMP

Looking Forward

- Possible AKS Reform
  - Hearing held on July 17, 2018
  - HHS Deputy Secretary Eric Hargan indicated that HHS will soon issue a Request for Information on AKS reforms
  - Part of HHS's "Regulatory Sprint to Coordinate Care"
    - "The goal of the sprint is to remove regulatory barriers to coordinated care while ensuring patient safety" – Hargan

Questions?

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