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# PURCHASING INTERNET LEADS: SURE, IT CAN BE DONE, BUT BE VERY CAREFUL

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# INTRODUCTION



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- There is an increase in utilization of durable medical equipment (“DME”); this is to be expected in light of the “graying of America.”
- Generally speaking, DME is expensive
- Unfortunately, not all suppliers are in the industry with the goal of providing high-quality care to its patients

# INTRODUCTION

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- As a result, the HME industry will have to deal with intrusive government scrutiny
- Many things perfectly legal in other industries will be illegal in the health care industry
- Compliance with the regulations is key to surviving
- However, because the regulations are broadly written and enforced, it is often hard to comply



# FRAUD AND ABUSE GUIDELINES



# FRAUD AND ABUSE GUIDELINES

- Federal Anti-Kickback Statute (“AKS”)
  - Prohibits a person from knowingly and willfully offering, paying, soliciting, or receiving remuneration, whether directly or indirectly, to induce referrals of items or services covered by Medicare, Medicaid, or any other federally funded health care program
- Applicable Safe Harbors
  - Personal Services and Management Agreements
  - Space and Equipment Leases, and
  - Employment

# FRAUD AND ABUSE GUIDELINES

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- Physician Self-Referral Law or Stark Law
  - Prohibits a physician from referring patients to an entity with which the physician or an immediate family member of the physician has a “financial relationship” for designated health services
  - There are exceptions to the restrictions. Relevant exceptions are similar to those for the Anti-Kickback Statute
    - Personal Services and Management Agreements
    - Space and Equipment Leases, and
    - Employment

# FRAUD AND ABUSE GUIDELINES

- Federal False Claims Act
  - Provides that persons and companies that submit false or fraudulent claims for payment to any of the federal health care programs are subject to a civil penalty of between \$5,500 and \$11,000 for each false claim (those amounts are adjusted from time to time) and treble the amount of the government's damages
- Beneficiary Inducement Statute
  - This statute does not prohibit the giving of incentives that are of "nominal value" (no more than \$15 per item or \$75 in the aggregate to any one beneficiary on an annual basis)



# FRAUD AND ABUSE GUIDELINES

## ■ Anti-Solicitation Statute

- A supplier of a covered item may not contact a Medicare beneficiary by telephone regarding the furnishing of a covered item unless
  - the beneficiary has given written permission for the contact;
  - a supplier has previously provided the covered item to the beneficiary and the supplier is contacting the beneficiary regarding the covered item; or
  - if the telephone contact is regarding the furnishing of a covered item other than an item already furnished to the beneficiary, the supplier has furnished at least one covered item to the beneficiary during the preceding 15 months



# UTILIZATION OF A MARKETING COMPANY



# BE AWARE OF KICKBACK PROBLEMS

- In the real world, it is common for a business to “outsource” marketing to a marketing company.
- Unfortunately, what works in the real world often does not work in the health care universe. An example of this has to do with marketing companies
- If a marketing company generates patients for a supplier when at least some of the patients are covered by a government health care program, then the supplier cannot pay commissions to the marketing company

# BE AWARE OF KICKBACK PROBLEMS

- The federal anti-kickback statute makes it a felony to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce a person to refer an individual for the furnishing, or arranging for the furnishing, of any Medicare-covered item or service or to induce such person to purchase or lease, or recommend the purchase or lease, of any Medicare-covered item or service.

# BE AWARE OF KICKBACK PROBLEMS

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- The only way that an independent contractor can be paid for marketing or promoting Medicare-covered items or services is if the arrangement complies with the personal services and management contracts safe harbor
- This safe harbor permits payments to referral sources as long as a number of requirements are met

# BE AWARE OF KICKBACK PROBLEMS

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- Two of the requirements are that
  - payments must be pursuant to a written agreement with a term of at least one year and
  - the aggregate compensation paid to the independent contractor must be set in advance (e.g., \$24,000 over the next 12 months), be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or business generated between the parties.

# BE AWARE OF KICKBACK PROBLEMS

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- The OIG has repeatedly expressed concern about percentage-based compensation arrangements involving 1099 independent contractor sales agents

# BE AWARE OF KICKBACK PROBLEMS

- As discussed above, in Advisory Opinion No. 06-02, the OIG stated that “[p]ercentage compensation arrangements are inherently problematic under the Anti-Kickback Statute, because they relate to the volume or value of business generated between the parties.” Moreover, in Advisory Opinion No. 99-3, the OIG stated
  - Sales agents are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals, typically manufacturers, or other sellers (collectively, “Sellers”)



# BE AWARE OF KICKBACK PROBLEMS

- Accordingly, any compensation arrangement between a Seller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the anti-kickback statute, irrespective of the methodology used to compensate the agent
- Moreover, because such agents are independent contractors, they are less accountable to the Seller than an employee
- For these reasons, this Office has a longstanding concern with independent sales agency arrangements

# BE AWARE OF KICKBACK PROBLEMS

- Further, in its response to comments submitted when the safe harbor regulations were originally proposed, the OIG stated
  - [M]any commentators suggested that we broaden the [employee safe harbor] to apply to independent contractors paid on a commission basis.
  - We have declined to adopt this approach because we are aware of many examples of abusive practices by sales personnel who are paid as independent contractors and who are not under appropriate supervision.

# BE AWARE OF KICKBACK PROBLEMS

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- 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.

# BE AWARE OF KICKBACK PROBLEMS

- A number of courts have held that marketing agreements are illegal under the anti-kickback statute and are, therefore, unenforceable
- In recent years, there have been a number of enforcement actions involving commission payments to independent contractors
- As previously discussed, the OIG has taken the position that even when an arrangement will only focus on commercial patients and “carve out” beneficiaries of federally-funded health care programs, the arrangement will still likely violate the anti-kickback statute



# INTERNET LEADS



# INTERNET LEADS

- Lead generation companies (“LGCs”) have been around for years in the non-health care space. However, in the last several years, LGCs have come into the health care market in droves
- Unfortunately, most LGCs that have been successful in the widget market are clueless regarding the multiple federal and state anti-fraud laws in the health care market, such as the federal anti-kickback statute and certain state anti-kickback statutes

# INTERNET LEADS

- When a DME supplier signs a lead generation agreement (“LGA”) with a LGC, an important legal issue involves the federal anti-kickback statute and certain state anti-kickback statutes
- It is acceptable to purchase a lead; however, it is a violation of anti-kickback statutes to pay for referrals. The line between the two can be blurry
- It is acceptable for a LGC to obtain basic information from a lead (name, address, and telephone number) and sell this “raw” lead to a DME supplier

# INTERNET LEADS

- The supplier can, in turn, pay the LGC on a per-lead basis. If, however, the LGC obtains “qualifying” information on the lead (e.g., Medicare number, other insurance information, medical condition, physician’s name, products currently being used, etc.) and sells the qualified lead to the supplier which, in turn, pays for the lead on a per-lead basis, then it is likely that an enforcement agency will take the position that the supplier is not buying a lead, but is paying for a referral ... which violates anti-kickback statutes.





# HIPAA RESTRICTIONS ON MARKETING



# HIPAA RESTRICTIONS ON MARKETING

- The Health Insurance Portability and Accountability Act (“HIPAA”) requires “covered entities” to obtain a valid authorization from individuals before using or disclosing protected health information (“PHI”) to market a product or service to them.

# HIPAA RESTRICTIONS ON MARKETING

- HIPAA broadly defines “use” of PHI to include the sharing, employment, application, utilization, examination, or analysis of such information. 42 CFR § 160.103. The new HIPAA definition of marketing states what is not marketing:
  - Marketing does not include a communication made: ... [f]or the following treatment and health care operations purposes, except where the covered entity receives financial remuneration in exchange for making the communication[,] ...
  - 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.



# TELEHEALTH



# TELEHEALTH

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- Definition
  - The electronic transfer of medical information for the purpose of providing patient care. The use of technology to deliver health care, health information, or health education at a distance
- Telehealth can be divided into three general types of applications
  - Real-Time Communication
    - Real-time communication may be a patient and a nurse practitioner consulting with a specialist via a live audio/video link or a physician and a patient in an exam room communicating through an interpreter who is connected by phone or webcam

# TELEHEALTH

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- Store-and-Forward or Asynchronous
  - The transmission of digital images for a diagnosis
- Remote Patient Monitoring
  - Involves collection of a patient's personal health and medical data via electronic communication technologies. Once collected, the data is transmitted to a health care provider at a different location, allowing the provider to continue tracking the patient's data once the patient has been released to his/her home or another care facility

# TELEHEALTH

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- The boundaries of telehealth are limited only by the technology available. New applications are being invented and tested every day
- Bottom line: It's a tool to enhance the provision of quality care



# TELEHEALTH ADVANTAGES





# TELEHEALTH ADVANTAGES

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- Increases access to specialists
- Enhances the quality and coordination of care
- Helps address the health care professional shortage in rural areas
- Utilizes professional time more efficiently
- Saves patient and provider travel
- Saves patient loss of work time or children loss of school time

# TELEHEALTH ADVANTAGES

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- Supports the local main street and health care community by keeping the patient at home
- Medical education can be obtained locally
- Enhances professional relationships
- Bridges the distance between hometown providers and advanced specialty practices

# GROWING IN POPULARITY

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- Hospitals are embracing the use of telehealth technologies
  - In 2013, 52% of hospitals utilized telehealth, and
  - another 10% were beginning the process of implementing telehealth services
- Consumer interest, acceptance, and confidence in telehealth are growing

# GROWING IN POPULARITY

- Recent studies on the use of telehealth services have shown that
  - 74% of U.S. consumers would use telehealth services;
  - 76% of patients prioritize access to care over the need for human interactions with their health care providers;
  - 70% of patients are comfortable communicating with their health care providers via text, e-mail, or video in lieu of seeing them in person; and
  - 30% of patients already use computers or mobile devices to check for medical or diagnostic information



# PAYMENT FOR TELEHEALTH SERVICES



# PAYMENT FOR TELEHEALTH SERVICES

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- Medicare

- At this time, limited payment

- Medicare coverage for telehealth services was authorized in 2000 as part of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA)
- BIPA specified that Medicare covers telehealth only for beneficiaries receiving services in a facility in a rural area, defined as a facility located in a rural health professional shortage area or a county that is not included in a Metropolitan Statistical Area (MSA)

# PAYMENT FOR TELEHEALTH SERVICES

- Medicare pays for a limited number of Part B services furnished by a physician or practitioner to an eligible beneficiary via a telecommunications system. For eligible telehealth services, the use of a telecommunications system substitutes for an in-person encounter
- As a condition of payment, the care must be provided by using an interactive audio and video telecommunications system that permits real-time communication between the caregiver at the distant site and the beneficiary at the originating site

# PAYMENT FOR TELEHEALTH SERVICES

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- Originating Site
  - An originating site is the location of an eligible Medicare beneficiary at the time the service furnished via a telecommunications system occurs and must be located in
    - A rural Health Professional Shortage Area (HPSA) located either outside of an MSA; or
    - in a rural census tract; or
    - county outside of an MSA



# PAYMENT FOR TELEHEALTH SERVICES

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- The originating sites authorized by law are
  - The offices of physicians or practitioners
  - Hospitals
  - Critical Access Hospitals (CAHs)
  - Rural Health Clinics
  - Federally Qualified Health Centers
  - Hospital-based or CAH-based Renal Dialysis Centers (including satellites)
    - Note: Independent Renal Dialysis Facilities are not eligible originating sites
  - Skilled Nursing Facilities (SNFs) and
  - Community Mental Health Centers (CMHCs)

# PAYMENT FOR TELEHEALTH SERVICES

- Distant Site Practitioners
  - Practitioners at the distant site who may furnish and receive payment for covered telehealth services (subject to state law) are
    - Physicians
    - Nurse Practitioners (NPs)
    - Physician assistants (PAs)
    - Nurse-midwives
    - Clinical nurse specialists (CNSs)
    - Certified registered nurse anesthetists
    - Clinical psychologists (CPs) and
    - Clinical social workers (CSWs)

# PAYMENT FOR TELEHEALTH SERVICES

- For services that meet these criteria, hospitals are paid a facility fee of approximately \$25 for each claim to cover services provided to patients in an inpatient or hospital outpatient clinic setting
  - Off-site hospital-owned sites also are considered “facilities” in the context of a facility fee
  - Professional fees for provision of telehealth services are the same as those paid for an in-person encounter and are based on physician fee schedule



# SHAM TELEHEALTH ARRANGEMENTS



# SHAM TELEHEALTH ARRANGEMENTS

- DME suppliers and pharmacies are aggressively engaged in marketing, and it is not uncommon for these suppliers to ship products to patients residing in multiple states
- When a DME supplier or pharmacy is marketing to patients in multiple states, the supplier may run into a “bottleneck”
- This involves the patient’s local physician. A patient may desire to purchase a product from the DME supplier or pharmacy, but it is too inconvenient for the patient to drive to his physician’s office

# SHAM TELEHEALTH ARRANGEMENTS

- Or if the patient is seen by his local physician, the physician may decide that the patient does not need the requested item, so the physician refuses to sign an order
- Or even if the physician does sign an order, he may be hesitant to send the order to an out-of-state supplier
- In order to address this challenge, some DME suppliers and pharmacies enter into arrangements that will get them into trouble

# SHAM TELEHEALTH ARRANGEMENTS

- This has to do with sham “telehealth” arrangements.
- A typical telehealth company has contracts with many physicians who practice in multiple states
- The telehealth company contracts with, and is paid by
  - self-funded employers that pay a membership fee for their employees
  - health plans and
  - patients who pay a per-visit fee

# SHAM TELEHEALTH ARRANGEMENTS

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- A DME supplier or pharmacy will find itself in trouble when it aligns itself with a telehealth company that is not paid by employers, health plans, and patients, but rather is directly or indirectly paid by the supplier.



# SHAM TELEHEALTH ARRANGEMENTS

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- Here is an example
  - DME supplier or pharmacy purchases leads from a marketing company.
  - The marketing company sends the leads to the telehealth company
  - The telehealth company contacts the leads and schedules audio or audio/visual encounters with physicians contracted with the telehealth company
  - The physicians sign orders for products
  - The telehealth company sends the orders to the supplier

# SHAM TELEHEALTH ARRANGEMENTS

- The marketing company pays compensation to the telehealth company for its services in contacting the leads and setting up the physician appointments
- The telehealth company pays the physicians for their patient encounters
- The DME supplier or pharmacy mails the product to the patient
- The supplier bills (and gets paid by) Medicare
- There can be a number of permutations to this example, but you get the picture
- **Stripping everything away, the DME supplier is paying the ordering physician**

# SHAM TELEHEALTH ARRANGEMENTS

- To the extent that a DME supplier, directly or indirectly, pays money to a telehealth company which in turn writes an order for a product that will be provided by the DME supplier, the arrangement will likely be viewed as remuneration for a referral (or remuneration for “arranging for” a referral)
- If the payer is a federal health care program, then the arrangement will likely violate the AKS
- If the payer is the state Medicaid program, then the arrangement will likely violate both the AKS and the state anti-kickback statute

# SHAM TELEHEALTH ARRANGEMENTS

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- If the item is a designated health service, you may have a Stark violation
- If the payer is a commercial insurer, then the arrangement may violate a state statute



# QUESTIONS?





**THANK YOU**

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