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# ANATOMY OF A GOVERNMENT INVESTIGATION: A LOOK AT THE CRIMINAL INVESTIGATION OF ORTHOTIC SUPPLIES

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# INTRODUCTION

# CONVERGENCE OF DIRECT-TO-CONSUMER ADVERTISING, TELEMARKETING, & TELEMEDICINE

- Direct-to-consumer advertising, telemarketing, and telemedicine are each highly scrutinized areas.
- However, if done correctly, these, either by themselves or together, are perfectly legal business activities, and very often can meet the needs of an under served portion of the population.
- However, because of certain inherent weaknesses of these activities, they are susceptible to abuse. Further, because many aspects of these arrangements involve work done by third parties outside the view of the DME company, compliance is much harder to confirm or maintain.
- In the last two years, the Government has cracked down on various marketing/telemedicine arrangements in three significant investigations/“Operations”.

# RECENT MAJOR GOVERNMENT “OPERATIONS”

- Operation Brace Yourself
  - Criminal prosecution of 24 defendants and administrative actions against 130 DME companies related to over \$1.2 billion in losses.
  - The Government alleged that the defendants engaged in a scheme involving telemarketing and telemedicine to push medically unnecessary “off-the-shelf” orthotic braces.
- Operation Double Helix
  - Criminal prosecution of 35 defendants related to over \$2.1 billion in losses.
  - The Government alleged that the defendants engaged in a scheme involving telemarketing and telemedicine to push medically unnecessary genetic testing.
- Operation Rubber Stamp
  - Allegations of an additional \$1.5 billion in fraudulent billing (again involving telemarketing and telehealth) for DME products, genetic testing, and pain medications.

# RECENT MAJOR GOVERNMENT “OPERATIONS”

- In addition to the extensive criminal prosecutions that resulted from the operations, there has also been extensive civil investigations by the Department of Justice (“DOJ”). Further, CMS and its various contractors have also been very active in auditing companies engaged in this sort of conduct.
- While these DOJ investigations demonstrate the level of scrutiny the Government can have for these types of business arrangements, these arrangements are not illegal or even improper in every case.
- There are a number of important lessons the industry can learn from the missteps and mistakes the subjects of these “Operations” made.



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# PRIMARY AREAS OF FEDERAL HEALTH CARE PROGRAM ENFORCEMENT

# KEY FEDERAL LAWS AND REGULATIONS

- Business models that include direct-to-consumer marketing (especially telemarketing) and/or telemedicine implicate numerous federal laws and regulations. This relates to both compliance and possible enforcement/liability.
- Key compliance laws:
  - HIPAA – any business arrangement involving medical matters, implicates patient privacy concerns and compliance with HIPAA is required at all levels
  - TCPA – any contact with a consumer for commercial/marketing purposes must comply with the requirements of the TCPA, significantly with the requirement that contact with the beneficiary be authorized by the beneficiary's express written consent
  - Stark/AKS/FCA – marketing arrangements and the submission of claims, must meet with the requirements and standards of these federal laws
  - Relevant standards for the use of telemedicine, for example:
    - Payment for services by a federal health care program based upon a telemedicine encounter is only allowed under certain limited circumstances
    - In many circumstances, certain requirements, such as medical necessity, cannot be satisfied through a telemedicine encounter

# KEY FEDERAL LAWS AND REGULATIONS

- In addition to providing the relevant compliance rules, the following statutes also have built in liability/enforcement provision:
  - TCPA – violations of the various provisions of the TCPA creates a private cause of action
  - HIPAA
  - Stark/AKS/FCA
    - Violation of the Stark law results in strict (no fault) civil liability
    - Violation of the AKS (requires intent) creates criminal liability
    - FCA liability can result from claims that are factually false (e.g. lack of medical necessity) or are legally false (violations of Stark or AKS)
- In addition to these, the Government has several other means of enforcement mechanisms :
  - Mail and Wire Fraud laws
  - The “Travel Act” – under this, the Federal Government has successfully prosecuted purely state law criminal violations involving only private insurance patients on the basis that these violations used interstate commerce as part of criminal scheme.



# HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)

- HIPAA requires that covered entities protect the privacy and security of protected health information (PHI).
- Covered entities are only permitted to disclose PHI to certain allowed persons or entities, including those with whom they have a Business Associate Agreement (BAA) with.
- Covered entities are also required to make certain notification in the event of a data breach.

# TELEPHONE CONSUMER PROTECTION ACT (TCPA)

- The TCPA is intended to protect consumers from certain abusive telemarketing activities, including calls using auto-dialing systems or prerecorded or artificial voices.
- In addition to this, the TCPA requires companies to maintain do-not-call lists and authorizes the creation of a national do-not-call list.
- In order to be protected from TCPA liability, a company must receive prior express consent or prior express written consent (depending on the circumstances).
- In order to be effective, this express written consent must be of sufficient specificity to be effective. However, what constitutes sufficient specificity is not always clear.

# FALSE CLAIMS ACT (FCA)

- The FCA imposes civil liability on any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the federal government, including claims submitted to a Medicaid program. (31 United States Code (U.S.C.) Sections 3729–3733)
- The terms “knowing” and “knowingly” mean a person has actual knowledge of the information or acts in deliberate ignorance or reckless disregard of the truth or falsity of the information related to the claim. However, no specific intent to defraud is required to violate the FCA.
- The penalty for each violation of the FCA can be 3x the amount of damages suffered by the government plus a penalty for each false claim between \$11,665 and \$23,331 (for 2020).

# FEDERAL ANTI-KICKBACK STATUTE (AKS)

- It is a federal crime to knowingly and willfully offer, pay, solicit, or receive any remuneration, directly or indirectly, to induce or reward patient referrals or the generation of business involving any item or service reimbursable by a federal health care program. (42 U.S.C. Section 1320a-7b(b))
- When a provider offers, pays, solicits, or receives unlawful remuneration, the provider violates the AKS.
- A remuneration is anything of value.
- The penalty for each violation of the AKS can be 3x the amount of damages suffered by the government plus a penalty for each false claim.
- Claims resulting from an arrangement involving an illegal kickback scheme are considered false claims for purposes of the FCA even if the claim was medically necessary and appropriate in all other respects.

# PHYSICIAN SELF-REFERRAL STATUTE (STARK LAW)

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- The Stark Law prohibits a physician from referring patients to receive “designated health services” payable by Medicare or Medicaid to an entity with which the physician or a member of the physician’s immediate family has a financial relationship.
- The penalty for each violation of the Stark Law can include fines and exclusion from participation in federal health care programs.
- Claims resulting from an arrangement involving a Stark violation are considered false claims for purposes of the FCA even if the claim was medically necessary and appropriate in all other respects.

# STATE ANTI-FRAUD STATUTES

- Each state has an anti-kickback statute that is similar to the federal AKS. The following are examples of some specific anti-kickback statutes:
  - Fla. Stat. Ann. § 817.505(1)(a)-(c) (criminal liability for offering/paying or soliciting/receiving any benefit for referral of a patient); Fla. Stat. Ann. § 395.0185 (professional liability for kickback for referral of patients to a licensed facility)
  - Cal. Welf. & Inst. Code § 14107.2(a)-(b) (criminal liability for paying for referral of claims reimbursable by state health care system); Cal. Health & Safety Code § 445 (criminal liability for referring patient to health care facility for profit)
  - Tex. Occ. Code Ann. § 102.001(a) (criminal liability for soliciting/accepting or offering/paying for the referral of patients)
- The DOJ has recently begun pursuing purely state law violations through the Federal Travel Act. Furthermore, each state can independently decide to prosecute companies that violate that state's respective AKS law.



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# HOW DOES THE GOVERNMENT SELECT ITS TARGETS

# WHY ME?

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- How are the subjects of investigations identified:
  - Data analytics
  - Complaint by patient or family member
  - Report by a whistleblower
  - Complaint by competitor regarding unfair business practices
  - Testimony or evidence obtained in the investigation of another medical provider or supplier



# DATA ANALYTICS

- Federal health care programs have begun to review and analyze claims and related data to detect aberrant trends, outliers, and unusual billing patterns.
- For many of these arrangement that the Government has targeted in recent years, there have been some key factors:
  - A significant increase in claims for certain products with high reimbursement rates (increase both in the number of companies billing for these claims, and the volume of claims being submitted by these companies). These have included the following:
    - Off-the shelf orthotics
    - Genetic testing
    - Glucose monitoring
    - Pain creams
  - The number of claims being submitted per beneficiary (a result of “upselling” the beneficiary”

# RESULT OF ANOTHER AUDIT OR INVESTIGATION

- In many of the Government's operations, there has been significant overlap in the people involved in the marketing and the telehealth companies.
  - Many key defendants operated multiple marketing and telehealth companies. It was a common practice for these individuals to shut down a company once it was under scrutiny, only to open another company using the same practices.
- Similarly, many of the doctors providing telehealth services were involved with multiple telehealth companies and DME companies.
- So as these companies and individuals are investigated, additional DME companies they worked with come under scrutiny.



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# SCRUTINY OF THESE OUTSIDE OF CRIMINAL PROSECUTIONS

# CMS AUDITS

- CMS and its various contractors have also been strictly scrutinizing these arrangements, paying particular attention to companies engaged in marketing and selling certain product types (e.g., orthotics and genetic tests).
- Fortunate DME companies only have a temporary payment suspension that is possibly accompanied by a recoupment.
- The less fortunate DME companies have their Medicare supplier number revoked due to allegations and findings of fraud, waste, and abuse.
- The even less fortunate DME companies have their cases referred to the DOJ for further investigation.

# CIVIL DOJ INVESTIGATIONS

- In addition to the criminal actions the DOJ has prosecuted, the DOJ's civil division has been equally busy, pursuing civil investigations against DME companies.
- These generally involve allegations of False Claims (FCA) due to illegal kickbacks in violation of the AKS.
- Under the FCA, the Government can seek to recover any amount paid for false claims. However, the Government can treble that amount and seek additional penalties in the amount of between \$11,665 and \$23,331 for each false claim.



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# COMMON RED FLAGS AND AREAS OF CONCERN IN THESE ARRANGEMENTS

# RED FLAGS

- Problems with the Agreements
  - In most of these cases, the DME's problems often start with the marketing and call-center service agreements.
  - These agreements usually follow one of a handful of forms that generally create significant risk of violating the AKS.
  - In effect, these agreements arrange for payment in exchange for qualified leads and physician's orders.
- Problems with the Marketing Calls
  - The arrangements have issues related to whether express written consent was actually acquired prior to contacting the beneficiary.
  - Additionally, these calls generally follow the same basic script that have several serious defects.

# RED FLAGS

- Problems with the doctor's order
  - The physician's order and clinical notes are usually from a handful of templates that are essentially fill-in-the blank forms.
- The type and number of claims
  - The claims are for one or more of a highly suspect product type—e.g., off-the-shelf orthotics.
  - Claims for multiple product types per beneficiary.
- Red flagged medical providers
  - Certain medical providers have been flagged as being significantly involved in these illegal schemes.
  - Orders and notes signed by these providers will be more highly scrutinized.





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# LESSONS IN COMPLIANCE

# COMPLIANCE TOUCHES EVERYTHING

- These arrangements must comply with numerous laws and regulations at all points in their structure and execution. This includes compliance with HIPAA, the TCPA, the AKS, Stark, and the FCA.
- It is not enough that these arrangements are originally structured to be compliant. More importantly, they must be executed in a compliant fashion.
- Failure to comply at any of these points opens the door to potential civil or criminal liability.

# ACCOUNTABLE FOR THE SINS OF ANOTHER

- A DME company that submits claims for payment is responsible for compliance with all relevant laws and regulations. This is the case, even if you have contracted with another party to perform certain duties and even for acts that, by necessity, are done by another (such as an examination by a medical provider).
- This duty ranges from issues as significant as determining medical necessity to as seemingly inconsequential as obtaining signed proof of delivery.

# THERE ARE NO SILVER BULLETS

- These arrangements must comply with multiple different laws and regulations.
- Each of these separate standards has different objectives in mind.
- Consequently, the steps and safeguards needed to ensure compliance with each of these standards will be different—i.e., each standard requires its own solution.
- For example, a marketing arrangement could fall within one of the AKS's safe harbors, but this does not protect against potential TCPA violations or other reasons a claim could be a false claim (e.g., medical necessity or an improper telemedicine encounter).



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# TIPS TO CONSIDER

# TIP NO. 1 – HIRE A LAWYER

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- Retain an experienced health care attorney to develop a compliance program that addresses all applicable compliance issues, and then stick to it.
- Have a health care attorney assist in preparing your marketing or lead generation and qualification agreements.

# TIP NO. 2 – LIMIT YOUR MARKETING TO JUST YOUR COMPANY

- Require that the beneficiary “opt-in” language be specific to your company and its products.
- Require the following in any marketing calls:
  - That the marketer clearly identify your company and your company only—i.e., do not allow your marketer to make calls on behalf of groups of companies.
  - Limit the calls to only those products the beneficiary “opted in” for.
  - Prohibit upselling for additional products.
  - Clearly inform the beneficiary that the call is simply to confirm the beneficiary’s eligibility, and that the beneficiary will only receive the product based upon an order written by a medical provider after an examination.

# TIP NO. 3 – AVOID TELEMEDICINE

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- If possible, only accept order written by the beneficiary's primary care provider.
- If possible, prohibit the discussion of telemedicine by your marketing service providers with beneficiaries.
- If telemedicine is necessary, require the following criteria be met:
  - That you be informed in writing, with an explanation, of any decision to use telemedicine.
  - That the telemedicine provider provide you with supporting documentation showing why telemedicine was necessary, and how the encounter was compliant.
  - Require that the telemedicine provider be paid by the beneficiary or the beneficiary's insurance.



# TIP NO. 4 – STRUCTURE PROTECTION INTO YOUR AGREEMENTS

- Structure marketing agreements to conform to an applicable safe harbor.
- Split up marketing and call-service duties among multiple, unrelated entities to avoid the risk that you are paying for qualified leads.
- As part of your agreements with your various service providers, require them to agree to be audited and to maintain records demonstrating their compliance with your company's standards and applicable laws and regulations.

# TIP NO. 5 – CONDUCT PERIODIC REVIEW AND AUDITS

- Regularly review your marketing company's work including the advertisements, opt-in language, and marketing calls.
- Review physician's orders and supporting documentation for compliance with all rules and regulations and your company's standards.
- For any investigations, clearly document the reason for the investigation, the steps taken in the investigation, and the results of the investigation.

# TIP NO. 6 – MAINTAIN CLEAR AND ORGANIZED RECORDS

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- Documents supporting medical necessity and physician compliance.
- Files supporting the submission of claims.
- Records detailing reviews and self-audits conducted in connection with your company's compliance program.
- Records and reports on any compliance issues, including what issues were identified and what steps were taken to correct the issue.



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# QUESTIONS?

Email us at [customerservice@achcu.com](mailto:customerservice@achcu.com)



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# THANK YOU

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