Legal and Regulatory Aspects of Marketing

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Objectives

- Define the federal anti-fraud laws that govern marketing programs and joint ventures and other arrangements with physicians, hospitals and other referral sources
- Identify the marketing arrangements, joint ventures, and other arrangements that are legally acceptable
- Identify the marketing arrangements, joint ventures, and other arrangements that must be avoided
Introduction
Introduction

- The “Greatest Generation” consisted of 23 million Americans.
- We now have 78 million “Baby Boomers”…those born between 1946 and 1964.
- Boomers are retiring at the rate of 10,000 per day.
Introduction

- The life span of Boomers is greater than earlier generations.
- As Boomers age, the demand for health care – particularly prescription drugs – will increase exponentially.
- At the same time, there is a limited amount of money to pay for this health care.
- This is the proverbial “irresistible force” running into the “immovable object.”
Introduction

- Like other health care providers, pharmacies are being squeezed.
- It is particularly difficult for a pharmacy to generate much of a profit selling commercially available drugs.
In order to succeed in today’s hyper-competitive environment, the pharmacy must establish its niche. It must “think outside the box.”

The successful pharmacy must set itself apart from its competition.

One very important way to do this is for the pharmacy to implement an aggressive marketing program and enter into joint ventures and other arrangements with physicians, hospitals and other providers; and offer “value-added” services to customers, physicians, other referral sources, and third party payers.
Beneficiary Inducement Statute

- This statute prohibits a pharmacy from offering or giving anything of value to a Medicare beneficiary that the pharmacy knows, or should know, is likely to persuade the person to purchase a Medicare-covered item.

- In the preamble to the regulations implementing this statute, the OIG stated that the inducement statute does not prohibit the giving of incentives that are of “nominal value.”
Beneficiary Inducement Statute

- The OIG defines “nominal value” as no more than $10 per item or $50 in the aggregate to any one beneficiary on an annual basis.
- “Nominal value” is based on the retail purchase price of the item.
Medicare Anti-Kickback Statute

- It is a felony for a health care provider to knowingly and willfully offer or pay any remuneration to induce a person/entity to refer an individual for the furnishing or arranging for the furnishing of any item for which payment may be made under a federal health care program, or the purchase or lease or the recommendation of the purchase or lease of any item for which payment may be made under a federal health care program.
Stark Physician Self-Referral Statute

- This statute provides that if a physician has a financial relationship with an entity providing “designated health services,” then the physician may not refer Medicare/Medicaid patients to the entity unless a Stark exception applies.

- Designated health services include DME; parenteral and enteral nutrients; prosthetics, orthotics and prosthetic devices and supplies; and out-patient prescription drugs.
Stark Physician Self-Referral Statute

- One of the exceptions to Stark provides that a health care provider may provide non-cash equivalent items to a physician if such items do not exceed approximately $392 in value during a 12-month period.
Safe Harbors
Safe Harbors

- Because of the breadth of the Medicare anti-kickback statute ("AKS"), the OIG has published a number of “safe harbors.”
- A safe harbor is a hypothetical fact situation such that if an arrangement falls within it, then the AKS is not violated.
- If an arrangement does not fall within a safe harbor, then it does not mean that the arrangement violates the AKS. Rather it means that the arrangement needs to be carefully scrutinized under the language of the AKS, applicable case law, and other published guidance.
- Five of the safe harbors are particularly relevant to pharmacies.
Safe Harbor - Small Investment Interest

- For investments in small entities, “remuneration” does not include a return on the investment if a number of standards are met, including the following: (iv) no more than 40% of the investment can be owned by persons who can generate business for or transact business with the entity, and (ii) no more than 40% of the gross revenue may come from business generated by investors.
Safe Harbor – Space Rental

- Remuneration does not include a lessee’s payment to a lessor as long as a number of standards are met, including the following:
  - (i) The lease agreement must be in writing and signed by the parties;
  - (ii) The lease must specify the premises covered by the lease
  - (iii) If the lease gives the lessee periodic access to the premises, then it must specify exactly the schedule, the intervals, the precise length, and the exact rent for each interval;
Safe Harbor - Space Rental

Cont’d:
– (iv) The term must be for not less than one year; and
– (v) The aggregate rental charge must be set in advance, be consistent with fair market value, and must not take into account business generated between the lessor and the lessee.
Safe Harbor - Equipment Rental

- Remuneration does not include any payment by a lessee of equipment to the lessor of equipment as long as a number of standards are met, including the following:
  - (i) The lease agreement must be in writing and signed by the parties;
  - (ii) The lease must specify the equipment;
  - (iii) For equipment to be leased over periods of time, the lease must specify exactly the scheduled intervals, their precise length and exact rent for each interval;
Safe Harbor - Equipment Rental

Cont’d:
– (iv) The term of the lease must be for not less than one year
– (v) The rent must be set in advance, be consistent with fair market value, and must not take into account any business generated between the lessor and the lessee.
Safe Harbor - Personal Services & Management Contracts

- Remuneration does not include any payment made to an independent contractor as long as a number of standards are met, including the following:
  - (i) The agreement must be in writing and signed by the parties;
  - (ii) The agreement must specify the services to be provided;
  - (iii) If the agreement provides for services on a sporadic or part-time basis, then it must specify exactly the scheduled intervals, their precise length and the exact charge for each interval;
Safe Harbor - Personal Services & Management Contracts

- Cont’d:
  - (iv) The term of the agreement must be for not less than one year;
  - (v) The compensation must be set in advance, be consistent with fair market value, and must not take into account any business generated between the parties; and
  - (vi) The services performed must not involve a business arrangement that violates any state or federal law.
Safe Harbor - Employees

- Remuneration does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made, in whole or in part, under Medicare or under a state health care program.
Advisory Opinions

- A health care provider may submit to the OIG a request for an advisory opinion concerning a business arrangement that the provider has entered into or wishes to enter into in the future.
- In submitting the advisory opinion request, the provider must give to the OIG specific facts.
- In response, the OIG will issue an advisory opinion concerning whether or not there is a likelihood that the arrangement will implicate the anti-kickback statute.
Special Fraud Alerts & Special Advisory Bulletins

- From time to time, the OIG publishes Special Fraud Alerts and Special Advisory Bulletins that discuss business arrangements that the OIG believes may be abusive, and educate health care providers concerning fraudulent and/or abusive practices that the OIG has observed and is observing in the industry.
Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B

- In this Special Fraud Alert, the OIG stated that routine waiver of Medicare cost-sharing amounts “is unlawful because it results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and services paid for by Medicare.”

- The fraud alert lists some “suspect marketing practices,” including
  - Advertisement stating “Medicare Accepted as Payment in Full.”
  - Routine use of “financial hardship” form with no good faith attempt to determine the beneficiary’s actual financial condition.
  - Collection of copayments and deductibles only from beneficiaries who have supplemental insurance.
States

- All states have enacted statutes prohibiting kickbacks, fee splitting, patient brokering, or self-referrals.
- Some statutes only apply when the payer is a government health care program.
- Other statutes apply regardless of the identity of the payer.
W2 Employee vs. 1099 Independent Contractor
W2 vs. 1099

- The OIG has repeatedly expressed concern about percentage-based compensation arrangements involving 1099 independent contractor sales agents.
- 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.”
A number of courts have held that marketing arrangements are illegal under the anti-kickback statute and are, therefore, unenforceable.

For example, the 1996 Florida Medical Development Network case involved an agreement wherein a durable medical equipment supplier agreed to pay an independent contractor marketing company (the “Marketer”) a percentage of the DME supplier’s sales in exchange for marketing its products to physicians, nursing homes, and others.
W2 vs. 1099

- When the DME supplier breached the contract, the Marketer sued and the DME supplier defended on the ground that the agreement was illegal under the anti-kickback statute.

- A Florida appeals court agreed and affirmed the trial court’s ruling, holding that the agreement was illegal and unenforceable because the Marketer’s receipt of a percentage of the sales it generates for the DME supplier violated the federal anti-kickback statute.
W2 vs. 1099

- In recent years, there have been a number of enforcement actions involving commission payments to independent contractors.
- In one example, a home health agency agreed to pay $130,000 after disclosing that it paid commissions for each patient referred to the home health agency by 1099 independent contractor sales representatives.
W2 vs. 1099

- In August 2012, federal and state officials investigating possible health care fraud raided three Alabama compounding pharmacies.
- Although details are scarce, reports from industry sources suggest that the allegedly fraudulent business practices included commission arrangements between the Alabama pharmacies and 1099 independent contractor sales representatives.
Additionally, 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.
Utilization of a Marketing Company
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 pharmacy universe. An example of this has to do with marketing companies.
- If a marketing company generates patients for a pharmacy, when at least some of the patients are covered by a government health care program, then the pharmacy cannot pay commissions to the marketing company.
Utilization of a 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.
Utilization of a Marketing Company: Be Aware of Kickback Problems

- The Office of Inspector General (the “OIG”) has adopted safe harbors that provide immunity for arrangements that satisfy certain requirements.
- The employee safe harbor permits an employer to pay an employee in whatever manner the employer chooses in exchange for the employee assisting in the solicitation of federal health care program business, as long as there is a bona fide employer-employee relationship.
Utilization of a Marketing Company: Be Aware of Kickback Problems

- 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.
Utilization of a Marketing Company: Be Aware of Kickback Problems

- Two of the requirements are that (i) payments must be pursuant to a written agreement with a term of at least one year, and (ii) 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.
Utilization of a Marketing Company: Be Aware of Kickback Problems

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

- 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:
Utilization of a Marketing Company: Be Aware of Kickback Problems

– 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”).
Utilization of a Marketing Company: 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.
Utilization of a Marketing Company: Be Aware of Kickback Problems

– 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.
Utilization of a Marketing Company: Be Aware of Kickback Problems

- Further, in its response to comments submitted when the safe harbor regulations were originally proposed, the OIG stated:
Utilization of a Marketing Company: Be Aware of Kickback Problems

– [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.
Utilization of a Marketing Company: Be Aware of Kickback Problems

– 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.
Utilization of a Marketing Company: 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.
Utilization of a Marketing Company: Be Aware of Kickback Problems

Additionally, 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.
Expenditures For Physicians
Introduction

- A physician is a referral source to the pharmacy.
- The physician refers patients who are covered by a government health care program, who are covered by commercial insurance, or desire to pay cash.
Introduction

- If a pharmacy pays money to a physician for services, or provides meals, gifts and entertainment to a physician, or subsidizes a trip that the physician will take, then both the pharmacy and the physician need to comply with the federal and state laws that govern these arrangements.
What a Pharmacy Can Spend on (or Pay to) a Physician

- While Stark allows a pharmacy to spend up to $392 per year for non-cash/non-cash equivalent items for a physician, the Medicare anti-kickback statute does not include a similar exception.

- Nevertheless, if the Stark exception is met, it is unlikely that the government will take the position that the non-cash/non-cash equivalent items provided by the pharmacy to the physician violate the anti-kickback statute.
What a Pharmacy Can Spend on (or Pay to) a Physician

- In addition to complying with Stark and the anti-kickback statute, the pharmacy and the physician also need to comply with applicable state law.
- Even though the pharmacy and the physician will need to confirm this, it is likely that compliance with the $392 Stark exception will avoid liability under state law.
What a Pharmacy Can Spend on (or Pay to) a Physician

- And so the bottom line is that a pharmacy can provide gifts, entertainment, trips, meals, and similar items to a physician so long as the combined value of all of these items do not exceed $392 in a 12 month period.
What a Pharmacy Can Spend on (or Pay to) a Physician

- For example, if a pharmacist wants a physician to accompany the pharmacist on a trip to a continuing education conference, then the pharmacist can safely subsidize up to $392 of the physician's trip expenses.
- The amount of the trip subsidy will be affected by other expenditures the pharmacy has made on behalf of the physician within the preceding 12 months.
What a Pharmacy Can Spend on (or Pay to) a Physician

- While the Stark $392 exception applies to expenditures on behalf of a physician, the exception does not apply to expenditures on behalf of the physician’s staff.
- In fact, Stark does not apply to the physician’s staff. Expenditures on behalf of the physician’s staff must be examined in light of the Medicare anti-kickback statute.
What a Pharmacy Can Spend on (or Pay to) a Physician

- Separate from furnishing gifts and entertainment, and subsidizing trips, the pharmacy can pay the physician for legitimate services.
- For example, if the pharmacy has a legitimate need for a Medical Director, then the pharmacy and physician can enter into a Medical Director Agreement that complies with both the PSMC safe harbor to the Medicare anti-kickback statute and the Personal Services exception to Stark.
What a Pharmacy Can Spend on (or Pay to) a Physician

- Another legitimate way for money to exchange hands between a pharmacy and a physician is for the physician to rent space to the pharmacy or vice versa.
- The rental arrangement needs to comply with the Space Rental safe harbor to the Medicare anti-kickback statute.
- This safe harbor is similar to the PSMC safe harbor.
What a Pharmacy Can Spend on (or Pay to) a Physician

Among other requirements:
- The parties must execute a written lease agreement that has a term of at least one year
- The rent paid must be fixed one year in advance (e.g., $48,000 over the next 12 months)
- The rent must be fair market value
What a Pharmacy Can Spend on (or Pay to) a Physician

- The rental arrangement needs to also comply with the Space Rental exception to Stark; this exception is similar to the Space Rental safe harbor to the anti-kickback statute.
Examples: Proper Value-Added Services
Example 1

- The health care delivery system is moving to the “clinical outcomes” model in which multiple clinicians/providers work collaboratively to solve a patient’s health care problem.
Example 1

• The forward-thinking pharmacy will gather “outcomes data” that it can present to physicians, other clinicians and, perhaps most importantly, to third-party payers.
• The outcomes data will show how the pharmacy’s products and services are helping the patient and saving money for the payer.
Example 2

- Under the Hospital Readmissions Reduction Program, if a patient is readmitted after discharge within a certain period of time, for a particular disease, then the hospital can be subjected to future payment reductions from Medicare.
Example 2

- The hospital can enter into an arrangement with a pharmacy to monitor/work with discharged patients so that they are not readmitted soon after being discharged.
- In working with discharged patients, the pharmacy can collaborate with a DME supplier, home health agency, primary care physician, etc.
Example 3

- The pharmacy uses a financial hardship form that asks a number of questions regarding the patient’s ability to pay his copayment.
- The pharmacy decides, on a patient-by-patient basis, whether to waive the copayment.
Example 4

- The pharmacy has several RTs on staff. On a quarterly basis, each of the pharmacy’s COPD patients will have the opportunity to meet with an RT.
- The pharmacy advertises that all of its COPD patients have the opportunity to meet with an RT once a quarter.
- Physicians and their staff can also interact with the pharmacy’s RTs in a collaborative effort to take care of patients.
Example 5

- Once a quarter, the pharmacy puts on a workshop, covering a particular disease state, for existing and prospective customers.
- Once a quarter, the pharmacy puts on a workshop of physicians’ staffs.
Example 6

- Assume that the pharmacy provides DME. After a customer decides to obtain an oxygen concentrator from the pharmacy, the pharmacy allows the beneficiary to use oxygen tanks (free of charge) as emergency back-up.
Example 7

- On a customer’s birthday, the pharmacy mails to him a cookbook that is specific to the type of foods the customer needs to eat in order to help the customer overcome a particular health problem.
Example 8

 Once a year, the pharmacy sponsors lunch at a retirement home during which the pharmacy provides an educational program.
 Once a year, the pharmacy sponsors lunch for a physician’s staff during which the pharmacy provides an educational program.
Example 9

- The pharmacy places a fax machine in a physician’s office. Title to the fax remains with the pharmacy.
- The fax is set up so that the physician’s office can use it only to fax orders to the pharmacy. The physician’s office is unable to use the fax for anything else.
Example 10

- Assume that the pharmacy provides DME. In order to encourage patients to return oxygen concentrators to the pharmacy after third party payment coverage ceases, the pharmacy offers a $25 gift card to the patient if he will deliver the concentrator to the pharmacy.
Example 11

- The pharmacy places an employee liaison at the hospital.
- After a patient, before he is discharged, selects the pharmacy for post-discharge products and services, then the liaison will facilitate a smooth transition to the service to be provided by the pharmacy.
- The employee liaison will not perform any services that the hospital is required to perform.
Example 12

- The physician sets up times during the year in which the patients can come to the physician’s office and attend a class taught by a pharmacy that covers treatment of a particular disease state.
Examples: Value-Added Services That End Up Being Prohibited Inducements/Kickbacks
Example 1

- Assume that the pharmacy provides DME. The pharmacy advertises that if a patient chooses to obtain an oxygen concentrator from the pharmacy, then the pharmacy will provide (free of charge) back-up oxygen tanks.
Example 2

- The pharmacy places an employee liaison on the hospital premises.
- The employee liaison performs some duties that a hospital employee would normally be obligated to perform.
Example 3

- The pharmacy advertises that if the patient purchases from the pharmacy, then the patient will not have to pay anything out of pocket.
Example 4

- The pharmacy advertises: “If you qualify for a hardship waiver, then you will pay nothing out-of-pocket.”
Example 5

- At the same time that the pharmacy informs the patient what the copayment is, the pharmacy volunteers to the patient that if he fills out a financial hardship waiver form, then the pharmacy might waive the patient’s copayment.
Example 6

- The pharmacy has, on paper, a proper protocol that addresses when the supplier will ... and will not ... waive a copayment.
- Notwithstanding what is on paper, the evidence shows that the pharmacy collects very few copayments.
Example 7

- 12 times a year, the pharmacy sponsors lunch at a particular retirement home during which the pharmacy provides an educational program.
- 12 times a year, the pharmacy sponsors lunch for a physician’s staff during which the pharmacy provides an educational program.
Example 8

- The pharmacy provides iPads to a physician’s employees. The iPads are to be used to collect and transmit data to the pharmacy.
- However, the physician’s employees are capable of using the iPads for personal use.
Collaboration With Hospital to Prevent Readmissions
Collaboration With Hospital to Prevent Readmissions

- Hospital Readmissions Reduction Program: if a patient is readmitted after discharge within a certain period of time, for a particular disease, then the hospital can be subjected to future payment reductions for Medicare.
Collaboration With Hospital to Prevent Readmissions

- Hospital can contract with a pharmacy to monitor/work with discharged patients so that they are not readmitted soon after being discharged.
- The parties need to follow the guidelines set out in the OIG’s Advisory Opinion No. 13-10. Among other requirements, the hospital needs to pay fair market value compensation for the pharmacy’s services.
Loan/Consignment Closets
Loan/Consignment Closets

- Assume that the pharmacy provides DME. A DME supplier may place inventory in a hospital or physician office. The inventory must be for the convenience only of the hospital’s/physician’s patients and the hospital/physician cannot financially benefit, directly or indirectly, from the inventory.
Loan/Consignment Closets

- If a DME supplier pays rent for a space in which the consigned inventory is placed, then the arrangement should comply with the Space Rental safe harbor.
Hospital Consignment Arrangement and “Chargeback” Obligation
Introduction

- DME suppliers often enter into consignment arrangements with hospitals.
- When a consignment arrangement with a hospital works properly, the DME supplier places products in a “closet” at the hospital, a physician will order a product for a patient to take and use at home, hospital staff will pull the item out of the closet and give it to the patient, the patient is discharged, and the DME supplier will collect the appropriate documents and bill for the item.
Introduction

- An important question is whether there should be a chargeback provision (i) for items that cannot be accounted for; (ii) for items dispensed with improper or insufficient paperwork or lack of medical necessity; or (iii) for instances where consigned items are used by the hospital for inpatient encounters.
Applicable Laws – Consignment Arrangements

A consignment arrangement is legally acceptable so long as the following requirements are met: (i) the consigned inventory is only for the convenience of the patient; (ii) the hospital cannot directly or indirectly profit from the consigned inventory; and (iii) the patient must be given the right to choose to purchase a product from the consigned inventory or from another DME supplier.
Applicable Laws – Consignment Arrangements

- Further, if the DME supplier pays rent for the consignment closet space, then the rental agreement must comply with the space rental safe harbor to the Medicare anti-kickback statute (“AKS”).
Applicable Laws – Medicare Anti-Kickback Statute

- The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive remuneration (monetary or anything of value) to induce, or in return for, referrals of health care services or items paid for by a federal health care program.

- A claim for items or services that results from a violation of the AKS also constitutes a false or fraudulent claim under the Federal False Claims Act (“FCA”).
Applicable Laws – False Claims Act

- The FCA is a civil statute that prohibits the knowing submission of false or fraudulent claims.
- The FCA creates a civil penalty of between $5,500 and $11,000 per claim filed, plus treble damages sustained by the Government due to the false claim.
- Claims that include items or services resulting from a violation of the AKS constitute a false claim under the FCA.
Applicable Laws – False Claims Act

- The FCA also prohibits conspiring to submit false or fraudulent claims.
- This means that persons who conspire to commit any type of FCA violation, have themselves committed an FCA violation, even though they may not present any false claims or make any false statements.
Applicable Laws – Medicare “48-Hour” Rule

- The Medicare Claims Processing Manual allows a DME supplier to deliver durable medical equipment, prosthetics, and orthotics (but not supplies) to an inpatient up to two days before discharge, if certain conditions are met.

- This is commonly referred to as the “48-Hour” Rule.
Applicable Laws – Medicare “48-Hour” Rule

- By definition, DME is covered by Part B only when intended for use in the home.
- One of the conditions that must be met under the 48-Hour Rule states that the reason the supplier furnishes the item cannot be for the purpose of eliminating the facility's responsibility to provide an item that is medically necessary for the beneficiary's use or treatment while the beneficiary is in the facility.
Applicable Laws – Medicare “48-Hour” Rule

- Such items are included in the Diagnostic Related Group (DRG) or Prospective Payment System (PPS) rates.
- Items or services provided by an entity, other than the hospital, to an inpatient of a hospital or to a hospital outpatient during an encounter, are excluded from Medicare coverage, subject to certain exceptions.
Applicable Laws – Medicare “48-Hour” Rule

- A hospital is responsible for furnishing medically necessary items to a beneficiary for the full duration of a beneficiary’s stay.
- A hospital is not allowed to delay furnishing or shift its costs for furnishing medically necessary items to a beneficiary, who is a resident in the facility, to Medicare Part B.
Applicable Laws – Medicare “48-Hour” Rule

- The Medicare Claims Processing Manual further states, “[a] facility may not prematurely remove a medically necessary item from the beneficiary’s use or treatment on the basis that a supplier delivered a similar or identical item to the beneficiary for the purpose of fitting or training.”
However, “beginning two days before the beneficiary’s discharge, a facility may take reasonable actions to... fit or train the beneficiary... include[ing] the substitution of the supplier-furnished item, in whole or in part, for the facility-furnished item during the beneficiary’s last two inpatient days provided the substitution is both reasonable and necessary for fitting or training... for subsequent use at the beneficiary’s home.”
Hospital “Chargeback” Obligation – Unaccounted For Items

- While there appears to be no OIG guidance directly addressing this issue, an argument can be made that consignment arrangements between DME suppliers and hospitals that lack a chargeback provision, holding the hospital financially responsible for items that are unaccounted for, implicates the AKS.

- One purpose of the lack of a chargeback provision may be interpreted as an offer of remuneration to induce or reward referrals.
Hospital “Chargeback” Obligation – Unaccounted For Items

- The remuneration offered to the hospital would be in the form of access to items without having to pay for them.
- Because the underlying service being provided by the DME supplier in consignment arrangements is to patients, and not the hospital, and because these items have independent value to the hospital, it may not be difficult for the government to prove that access to these free items was furnished for no purpose other than to induce recommendation of the DME supplier.
Hospital “Chargeback” Obligation – Unaccounted For Items

- Further, providing access to free items is a violation of an OIG Advisory Opinion prohibiting a consignment arrangement from benefiting the hospital in any way. Accordingly, the lack of a chargeback provisions in a consignment arrangement will be suspect under the AKS because it creates an incentive for influencing patient referrals.
Hospital “Chargeback” Obligation – Unaccounted For Items

- For this reason, DME suppliers and hospitals should include a chargeback provision in their consignment arrangement.
Hospital “Chargeback” Obligation – Lack of Medical Necessity

- Although there appears to be no OIG guidance directly addressing this issue, an argument can be made that a consignment arrangement that lacks a chargeback provision for claims denied due to lack of medical necessity or deficient paperwork implicates the AKS.
Hospital “Chargeback” Obligation – Lack of Medical Necessity

- The fact that a hospital is lax in regards to properly documenting medical necessity for consigned items it dispenses, or knowingly dispensing items the patient lacks a medical need for, suggests that the items were dispensed for the purpose of inducing the beneficiary to obtain additional services from the hospital or physician.
Hospital “Chargeback” Obligation – Lack of Medical Necessity

- Further, if the hospital is consistently dispensing items to patients that lack medical necessity or giving the DME supplier deficient paperwork, and the DME supplier does not require the hospital to reimburse the DME supplier for such claims, it suggests that the DME supplier is giving the hospital free items in order to induce or reward referrals from the hospital.
Hospital “Chargeback” Obligation – Lack of Medical Necessity

- To avoid potential AKS violations, the consignment arrangement should contain a chargeback provision for denied claims of consigned items which the hospital dispenses, if the claims are denied due to lack of medical necessity or deficient paperwork on the part of the hospital.
Hospital “Chargeback” Obligation – Restricting Use of Consigned Items

- Although there appears to be no OIG guidance directly addressing this particular issue, an argument can be made that not prohibiting, or not requiring reimbursement for, the use of consigned items for hospital inpatient encounters may result in a violation of the FCA.
Hospital “Chargeback” Obligation – Restricting Use of Consigned Items

- By using, and not paying for, a consigned item for the inpatient encounter, the hospital is able to shift its actual costs to the DME supplier.

- Submitting a Part A claim for services, some of which were actually provided by another entity, likely constitutes a violation of the FCA on the part of the hospital.
Hospital “Chargeback” Obligation – Restricting Use of Consigned Items

- In order to avoid violating the FCA by potentially conspiring to commit an FCA violation, the DME supplier and the hospital should state in the agreement that consignment items will not be used by the hospital for inpatient encounters, unless the DME supplier is reimbursed for the items or the items are provided in accordance to the 48-Hour Rule.
Preferred Provider Agreement
Preferred Provider Agreement

- The pharmacy can enter into a Preferred Provider Agreement with a hospital whereby, subject to patient choice, the hospital will recommend the pharmacy to its patients who are about to be discharged.
Employee Liaison
Employee Liaison

- A pharmacy may designate an employee to be on a facility’s premises for a certain number of hours each week.
- The employee may educate the facility staff regarding medical equipment (to be used in the home) and related services.
Employee Liaison

- The employee liaison may not assume responsibilities that the facility is required to fulfill.
- Doing so will save the facility money, which will likely constitute a violation of the Medicare anti-kickback statute.
Medical Director Agreement
A pharmacy can enter into an independent contractor Medical Director Agreement with a physician.

The MDA must comply with the (i) Personal Services and Management Contracts safe harbor and (ii) the Personal Services exception to the Stark physician self-referral statute.
Among other requirements:

- The MDA must be in writing and have a term of at least one year.
- The physician must provide substantive services.
- The compensation to the physician must be fixed one year in advance and be the fair market value equivalent of the physician’s services.
Avoiding “Sham” Clinical Studies
Avoiding “Sham” Clinical Studies

- Under the typical sham clinical study program, the physician refers patients to the pharmacy. The pharmacy dispenses a compounded medication (e.g., pain cream) to the patient.
- The physician “collects data” from the patient (e.g., “After applying the pain cream, from a scale of one to ten, what is your pain level?”).
Avoiding “Sham” Clinical Studies

- The physician shares the information with the pharmacy. The information is rudimentary, the pharmacy does not need it, and it is the same information that the pharmacy can secure itself.
- The pharmacy pays the physician $_____ per patient per month.
- The physician will make a large amount of money (e.g., $80,000) over a six month period.
Avoiding “Sham” Clinical Studies

- Sham clinical studies violate the federal anti-kickback statute…which makes it a felony to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce a person or entity to refer an individual for the furnishing or arranging for the furnishing of any item or service reimbursable by a federal health care program (Medicare, Medicaid, TRICARE, Medicare Advantage, etc.).
Avoiding “Sham” Clinical Studies

- The pharmacy may argue that it is not paying for referrals, but is paying for legitimate services.
- However, a number of courts have enumerated the “one purpose” test. This test states that if one purpose behind a payment is to induce referrals, then the federal anti-kickback statute is violated even if the principal purpose is to pay for legitimate services.
Avoiding “Sham” Clinical Studies

- With sham clinical studies, there is no question that “one purpose” behind the payments is to induce referrals. In fact, the primary purpose of the payments is to induce referrals.
Avoiding “Sham” Clinical Studies

- Assume that the physician refers no patients to the pharmacy who are covered by a government health care program.
- The pharmacy will need to look at its state anti-kickback statutes.
Avoiding “Sham” Clinical Studies

- All states have anti-kickback statutes that are similar to the federal statute. Some state statutes apply only if the payer is a state health care program (e.g., Medicaid).
- Other state statutes apply even if the payer is commercial insurance or the patient himself/herself.
Sham Telehealth Arrangements
Sham Telehealth Arrangements

- Pharmacies are aggressively engaged in marketing and it is not uncommon for a pharmacy to dispense drugs to patients residing in multiple states.
Sham Telehealth Arrangements

- When a pharmacy is marketing to patients in multiple states, the pharmacy may run into a “bottleneck.”
- This involves the patient’s local physician. A patient may desire to purchase a prescription drug from the out-of-state 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 drug and so the physician refuses to sign a prescription.
- Or even if the physician does sign a prescription, he may be hesitant to send the order to an out-of-state pharmacy.
Sham Telehealth Arrangements

- In order to address this challenge, we are witnessing some pharmacies enter into arrangements that will get them into trouble.
- This has to do with “telehealth” companies.
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 (i) self-funded employers that pay a membership fee for their employees, (ii) health plans, and (iii) patients who pay a per visit fee.
Sham Telehealth Arrangements

- Where a pharmacy will find itself in trouble is 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 pharmacy.
Sham Telehealth Arrangements

- Here is an example: *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 prescriptions for drugs…the telehealth company sends the prescriptions to the pharmacy…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 pharmacy mails the drug to the patient…the pharmacy bills (and gets paid by) Medicare.*
Sham Telehealth Arrangements

- There can be a number of permutations to this example, but you get the picture.
- **Stripping everything away, the pharmacy is paying the ordering physician.**
Sham Telehealth Arrangements

- To the extent that a pharmacy directly or indirectly pays money to a telehealth company, which in turn writes a prescription for drugs that will be dispensed by the pharmacy, the arrangement will likely be viewed as remuneration for a referral (or remuneration for “arranging for” a referral).
Sham Telehealth Arrangements

- 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.
- If the payer is a commercial insurer, then the arrangement may violate a state statute.
Failure to Collect Full Copayment
Failure to Collect Full Copayment

- Instead of collecting the full copayment, some pharmacies only collect a flat rate.
- By discounting the copayment owed by the patient, the pharmacy is essentially waiving the remainder of the copayment.
- A waiver of copayment (whole or partial) should only be made when financial hardship is documented.
Failure to Collect Full Copayment

- Furthermore, up-front discounting of the copayment will likely be viewed as a reduction of the pharmacy’s actual charge for the medication and will likely affect the pharmacy’s usual and customary charge for the medication.
Failure to Collect Full Copayment

- The pharmacy needs to avoid entering into a “sham” copayment subsidy arrangement.
- Such an arrangement can take many forms. However, the end result is that the patient ends up paying none of the copayment, or only a small portion of the copayment.
Sham Insurance Policies to Waive Copayments
Sham Insurance Policies

- In the compounding arena, the reimbursement for a drug may be abnormally high.
- If the copayment is 20%, then this will result in a high copayment.
- Most patients cannot afford a high copayment.
Sham Insurance Policies

- In an attempt to “solve” the copayment problem, the pharmacy may be tempted to enter into a “sham” insurance arrangement.
- This arrangement will normally take one of two forms.
Sham Insurance Policies

- In one scenario, the patient will pay a minimal “premium” (e.g., $10) to the pharmacy. In exchange, the pharmacy represents to the patient that he/she has purchased an “insurance policy” to cover the copayment.

- In the second scenario, the pharmacy will pay an upfront fee to the “insurance company” (“ABC”). ABC will, in turn, issue an “insurance policy” to the pharmacy.
Sham Insurance Policies

- The pharmacy will collect little to no copayments from its patients.
- If the pharmacy is subjected to a PBM audit and if the PBM asks to see if the pharmacy is collecting copayments from a list of named patients, then ABC will pay money to the pharmacy that constitutes the copayments the named patients should have paid.
Sham Insurance Policies

- Even then, the amount paid by ABC is less than what the patients should have paid.
- Both of these arrangements are subterfuges - or ruses - in an attempt not to impose a large copayment obligation on the patient.
- These arrangements are “shams” on their face.
Sham Insurance Policies

- One of the reasons these are not true insurance products is because an insurance policy must be licensed, as an insurance company, with the state.
- To be licensed as an insurance company, the pharmacy or ABC must meet many requirements imposed on insurance companies.
- One important requirement is that the insurance company must show the state that it has a minimum level of capital reserves.
Safeguards Against Routine Waivers
Safeguard Against Routine Waivers

- To avoid risks that the pharmacy may be engaging in a routine business practice of waiving copayments, the pharmacy may want to implement the following safeguards:
  - The pharmacy will implement a policy entitled “Collection of Deductibles and Copayments and Economic Hardship Waivers” (“Policy”).
  - The pharmacy should ensure the Policy reflects the pharmacy’s actual practices.
Safeguard Against Routine Waivers

- The pharmacy should require patients who may qualify for a full or partial waiver to complete and sign the application required under the Policy. The pharmacy should keep the signed applications on file.
- The pharmacy should request some form of documentation verifying the application (e.g., a pay stub or W-2) when possible. The pharmacy should require such documentation in the event the pharmacy has any doubts regarding the validity of information provided on the application.
Safeguard Against Routine Waivers

- The amounts of the copayment reductions should be granted on a sliding scale that is based upon the patients’ resources. For example, patients with incomes at 100% of the Federal Poverty Guidelines (“FPG”) may be eligible for full waivers, whereas patients with incomes between 200 and 400% of the FPG may only qualify for partial waivers. The amount of the actual waiver should depend on the particular patient’s resources, and the pharmacy should attempt to collect some copayment for patients with income levels above 100% of the applicable FPG.
Safeguard Against Routine Waivers

- The patient’s income level should not be the sole factor considered by the pharmacy. The pharmacy should evaluate the totality of the patient’s circumstances to determine whether the copayment is truly a financial hardship for the patient. Among other items, the pharmacy should consider the amount of the copayment resources available to the individual and the individual’s expenses.
Purchase of Internet Leads
Purchase of Internet Leads

- When a pharmacy signs a lead generation agreement (“LGA”) with a lead generation company (“LGC”), there are two main legal issues that must be addressed.
- The first one involves the Medicare anti-kickback statute.
Purchase of Internet Leads

- In the eyes of the OIG, there is a distinction between (i) a “raw” or “unqualified” lead and (ii) a “qualified” lead.
Purchase of Internet Leads

- While it is normally acceptable to purchase “raw” or “unqualified” leads on a per lead basis, the anti-kickback statute will likely be violated if “qualified” leads are purchased on a per lead basis.
Hiring Sales Rep Whose Spouse is a Physician
Introduction

- Assume that a pharmacy is contemplating employing the spouse of a physician as a sales representative.
- As a physician, the spouse of the sales representative will be in a position to, and likely will, refer patients to the pharmacy.
Introduction

- Assume that the pharmacy intends to pay the sales representative on a salaried basis with the potential for productivity bonuses or commissions based on the amount of business generated by the sales representative.

- Is this type of arrangement permitted by law?
The federal Anti-Kickback Statute ("AKS") prohibits knowingly and willfully offering, paying, soliciting, or receiving any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program.
Federal Anti-Kickback Statute

- The AKS excepts from its reach “any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.”
Federal Anti-Kickback Statute

- The OIG safe harbor uses substantially the same language; however, under the employment safe harbor, the term “employee” has the same meaning as it does for purposes of 26 U.S.C. § 3121(d)(2), which adopts the “usual common law rules.”
Federal Stark Law

- The federal Stark law prohibits a physician (or an immediate family member of such physician) who has a “financial relationship” with an entity from referring patients to the entity for “designated health services” covered by Medicare, Medicare Advantage, or Medicaid unless an exception is available.
Federal Stark Law

- Although the Stark law does not define the term “immediate family member,” regulations implementing the law define this term to include, among other things, a husband or wife.
Federal Stark Law

Similar to the employment safe harbor, the Stark law contains an exception for amounts paid by an employer to a “physician (or immediate family member),” if the physician or family member has a bona fide employment relationship and certain conditions are met.
Federal Stark Law

- It is important to note that although the payment made to an employee cannot be based on the volume or value of referrals made by the physician, the exceptions do not prohibit payments in the form of productivity bonuses based on services performed personally by the employee.
Federal Stark Law

- The productivity bonus of the employee cannot be based on or include, in any way, any of the referrals made by the physician family member.
State Law

- It is important to also analyze the arrangement under applicable state anti-kickback and physician self-referral laws.
Application of Law

- In the above example, the compensation paid by the DME supplier to the sales representative constitutes remuneration under the federal AKS.
- However, the DME supplier may avoid liability under the federal AKS if it structures the relationship to meet the OIG employment safe harbor, which requires the employment relationship to meet the common law rules.
Application of Law

- In other words, the DME supplier must have the ability to exercise control and direct the sales representative, not only as to the result to be accomplished, but also as to the details and means by which the result is accomplished.

- The substance, not the form, of the relationship will determine whether the sales representative meets these requirements.
Application of Law

- The Stark law will be implicated because a referring physician’s immediate family member will have a financial relationship with an entity with which the physician is making referrals for designated health services that are payable by Medicare, Medicare Advantage or Medicaid.
Application of Law

- However, the DME supplier may avoid liability under the Stark law if the relationship is structured to meet the employment exception to the Stark law.
Application of Law

- To meet this exception, the supplier must structure the employment relationship in such a manner that the remuneration paid is for identifiable services, is consistent with fair market value, is commercially reasonable even if no referrals are made by the spouse, and does not take into consideration, in any way, the volume or value of any referrals made by the spouse.
Application of Law

- A productivity bonus or commission that does not take into consideration the volume or value of referrals of the spouse, but is based on services performed personally by the sales representative, is permissible.
Charitable Contributions
Charitable Contributions

- The OIG takes the position that charitable donations to not-for-profit entities are essential to “sustaining and strengthening the health care safety net.”
- The OIG believes that most donors, even those with business relationships with donation recipients, are generally motivated by bona fide charitable purposes and desire to help their communities.
Charitable Contributions

- The fact that a business relationship exists between a donor and recipient does not make the donation automatically suspect.
- However, where the two entities are in a position to refer to each other, the arrangement does warrant additional scrutiny.
- Notably, the OIG opinions do not appear to differentiate between not-for-profit ("NFP") organizations and tax exempt organizations.
Charitable Contributions

- The OIG appears to use the same standards for both organizations (see e.g., Advisory Opinion No. 00-11 vs. No. 10-17).
- However if an entity has a tax exempt status, the OIG makes a point to note such status.
Charitable Contributions

- The OIG has issued several advisory opinions related to the provision of charitable donations from one organization to another where either or both organizations are in a position to refer to the other.

- These opinions have generally been favorable to the requesting entities where donations to charitable/not-for-profit entities (1) are for a bona fide charitable purpose; (2) are made in a manner that do not take into account the value or volume of referrals; and (3) incorporate other safeguards to ensure that donations are not tied to referrals or other business generated between the organizations.
Charitable Contributions

- Notwithstanding the above, in Advisory Opinion No. 08-02 the OIG provides examples of potentially problematic contributions, including:
  - Contributions to private foundations or other charitable organizations directed or controlled by referral sources; and
  - Contributions determined in any manner that take into account past or expected orders or purchases of items or services payable by any federal health care program.
Sale of Patient Information
Sale of Patient Information

- It is not uncommon for a DME supplier to accumulate a large database of patients that it has sold products to in the past.
- This database of patients (“patient list”) will likely include Medicare patients, Medicaid patients, and commercial insurance patients.
Sale of Patient Information

- Assume that the DME supplier would like to monetize the portion of the patient list that does not include patients covered by a government health care program.
The HIPAA Privacy Rule requires a covered entity or business associate to “not use or disclose protected health information, except as permitted or required.”
HIPAA

- Assume that the DME supplier desires to sell patient lists to laboratories that likely contain protected health information, such as patient names, telephone numbers, email addresses, medical conditions, health insurer information, or other information that may be used to market laboratory services.

- Such information may only be disclosed if permitted by the HIPAA Privacy Rule.
HIPAA

- The HIPAA Privacy Rule permits the sale of protected health information, with a valid authorization.
- A valid authorization for the sale of protected health information must be written in plain language and include a laundry list of information.
To meet the requirements of HIPAA, the DME supplier must document and retain the signed authorization that contains the above language and provide a copy to the patient.
State Kickback Issues

- In our example, because the patients will not be covered by a government health care program, then the Medicare anti-kickback statute will not be implicated.
- However, even if the HIPAA requirements are met, the DME supplier needs to determine if the arrangement violates an applicable state anti-kickback statute.
State Kickback Issues

- For example, the Illinois Patient and Client Procurement Statute, which is contained in the Illinois Insurance Claims Fraud Prevention Act, states, in pertinent part, that:
State Kickback Issues

- It is unlawful to knowingly offer or pay any remuneration directly or indirectly, in cash or in kind, to induce any person to procure clients or patients to obtain services or benefits under a contract of insurance or that will be the basis for a claim against an insured person or the person's insurer.
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:
HIPAA Restrictions on 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, including communications about:
HIPAA Restrictions on Marketing

- The entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits.
HIPAA Restrictions on Marketing

- Marketing communications require prior valid authorization from the customer.
HIPAA Restrictions on Marketing

- Therefore, to avoid HIPAA’s requirement that the DME supplier obtain a valid authorization from the customer before making a marketing communication, the marketing communication must concern a health-related product or service (i) provided by the supplier and (ii) the supplier cannot receive financial remuneration in exchange for making the communication.
HIPAA Restrictions on Marketing

- When the Department of Health and Human Services revised the definition of marketing communication, it issued the following comments to the final rule:
HIPAA Restrictions on Marketing

– We believe Congress intended that these provisions curtail a covered entity’s ability to use the exceptions to the definition of “marketing” in the Privacy Rule to send communications to the individual that are motivated more by commercial gain or other commercial purpose rather than for the purpose of the individual’s health care, despite the communication being about a health-related product or service.
HIPAA Restrictions on Marketing

- HIPAA applies to any patient...no matter how old or how young...and whether the patient is covered by Medicare or commercial insurance. In other words, HIPAA is not limited to Medicare patients.