# Lifeblood of the Successful Pharmacy: Marketing, Joint Ventures and Arrangements with Referral Sources … While Remaining Within Legal Parameters

**Presented by**

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## Disclosure

Jeff Baird is the Chairman of the Health Care Group with Brown & Fortunato, P.C. The conflict of interest was resolved by the peer review of the slide content.

## Learning Objectives

- Discuss federal regulations that affect pharmacy physician partnerships and medical director relationships.
- Describe the standards in anti-kickback regulations, the Stark laws, and pharmacy compliance.
- Discuss OIG fraud alerts and anti-fraud statutes.



# Introduction

## Introduction – Marketing and Arrangements with Referral Sources

- The "Greatest Generation," consisting of 23 million Americans, has been replaced by 78 million "Baby Boomers" who are retiring at the rate of 10,000 per day.
- Unlike earlier generations, Boomers will live long lives, their bodies will break down as they age, and it will cost the taxpayers a lot of money to keep Boomers alive.
- In opposition to this increasing demand is the reality of limited money … in other words, the proverbial "Irresistible Force Meeting the Immovable Object."



## Introduction – Marketing and Arrangements with Referral Sources

- And so while the demand for pharmacy products and services will increase exponentially, the pharmacy will need to be innovative and efficient to generate a profit.
- A key component to innovation is an aggressive and imaginative marketing program … within legal guidelines.
- Another key component to innovation is to enter into joint ventures and other arrangements with referral sources … within legal guidelines.
- The following slides will discuss these legal guidelines, how marketing programs and arrangements with referral sources can be properly set up, and those marketing activities and arrangements that need to be avoided.

# Legal Guidelines



## Medicare Anti-Kickback Statute ("AKS")

- 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 (e.g., Medicare, Medicare Advantage, Medicaid, TRICARE), or to induce such person to purchase or lease or recommend the purchase or lease of any item or service reimbursable by a federal health care program.

## Beneficiary Inducement Statute

- This statute prohibits a provider from offering or giving anything of value to a Medicare beneficiary that the provider knows, or should know, is likely to persuade the person to purchase an item covered by a federal health care program.



## Beneficiary Inducement Statute

- 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 $15 per item or $75 in the aggregate to any one beneficiary on an annual basis.
- "Nominal value" is based on the retail purchase price of the item.



## 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.

## Stark Physician Self-Referral Statute

- Designated health services include DME; parenteral and enteral nutrients; prosthetics, orthotics and prosthetic devices and supplies; out-patient prescription drugs; and rehab therapy services.



## 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 an annual amount established by CMS. For 2018, such amount is $407.

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# 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.

## Safe Harbors

- 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 Harbors – 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: (i) 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.

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## 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; and
  - (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.

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## 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

## 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.



## Advisory Opinions

- 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.

# Fraud Alerts and Bulletins



## 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.

# States



## States

- All states have enacted statutes prohibiting kickbacks, fee splitting, patient brokering, or self-referrals.
- Some state anti-fraud statutes only apply when the payer is a government health care program.
- Other state anti-fraud statutes that apply regardless of the identity of the payer.
- All states have a set of statutes and regulations that are specific to pharmacies.

# W-2 Employee vs. 1099 Independent Contractor



## W-2 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."

## W-2 vs. 1099

- 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.



## W-2 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.

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## W-2 vs. 1099

- In recent years, there have been a number of enforcement actions involving commission payments to independent contractors.



## W-2 vs. 1099

- 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 Problem

- 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.

## Utilization of a Marketing Company: Be Aware of Kickback Problem

- 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.
- Such payment of commissions will violate the AKS.



## Utilization of a Marketing Company: Be Aware of Kickback Problem

- 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.

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## Utilization of a Marketing Company: Be Aware of Kickback Problem

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## Utilization of a Marketing Company: Be Aware of Kickback Problem

- In Advisory Opinion No. 99-3, the OIG further 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").
  - 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.

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## Utilization of a Marketing Company: Be Aware of Kickback Problem

- In Advisory Opinion No. 99-3, the OIG further stated:
  - 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 Problem

- 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.

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## Utilization of a Marketing Company: Be Aware of Kickback Problem

- The OIG further stated:
  - 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.



## Failure to Collect Copayment

## Failure to Collect Full Copayment

- Instead of collecting the full copayments, some pharmacies only collect a flat rate.
- By discounting upfront 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 could 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.

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# Sham Insurance Policies to Waive Copayments



## Sham Insurance Policies

- Depending on the drug, the third party reimbursement to the pharmacy may be 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.



## Scenario One

- 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.

## Scenario Two

- 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.
- 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.
- Even then, the amount paid by ABC is less than what the patients should have paid.



## Sham Insurance Policies

- 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 issued by a licensed insurance company.
- 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.



# Data Mining

## Introduction

- Pharmacies are facing a "Perfect Storm" of challenges.
- These include (i) lower reimbursement for commercially available and compounded drugs; (ii) termination by PBMs of pharmacy contracts because pharmacies are engaged in compounding and/or mail-order; and (iii) aggressive audits.



## Introduction

- To counter these challenges, pharmacies are having to be innovative in how they market to customers and deal with third party payors. Recently, pharmacies have engaged in "data mining."
- While data mining is not wrong in and of itself, pharmacies need to be aware of the pitfalls attendant to certain data mining activities.

## Description of Program

- In one type of data mining arrangement, a company ("ABC") assists the pharmacy in researching alternative drug options that result in much larger reimbursement.
- The pharmacy then approaches physicians and suggests that they switch their prescriptions from the drug with lower reimbursement to the drug with higher reimbursement.



## Description of Program

- The pharmacy will educate the physicians regarding the clinical benefits of the more expensive drug.
- If the physicians agree and change prescriptions, then the pharmacy makes significantly more money, but the physicians do not financially benefit from the arrangement.
- With some data mining arrangements, the pharmacy pays ABC a percentage of the net revenue generated by the data mining program.

## Applicable Law

- In reviewing data mining arrangements, one needs to be mindful of the federal anti-kickback statute ("AKS") which states that the pharmacy cannot pay anything to ABC for (i) referring a government program patient to the pharmacy, (ii) arranging for the referral of a government program patient to the pharmacy, or (iii) recommending the purchase of a drug that a government program pays for.
- Each state has its own anti-kickback statute. Some state anti-kickback statutes apply only if the payor is the state's Medicaid program.



## Applicable Law

- Other state anti-kickback statutes apply even if the payor is a commercial insurer or a cash-paying customer.
- Each state also has a set of laws that are specific to pharmacies.
- Some of the pharmacy-specific state laws prohibit kickbacks, fee splitting, and similar arrangements.

## Legal Issues

- If a pharmacy engages in a data mining program, the pharmacy needs to be aware of the following:
  - Separate and apart from what the law says, does the data mining arrangement pass the "smell test?" If the motivation behind the arrangement is not patient care – but rather – is for the pharmacy and ABC to make more money, then even if the arrangement does not clearly violate the law...but is nevertheless "offensive"... a governmental agency or commercial third party payor may take steps to shut it down.



## Legal Issues

- Let us assume that a government health care program pays for the replacement drug. If the pharmacy is paying remuneration to ABC (i.e., a percent of net revenue), the question becomes: "Is ABC arranging for the referral of government program patients to the pharmacy and/or is ABC recommending the purchase of drugs that are reimbursable by a government health care program?" Both sides of the equation can be argued. On the one hand, one can argue that because ABC is not having any contact with the physicians (i.e., ABC is only working with the pharmacy), then ABC cannot be construed to be "arranging for the referral" of patients nor "recommending the purchase of drugs."

## Legal Issues

- Continued
  - On the other hand, one can argue that by allowing the pharmacy to use the ABC software platform and by showing the pharmacy how to find similar drugs with higher reimbursement, then such acts rise to the level of "arranging for the referral" of patients and "recommending the purchase of drugs." This is where the "smell test" comes in. Governmental agencies have a great deal of discretion in deciding whether or not to bring an enforcement action.



## Legal Issues

- Continued
  - If an arrangement falls within a "gray area," but it is not otherwise abusive or offensive, then the governmental agency will likely leave the arrangement alone. On the other hand, if it looks like the parties to the arrangement are "gaming the system" to substantially increase their revenue, then the governmental agency (and/or a third party payor) will likely be motivated to shut the arrangement down.

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## Legal Issues

› Now let's switch gears and assume that no government program is involved. Assume that the only payors are commercial insurers. If the pharmacy is operating in a state in which there is (i) a state anti-kickback statute that applies to all payors and/or (ii) there are pharmacy-specific laws addressing kickbacks/fee splitting, then the preceding discussion applies.



## Legal Issues

› Now let's assume that no government program is involved and there are no applicable state statutes that would prohibit the arrangement. Nevertheless, PBMs will likely take steps to neutralize the arrangement by removing the replacement drugs with higher reimbursement from the formulary. Additionally, most (if not all) PBM contracts give the PBM the right to terminate the pharmacy from the contract "without cause." A PBM may determine that the pharmacy is a "bad player" and terminate it from the contract. Also, there is a possibility that the contract between the pharmacy and the PBM contains restrictions that prohibit the data mining arrangement.

# Purchase of Internet Leads



## Purchase of Internet Leads

- When a pharmacy signs a lead generation agreement ("LGA") with a lead generation company ("LGC"), the parties must be careful not to violate the AKS.
- In the eyes of the OIG, there is a distinction between (i) a "raw" or "unqualified" lead and (ii) a "qualified" lead.
- While it is normally acceptable to purchase "raw" or "unqualified" leads on a per lead basis, the AKS will likely be violated if "qualified" leads are purchased on a per lead basis.

# Relationship With Physicians



## Collaborative Practice

- A Collaborative Practice Agreement ("CPA") formalizes the practice relationship between a physician and a pharmacy. This is a common way to integrate pharmacies into team-based care.
- Pursuant to the CPA, the physician authorizes the pharmacy to perform certain patient care functions, such as initiating or modifying medical therapy, ordering lab tests, and authorizing refills.

## Collaborative Practice

- Laws governing CPAs vary from state-to-state. State laws can differ on the following:
  - Whether the CPA applies to a single patient or to multiple patients.
  - Whether the CPA is limited certain practice settings.
  - Which parties are allowed to enter into the CPA (All prescribers? Physicians only? Physicians and Nurse Practitioners?).
  - Qualifications of the pharmacist
- Some states require the parties to have liability insurance. Some states declare the CPA invalid after a certain period of time.



## Sharing of Information

- If the physician is treating the patient, and if the pharmacy is dispensing prescription drugs to the patient for which the physician is treating the patient, then the physician and pharmacy can share patient information that is specific to their joint efforts to treat/serve the patient.
- In sharing the information, the joint goal of the physician and pharmacy is to facilitate the treatment of the patient's condition.
- With this data in hand, both the physician and pharmacy can share with hospitals and third party payors ("TPPs") the success they have had in treating conditions and keeping patients out of the hospital.

## Clinical Study

- The pharmacy and physician can participate together in a clinical study.
- Ideally, the clinical study will be sponsored by a hospital or medical school...and will be overseen by an Institutional Review Board ("IRB"). It is important that the clinical study not be a disguised kickback scheme designed to funnel compensation to referring physicians.
- The pharmacy can use the results of the clinical study to show physicians, hospitals and TPPs (i) that the pharmacy has a sophisticated business model and (ii) that the pharmacy's services are successful in treating conditions and keeping patients out of the hospital.



## Medical Director

- A physician (regardless of whether or not he is a referring physician) can be a 1099 independent contractor Medical Director for the pharmacy.
- If the physician refers to the pharmacy, then the Medical Director Agreement needs to comply with (i) the PSMC safe harbor to the AKS and (ii) the personal services exception to Stark.

## Education Workshops

- The physician can set up times for the pharmacy to send representatives to the physician's office to educate the physician's employees regarding (i) products and services offered by the pharmacy and (ii) how the pharmacy's products/services can treat specific conditions.
- The physician can set up times for the pharmacy to send representatives to the physician's office to present workshops to the physician's patients who have conditions that can be treated by the pharmacy's products and services.



## Sponsoring the Physician as a Speaker

- The pharmacy can pay the physician for speaking at educational workshops and dinners.
- In order to avoid problems with the AKS and Stark:
  - The topic presented by the physician must be substantive and relevant to the audience.
  - The audience must be made up of individuals who will benefit from what the physician has to say.
  - The compensation to the physician must be FMV.

## Renting Space to/from a Physician

- The pharmacy can rent space from...or to...a physician.
- The arrangement needs to comply with the Space Rental safe harbor to the AKS and the space rental exception to Stark. The safe harbor and exception say the same thing. Among other requirements:
  - The rental agreement must be in writing with a term of at least one year.
  - The rent paid must be fixed one year in advance and be FMV.



## Renting Equipment to/from a Physician

- The pharmacy can rent equipment from...or to...a physician.
- The arrangement needs to comply with the Equipment Rental safe harbor to the AKS and the equipment rental exception to Stark. The safe harbor and exception say the same thing. Among other requirements:
  - The rental agreement must be in writing with a term of at least one year.
  - The rent paid must be fixed one year in advance and be FMV.

## Employee Liaison

- The pharmacy can place an employee liaison in the physician's office. The liaison can be present in the physician's office for as many...or as few...hours as the physician and pharmacy agree on.
- The employee liaison cannot perform any duties that the physician is responsible to perform. Doing so will save the physician money...which constitutes "something of value" to the physician...hence, a violation of the AKS.



## Loan Closet

- If the pharmacy provides DME, it can store DME inventory at the physician's office. If the physician orders a DME item, and if the patient elects to obtain the items from the pharmacy (that has the consigned inventory at the physician's office), then the physician can "pull the item from the loan closet," hand the item to the patient, and send the patient home.
- It would be wise for the physician and pharmacy to memorialize the arrangement in a written Equipment Placement Agreement.

## Rural Community

- If the pharmacy qualifies as a "rural provider" under Stark, then a physician can own a percentage interest in the pharmacy...and can refer Medicare and Medicaid patients to the pharmacy. This will comply with the "rural provider" exception under Stark.
- In addition to satisfying Stark, it will be important that the arrangement not violate the AKS. Ideally, the arrangement will comply with the Small Investment Interest safe harbor to the AKS. If that is not possible, then the arrangement needs to comply with the (i) OIG's 1989 Special Fraud Alert ("Joint Ventures") and (ii) the OIG's April 2003 Special Advisory Opinion ("Contractual Joint Ventures"). Among other requirements:
  - The physician must purchase, at FMV, his percentage ownership interest in the pharmacy.
  - Profit distributions to the physician must be based on his percentage ownership interest in the pharmacy. The profit distributions cannot be tied to the number of (or dollar amount resulting from) the physician's referrals.



## Non-Rural Community

- If the pharmacy does not qualify as a "rural provider," then a physician can nevertheless own a percentage interest in the pharmacy. However, to avoid problems under Stark, the physician cannot refer Medicare and Medicaid patients to the pharmacy. Stark does not prohibit a physician from referring commercial insurance patients to the pharmacy.
- The physician and pharmacy will also need to examine state law to determine if there are any prohibitions or restrictions against the physician referring commercial insurance patients to a pharmacy in which the physician has an ownership interest.

## Preferred Provider

- The physician and pharmacy can enter into a Preferred Provider Agreement in which, subject to patient choice, the physician will refer patients to the pharmacy.
- In return, the pharmacy will commit to provide extraordinary services (i.e., services that pharmacies normally do not provide) in order to keep the patient healthy and keep the patient from going to the hospital.



## Continuing Education Conference

- The pharmacy may desire to subsidize the expenses of a physician for him to attend a continuing education conference that addresses disease states that the pharmacy treats with its products and services.
- The pharmacy may do this…but only up to a specific dollar limit. One of the Stark exceptions is the non-monetary compensation exception which allows a pharmacy to spend up to a specified annual dollar amount on a physician. For 2018, this dollar amount is $407.
- And so in 2018, a pharmacy can spend up to $407 for (or on behalf of) a physician for meals, entertainment, travel, conferences, etc.

## Gifts

- As previously stated, one of the exceptions to Stark provides that a health care provider (e.g., pharmacy) may provide non-cash equivalent items to a physician if the value of such items do not exceed an annual amount established by CMS. For 2018, such amount is $407.



# Paying Physicians: Guidance From a Criminal Case

## Criminal Case

- A federal grand jury in Connecticut indicted Jeffrey Pearlman, a former sales manager for Insys Therapeutics, Inc.
- According to a Department of Justice ("DOJ") statement, Mr. Pearlman allegedly used bogus educational events as a "cover" for paying kickbacks to physicians in exchange for their increased prescriptions of Subsys®, a spray version of the opioid fentanyl.



## Criminal Case

- The DOJ alleges that Mr. Pearlman arranged sham "speaker programs," which were billed as gatherings of physicians to educate them about Subsys®.
- In reality, according to the DOJ, the events - usually held at high-end restaurants - mostly consisted of friends and co-workers who lacked the ability to prescribe the drug, and there was no educational component.

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## Criminal Case

- According to the DOJ, the "speakers" were physicians who were paid fees ranging from $1000 to several thousand dollars to attend the dinners.
- The indictment says that these payments were kickbacks to the speakers "who were prescribing large amounts of Subsys® and to incentivize those [physicians] to continue to prescribe Subsys® in the future."



## Criminal Case

- Here are the "takeaways" from this criminal case:
  - Before the pharmacy provides "anything of value" to a physician, the pharmacy needs to consult with a health care attorney to ensure that the arrangement does not violate the AKS or Stark.
  - "Anything of value" can be a payment of money, it can be a trip, it can be a set of golf clubs, it can be tickets to a Springsteen concert, and it can be services that the physician would normally have to perform himself.

## Criminal Case

- "Takeaways" (cont'd):
  - It is permissible for a pharmacy to enter into a Medical Director Agreement ("MDA") with a physician who also refers Medicare patients to the pharmacy. The MDA needs to comply with the Personal Services and Management Contracts safe harbor to the AKS and with the Stark Personal Services exception. Among other requirements, (i) the MDA must be in writing and have a term of at least one year, (ii) the physician must render valuable (not "made up") services to the pharmacy, (iii) the compensation paid by the pharmacy to the physician must be fixed one year in advance, and (iv) the compensation must be the fair market value ("FMV") equivalent of the physician's services.



## Criminal Case

- "Takeaways" (cont'd):
  - If a pharmacy is going to pay a physician to put on an education program, then it must pass the "smell test." The physician must be qualified to make the presentation, the physician must actually make the presentation, the presentation topic must be substantive and timely, the audience must be in the position of benefitting from the presentation, and the compensation to the physician must be FMV.

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# Collaboration with Hospital to Prevent Readmissions



## Hospital Readmissions Reduction Program

- The Hospital Readmissions Reduction Program states that if a Medicare patient is treated in the hospital for one of six conditions (e.g., congestive heart failure, pneumonia, COPD) and is discharged, then if the patient is readmitted within 30 days for that some condition, the hospital will be subjected to future payment reductions by Medicare.

## Hospital Readmissions Reduction Program

- CMS recently released records identifying 2573 hospitals nationwide that will have their Medicare payments reduced by up to 3% for the fiscal year beginning 10/1/17 as a result of high readmission rates.



## Hospital Readmissions Reduction Program

- CMS data shows that readmissions following medical procedures are problematic because they can increase a patient's risk for complications, such as infections, and can significantly increase costs.
- Almost one in five Medicare patients are readmitted within 30 days, which costs about $15 billion a year, according to the Agency for Healthcare Research and Quality, an arm of DHHS. For example, CMS examined the readmission rates at 32 Utah hospitals.
- 17 were penalized. At St. Mark's, Medicare payments will be reduced for the second year in a row (2.81% up from 1.13% in the current year).

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## Hospital Readmissions Reduction Program

- In response to inquiries from the press, St. Mark's noted that it has improved its post-discharge procedure by "partnering with local skilled nursing facilities to make sure patients are following physicians' orders and ensuring that follow-up appointments are scheduled and kept."
- Also in response to inquiries from the press, University of Utah Hospitals and Clinics stated that "fewer people are readmitted to the hospital when they are discharged to their own home instead of a nursing home."



## Preferred Provider Agreement

- A hospital can partner with a number of providers and suppliers to help keep recently discharged patients healthy: SNFs, home health agencies, pharmacies, and DME suppliers.
- It is a good idea for the pharmacy to think outside the box and ask: "Why not me?"
- There is an opportunity for the pharmacy to approach the hospital and ask to be the hospital's "preferred pharmacy."
- In return, the pharmacy will offer to provide value-added services for the recently discharged patients.

## Preferred Provider Agreement

- These services can be as mundane as calling the patient and caregiver to remind the patient to take his medication as prescribed … or to see his physician as scheduled … or to take his breathing treatments as directed … or to drink plenty of water.
- Though these services may be mundane, they are effective in keeping patients from being readmitted.
- The pharmacy can coordinate its services with a home health agency, therapy clinic, and/or a DME supplier.



## Collection of Data

- In rendering these value-added services, it will be important for the pharmacy to collect data (i) describing the services that the pharmacy is rendering and (ii) describing the *outcome* of the services.
- The pharmacy can use this data to (i) justify, in the hospital's eyes, the "preferred provider" arrangement and (ii) pitch the same type of arrangement to other hospitals.
- The hospital can use the pharmacy's data to show to payors that the hospital is providing cost-efficient care.

## Expansion to Commercial Insurers

- A similar type of program (i.e., similar to Medicare's Hospital Readmissions Reduction Program) may be imposed by commercial insurers on hospitals … meaning that the post-discharge services offered by the pharmacy will become even more important to hospitals.



## 340 B

- The 340B Drug Discount Program is a federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices.
- Many 340B covered entities elect to dispense 340B drugs to patients through contract pharmacy services, an arrangement in which the 340B covered entity signs a contract with a pharmacy to provide pharmacy services.

## 340 B

- The 340B Drug Pricing Program allows certain hospitals and other health care providers ("covered entities") to obtain discounted prices on "covered outpatient drugs" (prescription drugs and biologics...other than vaccines) from drug manufacturers.
- Covered entities participating in the 340B Program may contract with pharmacies to dispense drugs purchased through the program. These pharmacies are called "Contract Pharmacies."



# Joint Venture with Hospital

## Joint Venture with Hospital

- In its most simplistic term, a "joint venture" is when two or more people or companies own something together.
- A number of hospitals and existing pharmacies are forming new pharmacies, partially owned by the hospital and partially owned by the existing pharmacy.
- One of the reasons why a hospital would be interested in forming a new pharmacy, owned by the hospital and an existing pharmacy, is to help insure "continuum of care" for the patient when he is discharged from the hospital.



## Joint Venture with Hospital

- In putting together such a joint venture, it is important to keep in mind that the hospital will be a referral source to the joint venture.
- As an owner of the joint venture, the hospital will be entitled to profit distributions.
- Because of this, the joint venture cannot be a subterfuge to funnel remuneration to the hospital for referrals of patients.
- Such a subterfuge would violate the AKS.

## Joint Venture with Hospital

- In determining whether the joint venture is a legitimate arrangement, or is a violation of the AKS, the three principal sources of guidance are (i) the Small Investment Interest safe harbor to the AKS, (ii) the OIG's 1989 Special Fraud Alert entitled "Joint Ventures" and (iii) the OIG's April 2003 Special Advisory Bulletin entitled "Contractual Joint Ventures."
- See the previous slide addressing the Small Investment Interest safe harbor. Because of the two "60-40 tests" associated with this safe harbor, it is difficult to comply with this safe harbor. As such, focus needs to be on the 1989 Fraud Alert and the 2003 Advisory Bulletin.



## OIG's 1989 Special Fraud Alert ("Joint Ventures")

- The 1989 Special Fraud Alert lists characteristics of a joint venture that indicate that the arrangement is not a legitimate arrangement, but rather, is a subterfuge to funnel remuneration to the referral source. The italicized print is the author's comments to the characteristics listed by the OIG.

## OIG's 1989 Special Fraud Alert ("Joint Ventures")

- Investors are chosen because they are in a position to make referrals.
- Physicians who are expected to make a large number of referrals may be offered a greater investment opportunity in the joint venture than those anticipated to make fewer referrals. *Substitute "Hospital" for "Physicians."*



## OIG's 1989 Special Fraud Alert ("Joint Ventures")

- Physician investors may be actively encouraged to make referrals to the joint venture, and may be encouraged to divest their ownership interest if they fail to sustain an 'acceptable' level of referrals. *Substitute "The Hospital" for "Physician investors." To avoid triggering this characteristic, the Hospital will need to implement a protocol in which the Hospital offers patient choice. Additionally, the joint venture entity cannot have the right to demand that the hospital divest its interest based on the number of referrals, or lack thereof, to the joint venture entity.*

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## OIG's 1989 Special Fraud Alert ("Joint Ventures")

- The joint venture tracks its sources of referrals, and distributes this information to the investors.
- Investors may be required to divest their ownership interest if they cease to practice in the service area, for example, if they move, become disabled or retire. *This characteristic should not apply to a hospital.*
- Investment interests may be nontransferable. *The investment interests held by each owner must be transferable. It would, however, be appropriate to give each investor a standard right of first refusal.*



## OIG's 1989 Special Fraud Alert ("Joint Ventures")

- The structure of some joint ventures may be suspect. For example, one of the parties may be an ongoing entity already engaged in a particular line of business. In some of these cases, the joint venture can be best characterized as a "shell.'" *One of the owners of the joint venture is an existing pharmacy. It will be important that the pharmacy investor not be a provider for the joint venture entity. In other words, the joint venture entity must be a free-standing provider; it must have operational responsibilities and financial risk.*

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## OIG's 1989 Special Fraud Alert ("Joint Ventures")

- *At a minimum, the joint venture entity needs to have intake personnel; it needs to have one or more delivery drivers (and one or more vans for the delivery drivers); and it needs to purchase and store inventory. It is acceptable for the pharmacy investor to provide some services for the joint venture entity such as (i) billing services and (ii) delivery services if the joint venture entity's delivery drivers are overloaded.*



## OIG's 1989 Special Fraud Alert ("Joint Ventures")

- *The joint venture entity will need to pay fair market value compensation for these services. At the end of the day, while the pharmacy investor can provide some services to the joint venture entity, the pharmacy investor cannot run the joint venture on a turnkey basis. If the joint venture entity has "skin in the game," then the joint venture should not be characterized as a "shell.*

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## OIG's 1989 Special Fraud Alert ("Joint Ventures")

- In the case of a shell pharmacy joint venture, for example: -- It owns very little of the inventory or capital equipment; rather, the ongoing pharmacy owns them. – The ongoing pharmacy is responsible for all day-to-day operations of the joint venture. *See the preceding bullet. The joint venture entity needs to own delivery vehicles, non-inventory property, and inventory.*



## OIG's 1989 Special Fraud Alert ("Joint Ventures")

- *The joint venture entity needs to handle intake and assessment. The joint venture entity needs to provide delivery. This should result in the joint venture entity having sufficient operational responsibilities and financial risk. If the joint venture entity has these responsibilities, then the pharmacy investor services such as billing and overflow delivery should be appropriate.*

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## OIG's 1989 Special Fraud Alert ("Joint Ventures")

- The amount of capital investment by the physician may be disproportionately small and the returns on investment may be disproportionately large when compared to a typical investment in a new business enterprise. *Substitute "hospital" for "physician." This is a difficult characteristic to address. As to when an investment is "disproportionately small" as compared to a return on investment is subject to interpretation. This characteristic should normally not be an issue so long as (i) the hospital invests risk capital in proportion to its percentage ownership interest and (ii) the joint venture entity generates the types of profits that similar providers normally generate.*



## OIG's 1989 Special Fraud Alert ("Joint Ventures")

- Physician investors may invest only a nominal amount, such as $500 to $1500. *Substitute "The Hospital" for "Physician investors." This characteristic should not be an issue so long as the hospital invests risk capital in proportion to its percentage ownership interest.*
- Physician investors may be permitted to 'borrow' the amount of the 'investment' from the entity, and pay it back through deductions from profit distributions, thus eliminating even the need to contribute cash to the partnership. *Substitute "The Hospital" for "Physician investors." This characteristic should not be an issue if the hospital will contribute its risk capital up front.*

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## OIG's 1989 Special Fraud Alert ("Joint Ventures")

- Investors may be paid extraordinary returns on the investment in comparison with the risk involved, often well over 50 to 100 percent per year. *Normally, the joint venture entity will generate the types of profits that similar providers generate. If so, then this characteristic should not be an issue.*



## OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures")

- The advisory bulletin discusses "questionable contractual arrangements where a health care provider in one line of business ("Owner") expands into a related health care business by contracting with an existing provider of a related item or service (""Manager/Supplier") to provide the new item or service to the Owner's existing patient population, including federal health care program patients."

## OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures")

- The advisory bulletin goes on to say that the "Manager/Supplier not only manages the new line of business, but may also supply it with inventory, employees, space, billing, and other services. In other words, the Owner contracts out substantially the entire operation of the related line of business to the Manager/Supplier – otherwise a potential competitor – receiving in return the profits of the business as remuneration for its federal program referrals."
- The advisory bulletin gives some examples of "potentially problematic contractual arrangements."



## OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures")

- The advisory bulletin then states that problematic arrangements typically exhibit the following common elements:
  - The Owner expands into a related line of business, which is dependent on referrals from, or other business generated by, the Owner's existing business. The new business line may be organized as a part of the existing entity or as a separate subsidiary. Typically, the new business primarily serves the Owner's existing patient base.

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## OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures")

- The Owner neither operates the new business itself nor commits substantial financial, capital, or human resources to the venture. Instead, it contracts our substantially all of the operations of the new business. The Manager/Supplier typically agrees to provide not only management services, but also a range of other services, such as the inventory necessary to run the business, office and health care personnel, billing support, and space.



## OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures")

- The Manager/Supplier is an established provider of the same services as the Owner's new line of business. In other words, absent the contractual arrangement, the Manager/Supplier would be a competitor of the new line of business, providing items and services in its own right, billing insurers and patients in its own name, and collecting reimbursement.
- The Owner and the Manager/Supplier share in the economic benefit of the Owner's new business. The Manager/Supplier takes its share in the form of payments under the various contracts with the Owner; the Owner receives its share in the form of the residual profit from the new business.

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## OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures")

- Aggregate payments to the Manager/Supplier typically vary with the value or volume of business generated for the new business by the Owner … In other words, the aggregate payment to the Manager/Supplier from the whole arrangement will vary with referrals from the Owner.



## OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures")

- The advisory bulletin then describes characteristics that, taken separately or together, potentially indicate a prohibited arrangement:
  - New Line of Business – The Owner typically seeks to expand into a health care service that can be provided to the Owner's existing patients … [E]xamples include … hospitals expanding into DME services.
  - Captive Referral Base – The newly-created business predominantly or exclusively serves the Owner's existing patient base (or patients under the control or influence of the Owner). The Owner typically does not intend to expand the business to serve new customers (i.e., customers not already served in its main business) and, therefore, makes no or few bona fide efforts to do so.

## OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures")

- Little to No Bona Fide Business Risk – The Owner's primary contribution to the venture is referrals; it makes little or no financial or other investment in the business, delegating the entire operation to the Manager/Supplier, while retaining profits generated from its captive referral base.
- Status of the Manager/Supplier – The Manager/Supplier is a would-be competitor of the Owner's new line of business and would normally compete for the captive referrals. It has the capacity to provide virtually identical services in its own right and bill insurers and patients for them in its own name.



## OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures")

- Scope of Services Provided by the Manager/Supplier – The Manager/Supplier provides all, or many, of the following key services: (i) day-to-day management; (ii) billing services; (iii) equipment; (iv) personnel and related services; (v) office space; (vi) training; and (vii) health care items, supplies, and services. In general, the greater the scope of services provided by the Manager/Supplier, the greater the likelihood that the arrangement is a contractual joint venture.

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## OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures")

- Remuneration – The practical effect of the arrangement, viewed in its entirety, is to provide the Owner the opportunity to bill insurers and patients for business otherwise provided by the Manager/Supplier. The remuneration from the venture to the Owner (i.e., the profits of the venture) takes into account the value and volume of business the Owner generates.
- Exclusivity – The parties may agree to a non-compete clause, barring the Owner from providing items or services to any patients other than those coming from Owner and/or barring the Manager/Supplier from providing services in its own right to the Owner's patients.



## OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures")

- In a typical hospital-pharmacy joint venture, (i) at least initially most of the referrals to the joint venture entity will come from the hospital-owner and (ii) the pharmacy-owner, not the joint venture entity itself, will have the expertise to run a pharmacy operation. In order to avoid kickback issues, the following guidelines must be met:

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## OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures")

- The hospital must insure patient choice. Initially, the hospital should ask a patient (about to be discharged and for whom drugs have been prescribed) who he wants to receive the drugs from. Only if the patient expresses no preference is it appropriate for the hospital to recommend the joint venture entity.
- The joint venture entity must be an independent operating entity.



## OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures")

- The pharmacy-owner can provide some services for the joint venture entity, for which the joint venture entity must pay fair market value compensation. These services can include billing (on behalf of the joint venture entity) and delivery when the joint venture entity's ability to deliver has met its limit. However, the pharmacy owner cannot run (or "manage") the joint venture entity on a turnkey basis. The joint venture entity must have financial risk and operational responsibilities. In short, the joint venture entity must have "skin in the game."

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# 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 services the pharmacy can offer on a post-discharge basis.

## 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 AKS.



# 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.



# Paying for a Facility's EHR

## Paying for a Facility's EHR

- Many pharmacies work with skilled nursing facilities ("SNFs") and custodial care facilities (collectively referred to as "Facilities").
- A Facility is a "referral source" to the pharmacy. Even though the Facility may give "patient choice," if the pharmacy dispenses a drug to a Facility patient, the law considers the patient to be a "referral" from the Facility.
- If the pharmacy gives "anything of value" to the Facility, then the pharmacy is at risk of being construed to be "paying for a referral" … hence, a "kickback."



## Paying for a Facility's EHR

- The federal anti-kickback statute ("AKS") applies to any patient covered by a federally funded health care program.
- The AKS prohibits the pharmacy from giving anything of value to a referral source in exchange for (i) referring, or arranging for the referral of, a federally funded health care program patient to the pharmacy or (ii) recommending the purchase of a product that is paid for by a federally funded health care program.
- Under the AKS, the party providing something of value (the pharmacy) and the party receiving something of value (the Facility) are *both* liable.

## Paying for a Facility's EHR

- Separate and apart from the AKS, each state has its own anti-kickback statute.
- Some state anti-kickback statutes apply only when the payer is the state Medicaid program.
- Other state anti-kickback statutes apply even if the payer is commercial insurance or a cash-paying patient.



## Paying for a Facility's EHR

- In order for a Facility to serve Medicare and Medicaid patients, federal law imposes a number of requirements on the Facility.
- These requirements cost the Facility money in order to comply.
- One such requirement is for the Facility to have a pharmacy perform a monthly drug regimen review ("DRR") on each patient.

## Paying for a Facility's EHR

- Electronic medication administrative records ("eMARs") are not required for DRR; hard copy records are acceptable. Nevertheless, a Facility may desire to utilize eMAR software ("Software") for DRR and for other purposes.
- The Facility and a pharmacy (that receives referrals from the Facility) may wish to enter into an arrangement in which the pharmacy pays for the Software. It is at this juncture that the Facility and pharmacy find themselves on the proverbial "slippery slope."
- Assume that the pharmacy receives referrals from the Facility and desires to pay for the Software. By virtue of paying for the Software, the pharmacy is providing "something of value" to the Facility … hence, the AKS is implicated.



## Paying for a Facility's EHR

- The Office of Inspector General ("OIG") has published a number of "safe harbors" to the AKS.
- If an arrangement complies with all of the elements of a safe harbor, then as a matter of law the AKS is not violated. If an arrangement does not comply with all of the elements of a safe harbor, then it does not mean that the AKS is violated.
- Rather, it means that the arrangement must be carefully scrutinized in light of the language of the AKS, court decisions, and other published guidance.

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## Paying for a Facility's EHR

- The applicable safe harbor is the Electronic Health Records safe harbor ("EHR Safe Harbor").
- It states than an entity may donate software and training services "necessary and used predominantly to create, maintain, transmit, or receive electronic health records" if the following 12 requirements are satisfied:



## Paying for a Facility's EHR

- The donation must be made to an entity engaged in delivery of health care by an entity (except for a laboratory company) that provides and submits claims for services to a federal health care program. A pharmacy is an acceptable donor and a Facility is an acceptable recipient.

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## Paying for a Facility's EHR

- The Software must be interoperable at the time it is provided to the recipient. Software is deemed to be interoperable if it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology. Interoperable means that the Software is able to (i) "communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings," and (ii) "exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered." The Software can be used for tasks like patient administration, scheduling functions, and billing and clinical support, but electronic health records purposes must be predominant.



## Paying for a Facility's EHR

- The donor cannot place a restriction on the use, compatibility, or interoperability of the item or service with other EHR systems.
- Receipt of items or services is not conditioned on doing business with the donor.
- Eligibility for, and the amount or nature of, the items or services provided is not based on the volume or value of referrals or other business generated between the parties.

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## Paying for a Facility's EHR

- There must be a written, signed, agreement specifying: (i) the items and services; (ii) the donor's cost of providing the items and services; and (iii) the amount of the recipient's contribution.
- The recipient cannot already possess or have obtained items or services with similar capabilities as those provided by the donor.
- For items or services that can be used for any patient regardless of payer status, the donor does not restrict the recipient's ability to use the items or services for any patient.
- The items and services do not include office staffing and are not used to conduct personal business or business unrelated to the recipient's health care practice.



## Paying for a Facility's EHR

- The recipient must pay 15% of the donor's cost for the items and services prior to receipt, and the donor cannot finance or loan funds for this payment.
- The donor's cost for the items or services cannot be shifted to a federal health care program.
- Transfer of the items or service must occur on or before December 31, 2021.

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## Paying for a Facility's EHR

- As noted above, the Software can be used for services beyond the pharmacy's DRR as long as (i) the Software is not used primarily for personal business or business unrelated to the Facility's clinical operations, and (ii) the pharmacy does not restrict the Facility from otherwise using the Software or from interfacing with other electronic prescribing or electronic health records systems.



## Paying for a Facility's EHR

- If the arrangement does not comply with all of the elements of the EHR Safe Harbor, then the arrangement will need to be examined in light of the language of the AKS, court decisions, and other published guidance.
- An important guidance is the OIG's December 7, 2012 Advisory Opinion No. 12-19, which addressed four proposed arrangements involving a pharmacy's provision of items and services to Community Homes in which the pharmacy's customers reside.

## Paying for a Facility's EHR

- The OIG opined that it would not impose administrative sanctions in connection with Proposals A – C, but would likely impose such sanctions against Proposal D. Under Proposal D, the pharmacy would provide to Community Homes a free sublicense for "Software Z" for use in connection with the pharmacy's customers.
- In determining that Proposal D would likely result in administrative sanctions, the OIG pointed out the following: "Software Z is not interoperable.



## Paying for a Facility's EHR

- Data that a Community Home would create and store in Software Z, including MAR documentation, would not be readily transferable to other systems, resulting in Community Home data lock-in and, thereby, referral lock-in…[I]f a Community Home resident began receiving medications from the [donor pharmacy] and later decided to receive medications from another pharmacy, then the Community Home could face having to either transition that resident's data to another system or assume the full payment for a Software Z sublicense.
- This situation could give rise to a significant incentive for the Community Homes to steer patients to the [donor pharmacy] rather than one of its competitor[s]."

# Avoiding "Sham" Clinical Studies



## Avoiding "Sham" Clinical Studies

- In a sham clinical study program, the physician refers patients to the pharmacy. The pharmacy provides prescription drugs to the patients.
- The physician "collects data" from the patient (e.g., "After using the drug, 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.



## Avoiding "Sham" Clinical Studies

- Sham clinical studies violate the AKS.
- 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 AKS is violated even if the principal purpose is to pay for legitimate services.

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## 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.
- 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's AKS.



## 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.

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## 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, some pharmacies are entering into arrangements that will get them into trouble.
- This has to do with "telehealth" companies.

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## 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.

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## 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 issue 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) a government program.*



## 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 physician, who 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.

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# 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.



## Charitable Contributions

- 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.



# 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.

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## 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 pharmacy 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 pharmacy and (ii) the pharmacy 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:
  - 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.

## THE END

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