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# DEVELOPMENT OF A PHARMACY COLLABORATIVE PRACTICE AGREEMENT

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# INTRODUCTION

# INTRODUCTION

- There are two overriding reasons for a pharmacy desiring to collaborate with physician.
- Coordination of Care
  - Historically, health care remuneration has been based on the fee-for-service (“FFS”) model.
  - Under the FFS model, providers are paid for the services and products they provide regardless of patient outcome.
  - Under this model, there is little coordination among the providers treating the same patient.
  - The FFS model has proven to be expensive and inefficient.
  - As such, third-party payors (“TPPs”) are pushing providers into the collaborative care (“CC”) model.
  - Under the CC model, providers are expected to coordinate with each other with the goal of healing the patient and keeping the patient healthy.
  - Therefore, pharmacies, physicians and other providers are motivated to work with each other.

# INTRODUCTION

- Generate referrals
  - Physicians are important referral sources for pharmacies
  - If a physician knows the pharmacy and is confident in the pharmacy's abilities to service patients, then it is likely that the physician will refer patients to the pharmacy.
  - However, if the collaborative relationship results in remuneration ("anything of value") to the physician, then federal and state anti-fraud laws are implicated.
  - As such, it is important that collaborative relationships fall within exceptions or "safe harbors" to the anti-fraud laws.
  - Note that most of the legal guidelines contained in these slides also apply to Nurse Practitioners and Physician Assistants.



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# ANTI-FRAUD LAWS

# FEDERAL ANTI-KICKBACK STATUTE

- The federal anti-kickback statute (“AKS”) prohibits a pharmacy from giving “anything of value” to a physician in exchange for the physician
  - (i) referring federal health care program (“FHP”) patients to the pharmacy,
  - (ii) arranging for the referral of FHP patients to the pharmacy, or
  - (iii) recommending the purchase of a service or product from the pharmacy that is covered by an FHP.
- The term “anything of value” is quite broad and includes
  - (i) payment of money,
  - (ii) payment of expenses, and
  - (iii) providing gifts.

# FEDERAL ANTI-KICKBACK STATUTE

- A violation of the AKS is a criminal offense. But there are a number of “safe harbors” to the AKS. If an arrangement falls within a safe harbor, then as a matter of law, the AKS is not violated. If an arrangement does not fall within a safe harbor, that does not necessarily mean the AKS is violated; rather, it means that a thorough examination of the arrangement will need to be made under the wording of the AKS, court decisions, and other published legal guidance.

# FEDERAL STARK PHYSICIAN SELF-REFERRAL STATUTE

- The federal Stark physician self-referral statute (“Stark”) prohibits a physician from referring Medicare and Medicaid patients, for designated health services (“DHS”), to a pharmacy with which the physician (or an immediate family member of the physician) has a financial relationship unless the financial relationship fits within a Stark exception.
- The term “financial relationship” includes
  - (i) an ownership interest by the physician (or an immediate family member of the physician) in the pharmacy and/or
  - (ii) compensation (or anything else of value) from the pharmacy to the physician (or an immediate family member of the physician).



# FEDERAL STARK PHYSICIAN SELF-REFERRAL STATUTE

- DHS includes prescription drugs.
- Violation of Stark results in civil liability.
- There are a number of exceptions to Stark, including the Non-Monetary Compensation Exception (“NMC Exception”) that allows a pharmacy to spend money each year on gifts, meals and entertainment for a physician so long as the amount spent does not exceed a set amount. For 2020, that amount is \$423.

# STATE ANTI-FRAUD LAWS

- In addition to federal laws, there are state laws that need to be examined. These include
  - State anti-kickback statutes - Some statutes apply only when the payor is the state Medicaid program. Other statutes apply even if the payor is a commercial insurer or a cash-paying patient.
  - A number of states have physician self-referral statutes that are similar to Stark.
  - Each state has a set of statutes that are specific to physicians.
- Health care attorneys can fairly easily locate these state laws. The non-attorney can obtain a basic understanding by going to Google, typing in the name of the state, and then typing in the following key words: kickback, anti-kickback, referral, fee splitting, patient brokering and/or self-referral.



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# EXAMPLES OF COLLABORATIVE ARRANGEMENTS

# 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 third-party payors
  - (i) that the pharmacy has a sophisticated business model and
  - (ii) that the pharmacy’s products and 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 (“MDA”) needs to comply with
  - (i) the Personal Services and Management Contracts safe harbor to the AKS and
  - (ii) the personal services exception to Stark.

# MEDICAL DIRECTOR

- Among other requirements
  - (i) the MDA needs to be in writing,
  - (ii) the MDA must have a term of at least one year,
  - (iii) the compensation must be fixed on year in advance, and
  - (iv) the compensation must be the fair market value (“FMV”) equivalent of the physicians’ services and cannot take into account the anticipated number of referrals from the physician to the pharmacy.
- Further, the services provided by the physician to the pharmacy must be substantive and valuable. They cannot be “made up” services.

# 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

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- 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.

# EMPLOYEE LIAISON

- Examples of what the liaison *can* and *cannot* do are
  - The liaison *can* educate the physician's employees regarding the products and services provided by the pharmacy. The liaison can do so through formal educational lunches and through informal one-on-one conversations with the physician's employees.
  - The liaison *can* educate the physician's patients regarding the products and services provided by the pharmacy. The liaison can do so by presenting formal educational workshops and through informal one-on-one conversations with the physician's patients.
  - If a patient of the physician decides that he/she will use the pharmacy, then the liaison *can* work with the patient to transition him/her to the pharmacy.

# EMPLOYEE LIAISON

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- Unless the physician pays fair market value compensation to the pharmacy for the liaison's services
  - The liaison *cannot* handle preauthorization calls on behalf of the physician.
  - The liaison *cannot* provide billing services on behalf of the physician.
  - The liaison *cannot* provide data input services on behalf of the physician.

# ANNUAL WELLNESS VISITS (“AWVS”)/REMOTE PATIENT MONITORING (“RPM”)/CHRONIC CARE MANAGEMENT (“CCM”)

- Assume that the physician (i) has AWVs with patients, (ii) provides RPM to patients and/or (iii) provides CCM to patients.
- Assume that the pharmacy assists the physician in (i) conducting AWVs and (ii) providing RPM and CCM.
- It is the physician that is paid for AWVs, RPM and CCM. If the pharmacy assists with AWVs, RPM and CCM for free, then such assistance constitutes “something of value” to a referral source, thereby implicating the AKS and Stark.
- In order to avoid AKS and Stark problems, the physician must pay fair market value compensation to the pharmacy for the pharmacy’s services.

# LOAN CLOSET

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- If the pharmacy sells DME, then it can store 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, 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”).



# RURAL COMMUNITY

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- Among other requirements:
  - The physician must purchase, at FMV, his percentage ownership interest in the rural 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

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- 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) in order to keep the patient healthy.

# 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 2020, this dollar amount is \$423.

# ACO

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- A physician can lobby an ACO for a pharmacy to be a “preferred provider” for hospitals and physicians that comprise the ACO.

# PROVISION OF EQUIPMENT TO THE PHYSICIAN

- In addressing this scenario, the Office of Inspector General (“OIG”) contrasted situations in which a lab provides a computer to a physician (i) that can only be used to print results of lab tests vs. (ii) one that the physician is free to use for a variety of purposes.
- With regard to the first situation, the OIG stated “that the computer has no independent value apart from the service being provided and ... the purpose of the free computer is not to induce an act prohibited by the [anti-kickback] statute ...” With regard to the second situation, the OIG stated that “the computer has a definite value to the physician, and, depending on the circumstances, may well constitute an illegal inducement.”

# PROVISION OF EQUIPMENT TO THE PHYSICIAN

- Based on OIG guidance, the safest way for a pharmacy to reduce the kickback risk associated with the provision of free equipment is to limit the functionality of the equipment so that it can only be utilized in conjunction with the pharmacy's services.
- For example, if the pharmacy furnishes an iPad in order to enable the physician or his employees to submit orders and documentation to the pharmacy, that is all the physician and his employees should be able to do with the iPad.
- The physician and his employees should not be able to access personal email accounts, surf ESPN.com, change a Facebook status, etc.



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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 same condition, the hospital will be subjected to future payment reductions by Medicare.

# PREFERRED PROVIDER AGREEMENT

- A hospital can partner with a number of providers 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.



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# QUESTIONS?

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# THANK YOU

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