



EDUCATIONAL RESOURCES

LEGAL ISSUES FACING PHARMACIES

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INTRODUCTION

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- There are 78 million Baby Boomers, and they are retiring at a rate of 10,000 per day. Unlike earlier generations, Boomers will live a long time. And it will be costly for Medicare to provide health care to Boomers, particularly during their later years.
- Understandably, there is a push by third-party payors (“TPPs”) to (i) contain costs and (ii) require health care providers to engage in a collaborative care/patient outcome model of health care delivery. Said another way, TPPs want providers to work together to treat patients and to keep them healthy.

INTRODUCTION

- Pharmacies play an integral role in treating patients and in keeping them healthy. Of course, the drugs that pharmacies dispense are important. But, also, increasingly, pharmacies provide valuable services to patients.
- Because of the role that pharmacies play, and because of the large amounts of money that TPPs pay to pharmacies, pharmacies live in a glass house. They are under the spotlight by government enforcement agencies, TPPs, and others.
- This program will discuss the key legal issues that pharmacies face now and will face in the foreseeable future.



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COLLABORATION WITH PHYSICIANS

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, 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, 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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COLLABORATION WITH PHYSICIANS

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
 - referring federal health care program (“FHP”) patients to the pharmacy,
 - arranging for the referral of FHP patients to the pharmacy, or
 - 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
 - payment of money,
 - payment of expenses, and
 - providing gifts.

FEDERAL ANTI-KICKBACK STATUTE

- A violation of the AKS is a criminal offense.
- There are a number of “safe harbors” to the AKS.
- If an arrangement falls within a safe harbor, 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
 - an ownership interest by the physician (or an immediate family member of the physician) in the pharmacy and/or
 - 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 2021, that amount is \$429.

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
 - that the pharmacy has a sophisticated business model and
 - 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, the Medical Director Agreement (“MDA”) needs to comply with
 - the Personal Services and Management Contracts safe harbor to the AKS and
 - the personal services exception to Stark.

MEDICAL DIRECTOR

- Among other requirements
 - the MDA needs to be in writing,
 - the MDA must have a term of at least one year
 - the compensation must be fixed on year in advance, and
 - 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
 - products and services offered by the pharmacy and
 - 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.

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.

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

- 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.



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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."
- 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.

PAYING FOR A FACILITY'S EHR

- One such requirement is for the Facility to have a pharmacy perform a monthly drug regimen review ("DRR") on each patient.
- 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."

PAYING FOR A FACILITY'S EHR

- 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.
- The applicable safe harbor is the Electronic Health Records safe harbor (“EHR Safe Harbor”).
- It states that an entity may donate software and training services “necessary and used predominantly to create, maintain, transmit, or receive electronic health records” if 12 requirements are satisfied. Two of the most important requirements are
 - The Software must be interoperable.
 - The recipient must pay 15% of the donor’s cost.

PAYING FOR A FACILITY'S EHR

- If the arrangement does not comply with all of the elements of the EHR Safe Harbor, 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 4 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.”



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CONSULTING PHARMACY SERVICES

CONSULTING PHARMACY SERVICES

- As noted above, in order for a Facility to serve Medicare and Medicaid patients, federal law imposes a number of requirements on the Facility.
- One such requirement is for the Facility to have a pharmacy perform a monthly drug regimen review (“DRR”) on each patient.
- In order to meet the DRR requirement, the Facility will need to enter into a Pharmacy Consulting Agreement (“PCA”) with a pharmacy.

CONSULTING PHARMACY SERVICES

- Assume that the pharmacy dispenses drugs to the Facility's patients.
- Regardless of how much "patient choice" the Facility gives the patients, under the AKS the Facility will be considered to be a "referral source" to the pharmacy.
- Under the AKS, the pharmacy cannot "give anything of value" to a referral source (i.e., the Facility).
- "Anything of value" includes subsidizing the Facility's expenses.
- Therefore, violation of the AKS can occur if the pharmacy provides consulting services for free or for compensation that is below FMV.

CONSULTING PHARMACY SERVICES

- The safest form of compensation by the Facility to the pharmacy is for the Facility to pay fixed annual compensation (e.g., \$12,000 over the next 12 months) to the pharmacy that is the FMV equivalent of the pharmacy's services.
- Fixed annual (FMV) compensation is an important element of the Personal Services and Management Contracts safe harbor to the AKS.
- A less conservative method of compensation (but one that is low risk from a kickback standpoint) is for the Facility to pay the pharmacy by the hour.
 - Such per hour compensation needs to be FMV.
- The guidance set out above is not limited to DRR services.
- Rather, the guidance applies to any type of services rendered by a pharmacy to a Facility.



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DRUG CARTS AND OTHER PRODUCTS

DRUG CARTS AND OTHER PRODUCTS

- It is not uncommon for a Facility to request a pharmacy (that serves the Facility's patients) to donate a drug cart or iPads or bedding or other items to the Facility.
- These items constitute "something of value" to a referral source.
- As a result, the AKS comes into play.

DRUG CARTS AND OTHER PRODUCTS

- The AKS prohibits the pharmacy from donating these types of items to the Facility. However, here are some steps that the pharmacy and Facility can take:
 - The pharmacy can deliver possession of a drug cart to a Facility so long as
 - title to the drug cart remains with the pharmacy and
 - the Facility uses the drug cart only in conjunction with drugs furnished by the pharmacy.
 - The pharmacy can deliver possession of iPads to a Facility so long as
 - title to the iPads remains with the pharmacy and
 - the Facility uses the iPads only in conjunction with its relationship with the pharmacy.
- On the other hand, the pharmacy cannot donate bedding to the Facility because such bedding cannot be limited to the Facility's relationship with the pharmacy. Rather, donation of bedding is simply relieving the Facility of its costs to purchase bedding.



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SHAM CLINICAL STUDIES

SHAM CLINICAL STUDIES

- “You can put lipstick on a pig, but it is still a pig.”
- Under the typical sham clinical study program, the physician refers patients to the pharmacy. The pharmacy dispenses a compounded medication (e.g., pain cream) to the patient.
- The physician “collects data” from the patient (e.g., “After applying the pain cream, from a scale of one to ten, what is your pain level?”).
- The physician shares the information with the pharmacy.
- The information is rudimentary; the pharmacy does not need it.
- It is the same information that the pharmacy can secure itself.

SHAM CLINICAL STUDIES

- The pharmacy pays the physician \$__ per patient per month.
- In some clinical studies physicians have been known to make about \$80,000 over a 6-month period.
- These “sham” studies violate the AKS.
- The pharmacy may argue that it is not paying for referrals but is paying for legitimate services.

SHAM CLINICAL STUDIES

- Remember the statement about “putting lipstick on a pig.”
- A number of courts have enumerated the “one purpose” test.
 - This test states that if one purpose behind a payment is to induce referrals, the AKS is violated even if the principal purpose is to pay for legitimate services.
- In a sham clinical study, 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 anti-kickback statutes.



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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.
- When a pharmacy is marketing to patients in multiple states, the pharmacy may run into a “bottleneck.”
- This involves the patient’s local physician.
- A patient may desire to purchase a prescription drug from the out-of-state pharmacy, but it is too inconvenient for the patient to drive to his physician’s office.

SHAM TELEHEALTH ARRANGEMENTS

- Or if the patient is seen by his local physician, the physician may decide that the patient does not need the drug and so the physician refuses to sign a prescription.
- Or even if the physician does sign a prescription, he may be hesitant to send the order to an out-of-state pharmacy.
- 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.

SHAM TELEHEALTH ARRANGEMENTS

- A typical telehealth company has contracts with many physicians who practice in multiple states.
- The telehealth company contracts with and is paid by
 - self-funded employers that pay a membership fee for their employees
 - health plans, and
 - patients who pay a per visit fee.
- Where a pharmacy will find itself in trouble is when it aligns itself with a telehealth company that is not paid by employers, health plans, and patients but, rather, is directly or indirectly paid by the pharmacy.

SHAM TELEHEALTH ARRANGEMENTS

- Here is an example:
 - Pharmacy purchases leads from a marketing company
 - The marketing company sends the leads to the telehealth company
 - The telehealth company contacts the leads and schedules audio or audio/visual encounters with physicians contracted with the telehealth company
 - The physicians 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.
- 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).
- If the payer is a federal health care program, the arrangement will likely violate the AKS.
- If the payer is the state Medicaid program, the arrangement will likely violate both the AKS and the state anti-kickback statute.
- If the payer is a commercial insurer, the arrangement may violate a state statute.



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FAILURE TO COLLECT COPAYMENT

FAILURE TO COLLECT COPAYMENT

- A pharmacy is legally required to make a reasonable effort to collect copayments.
 - A pharmacy should only reduce or waive the patient's copayment if the patient establishes a financial inability to pay.
 - If a pharmacy routinely waives copayments, it likely violates the AKS, federal False Claims Act, the beneficiary inducement statute, applicable state statutes, and contracts with PBMs and other TPPs.
 - 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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GOVERNMENT SCRUTINY AND QUITAMS

INCREASED SCRUTINY BY GOVERNMENT AGENCIES

- The DOJ and the OIG are becoming much more aggressive in bringing civil and criminal investigations against pharmacies and their owners.

PROLIFERATION OF QUI TAM LAWSUITS

- Many investigations are a result of qui tam (whistleblower) lawsuits.
- This is when a disgruntled ex-employee, disgruntled current employee, or any other person with “original facts,” files a federal lawsuit against the pharmacy and its owners
- The lawsuit will be in the name of the current/ex employee (“relator”) and in the name of the U.S.



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QUI TAM LAWSUITS

QUI TAM LAWSUITS

- False Claims Act
 - The False Claims Act contains a whistleblower provision that allows a private individual to file a lawsuit on behalf of the United States, also known as a qui tam.
- Whistleblowers
 - Entitled to a percentage of any recoveries
 - Could be current or ex-employees, current or ex-business partners, patients, competitors, or any other person with “original facts”

QUI TAM LAWSUITS

- The qui tam lawsuit will be based on the federal False Claims Act.
- It is the position of the DOJ that if the provider commits an act that violates any law (civil or criminal), and if the provider eventually submits a claim to a government health care program (in which the claim directly or indirectly is related to the acts), then the claim is a "false claim."
- Under the FCA the provider (and its individual owner) can be liable for actual damages, treble damages, and between \$10,781 to \$21,563 per claim.
- When the qui tam lawsuit is initially filed, it will go "under seal," meaning that nobody (except for the DOJ) will know about it.

QUI TAM LAWSUITS

- An Assistant U.S. Attorney (in the jurisdiction in which the qui tam is filed), who specializes in civil health care fraud cases, will review the lawsuit and will ask investigative agents (FBI, OIG) to investigate the allegations set out in the qui tam suit.
- The agents may talk to current employees and/or ex-employees.
- The agents may talk to patients, marketers, and referring physicians.
- The agents may talk to others who may have information regarding the allegations set out in the qui tam.

QUI TAM LAWSUITS

- The investigation may take 6 months, or it may take several years.
- If the civil AUSA believes that the provider's actions are particularly serious, he/she may ask a criminal AUSA to launch a criminal investigation.
- In fact, most criminal health care fraud investigations arise out of qui tam lawsuits.
- If the civil AUSA believes that the qui tam has merit, then the DOJ will take the lawsuit over and the relator's attorney will "sit on the sidelines."
- If the DOJ does not "intervene" (i.e., take the lawsuit over), then the relator's attorney can proceed without the DOJ's assistance.
- Because of the potential massive liability under the FCA, most qui tam lawsuits are settled (i.e., the provider pays a lot of money).

QUI TAM LAWSUITS

- In addition to paying money to the DOJ (of which 15% to 20% will go to the relator), the provider will usually be required to enter into a Corporate Integrity Agreement (“CIA”) with the OIG.
- A CIA normally has a 5-year term.
- Under the CIA, the provider must fulfill a number of obligations to the OIG.



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QUESTIONS?

Email us at customerservice@achcu.com



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THANK YOU

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