



EDUCATIONAL RESOURCES

# GAZING INTO THE CRYSTAL BALL

## Legal Challenges Facing Pharmacies

Denise M. Leard, Esq.

Brown & Fortunato



EDUCATIONAL RESOURCES

# INTRODUCTION

# INTRODUCTION

---

- Pharmacies have been an integral component of our nation's health care delivery system since the foundation of our country.
- Until the 1930s, pharmacies were subject to very little government oversight.
- Beginning in the first half of the 20th century, particularly with the advent of the Food and Drug Administration and the Drug Enforcement Administration, the federal government began to take an increasing role in regulating pharmacies.

# INTRODUCTION

---

- The same can be said for the states. Beginning in the first half of the 20th century, state boards of pharmacy became more active in regulating pharmacies operating in their states.

# INTRODUCTION

- Nevertheless, compared to other health care providers (hospitals, physicians, labs, etc.), regulatory requirements imposed on pharmacies were not particularly stringent.
- This has changed and there are several reasons for the change.
  - In the past, with few exceptions pharmacies did not bill Medicare. As a result, there was not a great deal of federal governmental scrutiny of pharmacies. But then there was a “sea change.”
  - In the first decade of the 21st century, Medicare began paying for prescription drugs for Medicare beneficiaries under Part D. As a result, Medicare now has serious “skin in the game.”
  - Because Medicare is paying a great deal of money for prescription drugs, Medicare is motivated to scrutinize pharmacy operations to ensure that Medicare funds are being wisely spent.
  - The same can be said of TRICARE. For the past several years, a number of pharmacies submitted large numbers of claims to TRICARE for compounded drugs ... particularly pain and scar creams.

# INTRODUCTION

---

- TRICARE paid these claims until it concluded that the pharmacies were “gaming the system,” at which time TRICARE ceased paying for compounded drugs and launched government investigations of compounding pharmacies.
- Because pharmacies are billing Medicare and other government programs, the pharmacies must comply with an array of federal anti-fraud laws such as the federal anti-kickback statute, the Stark physician self-referral statute, the beneficiary inducement statute, and the False Claims Act.

# INTRODUCTION

---

- And so pharmacies live in the proverbial “glass house.” There are multiple eyes on the pharmacy’s operations: third party payors, government agencies, and the pharmacy’s own employees.
- This program will discuss the most important “hot button” legal issues that pharmacies will face over the next year.



EDUCATIONAL RESOURCES

# ANTI-FRAUD LEGAL GUIDELINES



# FEDERAL 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, Medicaid Managed Care, 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

---

- Imposes civil monetary penalties upon a person or entity that offers or gives remuneration to any Medicare/Medicaid beneficiary that the offeror knows or should know is likely to influence the recipient to order an item for which payment may be made under a federal or state health care program.
- This statute does not prohibit the giving of incentives that are of “nominal value” (no more than \$15 per item or \$75 in the aggregate to any one beneficiary on an annual basis).

# STARK PHYSICIAN SELF-REFERRAL STATUTE

---

- Provides that if a physician has a financial relationship with an entity providing designated health services (“DHS”), then the physician may not refer patients to the entity unless one of the statutory or regulatory exceptions apply.
- DHS includes prescription drugs.

# SAFE HARBORS

- Because of the breadth and scope of the AKS, the Office of Inspector General (“OIG”) has published a number of “safe harbors.” If an arrangement meets the requirements of a safe harbor, then as a matter of law the arrangement does not violate the AKS. If an arrangement does not meet the requirements of a safe harbor, then it does not mean that the arrangement automatically violates the AKS. Rather, the arrangement must be carefully scrutinized under the wording of the AKS, court decisions, and published guidance by the OIG.

# SAFE HARBORS

---

- Six of the most important safe harbors for pharmacies are:
  - Small Investment Interest
  - Space Rental
  - Equipment Rental
  - Personal Services and Management Contracts
  - Employees
  - Electronic Health Records

# 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

---

- All states have enacted statutes prohibiting kickbacks, fee splitting, patient brokering, or self-referrals.
- Some state anti-kickback statutes only apply when the payor is a government health care program.
- Other state anti-kickback statutes apply regardless of the identity of the payor.
- In addition, each state has laws that are specific to pharmacies. These laws normally include provisions addressing kickbacks.



EDUCATIONAL RESOURCES

# WORKING WITH PBM<sub>s</sub>



# INTRODUCTION

---

- There is an old saying: “Possession is 9/10ths of the law.”
- This saying applies to PBMs. At the end of the day, the PBM “possesses the pharmacy’s money.”

# INTRODUCTION

---

- Most, if not all, PBM contracts give the PBM the right to terminate its contract with the pharmacy with...or without...cause.
- “With cause” can include (i) misrepresentations by the pharmacy to the PBM in e.g., a recredentialing questionnaire, (ii) failure by the pharmacy to adhere to the requirements imposed by the PBM on its member pharmacies, and (iii) breach by the pharmacy of terms of the PBM contract.
- “Without cause” means exactly what it says. If the PBM simply “does not like what the pharmacy is doing,” then the PBM can terminate the contract.

# PBM RECREDENTIALING

---

- PBMs and payors must validate the credentials of pharmacies to ensure they are in good standing with state and federal laws and meet quality performance standards. Under the current approach, PBMs collect data from their network pharmacies using batch spreadsheets and questionnaires, as well as confirming they meet requirements through internal checks.
- PBMs will recredential pharmacies every year or couple of years, depending on the PBM, to ensure each pharmacy meets the PBM's participation requirements.

# PBM RECREDENTIALING

---

- Many PBMs have recently adopted new recredentialing processes specifically for compounding pharmacies. The questionnaire asks new, specific questions of compounding pharmacies, that cover various aspects of the pharmacy's business. The new recredentialing process also requires the pharmacy to maintain and submit Policies and Procedures relating to various aspects of pharmacy operations and billing practices, such as kickback issues, billing processes, and USP <795> compliance.

# PBM RECREDENTIALING

---

- Additionally, the recredentialing application inquires about (i) the use of pharmacy marketing representatives, (ii) the use of W-2 employees vs. 1099 independent contractors, (iii) central fill relationships, (iv) pre-printed prescription pads, (v) reduction or waiver of copayments, (vi) out-of-state licensure, (vii) extent of the pharmacy's mail-order business, and (viii) extent of the pharmacy's compounding.

# QUESTIONS PERTAINING TO MAIL ORDER

---

- Does your pharmacy fill prescription claims under multiple NCPDPs?
- Does your pharmacy hold a license in more than one state?
- Is your pharmacy a retail walk-in pharmacy that services the general public?
- Is your pharmacy a closed-door pharmacy?
- Is 25% or more of your pharmacy business mail order?

# QUESTIONS PERTAINING TO COMPOUNDING

---

- Does your pharmacy participate in complex compounding?
- Is your pharmacy registered/affiliated with a compounding supplier?
- Does our pharmacy have a dedicated lab/area for compounding?
- Does your pharmacy have dedicated technicians for compounding only?
- Does your pharmacy have any of the following compound equipment: unguator, hot plate, homogenizer, ointment mill, tube sealer, capsule filling system?

# QUESTIONS PERTAINING TO COPAYMENTS

---

- Does your pharmacy ever waive or offer a reduction of member copayments?
  - If yes, please provide a copy of your written policy relating to the waiver/reduction of copayments.



# QUESTIONS PERTAINING TO MARKETING

---

- Does your pharmacy contract with or employ a sales force?
  - If yes, please describe the activities of the sales force.

# QUESTIONS PERTAINING TO AFFILIATED PHARMACIES

---

- Is your pharmacy directly or indirectly affiliated with any other pharmacies?
- List the identity of any person who has a direct or indirect ownership interest in your pharmacy.
- Do any of the pharmacy owners have a direct or indirect ownership interest in any other pharmacy?

# CERTIFICATION

---

- I certify that each answer on this Questionnaire is true and correct.
- I agree to notify [Name of PBM] immediately in writing in the event of a change in the information provided which would make any part of the Questionnaire untrue or inaccurate. I understand that failure to do so will be considered a breach of my Provider Agreement and could result in disciplinary action including, but not limited to, immediate termination of my Provider Agreement.

# CERTIFICATION

---

- I give [Name of PBM], and its designers, permission to contact any individual, company, organization, etc., including state and federal licensing agencies, as may be necessary to verify the information submitted herein and to ask questions about disciplinary actions, the pharmacy's license, or any pharmacist licensed, employed by or dispensing prescriptions at the pharmacy.
- I certify that training, which meets the CMS requirement for fraud, waste and compliance training, has been conducted within 90 days of hire and annually thereafter for all employees and other persons who administer or deliver the Medicare Part D benefit.

# GOAL OF PBM AUDIT

---

- PBMs typically audit pharmacies in order to detect any improper payment by the PBM on behalf of the plan or consumer and to verify that the patient received the correct medication in the appropriate dose. PBMs will also conduct an audit on a pharmacy to verify that contracts are being adhered to.

# INCORPORATION OF OUTSIDE DOCUMENTS

---

- A challenge to pharmacies is the incorporation of the PBM's policy manuals into its contracts. The manuals can end up having the same importance as the contracts. Compounding is one area of health care that is often outlined in PBM policy manuals. Due to unfamiliarity with compounding policies, a pharmacy can inadvertently violate its contract with the PBM. To ensure policies are being followed, contracts usually give the PBM the authority to conduct an audit.

# PREPARING FOR AN AUDIT

---

- The pharmacy should understand what its contract with the PBM says.
- If the PBM contract incorporates outside documents (e.g., policy manuals), then the pharmacy should understand what the outside documents say.
- The pharmacy should determine if its operations comply with the contract and outside documents.

# PREPARING FOR AN AUDIT

---

- The pharmacy should review its previously submitted questionnaires to the PBM so that the pharmacy will know what it has represented to the PBM.
- The pharmacy should understand what the “hot button” issues are for the PBM. Examples include:
  - Extent of pharmacy’s mail-order business
  - Extent of pharmacy’s compounding
  - Whether the pharmacy has out-of-state pharmacy licenses
  - Pharmacy’s policy towards reducing or waiving copayments
  - Whether the pharmacy markets through W2 employees or 1099 independent contractors



# AUDIT RESPONSE PROTOCOL

---

- The pharmacy should adopt a formal protocol to respond to an audit. Specifically:
  - Employees who open mail should be alerted to look for any envelope from a PBM.
  - Employees who answer the phone should be alerted to look for phone calls from PBMs.
  - When an employee is alerted to the possible existence of a PBM audit, he/she should immediately notify pharmacy management.

# RESPONDING TO AUDIT

- The pharmacy should consult with a health care attorney who has experience with PBMs. The attorney should (i) guide the pharmacy in responding to the audit and (ii) approve any documents that the pharmacy submits to the PBM.
- The pharmacy's approach should be "let's resolve the problem" as opposed to "let's win the argument."
  - It is highly unlikely that the PBM will back down and concede to the pharmacy.
  - On the other hand, unless the facts are egregious, there is a reasonable possibility that the PBM will agree to an amicable resolution.
- It is important that the pharmacy meet the deadlines imposed by the PBM. The PBM will likely agree to a reasonable request for a deadline extension.
- It is equally important that the information submitted by the pharmacy be complete and accurate.

# REASONS FOR TERMINATION BY PBM

---

- Pharmacy is engaged in mail-order
  - Many PBMs have their own mail-order pharmacy.
  - PBMs do not like their contract retail pharmacies to compete with the PBMs' mail-order pharmacies.
  - Most recredentialing questionnaires inquire about the extent of the pharmacy's mail-order business. If the pharmacy discloses information that it is engaged in mail-order beyond a certain threshold, then the PBM may decide to terminate the contract.
  - Or if the PBM finds out (through other means) that the pharmacy is engaged in mail-order beyond a certain threshold, then the PBM may decide to terminate the contract.

# REASONS FOR TERMINATION BY PBM

- Pharmacy is engaged in compounding
  - TRICARE and PBMs have been “burned” by some compounding pharmacies.
  - For several years, a number of compounding pharmacies contracted with marketing/lead generation companies (“LGCs”) to generate patients who wanted compounded pain and scar creams.
  - The compounding pharmacies would dispense the pain/scar creams and bill the PBMs an exorbitant amount per month/per patient for the creams.
  - The commercial insurers (that were footing the bills) came down on the PBMs.
  - In turn, PBMs do not want their contract retail pharmacies to be engaged in compounding in a meaningful way.
  - Most recredentialing questionnaires inquire about the extent of the pharmacy’s compounding. If the pharmacy discloses information that it is engaged in compounding beyond a certain threshold, then the PBM may decide to terminate the contract.
  - Or if the PBM finds out (through other means) that the pharmacy is engaged in compounding beyond a certain threshold, then the PBM may decide to terminate the contract.

# REASONS FOR TERMINATION BY PBM

- Pharmacy is routinely waiving copayments
  - Federal law, most state laws, and most PBM contracts require the pharmacy to “take reasonable steps” to collect copayments.
  - Pharmacies are prohibited from routinely waiving copayments.
  - A pharmacy can waive copayments, on a patient-by-patient basis, if the patient submits financial information justifying the waiver.
  - A pharmacy cannot advertise, or otherwise let a patient know in advance, that the pharmacy might waive the copayment if the patient submits financial information justifying the waiver.
  - Rather, when the pharmacy delivers the drug, it should tell the patient what his/her copayment is...and request payment.
  - Only if the patient responds by saying that he/she does not have the ability to pay the copayment can the pharmacy suggest to the patient that he/she complete a financial hardship waiver form.

# REASONS FOR TERMINATION BY PBM

---

- After reviewing the completed financial hardship waiver form, if the pharmacy concludes that the patient cannot pay the copayment, then the pharmacy can waive it.
- The pharmacy needs to avoid sham (i) copayment assistance programs and (ii) “insurance” programs.
- As part of the recredentialing process, the PBM may ask the pharmacy to provide information and documents that pertain to the collection of copayments by the pharmacy. If the information/documents provided by the pharmacy indicate that the pharmacy is routinely waiving copayments, then the PBM may decide to terminate the contract.

# REASONS FOR TERMINATION BY PBM

---

- Pharmacy markets through 1099 independent contractors
  - The federal anti-kickback statute (“AKS”) states that a pharmacy cannot “give anything of value” to a person/entity in exchange for the person/entity referring (or arranging for the referral of) patients to the pharmacy who are covered by a federal government health care program.
  - Each state has an anti-kickback statute that essentially says the same thing as the AKS. Some state anti-kickback statutes apply only when the payor is the state Medicaid program. Other state anti-kickback statutes apply even if the payor is a commercial insurer or a cash-paying patient.

# REASONS FOR TERMINATION BY PBM

---

- If a pharmacy pays percentage compensation to a 1099 independent contractor (individual sales rep or LGC) that arranges for the referral of government health care program patients to the pharmacy, then the AKS is implicated...and an applicable state anti-kickback statute may be implicated.
- As part of the recredentialing process, the PBM may ask the pharmacy to provide information and documents pertaining to the use by the pharmacy of 1099 independent contractors for marketing. If the information/documents provided by the pharmacy indicate that the pharmacy is paying commissions to 1099 independent contractors, then the PBM may decide to terminate the contract.



# RESPONSE TO PBM TERMINATION LETTER

- The first thing that the pharmacy needs to realize is that it and the PBM have unequal bargaining positions.
- Specifically, the PBM (i) “possesses the pharmacy’s money” and (ii) has an unlimited capacity to litigate with the pharmacy.
- If the pharmacy sues the PBM, or threatens to sue, then the PBM will not be fazed.
- The approach that has the best chance of being successful is for the pharmacy to contact the PBM in order to “work the problem.”
- The termination letter will likely give a reason for the termination. The pharmacy should attempt to work with the PBM to address – and resolve – that “reason.”
- If the pharmacy is unsuccessful at resolving the termination “at the lower level,” then the pharmacy’s attorney should reach out to one of the PBM’s in-house attorneys.



EDUCATIONAL RESOURCES

# 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.
- 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.

# UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEM

- 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.”

# 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.

# 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.



# 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.



EDUCATIONAL RESOURCES

# 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.



# PAYING FOR A FACILITY'S EHR

---

- 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 specific requirements are met.



EDUCATIONAL RESOURCES

# CONSULTING PHARMACY SERVICES

# CONSULTING PHARMACY SERVICES

---

- 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 fair market value.

# 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 fair market value equivalent of the pharmacy's services. Fixed annual (fair market value) 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 fair market value.
- 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.



EDUCATIONAL RESOURCES

# DRUG CARTS & 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 & 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 (i) title to the drug cart remains with the pharmacy and (ii) 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 (i) title to the iPads remains with the pharmacy and (ii) 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.





EDUCATIONAL RESOURCES

# MEDICAL DIRECTOR AGREEMENT

# MEDICAL DIRECTOR AGREEMENT

---

- A pharmacy can enter into an independent contractor Medical Director Agreement with a physician.
- The MDA must comply with the (i) Personal Services and Management Contracts safe harbor and (ii) the Personal Services exception to the Stark physician self-referral statute.

# MEDICAL DIRECTOR AGREEMENT

---

- Among other requirements:
  - The MDA must be in writing and have a term of at least one year.
  - The physician must provide substantive services.
  - The compensation to the physician must be fixed one year in advance and be the fair market value equivalent of the physician's services.



EDUCATIONAL RESOURCES

# QUESTIONS?

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



EDUCATIONAL RESOURCES

# THANK YOU

Denise M. Leard, Esq. 

Brown & Fortunato, P.C.

905 S. Fillmore St., Ste. 400

Amarillo, TX 79101

[dleard@bf-law.com](mailto:dleard@bf-law.com) | 806-345-6318