Dos and Don'ts of Providing Consulting Pharmacy Services, EHR Software, Drug Carts and Other Products and Services to Long-Term Care Facilities

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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 peer review of the slide content.

Learning Objectives

- Describe ways to avoid long-term care kickback violations.
- Explore the new trends in long-term care.
- Explain who is responsible for paying for electronic health records.

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.

Introduction

- 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.

Introduction

- 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."

Introduction

- Because Medicare is paying a great deal of money for prescription drugs, Medicare is motivated to scrutinize pharmacy operations to insure 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

- The primary users of maintenance prescription drugs are the elderly.
- Initially, the elderly primarily consisted of the 23 million of the "Greatest Generation."
- The Greatest Generation has been replaced by 78 million "Baby Boomers" who are retiring at the rate of 10,000 per day.

Introduction

- As a result, the demand for health care services, including prescription drugs, is increasing exponentially.
- While most of the aging Boomers will not spend their last years in long term care facilities, because of the sheer number of Boomers, there will be many aging Boomer who will live in facilities.
- This presents an opportunity for pharmacies to develop a niche in serving the elderly.

Introduction

- Equally as important, this also imposes an obligation on long term care pharmacies to comply with federal and state anti-fraud laws.
- As a result of the large outlays by Medicare and other government programs, there is motivation on the government's part to scrutinize pharmacy operation… including long term care pharmacies.

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.

Beneficiary Inducement Statute

- 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).

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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 arrangements 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

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.

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;

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.

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;

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.

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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;

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.

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.

Electronic Health Records

- See slides entitled "Paying for a Facility's EHR."

Advisory Opinions

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

Special Fraud Alerts & Special Advisory Bulletins

- From time to time, the OIG publishes Special Fraud Alerts and Special Advisory Bulletins that discuss business arrangements that the OIG believes may be abusive, and educate health care providers concerning fraudulent and/or abusive practices that the OIG has observed and is observing in the industry.

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.

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.

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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.

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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.

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]."

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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.

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.

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.

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 (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.

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.

Expenditures for Physicians

Introduction

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

Introduction

- If a pharmacy pays money to a physician for services, or provides meals, gifts and entertainment to a physician, or subsidizes a trip that the physician will take, then both the pharmacy and the physician need to comply with the federal and state laws that govern these arrangements.

What a Pharmacy Can Spend on (or Pay to) a Physician

- While the Stark non-monetary compensation exception allows a pharmacy to spend up to a set amount per year (e.g., $407 in 2018) for non-cash/non-cash equivalent items for a physician, the Medicare anti-kickback statute does not include a similar exception.
- Nevertheless, if the Stark exception is met, it is unlikely that the government will take the position that the non-cash/non-cash equivalent items provided by the pharmacy to the physician violate the AKS.

What a Pharmacy Can Spend on (or Pay to) a Physician

- In addition to complying with Stark and the AKS, the pharmacy and the physician also need to comply with applicable state law.
- Even though the pharmacy and the physician will need to confirm this, it is likely that compliance with the non-monetary compensation exception will avoid liability under state law.

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What a Pharmacy Can Spend on (or Pay to) a Physician

- And so the bottom line is that a pharmacy can provide gifts, entertainment, trips, meals, and similar items to a physician so long as the combined value of all of these items do not exceed the annual amount set by CMS ($407 in 2018).

What a Pharmacy Can Spend on (or Pay to) a Physician

- For example, if a pharmacy wants a physician to accompany the pharmacy on a trip to a continuing education conference, in 2018 the pharmacy can safely subsidize up to $407 of the physician's trip expenses.
- The amount of the trip subsidy will be affected by other expenditures the pharmacy has made on behalf of the physician during the year.

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What a Pharmacy Can Spend on (or Pay to) a Physician

- While the Stark non-monetary compensation exception applies to expenditures on behalf of a physician, the exception does not apply to expenditures on behalf of the physician's staff.
- In fact, Stark does not apply to the physician's staff. Expenditures on behalf of the physician's staff must be examined in light of the AKS.

What a Pharmacy Can Spend on (or Pay to) a Physician

- Separate from furnishing gifts and entertainment, and subsidizing trips, the pharmacy can pay the physician for legitimate services.
- For example, if the pharmacy has a legitimate need for a Medical Director, then the pharmacy and physician can enter into a Medical Director Agreement that complies with both the PSMC safe harbor to the AKS and the Personal Services exception to Stark.

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What a Pharmacy Can Spend on (or Pay to) a Physician

- Another legitimate way for money to exchange hands between a pharmacy and a physician is for the physician to rent space to the pharmacy or vice versa.
- The rental arrangement needs to comply with the Space Rental safe harbor to the AKS.
- This safe harbor is similar to the PSMC safe harbor.

What a Pharmacy Can Spend on (or Pay to) a Physician

- Among other requirements:
  - the parties must execute a written lease agreement that has a term of at least one year;
  - the rent paid must be fixed one year in advance (e.g., $48,000 over the next 12 months), and
  - the rent must be fair market value.

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What a Pharmacy Can Spend on (or Pay to) a Physician

- The rental arrangement needs to also comply with the Space Rental exception to Stark; this exception is similar to the Space Rental safe harbor to the AKS.

Paying Physician to Provide Education Program

Paying Physician to Provide Education Program

- It is permissible for a pharmacy to pay a physician to present an education program if the following requirements are met:
  - The program is substantive and valuable to the audience.
  - The compensation paid to the physician is the fair market value equivalent of the time and effort the physician expended to (i) prepare for the program and (ii) present the program.

Sham Education Programs: 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.

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.

Criminal Case

- "Takeaways" (cont'd):
  - If a pharmacy submits a claim to a government program that arises out of an improper arrangement with a physician, then the claim is "tainted" and becomes a false claim. Penalties under the FCA can be massive.

Preferred Provider Agreement

Preferred Provider Agreement

- The pharmacy can enter into a Preferred Provider Agreement with a Facility whereby, subject to patient choice, the Facility will recommend the pharmacy to its patients.
- The pharmacy can enter into a similar type of Preferred Provider Agreement with a hospital, physician, home health agency, wound care center, or other type of provider.

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.

Government Scrutiny and Qui Tams

Increased Scrutiny By Government Agencies

- The U.S. Department of Justice ("DOJ") and the Office of Inspector General ("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.

Qui Tam Lawsuits

Qui Tam Lawsuits

- False Claims Act
  - Civil FCA 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."

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Qui Tam Lawsuits

- 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.

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Qui Tam Lawsuits

- 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 six months, or it may take several years.
- If the civil AUSA believes that the provider's actions are particularly serious, then he/she may ask a criminal AUSA to launch a criminal investigation.

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Qui Tam Lawsuits

- In fact, most criminal health care fraud investigations arise out of qui tam lawsuits.
- Often, a provider will have to resolve two cases brought by the DOJ: a civil case … and a criminal case.
- Once the investigation is completed, then the DOJ will "unseal" the lawsuit, meaning that the defendant provider will find out about it.

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.

Qui Tam Lawsuits

- Because of the potential massive liability under the FCA, most qui tam lawsuits are settled (i.e., the provider pays a lot of money).
- 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.

Regulators Sift Through Data To Find Cases

Sifting Through Data

- Law enforcement estimates that fraud accounts for 10% of Medicare's annual spending
- This is almost $58 billion in bogus payments
- And Pharmacies Are A Big Target!

Sifting Through Data

- In addition to receiving information from relators, the DOJ/OIG uncover fraudulent activity through "data mining."
- Example: Agents look to the volume of prescriptions/sales compared to other providers and to previous years.

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Government Interviews Witnesses

Witnesses

- The government interviews patients to determine whether they received the products or services and if so, the products or services they actually received.
- Said another way, did the pharmacy properly bill for what was provided?

Witnesses

- The government interviews physicians to determine the nature of the prescriber-patient relationship.
- The government interviews company marketers to determine if free products or services were offered – these individuals can be cooperating witnesses for the Government.

Importance of Compliance Program

Introduction

- The OIG has stressed the importance of compliance programs for providers by issuing guidance on how the programs should be structured and implemented.

Introduction

- An effective compliance program sets out clear guidelines…clear "markers"… that the provider should follow. In doing so, the provider will avoid most of the pitfalls that its competitors, that do not have a compliance program, fall into.

Introduction

- A compliance officer is the "canary in the mine shaft." While the compliance officer does not have to know everything, and while the compliance officer is usually not an attorney, he/she is the one person who is focusing on compliance. The compliance officer will know enough and will have enough knowledge regarding anti-fraud laws to develop a "Pavlovian nervous twitch" when the provider starts going down a questionable road.

Introduction

- This Pavlovian response will be enough to cause the compliance officer to seek guidance from a health care attorney. Such a "canary in the mine shaft" will head off 95% of the compliance problems that may befall a provider.

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Why Implement a Compliance Program?

Why Implement a Compliance Program

- The following are reasons that providers should implement corporate compliance programs …

Ten Reasons to Implement a Compliance Program

1- Adopting a compliance program concretely demonstrates to the community at large that a provider has a strong commitment to honesty and responsible corporate citizenship.
2- Compliance programs reinforce employees' innate sense of right and wrong.
3- An effective compliance program helps a provider fulfill its legal duty to government and private payors.
4- Compliance programs are cost effective.

Ten Reasons to Implement a Compliance Program

5- A compliance program provides a more accurate view of employee and contractor behavior relating to fraud and abuse.
6- The quality of care provided to patients is enhanced by an effective compliance program.
7- A compliance program provides procedures to promptly correct misconduct .
8- An effective compliance program may mitigate any sanction imposed by the government.

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Ten Reasons to Implement a Compliance Program

9- Voluntarily implementing a compliance program is preferable to waiting for the OIG to impose a corporate integrity agreement.

10- Effective corporate compliance programs may protect corporate directors from personal liability.

Compliance Obstacles

➢Following are ten obstacles that providers may face in implementing effective compliance programs …

Ten Obstacles in Implementing a Compliance Program

1- Creating buy-in and enthusiasm
2- Changing past behavior
3- Lack of or poor communication
4- Too many roles for compliance officer
5- Not enough financial support

Ten Obstacles in Implementing a Compliance Program

6- Integrating compliance with other systems
7- Overcoming fear of retaliation/retribution
8- Finding qualified people
9- Lack of procedures
10-Education and training

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THE END

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