



EDUCATIONAL RESOURCES

PHARMACIES AND LONG-TERM CARE FACILITIES

Avoiding Kickbacks and Other Problem Arrangements

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INTRODUCTION

INTRODUCTION

- In 1965, when the Medicare law was signed, there were 23 million of the Greatest Generation.
- The Greatest Generation has pretty much left us. That generation has been replaced by 78 million Baby Boomers...who are retiring at the rate of 10,000 per day.
- Unlike earlier generations, many Boomers will live well into their 80s.

INTRODUCTION

- One of the by-products of aging Boomers is the increased demand for long term care facilities...and the increased demand for the pharmacies that serve the facilities.
- At the end of the day, a facility is a referral source for the pharmacy. If the pharmacy provides “something of value” (cash, equipment, supplies, services, etc.) to the facility, then both the pharmacy and facility run the risk of violating the federal anti-kickback statute.
- Likewise, if the pharmacy provides a gift to a facility resident, then both the pharmacy and the resident run the risk of violating the federal beneficiary inducement statute.

INTRODUCTION

- What all of this means is that pharmacy “lives in the proverbial glass house.” If the pharmacy is doing something it should not be doing, then someone knows about it. That “someone” can be an employee, a government agency or a third party payor.
- In everything it does, the pharmacy has no choice but to comply with the many federal and state anti-fraud laws.



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ANTI-FRAUD LEGAL GUIDELINES

MEDICARE ANTI-KICKBACK STATUTE (“AKS”)

- Makes it a felony to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce a person or entity to refer an individual for the furnishing or arranging for the furnishing of any item or service reimbursable by a federal health care program (e.g., Medicare, Medicare Advantage, Medicaid, TRICARE), or to induce such person to purchase or lease or recommend the purchase or lease of any item or service reimbursable by a federal health care program.

BENEFICIARY INDUCEMENT STATUTE

- 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).

ANTI-SOLICITATION STATUTE

- A DME supplier of a covered item may not contact a Medicare beneficiary by telephone regarding the furnishing of a covered item unless:
 - (i) the beneficiary has given written permission for the contact;
 - (ii) a supplier has previously provided the covered item to the beneficiary and the supplier is contacting the beneficiary regarding the covered item; or
 - (iii) if the telephone contact is regarding the furnishing of a covered item other than an item already furnished to the beneficiary, the supplier has furnished at least one covered item to the beneficiary during the preceding 15 months.

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 and DME.

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.
- Set out hereafter are five of the most important safe harbors for pharmacies.

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;
 - (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;
 - (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.

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.

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.



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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.



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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?”).

SHAM CLINICAL STUDIES

- The physician shares the information with the pharmacy. The information is rudimentary, the pharmacy does not need it, and it is the same information that the pharmacy can secure itself.
- The pharmacy pays the physician \$__ per patient per month.
- In some clinical studies physicians have been known to make about \$80,000 over a six month period.
- These “sham” studies violate the AKS.

SHAM CLINICAL STUDIES

- The pharmacy may argue that it is not paying for referrals, but is paying for legitimate services.
- 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, then 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.

SHAM CLINICAL STUDIES

- 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.



EDUCATIONAL RESOURCES

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 (i) self-funded employers that pay a membership fee for their employees, (ii) health plans, and (iii) 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).

SHAM TELEHEALTH ARRANGEMENTS

- If the payer is a federal health care program, then the arrangement will likely violate the AKS.
- If the payer is the state Medicaid program, then the arrangement will likely violate both the AKS and the state anti-kickback statute.
- If the payer is a commercial insurer, then the arrangement may violate a state statute.



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W2 EMPLOYEE VS. 1099 INDEPENDENT CONTRACTOR

W2 VS. 1099

- The OIG has repeatedly expressed concern about percentage-based compensation arrangements involving 1099 independent contractor sales agents.
- In Advisory Opinion No. 06-02, the OIG stated that “[p]ercentage compensation arrangements are inherently problematic under the Anti-Kickback Statute, because they relate to the volume or value of business generated between the parties.”

W2 VS. 1099

- A number of courts have held that marketing arrangements are illegal under the anti-kickback statute and are, therefore, unenforceable.
- In recent years, there have been a number of enforcement actions involving commission payments to independent contractors.
- Additionally, the OIG has taken the position that even when an arrangement will only focus on commercial patients and “carve out” beneficiaries of federally-funded health care programs, the arrangement will still likely violate the anti-kickback statute.



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FAILURE TO COLLECT COPAYMENT

FAILURE TO COLLECT FULL COPAYMENT

- Instead of collecting the full copayments, some pharmacies only collect a flat rate.
- By discounting upfront the copayment owed by the patient, the pharmacy is essentially waiving the remainder of the copayment.
- A waiver of copayment (whole or partial) should only be made when financial hardship is documented.

FAILURE TO COLLECT FULL COPAYMENT

- Furthermore, up-front discounting of the copayment could be viewed as a reduction of the pharmacy's actual charge for the product and will likely affect the pharmacy's usual and customary charge for the product.



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COPAYMENT ASSISTANCE PROGRAM

COPAYMENT ASSISTANCE PROGRAM

- In September 2014, the OIG issued a Special Advisory Bulletin addressing copayment coupons, and it stated that copayment coupons offered to insured patients to reduce or eliminate their out-of-pocket copayments for specific drugs constitute remuneration to induce the purchase of those drugs.
- The Bulletin, which addresses copayment coupon programs only in the context of the AKS, goes on to state that (i) copayment coupons used for drugs covered by a federal health care program implicate the AKS and (ii) coupons purposefully used to induce or reward purchases of drugs covered by a federal health care program violate the AKS.

COPAYMENT ASSISTANCE PROGRAM

- Additional guidance from the OIG makes it clear that programs to help patients, who cannot afford their cost-sharing obligations for prescription drugs, can be designed to allow parties like manufacturers or wholesalers to lawfully help patients who cannot afford their drugs. The lawful programs described by the OIG consist primarily of charitable programs that are run independently of parties that make contributions to the programs and sell products covered by the programs.
- But even charitable programs “may be subject to scrutiny if the ... funding exclusively or primarily [goes toward] the products of donors or if other facts and circumstances suggest that the ... fund is operated to induce the purchase of donors’ products.”

COPAYMENT ASSISTANCE PROGRAM

- In line with the OIG's guidance about patient assistance programs, including copayment assistance programs, there can be a kickback risk if donor contributions to a copayment assistance program are made to induce the program to recommend or arrange for the purchase of the donor's items.
- And there can be a risk if a copayment assistance program's grant of assistance to a patient is made to influence the patient to purchase certain items.
- So it is possible that an enforcement authority could argue that a wholesaler making contributions to a copayment assistance program is doing so in violation of the AKS to (i) arrange for the pharmacies participating in the program to sell more items to patients that the pharmacies will purchase from the wholesaler or (ii) influence patients receiving assistance to purchase the items covered by the program.



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SAFEGUARDS AGAINST ROUTINE WAIVERS

SAFEGUARDS AGAINST ROUTINE WAIVERS

- To avoid risks that the pharmacy may be engaging in a routine business practice of waiving copayments, the pharmacy may want to implement the following safeguards:
 - The pharmacy will implement a policy entitled “Collection of Deductibles and Copayments and Economic Hardship Waivers” (“Policy”).
 - The pharmacy should ensure the Policy reflects the pharmacy’s actual practices.

SAFEGUARDS AGAINST ROUTINE WAIVERS

- The pharmacy should require patients, who may qualify for a full or partial waiver, to complete and sign the application required under the Policy. The pharmacy should keep the signed applications on file.
- The pharmacy should request some form of documentation verifying the application (e.g., a pay stub or W-2) when possible. The pharmacy should require such documentation in the event the pharmacy has any doubts regarding the validity of information provided on the application.

SAFEGUARDS AGAINST ROUTINE WAIVERS

- The amounts of the copayment reductions should be granted on a sliding scale that is based upon the patients' resources. For example, patients with incomes at 100% of the Federal Poverty Guidelines ("FPG") may be eligible for full waivers, whereas patients with incomes between 200% and 400% of the FPG may only qualify for partial waivers. The amount of the actual waiver should depend on the particular patient's resources, and the pharmacy should attempt to collect some copayment for patients with income levels above 100% of the applicable FPG.

SAFEGUARDS AGAINST ROUTINE WAIVERS

- The patient's income level should not be the sole factor considered by the pharmacy. The pharmacy should evaluate the totality of the patient's circumstances to determine whether the copayment is truly a financial hardship for the patient. Among other items, the pharmacy should consider the amount of the copayment resources available to the individual and the individual's expenses.



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SHAM INSURANCE POLICIES TO WAIVE COPAYMENTS

SHAM INSURANCE POLICIES

- Depending on the drug, the third party reimbursement to the pharmacy may be high.
- If the copayment is 20%, then this will result in a high copayment.
- Most patients cannot afford a high copayment.
- In an attempt to “solve” the copayment problem, the pharmacy may be tempted to enter into a “sham” insurance arrangement.
- This arrangement will normally take one of two forms.

SCENARIO ONE

- In one scenario, the patient will pay a minimal “premium” (e.g., \$10) to the pharmacy. In exchange, the pharmacy represents to the patient that he/she has purchased an “insurance policy” to cover the copayment.

SCENARIO TWO

- In the second scenario, the pharmacy will pay an upfront fee to the “insurance company” (“ABC”). ABC will, in turn, issue an “insurance policy” to the pharmacy.
- The pharmacy will collect little to no copayments from its patients.
- If the pharmacy is subjected to a PBM audit and if the PBM asks to see if the pharmacy is collecting copayments from a list of named patients, then ABC will pay money to the pharmacy that constitutes the copayments the named patients should have paid.
- Even then, the amount paid by ABC is less than what the patients should have paid.

SHAM INSURANCE POLICIES

- Both of these arrangements are subterfuges—or ruses—in an attempt not to impose a large copayment obligation on the patient.
- These arrangements are “shams” on their face.

SHAM INSURANCE POLICIES

- One of the reasons these are not true insurance products is because an insurance policy must be issued by a licensed insurance company.
- To be licensed as an insurance company, the pharmacy or ABC must meet many requirements imposed on insurance companies.
- One important requirement is that the insurance company must show the state that it has a minimum level of capital reserves.



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PERMITTED VALUE-ADDED SERVICES TO FACILITY RESIDENTS

DISTINCTION

- It is permissible for a pharmacy to provide “value-added” services to Facility residents.
- However, there is a line that the pharmacy cannot cross where the “value-added” services become a prohibited inducement ... in violation of the beneficiary inducement statute.

EXAMPLES OF PERMITTED VALUE-ADDED SERVICES

- The pharmacy may physically visit the resident to determine if (i) the patient is taking the drugs as prescribed, and (ii) the drugs are helping the patient.
- The pharmacy may stay in communication with the resident via phone, email, electronic monitoring, and social media.
- The pharmacy may stay in communication with the resident's family members and caregivers.
- If as a result of the communications, the pharmacy determines that the treating physician should be aware of certain information, then the pharmacy can forward such information to the physician.



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PERMITTED GIFTS TO FACILITY RESIDENTS

PERMITTED GIFTS

- The pharmacy can provide a gift to a resident if the gift has a retail value of \$15 or less.
- The gift cannot be cash or cash equivalent such as a gift card or pre-paid credit card.
- The pharmacy can provide multiple gifts to a resident so long as the retail value of all the gifts, combined, during any given 12 month period does not exceed \$75.

EXAMPLES OF ACCEPTABLE GIFTS

- Books
- Electronic products
- Food
- Flowers
- Tickets to a movie or play
- Vitamins
- Skin care products



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IMPERMISSIBLE GIFTS

IMPERMISSIBLE GIFTS

- Cash, gift cards, pre-paid credit cards
- Individual gift that has a retail value in excess of \$15
- Multiple gifts during the course of 12 months that, combined, have a retail value in excess of \$75



EDUCATIONAL RESOURCES

PATIENT INCENTIVE ARRANGEMENT THAT PROMOTES ACCESS TO CARE

PATIENT INCENTIVE ARRANGEMENT THAT PROMOTES ACCESS TO CARE

- The federal Civil Monetary Penalties (“CMP”) prohibition forbids offering any remuneration to federal health care program patients if a pharmacy knows or should know it is likely to influence the patient’s selection of the pharmacy.
- Notwithstanding this prohibition, the Affordable Care Act makes some exceptions for things that would otherwise constitute remuneration under the CMP.

PATIENT INCENTIVE ARRANGEMENT THAT PROMOTES ACCESS TO CARE

- This includes an exception for remuneration that that (i) poses a low risk of harm and (ii) promotes access to care.”
- And more recently, the Office of Inspector General (“OIG”) has issued final regulations and an Advisory Opinion (“AO 17-01”) that both address how patient engagement and access incentives can be structured to avoid penalties under the CMP.

PATIENT INCENTIVE ARRANGEMENT THAT PROMOTES ACCESS TO CARE

- With regard to the types of activities that carry a “low risk of harm,” the OIG stated that remuneration poses a low risk of harm if it (i) is unlikely to interfere with, or skew, clinical decision making, (ii) is unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization, and (iii) does not raise patient safety or quality of care concerns.

PATIENT INCENTIVE ARRANGEMENT THAT PROMOTES ACCESS TO CARE

- The OIG expands on these factors in AO 17-01. It states that a pharmacy should look at the following to determine whether something might skew clinical decision making: (i) whether eligibility for remuneration is conditioned on receiving a service and (ii) whether remuneration to the physician encourages referrals to the pharmacy.
- As to whether something will increase costs to federal health care programs, a pharmacy should look at whether the patient incentive arrangement will shift cost to federal health care programs.

PATIENT INCENTIVE ARRANGEMENT THAT PROMOTES ACCESS TO CARE

- And in addressing the potential for overutilization, a pharmacy should look at whether (i) it is actively marketing the program to attract patients, (ii) the program is being offered before the patient decides to use the pharmacy, and (iii) the offered remuneration is encouraging patients to seek out unnecessary or poor quality of care.
- These factors help determine whether a patient incentive arrangement carries a low risk of harm.

PATIENT INCENTIVE ARRANGEMENT THAT PROMOTES ACCESS TO CARE

- When discussing activities that facilitate access to care, the OIG says that “promoting access to care” constitutes “improving a particular beneficiary’s, or a defined beneficiary population’s, ability to obtain items and services”
- This includes removing “socioeconomic, educational, geographic, mobility or other barriers that could prevent patients from seeking care . . . or following through with a treatment plan.”

PATIENT INCENTIVE ARRANGEMENT THAT PROMOTES ACCESS TO CARE

- But the OIG is careful to distinguish things that directly provide access to care from things that are not directly related. For instance, “providing free child care during appointments ... could promote access to care ... [while] offering movie tickets to a patient whenever the patient attends an appointment ... would be a reward for receiving care and does not help the patient access care”

PATIENT INCENTIVE ARRANGEMENT THAT PROMOTES ACCESS TO CARE

- Based on this, a pharmacy should remember the following: (i) do not engage in activities likely to skew clinical decisions or lead to overutilization, and (ii) it may promote access to care...not to reward access to care.



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 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.

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.

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]."



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 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.



EDUCATIONAL RESOURCES

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.



EDUCATIONAL RESOURCES

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.
- 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.



EDUCATIONAL RESOURCES

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.
- 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., \$423 in 2020) 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.
- 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 (\$423 in 2020).

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 2020 the pharmacy can safely subsidize up to \$423 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.

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.

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.
- 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.



EDUCATIONAL RESOURCES

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.



EDUCATIONAL RESOURCES

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.
 - 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.



EDUCATIONAL RESOURCES

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.



EDUCATIONAL RESOURCES

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."

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.
- 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.

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.
- 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.

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.



EDUCATIONAL RESOURCES

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!
- 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.



EDUCATIONAL RESOURCES

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?
- 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.



EDUCATIONAL RESOURCES

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.
- 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.



EDUCATIONAL RESOURCES

QUESTIONS?

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EDUCATIONAL RESOURCES

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