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PHARMACY

SCHEMES, SCAMS, AND FLIM FLAMS: HOW PHARMACIES CAN RECOGNIZE AND AVOID LANDMINES

Denise M. Leard, Esq.
Bradley W. Howard, Esq.
Brown & Fortunato

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INTRODUCTION

INTRODUCTION

- Pharmacies and other health care providers operate in a highly regulated environment. Providers must comply with (i) federal anti-fraud laws, (ii) state anti-fraud laws, (iii) Office of Inspector General ("OIG") Guidance, and (iv) guidance from Medicare, Medicaid and other third-party payors ("TPPs").
- If a provider is doing something it should not be doing, then "someone knows about it." That "someone" can be an employee, a competitor, a referral source, or a government program/contractor.

INTRODUCTION

- If a provider violates one or more of the federal anti-fraud laws, then it can (i) have potential criminal liability, (ii) potential civil liability, and (iii) be subject to having its billing privileges revoked.
- The risks are too high for the provider to be cavalier regarding compliance with anti-fraud laws. It is important that on a day-to-day basis, the provider (i) be aware of the applicable federal and state anti-fraud laws and (ii) be aware of whether it is in compliance with the laws.

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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, 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 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.
- Set out hereafter are six of the most important safe harbors for pharmacies and other providers.

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

- Continued:
  - (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 the section entitled "Paying for a Facility's EHR"

ADVISORY OPINIONS

- A 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.


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PAYING FOR A FACILITY'S EHR

PAYING FOR A FACILITY'S EHR

- Many pharmacies work with skilled nursing facilities ("SNFs") and custodial care facilities (collectively referred to as "Facilities").
- A Facility is a "referral source" to the pharmacy. Even though the Facility may give "patient choice," if the pharmacy provides a product 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

- 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 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:
  - 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.

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.
- 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.
- 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 Facility'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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MEDICAL DIRECTOR AGREEMENT

MEDICAL DIRECTOR AGREEMENT

- A provider 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 TELEHEALTH ARRANGEMENTS

SHAM TELEHEALTH ARRANGEMENTS

- Pharmacies are aggressively engaged in marketing and it is not uncommon for a pharmacy to ship products to patients residing in multiple states.
- When a provider is marketing to patients in multiple states, the provider may run into a "bottleneck."
- This involves the patient's local physician. A patient may desire to purchase a product from the out-of-state provider 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 product and so the physician refuses to sign an order.
- Or even if the physician does sign an order, he may be hesitant to send the order to an out-of-state provider.
- In order to address this challenge, some providers 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.

SHAM TELEHEALTH ARRANGEMENTS

- Where a provider 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 provider.

SHAM TELEHEALTH ARRANGEMENTS

- Here is an example: provider 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 write orders for products…the telehealth company sends the orders to the provider … 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 provider mails the product to the patient … the provider 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 provider is paying the ordering physician.
- To the extent that a provider directly or indirectly pays money to a telehealth physician, who in turn writes an order for a product that will be sold by the provider, 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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DATA MINING

INTRODUCTION

- Pharmacies are facing a "Perfect Storm" of challenges.
- These include (i) lower reimbursement; (ii) stringent documentation requirements; and (iii) aggressive audits.
- To counter these challenges, pharmacies are having to be innovative in how they market to patients and deal with third party payors. A pharmacy may desire to engage 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 product options that result in larger reimbursement.
- The pharmacy then approaches physicians and suggests that they switch their orders from the product with lower reimbursement to the product with higher reimbursement.

DESCRIPTION OF PROGRAM

- The pharmacy will educate the physicians regarding the clinical benefits of the more expensive product.
- If the physicians agree and change orders, then the pharmacy makes 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 AKS and comparable state anti-kickback statutes.

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 product. 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 products 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 products."

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 products with higher reimbursement, then such acts rise to the level of "arranging for the referral" of patients and "recommending the purchase of products." 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 a state anti-kickback statute that applies to all payors, then the preceding discussion applies.
- If a PBM notices that the dollar amount of claims submissions from a pharmacy has noticeably increased, then the PBM may be inclined to "term" the pharmacy (i.e., kick it out of the network).

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PURCHASE OF INTERNET LEADS

PURCHASE OF INTERNET LEADS

- When a provider signs a lead generation agreement ("LGA") with a lead generation company ("LGC"), the parties must be careful not to violate the AKS.
- In the eyes of the OIG, there is a distinction between (i) a "raw" or "unqualified" lead and (ii) a "qualified" lead.
- While it is normally acceptable to purchase "raw" or "unqualified" leads on a per lead basis, the AKS will likely be violated if "qualified" leads are purchased on a per lead basis.

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FAILURE TO COLLECT COPAYMENT

FAILURE TO COLLECT FULL COPAYMENT

- Instead of collecting the full copayments, some providers only collect a flat rate.
- By discounting upfront the copayment owed by the patient, the provider 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 provider's actual charge for the product and will likely affect the provider's usual and customary charge for the product.

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W-2 EMPLOYEE VS. 1099 INDEPENDENT CONTRACTOR

W-2 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."

W-2 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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UTILIZATION OF MARKETING COMPANY

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- In the real world, it is common for a business to "outsource" marketing to a marketing company.
- Unfortunately, what works in the real world often does not work in the pharmacy universe. An example of this has to do with marketing companies.
- If a marketing company generates patients for a provider, when at least some of the patients are covered by a government health care program, then the provider cannot pay commissions to the marketing company. Doing so will violate the AKS.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- The Office of Inspector General (the "OIG") has adopted safe harbors that provide immunity for arrangements that satisfy certain requirements.
- The employee safe harbor permits an employer to pay an employee in whatever manner the employer chooses in exchange for the employee assisting in the solicitation of federal health care program business, as long as there is a bona fide employer-employee relationship.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- The only way that an independent contractor can be paid for marketing or promoting Medicare-covered items or services is if the arrangement complies with, or substantially complies with, the personal services and management contracts safe harbor.
- This safe harbor permits payments to referral sources as long as a number of requirements are met.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- Two of the requirements are that (i) payments must be pursuant to a written agreement with a term of at least one year, and (ii) the aggregate compensation paid to the independent contractor must be set in advance (e.g., $24,000 over the next 12 months), be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or business generated between the parties.

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QUESTIONS?

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THANK YOU

Denise M. Leard, Esq.
Brown & Fortunato, P.C.
905 S. Fillmore St., Ste. 400
Amarillo, Texas 79101
dleard@bf-law.com | 806-345-6318

Bradley W. Howard, Esq.
Brown & Fortunato, P.C.
905 S. Fillmore St., Ste. 400
Amarillo, Texas 79101
bhoward@bf-law.com | 806-345-6310