



WHAT BUSINESS PRACTICES WILL GET YOU INVESTIGATED: HOT-BUTTON ISSUES FOR THE DEPARTMENT OF JUSTICE

Denise M. Leard, Esq., and Bradley W. Howard, Esq.

© 2018 Brown & Fortunato, P.C.





INTRODUCTION



Denise M. Leard, Esq.
Brown & Fortunato, P.C.



INTRODUCTION

- The industry is witnessing an increasing number of civil and criminal investigations brought against pharmacies by the Department of Justice ("DOJ"), Office of Inspector General ("OIG"), state Attorneys General offices, and other federal and state government agencies.
- This program will discuss key federal anti-fraud laws and will then discuss what triggers government investigations against pharmacies and their owners.



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.

ANTI-SOLICITATION 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 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 durable medical equipment (“DME”).

SAFE HARBORS

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

SAFE HARBORS

- Set out hereafter are 5 of the most important safe harbors for suppliers.

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 1 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.

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 1 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.

STATES

- Most states have enacted statutes prohibiting kickbacks, fee splitting, patient brokering, or self-referrals.
- Some statutes only apply when the payor is a government health care program.
- Other statutes apply regardless of the identity of the payor.



FAILURE TO COLLECT CO-PAY



FAILURE TO COLLECT FULL CO-PAY

- Instead of collecting the full co-pays, some suppliers only collect a flat rate.
- By discounting the copayment owed by the patient, the supplier 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 CO-PAY

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



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.
- For example, the 1996 Florida *Medical Development Network* case involved an agreement wherein a durable medical equipment supplier agreed to pay an independent contractor marketing company (the “Marketer”) a percentage of the DME supplier’s sales in exchange for marketing its products to physicians, nursing homes, and others.

W-2 VS. 1099

- When the DME supplier breached the contract, the Marketer sued; and the DME supplier defended on the ground that the agreement was illegal under the Anti-Kickback Statute.
- A Florida appeals court agreed and affirmed the trial court's ruling, holding that the agreement was illegal and unenforceable because the Marketer's receipt of a percentage of the sales it generates for the DME supplier violated the federal Anti-Kickback Statute.

W-2 VS. 1099

- 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.



GIFTS TO 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 supplier 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 supplier and the physician need to comply with the federal and state laws that govern these arrangements.

WHAT A SUPPLIER CAN SPEND ON (OR PAY TO) A PHYSICIAN

- While Stark allows a supplier to spend up to \$398 per year 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 supplier to the physician violate the Anti-Kickback Statute.

WHAT A SUPPLIER CAN SPEND ON (OR PAY TO) A PHYSICIAN

- In addition to complying with Stark and the Anti-Kickback Statute, the supplier and the physician also need to comply with applicable state law.
- Even though the supplier and the physician will need to confirm this, it is likely that compliance with the \$398 Stark exception will avoid liability under state law.
- So, the bottom line is that a supplier 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 \$398 in a 12-month period.

WHAT A SUPPLIER CAN SPEND ON (OR PAY TO) A PHYSICIAN

- For example, if a supplier wants a physician to accompany the supplier on a trip to a continuing education conference, then the supplier can safely subsidize up to \$398 of the physician's trip expenses.
- The amount of the trip subsidy will be affected by other expenditures the supplier has made on behalf of the physician within the preceding 12 months.
- Separate from furnishing gifts and entertainment and subsidizing trips, the supplier can pay the physician for legitimate services.

WHAT A SUPPLIER CAN SPEND ON (OR PAY TO) A PHYSICIAN

- For example, if the supplier has a legitimate need for a Medical Director, then the supplier and physician can enter into a Medical Director Agreement that complies with both the PSMC safe harbor to the Anti-Kickback Statute and the Personal Services exception to Stark.
- Another legitimate way for money to exchange hands between a supplier and a physician is for the physician to rent space to the supplier or vice versa.

WHAT A SUPPLIER CAN SPEND ON (OR PAY TO) A PHYSICIAN

- The rental arrangement needs to comply with the Space Rental safe harbor to the Anti-Kickback Statute.
- This safe harbor is similar to the PSMC safe harbor.

WHAT A SUPPLIER 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 1 year;
 - the rent paid must be fixed 1 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 Anti-Kickback Statute.



UTILIZATION OF A 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 supplier universe. An example of this has to do with marketing companies.
- If a marketing company generates patients for a supplier, when at least some of the patients are covered by a government health care program, then the supplier cannot pay commissions to the marketing company.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- The federal Anti-Kickback Statute makes it a felony to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce a person to refer an individual for the furnishing or arranging for the furnishing of any Medicare-covered item or service or to induce such person to purchase or lease or recommend the purchase or lease of any Medicare-covered item or service.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- 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 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 1 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.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- 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.”
- Moreover, in Advisory Opinion No. 99-3, the OIG stated:

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- “Sales agents are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals, typically manufacturers, or other sellers (collectively, “Sellers”).
- Accordingly, any compensation arrangement between a Seller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the anti-kickback statute, irrespective of the methodology used to compensate the agent.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- Moreover, because such agents are independent contractors, they are less accountable to the Seller than an employee.
- For these reasons, this Office has a longstanding concern with independent sales agency arrangements.”
- Further, in its response to comments submitted when the safe harbor regulations were originally proposed, the OIG stated:

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- “[M]any commentators suggested that we broaden the [employee safe harbor] to apply to independent contractors paid on a commission basis.
- We have declined to adopt this approach because we are aware of many examples of abusive practices by sales personnel who are paid as independent contractors and who are not under appropriate supervision.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- We believe that if individuals and entities desire to pay a salesperson on the basis of the amount of business they generate, then to be exempt from civil or criminal prosecution, they should make these salespersons employees where they can and should exert appropriate supervision for the individual's acts.”
- A number of courts have held that marketing agreements are illegal under the Anti-Kickback Statute and are, therefore, unenforceable.

UTILIZATION OF A MARKETING COMPANY: BE AWARE OF KICKBACK PROBLEMS

- 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.



INTRODUCTION



Bradley W. Howard, Esq.
Brown & Fortunato, P.C.





GOVERNMENT SCRUTINY AND QUI TAMS



INCREASED SCRUTINY BY GOVERNMENT AGENCIES

- The U.S. Department of Justice and the Office of Inspector General are becoming much more aggressive in bringing civil and criminal investigations against pharmacies and their owners.



-



QUI TAM LAWSUITS



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 supplier commits an act that violates any law (civil or criminal), and if the supplier 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 supplier (and its individual owners) 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 6 months, or it may take several years.
- If the civil AUSA believes that the pharmacy'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 pharmacy 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 pharmacy will find out about it.
- 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.”

QUI TAM LAWSUITS

- If the DOJ does not “intervene” (i.e., take the lawsuit over), then the relator’s attorney can proceed without the DOJ’s assistance.
- Because of the potential massive liability under the FCA, most qui tam lawsuits are settled (i.e., the supplier pays a lot of money).



GOVERNMENT INTERVIEWS WITNESSES



INTERVIEW OF PATIENTS

- Agents will call or personally visit patients to determine (i) if they received the product for which the government was billed and (ii) if they really wanted the product (or if the process was “pharmacy driven”).
- Agents often intimidate elderly or less educated patients. The patients will often say whatever the agents “lead them on to say.”



INTERVIEW OF CURRENT AND EX-EMPLOYEES

- Agents will call or personally visit current and ex-employees.
- As with patients, agents will intimidate the current/ex-employees. The current/ex-employees, out of fear that “they may have done something wrong,” will be inclined to say whatever the agents “lead them on to say.”



RECENT CASES DEMONSTRATING THE GOVERNMENT'S INTEREST IN PHARMACIES

RECENT CASES

Orlando, Florida, area pharmacy use shows danger of close relationships with physicians.



RECENT CASES

Florida case demonstrates danger of improper billing practices.



RECENT CASES

Recent case proves that the government will bring claims against pharmacies, investors, and individuals.



RECENT CASES

Recent Mississippi case proves pharmacies need to be careful about the physicians they do business with.



RECENT CASES

Philadelphia case outlines concerns when billing Medicare for prescription drugs.



RECENT CASES

Four area pharmacists, one doctor, and one patient recruiter charged.



Recruiter

TIP

Do not run afoul of pharmacy benefit managers (PBMs) that can refer cases to the government.



TIP

Take PBM audits very seriously.



TIP

Be careful how you treat potential whistleblowers, e.g.: ex-employees and business associates.



shutterstock.com - 591068855

TIP

Treat subpoenas and government contact as very serious matters.





QUESTIONS?





THANK YOU

Denise M. Leard, Esq.
dleard@bf-law.com
806-345-6318

Bradley W. Howard, Esq.
bhoward@bf-law.com
806-345-6310

Brown & Fortunato, P.C.
905 S. Fillmore St., Ste. 400
Amarillo, Texas 79101



2CV7995
