



EDUCATIONAL RESOURCES

BUILDING A LEGALLY COMPLIANT REFERRAL NETWORK

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LEGAL GUIDELINES

MEDICARE ANTI-KICKBACK STATUTE

- It is a felony for a health care provider to knowingly and willfully offer or pay any remuneration to induce a person/entity to refer an individual for the furnishing or arranging for the furnishing of any item for which payment may be made under a federal health care program, or the purchase or lease or the recommendation of the purchase or lease of any item for which payment may be made under a federal health care program.

BENEFICIARY INDUCEMENT STATUTE

- This statute prohibits a provider from offering or giving anything of value to a Medicare beneficiary that the provider knows, or should know, is likely to persuade the person to purchase an item covered by a federal health care program.
- In the preamble to the regulations implementing this statute, the OIG stated that the inducement statute does not prohibit the giving of incentives that are of “nominal value.”
- The OIG defines “nominal value” as no more than \$15 per item or \$75 in the aggregate to any one beneficiary on an annual basis.
- “Nominal value” is based on the retail purchase price of the item.

STARK PHYSICIAN SELF-REFERRAL STATUTE

- This statute provides that if a physician has a financial relationship with an entity providing “designated health services,” then the physician may not refer Medicare/Medicaid patients to the entity unless a Stark exception applies.
- Designated health services include DME; parenteral and enteral nutrients; prosthetics, orthotics and prosthetic devices and supplies; out-patient prescription drugs; and rehab therapy services.
- One of the exceptions to Stark provides that a health care provider may provide non-cash equivalent items to a physician if such items do not exceed an annual amount established by CMS. For 2019, such amount is \$416.



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SAFE HARBORS

SAFE HARBORS

- Because of the breadth of the Medicare anti-kickback statute (“AKS”), the OIG has published a number of “safe harbors.”
- A safe harbor is a hypothetical fact situation such that if an arrangement falls within it, then the AKS is not violated.
- If an arrangement does not fall within a safe harbor, then it does not mean that the arrangement violates the AKS. Rather it means that the arrangement needs to be carefully scrutinized under the language of the AKS, applicable case law, and other published guidance.
- Five of the safe harbors are particularly relevant to DME suppliers.

SAFE HARBORS – 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.

SAFE HARBORS – 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.

SAFE HARBOR – 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;
 - (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.

SAFE HARBORS – 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.



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ADVISORY OPINIONS

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- 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.



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FRAUD ALERTS & BULLETINS

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.



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STATES

STATES

- All states have enacted statutes prohibiting kickbacks, fee splitting, patient brokering, or self-referrals.
- Some state anti-fraud statutes only apply when the payer is a government health care program.
- Other state anti-fraud statutes that apply regardless of the identity of the payer.
- All states have a set of statutes and regulations that are specific to pharmacies.



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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.”
- 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.
- In recent years, there have been a number of enforcement actions involving commission payments to independent contractors.



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EXPENDITURES FOR PHYSICIANS

INTRODUCTION

- A physician is a referral source to the DME supplier.
- 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 DME 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 DME supplier and the physician need to comply with the federal and state laws that govern these arrangements.

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

- While the Stark non-monetary compensation exception allows a DME supplier to spend up to a set amount per year (e.g., \$416 in 2019) 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 DME supplier to the physician violate the AKS.
- In addition to complying with Stark and the AKS, the DME supplier and the physician also need to comply with applicable state law.

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

- Even though the DME supplier 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 DME 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 the annual amount set by CMS (\$416 in 2019).
- For example, if a DME supplier wants a physician to accompany the DME supplier on a trip to a continuing education conference, in 2019 the pharmacy can safely subsidize up to \$416 of the physician's trip expenses.

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

- The amount of the trip subsidy will be affected by other expenditures the DME supplier has made on behalf of the physician during the year.
- 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 DME SUPPLIER CAN SPEND ON (OR PAY TO) A PHYSICIAN

- Separate from furnishing gifts and entertainment, and subsidizing trips, the DME supplier can pay the physician for legitimate services.
- For example, if the DME supplier has a legitimate need for a Medical Director, then the DME supplier 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.
- Another legitimate way for money to exchange hands between a DME supplier and a physician is for the physician to rent space to the DME supplier or vice versa.

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

- 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.
- 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.



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PAYING PHYSICIAN TO PROVIDE EDUCATION PROGRAM

PAYING PHYSICIAN TO PROVIDE EDUCATION PROGRAM

- It is permissible for a DME supplier 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



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COLLABORATION WITH HOSPITAL TO PREVENT READMISSIONS

COLLABORATION WITH HOSPITAL TO PREVENT READMISSIONS

- Hospital Readmissions Reduction Program: if a patient is readmitted after discharge within a certain period of time, for a particular disease, then the hospital can be subjected to future payment reductions for Medicare.
- Hospital can contract with a DME supplier to monitor/work with discharged patients so that they are not readmitted soon after being discharged.



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LOAN/CONSIGNMENT CLOSETS

LOAN/CONSIGNMENT CLOSETS

- A DME supplier may place inventory in a hospital or physician office. The inventory must be for the convenience only of the hospital's/physician's patients and the hospital/physician cannot financially benefit, directly or indirectly, from the inventory.
- If a DME supplier pays rent for a space in which the consigned inventory is placed, then the arrangement should comply with the Space Rental safe harbor.



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PREFERRED PROVIDER AGREEMENT

PREFERRED PROVIDER AGREEMENT

- The DME supplier can enter into a Preferred Provider Agreement with a hospital whereby, subject to patient choice, the hospital will recommend the DME supplier to its patients who are about to be discharged.
- The DME supplier can enter into a similar type of Preferred Provider Agreement with a physician, home health agency, long term care facility, wound care center, or other type of provider.



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EMPLOYEE LIAISON

EMPLOYEE LIAISON

- A DME supplier 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 DME supplier 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.



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MEDICAL DIRECTOR AGREEMENT

MEDICAL DIRECTOR AGREEMENT

- A DME supplier 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 to the AKS and
 - (ii) the Personal Services exception to the Stark physician self-referral statute.
- 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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RENTING SPACE TO/FROM A PHYSICIAN OR OTHER REFERRAL SOURCE

RENTING SPACE

- A DME supplier can rent space to/from a physician so long as the rental agreement complies with the:
 - (i) Space Rental safe harbor to the AKS and
 - (ii) space rental exception to Stark.
- Among other requirements:
 - The rental agreement must be in writing and have a term of at least one year.
 - The rent must be fixed one year in advance and be fair market value.
- A DME supplier can rent space to/from a non-physician referral source so long as the rental agreement complies with the Space Rental safe harbor to the AKS. See the preceding sub-bullets.



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SUMMARY: DOS & DON'TS OF SETTING UP REFERRAL NETWORK

“DOS” OF SETTING UP REFERRAL NETWORK

- Use of Employees - The DME supplier can pay commissions to full-time or part-time bona fide employees.
- Use of Independent Contractors - The DME supplier can compensate 1099 independent contractors for marketing to government program patients so long as the arrangement complies with the Personal Services and Management Contracts Safe Harbor to the AKS.
- Expenditures for Physicians - The DME supplier can spend up to a certain amount per year (\$416 in 2019) on a physician for non-cash/non-cash equivalent items such as meals and golf.

“DOS” OF SETTING UP REFERRAL NETWORK

- Expenditures for Physicians' Staffs, Hospital Discharge Planners, and Other Referral Sources - It is permissible for the DME supplier to provide non-cash/non-cash equivalent items to non-physicians so long as the amount spent is modest. For example, while it is permissible for the DME supplier to sponsor lunch (with an in-service) for the physician's staff twice a year, it is not permissible for the DME supplier to sponsor lunch every month. In determining whether an arrangement amounts to a kickback, the "duck" test applies: "If it looks like a duck, walks like a duck, and sounds like a duck, then it is a duck."
- Medical Director Agreement - It is permissible for a DME supplier to enter into a 1099 independent contractor Medical Director Agreement ("MDA") with a referring physician so long as the MDA complies with the Personal Services and Management Contracts Safe Harbor to the AKS and the personal services exception to Stark. The safe harbor and exception essentially say the same thing.

“DOS” OF SETTING UP REFERRAL NETWORK

- Employee Liaison - The DME supplier can place an employee liaison at a facility so long as the liaison does not perform services that the facility would normally have to perform.
- Waiver of Copayments - A DME supplier must make a reasonable attempt to collect copayments. The DME supplier can waive a patient's copayment only if the patient's financial condition justifies the waiver.

"DON'TS" OF SETTING UP REFERRAL NETWORK

- Use of Independent Contractors - If a 1099 independent contractor is generating government program patients for the DME supplier, then the DME supplier cannot pay percentage compensation to the independent contractor. Rather, the compensation must comply with the Personal Services and Management Contracts Safe Harbor to the AKS. The DME supplier and independent contractor cannot engage in a "carve out" arrangement in which the DME supplier pays (i) the independent contractor percentage compensation for commercial insurance patients and (ii) nothing for government program patients.
- Expenditures for Physicians - The DME supplier cannot give cash or cash equivalents (e.g., gift cards) to physicians. The DME supplier cannot give non-cash/non-cash equivalent gifts to physicians that exceed \$416 in 2019.

“DON'TS” OF SETTING UP REFERRAL NETWORK

- Expenditures for Non-Physician Referral Sources - The DME supplier should not spend more than a modest amount on non-cash/non-cash equivalent items (e.g., meals with an in-service) on physicians' staffs, hospital discharge planners, and other referral sources.
- Medical Director Agreements - The compensation paid by the DME supplier to a Medical Director cannot vary based on the number of referrals from the Medical Director to the DME supplier. The services by the Medical Director must be important and substantive, not “made up.”

"DON'TS" OF SETTING UP REFERRAL NETWORK

- Sham Clinical Studies - In a "sham" clinical study, a clinical study company ("CSC") brings referring physicians and DME suppliers together. The physicians write orders that go to the DME suppliers. The DME suppliers pay the CSC "X" dollars per patient per month. The CSC retains part of the payments as administrative fees and remits the balance to the physicians. The physicians gather (mostly unnecessary) information from the patients regarding the effectiveness of the DME supplier's products and services, the physicians transmit the information to the CSC, and the CSC transmits the information to the DME suppliers. These clinical studies are not associated with hospitals, medical schools, or Institutional Review Boards ("IRBs"). These types of studies are subterfuges designed to funnel money from the DME suppliers to the referring physicians.



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QUESTIONS?

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THANK YOU

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