



EDUCATIONAL RESOURCES

HOW TO PROVIDE VALUE-ADDED SERVICES TO CUSTOMERS WHILE AVOIDING KICKBACKS & INDUCEMENTS

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INTRODUCTION



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LEGAL GUIDELINES

BENEFICIARY INDUCEMENT STATUTE

- This statute prohibits a durable medical equipment supplier (“DME”) from offering or giving anything of value to a Medicare beneficiary that the DME knows, or should know, is likely to persuade the person to purchase a Medicare-covered item.
- 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 \$10 per item or \$50 in the aggregate to any one beneficiary on an annual basis.
- “Nominal value” is based on the retail purchase price of the item.

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.

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; and out-patient prescription drugs.
- 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 approximately \$392 in value during a 12-month period.



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SAFE HARBORS

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- 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 DMEs.

SAFE HARBOR – 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 HARBOR - 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;

SAFE HARBOR - 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.

SAFE HARBOR - 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 statutes only apply when the payer is a government health care program.
- Other statutes that apply regardless of the identity of the payer.



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COLLABORATION WITH HOSPITALS 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 to monitor/work with discharged patients so that they are not readmitted soon after being discharged.
- The parties need to follow the guidelines set out in the OIG's Advisory Opinion No. 13-10. Among other requirements, the hospital needs to pay fair market value compensation for the DME's services.



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LOAN/CONSIGNMENT CLOSETS

LOAN/CONSIGNMENT CLOSETS

- Assume that the DME provides DME. A DME 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 can enter into a Preferred Provider Agreement with a hospital whereby, subject to patient choice, the hospital will recommend the DME to its patients who are about to be discharged.



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EMPLOYEE LIAISON

EMPLOYEE LIAISON

- A DME 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 medical equipment (to be used in the home) and related services.
- 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 Medicare anti-kickback statute.



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MEDICAL DIRECTOR AGREEMENT

MEDICAL DIRECTOR AGREEMENT

- A DME 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.
- 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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FAILURE TO COLLECT FULL CO-PAYMENT

FAILURE TO COLLECT FULL COPAYMENT

- Instead of collecting the full copayment, some DMEs only collect a flat rate.
- By discounting the copayment owed by the patient, the DME is essentially waiving the remainder of the copayment.
- A waiver of copayment (whole or partial) should only be made when financial hardship is documented.
- Furthermore, up-front discounting of the copayment will likely be viewed as a reduction of the DME's actual charge for the items and services. This will likely affect the DME's usual and customary charge for the items and services.
- The DME needs to avoid entering into a "sham" copayment subsidy arrangement.
- Such an arrangement can take many forms. However, the end result is that the patient ends up paying none of the copayment, or only a small portion of the copayment.



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EXPENDITURES FOR PHYSICIANS

BACKGROUND

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

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

- While Stark allows a DME to spend up to \$392 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 DME to the physician violate the anti-kickback statute.
- In addition to complying with Stark and the anti-kickback statute, the DME and the physician also need to comply with applicable state law.
- Even though the DME and the physician will need to confirm this, it is likely that compliance with the \$392 Stark exception will avoid liability under state law.

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

- And so, the bottom line is that a DME 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 \$392 in a 12-month period.
- For example, if a DME supplier wants a physician to accompany the supplier on a trip to a continuing education conference, then the supplier can safely subsidize up to \$392 of the physician's trip expenses.
- The amount of the trip subsidy will be affected by other expenditures the DME has made on behalf of the physician within the preceding 12 months.

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

- While the Stark \$392 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 Medicare anti-kickback statute.
- Separate from furnishing gifts and entertainment, and subsidizing trips, the DME can pay the physician for legitimate services.

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

- For example, if the DME has a legitimate need for a Medical Director, then the DME and physician can enter into a Medical Director Agreement that complies with both the PSMC safe harbor to the Medicare anti-kickback statute and the Personal Services exception to Stark.
- Another legitimate way for money to exchange hands between a DME and a physician is for the physician to rent space to the DME or vice versa.
- The rental arrangement needs to comply with the Space Rental safe harbor to the Medicare anti-kickback statute.
- This safe harbor is similar to the PSMC safe harbor.

WHAT A DME 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 anti-kickback statute.



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SHAM TELEHEALTH ARRANGEMENTS

SHAM TELEHEALTH ARRANGEMENTS

- DMEs are aggressively engaged in marketing and it is not uncommon for a DME to dispense equipment and supplies to patients residing in multiple states.
- When a DME is marketing to patients in multiple states, the DME 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 DME but it is too inconvenient for the patient to drive to his physician’s office.
- 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 an order, he may be hesitant to send the order to an out-of-state DME.

SHAM TELEHEALTH ARRANGEMENTS

- In order to address this challenge, we are witnessing some DMEs enter into arrangements that will get them into trouble.
- This has to do with “telehealth” companies.
- 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 DME 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 DME.

SHAM TELEHEALTH ARRANGEMENTS

- Here is an example:
 - *DME 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 sign prescriptions for drugs...the telehealth company sends the prescriptions to the DME... 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 DME mails the drug to the patient... the DME bills (and gets paid by) Medicare.*

SHAM TELEHEALTH ARRANGEMENTS

- There can be a number of permutations to this example, but you get the picture.
- Stripping everything away, the DME is paying the ordering physician.
- To the extent that a DME directly or indirectly pays money to a telehealth company, which in turn writes a prescription for drugs that will be dispensed by the DME, the arrangement will likely be viewed as remuneration for a referral (or remuneration for “arranging for” a referral).
- If the payer is a federal health care program, then the arrangement will likely violate the AKS.

SHAM TELEHEALTH ARRANGEMENTS

- 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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CHARITABLE CONTRIBUTIONS

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- The OIG takes the position that charitable donations to not-for-profit entities are essential to “sustaining and strengthening the health care safety net.”
- The OIG believes that most donors, even those with business relationships with donation recipients, are generally motivated by bona fide charitable purposes and desire to help their communities.
- The fact that a business relationship exists between a donor and recipient does not make the donation automatically suspect.
- However, where the two entities are in a position to refer to each other, the arrangement does warrant additional scrutiny.
- Notably, the OIG opinions do not appear to differentiate between not-for-profit (“NFP”) organizations and tax-exempt organizations.

CHARITABLE CONTRIBUTIONS

- The OIG appears to use the same standards for both organizations (see e.g., Advisory Opinion No. 00-11 vs. No. 10-17).
- However if an entity has a tax-exempt status, the OIG makes a point to note such status.
- The OIG has issued several advisory opinions related to the provision of charitable donations from one organization to another where either or both organizations are in a position to refer to the other.

CHARITABLE CONTRIBUTIONS

- These opinions have generally been favorable to the requesting entities where donations to charitable/not-for-profit entities (1) are for a bona fide charitable purpose; (2) are made in a manner that do not take into account the value or volume of referrals; and (3) incorporate other safeguards to ensure that donations are not tied to referrals or other business generated between the organizations.
- Notwithstanding the above, in Advisory Opinion No. 08-02 the OIG provides examples of potentially problematic contributions, including:
 - Contributions to private foundations or other charitable organizations directed or controlled by referral sources; and
 - Contributions determined in any manner that take into account past or expected orders or purchases of items or services payable by any federal health care program.



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QUESTIONS?

Email us at auweb@achcu.com



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THANK YOU

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