

Health Law

Durable Medical Equipment

Physician Arrangements

Navigating the Minefield of Arrangements between DMEPOS Suppliers and Physicians



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Physician referrals are the lifeblood of suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). In recent years, common relationships between DMEPOS suppliers and physicians have come under regulatory attack, and ethical suppliers often face pressures to match arrangements offered by more aggressive competitors. Inconsistent guidance from enforcement agencies has led to conflicting rumors and advice within the industry. “But everyone else is doing it” is not a valid defense. There are still a variety of ways suppliers can work with referring physicians that reduce both parties’ exposure to liability.

The Legal Minefield

The most lethal landmines planted by Congress are the federal [physician self-referral prohibition](#) (Stark Law) and the federal [Anti-Kickback Law](#). Additionally, the [False Claims Act](#) allows whistleblower plaintiffs (“relators”) to bring suits on behalf of the government, and successful whistleblowers can receive between 15 percent and 30 percent of the monetary proceeds of the action or settlement recovered by the government.

The Stark Law prohibits a physician from making referrals for certain “designated health services” (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity or third-party payer) for those referred services. Designated health services are clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging, computerized axial tomography scans and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

The Anti-Kickback Law provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce business reimbursable under federal or state health care programs. The offense is classified as a felony and is punishable by fines of up to \$25,000 and imprisonment for up to five years. Violations of the Anti-Kickback Law may also result in the imposition of a civil money penalty or program exclusion under section 1128 of the Act. Section 6402(f) of the [Patient Protection and Affordable Care Act](#) (codified at [42 U.S.C. § 1320a-7b\(g\)](#)) clarified that violations of the Anti-Kickback Law are automatic violations of the False Claims Act and modifies the intent required to establish a violation.

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The Office of Inspector General (OIG) has issued compliance guidance documents focusing on various sectors of the health industry including DMEPOS suppliers.¹ This guidance describes a number of compliance problems that frequently arise in the DMEPOS field, including improper relationships with referring physicians.

Stock-and-Bill Arrangements/Compliance Closets

One of the most common arrangements between suppliers and physicians is for the supplier to lease storage space in a physician's office to store inventory of DMEPOS items and dispense those items from the physician's office. This is referred to as a "stock-and-bill" or "consignment closet" arrangement. The amount of rent that can legally be paid for a closet or storeroom in a physician's office is typically modest. Nevertheless, physicians often find these arrangements to be desirable, both for the convenience factor, which affords their patients one-stop shopping, as well as the small financial reward. These arrangements have never been popular with regulators, and disparaging descriptions of them abound in the official literature. For instance, in the DMEPOS Supplier Compliance Guidance, the OIG lists among its risk factors:

Co-location of DMEPOS items and supplies with the referral source; in this situation, a physician allows a DMEPOS supplier to stock inventory (the storage space may or may not be rented by the DMEPOS supplier) in a physician's office. When such items and supplies are dispensed to the patient, Medicare is then billed. Although such arrangements are not prohibited per se, the OIG believes that such arrangements may potentially raise anti-kickback and self-referral issues, particularly when the DMEPOS supplier pays the physician an amount above fair market value to rent the space.²

In February 2000, the OIG issued a Special Fraud Alert on "Rental Of Space In Physician Offices By Persons Or Entities To Which Physicians Refer."³ This bulletin addressed a number of questionable rental arrangements for space in physician offices:

A number of suppliers that provide health care items or services rent space in the offices of physicians or other practitioners. Typically, most of the items or services provided in the rented space are for patients, referred or sent, either directly or indirectly, to the supplier by the physician-landlord.

In particular, we are aware of rental arrangements between physician-landlords and . . . suppliers of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) that set up "consignment closets" for their supplies in physicians' offices.

The OIG is concerned that in such arrangements, the rental payments may be disguised kickbacks to the physician-landlords to induce referrals. We have received numerous credible reports that in many cases, suppliers, whose businesses depend on physicians' referrals, offer and pay

"rents" either voluntarily or in response to physicians' requests that are either unnecessary or in excess of the fair market value for the space to access the physicians' potential referrals.

Payments of "rent" for space that traditionally has been provided for free or for a nominal charge as an accommodation between the parties for the benefit of the physicians' patients, such as consignment closets for DMEPOS, may be disguised kickbacks. In general, payments for rent of consignment closets in physicians' offices are suspect.

Both the Stark Law exception and the Anti-Kickback Law safe harbor exception for space leases require the amount paid be consistent with fair market value. Despite the harsh language used by the OIG in this Bulletin, the OIG has cited no authority to suggest the fair market value of storage space is zero. All the same, suppliers and physicians should scrupulously document the evidence of fair market value for such payments. Such evidence should include the method of proration of the physician's rent as well as an independent appraisal of the rental value per square foot of comparable office space. The OIG Bulletin sets forth a formula for prorating space in physicians' offices, and I recommend to my clients that their leases track this formula as closely as possible.

The suppliers' payments to the physicians are only one element of a stock-and-bill arrangement. For the deal to work, the supplier needs to be able to bill Medicare for DMEPOS items dispensed out of the leased space. The Centers for Medicare and Medicaid Services (CMS) muddied the waters in 2009 by issuing, delaying, then ultimately retracting a new Medicare Program Integrity Manual provision that restricted the use of consignment closets or stock-and-bill arrangements in physician offices by suppliers. The transmittal prohibited stock-and-bill arrangements where an enrolled DMEPOS supplier maintains inventory at a practice location that is owned for the purpose of distribution by a physician, non-physician practitioner, or other health care professional rather than the enrolled DMEPOS supplier. This transmittal would have forced the supplier to sell its products to the physician and require the physician to meet the strict new supplier standards in order to bill Medicare. Heavy lobbying by the DMEPOS industry educated CMS about the prevalence of this type of arrangement and the disruption that its ban would create, resulting in a decision to rescind the rule for now.⁴ At this time, there is no indication as to whether any new version of the transmittal will be issued.

In 2010, CMS finalized a proposed final rule setting forth standards for DMEPOS suppliers, which included a prohibition on "sharing practice locations" with other enrolled providers and included requirements for minimum space and hours of operation. Initially, many suppliers thought this rule may have been targeted at compliance closets, but informally CMS has indicated to a number of industry representatives that it is only to be applied to a DMEPOS supplier's location as set forth on its enrollment application. This would mean a supplier that

maintains a retail office where patients and regulators can visit during defined business hours would need to meet the standards at that location, but not at physician offices where inventory is maintained and dispensed. Reportedly, the target for this rule was DMEPOS manufacturers that do not maintain compliant physical locations and seek to enroll their physician office-based sites.

Physician Billing for DMEPOS

When can a physician practice bill for DMEPOS products? The Stark Law draws a distinction between most DME and POS items. Although prosthetics, orthotics and related supplies are designated health services under Stark, they are eligible for the “in-office ancillary services” exception allowing them to be supplied by physician practices under certain circumstances. There is a narrow exception for certain DME provided in a physician’s office, but it is limited to ambulatory aids such as canes, walkers and non-motorized wheelchairs. In the case of all DME and POS items, the Stark Law only applies if a physician makes a “referral” as defined in the law, and there is no referral where a physician personally performs or provides a service. So, can a physician bill Medicare directly for DMEPOS he or she dispenses? Not so fast CMS says personal means personal.

There are few, if any, situations in which a referring physician would personally furnish DME and supplies to a patient, because doing so would require that the physician himself or herself be enrolled in Medicare as a DME supplier and personally perform all of the duties of a supplier as set forth in the supplier standards in § 424.57(c).

DME suppliers are entities that provide services under the specific Part B benefit for the provision of medical equipment and supplies for use in the patient’s home. These entities must be enrolled with the appropriate Medicare contractor as a DME supplier and must meet all of the professional supplier standards and quality standards that we require through regulations and administrative or program instructions. The enrollment requirements and professional supplier standards are not waived in those situations in which a physician furnishes DME directly to the patient. The services to be personally performed by the physician would include, but not be limited to, the following, as appropriate—

- Personally fit the item for the beneficiary;
- Provide necessary information and instructions concerning use of the DME;
- Advise the beneficiary that he or she may either rent or purchase inexpensive or routinely purchased DME;
- Explain the purchase option for capped rental DME;
- Explain all warranties;
- (Usually) deliver the DME to the beneficiary at home; and
- Explain to the beneficiary at the time of delivery how to contact the physician in his or her capacity as a DME supplier by telephone.

A referring physician claiming to provide DME personally would need to maintain adequate documentation to establish that the physician personally performed these and other required DME supplier activities. All of these supplier requirements would need to be satisfied in order for a physician to be considered to be providing personally DME items and supplies.⁵

CMS has intentionally set the bar high for meeting the standards of a DME supplier, but it is not impossible. It requires the physician submit an application to be enrolled as a DME supplier and obtain a DME supplier number and requires that many activities ordinarily be delegated to technologists or staff be personally performed by the physician him or herself and be documented as such. As CMS considers it “unlikely” that a physician could meet those standards, a physician would need to be particularly diligent and thorough in documenting the personal performance of each task.

Personal Service Arrangements

What other arrangements between suppliers and physicians are permissible? It is possible for a supplier to pay a physician or a physician practice for defined services including medical directorships, certain patient education or fitting services, billing, consulting or other administrative services. Both the Stark Law exceptions and the Anti-Kickback Law safe harbors impose strict requirements on such arrangements, and “sham” service contracts are among the highest enforcement priorities.

The Stark Law requires all personal service arrangements to meet the following criteria, in order to satisfy the exception:

1. The arrangement is in writing and specifies the services covered by the arrangement.
2. The arrangement covers all of the services to be furnished by the physician to the entity.
3. The term of the arrangement must be for at least one year.
4. The aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement.
5. The compensation paid must be set in advance and be of a fair market value for the services provided and is not conditioned upon the volume or value of any referrals or other business generated between the parties.
6. The services do not involve the counseling or promotion of a business arrangement or other activity that violates any federal or state law

The Anti-Kickback Law safe harbor includes similar requirements and also states that if the agreement is intended to provide for services on a periodic, sporadic or part-time basis, the agreement must specify the schedule of such interval, the precise length and the exact charge for such intervals over the term of the agreement.

Gifts, Meals, Etc.

What about sending your loyal physicians a holiday gift, buying them a fancy dinner or providing some other token of appreciation? Although there are certain thresholds under the Stark Law for hospitals providing incidental benefits to their medical staffs, there are no similar exceptions for DMEPOS suppliers. Similarly, there is no “de minimis” threshold under the Anti-Kickback Law safe harbor for such items. Suppliers should nonetheless proceed with caution when considering gifts to referring physicians.

Trade associations such as the Advanced Medical Technology Association (AdvaMed) and the Pharmaceutical Research and Manufacturers of America (PhRMA) have adopted their own ethical codes governing interaction with health care professionals.⁶ AdvaMed’s code limits its members to providing meals only incidental to the *bona fide* presentation of scientific, educational or business information and provided in a manner conducive to the presentation of such information. The meal should not be part of an entertainment or recreational event. With regard to gifts, the code states:

Other than medical textbooks or anatomical models used for educational purposes, any such item should have a fair market value of less than \$100. A Company may not provide items that are capable of use by the Health Care Professional (or his or her family members, office staff or friends) for noneducational or non-patient-related purposes, for example, a DVD player or MP3 player/iPod.

These industry codes, while not officially endorsed, create a minimum compliance level that suppliers will be expected to honor or explain why their circumstances differ.

Get Guidance First

Ultimately, DMEPOS suppliers need to recognize they operate in a heightened risk environment. Reimbursements are shrinking for suppliers and referring physicians alike, which has driven some players to take ill-advised risks to preserve or grow their market share. Referring physicians may be approached with offers that are too good to be true, and an ethical supplier will help educate physicians about the risks they take by accepting such sweetheart deals. Both parties to an arrangement that violates the Stark Law or the Anti-Kickback Law face staggering potential penalties, and legal fees to challenge a defensible arrangement can quickly exceed any benefit the arrangement provided. Only with the input and guidance of experienced health care counsel can a supplier minimize its risk exposure while meeting today’s competitive pressures.

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¹ <http://oig.hhs.gov/authorities/docs/frdme.pdf>.

² Publication of OIG Compliance Program Guidance for the Durable Medical

Equipment, Prosthetics, Orthotics and Supply Industry, 64 Fed. Reg. 36368, 36374 (July 6, 1999).

³ <http://oig.hhs.gov/fraud/docs/alertsandbulletins/office%20space.htm>.

⁴ <http://www.cms.gov/transmittals/downloads/R300PI.pdf>.

⁵ *Medicare Program; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)*, 72 Fed. Reg. 51012, 51019 (Sept. 5, 2007).

⁶ <http://www.advamed.org/NR/rdonlyres/61D30455-F7E9-4081-B219-12D6CE347585/0/AdvaMedCodeofEthicsRevisedandRestatedEffective20090701.pdf>; http://www.phrma.org/sites/default/files/108/phrma_marketing_code_2008.pdf.