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Hospital - DMEPOS supplier arrangements and the Anti-kickback Statute

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This article is the fifth in a series on DMEPOS compliance issues by Foley & Lardner LLP published in **Compliance Today**.
In the September 2011 issue of **Compliance Today**, *the authors discussed the HIPAA implications for DMEPOS supplier marketing arrangements and provided a sample marketing authorization form as a supplier tool. This month, the authors discuss hospital-DMEPOS supplier arrangements under the Anti-kickback Statute.*

Subsequent articles will discuss strategies for DMEPOS promotions and arrangements with manufacturers and DMEPOS reimbursement compliance.

Most owners and operators by now recognize that durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers are a frequent target of government enforcement actions. One segment of the DMEPOS industry—the provision of DMEPOS items to hospital patients—has also received the attention of federal regulators. Indeed, the US Department of Health and Human Services (DHHS) Office of Inspector General (OIG) considers arrangements under which DMEPOS suppliers have opportunities to access hospital patients as susceptible to problematic marketing schemes.[1] Given the increasing level of government interest in DMEPOS compliance, DMEPOS suppliers and hospitals should take care to structure their arrangements in a manner to comply with these fraud and abuse laws.

DMEPOS suppliers use a variety of structures to collaborate with hospitals to deliver items to hospital patients. This article provides an overview of three models used by DMEPOS suppliers and hospitals, along with the compliance concerns for the parties attendant to those arrangements. The models are:

- DMEPOS suppliers operating as hospital affiliates;
- Independent DMEPOS suppliers that provide items to hospitals for inpatient use; and
- Independent DMEPOS suppliers that provide items to patients through convenience or consignment closets at hospitals.

By understanding how to implement these models in accordance with existing laws, DMEPOS suppliers and hospitals can explore new opportunities to deliver quality care to patients.

Overview of applicable laws

The primary federal fraud and abuse laws implicated by these arrangements include the Anti-kickback Statute (AKS) and the Civil Monetary Penalties Law (CMPL). Of course, DMEPOS suppliers and hospitals must comply with other applicable federal and state health care laws and regulations as well.

The AKS prohibits any person from knowingly and willfully

paying, offering, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce the referral of any item or service covered by a federal health care program, or in exchange for arranging for or recommending purchasing, leasing, or ordering any good, facility, service or item covered by a federal health care program, including Medicare and Medicaid.[2] A violation is punishable by a $25,000 fine or imprisonment, may subject a violator to civil monetary penalties, and is grounds for exclusion from participation in the Medicare and Medicaid programs. There are various statutory and regulatory exceptions and safe harbors to the AKS available to protect certain arrangements. Violations of the AKS may also trigger a violation of the False Claims Act, which can result in substantial monetary penalties.[3]

The CMPL prohibits any person from offering or giving remuneration to any individual eligible for benefits under Medicare or Medicaid whom that person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under Medicare or Medicaid.[4] Violation of the CMPL is punishable by a $10,000 penalty per item or service, treble damages, and potential exclusion from Medicare. Similar to the AKS, there are several exceptions to the CMPL that, if met, can protect the arrangement.

DMEPOS suppliers as hospital affiliates

One arrangement DMEPOS suppliers and hospitals use is for a hospital to create its own DMEPOS company as a subsidiary or affiliate. This is often achieved by creating a separate corporate entity whose stock is owned by the hospital or the hospital's parent company, or by creating a limited liability company in which the hospital is a sole member, or by creating a non-profit affiliate of which the hospital is the sole corporate member. In some cases, a hospital may joint venture with a third party, such as an existing DMEPOS company, to create the affiliated entity. Under that structure, the subsidiary DMEPOS supplier hires its own employees to operate the DMEPOS business or leases the employees (as well as certain administrative services) from the hospital. The subsidiary entity then enrolls in Medicare Part B and obtains its own National Provider Identifier (NPI) number. Although some states exempt hospitals from DMEPOS licensing requirements, many do not exempt DMEPOS suppliers from licensure, even if the supplier is a division, subsidiary, or affiliate of the licensed hospital.

Compliance concerns and potential safeguards

The advantage to hospitals of the DMEPOS subsidiary structure is that it allows the hospital to direct its charity care policy and provides an increased amount of control over the DMEPOS supplier's operations and an opportunity to participate in the revenue. Given the alignment of the hospital's and supplier's financial incentives, the parties must be sure to structure the arrangement in a manner that complies with state and federal fraud and abuse laws. Although the AKS does not apply to divisions within a company, OIG has in the past contended that the statute does apply to affiliates that are separate corporate entities.[5] Many health care law practitioners would conclude that a wholly-owned subsidiary is at low risk for an AKS violation in this scenario. However, hospitals can look to certain safeguards commonly employed by hospital discharge planners when referring patients to DMEPOS suppliers.

Overall, the hospital should not engage in conduct—whether through the discharge planning process or otherwise—that could be viewed as improperly

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steering patients to the affiliated DMEPOS supplier in return for unpermitted financial gain. For example, hospitals could consider providing patients with a list of alternate DMEPOS suppliers available to provide the necessary items for patients, and not to require that the hospital's patients only use the hospital-affiliated DMEPOS supplier. Safeguards such as these were viewed favorably by OIG in Advisory Opinion No. 02-04, which involved a consignment closet arrangement between a DMEPOS supplier and a hospital.[6] As additional safeguards, the hospital might consider disclosing to patients its ownership of the DMEPOS supplier and avoiding any improper contact between the DMEPOS supplier's personnel and the hospital's patients before the patients select the DMEPOS supplier.

Hospitals that joint venture with third parties to create a DMEPOS affiliate should attempt to structure the joint venture to comply with the AKS safe harbor for small entity investments. To qualify for the small entity investment safe harbor, no more than 40% of the value the investment interests may be held by an investor that is a referral source, nor may more than 40% of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period come from referrals or business otherwise generated from investors.[7] In other words, if a hospital (which is a potential referral source to the DMEPOS supplier) owns 40% or more of the joint venture, or if 40% or more of the revenues of the DMEPOS supplier are attributable to referrals from the hospital owner, the DMEPOS supplier joint venture will not qualify for safe harbor treatment. Because many of the referrals to a hospital-affiliated DMEPOS supplier will typically come from the hospital, and the hospital will likely want to own at least 40% of the joint venture, many DMEPOS joint ventures cannot be structured to meet every element of the small entity safe harbor.

Those joint ventures that do not fit within a safe harbor should take care to comply with the OIG's published guidance regarding joint ventures, such as its 1989 Special Fraud Alert on Joint Venture Arrangements.[8] Among other things, the OIG guidance emphasizes that the parties' ownership interests in the joint venture should reflect their capital contributions, and that investors
should not be targeted or rewarded based on referrals. In the context of a DMEPOS supplier joint venture, the non-hospital joint venture may not allow the hospital to own a higher percentage of the joint venture simply because the hospital may be in a position to generate business for the DMEPOS supplier through its existing patient base. OIG also cautions against certain "shell" joint ventures in which one joint venture partner owns the majority of the DMEPOS items and capital equipment and provides all of the day-to-day management of the DMEPOS supplier, and teams with the other entity as a joint venture partner simply because of the other entity's referral base.[9]

DMEPOS suppliers that provide items to hospital patients

Many independent DMEPOS suppliers have arrangements with hospitals where the supplier provides DMEPOS items to the hospital's patients. In this scenario, there is no ownership of the DMEPOS supplier by the hospital, but rather a contractual relationship between the parties under which the DMEPOS supplier provides items to the hospital for inpatient use. The hospital directly pays the DMEPOS supplier and then the hospital bills for the item. In this respect, the DMEPOS supplier is acting more like a vendor of items for the hospital's use; the DMEPOS supplier does not bill Medicare for the items.

The contract between the parties typically includes, among other provisions:

- Representations and warranties regarding the DMEPOS supplier's compliance with Medicare Supplier Standards and all other relevant federal and state laws;
- A requirement that the DMEPOS supplier not bill the patient, Medicare, Medicaid, and/or any other third party payor for the items; and
- A description of the items covered by the agreement.

Compliance concerns and potential safeguards

Under this arrangement, the primary concern would be compliance with the AKS's regulatory discount safe harbor or the statutory discount exception, if the items are sold to the hospital with any sort of discount. Not only does the Centers for Medicare and Medicaid Services (CMS) require the hospital to accurately report all such discounts, compliance with the discount safe harbor is important, because a sale of DMEPOS items at below market value, by itself, could be considered an inducement to buy the items or could also be considered an inducement for the hospital to direct its discharge planners to refer patients to that particular DMEPOS supplier.

In order for the regulatory discount safe harbor to apply to a buyer who submits cost reports, the following requirements must be met:

- The buyer is an entity which reports its costs on a cost report required by the DHHS or a state Medicaid program;
- The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;
- The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;
- The buyer must fully and accurately report the discount in the applicable cost report;
- The buyer must provide, upon request by the Secretary of the DHHS or a state agency, a copy of the discount disclosure information the seller is required to provide the buyer; and
- The seller must fully and accurately report such discount on the invoice, coupon, or statement submitted to the buyer; inform the buyer of its obligations to report such discount and to provide information upon request; and refrain from doing anything that would impede the buyer from meeting its obligations.[10]

Not all contractual arrangements with discounts qualify for the regulatory discount safe harbor. However, such arrangements may meet the statutory discount exception to the AKS.[11] The statutory discount exception protects "a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program."

Generally, it is easier to meet the statutory discount exception than the regulatory discount safe harbor. The statutory discount exception does not require all the specific procedures and provisions in the discount safe harbor. Unlike the discount safe harbor, the statutory exemption simply requires that the discount be "properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program." The statutory discount exception reflects Congress' intent to encourage price competition that benefits the federal health care programs.

In addition, the DMEPOS supplier should be careful not to provide any items of value to the hospital's patients or the hospital employees that may influence the selection of a DMEPOS supplier. The CMPL imposes a $10,000 fine per item or service (plus treble damages and potential exclusion from Medicare) for

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payments made in violation of the law's patient inducement prohibition. Thus, gifts and other items of value provided by the DMEPOS supplier to patients or referral sources are problematic under the CMPL, if they are likely to influence the selection of a DMEPOS supplier. Note, there is an exception to this prohibition for non-cash items of nominal value, which has been interpreted as $10 per item per patient, and no more than $50 in the aggregate annually per patient.[12]

DMEPOS supplier convenience and consignment closet arrangements

A third model used by DMEPOS suppliers and hospitals is to store items on-site at hospitals for use by the hospital's patients. This model is used at physician offices as well.[13] These arrangements are referred to as convenience or consignment closets. Under this model, the hospital and its patients enjoy the benefit of immediate access to the items. Under the convenience closet model, the DMEPOS supplier retains title to the items and is the entity that bills the patients or payors for the items. Under the consignment closet model, the hospital bills the patients or payors for the items and then makes payment to the DMEPOS supplier. Under both models, the parties typically enter into a written agreement under which the hospital agrees to provide space for the DMEPOS supplier's items, and the DMEPOS supplier agrees to sell to those patients who request the items. Under some arrangements, the DMEPOS supplier pays rent to the hospital for the use of the closet space.

Compliance concerns and potential safeguards

A primary concern with convenience or consignment closet arrangements is compliance with the AKS. Although OIG has issued Advisory Opinions in which it approved certain consignment closet arrangements, it has also identified a number of risk areas that should be addressed when structuring consignment closet arrangements.[14] Key to the analysis of convenience or consignment closets is understanding the flow of the remuneration between the parties. Specifically, remuneration from a hospital to a DMEPOS supplier (e.g., use of hospital desks and telephones by the DMEPOS supplier) is likely not problematic, because the remuneration and referrals flow in the same direction (i.e., there is no remuneration from the DMEPOS supplier to the hospital in exchange for hospital referrals).[15] In contrast, OIG views with greater suspicion payments made by a DMEPOS supplier to a hospital in connection with a consignment closet arrangement, noting that "[i]n general, payments for rent for of consignment closets in physicians' officers are suspect."[16]

To the extent a convenience or consignment closet arrangement does involve rental payments by the DMEPOS supplier to the hospital, the arrangement should be at fair market value and structured to comply with the space lease safe harbor and the OIG guidance in the February 2000 Special Fraud Alert. Of course, payment of fair market value rent, under a written lease for a term of one year of more is a requirement for meeting the space lease safe harbor. Ironically, then, attempting to meet the safe harbor appears to place these arrangements under greater OIG scrutiny, because remuneration (in the form of fair market value rent, but remuneration nonetheless) is flowing from the DMEPOS supplier to the hospital landlord.

CMS has also addressed convenience and consignment closet arrangements and flirted with guidance that would have limited many common features of consignment closets (at least those used in physician offices). In August 2009, CMS issued a change request to the Medicare Program Integrity Manual that would have permitted such closets only where the following requirements are met:

- Title to the item transfers to the physician at the time the item is furnished to the beneficiary;

- The item is billed by the physician using his or her own DMEPOS billing number;
- Fitting or other services related to the item are performed by individuals associated with the physician and not by the DMEPOS supplier; and
- Beneficiaries are instructed to contact the physician and not the DMEPOS supplier for problems or questions regarding the item.[17]

Yet, soon after issuing the provision, CMS rescinded it.

DMEPOS suppliers should keep in mind that consignment closets are potentially an area of CMS concern. CMS has not issued any recent guidance prohibiting consignment closet arrangements and, during the January 19, 2010 Open Door Forum, stated that the updated DMEPOS Supplier Standards do not address consignment closet arrangements. Parties that enter into consignment closet arrangements should consider inserting jeopardy clauses into their agreements in case the laws affecting consignment closets (or the government's interpretation of those laws) change.

Conclusion

DMEPOS suppliers must ensure their arrangements with hospitals, whether contractual or joint venture, comply with applicable health care fraud and abuse laws, including the AKS and CMPL. Maintaining compliant contractual relationships will help ensure that the needs of hospital patients can be met without presenting legal risk to the hospital or the DMEPOS supplier. ■

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1. OIG Adv. Op. 08-20 (Nov. 19, 2008).
2. 42 U.S.C. § 1320a-7b(b).
3. 42 U.S.C. § 1320a-7b(g).
4. 42 U.S.C. § 1320a-7a(5).
5. 56 Fed. Reg. 35952 (Jul. 29, 1991).
6. See OIG Adv. Op. 02-04 (Apr. 19, 2002).
7. 42 C.F.R. § 1001.952(a)(2)(vi).
8. Reprinted at 59 Fed. Reg. 65372 (Dec. 19, 1994).
9. Contractual Joint Ventures, OIG Special Advisory Bulletin (Apr. 2003).
10. 42 C.F.R. § 1001.952(h).
11. 42 U.S.C. §1320a-7b(b)(3)(A); Section 1128B(b)(3)(A) of the Social Security Act.
12. 65 Fed. Reg. 24400, 24411 (Apr. 26, 2000); Offering Gifts and Other Inducements to Beneficiaries, OIG Special Advisory Bulletin (Aug. 2002).
13. Note, the legal and compliance issues affecting such arrangements in physician offices differ from hospitals and this article does not analyze convenience and consignment closet arrangements in physician office settings.
14. See OIG Adv. Op. 06-02 (Mar. 21, 2006); OIG Adv. Op. 08-20 (Nov. 19, 2008). Although OIG Advisory Opinions are useful guidance for the health care industry, they are only binding authority for the parties who submitted the Advisory Opinion request. Other parties are not entitled to rely on the Advisory Opinions.
15. See OIG Adv. Op. 08-20, supra.
16. Rental of Space in Physician Officers by Persons or Entities to Which Physicians Refer, OIG Special Fraud Alert (Feb. 2000).
17. CMS, Medicare Program Integrity Manual, Transmittal 297 (Aug. 7, 2009) and Transmittal 300 (Sept. 1, 2009).