

**ARRANGEMENTS  
BETWEEN  
MANUFACTURERS AND  
DME SUPPLIERS**

PREPARED FOR  
AAHOMECARE'S  
RETAIL WORK  
GROUP

## **RETAIL WORK GROUP**

AAHomecare recognizes that billing Medicare on an assignment basis has become very challenging for many DME suppliers. AAHomecare also understands that many DME suppliers see an opportunity in implementing an innovative retail business in which customers pay cash. For these reasons, AAHomecare has formed a Retail Work Group comprised of stakeholders in the DME industry. The Retail Work Group is developing tools for suppliers to utilize as they move into the retail market. These tools include educational “white papers” such as this paper entitled “Arrangements Between Manufacturers and DME Suppliers.”

This white paper was prepared for the Retail Work Group by Jeffrey S. Baird, Esq., Chairman of the Health Care Group of Brown & Fortunato, P.C. Mr. Baird can be contacted at 806-345-6320 and [jbaird@bf-law.com](mailto:jbaird@bf-law.com).

The AAHomecare staff liaison for the Retail Work Group is Ashley Plauché, Manager of Government Affairs. Ms. Plauché can be contacted at [ashleyp@aahomecare.org](mailto:ashleyp@aahomecare.org).

For further information about this white paper, contact Mr. Baird. For information about the Retail Work Group, contact Ms. Plauché.

## ARRANGEMENTS BETWEEN MANUFACTURERS AND DME SUPPLIERS

By: Jeffrey S. Baird, Esq.

DME suppliers and manufacturers are dependent on each other for success. Manufacturers need financially stable suppliers to purchase their products. Suppliers need their manufacturers to (i) provide quality products and (ii) offer reasonable credit terms. Suppliers and manufacturers, justifiably, work together to promote the manufacturer's products and the supplier's business. As they work together, manufacturers and DME suppliers need to avoid implicating the federal anti-kickback statute ("AKS") and the federal False Claims Act ("FCA").

And so the question becomes: What kind of arrangements can a manufacturer and supplier legally enter into ... and what kind of arrangements should the manufacturer and supplier avoid? This white paper addresses these two questions.

### Applicable Law

The 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 ("FHCP") (e.g., Medicare, Medicare Advantage, Medicaid, Medicaid Managed Care, TRICARE), or to induce a person to purchase, lease, or recommend the purchase or lease of any item or service reimbursable by a FHCP. A number of courts have adopted the "one purpose" test, which is if one purpose of a payment is to induce referrals, then it violates the AKS regardless of whether the payment is fair market value for otherwise legitimate services rendered.

The FCA states that any person or entity who knowingly presents to a federal health care program a fraudulent claim for payment, or knowingly uses a false record or statement to obtain payment from a federal program, is subject to civil monetary penalties.

Because of the breadth of the AKS, the Office of Inspector General ("OIG") has adopted "safe harbors" that provide immunity from the AKS if certain requirements are met. Two safe harbors are particularly relevant to arrangements between manufacturers and DME suppliers:

- **Personal Services and Management Contracts Safe Harbor** - This safe harbor permits payments to referral sources as long as a number of requirements are met. Two of the most important requirements are that (i) payments must be pursuant to a written agreement with a term of at least one year and (ii) the aggregate compensation must be set in advance (e.g., \$60,000 over the next 12 months, or \$5000 per month), 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.
- **Discount Safe Harbor** – On condition that certain requirements are met, this safe harbor permits discounts on items or services for which the federal government may pay, either fully or in part, under Medicare, Medicaid, or another federal health care program. The

term "discount" refers to either (i) a reduction in the amount a buyer is charged for an item or service based on an arm's length transaction or (ii) a rebate, which is an amount that is described in writing at the time of the purchase but is paid at a later date. The safe harbor specifically excludes the following from the definition of a discount: (i) cash payments or cash equivalents (except rebate checks); (ii) supplying one good or service without charge to induce the purchase of a different good or service, unless the goods and services are reimbursed by the same federal programs using the same methodology and the reduced charge is fully and appropriately disclosed to the federal programs; and (iii) other remuneration, in cash or in kind, not explicitly described by the safe harbor. The safe harbor establishes distinct disclosure obligations for the different types of entities in a discount arrangement: sellers (e.g., manufacturers), buyers (e.g., suppliers that purchase goods or services), and offerors (e.g., parties who serve as middlemen and arrange for discounts between buyers and sellers). The safe harbor's obligations for buyers are further defined depending on whether the entity is (i) acting under a risk contract; (ii) reports costs on a cost report; or (iii) submits a claim or a request for payment for the discounted item or service and payment may be made, in whole or in part, under Medicare, Medicaid, or other federal health care programs. A DME supplier must comply with specific standards in order to invoke the protection of the discount safe harbor. First, the "discount must be made at the time of the sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service." Second, the buyer must provide, "upon request by the Secretary or a State agency" an "invoice, coupon or statement" from the seller that "fully and accurately" reports such discount.

### Arrangements to Avoid

**Manufacturer Provides Free Advertising for Supplier** – Normally, a television commercial, print ad, or website, paid for by a manufacturer, will only promote the manufacturer and its products. The manufacturer's ad typically makes no mention of a particular DME supplier. Assume, however, that a manufacturer pays for an ad that not only promotes the manufacturer and its products, but also promotes ABC Medical Equipment, Inc. ("ABC"). Assume further that ABC pays nothing to the manufacturer for the ad. This arrangement implicates the AKS because (i) the manufacturer is providing "something of value" to ABC (free advertising) and (ii) ABC is, in turn, purchasing products from the manufacturer.....that a FHCP will eventually pay for.

**Manufacturer Provides Advertising for Supplier and Supplier Pays Less Than Fair Market Value** - Same as the preceding paragraph except that ABC pays the manufacturer for the advertising, but the payments are less than fair market value ("FMV"). This arrangement implicates the AKS because (i) the manufacturer is providing "something of value" to ABC (advertising for a cost that is below FMV) and (ii) ABC is, in turn, purchasing products from the manufacturer.....that a FHCP will eventually pay for.

**Rebates and Discounts Tied to Conversions** - The manufacturer offers rebates and discounts to ABC that are tied to the number of FHCP beneficiaries who, at the prompting of ABC, switch (or "convert") from products made by other manufacturers to products made by the

manufacturer offering the rebates/discounts to ABC. This arrangement implicates the AKS because (i) the manufacturer is providing "something of value" to ABC (rebates and discounts) and (ii) ABC is, in turn, converting patients to purchase the manufacturer's products ... that a FHCP will eventually pay for.

**Payments/Gifts by Manufacturer to ABC's Sales Reps** - The manufacturer offers payments, normally in the form of percentage commissions, to ABC's sales reps as a reward for promoting the sale of the manufacturer's products. Alternatively, the manufacturer offers gifts (e.g., a trip to Cabo) to ABC's sales reps as a reward for promoting the sale of the manufacturer's products. This arrangement implicates the AKS because (i) the manufacturer is providing "something of value" to ABC (payments and gifts to ABC's sales reps) and (ii) ABC is, in turn, promoting the sale of the manufacturer's products ... that a FHCP will eventually pay for.

**Referrals Tied to the Purchase of the Manufacturer's Products** - Assume that the manufacturer advertises its products through television commercials, print ads, and the manufacturer's website. Assume that the advertisements include (i) a toll-free number for the prospective customers to call the manufacturer and (ii) a place on the website that allows the prospective customer to contact the manufacturer. Assume that the manufacturer forwards these leads only to those DME suppliers that commit to provide the manufacturer's products to the leads. This arrangement implicates the AKS because (i) the manufacturer is providing "something of value" to ABC (forwarding of leads, including FHCP patient leads) and (ii) ABC is, in turn, committing to only sell the manufacturer's products to the leads ... some of which a FHCP will eventually pay for.

**Manufacturer Provides Services, At No Charge, to the Supplier** - The manufacturer provides services, at no charge, to the supplier. For example, the manufacturer may (i) provide "call center" services in which the manufacturer calls the supplier's customers (on behalf of the supplier) to determine if the customers need a refill of the manufacturer's products and/or (ii) provide billing services (or billing consulting services) to the supplier. The arrangement implicates the AKS because (i) the manufacturer is providing "something of value" to ABC (free services) and (ii) ABC is, in turn, purchasing the manufacturer's products ... that a FHCP will eventually pay for.

**Manufacturer Provides Services, At Below FMV, to the Supplier** - Same as the preceding paragraph except that the supplier pays the manufacturer for the services. However, the payment by the supplier is below FMV. The arrangement implicates the AKS because (i) the manufacturer is providing "something of value" to ABC (services at below FMV) and (ii) ABC is, in turn, purchasing the manufacturer's products ... that Medicare will eventually pay for.

#### Acceptable Arrangements

**Cooperative Marketing Agreement** - The manufacturer and DME supplier enter into an arrangement in which the manufacturer advertises its products and the supplier's ability to provide the products. The supplier pays the manufacturer for the supplier's prorated share of the expenses of the advertisements.

**Discounts and Rebates Tied to Volume of Purchases** - The manufacturer and supplier enter into an agreement in which the manufacturer provides properly-disclosed discounts and rebates to the supplier that are tied only to the volume of the manufacturer's products purchased by the supplier. The arrangement complies with the discount safe harbor to the AKS.

**Referrals by the Manufacturer Not Tied to Purchases** - The manufacturer advertises its products on television, in print media, and on its website. As a result, the prospective customers ("leads") contact the manufacturer about the manufacturer's products. The manufacturer forwards the leads to DME suppliers. In so doing the manufacturer does not require the suppliers to sell the manufacturer's products to the leads or reward suppliers who sell the manufacturer's products with more leads.

**Payment by the Supplier of FMV Compensation to the Manufacturer for Services** - The manufacturer provides a variety of services to the DME supplier. These services include: (i) call center services in which the manufacturer calls the supplier's customers (on behalf of the supplier) to determine if they need a refill of the supplier's products; (ii) fulfillment services in which the manufacturer ships products (on behalf of the supplier) to the supplier's customers; (iii) billing services in which the manufacturer submits claims to third party payors on behalf of the supplier; and (iv) consulting services in which the manufacturer provides expertise to the supplier on a number of matters. The supplier pays FMV compensation to the manufacturer for these services.

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THIS ARTICLE DOES NOT CONSTITUTE LEGAL ADVICE. THIS ARTICLE WAS PREPARED ON A SPECIFIC DATE. THE LAW MAY HAVE CHANGED SINCE THIS ARTICLE WAS WRITTEN. BEFORE ACTING ON THE ISSUES DISCUSSED IN THIS ARTICLE, IT IS IMPORTANT THAT THE READER OBTAIN ADVICE FROM A HEALTH CARE ATTORNEY.

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