



EDUCATIONAL RESOURCES

# Properly Working With a Manufacturer and Pitfalls to Avoid

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# Introduction



# Introduction

- Historically, the relationship between manufacturers and DME suppliers was viewed as “vendor-purchaser.”
- The supplier would purchase products from the manufacturer and that was it.
- Over the years, this relationship has shifted to more of a cooperative relationship. Manufacturers and DME suppliers understand that they are dependent on each other.
- The manufacturer understand that it needs financially stable DME suppliers to purchase the manufacturer’s products.
- And the supplier recognizes that it needs a financially stable manufacturer to provide quality products at a fair price.

# Introduction

- Increasingly, manufacturers and suppliers are working together to promote the sale (by the DME supplier) of the manufacturer's products.
- This is a win-win goal for both. Generally speaking, it is acceptable for manufacturers and DME suppliers to work together; but as is often the case, the "devil is in the details."
- It is important that the cooperative arrangement not morph into a violation of the federal anti-kickback statute ("AKS").

# Applicable Law



# 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 an FHCP.
- A number of federal appellate courts have adopted the "one purpose" test that states that 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.

# Applicable Law

- The federal False Claims Act (“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 potential criminal liability and/or civil monetary penalties.
- If a claim (submitted to an FHCP) arises out of a kickback arrangement, then the claim will be construed to be a “false claim” in violation of the FCA.

# Applicable Law

- 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.
- If an arrangement does not fit within a safe harbor, it does not mean that the arrangement violates the AKS.
- Rather, it means that the parties to the arrangement need to conduct a careful analysis in light of the language of the AKS, case law, and OIG guidance.



# Applicable Law

- 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
    - payments must be pursuant to a written agreement with a term of at least one year and
    - the methodology for calculating the compensation must be set in advance, the compensation must be consistent with fair market value, and the compensation must not be determined in a manner that takes into account the volume or value of any referrals or business generated between the parties.

# Applicable Law

- Discount Safe Harbor – This safe harbor is specific to arrangements between manufacturers and companies that purchase from the manufacturers. 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 an FHCP. The term "discount" refers to either
  - a reduction in the amount a buyer is charged for an item or service based on an arm's length transaction or
  - a rebate, which is an amount that is described in writing at the time of the purchase but is paid at a later date.

# Applicable Law

- Discount Safe Harbor (Cont'd)
  - The safe harbor specifically excludes the following from the definition of a discount:
    - cash payments or cash equivalents (except rebate checks);
    - 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
    - other remuneration, in cash or in kind, not explicitly described by the safe harbor.

# Applicable Law

- 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
  - acting under a risk contract;
  - reports costs on a cost report; or
  - 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 an FHCP.

# Applicable Law

- 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



# Arrangements to Avoid

- Payments/Gifts by Manufacturer to ABC Medical Equipment'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
    - the manufacturer is providing "something of value" to ABC (payments and gifts to ABC's sales reps) and
    - ABC is, in turn, promoting the sale of the manufacturer's products that an FHCP will eventually pay for.

# Arrangements to Avoid

- 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
    - a toll-free number for the prospective customers to call the manufacturer and
    - a place on the website that allows the prospective customer to contact the manufacturer.



# Arrangements to Avoid

- Referrals Tied to the Purchase of the Manufacturer's Products (Cont'd)
  - 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
    - the manufacturer is providing "something of value" to ABC (forwarding of leads, including FHCP patient leads) and
    - ABC is, in turn, committing to only sell the manufacturer's products to the leads some of which an FHCP will eventually pay for.

# Arrangements to Avoid

- Manufacturer Provides Services, At No Charge, to the Supplier
  - The manufacturer provides services, at no charge, to the supplier. For example, the manufacturer may
    - 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
    - provide billing services (or billing consulting services) to the supplier.

# Arrangements to Avoid

- Manufacturer Provides Services, At No Charge, to the Supplier (Cont'd)
  - The arrangement implicates the AKS because
    - the manufacturer is providing "something of value" to ABC (free services) and
    - ABC is, in turn, purchasing the manufacturer's products that an FHCP will eventually pay for.

# Arrangements to Avoid

- 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
    - the manufacturer is providing "something of value" to ABC (services at below FMV) and
    - ABC is, in turn, purchasing the manufacturer's products that an FHCP will eventually pay for.

# Arrangements to Avoid

- Rebates and Discounts Tied to Conversions
  - The manufacturer offers rebates and discounts to ABC that are tied to the number of FHCP patients 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
    - the manufacturer is providing "something of value" to ABC (rebates and discounts) and
    - ABC is, in turn, converting patients to purchase the manufacturer's products that an FHCP will eventually pay for.

# 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
    - the manufacturer is providing "something of value" to ABC (free advertising) and
    - ABC is, in turn, purchasing products from the manufacturer that an FHCP will eventually pay for.

# Arrangements to Avoid

- 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
    - the manufacturer is providing "something of value" to ABC (advertising for a cost that is below FMV) and
    - ABC is, in turn, purchasing products from the manufacturer that an FHCP will eventually pay for.

# Acceptable Arrangements





# Acceptable Arrangements

- 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.

# Acceptable Arrangements

- When the supplier receives a lead from the manufacturer, the supplier can only call the lead if the requirements of the telephone solicitation statute and Supplier Standard #11 are met. According to the statute/standard, the supplier can call the lead only if one of three requirements are met. When the lead is a prospective customer of the supplier (i.e., the supplier has not transacted business with the lead in the past), then the applicable requirement is for the lead to give his electronic or “blue ink” consent to be called by the supplier that receives the lead from the manufacturer. If before the manufacturer transmits the lead to the supplier, the manufacturer has not secured the required consent for the supplier to call the lead, then the supplier will have to reach out to the lead in another legally acceptable way.

# Acceptable Arrangements

- The HIPAA Privacy Rule generally allows a “covered entity” to use or disclose an individual’s protected health information (“PHI”) only with the individual’s consent or in other limited circumstances. The question becomes: “If a manufacturer gathers patient information and shares it with a DME supplier, then does that violate HIPAA?” Normally, the answer is “no.” In most cases, the manufacturer will not meet the HIPAA definition of a “covered entity.”

# 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 pro rata share of the expenses of the advertisements.

# Acceptable Arrangements

- 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 might include:
    - 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;
    - fulfillment services in which the manufacturer ships products (on behalf of the supplier) to the supplier's customers;
    - billing services in which the manufacturer submits claims to third-party payors on behalf of the supplier; and
    - 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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# Examples of Government Enforcement Actions Against Manufacturer-Provider Arrangements



# Examples of Government Enforcement Actions Against Manufacturer-Provider Arrangements

- United States ex rel. Lisitza et al. v. Johnson & Johnson et al.
  - In late 2013, Johnson & Johnson, a New Jersey-based pharmaceutical manufacturer, entered into a civil settlement agreement with the Department of Justice in order to settle allegations of illegal kickbacks that were raised by relators under the False Claims Act.
  - In particular, the relators alleged that Johnson & Johnson initiated a “kickbacks-for-switches” scheme wherein the manufacturer induced long-term care pharmacies to promote and switch patients from non-Johnson & Johnson drug products approved by the patient’s physician to Johnson & Johnson brand pharmaceuticals.

# Examples of Government Enforcement Actions Against Manufacturer-Provider Arrangements

- The relators further alleged that Johnson & Johnson and Omnicare, Inc., a supplier of pharmaceutical drugs to nursing homes, entered into written agreements under which Omnicare received rebates on the purchase price of select Johnson & Johnson drugs as long as the pharmacy's purchases of selected drug products met a pre-determined market share amount as determined by a comparison to Omnicare's purchases of similar drugs from the manufacturer's competitors (i.e. a market share rebate agreement).



# Examples of Government Enforcement Actions Against Manufacturer-Provider Arrangements

- In addition, Omnicare was required to successfully implement programs designed to shift market share in favor of Johnson & Johnson products; such programs included disease management initiatives, written correspondence to providers prescribing or dispensing medications, educating nursing home staff regarding Johnson & Johnson products, conducting clinical intervention programs through which Omnicare's consulting pharmacists recommend specific products when appropriate, and placing Johnson & Johnson products on a selected formulary position.

# Examples of Government Enforcement Actions Against Manufacturer-Provider Arrangements

- Although Johnson & Johnson argued that payments to Omnicare fell within the Discount safe harbor to the AKS, the court disagreed.
- In particular, the court reasoned that “[w]hile the raw amounts of the rebates may have been disclosed, the terms and conditions of their payment were not.” In particular, the court noted a lack of disclosure regarding the rebate qualification requirement of market share thresholds and successful implementation of required programs.

# Examples of Government Enforcement Actions Against Manufacturer-Provider Arrangements

- The government alleged that Omnicare, in response to the remuneration received from the manufacturer, initiated and participated in various “intervention” programs that serve to promote several Johnson & Johnson drug products.
- For example, the pharmacy provided to its consulting pharmacists recommended oral and written statements to be used in encouraging physicians to prescribe Johnson & Johnson drugs. In addition, Omnicare created fax, mail, and telephone campaigns directed at physicians that encouraged the switching of patients to the manufacturer’s drugs.
- Lastly, Omnicare promoted the use of Physician Authorization Letters that, when signed by a physician, allowed a pharmacist to substitute a prescribed drug.

# Examples of Government Enforcement Actions Against Manufacturer-Provider Arrangements

- Thus, the government maintained that Johnson & Johnson's payments of market share rebates, data-purchase agreements, grants, and educational funding constituted kickbacks to Omnicare and were intended to induce the pharmacy and its pharmacists to promote the use of Johnson & Johnson drugs in its client nursing homes.
- As a result, the government contended that the claims presented to federal health care programs by the pharmacy for those Johnson & Johnson drugs were allegedly false and fraudulent.

# Examples of Government Enforcement Actions Against Manufacturer-Provider Arrangements

- United States ex rel. Banigan et al. v. Organon USA Inc., et al.
  - Banigan is a federal qui tam case also involving discounts and other remuneration between a pharmaceutical manufacturer and long-term care pharmacies.
  - Here, the relators allege that Organon, a pharmaceutical manufacturer of antidepressants, violated the AKS by engaging in a scheme to increase its product's market share by switching as many long-term care patient prescriptions as possible from the competitors' antidepressants to its brand. In particular, the relators stated that Organon offered illegal kickbacks to pharmacies in the form of both market share discounts pursuant to written purchasing agreements as well as other incentives, including research grants, sponsorship of annual meetings, data purchase agreements, nominal-price transactions, and participation in corporate partnership programs.

# Examples of Government Enforcement Actions Against Manufacturer-Provider Arrangements

- Similar to Johnson & Johnson, Omnicare argued that the remuneration received did not constitute illegal kickbacks as all discounts and rebates were disclosed in accordance with the Discount safe harbor to the AKS.
- Upon review, the court sided with the relators and found that the rebate or discount amounts were not properly disclosed as required by the Discount safe harbor since the contracts did not disclose the complete terms and conditions of the rebate (i.e. that the payments either were made to induce or were in exchange for drug conversion and therapeutic interchange) and that the full terms and amounts of the discount were, instead, concealed in various collateral agreements entered into outside of the written contract.

# Examples of Government Enforcement Actions Against Manufacturer-Provider Arrangements

- Furthermore, the court noted that “discounts,” as defined in the federal regulations, is an exhaustive definition and does not include collateral kickbacks or reductions in price that are not passed on to the health plan.
- With regards to Omnicare’s affirmative actions in connection with the arrangement with Organon, the relators alleged that, similar to the pharmacy in Lisitza, Omnicare undertook certain actions to promote the use of the manufacturer’s products. Specifically, the allegations included Omnicare’s instructions to its pharmacy to convert to a specified Johnson & Johnson drug product as well as meetings between Omnicare and Organon concerning plans for or hopes to drive up market share.

# Examples of Government Enforcement Actions Against Manufacturer-Provider Arrangements

- The government further provided insight regarding its position on discounts that are linked to recommendations or purchases of certain products in its statement of interest in this case. The United States distinguished ordinary price reductions from remuneration “for switching patients from one drug to another, and for other efforts to increase a drug’s utilization” by stating that the latter “do not qualify as protected price reductions simply because the payments are labeled as ‘rebates’ or ‘discounts’.”
- Rather, to determine the legality of an arrangement, the question should be “whether the reason for offering or accepting the ‘discount or other reduction in price’ was to induce referrals of or be reimbursed for federal health care business’.”



# Examples of Government Enforcement Actions Against Manufacturer-Provider Arrangements

- Accordingly, the government argued that the arrangements in Banignon “were not mere price reductions because Organon allegedly conditioned the payments on Omnicare not only purchasing its products, but also engaging in ‘therapeutic interchange programs’ or switching efforts to promote utilization of Organon’s drugs at the nursing facilities where Omnicare filled prescription.

# Examples of Government Enforcement Actions Against Manufacturer-Provider Arrangements

- As such, the payments were not true price discounts, but rather were remuneration that Organon offered and paid to induce Omnicare ... to recommend its products.” In its statement of interest, the government maintained that conversion requirements between a pharmacy and a manufacturer removed the arrangement from the scope of a rebate within the meaning of the Discount safe harbor and placed the arrangement into illegal kickback considerations.

# Questions?





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# Thank you

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