Practice Resource

Complicated Kickback Arrangements Between Vendors and Providers for Items and Services Paid for by Federal Health Care Programs

Mary Beth F. Johnston, Hilary H. Bowman, Carolyn F. Merritt, and Kelsey U. Jernigan

What is the issue? Vendor pricing and financial arrangements with health care providers are becoming more complex, and the Anti-Kickback Statute implications are becoming less obvious.

What is at stake? An arrangement that violates the Anti-Kickback Statute can have serious consequences for the health care provider, the vendor, or both, including felony conviction, hefty monetary penalties, and/or prison time.

What do you need to know? Being knowledgeable about the current laws, regulations, case law, and advisory opinions that have addressed a variety of provider-vendor arrangements—and understanding the incentives that drive both parties—will help health law counsel find protection under a safe harbor or determine whether an arrangement might implicate federal and/or state anti-kickback laws.

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Introduction

Enforcement actions and settlements involving medical device manufacturers, medical and equipment suppliers, and pharmaceutical manufacturers (collectively referred to as "vendors") appear to grow in frequency and magnitude each year. At the end of 2017, the U.S. Department of Justice (DOJ) announced that the federal government recovered $900 million in the form of judgments and settlements from the drug and medical device sectors of the health care industry for alleged violations of the federal Anti-Kickback Statute (Anti-Kickback Statute).[1] Certainly, some of these actions involve financial arrangements with health care providers that had fairly obvious Anti-Kickback Statute implications. These "garden variety" kickback arrangements generally include extravagant dinners, drinks, entertainment and travel, unwarranted payments for unattended speaking engagements, and sham case studies.[2]

The original purpose of the Anti-Kickback Statute at its foundational core was to outlaw these types of financial incentives to health care providers given to induce the purchase of items that are then reimbursed by a federal health program, such as Medicare and Medicaid. Providers with a reasonably robust compliance program should be able to prevent, or at least detect, the acceptance of these kinds of financial rewards.

With the increase in enforcement activity, as well as increased competition, vendor pricing and financial arrangements with health care providers are becoming more complex and the Anti-Kickback Statute implications less obvious. It is not uncommon for medical supply and pharmaceutical pricing terms to be directly negotiated between vendor sales representatives and provider supply chain management personnel, with very little input from legal counsel. If counsel is involved, it may be at the very end of the contract process and by lawyers who do not routinely perform complicated Anti-Kickback

1 *Justice Department Recovers Over $3.7 Billion from False Claims Act Cases in Fiscal Year 2017*, U.S. Dep't of Justice (Feb. 18, 2018), www.justice.gov/opa/pr/justice-department-recovers-over-37-billion-false-claims-act-cases-fiscal-year-2017.

2 *Shire PLC Subsidiaries to Pay $350 Million to Settle False Claims Act Allegations*, U.S. Dep't of Justice (Jan. 11, 2017), www.justice.gov/opa/pr/shire-plc-subsidiaries-pay-350-million-settle-false-claims-act-allegations.

Statute analyses. However, even the most seasoned regulatory lawyer may not easily spot some of the possible pitfalls due to the complicated financial measures and pricing triggers, or because some of the agreed upon assumptions underlying the financial terms are either not expressly stated in the contract or are contained in some other agreement.

As a result, health care provider counsel must be more vigilant in discussing the contract details with their clients, understanding the incentives driving both parties, and analyzing these arrangements for Anti-Kickback Statute compliance. Regulatory lawyers must be in a position to look behind the representations or labels provided by the vendor or vendor's counsel. For example, the following arrangements may or may not create significant Anti-Kickback Statute risks depending on the circumstances:

- Free use of equipment with the purchase of related disposables
- The gift of equipment to be used exclusively for research during the negotiation of a supply agreement
- Credit programs or rebates that must be used toward the purchase of future products
- Graduated discounts that are tied to provider market share or overall spend as opposed to volume
- Combination pricing for leased equipment and disposables
- Floating discounts or rent tied to the purchase of a bundle of products

All such arrangements must still be analyzed for compliance, even if it ultimately means the provider will have to pay more. This Practice Resource will provide a framework for the analysis of such arrangements and explore their potential legal, regulatory, and ethical concerns. This resource also will discuss the pertinent enforcement actions and settlements, which indicate that the government is looking beyond the typical kickback scheme; summarize the Anti-Kickback Statute and the various safe harbors under which an arrangement might be protected; provide a valuable checklist of questions that parties to an arrangement should consider to minimize scrutiny under the Anti-Kickback Statute and/or to ensure safe harbor protection; and provide analysis by

way of hypotheticals to illustrate when the Anti-Kickback Statute might be implicated and/or why the requirements of a certain safe harbor were not met.

Pertinent Enforcement Actions and Settlements

There are a number of enforcement actions and settlements involving vendors and health care providers that suggest the government is looking beyond the typical garden variety kickback schemes. While not exhaustive, some examples are discussed below.

OIG and DOJ settlements

Notably in 2017, Shire Pharmaceuticals LLC (Shire) and Advanced BioHealing (ABH) collectively paid $350 million[3] to settle allegations that they improperly induced health care providers to use their "bioengineered human skin substitute" called Dermagraft. While the inducements allegedly included "lavish dinners, drinks, entertainment and travel; medical equipment and supplies; unwarranted payments for purported speaking engagements and bogus case studies,"[4] the *qui tam* complaint further alleged that Shire and ABH induced health care providers to use Dermagraft over other competing products by loaning, on an annual basis, freezers worth almost $6,000 for storing Dermagraft "in exchange for purchases of large quantities of the product,"[5] i.e., at least five Dermagraft products initially and at least five Dermagraft products in each future order.[6] In addition, the defendants offered free supplies, such as "cast-like boots with insoles" that could be used to assist patients with foot ulcers.[7] These types of incentives—which appear ancillary to the main purchase or intended for patients—may not strike some providers as raising anti-kickback concerns, but they were relevant in the false claim allegations.

3 The DOJ stated that this settlement "represent[ed] the largest False Claims Act recovery by the United States in a kickback case involving a medical device." *Id.*
4 *Id.*
5 Complaint at 50, para. 253-254, *United States, et al., ex rel. Petty v. Shire Regenerative Medicine Inc. et al.*, No. 8:14-cv-00969 (E.D. Pa. Nov. 26, 2012).
6 *Id.* at 50-51, para. 254-255.
7 *Id.* at 51, para. 259.

In 2013, Henry Schein, Inc., a medical and dental supplier, paid more than $1 million to resolve Anti-Kickback Statute allegations in which the problematic activity involved the reward of points to health care provider customers for every item purchased electronically through its "Medical Privileges Program."[8] As members of the program, providers earned credits that could be used to redeem the points for an array of other products;[9] however, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) determined that the program did not qualify as a discount or a rebate, which might otherwise be protected under the Anti-Kickback Statute safe harbor regulations.[10]

Similarly, in 2015, the OIG took the position that certain financial incentives offered as discounts and rebates by Novartis Pharmaceutical Corporation to specialty pharmacies were instead kickbacks to reward the switching of prescriptions to its products.[11] To resolve the matter, Novartis paid $390 million in its settlement with the OIG.[12] Couching the incentives in language that might suggest they were eligible for Anti-Kickback Statute safe harbor protection did not succeed in preventing liability.[13]

In 2016, Olympus Corporation of the Americas, the nation's largest distributor of endoscopes and related equipment, paid $623.2 million to resolve alleged violations of the federal Anti-Kickback Statute, which included unlawful

8 Nina Youngstrom, *Reward Program for Medical Supplies Leads to $1M Settlement*, 22 Report on Medicare Compliance No. 42 at 4 (Nov. 25, 2013), *available at* https://aishealth.com/sites/all/files/latest-issue-pdf/nov._22_2013/rmc112513.pdf; Health Care Compliance: Settlement and Corporate Integrity Agreements, Settlement Agreement between OIG and Henry Schein, Inc., Office of Inspector General, (Oct. 17, 2013), available through Wolters Kluwer.

9 Youngstrom, at 4.

10 *Id.*; *Civil Monetary Penalties and Affirmative Exclusions*, U.S. Dep't. of Health & Human Servs. Office of Inspector General (Oct. 17, 2013), https://oig.hhs.gov/fraud/enforcement/cmp/cmp-ae.asp.

11 *Manhattan U.S. Attorney Announces $370 Million Civil Fraud Settlement Against Novartis Pharmaceuticals for Kickback Scheme Involving High-Priced Prescription Drugs, Along with $20 Million Forfeiture of Proceeds from the Scheme*, U.S. Dep't of Justice (Nov. 20, 2015), www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-370-million-civil-fraud-settlement-against-novartis.

12 *Id.*

13 *Id.*

incentives to both hospitals and physicians that involved grants and the free use of equipment valued up to $400,000.[14]

Federal case law

A review of federal case law further indicates that the government is looking beyond the typical garden variety kickback scheme. For example, in *United States v. Carroll*, a federal district court found that the arrangement between the vendor and providers failed to satisfy both the Discount Safe Harbor and the Equipment Rental Safe Harbor under the Anti-Kickback Statute.[15]

The defendants in *United States v. Carroll* sold enteral feeding supplies to nursing homes and durable medical equipment (DME) suppliers.[16] The defendants were indicted for fraudulently concealing kickbacks during the sale of the nutrient supplies for ultimate use by Medicare beneficiaries.[17] In one particular arrangement, an undercover governmental entity was set up to look like a DME company (the customer). Defendants gave the customer 95 free pumps worth $76,000 in exchange for the customer's purchase of related supplies.[18] Under this arrangement, the customer would pay an arbitrary rental fee that would be offset by an equal reduction in the purchase price of the related supplies instead of receiving the pumps for free and paying an established price for related supplies. For instance, defendants would "pay" $5 per month for renting the pumps and pay a discounted $95 for related supplies instead of paying $100 for the supplies.[19] The defendants manipulated the invoices to reflect this arrangement.[20]

14 *Medical Equipment Company Will Pay $646 Million for Making Illegal Payments to Doctors and Hospitals in United States and Latin America*, U.S. Dep't of Justice (Mar. 1, 2016), www.justice.gov/opa/pr/medical-equipment-company-will-pay-646-million-making-illegal-payments-doctors-and-hospitals.
15 United States v. Carroll, 320 F. Supp. 2d 748 (S.D. Ill. 2004).
16 *Id.* at 751.
17 *Id.*
18 *Id.* at 752.
19 *Id.*
20 *Id.*

The district court in *Carroll* found that defendants' arrangement was not protected by the Anti-Kickback Statute's Discount Safe Harbor[21] because it did not constitute a "discount" and such discount was not accurately reported.[22] The court reasoned that if the customer actually paid $5 per month for renting a pump in the provided example, the arrangement would involve an equipment lease, implicating the Equipment Rental Safe Harbor[23] rather than the Discount Safe Harbor. The arrangement did not satisfy the Equipment Rental Safe Harbor, and because the invoices failed to accurately represent the discount (i.e., indicating that the customer paid $5 in monthly rent per pump when the customer actually received them for $0), the defendants also failed to meet the Discount Safe Harbor. For these reasons, the court denied the defendants' motion to dismiss their indictment.[24] This case underscores the importance of not only having safe harbor protection, but understanding which safe harbor actually applies.

Similarly, *qui tam* actions filed against vendors for violating the Anti-Kickback Statute and False Claims Act rely on written agreements between the parties as evidence of prohibited activities. In October of 2017, a Florida federal court unsealed a lawsuit filed by two whistleblower employees against Alere, Inc. (Alere) alleging that Alere violated the federal False Claims Act and federal Anti-Kickback Statute for "providing CLIA waived testing strips and cups to [providers] as a means of inducing [the providers] to purchase, order, and use Alere's chemical supplies (reagent) and to perform in-office drug screening tests—products and services for which payment may be made under Government Health Care Programs"[25] and providing free or deeply discounted analyzers to providers for the purpose of inducing purchase of chemical reagents payable under Government Health Care Programs.[26] The whistle-blower-employees attached to their complaint a lease agreement containing

21 *See* discussion *infra* Discount safe harbor.
22 *Carroll*, 320 F. Supp. 2d at 756.
23 *See* discussion *infra* Equipment rental safe harbor.
24 *Id.*
25 Complaint at 20, para. 66, United States ex rel. Nolan v. Alere, Inc., No. 3:15-cv-00404 (M.D. Fla. Oct. 5, 2017).
26 *Id.* at 20, para. 66–67.

"no set lease or sale price for the equipment, supplies and chemicals referenced" as evidence of such prohibited practices with providers.[27]

As the frequency and magnitude of *qui tam* actions, settlements, and cases involving vendor relationships continues to grow, every aspect of an arrangement must be scrutinized. As discussed herein, the federal Anti-Kickback Statute applies to both parties in an arrangement; thus, even if only one party has an impermissible intent, both parties can be held criminally liable under the Anti-Kickback Statute. While providers may have taken comfort in the fact that the vendor has historically been the target of scrutiny and often the deeper pocket, it may be only a matter of time before providers—particularly health systems and hospitals—are more routinely the subject of scrutiny by whistleblowers and the federal government.

Summary of Applicable Laws, Regulations, and Guidance

Federal and state anti-kickback laws, regulations, and guidance from the federal government by way of advisory opinions issued by the OIG provide a general framework to help understand how health care provider-vendor arrangements can minimize anti-kickback scrutiny and leverage the safe harbors that are available if all elements of a safe harbor are met.

The Anti-Kickback Statute

The federal Anti-Kickback Statute prohibits the knowing and willful offer, payment, solicitation or receipt of remuneration in exchange for referring, purchasing, leasing, ordering or arranging for items or services that are paid in whole or in part by a federal health care program.[28] Remuneration is described broadly to include "any kickback, bribe, or rebate . . . directly or indirectly, overtly or covertly, in cash or in kind."[29]

27 *Id.* at 21, para. 68.
28 *See* 42 U.S.C. § 1320a-7b(b).
29 42 U.S.C. §§ 1320a-7b(b)(1)-(2).

A violation of the federal Anti-Kickback Statute is a felony that may be penalized by criminal fines reaching $100,000 per violation and imprisonment for up to ten years, or both.[30] Violations are also punishable by civil monetary penalties[31] in an amount up to $100,000 for each act and an additional assessment of penalties up to three times the total amount of remuneration exchanged.[32] The Secretary of the U.S. Department of Health & Human Services (HHS), acting through the OIG, also has the authority to recommend that violators be excluded from participating in any federal health care programs and may recommend similar actions by state agencies.[33] An individual or entity found in violation of the Anti-Kickback Statute can be subject to liability under the False Claims Act as well.[34] Parties on both sides of an illegal arrangement can be held liable under federal law.

Since the Anti-Kickback Statute is intent-based, remuneration paid or received in exchange for referrals will only result in liability if the parties to the arrangement intend for the remuneration to induce referrals, purchases, leases or orders for items and services paid for by a federal health care program.[35] Several federal circuit courts have held that a party violates the Anti-Kickback Statute if one purpose (as opposed to a primary purpose or sole purpose) of the remuneration is to induce referrals.[36]

The Anti-Kickback Statute contains statutory safe harbors, and the OIG has promulgated regulatory safe harbors. These "safe harbors" protect parties from liability if all elements of a safe harbor are met.[37] If, however, an arrangement fails to meet all of the required elements, it does not mean that the arrangement

30 *Id.*
31 *Id.* at § 1320a-7a(a)(7).
32 *Id.* at § 1320a-7a(a).
33 *Id.*; *see also* 42 U.S.C. §§ 1320a-7, 7c; 42 C.F.R. §1001.951.
34 *See* 42 U.S.C. § 1320a-7b(g); 31 U.S.C. § 3729.
35 *See* 42 U.S.C. § 1320a-7b(b).
36 *See* U.S. v. Greber, 760 F.2d 68 (3rd Cir. 1985); U.S. v. Davis, 132 F.3d 1092 (5th Cir. 1998); U.S. v. Kats, 871 F.2d 105 (9th Cir. 1989); U.S. v. McClatchey, 217 F.3d 823 (10th Cir. 2000); U.S. v. Borrasi, 639 F.3d 774 (7th Cir. 2011).
37 *See* 42 C.F.R. § 1001.952.

is *per se* unlawful. It is also important to note that states may have their own anti-kickback laws, which will need to be examined when analyzing applicable vendor arrangements.

Discount safe harbor

The safest course of action when analyzing vendor relationships involving discounts on items and services is to seek protection under the federal Anti-Kickback Statute's safe harbor on discounts,[38] which protects certain discounts on an item or service paid for by a federal health care program. The term "discount" generally means a reduction in price.[39] Notably, however, it does not include (i) cash payments unless they are rebates;[40] (ii) the provision of a free or a reduced price item or service to encourage the purchase of another item or service (bundled discount, discussed in greater detail below)[41] unless they are reimbursed by the same methodology; (iii) reductions in price applicable

38 *See* 42 C.F.R. § 1001.952(h).

39 The term "discount" is defined by applicable regulation as "a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction," but does not include: (i) cash payments or cash equivalents, except rebates, (ii) "[s]upplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service, unless the goods or services are reimbursed by the same Federal health care program using the same methodology and the reduced charge is fully disclosed to the Federal health care program and accurately reflected where appropriate, and as appropriate, to the reimbursement methodology," (iii) price reductions applicable to one payer, but not Medicare, Medicaid, or other federal health care programs, (iv) routine reduction or waiver of a beneficiary's coinsurance or deductible, (v) warranties, (vi) services performed according to personal or management services contracts, (vii) other remuneration not explicitly described in the definition of a "discount." 42 C.F.R. § 1001.952(h)(5).

40 The term "rebate," as discussed herein, is defined by applicable regulations as "any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale." 42 C.F.R. § 1001.952(h)(4).

41 *Id.* at § 1001.952(h)(5).

to one payer but not a federal health care program;[42] or (iv) routine reduction or waiver of coinsurance or deductibles.[43]

The discount safe harbor also requires that the discount be based on an arms-length transaction, which would also appear to exclude a price reduction that does not appear to be commercially reasonable (e.g., 99% discount on the list price).[44] In short, the DOJ has commented "if a price reduction is conditioned on more than the purchase of a product, then it is not a mere discount" but rather, a form of remuneration whose legitimacy must be evaluated under the Anti-Kickback Statute separate and apart from the discount safe harbor.[45]

42 *See* OIG Advisory Op. No. 12-09 (July 23, 2012), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/AdvOpn12-09.pdf; OIG Advisory Op. No. 10-26 (Dec. 20, 2010), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2010/AdvOpn10-26.pdf; OIG Advisory Op. No. 99-13 (Nov. 30, 1999), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_13.htm; OIG Advisory Op. No. 99-2 (Feb. 26, 1999), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_2.htm. Additionally, in 1991, the OIG explained that Congress did not intend for the Discount Safe Harbor to protect arrangements that provide discounts to private payers, but not to federal health care programs such as Medicare and Medicaid. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35978 (July 29, 1991), *available at* www.gpo.gov/fdsys/pkg/FR-1991-07-29/pdf/FR-1991-07-29.pdf [hereinafter OIG Anti-Kickback Provisions]. In 1999, the OIG referred to such arrangements as "swapping" arrangements through which "remuneration in the form of discounts on items or services for private pay patients is offered to a provider to induce referrals of Federal health care program patients." OIG, Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518, 63528 (Nov. 19, 1999), *available at* www.gpo.gov/fdsys/pkg/FR-1999-11-19/pdf/FR-1999-11-19.pdf. The OIG provided the example of an arrangement that offers physicians discount on laboratory services for private pay patients "on the condition that the physicians refer all of their Medicare and Medicaid business to the laboratory." *Id.* The OIG remains skeptical of these arrangements because they "essentially shift costs to the Federal health care programs" and "serve as *de facto* subsidy programs for other reimbursement systems." *Id.*

43 *See* 42 C.F.R. § 1001.952(h).

44 *See, e.g.*, OIG Advisory Op. No. 99-2 (Feb. 26, 1999), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_2.htm ("In evaluating whether an improper nexus exists between a discount and referrals of Federal business in a particular arrangement, we look for indicia that the discount is not commercially reasonable in the absence of other, non-discounted business. In this regard, discounts . . . that are particularly suspect include, but are not limited to . . . discounted prices that are below the supplier's cost . . .").

45 United States' Statement of Interest Regarding Plaintiff's Motion for Reconsideration of the Court's Dismissal of CCS, United States ex. rel. Herman v. Coloplast, No. 11-12131-RWZ (D. Mass. Aug. 8, 2016) [hereinafter *Coloplast SOI*].

If an arrangement is set up to include a permissible discount, the buyer, seller, and offeror of the discount will have the protection of the discount safe harbor if they satisfy the obligations described below:

- First, if the buyer reports its costs on a cost report, the discount safe harbor requires that (i) the discount be earned on purchases for such goods and services within the same fiscal year of the buyer; (ii) the buyer claim the discount in the same fiscal year it was earned or the following year; (iii) the buyer fully and accurately reports the discount on the cost report; and (iv) the buyer respond to any request by the Secretary of HHS for documentation of the discount that was provided by the seller.[46]
- Second, if the seller permits the buyer to take a discount, the discount safe harbor also requires that (i) the discount be fully and accurately reported to the buyer on an invoice, coupon, or statement to the buyer; (ii) the seller inform the buyer "in a manner reasonably calculated to give notice" of its reporting obligations; and (iii) the seller refrain from anything that would impede buyer's ability to meet such obligations.[47]
- Third, if an offeror (other than the seller) promotes a buyer's purchase of a discounted item, the offeror must inform the buyer "in a manner reasonably calculated to give notice" of its obligation to report the discount and respond to any requests by the Secretary of HHS.[48] The offeror must also refrain from anything that would impede the buyer's ability to meet such obligations.[49]

46 *See* 42 C.F.R. § 1001.952(h)(1). If the buyer does not report its costs on a cost report, the applicable regulations for buyers that are health maintenance organizations, competitive medical plans, and all other entities must follow the discount reporting requirements set out in § 1001.952(h)(1)(i) and (h)(1)(iii).

47 42 C.F.R. § 1001.952(h)(2)(ii)(B), (iii)(B). If the buyer does not report its costs on a cost report, the applicable regulations require the seller to follow the standards set out in § 1001.952(h)(2)(i) and (h)(2)(iii).

48 *Id.* § 1001.952(h)(3)(ii)(A), (iii)(A). If the buyer does not report its costs on a cost report, the applicable regulations require the offeror to following the standards set out in § 1001.952(h)(3)(i) and (h)(3)(iii).

49 *Id.* § 1001.952(h)(3).

Rebates and credits

Rebates and credits are two forms of discounts that are earned on actual purchases and redeemed some time after the initial purchase. In the 1991 final rule on Anti-Kickback Statute Safe Harbors, the OIG noted that it revised the definition of "discount" to specifically include rebates and credits.[50] However, the OIG (i) limited the ability of recipients to negotiate these instruments to third parties; (ii) required that discounts be redeemed only by the seller;[51] (iii) clarified that a rebate or credit earned on one good could not be used toward the purchase of a different good;[52] (iv) required that discounts be "fully and accurately reported;" and (v) required that the provider earns the rebate "at the time the good or service was purchased or provided," and the buyer reports the discounts "on the applicable cost report or claim form covering the goods or services for which the credit is being used."[53]

In Advisory Opinion 13-07, the OIG found that a tiered, percentage-based rebate program would be protected by the discount safe harbor.[54] The vendor proposed to set up a "rebate program" on the purchase of its ophthalmology surgical supplies and devices where the percentage rebate to a customer would be based on the total products purchased by the customer.[55] The amount of the rebate would not be based on products reimbursed by a federal health care program.[56] The agreement between the parties, invoices, and an end-of-year report would summarize the terms of the arrangement and applicable purchases

50 *OIG Anti-Kickback Provisions*, 56 Fed. Reg. 35952, 35979.
51 *Id.* (i.e. rebates issued by a particular seller may only be exchanged for cash value by the holder at the same seller).
52 As noted herein, this requirement was later amended to allow a discount to be earned on one good to induce the purchase of a different good or service so long as they are reimbursed by the federal health care program using the same methodology.
53 *OIG Anti-Kickback Provisions,* 56 Fed. Reg. 35952.
54 *See* OIG Advisory Op. No. 13-07, at 2 (June 24, 2013), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2013/advopn13-07.pdf.
55 *Id.*
56 *Id.*

and inform customers that the vendor would provide all information necessary for federal reporting obligations.[57]

In analyzing the proposed arrangement in Advisory Opinion 13-07, the OIG considered whether the proposed rebate was within the definition of a "discount" and "rebate," and whether it satisfied the elements of the discount safe harbor.[58] The OIG determined that the rebate in the proposed arrangement would be within the definition of a "discount" because the discount on one product is not contingent upon the discount of another product and the discount would be attributable to the items purchased.[59] The OIG also determined that the proposed rebate satisfied the definition of "rebate" because the terms are set out prior to the initial purchase, even though the rebate is redeemed at a later date.[60] Finally, the OIG determined that the vendor would meet its obligations with respect to providing the customer with the information necessary to satisfy its reporting obligations.[61] Taking into consideration the nature and timing of the discount, the OIG determined the proposed arrangement in Advisory Opinion 13-07 would satisfy the discount safe harbor and not be subject to administrative sanctions under the Anti-Kickback Statute.

Prebates

Prebates, on the other hand, are *not* earned on actual purchases and instead are redeemed at the outset of an arrangement. In contrast to discounts and rebates, the OIG has concluded that prebates are *not* protected by the discount safe harbor. In a letter written by the Chief Counsel of the OIG in 2000, the OIG addressed the legality of prebates.[62] The letter was in response to a requestor who proposed an arrangement between a vendor of medical products and

57 *Id.* at 3.
58 *Id.* at 4.
59 *Id.* at 5–6.
60 *Id.* at 6.
61 *Id.* at 7.
62 OIG Advisory Letter from D. McCarty Thornton, Chief Counsel to the Inspector General (July 17, 2000), *available at* https://oig.hhs.gov/fraud/docs/safeharborregulations/prebate.htm [hereinafter *Thornton Letter*].

services and a group purchasing organization (GPO).[63] Upon execution of the agreement, the vendor would pay the customer substantial amounts and would not request a refund if the customer did not meet certain purchase thresholds during the term of the agreement.[64] The OIG found that this arrangement would not constitute a discount or rebate protected by the discount safe harbor because the vendor's payments are made prior to any actual purchases, the payments are difficult to track, and they have the "practical effects of 'locking in' the purchasers for an extended period of time, increasing the potential for overutilization and interfering with a purchaser's normal cost/quality considerations in ordering specific goods or service."[65]

Bundled discounts

One of the most common vendor arrangements is the "bundled discount" arrangement,[66] which involves an individual or entity purchasing an item or service and earning a financial benefit on something other than the purchase. Past examples provided by the OIG include ophthalmologists receiving free surgical packs with the purchase of intraocular lenses, and physicians receiving free computers from credits earned on purchases.[67]

Initially, bundled discounts were not protected by the discount safe harbor. In the 1991 final rule for Anti-Kickback Statute Safe Harbors, the OIG explained that protection of bundled discounts would be inconsistent with Congress's intent because such discounts could not be "measured and fully reported to the Medicare and Medicaid programs."[68] The OIG said it would consider several factors when evaluating whether to prosecute a bundled discount, including (i) whether the discount is reported and received by federal

63 *Id.*
64 *Id.*
65 *Id.*
66 *OIG Anti-Kickback Provisions*, 56 Fed. Reg. 35952, 35978.
67 *Id.*
68 *Id.*

health care programs, (ii) whether the goods are "separately reimbursable," and (iii) whether the parties intended the arrangement to induce referrals.[69]

Since then, the OIG has amended its position and protects certain bundled discounts in different items as long as they are reimbursed by the same methodology. In 1999, the OIG concluded that it was:

> . . . persuaded that in certain circumstances, discounts offered on one good or service to induce the purchase of a different good or service where the net value can be properly reported do not pose a risk of program abuse and may benefit the programs through lower costs or charges achieved through volume purchasing and other economies of scale. *Such circumstances exist where the goods and services are reimbursed by the same Federal health care program in the same manner, such as under a DRG payment.*[70]

The OIG also has found that certain bundled discounts may present a sufficiently low risk of fraud and abuse when free items have no independent value. In 1997, the OIG issued guidance through an advisory letter on whether a supplier implicated the Anti-Kickback Statute by providing free fax machines, computers, and fax lines to health care providers referring Medicare and Medicaid beneficiaries to the supplier.[71] The OIG referred to its previous guidance that free computers with no independent value (i.e., cannot be used by a provider for a purpose outside of the arrangement) is not a prohibited inducement of referrals in violation of the Anti-Kickback Statute, whereas a free computer with independent value (i.e., can be used by a provider for various reasons beyond the arrangement) could be considered a prohibited inducement of referrals.[72] The OIG added that it is aware some suppliers give "multi-use equipment" to providers, but clarified that the equipment could only

69 *Id.*
70 *Id.* (emphasis added).
71 OIG Advisory Letter from Kevin G. McAnaney, Chief, Industry Guidance Branch (July 3, 1997), *available at* https://oig.hhs.gov/fraud/docs/safeharborregulations/freecomputers.htm [hereinafter *McAnaney Letter*].
72 *Id.*

be used for services related to the arrangement.[73] The OIG emphasized that in such circumstances "the substance—not the form—of the transaction controls" and both parties to the arrangement will be liable if such equipment is misused.[74]

The OIG has further stated that it will consider several factors when determining whether an item has "no independent value," including (i) the criteria used by the supplier of the equipment to determine which customers receive the equipment; (ii) the ownership of the equipment; (iii) the location and access to the equipment at the customer's place of business; (iv) the procedures used by the customer and supplier to prohibit unauthorized use of the equipment; (v) the value added to the customer's services by the equipment; and (vi) the number and extent of similar arrangements with other parties.[75] The OIG has previously identified the following examples[76] of items with no independent value:

- A free computer provided to a physician by a laboratory, if the computer could be used only to print out test results produced by the laboratory;
- Access to an electronic/software interface to be used by physicians only to transmit orders for laboratory and diagnostic services to a laboratory, and to receive the results of those services;
- An informational kiosk placed by a pharmaceutical manufacturer in physicians' offices that essentially functioned as a brochure; and
- Fax machine used only in connection with ordering and receiving results from laboratory.

While the OIG continues to express "longstanding concern" that free goods and services "may be used as a vehicle to disguise or confer an unlawful payment

73 *Id.*
74 *Id.*
75 *Id.*
76 *OIG Anti-Kickback Provisions*, 56 Fed. Reg. 35952, 35978; OIG Advisory Op. No. 12-20 (Dec. 12, 2012), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2012/advopn12-20.pdf; OIG Advisory Op. No. 08-05 (Feb. 15, 2008), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-05B.pdf; *McAnaney Letter* (here, the OIG cautions that the provision of a free fax machine creates potential liability under the Anti-Kickback Statute only if it is used by the recipient for any purpose other than in connection with the ordered service).

for referrals of Federal health care program business,"[77] it has issued advisory opinions that find certain bundled discount arrangements would not present significant risk of fraud and abuse. For example, in OIG Advisory Opinion 16-09, the vendor proposed to place a vaccine refrigeration storage system in a physician's office free of charge in exchange for the physician stocking at least one "sole-source" vaccine from a manufacturer that contracts with the vendor.[78] The vendor would retain title to the system; however, the physician would be required to pay for related internet access and utilities.[79] "In addition, the physician could use the system to store certain types of vaccines from other manufacturers that were not considered sole-source vaccines.[80] The vendor would also enter into arrangements with sole-source vaccine manufacturers whereby the manufacturer would pay the vendor a fee each time the physician dispensed one of its vaccines.[81] The physician would not share any portion of the fee with the physician.[82] The OIG ultimately determined that this arrangement would not be subject to administrative sanctions.[83]

The OIG noted that vaccines from more than one manufacturer could be stored in the refrigeration system (including manufacturers with whom the vendor did not have a contractual arrangement), and there was no minimum number of vaccines to be stored in order for the physician to use the system free of charge. The arrangement included a per-dispense fee structure that reflected the volume and value of referrals, but the OIG identified other favorable factors too, e.g., the vendor would receive the fee, the vendor would not be sharing the fee with the physician, and the vendor would not be in a position to make referrals that are paid for by federal health care programs.[84] Taking into account various aspects of the arrangement, including lack of

77 OIG Advisory Op. No. 16-09, at 5 (Sept. 16, 2016), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2016/AdvOpn16-09.pdf.
78 *Id*. at 3.
79 *Id*.
80 *Id*.
81 *Id*. at 4.
82 *Id*.
83 *Id*. at 2.
84 *Id*.

exclusivity, compensation, public policy, and the unique relationships among the entity providing free equipment, the referral source and the vaccine manufacturers, the OIG concluded that the arrangement described in OIG Advisory Opinion 16-09 would *not* be subject to administrative sanctions. However, as discussed in further detail below, the theory of items having no independent value to the provider may only apply in narrow instances.

Equipment rental safe harbor

Vendor relationships, which involve the lease or placement of equipment with a health care provider, should seek the protection of the Anti-Kickback Statute safe harbor for equipment rental when possible. The equipment rental safe harbor[85] protects arrangements to lease equipment, as long as all of the following elements are satisfied: (i) there is a written lease agreement signed by the parties; (ii) the agreement covers all equipment leased between the parties and specifies the equipment; (iii) if the lease is periodic, the agreement provides a schedule of the lease intervals and the rent for each interval; (iv) the term of the agreement is at least one year; (v) the aggregate rent is set in advance, at fair market value[86] and does not take into account the volume or value of any referrals for items or services paid for by a federal health care program; and (vi) the aggregate rent is commercially reasonable.

Warranty safe harbor

Vendor relationships involving replacement equipment or maintenance and repair services could potentially try to seek the protection of the Anti-Kickback Statute safe harbor for warranties.[87] The warranty safe harbor protects

85 *See* 42 C.F.R. § 1001.952(c).

86 The term "fair market value" is defined by applicable regulations as the "value of the equipment when obtained from a manufacturer or professional distributor, but [which does] not reflect the additional value one party . . . would attribute to the equipment as a result of its proximity or convenience to sources of referral or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs." 42 C.F.R. § 1001.952(c)(6).

87 *See* 42 C.F.R. § 1001.952(g). *See also* OIG Advisory Op. 17-03 (Aug. 18, 2017), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-03.pdf (finding that the definition of "warranty" was not met in this case as replaced products were not defective or otherwise substandard).

warranties[88] provided to the buyer of a manufacturer's or supplier's item, as long as (i) the buyer accurately reports on a Medicare cost report any item of reduced price (or free item) received through a warranty and responds to requests from the Secretary of HHS with documentation of any received price reductions, and (ii) the manufacturer or supplier accurately reports any item of reduced price (or free item) received by the buyer from a warranty on an invoice or statement submitted to the buyer and informs the buyer of its reporting obligations and refrains from paying any individual (except the beneficiary) or entity for expenses incurred by the beneficiary, except for the cost of the item itself.

Group purchasing organization safe harbor

Vendor relationships involving a contracting party that operates as a group purchasing organization (GPO) could potentially seek the protection of the applicable Anti-Kickback Statute group purchasing organization safe harbor.[89] The GPO safe harbor protects payments between a vendor and a GPO[90] for goods and services, as long as (i) the GPO has a written agreement with every entity that either states the participating vendors "will pay a fee to the GPO of three (3) percent or less of the purchase price of goods or services provided by that vendor" or if the fee is not fixed at 3% or less, the agreement sets forth the

88 The term "warranty" in the Warranty Safe Harbor is defined by statute as "(A) any written affirmation of fact or written promise made in connection with the sale of a consumer product by a supplier to a buyer which relates to the nature of the material or workmanship and affirms or promises that such material or workmanship is defect free or will meet a specified level of performance over a specified period of time, or (B) any undertaking in writing in connection with the sale by a supplier of a consumer product to refund, repair, replace, or take other remedial action with respect to such product in the event that such product fails to meet the specifications set forth in the undertaking, which written affirmation, promise, or undertaking becomes part of the basis of the bargain between a supplier and a buyer for purposes other than resale of such product." 15 U.S.C. § 2301(6).

89 *See* 42 C.F.R. § 1001.952(j).

90 The term "group purchasing organization" is defined by applicable regulations as "an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services" paid for by a federal health care program, as long as such entities are "neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO." 42 C.F.R. § 1001.952(j)(2).

amount (or if not known, the maximum amount) the GPO will be paid by each vendor,[91] and (ii) the GPO discloses to any entity that is a health care provider in writing at least annually the amount received from each vendor with respect to purchases made by or on behalf of the entity.[92]

Factual & Legal Framework

When health care providers consider a proposed drug or medical supply purchase and related equipment purchase or lease, they should start by understanding key factual aspects of the arrangement. Consider the following questions that will help in this process:

- What items, services (or both) will be sold or provided to the health care provider?
- Are the items (disposables and/or equipment) separately reimbursed, or part of a diagnosis-related group (DRG) or other bundled reimbursement payment?
- Can the equipment be used without the purchase of consumables?
- Is the equipment of high value relative to the cost of the consumables?
- Is there a list price for the equipment being provided? Will the equipment be used in providing a billable health care service?
- Will title to the equipment pass to the provider at the end of the contract or will the equipment be returned?
- Are there conditions on the overall pricing terms or the related provision of equipment (e.g., product switching, exclusivity, marketing)?
- What is the term of the arrangement? Can the parties terminate the agreement early? If so, what are the financial consequences?

91 Where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO.

92 *See* 42 C.F.R. § 1001.952(j).

Next, health care providers should consult with their legal counsel to consider the applicable laws, regulations, and guidance that will determine whether an arrangement exposes them to the risk of civil and criminal liability. They should evaluate the arrangement by asking the following questions:

- Does the arrangement implicate the federal Anti-Kickback Statute?
- Does the arrangement satisfy any applicable safe harbor of the Anti-Kickback Statute?
- What is the intent of the parties in entering into the arrangement? Is the correspondence with the vendor consistent with that intent?
- Does the arrangement in any way implicate the Stark Law, and if so, does it fit within an exception?
- Does the arrangement implicate any state fraud and abuse laws?
- What does the AdvaMed Code of Ethics recommend about such arrangement?
- Is a health care provider's procurement or formulary committee involved in the arrangement? How does this affect the arrangement from a conflicts of interest perspective?
- Is the arrangement within an acceptable range of compliance risk?

Hypotheticals & Analysis

Described below are several common arrangements among vendors in the context of proposed equipment placement and product purchases. The scenarios illustrate when an arrangement may implicate the Anti-Kickback Statute or be protected by a safe harbor.

Equipment rental and disposable purchase commitment arrangement

Hypothetical 1: A vendor places free equipment at a health care provider's facility in exchange for the provider purchasing related disposables in a volume that meets or exceeds a minimum annual purchase commitment of 50 units. The vendor retains title to the equipment throughout the term

of the agreement. The provider purchases disposables at $100 per unit. If the provider does not purchase at least 50 units of the related disposables, the provider is required to (i) return the equipment to the vendor; (ii) purchase the equipment from the vendor; or (iii) pay the fair market value rental rate to the vendor.

This arrangement may implicate the Anti-Kickback Statute because the vendor provides free equipment to a health care provider, who will also purchase disposable products reimbursable by a federal health care program. The OIG could potentially view this as the payment of remuneration in exchange for purchasing an item or service for which payment may be made under a federal health care program. If that is the case, both parties involved in the arrangement could potentially face civil and criminal penalties for violating the Anti-Kickback Statute if either party was found to have an improper intent. The parties would, however, be protected from liability if the arrangement was restructured to satisfy applicable safe harbors. Because the title of the equipment in this arrangement does not transfer to the provider, the parties should consider restructuring the arrangement so that it fits within the equipment rental safe harbor and the discount safe harbor.[93] These requirements can be met in a few different ways, such as via separate payment or bundled payment or by establishing the absence of independent value. In other cases, however, the "floating

93 To satisfy the Equipment Rental Safe Harbor, the parties need to memorialize the equipment portion of the arrangement in a written agreement. The agreement must have a term of at least one year, which practically speaking, means the agreement cannot be terminated without cause during the initial year. Additionally, the rental rate must be "set in advance" at "fair market value," must not consider "the volume or value of any referrals," and the aggregate rent must be "commercially reasonable." When the parties allocate a rental rate to the equipment placed with the health care provider, the health care provider must actually pay the rental amount, and the related documentation (e.g., invoices) should be consistent with the written agreement.
To satisfy the Discount Safe Harbor, the vendor would need to fully and accurately report the discounted price of the disposable to the health care provider, inform the health care provider of its reporting obligations, and refrain from anything that would impede the health care provider from meeting such obligations. The health care provider would need to comply with applicable reporting requirements. For example, if the health care provider buyer is a hospital, the hospital must fully and accurately report the discounted disposable price on its cost report during the same fiscal year in which the purchases were made and respond to any requests from the Secretary of HHS regarding documentation of such discount.

nature" of a rental payment may not comport with fair market value and prevent an arrangement from being protected by a safe harbor.

Separate payment

If the equipment in Hypothetical 1 has a fair market value rental rate of $1,200 per year, the parties could allocate $24 per unit of disposables to the rental of the equipment. The simplest way to achieve this outcome is for the provider to pay the $1,200 separately, or by installments, and for the disposable price to be set at $76 per unit. This would likely work operationally, however, only if the parties had a firm idea of the estimated volume of disposables to be purchased. Such an arrangement should generally be able to fit within both the equipment rental safe harbor and the discount safe harbor provided all other safe harbor elements are met, such that the remaining $76 per unit would represent a discounted disposable purchase price.

Bundled payment

Many vendors may not want to renegotiate the disposable price on the front end and instead insist on a bundled payment that includes both the rent allocation and disposable price. Such an arrangement may still meet the requirements of the safe harbors. If the parties are only able to negotiate a bundled payment, the parties would need to ensure that the price of the disposables drops once the total fair market rental rate for the equipment has been paid through purchases of the disposable products in a given contract year. For example, if the parties specified that $24 of the $100 per unit price is fairly allocated to equipment rent, then once the health care provider has purchased 50 disposables at $100 per unit, the provider has paid a total of $1,200 towards rent, and the per unit price of the disposable should drop to $76 beginning with the fifty-first disposable purchased during the year. If the contract is terminated prior to the end of the contract year, the health care provider would pay the vendor any remaining rental amount for the period of time the provider rented the equipment. Such a structure may allow the parties to arguably meet both applicable safe harbors and retain a bundled pricing model.

Independent value

Vendors may argue that they can provide the free equipment as part of an arrangement for the purchase of disposables because the equipment has "no independent value" apart from the disposables being purchased. The OIG is skeptical of such an argument and has previously expressed concern that many of these arrangements could be shams.[94] Nonetheless, it is worth noting that the OIG recognizes in rare circumstances that certain equipment may not have value outside the vendor's arrangement (e.g., a printer that can only be used to print laboratory test results generated through the vendor's arrangement with the health care provider).[95] Factors that may likely support equipment having no independent value include the following:

- Vendor does not have a list price or rental price for the equipment
- Health care provider cannot separately purchase or rent the equipment on the open market
- Competing vendors do not charge to rent or sell the equipment
- Equipment cannot be used without related disposables being purchased
- Equipment is not integral in the provision of a billable health care service
- Use of the equipment is not separately reimbursable from the disposables
- Equipment location limits access and use outside of the arrangement
- Equipment only adds limited value to health care provider's core services

While the OIG has historically identified that, in limited circumstances, certain equipment can be provided for free because it has no independent value, the frequency with which the argument is invoked suggests that this concept is frequently misunderstood and misapplied. If the provision of free equipment has a fair market value associated with it on the open market, or if it is integral to the provision of a billable health care service, providers and their counsel should proceed with caution.

94 *McAnaney Letter*.
95 *OIG Anti-Kickback Provisions*, 56 Fed. Reg. 35952, 35978.

There are several variations on Hypothetical 1 that appear to accomplish the same objectives; however, upon closer inspection, they would not likely have the protection of the equipment rental safe harbor and discount safe harbor under the Anti-Kickback Statute, as illustrated in Variation A below:

> Variation A: The health care provider pays the vendor a disposable per unit price of $100, which the written agreement states includes both $24 for the fair market value rental rate of the equipment and $76 for purchase of the discounted disposable. The per unit price of the disposable does not change during the term. Further, the annual purchase commitment is only 100 disposables and the estimated fair market value of the equipment rental is $5,000 per year.

Floating rent

Based on such terms, the agreement described in Variation A would not satisfy the equipment rental safe harbor because the health care provider is not paying a rental rate for the equipment that is set in advance and consistent with fair market value. Given the floating nature of the rental payment, it is unclear whether it would comport with fair market value. For example, if the health care provider satisfies the annual purchase commitment for disposables and buys 110 disposables in the first contract year, it will only pay $2,640 in annual rent towards the equipment (110 x $24), which is far below the estimated fair market value rental rate of $5,000 per year. On the other hand, if the health care provider buys 250 disposables in the first contract year, it will pay $6,000 (250 x $24) in annual rent towards the equipment, which is far above the estimated fair market value of the equipment. This variation illustrates the importance of negotiating the terms of the agreement so that either (a) rent is paid separately from the disposables, or (b) the disposable price—including the equipment rent—decreases by the per unit rental amount when the health care provider has satisfied the fair market value rental rate of the equipment through purchases of the disposables in a given contract year, and, if the applicable volume requirement of disposables is not met, the provider will pay the difference in the fair market value rental rate of the equipment due to the

shortfall of the disposables purchased. Given that the total amount of equipment rent paid during the year fluctuates based on the volume of purchases during the year, this variation may run afoul of the fair market value requirement under the equipment rental safe harbor, and also fail to meet the safe harbor's requirement that the aggregate rental rate be set in advance.

Equipment purchase and rebates on disposable purchase arrangement

The arrangement described in Hypothetical 2 below should be analyzed under the Anti-Kickback Statute. In this example, a health care provider is earning rebates on the purchases of disposable products that can be redeemed to purchase equipment, which could potentially be considered the offer or payment of remuneration in exchange for purchasing an item for which payment is made under a federal health care program.

> Hypothetical 2: A health care provider contemplates purchasing a $5,000 piece of equipment from a vendor pursuant to a five year installment payment plan under which title transfers at the end of the plan. During the term of the agreement, the health care provider purchases related disposable products at $100 per unit, and the provider can earn a rebate on the purchase of disposables that can be credited against the amount owed for the purchase of the equipment. For each contract year during the five-year term, the total rebate amount earned on disposable purchases may meet, but not exceed, the amount of installment payment owed to the vendor for the equipment. Thus, the health care provider can earn a $10 rebate on the first 100 disposables purchased in a given contract year, which means $1,000 in rebates can be applied to the equipment installment payment that year. Once the health care provider has earned $1,000 in rebates on disposable purchases, the health care provider will continue to pay $100 per unit for any disposable purchased above 100 units, but will not receive a rebate. The vendor also agrees to provide all necessary maintenance, repair, and replacement services for the equipment at no extra charge to the health care provider during the term of the agreement.

To satisfy the discount safe harbor, the parties in Hypothetical 2 should ensure that the rebate, which is earned on disposable products and applied to the purchase of the equipment, involves items that are reimbursed under the same methodology and that other requirements of the safe harbor are satisfied. The parties should also structure the arrangement such that the health care provider will pay the difference between the equipment installment payment and the earned rebate in any given contract year when the earned rebate falls short of the installment payment to reduce the risk that the provider receives free equipment under the arrangement in violation of the Anti-Kickback Statute.

Capped rebate

The more complicated question lies in whether it is commercially reasonable to cap the rebate at the cost of the installment price of the equipment. One would imagine that a rebate would continue in the same manner as a volume based discount. There is the possibility that regulators may scrutinize whether the arrangement was a mechanism to provide free equipment to the provider. The authors note, however, that there is nothing *per se* illegal about providing a capped rebate, and many vendors employ this model, relying on the fact that the discount safe harbor does not prohibit capped rebates.

Warranty

Regarding the services provided in Hypothetical 2, the parties should also keep the Anti-Kickback Statute warranty safe harbor in mind. The OIG definition of a "warranty" references the definition in 15 U.S.C. § 2301(6), which provides that a warranty is a written promise that an item will meet certain performance specifications and will be defect free, or the seller will repair and replace a product.[96] Depending on the specific circumstances, the provision of services by a vendor to a provider may meet the definition of a "warranty" under the warranty safe harbor.[97] To satisfy this safe harbor, the parties must ensure that the vendor's promise to provide maintenance, repair, and replacement services for the equipment during the term of the arrangement for no extra charge is

96 *See* 42 C.F.R. § 1001.952(g); 15 U.S.C. § 2301(6).
97 *See* OIG Advisory Op. 17-03 (Aug. 18, 2017).

accurately reported by the seller on an invoice and other written documentation to the buyer, and the warranty is accurately reported by the buyer on its Medicare cost report. As long as the vendor meets the warranty safe harbor requirements of a seller and the health care provider meets the requirements of a buyer, this portion of the arrangement could be protected by the warranty safe harbor.

Finally, it is worth noting that one variation on Hypothetical 2 would not have the protection of the discount safe harbor under the Anti-Kickback Statute:

> Variation A: The vendor enters into an arrangement to sell the equipment to the health care provider under the same installment payment plan outlined in Hypothetical 2, but in this instance, the vendor immediately transfers title to the equipment upon delivery and installation at the provider's facility. In the event the provider does not purchase 100 disposables in a contract year, and thus does not earn $1,000 in rebates to apply to the annual equipment installment payment owed to the vendor, there is no penalty against the provider. The provider retains title to the equipment even if the provider defaults on its obligations to make the installment payments or terminates the agreement prior to the end of the five-year term.

Based on such terms, the agreement potentially would not satisfy the discount safe harbor. The fact that the vendor sells the equipment and transfers title immediately without any security agreement or restriction on the transfer of the equipment suggests that the provision of the equipment could be considered a prebate. As noted above, a prebate is a rebate-like discount that is not earned on actual purchases but given at the start of the arrangement.[98] Prebates are not protected by the discount safe harbor because they have the effect of "locking in" purchasers and encouraging overutilization.[99] Thus, this variation could potentially subject the parties to additional scrutiny under the Anti-Kickback Statute.

98 *See Thornton Letter*.
99 *Id.*

Discounted products purchased by GPOs

The next hypothetical describes an arrangement that should be analyzed under the Anti-Kickback Statute. In this case, a health care provider's receipt of administrative fees from the GPO, which are paid to the GPO by the vendor based on purchases made by the provider, could potentially be considered remuneration in exchange for the provider purchasing an item for which payment may be made under a federal health care program.

Hypothetical 3: The vendor enters into a written agreement with a GPO through which the vendor agrees to sell products to the GPO's participating health care providers at a price based on an annual volume commitment. The greater the volume commitment, the less the GPO health care providers pay per unit for the product (see Table 1 below). In addition, the GPO has a separate written agreement with each participating health care provider that states the vendor will pay the GPO an annual administrative fee equal to 3% or less of the total purchase price of the products that the vendor provides to the GPO's participating health care providers per year. The GPO also agrees to remit 10% of all administrative fees from vendors contracting with the GPO to each participating health care provider.

Table 1. Volume commitment and cost per unit

ITEM	LEVEL 1: 1-100 units purchased per year	LEVEL 2: 100-200 units purchased per year	LEVEL 3: 200+ units purchased per year
ITEM A	$15 per unit	$14 per unit	$13 per unit

The parties in Hypothetical 3 should consider the GPO safe harbor. As described above, the agreement between the GPO and the health care provider satisfies the GPO safe harbor requirements if the agreement is in writing and states that the vendor will pay a fee of 3% or less to the GPO based on products provided by the vendor. To ensure the parties are protected by this safe harbor,

the GPO must also disclose to the provider in writing at least annually the amount received from the vendor with respect to the purchases made by or on behalf of the provider.

The discount safe harbor is also applicable to the discount on product prices that the vendor provides to the health care provider through the GPO. So long as the arrangement meets the documentation and reporting requirements of the discount safe harbor applicable to the type of buyer/seller, the discounted pricing should fit within this specific safe harbor. For example, from a best practices standpoint, if the buyer is a hospital, the arrangement should be properly documented in a signed, written agreement between the parties. Additionally, the hospital buyer should properly report the discounts earned in its cost report, and the vendor should fully and accurately report the discount on the applicable invoices. Because the tiered pricing is structured based on the hospital's annual volume, the arrangement likely satisfies the requirement of the discount safe harbor that the discounts are earned based on the buyer's volume of purchases during a single fiscal year; however, the parties should still assess the volume earned during the buyer's fiscal year as compared to a year under the contract term. The discounts are claimed during the same fiscal year in which they were earned, or the following fiscal year. In this example, there is no requirement that the buyer implement sales tactics to increase purchase volume in order to achieve the discounted pricing. The DOJ has commented that if parties to an arrangement "simply agreed to a pricing structure that offered escalating discounts in return for increased sales," and the buyer then independently (not pursuant to an agreement with the vendor) relied on certain sales tactics to achieve the increased sales that result in discounted pricing under the arrangement, then the arrangement would qualify as a discount and therefore would not violate the Anti-Kickback Statute.[100]

On the other hand, the following variation on Hypothetical 3 raises further issues that should be carefully analyzed under the Anti-Kickback Statute:

100 *See Coloplast SOI.*

Variation A: The vendor enters into a written agreement with a GPO through which the vendor agrees to sell products to the GPO's participating health care providers at a price based on a market-share commitment. The greater the market-share commitment, the less the GPO health care providers pay per unit for the product (see Table 2 below).

Table 2. Market-share commitment and cost per unit

ITEM	LEVEL 1: No purchase commitment	LEVEL 2: GPO purchases 50% of total product needs from vendor	LEVEL 3: GPO purchases 75% of total product needs from vendor
ITEM A	$15 per unit	$14 per unit	$13 per unit

In this variation of Hypothetical 3, the arrangement could potentially be considered remuneration in exchange for the health care provider purchasing an item for which payment may be made under a federal health care program because the provider's receipt of administrative fees from the GPO are paid to the GPO by the vendor based on purchases made by the health care provider.

Case law and OIG guidance

In addition to the GPO safe harbor considerations, the parties should contemplate relevant case law and OIG guidance, which warns of the unique risks associated with discounts tied to market-share. For example, in *United States ex rel. Banigan et al. v. Organon USA Inc., et al.*, relators alleged that Organon offered long term care pharmacies "kickbacks, allegedly disguised as market-share discounts and rebates" in addition to other incentives to induce such pharmacies to switch patients to Organon's drugs.[101] The DOJ did not intervene in the case, but issued a Statement of Interest that explained a discount or rebate

101 United States ex rel. Banigan et al. v. Organon USA Inc., et al., 883 F. Supp. 2d 277 (2012).

given in an effort to switch patients to the manufacturer's drugs are not protected by the discount safe harbor simply because they are called discounts or rebates.[102] Organon paid $34 million to settle alleged violations of the Anti-Kickback Statute and false claims paid by Medicaid in New York.[103] Similarly, in *United States ex rel. Lisitza et al. v. Johnson & Johnson et al.*, it was alleged that Johnson & Johnson paid kickbacks, "including market share rebate payments . . . which J&J intended to induce Omnicare to purchase and to recommend J&J drugs."[104] In 2013, Johnson & Johnson settled all criminal and civil allegations arising from these arrangements for $2.2 billion.[105]

Based on such guidance and case law, health care providers that enter into arrangements should do so understanding that such arrangements are subject to additional scrutiny under the Anti-Kickback Statute.

Discounts on "preferred products"

This last hypothetical illustrates how earning discounts on drugs in exchange for listing those drugs as "preferred products" may implicate the Anti-Kickback Statute.

> Hypothetical 4: The vendor enters into an agreement with a health care provider to purchase drugs at a discounted price set forth in the agreement. In exchange, the health care provider is required to list the vendor's drugs as one of three "preferred" products. Upon request from the vendor, the health care provider must produce documentation that demonstrates the vendor's drug is listed as a preferred product.

102 Statement of Interest on Behalf of the United States of America in Response to Defendant's Motions toDismiss the Complaint at 6, United States ex. rel. Banigan v. Organon USA, No. 07-121153 (D. Mass. Sept. 30, 2011).

103 *Organon to Pay $34 Million to Settle False Claims Charge*, Corp. Crime Rep. (Oct. 15, 2014), www.corporatecrimereporter.com/news/200/organon-pay-34-million-settle-false-claims-charge/.

104 United States ex rel. Lisitza, et al. v. Johnson & Johnson, et al., Nos. 07-10288-RGS & 05-11518-RGS (D. Mass. Jan. 15, 2010).

105 *Johnson & Johnson to Pay More than $2.2 Billion to Resolve Criminal and Civil Investigations*, U.S. Dep't of Justice (Nov. 4, 2013), www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations.

This arrangement should be analyzed under the Anti-Kickback Statute because a health care provider earning a discount on drugs in exchange for listing it as a "preferred product" could potentially be considered the offer or payment of remuneration in exchange for purchasing or recommending the purchase of an item for which payment would be made under a federal health care program. In addition to considerations of the discount safe harbor, the parties should review the arrangement in light of the OIG Compliance Guidance to Pharmaceutical Manufacturers, which specifically warns of the potential for fraud and abuse arising out of a pharmaceutical manufacturer's relationship with members of a committee that makes decisions about preferred products and develops formularies.[106] Specifically, the OIG expressed concern that any direct or indirect remuneration to an individual on such committee could influence their decisions about the vendor's product and such arrangements are "suspect and should be carefully scrutinized."[107]

Based on such guidance, health care providers that enter into such arrangements have a heightened risk of governmental scrutiny under the Anti-Kickback Statute and should, therefore, ensure that all vendors are prohibited from funding, participating in, and/or preparing materials for committee meetings on preferred products or formularies. A health care provider committee that is tasked with identifying preferred products or developing a formulary should comply with the provider's policies and procedures regarding conflicts of interest. Finally, a provider should not allow a committee's decision on preferred products or formularies to be reviewed or revised in conjunction with negotiating vendor agreements. The authors note that the issues related to the activities of a formulary committee can be numerous, and these are just some of the key parameters for providers and their counsel to consider.

106 OIG Compliance Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23736 (May 5, 2003), *available at* www.gpo.gov/fdsys/pkg/FR-2003-05-05/pdf/03-10949.pdf.

107 *Id.*

Conclusion

The OIG's active targeting of suspect vendor arrangements that involve obvious violations of health care fraud and abuse laws and/or conflicts of interest, such as vendors giving health care providers free travel, meals, or other unrelated remuneration in exchange for their referrals or health care providers accepting financial benefits in exchange for their promotion of particular product or piece of equipment, are widely publicized. Other arrangements will also require that providers and their counsel understand how such arrangements may implicate health care fraud and abuse laws, such as vendor arrangements that involve the purchase of disposables coupled with the purchase or the placement or lease of free or discounted equipment. Parties that find themselves negotiating these agreements should clarify the financial terms, involve legal counsel early in the negotiation process, encourage direct communication between the parties' legal counsel when operational and clinical stakeholders encounter roadblocks, and develop template financial arrangements and standard contract provisions for the organization that also takes into consideration its risk tolerance. J

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