HCCA
HEALTH CARE COMPLIANCE ASSOCIATION

Compliance TODAY

June 2015

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

WWW.HCCA-INFO.ORG

20 years of HCCA

How the association came to be, where it has been, and where it is going

an interview with Debbie Troklus

Managing Director, Aegis Compliance and Ethics Center;
Co-founder, Health Care Compliance Association

See page 16

by Thomas N. Bulleit and Peter P. Holman, Jr.

Medicare "carve-out" arrangements: No safe haven for PODs

- OIG's 2013 Special Fraud Alert declared that physician-owned distributors (PODs) of implantable medical devices, are "inherently suspect" under the Anti-Kickback Statute (AKS).
- Based in part on OIG's declaration, the U.S. DOJ initiated at least two false claims lawsuits against hospitals for surgeries using POD implants.
- The risk of dealing with PODs is not eliminated by "carving out" purchases of implants for federal healthcare program patients and buying from the POD only for private-pay patients.
- In 2014, OIG reaffirmed its longstanding view that limiting improper payments to private-pay only business may actually show intent to violate the AKS.
- Hospitals should carefully consider these regulatory and enforcement concerns when approached about purchasing from PODs, even if only for private-pay referrals.

Thomas N. Bulleit *(tom.bulleit@ropesgray.com) is a Partner at Ropes & Gray in Washington DC and* ***Peter P. Holman, Jr.****, a former Ropes & Gray Associate, is an Associate General Counsel at Dartmouth-Hitchcock Medical Center in Lebanon, NH.*

You are a hospital chief compliance officer who has just been approached with a proposition by the manager of the Orthopaedic Surgery department. A pair of your star surgeons—one specializing in spinal fusions and the other in knee replacements—have announced that they want the hospital to buy implants for their procedures through a new company in which they will be part owners. You've heard of these arrangements—physician owned distributors (PODs)—and you remember that the Office of Inspector General of the U.S. Department of Health and Human Services (OIG), in a recent Special Fraud Alert,[1] has called them "inherently suspect" under the Anti-Kickback Statute (AKS). You also recall that the same Special Fraud Alert specifically stated that AKS liability exists for the purchasing hospital if even one purpose of the decision to buy from a POD is to maintain or secure referrals from the POD's physician-owners. You advise the manager that, as much as you'd like to accommodate these heavy-hitters, you don't think the hospital can take the compliance risk.

Bulleit

Holman

But, the manager tells you, here the surgeons have offered a twist: This POD will supply implants only for private-pay patients. The manager suggests that this avoids the AKS risk, which seems to make sense: the AKS is about remuneration for referrals of patients on Medicare and other federal healthcare programs, right? So the manager says that the arrangement will work if the surgeons just

continue to order from their usual supplier for their Medicare cases, and order from the POD only for their private-pay patients. Sounds like a great solution, right?

Unfortunately, it is an entirely wrong interpretation of the AKS. As explained below, the AKS applies to remuneration that is intended to induce the referral of federal healthcare program patients, including remuneration that is paid only in connection with the referral of private-pay patients. There is abundant guidance from OIG that Medicare "carve-outs" (and the corollary practice of "swapping" remuneration on private-pay business for federal healthcare program referrals) not only do not protect against AKS liability, they may actually be evidence from which the government (or a *qui tam* relator) may infer the bad intent necessary to make out an AKS violation.

Under the AKS, as amended by the Affordable Care Act, claims submitted to the government for federal healthcare programs may be "false" if they were the product of illegal kickbacks in violation of the AKS.

AKS basics

The AKS prohibits giving or receiving any remuneration in exchange for, or to induce, the referral of any patients for any item or service for which payment may be made under any federal healthcare program.[2] Penalties for violation of the statute include criminal fines, imprisonment, civil monetary penalties, and exclusion from participation in federal healthcare programs.[3] Courts and administrative bodies interpreting the law have stated that the statute is violated even if "one purpose"—as opposed to the sole or primary purpose—of a payment arrangement is to induce referrals for services or purchases of items reimbursable under federal healthcare programs.[4] Intent need not be shown by direct evidence, but may be inferred from the surrounding circumstances; for example, where a compensation arrangement exceeds fair market value, the amount above fair market value has been found to be intended as a payment for referrals.[5]

Importantly, where improper intent was present, courts have found unlawful remuneration in the giving of an opportunity to earn a profit,[6] and in earning a return on investment.[7]

In recent years, potential AKS violations often have been pursued under the federal False Claims Act (FCA), which prohibits the knowing submission of false claims to the government.[8] Under the AKS, as amended by the Affordable Care Act, claims submitted to the government for federal healthcare programs may be "false" if they were the product of illegal kickbacks in violation of the AKS.[9] Penalties under the FCA greatly increase the potential financial harm of an AKS violation, with penalties of up to $11,000 per false claim, and treble the amount of damages to the government.[10]

A hospital's arrangement to buy through a POD may violate the AKS if one purpose of the agreement is for the physician's POD payouts to induce the physician to refer patients to the hospital.[11] A recent enforcement action has highlighted the risk that hospitals face. On September 8, 2014, the U.S. Department of Justice (DOJ) alleged FCA violations against

physician and non-physician owners of two PODs. In the complaint, the DOJ stated that hospital claims filed pursuant to the POD-induced referrals were themselves violations of the FCA. Although the government did not pursue sanctions against the hospital in this instance—noting that the hospital was unaware of the physician's relationship with the POD—the complaint opened the door to future actions against hospitals for their POD relationships.[12] Indeed, in light of the Special Fraud Alert, hospitals are effectively on notice to conduct due diligence on physician ownership interests with device distributors, as part of an effective compliance program. In other words, lack of knowledge of a physician's relationship with a POD, in the absence of appropriate inquiry, likely will not serve hospitals as an effective defense.

Skepticism of carve-outs

Because the AKS applies only to federal healthcare program business, enterprising healthcare providers have long looked for ways to segregate their Medicare referrals from their private-pay business. For just as long, OIG has been reminding providers that this is not an effective way of avoiding AKS liability.

In Advisory Opinion 99-13, OIG considered a practice in which a pathology laboratory furnished its services to referring physicians. For federal healthcare program patients, the company billed the government program directly. For non-federal healthcare program patients, the company would bill the referring physician at a discount (claiming that the discount reflected, in part, administrative savings), and the physician would bill the private payer and keep the spread. Importantly, the referring physicians typically sent their federal healthcare program business as well as their private-pay business to the company. Furthermore, the company's discounts to physicians allegedly resulted in charges to the physician that were lower than the cost savings the company purportedly achieved. Despite the fact that the referring physicians received remuneration from the company only for their private-pay business, OIG concluded that "the [referring] physicians may be soliciting improper discounts on business for which they have the opportunity to earn money in exchange for referrals of [federal healthcare program] business for which they have no opportunity, but for which the [company] can receive additional revenue."

In Advisory Opinion 11-08, the OIG addressed a case in which a durable medical equipment (DME) supplier received referrals of federal healthcare program and private-pay patients from certain physician-owned independent diagnostic testing facilities (IDTFs) for equipment used to treat obstructive sleep apnea. For private-pay patients only, the DME supplier would make payments to the IDTFs for services related to setting up the equipment and educating the patient; the supplier would not make such payments for federal healthcare program beneficiaries. OIG observed its "long-standing concern about arrangements pursuant to which parties 'carve out' Federal healthcare program business…from otherwise questionable financial arrangements."[13] OIG went on to observe that "[s]uch arrangements implicate and may violate the [AKS] by disguising remuneration for Federal business through the payment of amounts purportedly related to non-Federal business." OIG concluded that such could be the case in the indicated arrangement, because "IDTFs… may still influence referrals of [federal healthcare program] business to the [DME provider]."

In another recent carve-out example, described in Advisory Opinion 13-03, a parent clinical laboratory proposed to establish a subsidiary management company that would

provide facility space, equipment, and laboratory management and support services to physician-group laboratories (PGLs). Under the supervision of the management company, the PGLs would process samples and bill only for private-pay patients. The PGLs would send samples for federal healthcare program patients elsewhere, including possibly the parent clinical laboratory. The OIG concluded that the proposed arrangement provided remuneration to physician groups by furnishing them access to the "potentially lucrative" clinical laboratory business for "little or no risk," and highlighted the potential AKS risk by noting that "[a]lthough the [PGLs] would bill only for services for non-[federal healthcare program] patients, participation in the Proposed Arrangement may increase the likelihood that physicians will order services from the Parent Laboratory for FHCP beneficiaries."

In addition to the OIG, the DOJ has condemned these practices, and has pursued providers found to engage in them. In one high-profile case, a large ambulance provider, American Medical Response, Inc. (AMR), agreed to pay the government $9 million for AKS and FCA violations resulting from an alleged swapping scheme. Under the arrangement, AMR allegedly agreed with hospitals to transport non-federal healthcare program patients at discounts generally below AMR's actual costs, in exchange for the exclusive right to transfer all or nearly all discharged patients, including federal healthcare program beneficiaries, for which AMR would bill the full cost. Because the discounts helped secure referrals of federal healthcare program beneficiaries, DOJ alleged that they were "illegal inducements" under the AKS.[14]

In June of 2014, OIG issued a Special Fraud Alert on Laboratory Payments to Referring Physicians. As above, it emphasized that "[a]rrangements that "carve out" [federal healthcare program] beneficiaries or business from otherwise questionable arrangements implicate the [AKS] and may violate it by *disguising remuneration* for [federal healthcare program] business through the payment of amounts purportedly related to non-[federal healthcare program] business."(emphasis added)[15] In other words, the OIG suggests that the mere fact that an arrangement is designed to carve out remuneration for federal healthcare program referrals may itself be an inference of improper intent under the AKS. Notably, OIG's past advisory opinions have focused on the AKS liability of the referral recipient for offering or *paying* remuneration. In contrast, in the 2014 Special Fraud Alert, OIG goes out of its way not only to highlight compliance risks to the referral recipient, but also to state that participating in a carve-out may be evidence of improper intent on the part of the referring physician.[16]

The rule that emerges from these examples is that, at least where the remuneration itself is suspect (e.g., below-cost discounts, lucrative business opportunities with little or no financial risk, or other "inherently suspect" business arrangements) the fact that payment is limited only to private-pay business is essentially irrelevant if the recipient also sends Medicare or other federal healthcare program business to the same provider or supplier. It is easily inferred that one purpose of the arrangement is to trade payment on the private-pay side for the referral of all business, private and federal. A corollary to this rule is that only by completely segregating its business (i.e., sending all federal referrals to Provider A, and all private-pay patients to Provider B) could the referrer avoid this problem. Note that this means not just all Medicare referrals for the particular product on which the private-pay payment is made, but all Medicare patients of any kind, for any purpose. Even if this kind of arrangement were possible, it seems doubtful that it could effect good clinical practice.

The continuing POD risk for hospitals

The application of the "no carve-outs" rule to hospitals and PODs is obvious. As long as the same physicians who make POD earnings from their private-pay referrals to the hospital also send Medicare or other federal healthcare program patients to the hospital, the carve-out is ineffective. Moreover, the very existence of the carve-out is evidence from which it may be inferred that the parties are aware that remuneration for non-federal healthcare program patients "disguises" remuneration for federal healthcare program referrals.

Conclusion

It is "inherently suspect" under the AKS for hospitals to receive any federal healthcare program referrals from the physician-owners of a POD, even if the hospital buys from the POD only for the physicians' private-pay patients. The carve-out of federal healthcare program business from the POD only emphasizes that the hospital is—or should be—aware of the impropriety of the arrangement, thus providing the evidence for the government or a *qui tam* relator to allege bad intent. Hospital compliance officers should be wary of this variation on the POD theme, and should make sure their executives are equally informed.

1. Office of Inspector General of the U.S. Department of Health and Human Services: Special Fraud Alert: Physician-Owned Entities. March 26, 2013. Available at http://1.usa.gov/1Gn12xw
2. 42 U.S.C. § 1320a-7b(b).
3. 42 U.S.C. § 1320a-7 (exclusion from federal healthcare programs); § 1320a-7a (civil monetary penalties of up to $50,000 per act plus three times the remuneration); § 1320a-7b(b) (imprisonment of up to five years or criminal fines of $25,000 or both); 18 U.S.C. § 3571 (augmenting penalties: $250,000 per violation for individuals and $500,000 per violation for entities).
4. See, e.g., *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985), *cert. denied*, 474 U.S. 988 (1985). Available at http://bit.ly/1FhuXWk
5. *United States v. Lipkis*, 770 F.2d 1447 (Ninth Circuit Court of Appeals, 1985). Available at http://bit.ly/1DgWEZk
6. *United States v. Bay State Ambulance and Hosp. Rental Servs., Inc.*, 874 F.2d 20, 29 (1st Cir. 1989). Available at http://bit.ly/1aVQQWs
7. *Hanlester Network v. Shalala*, 51 F.3d 1390, 1401 (9th Cir. 1995). Available at http://bit.ly/1GmK4fQ
8. 31 U.S.C. §§ 3729-3733.
9. 42 U.S.C. § 1320a–7b(g).
10. 31 U.S.C. § 3729(a).
11. *Idem*, ref #1; see also *Greber*, 760 F.2d at 72.
12. United States' Complaint, *United States v. Reliance Medical Systems, LLC*, Case No. CV14-6979 (Sep. 8, 2014). Available at http://bit.ly/1yXM7hY
13. See also 56 Fed. Reg. 35977 (July 29, 1991) on joint ventures. Available at http://bit.ly/1EiY4i3
14. U.S. Department of Justice press release: American Medical Response Pays $9 Million to Settle Civil Fraud Case, October 5, 2006. Available at http://1.usa.gov/1Ew1cC8 ; United States' Complaint, *United States v. Laidlaw, Inc.*, Case No. SA-01-CA-0256 (March 26, 2011).
15. Office of Inspector General of the U.S Department of Health and Human Services: Special Fraud Alert: Laboratory Payments to Referring Physicians. June 25, 2014. Available at http://1.usa.gov/1GbDLsW
16. *Id.*