QUALITY IMPLANT COALITION BACKGROUNDER

PODs v. Physician-Owned Providers of Health Care Services

Physician-owned medical device distributors (PODs), which allow physician-investors to receive a share of the POD's profits from sales of the implantable medical devices that the physician-investors order for their own patients, represent the latest in a long history of ethically and legally questionable arrangements designed to allow physicians to profit from their self-referrals for items and services. Through a series of modifications to the Medicare program, Congress and the Department of Health and Human Services have gradually diminished these opportunities, except for services provided in the doctor's own office and for ambulatory surgical centers (ASCs) and certain hospitals. The history and rationale behind why physician ownership is permitted in these limited circumstances but prohibited in others illustrates why physician ownership of PODs – supply chain vendors that lack even the dubious legitimacy of freestanding providers of regulated health care ancillary services – ought to be viewed as inherently suspect under the fraud and abuse laws.

Historical and Legal Background on Physician Ownership

- In the 1980s and early 1990s, referring physicians were fairly routinely offered opportunities to "invest" in ancillary service ventures, including clinical laboratories, imaging, radiation, home infusion, and durable medical equipment companies.[i]
- Relying on several studies that showed higher rates of ancillary service utilization when the referring physicians were owners than when they were not, Congress and OIG acted to curb these abusive self-referrals in two principal ways.[ii]
    - First, OIG issued its Special Fraud Alert on Joint Venture Arrangements, identifying characteristics of physician ownership of ancillaries that were suspect under the antikickback law (AKL).[iii]
    - Second, Congress enacted the Ethics in Patient Referrals (Stark) Act, outright forbidding physician self-referral to a wide range of ancillary service providers.[iv]
- Notably, under both the AKL and the Stark law, physicians were permitted to continue to offer most ancillary services as a part of their office practice, where their professional and economic responsibility for the service (along with meeting certain regulatory requirements) is deemed a suitable protection from patient and program abuse.[v]
- Consistent with this idea that doctors should not be restricted in the types of services furnished in their own office practices, physician ownership also was permitted under the Stark law in whole hospitals where the physicians practiced, and ASCs were never included in the law's prohibition.[vi]
    - Though there was never an AKL exception or safe harbor for hospital ownership, OIG has only once acted to challenge physician owned hospitals under the AKL, and that circumstance involved a large number of allegations that ownership was not acquired for fair market value and was only one of several other financial relationships that in total demonstrated an intent to pay the doctors for their referrals.[vii]
- In addition, OIG acted to create antikickback law safe harbors for several different ASC models to protect ownership of ASCs by surgeons who use the facility as an extension of their office practice.[viii]
- A proliferation of physician-owned specialty surgical hospitals in the years following, and concerns that such hospitals were leading to diversion of sicker (and thus less profitable)

patients to general hospitals, led Congress ultimately to cut off new physician-investment in hospitals that treat Medicare patients. The new law grandfathered existing arrangements.[ix]

- OIG most recently spoke to the subject of physician ownership in its Special Advisory Bulletin on Contractual Joint Ventures, in which it elaborated on the AKL concerns that arise when physicians purport to offer a service through their office practice, but in fact outsource that service to a joint venture partner and contribute little but referrals to the venture.[x]
- A recent GAO report prepared at the request of Members of Congress affirmed that physician ownership of imaging services continues to result in higher rates of utilization and demonstrates continued Congressional concern with self-referral.[xi]

So it is a fair summary to say that the federal fraud and abuse laws have always taken a more approving attitude towards physicians actively owning and providing ancillary services as a part of, or an extension of, their office practice than towards physician-ownership of separate vendors where the physician is simply a passive investor and source of referrals.[xii] Furthermore, as it has identified new concerns – first clinical laboratories, then imaging and other designated health services, and most recently specialty surgical hospitals – the federal government has acted to tighten still further the ability of a physician to benefit as a passive investor from a financial return on referrals.

Comparison of PODs to Accepted Physician Ownership Models

Notably, supply chain vendors, such as PODs, are nowhere to be found in the continuum of physician ownership models previously examined by Congress, OIG, and CMS. They are beyond the fringe even of ancillary service providers that are not a part or an extension of the doctor's practice and as to which the doctor is simply a passive source of referrals.

- First, PODs do not provide medical services to patients. They are supply chain companies that are inserted between manufacturers and facilities. Their function in the supply chain is to offer physician-investors the opportunity to profit from the purchase and resale of orthopaedic implants to the hospitals to which they refer patients.
- Second, physician ownership of an ancillary services provider allows the physician to benefit financially from the services furnished by the facility only to the extent that its revenues exceed its costs. Its revenues are not impacted in any way by this physician investment. While physicians refer patients to the ancillary services provider, the patient or payor ultimately chooses the provider, not the physician. The physician receives no direct compensation for the referral.
    - In contrast, physician ownership of the implant supplier gives the doctor a direct return on a product that the facility must buy from the doctor at prices the doctor sets, without taking account of the facility's costs of operation. The physician-investor has an incentive to overutilize services as well as to increase the cost of the implant to the hospital.
    - Unlike a third party payor who can determine reimbursement rates independent of physician control of referral decisions, the hospital cannot make a purchase decision based on cost or profit or other objective concerns independent of the physician-investor's control of referrals to the hospital.
- Third, a POD is not even a regulated provider of a health care service; it has no quality or utilization review standards to meet, and no governmental scrutiny of its operations.
    - In contrast, physician-owned ancillary providers are subject to regulatory requirements including licensing and quality standards and certifications as well as audits and payment reviews and/or denials.

- Fourth, unlike medical practices and surgical facilities, physicians have no special expertise in medical device supply chain management, so to the extent the POD offers any services at all, the physician is not active in the management or oversight of that service.
    - Hospitals that typically would buy directly from the manufacturer instead pay a markup to buy through a POD and receive the same products they would if they had purchased from the manufacturer. It is difficult to see how hospitals could justify the prudence of this purchasing decision.
- Fifth, OIG and CMS have squarely expressed the opinion that PODs represent potential abuses that must be closely scrutinized under the fraud and abuse laws.

Acceptance of physician ownership of health care services thus is not universal, but there is a continuum of accepted physician ownership arrangements that does have logic and experience behind it and that has no place for PODs. At one end of the continuum, physicians who offer ancillary services for which they have professional and financial responsibility as a part of their office practice generally have specific regulatory approval. Next, services that are an extension of the physician's office practice (i.e., ownership in facilities where the doctors perform their procedures) traditionally either have been explicitly approved or viewed as sufficiently non-abusive to be tolerated by enforcement officials. At the other end of the continuum is passive physician ownership of ancillary service providers (including contractual joint ventures) where the doctor is principally a referral source. Most such arrangements that were in existence when the Stark law was enacted have been unlawful for Medicare patients for almost two decades. Those that are not strictly prohibited by Stark operate in a dubious legal landscape under threat of AKL prosecution.[xiii] Even this last category, however, at least involves only indirect profits based on a number of factors outside of the physician-investor's control that result from actual health care services rendered by providers who submit bills to Medicare and other payors and are subject to regulatory scrutiny.

PODs, however, are different from accepted physician ownership models and fall completely outside this continuum. They allow physician-investors to profit directly from their own services and involve only passive investments presenting no business risk with no accountability to patients, payors, or facilities, and they do not add any value to the supply chain or the implanting procedure.

December 2012

---

[i] *See, e.g.*, Hanlester Network v. Shalala, 51 F.3d 1390, 1401 (9th Cir. 1995) ("At the time appellants entered into the [laboratory] management agreements, these types of arrangements were fairly common"). *See also* Shalala v. RadiationCare, No. 1 :94-CV-3339-RCF, 1995 U.S. Dist. LEXIS 749 (N. D. Ga. 1995) and Shalala v. T2 Medical, No. 1-94-CV-2549-ODE, 1994 WL 686949 (N.D. Ga. 1994) (addressing physician investment in radiation therapy and home infusion centers).

[ii] "Joint Ventures Among Health Care Providers in Florida," State of Florida Health Care Cost Containment Board, January 1991.

[iii] *See* Department of Health and Human Services, Office of Inspector General, Special Fraud Alert: Joint Venture Arrangements (August 1989), *reprinted at* 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994).

[iv] 42 U.S.C. § 1395nn (enacted by § 6204(a) of Pub. L. No. 101-239 (Dec. 19, 1989) and § 13562(a)(1) of Pub. L. No. 103-66 (Aug. 10, 1993)).

[v] *See* 42 U.S.C. §§ 1395nn(b)(2) (enacted by § 6204(a) of Pub. L. No. 101-239), 1395nn(e)(7) (enacted by § 13562(a)(1) of Pub. L. No. 103-66); 42 C.F.R. § 411.355(b) (*published at* 60 Fed. Reg. 41914,

41978 (Aug. 14, 1995) (establishing Stark in-office ancillary services exception). *See generally* 42 U.S.C. § 1320a-7b (enacted by §§ 242, 278 of Pub. L. No. 92-603 (Oct. 30, 1972), 42 C.F.R. § 1001.952 (*published at* 57 Fed. Reg. 3330, 3334 (Jan. 29, 1992)) (establishing AKL without restrictions on in-office ancillary services).

[vi] 42 U.S.C. § 1395nn(d)(3) (enacted by § 6204(a) of Pub. L. No. 101-239). *See also* 42 U.S.C. § 1395nn(i)(1) (enacted by § 6001(a)(3) of Pub. L. 111-148 (March 23, 2010) (listing requirements for hospitals to qualify for hospital exception to ownership or investment prohibition).

[vii] Press Release, "Largest Health Care Fraud Case in US History Settled; HCA Investigation Nets Record Total of $1.7 Billion," U.S. Department of Justice, June 26, 2003, *available at* http://www.justice.gov/opa/pr/2003/June/03_civ_386.htm.

[viii] 42 C.F.R. § 1001.952(r) (*published at* 64 Fed. Reg. 63,551, 63,555 (Nov. 19, 1999)).

[ix] 42 U.S.C. § 1395nn(d)(3).

[x] *See* Department of Health and Human Services, Office of Inspector General, Special Advisory Bulletin on Contractual Joint Ventures (April 2003), *published at* 68 Fed. Reg. 23,148, 23,149 (April 30, 2003).

[xi] *See* Government Accountability Office, Report to Congressional Requesters: Higher Use of Advanced Imaging Services by Providers Who Self-Refer Costing Medicare Millions, September 2012, *available at* http://gao.gov/assets/650/648988.pdf (finding that the number of self-referrals for MRI and CT services from 2004-2010 increased substantially more than the corresponding increase for non-self-referred services during that time period).

[xii] Arguably an exception to this principle is physician-ownership of mobile lithotripsy providers. However, this exception arose only after extensive litigation by urologists in which CMS ultimately acquiesced (*See* American Lithotripsy Society v. Thompson, 215 F.Supp.2d 23 (2002)), and as recently as 2010, OIG prosecuted and obtained a settlement with a physician-owned lithotripsy provider under the AKL. *See* OIG Press Release, "OIG Enters Into $7.3 Million Civil Monetary Penalty Settlement With Physician-Owned Enterprise," July 8, 2010, *available at* http://oig.hhs.gov/publications/docs/press/2010/United_Shockwave_Press_Release.pdf.

[xiii] *See* OIG Press Release, "OIG Enters Into $7.3 Million Civil Monetary Penalty Settlement With Physician-Owned Enterprise," July 8, 2010, *available at* http://oig.hhs.gov/publications/docs/press/2010/United_Shockwave_Press_Release.pdf (imposing $7.3 million settlement with physician-owned lithotripsy and laser provider for allegations of federal anti-kickback law violations).