Physician-Owned Distributors: To Be or Not To Be?

This webinar is brought to you by the Life Sciences (LS) Practice Group and is co-sponsored by the Fraud and Abuse (Fraud) and Physician Organizations (Physicians) Practice Groups.

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Key Fraud and Abuse Laws

- Stark Law – Also Referred to as Physician Self-Referral Law
- Anti-Kickback Statute
Stark Law

• Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.

• Prohibits the entity from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third party payer) for those referred services.

• Establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.
The Anti-Kickback Statute

- Prohibits anyone from purposefully offering, soliciting, or receiving anything of value to generate referrals for items or services payable by any Federal health care program

- 42 states and D.C. have enacted their own anti-kickback statutes
Physician Owned Distributors (PODs)

- In Spring 2011, Senate Finance Committee began looking at PODs to determine what role they played in the marketplace.
- Sent letters to CMS and OIG in June 2011 asking for specific information about the role of PODs and how CMS/OIG current and future authorities addressed PODs.
PODs, Cont.

- In their 2012 work plan, OIG has included a study looking at the impact of PODs.
- Senate Finance has held numerous meetings with individuals and entities to better understand the role of PODs.
- To date, no determination as to the benefit/detriment of PODs has been issued by the Finance Committee.
Physician-Owned Distributors and Device Companies

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PHYSICIAN-OWNED DEVICE COMPANIES

- Boon or Boondoggle?
- Who is for/against them?
  - Big Device Companies
  - Their Competitors & Hospitals/Physicians
- When you’ve seen one physician-owned device company, you’ve seen one physician owned device company
PHYSICIAN-OWNED DEVICE COMPANIES: LEGAL LANDSCAPE

- Federal Anti-Kickback Statute
- Federal Physician Self-Referral Statute (the “Stark law”)
- State Equivalents
FEDERAL ANTI-KICKBACK STATUTE

- Understanding the “one purpose” test
  - Stated in cases; repeated by OIG
  - To what extent is it *dicta*?
- What does it mean to intend to “induce” someone?
  - Encouragement v. Inducement ("an intent to exercise influence over the reason or judgment of another")
  - (Hoping, expecting or believing referrals may ensue from remuneration is not the same as inducement)
- What does “knowingly and willfully” mean?
  - High level of *sciente*r
  - Knowing you are breaking the law or knowing your conduct is wrongful or corrupt is necessary
Potentially applicable to Physician-Owned Device Companies in Two Ways:

- Is investment in Company inducement to physicians to order company’s devices?
- Is the hospital’s purchase of devices inducement to physicians to refer patients?
Physician-owned laboratories

OIG asserted profit shares were illegal inducements

Court rejects OIG’s position, and holds physician investments are permitted under the anti-kickback statute

But, certain elements that tie the investment too closely with referrals can result in illegality
HANLESTER (Cont’d)

- What’s okay?
  - Selecting investors based on potential for referrals
  - High profits to investors
  - Venture dependant on physician investor referrals
  - But, return on investment must be based on ownership percentage, not referrals

- What’s not okay?
  - Implying that eligibility to purchase an investment interest in the business depends on an agreement to make referrals;
  - Telling investors that the size of the investment interests they would be allowed to purchase would depend upon the volume of business they referred; or
  - Stating that partners would be pressured to leave the partnerships if they did not make referrals
HOSPITAL – POD ARRANGEMENT (Kickback Compliance)

- Written purchase and sale agreement
- Fair market value prices (volume discounts are okay; increases based on referrals aren’t okay)
- No coercion by physician; no leveraging referrals
- Prices and other terms equal or better than non-physician owned vendors for comparable items
OIG alleged physician owners of lithotripsy companies “leveraged” their referrals to get business

Lithotripsy companies paid $7.3 million to settle

Problem was alleged link between using physician-owned business and physician referrals, i.e., physicians using the leverage of their referrals to pressure hospital to purchase from their business
Under indirect analysis the “aggregate” compensation received by POD varies with referrals to hospital, so physician owners have an indirect compensation arrangement with hospital.
STARK LAW: INDIRECT COMP. EXCEPTION

- Requires a written agreement
- Fair market value compensation that does not vary with referrals (note that per use payments are ok if the rate of payment does not increase with referrals)
- Arrangement must not violate the anti-kickback statute
PRACTICAL POINTERS & BEST PRACTICES:

The following “do’s and don’ts” are intended to provide practical advice and identify best practices, but are not necessarily absolute mandates or prohibitions in every case.
PRACTICAL POINTERS & BEST PRACTICES: (Cont’d)

- **DO** ensure that the Company provides the Hospitals with comparable (but preferably better) prices and price terms for the products, consistent with fair market value, than the Hospitals would be able to obtain if they purchased the products (or comparable products) from alternative sources.

- **DO** ensure that the Company offers the hospitals commercially reasonable representations, warranties, return policies, shipment terms and other non-price contract terms that are equal to or better than other vendors of comparable products, using signed, written agreements.

- **DO** have the Company employ its own personnel, who are well-trained on regulatory compliance issues and who perform the Company’s marketing, contract negotiations, and billing and collections.
PRACTICAL POINTERS & BEST PRACTICES: (Cont’d)

- **DO** encourage Hospitals to provide all the physicians on the medical staff with a choice of whichever products they prefer to use in their surgeries, and discourage the Hospitals from contracting with the Company on an exclusive basis or carrying the products exclusively.

- **DO** ensure that the Company enters into its own contracts with vendors, maintains, manages and ships from its own inventory, and bills in its own name.

- **DO** make sure the devices are of high quality and FDA approved.

- **DO** ensure that any and all products acquired by the Company from manufacturers and/or vendors are purchased as true sales, not as part of a consignment arrangement, and are paid for with cash, not financed by the manufacturers and/or vendors.
PRACTICAL POINTERS & BEST PRACTICES:
(Cont’d)

- DO ensure the Company is adequately and appropriately capitalized and insured, as reasonable and customary for a medical device distributor, and that investments made by physician owners are not nominal in amount.
- DO ensure that the return on investment received by each investor in the Company is directly proportionate to such investor’s ownership interest, without regard to the volume or value of products used by such investor (if any).
- DO ensure that the use of the products in all instances is medically necessary.
PRACTICAL POINTERS & BEST PRACTICES: (Cont’d)

- DON’T require, coerce or pressure any hospital to contract with the Company or purchase products, including but not limited to any explicit or implicit threat that any of the physician’s future referrals to the Hospital might be conditioned on or related to whether or not the Hospital chooses to contract with the Company or how much (if any) of the products a hospital might or might not purchase from the Company.

- DON’T alter the size of the investment opportunity in the Company offered to physician investors based on the expected or actual volume of products used by such potential physician investor.
PRACTICAL POINTERS & BEST PRACTICES: (Cont’d)

- DON’T guarantee any physician a return on his or her investment in the Company.
- DON’T permit the Company to loan any money to an investor or potential investor, including, without limitation, financing any investor’s acquisition of an interest in the Company or guaranteeing any loan taken out by an investor.
- DON’T provide the Company with the right to repurchase any investor’s interest for failing to use the Company’s products (or failing to use any particular volume of such products).
- DON’T permit the Company to enter into any compensation or other arrangement with any physician that is not both commercially reasonable and consistent with fair market value, without taking account of the amount of products (if any) ordered or used by such physician.
Physician-Owned Distributors: To Be or Not To Be?

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Summary of Presentation

- What is a POD?
- Do PODs Violate the Antikickback Law?
- What About the Stark Law?
- Are PODs at risk under the False Claims Act?
- Are there Mitigating Features That Would Deter Enforcement Against Pods?
- Conclusions
What is a POD?

- A physician-owned distributor (POD) is an entity that recruits implanting surgeons as investors, thereby sharing with the physicians profits from the purchase by hospitals of the devices that they implant in their patients at hospitals that have agreed to purchase through the POD.

- PODs are one of several types of physician-owned implant companies (POCs). POCs take several forms, including manufacturers, GPOs, and PODs.

- The prevailing POD model is a “stocking distributor” (buys and resells inventory).
Do PODs Violate the Federal Antikickback Law?

- ALK prohibits any remuneration to induce physicians to purchase or order (or arrange for purchase or order of) products, or refer patients for a procedure, for which payment may be made under Medicare/Medicaid/Other FHCPs¹
  - Orthopaedic/spinal implants used in FHCP patients are deemed paid for in the payment to the hospital or ASC
  - Remuneration includes return on investment (Hanlester) and the opportunity to earn a profit (Bay State)²
  - Law is violated if one purpose is to induce the prohibited purchase, order or referral, even if there are other legitimate purposes
Do PODS Violate the Federal AKL?, cont.

- **Who is at risk under AKL?**
  - Is one purpose of the investment opportunity to induce physician’s to order a manufacturer’s implantable devices?
    - If yes, the physician and the POD’s other entrepreneurs are at risk for receiving the investment return, and
    - The manufacturer is at risk for creating the profit opportunity by selling to the POD
  - Is one purpose of the investment opportunity to induce physicians to refer their patients to hospitals who agree to buy through the POD?
    - If yes, the hospital is also at risk for creating the profit opportunity by purchasing from the POD
Do PODs Violate the Federal AKL?, cont.

- There are only two essential elements for an AKL violation:
  - Is there remuneration to a referring physician?
  - Is one purpose of giving the physician the remuneration to induce the physician to order covered product or make a covered referral?

- If these elements are present, then the participants are solely in the realm of prosecutorial discretion as to whether they are subjected to the AKL’s sanctions
  - Civil money penalty and exclusion by OIG
  - Direct criminal proceeding by DOJ
  - Qui Tam proceeding under the False Claims Act
Do PODs Violate the Federal AKL?, cont.

■ Essential Element #1: Is there remuneration?
  □ Remuneration includes the opportunity to earn money (Bay State) and return on investment (Hanlester)
  □ Investment return is not protected simply because it is proportional to the amount invested, or otherwise has the indicia of a “legitimate” investment, but only if it is not motivated by improper intent (Hanlester, JV Fraud Alert)³
    ■ Recently affirmed in OIG Advisory Op 11-15 (declining to approve physician-owned lab management agreement despite returns being proportional to investment interests)
Do PODs Violate the Federal AKL?, cont.

- Essential Element #2: Is there an unlawful intent to induce?
  - Unlawful inducement means “an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.” (Hanlester)
    - So, is one purpose of giving the physicians the opportunity to profit from their investment to affect their judgment about which implant or which hospital to use?
  - Direct evidence of unlawful intent is not required, but may be inferred from the surrounding circumstances
    - Is there really any doubt that unlawful intent could be inferred in every POD arrangement?
Do PODs Violate the Federal AKL?, cont.

- Failure to follow OIG Guidance is evidence from which unlawful intent may be inferred
  - Hornbook administrative law: Agency interpretations are entitled to deference when a court is required to test a regulated person’s conduct against that interpretation. E.g. Chevron\(^4\)
    - Deference due even under a criminal statute if it is being enforced only civilly. E.g. Sash v. Zenk\(^5\)
  - Hanlester court acknowledged that absence of liability for some of the Hanlester defendants was because at the time the arrangements were entered into, joint ventures of that kind were fairly common and were not per se unlawful, and recognizing that OIG’s first JV guidance was not issued until after the events underlying the prosecution took place\(^6\)
Do PODs Violate the Federal AKL?, cont.

- Hanlester case, often cited by POD proponents as evidence that “legitimate” investments do not violate the AKL, is of little relevance to PODs, e.g.
  - Hanlester was decided based on facts that preceded any OIG guidance on physician investment interests
  - Hanlester applied to investment in a supplier of health care services (clinical laboratory), not an unregulated entity
  - In Hanlester there were a substantial number of investors diluting the effect of referrals; PODs involve small numbers of investors;
  - In Hanlester there were no findings concerning excessive return on investment, unnecessary services, or potential harm to patients
Do PODs Violate the Federal AKL?, cont.

- OIG agency guidance concerning physician-owned entities is now open and notorious
  - Special Fraud Alert on Joint Venture Arrangements (1989)
    - Emphasizes choice of referring investors and “shell” business structure outsourcing key functions
  - Safe Harbor Regulations (1994)
    - Investment return constitutes remuneration
    - More than 40% of revenues from referring investors fails
  - Special Advisory Bulletin on Contractual Joint Ventures
    - Demonstrates continuing concern with outsourcing and profit from passive referrals
  - United Shockwave Settlement (2010) “We continue to have serious kickback concerns when companies link investment opportunities to the ability to generate business and offer returns on investment that are disproportionate to business risk.”
Do PODs Violate the Federal AKL?, cont.

- Advisory Opinion 11-15 Suspect Physician Investment:
  - Management fee not saved even though each doctor’s return was proportional to his investment interest, because overall the entity’s revenues (and profits) were based on volume/value of aggregate referrals of all the physician investors
  - More than 40% of revenue from the referring investors
  - Fact that owners had no experience in lab services but could refer suggests that there is no purpose other than to permit physician investors to profit from their own referrals
Do PODs Violate the Federal AKL?, cont.

- Management Company Advisory Opinions
  - OIG has failed to grant approval of provider investment in management company arrangements designed to exploit the provider’s referral base
  - 98-4 (physician practice management services), 03-08 (inpatient rehabilitation unit management services); 06-02 (DME/orthotics delivery management, coding, billing and collection, and leased technician services); and 11-03 (long term care pharmacy management services)
Do PODs Violate the Federal AKL?, cont.

- Recent government statements echo concerns
  - OIG (2006, 2008): PODs “should be closely scrutinized under the fraud and abuse laws” because relationships between manufacturers and physicians “raise the type of risks that [the anti-fraud and abuse] statutes were designed to address.”
  - CMS (2008): PODs “may serve little purpose other than providing physicians the opportunity to earn economic benefits in exchange for nothing more than ordering medical devices” from their POD.
  - Senate Finance Committee (2011): PODs “seem to create financial incentives for physician investors to use those devices that give them the greatest financial return and that, in the process, patient treatment decisions may be based on personal financial gain.”
    - Senate letter does NOT indicate that some PODs are OK: its only example of a potentially lawful POD is one that does not sell to hospitals where the investor physicians practice
    - OIG response does NOT indicate that some PODs are OK: it simply lays out the factors that OIG uses in analyzing physician investment
Do PODs Violate the Federal AKL?, cont.

- PODs implicate the OIG’s suspect factors
  - Investor recruitment and retention
    - PODs recruit investors in position to make referrals and encourage investors to refer
    - POD owner: “My idea was to form a limited liability company that consisted of approximately one hundred doctors who would also act as the company’s customer base…this concept created a built-in market” for POD products\(^7\)
  - Financing and profit distribution
    - Little if any business risk: POD is both buyer and seller, capital invested is not substantial, returns on investment exceptional
    - Some PODs have advertised 25% return on investment, and one uses assumptions of $2,750 purchase price per 1% ownership share, and $3,770 annual return per 1% ownership share\(^8\)
Do PODs Violate the Federal AKL?, cont.

- **Business structure**
  - PODs often are “shell” entities that outsource principal operations
  - POD organizations market “turn-key stocking distributorship” and management of “every step of the project”\(^9\)

- **Captive referral base**
  - POD advertisements state “in the beginning, physician investors may be the only users of your distribution company’s implants … the pro forma is based on 80% of the physician investors’ annual surgical cases”\(^10\)

- Investment interests safe harbor not available because PODs do not meet “40% test” – typically all POD business generated by investors, and SH requires that no more than 40% of a venture’s revenues may be generated by investors in position to make or influence referrals
PODs are different from other approved physician ownership models

- Other physician ownership models contain protective factors that PODs lack
- Joint ventures like ASCs and physician-owned hospitals are regulated providers subject to licensure and clinical oversight
- They also have mechanisms in place to track factors like utilization and medical necessity
- No similar checks and balances are present in PODs
  - PODs are not themselves Medicare providers or suppliers and do not have to meet conditions of participation, utilization review, licensure standards
PODs are not gainsharing

- OIG has approved “gainsharing” models in which physicians share in demonstrated cost savings
- PODs are different because physicians share in profits, not in cost savings
  - Money earned through POD is markup on implant sale price
- Profits are maximized not by generating cost savings but by ordering more, and more expensive, products
- Gainsharing arrangements have safeguards against patient and program abuse
  - Freedom to choose any product, limited to one year, ceiling on amount that can be earned based on historical practice patterns
What About the Stark Law?

- Stark prohibits physicians from making Medicare referrals for certain designated health services to an entity with which they have a financial relationship absent an exception.
- Inpatient and outpatient hospital services, including implant surgeries, are “designated health services”
What About the Stark Law?, cont.

The Arguably relevant exception is for Indirect Compensation Arrangements

- Not available if arrangement violates the AKL
- In any event allows hospitals to pay physician-owned entity if the payment is FMV and doesn’t vary based on v/v referrals, defined to allow per unit payments
  - Query whether a purchase from a POD that adds no value to the implant purchase transaction could meet FMV standards?
  - Query whether when the hospital confers on the physician the opportunity to profit by agreeing to purchase from his POD,
    - that is a separate stream of direct remuneration, for which the Indirect Comp exception would not be available, or
    - fails the exception because that opportunity to profit is conferred only because of the volume or value of referrals, and is not eligible for the per unit qualifier
What is the risk under the False Claims Act?

- Every claim submitted to Medicare pursuant to a referral prohibited under Stark or the AKL is a False Claim (cites)
- As discussed above, there is ample basis for the government, or a qui tam relator to bring a case
  - Anyone who is disadvantaged by the advent of a POD can bring a qui tam case
- Consequences of losing such a case are catastrophic
- Just the expense and difficulty of having to defend such a case will strain the resources of a hospital or a manufacturer, and could be ruinous to a physician practice
Other Risks to PODs?

- Becoming a product supplier carries with it products liability risk and FDA reporting requirements
  - When physicians become POD owners, they become resellers of implants and are subject to products liability lawsuits.
  - They also become subject to FDA reporting requirements and fall under FDA jurisdiction for enforcement of adulteration and misbranding violations.
Are there Mitigating Features That Will Deter Enforcement Against Pods?

- Price of Implants? Proponents claim prices are going up, but the average sales price of spine implants has decreased since 2008 and the average sales price of hip/knee implants has remained relatively flat since 2005.

- Cost Savings? Aligning hospital/physician interests to improve quality and control cost is the essence of Accountable Care, which doesn’t depend on PODs.

- Innovation? If all is about the lowest cost implants, product innovation and improvement is deterred, to the detriment of patient care.

- Competition? PODs don’t increase competition – they eliminate competition.
Conclusions

- The case that the basic POD model violates the AKL is simple and strong
  - Easy to infer that one purpose of every POD is that financial benefit will influence the judgment of the investor-physician on product and hospital choice
  - That is all that’s necessary to make an AKL case
  - Relying on prosecutorial discretion is a questionable business strategy
- Adjunct case may be made under Stark, both because of the AKL violation and based on arguments about indirect compensation exception
- False Claims Act provides a vehicle for disgruntled competitors and others to act while government bides its time.
Endnotes

1. 42 U.S.C. § 1320a-7b(b).
2. See Hanlester Network v. Shalala, 51 F.3d 1390, 1401 (9th Cir. 1995) (affirming the finding of the Department of Health and Human Services Departmental Appeals Board that the opportunity for physician investors to earn money from their investment in a laboratory partnership was remuneration for purposes of the anti-kickback statute), See United States vs. Bay State Ambulance and Hospital Rental Services, Inc., 874 F.2d 20, 29 (1st Cir. 1989) (“[g]iving a person an opportunity to earn money may well be an inducement to that person to channel Medicare payments toward a particular recipient”).
5. 439 F.3d 61 (2d Cir. 2006).
8. See, e.g., Omega Solutions Physician Recruitment Letter, Alliance Surgical Distributors “Financial Considerations” material.
9. See Alliance Surgical Distributors physician information packet.
10. Id.
Questions?