Physician-Owned Distributors Under Congressional Scrutiny

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The Headlines

“Top Spine Surgeons Reap Royalties, Medicare Bounty”
Wall Street Journal, December 20, 2010

“Medicare Records Reveal Troubling Trail of Surgeries”
Wall Street Journal, March 29, 2011

“Senators Request Probe of Surgeons”
Wall Street Journal, June 9, 2011
What is a POD?

“A POD is an arrangement where a physician investor purchases ownership shares in an entity that then purchases or serves as a medical device distributor for the products the physician utilizes in surgery”

Letters from U.S. Senate Finance, Special Committee on Aging to CMS and OIG
June 9, 2011

Business Models

- Distributorships
- Group Purchasing Organizations
- Manufacturers
- Combination of all of the above
- Primary focus on orthopedic and cardiac devices
POD Basic Distributor Model

Other Business Models

- Not Limited to Distributor/Supplier model or orthopedics
- Surgical Lasers
  - Provide laser rental and technician to hospital on per case basis
  - Referring surgeon ownership of company
- Neurodiagnostic Monitoring
  - Provide monitor rental and technician/neurophysiologist on per case basis
  - Some transmit data to off-site physician for real time interpretation
  - Neurosurgeon ownership of company
OIG Enforcement Activity

POD Pays $7.3 Million

PODs – The Proponents’ View

- Savings to hospitals and payors
  - Eliminate the cost of marketing and sales staff
  - Better inventory control and reduced carrying costs
  - Volume purchasing
- Increased quality of products
  - Surgeons are able to work directly with manufacturers
  - Customization of devices, tools, implements and kits to better suit patient needs
- Innovative response to Health Care Reform
  - Promotes hospital-physician alignment on cost control
- Surgeons are best qualified to understand the products and needs of their patients
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<th>PODs – The Opponents’ View</th>
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<td>▪ Costs will increase as PODs control more of the market</td>
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<td>▪ Medical decision-making will be influenced by financial gain</td>
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<td>▪ Unfair competition resulting from pressure on hospital to use POD even if lower price, higher quality alternative available</td>
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<td>▪ Costs will increase because surgeon has financial incentive to use more expensive devices</td>
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<td>▪ Lack of adequate disclosure to patients</td>
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<td>▪ Indirect Compensation Arrangement likely exists (42 C.F.R. §411.354(c)(2))</td>
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<td>– Chain of financial relationships exist from hospital to physician owners</td>
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<td>– “Aggregate” compensation received by POD <em>does</em> vary with volume/value because of per unit pricing</td>
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<td>– Because of per unit pricing, hospital likely has knowledge that profit distributions to physicians will vary volume of referrals to hospital</td>
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Stark Law (Continued)

- Indirect Compensation Exception often can be satisfied (42 C.F.R. §411.357(p))
  - Written and signed agreement
  - Fair market value pricing of items
  - Pricing not determined based on value or volume of physicians’ referrals or other business referred to hospital
  - Arrangement doesn’t violate the anti-kickback statute

Stark Law (Continued)

- “Volume or Value” Standard
  - Unlike the definition of indirect compensation, the exception does not require that the “aggregate” compensation not vary with volume or value of referrals
  - Unit based pricing that does vary with volume or value can satisfy the exception if:
    - Per unit price is fair market value, and
    - Per unit price does not vary over term of agreement in any manner that accounts for volume or value of referrals (42 C.F.R. §354(d)(2))
### P.O.R.A.
CALIFORNIA PHYSICIAN OWNERSHIP AND REFERRAL ACT OF 1993

- Broad exception for referrals by physician to a hospital can be satisfied if “the recipient of the referral does not compensate the licensee for the patient referral.” (Cal. B&P Code 650.02(c))

- If hospital paying FMV for the devices purchased, exception should be satisfied because there’s no other compensation to be construed as payment for referrals

- California Business & Professions Code §650.01 and 650.02

### California Disclosure Requirements

- California Business & Professions Code §650.01(f)
  - Disclosure of “financial interest” to patient
  - Must disclose at time of referral or consultation

- California Business & Professions Code §654.2(a)
  - Prohibits billing and referral without prior disclosure of “significant beneficial interest”
  - Patient disclosure can be via posting of sign in office
  - Disclosure to payers required on request

- Burden of disclosure is on physician owners of POD
Federal Anti-Kickback Statute

- Up to 5 years in prison and $25,000 per violation
- Exclusion from federal program participation
- Applies to all parties involved, **not just the hospital**
- Investigation alone enough to destroy many businesses and careers

Federal Anti-Kickback Statute (Continued)

- Relationship to Analyze: Hospital and POD Owner/Referring Surgeon
- Possible Safe Harbor: Personal Services and Equipment Safe Harbors
  - Both safe harbors require that "aggregate" compensation be fixed
  - Per unit pricing does not qualify because it varies with number of units sold
- Likely no applicable safe harbor
- Rely upon intent based analysis
Federal Anti-Kickback Statute (Continued)

- Relationship to Analyze: POD and POD Owner/Referring Surgeon

- Possible Safe harbor: Investment in Small Business Entity
  - Requires that no more than 40% of the POD’s gross revenue in previous year come from referrals or business otherwise generated by investors
  - Requires that no more than 40% of equity in POD be held by investors in position to make or influence referrals, furnish items or service to, or otherwise generate business for the POD
  - Most PODs cannot satisfy these requirements

- Likely no applicable safe harbor

- Rely upon intent based analysis

Federal Anti-Kickback Statute (Continued)

- Intent Based Analysis – Consider Everything!

- OIG General Considerations
  - Is arrangement commercial reasonable and necessary for purposes other than referrals?
  - Is compensation FMV and not connected to value or volume of referrals?
  - Can the hospital obtain the same items elsewhere at a lower price?
  - Can the methodology used to establish FMV be documented as reasonable?
  - Were physicians in the arrangement selected based on referrals?

Federal Anti-Kickback Statute (Continued)

- The Old Rule: *Hanlester Network v. Shalala*
  (51 F.3d 1390 (9th Cir. 1995))
  - Required knowledge of illegal conduct and specific intent to violate the statute

- The New Rule: PPACA
  (Patient Protection and Affordable Care Act of 2010, Section 6402)
  - “a person need not have actual knowledge of this section or specific intent to commit a violation of this section”

“One Purpose” Rule:

“If one purpose for the payments was intended to induce physicians to use Cardio-Meds services, the statute was violated, even if the payments were also intended to compensation for professional services”

### California Anti-kickback Statute

- **California Business & Professions Code § 650**

- Specific exception if physician’s return from company is based on the amount of capital investment or proportional ownership and not based on the number or value of patients referred

- “Section 650 was never intended to prohibit a physician from referring patients to a facility merely because he or she might have an ownership interest in it and thereby might derive greater income from its increased profit margin”
  

### OIG Special Fraud Alert on Joint Venture Arrangements – Aug. 1989

- Listed numerous “questionable features” including (but not limited to):
  - Investors chosen because they are in a position to make referrals
  - The JV tracks its sources of referrals and distributes that information to the investors
  - Investors may be required to divest their ownership interest if they cease to practice in the area, move, retire or become disabled
  - If the JV is a shell operation relying upon another entity to conduct the actual business
  - Capital investment by physicians is disproportionately small compared to return on investment in a typical new business
  - Physicians are allowed to “borrow” their capital contribution from the JV and pay it back thru deductions in profit distributions
OIG Special Advisory Bulletin on Contractual Joint Ventures – April 2003

- What is a Contractual JV? When a health care provider in one line of business expands into a related health care business by contracting with an existing provider of a related item of service
- Indicia of suspect Contractual JVs:
  - New line of business for physician owners of JV
  - The JV predominantly serves the physicians’ existing patient base
  - Little or no risk to physicians because their primary contribution is referrals
  - The party delivering the actual service is a competitor of the JV that would normally compete for the same referrals; has capacity to do business without the JV
  - Remuneration from JV to physicians takes into account value/volume of referrals

OIG Guidance Letter – Oct. 6, 2006
Vicki Robinson, Chief, Industry Guidance Branch

- Re: “Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries”
- Acknowledges awareness of proliferation of physician investment in medical device and distribution entities
- Confirms that principles set forth in 1989 Special Fraud Alert on Joint Ventures applies to physician investment in device distributors
- Acknowledges that “every arrangement is evaluated on a case by case basis”
- Confirms that the amount of revenue received by the physician investor is a relevant factor in analysis
- Commits to considering physician investor concerns in future OIG guidance projects
OIG Congressional Testimony – Feb. 27, 2008
Gregory Demske, Associate Inspector General for Legal Affairs

- Primarily focused on relationship between manufacturers and physicians that used their products (not necessarily as owners)
- Acknowledges that financial relationship with physicians “can benefit patients and federal health care programs by promoting innovation and improving care”
- From 2002–2006, four manufacturers paid over $800 million to 6,500 physician consultants
- “We believe [entities with physician investors] should be closely scrutinized under the fraud and abuse laws”
- Enforcement is happening; see testimony transcript in binder for discussion of enforcements actions

Interesting Material

- Google “Physician owned distributorships”
  - Numerous results

- American Academy of Orthopedic Surgeons
  www.aoss.org

- American Association of Surgeon Distributors
  www.aasdonline.org

- Hogan & Hartson White Paper
  www.hoganlovells.com

- Association for Medical Ethics
  www.ethicaldoctor.org
U.S. Senate Inquiry – June 2011

- Senate Finance Committee Minority Staff Report
  - Committee Members: Hatch, Baucus, Grassley, Kohl, Corker
  - Reviews history of PODs and expresses concern about proliferation of a business model that can be easily abused
  - POD model seems inconsistent with fraud and abuse concepts in healthcare
  - Acknowledges that absence of federal regulation and guidance has resulted in confusion about legality of PODs
  - Highlights two major law firms with opposing views on the legality of PODs

U.S. Senate Inquiry – Letter to CMS June 9, 2011

- Expresses concern about proliferation of PODs and the lack of guidance being provided to physicians
- “The POD model at its basic level is exactly the type of entities envisioned by the Sunshine Act, which would require disclosure of the financial interests of their physician investors”
- “The final [ACO] rule should prohibit ACOs from purchasing products or services from entities that are owned by physicians participating in the ACO”
- “It should also be made clear that waivers of Stark and Anti-kickback laws should not extend to PODs”
U.S. Senate Inquiry – Letter to OIG June 9, 2011

- Expresses concern about proliferation of PODs, the lack of guidance being provided to physicians, and risk of overutilization
- “The extent to which the medical community remains deeply divided as to the legality of the POD model indicates that previous OIG guidance on this topic is not sufficient”
- “An inquiry [by Senate committee staff] indicates that there are some POD models that appear to have appropriate frameworks developed to try to ensure their activities are legally compliant, but there are far more that which are operating in a manner that appears to be unethical and illegal”

U.S. Senate Inquiry – Questions to OIG

- Attachment A to June 9, 2011 Letter to OIG
- 30 questions submitted to OIG including:
  - Do PODs add any value to hospital customers that hospitals could not obtain directly in this way?
  - What is the typical capital structure of a POD?
  - Is there evidence of overutilization of medical services or inappropriate choice of products by physicians who are POD investors?
  - How could any POD pass the anti-kickback law “one purpose” test?
  - Does a physician’s sudden switch in implant use to different products furnished by his/her POD provide evidence that the physician is accepting remuneration in exchange for his/her use of the POD products?
U.S. Senate Inquiry – CMS Response

- Letter from CMS Administrator Donald Berwick – August 10, 2011
  - Response to Senate’s concern regarding Sunshine Law:
    - “We appreciate your suggestions regarding defining GPOs as potentially including PODs [under the Sunshine Law], and will consider this issue carefully as we work to develop our proposed regulations”
  - Response to Senate’s concern about POD’s taking advantage of ACO waivers of Stark and anti-kickback laws:
    - “We are currently reviewing the comments we received [to the proposed ACO rules], and developing our final policies regarding the exercise of our waiver authority”

U.S. Senate Inquiry – OIG Response

- Letter from HHS IG Daniel Levinson – September 13, 2011
  - “[T]he answers to many of the important legal questions you posed about PODs depend on the specific facts of each case . . . For these reasons, the OIG’s ability to issue guidance about the application of the statute to these business structures is limited.”
  - OIG to conduct nationwide review of PODs to determine whether to issue additional guidance
  - Reiterated that current guidance already addresses key factors including:
    - Terms of physician investment and divestment in POD
    - Annual and projected returns on physician investment
    - Amount of revenue generated for POD by physician investors
  - Commitment to ongoing monitoring and enforcement (see United Urology Centers case – slide 7)
Where Does OIG Stand?

“The legality of any individual physician-owned entity under the Federal Anti-kickback Statute is highly dependent on each entity’s particular characteristics, including the details of its legal structure; its operational safeguards; and, importantly, the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations.”

“It has been OIG’s longstanding view that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates referrals, could constitute an illegal inducement under the Federal Anti-kickback statute.”

HHS IG Daniel Levinson
Letter to U.S. Senate
September 13, 2011

What to Watch For

- **OIG Action**
  - Study of PODs – Hospitals will be primary source of information
    - Challenge: Many hospitals don’t actually know they’re doing business with a POD so how can they provide good data
  - Enforcement against patently illegal PODs

- **CMS Action**
  - Watch for Sunshine Law proposed regulations to see if PODs are included within the definition of GPOs and thus required to publically disclose physician ownership
  - Watch for final ACO regulations to determine if PODs are eligible for Stark and anti-kickback waivers
What to Watch For

- Possible changes to the Stark Law

  “We are not adopting the position that physician-owned implant or other medical device companies necessarily ‘perform the DHS’ and are therefore an ‘entity’ on that basis . . . We may decide to issue proposed rulemaking on this issue in the future.”
  (2009 IPPS Final Rule; 73 F.R. 48727)

- Large manufacturers lobbying for change

- Competitors without physician ownership claiming unfair competition due to influence of physicians over hospitals

PODs: Considerations for Hospitals

- Understanding the risk – prison, fines, exclusion, loss of career

- Motivation must be to maintain or improve quality at a lower cost

- Utilization of POD products by physician owners must be monitored for abuse

- Must maintain quality control over products to ensure not receiving inferior or black market products

- Medical Staff politics

- Knowledge of PODs:
  - Many hospitals don’t know they’re doing business with a POD
  - Is anyone reading disclosures in credentialing files?
PODs: Considerations for Physicians

- Understanding the Regulatory Risk
  - Fines, program exclusion, prison
  - *Not just a hospital risk*
  - Physicians need to be educated on risks and regulatory requirements

- Understanding Compliance Requirements
  - Physicians must make a real investment in a legitimate business operation; cannot be a pure contractual joint venture or drop shipper
  - POD needs to maintain an office location, hold and deliver inventory, employ staff to operate business
  - POD must supply quality products
  - Physicians cannot leverage referrals for benefit of POD
  - Utilization of POD devices should be monitored for abuse

PODs: Contracting Considerations

- Due diligence to confirm POD is a legitimate business operation
- Contract must be tailored and carefully administered
  - Strong representations and warranties
  - Parties must understand and follow requirements of the contract
- Fair market value of pricing for quality products is critical
  - POD must provide quality products with FDA approvals
  - POD pricing must be better than competitors
  - Insist on independent consultant to review and verify in writing
- See Fall Seminar binder for additional contracting considerations