

# ANCILLARY SERVICES: HOW TO STAY OUT OF TROUBLE

Richard N.W. Wohns, M.D. JD, MBA  
NeoSpine, Puget Sound Region, Washington



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# THE NEUROSURGICAL MINEFIELD 2013

- Informed consent
- HIPAA
  - ARRA and HITECH
- Anti-Kickback Law
  - PODs
- Stark
- Medicare Fraud and Abuse
- False Claims Act
- Consulting Agreements
- Accountable Care Organizations
- Payor Relations
- Hospital Employment
- Sunshine Act



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# INFORMED CONSENT

- Requirement for adequate info to make reasonable choice
- Provides autonomy to patients
- Developed into something like negligence theory, with duty of providers to obtain informed consent
- Reasonable patient standard (four elements)
  - Health care provider failed to inform patient of material fact
  - Patient consented to treatment without being aware of material fact
  - Reasonably prudent patient under similar circumstances would not have consented if informed of material fact
  - Treatment in question proximately caused injury
- Role of expert testimony in informed consent claim
  - Reasonable provider standard requires expert witness
  - Reasonable patient standard does not (but still need expert to provide proximate cause)
  - Also need expert testimony as to what the risks actually are, and what the alternatives are inc/ non-treatment

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## INFORMED CONSENT

- The form containing the language is just evidence and is not sufficient to prove that patient obtained true informed consent
- Full disclosure of ownership interests



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## HIPAA

- **Health Insurance Portability and Accountability Act**
  - Applies to “covered entities”
  - Protects privacy and security of health information
- **American Recovery and Reinvestment Act (ARRA)**
  - Subset of ARRA: Health Information Technology for Economic and Clinical Health Act (HITECH)
    - Privacy and security concerns related to electronic transmission of health information
    - Increases penalty amounts for HIPAA violations (tiered penalties based on violation)
    - Requires notification of patient (and potentially other entities such as media and HHS secretary) in the event of breaches of unsecured patient health information

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## ANTI-KICKBACK LAW

- **Prohibits:**
  - **knowing and willful** solicitation, receipt, offer, or payment
  - of **anything of value** (“remuneration”)
  - in exchange for or to induce the **referral** of business
  - for which payment may otherwise be made under **Medicare, Medicaid, or any other federally funded health benefit program** other than the federal employee health benefit plan
- **Elemental analysis**
- **If yes, anti-kickback issue**
- **Question of intent** (often subjective)
  - Specific intent is not required

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## ANTI-KICKBACK LAW

- **“Safe harbor” rules create narrow but attainable exceptions:**
  - Space rental, equipment rental, and personal services and management contracts
  - Practitioner recruitment arrangements
  - Investments in group practices
  - Ambulatory surgery centers
- **Failure to met a safe harbor does not mean that an activity is necessarily illegal.**
  - It does mean that the activity may be subjected to scrutiny under the statute
- **Anti-Kickback violations are false claims under the federal False Claims Act.**

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## PODs and ANTI-KICKBACK

- Physician owned distributorships
- **OIG guidance makes clear that opportunity for referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute illegal remuneration under anti-kickback statute – which is violated if even one purpose of the remuneration is to induce such referrals.**
- **Questionable features of PODs:**
  - Selecting investors because they are in a position to generate substantial business for the entity
  - Requiring investors who cease practicing in the service area to divest their ownership interests
  - Distributing extraordinary returns on investment compared to the level of risk involved

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## POD'S SUSPECT CHARACTERISTICS

- **Size of investment offered to each physician varies w/ expected or actual volume or value of devices used**
- **Distributions are not made in proportion to ownership interest, or physician-owners pay different prices for their ownership interests, because of expected or actual volume or value of devices used**
- **Physician-owners conditions referrals to hospitals or ASCs on their purchase of the POD's devices thru coercion or promises**
- **Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for purchase of devices sold by POD**
- **POD retains right to repurchase a physician-owner's interest for physician's failure to refer, recommend or arrange for purchase of POD's devices**
- **POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or contract w/ personnel necessary for operations**
- **POD does not maintain continuous oversight of all distribution functions**
- **When hospital or ASC requires physicians to disclose conflicts of interest, POD's physician-owners either fail to inform the hospital or ASC of, or actively conceal thru misrepresentations, their ownership in POD**

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## ANTI-KICKBACK VS STARK

- Stark regulations are generally more stringent than anti-kickback
- Stark compliance will often entail anti-kickback compliance
- Anti-kickback safe harbors are not the only way to avoid the statute
  - They identify immune conduct
  - Statute is intent-based
- Stark exceptions are mandatory
  - If Stark law applies, failure to come within an exception means that the activity is prohibited
  - Proof of intent is not required
- Scope and purpose of anti-kickback and Stark laws are different, threshold issue in most cases will be on Stark regulations

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## STARK LAW

- A **physician** who has a **financial relationship** with an entity is prohibited from making **referrals** to the entity for the provision of **“designated” health services** for which payment may otherwise be made under Medicare.



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## STARK LAW

- **Physician:**
  - MD or DO, or member of “immediate family”
  - Hospitals and medical groups are not physicians and not themselves subject to Stark, but a physician “stands in the shoes” of his/her group practice
  - A relationship with a medical group becomes a direct relationship with every physician owner of the group

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## STARK LAW

- **Financial relationship:**
  - **Ownership or investment interest**
    - Broad
    - Can include debt as well as equity
    - Direct or indirect
  - **Compensation arrangements**
    - Broad
    - Includes anything of value (“remuneration”)

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## STARK LAW

- **Designated health services:**
  - Clinical laboratory
  - PT, OT
  - Radiology and certain other imaging services
  - Radiation therapy
  - Durable medical equipment
  - Prosthetics and orthotics
  - Outpatient prescription drugs
  - Inpatient and outpatient hospital services
- **Must provide list of at least ten imaging centers within 25 miles to parties who are being referred to practice- owned imaging centers**
  - Effective January 1, 2011
  - Must obtain signature from patient acknowledging receipt of this notice and maintain those records

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## MEDICARE FRAUD & ABUSE

- **Purposefully billing Medicare for services that were never provided**
- **Upcoding**
- **Unbundling**
- **Soliciting, offering, or receiving a bribe or kickback**
- **Billing non-covered services as covered**

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## FALSE CLAIMS ACT

- **Knowingly presenting, or causing to be presented a false claim for payment or approval**
- **Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim**
- **Self-Disclosure**
  - OIG says “duty to voluntarily disclose certain conduct” (e.g., overpayments)
  - Not less than double, as opposed to treble damages
  - Disclosure within 30 days after “event”
  - If physician discovers over-payment from federal healthcare program, physician must report and return overpayment within 60 days, otherwise the overpayment is a “false claim”

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## CONSULTING AGREEMENTS

- **Compliance with Personal Services and Management Agreement Safe Harbor, 42 CFR 1001.952(d)**
  - In writing and signed by the parties
  - Covers all of and specifies the services
  - Specifies exactly the schedule of services
  - Not less than one year
  - Aggregate compensation is set in advance
    - Consistent with fair market value in arms-length transaction
    - Not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or Medicaid
  - Services do not involve counseling or promotion of a business arrangement or other activity that violates law
  - Aggregate services do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services
  - Sunshine Law requires medical device companies to publicly disclose financial relationships with doctors (gifts, consulting fees, research activities, speaking fees, meals and travel)

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## ACCOUNTABLE CARE ORGANIZATIONS

- **The ability to provide, and manage with patients, the continuum of care across different institutional settings, including at least ambulatory and inpatient hospital care and possibly post acute care.**
- **The capability of prospectively planning budgets and resource needs.**
- **Sufficient size to support comprehensive, valid, and reliable performance measurement.**
- **May make Stark and anti-kickback increasingly less relevant**
- [YouTube - Setting Up An Accountable Care Organization](#)

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# HOSPITAL EMPLOYMENT

- Fair market valuation
- Prohibited:
  - Kickbacks
  - Rebates
  - Payment of unreasonable compensation
  - Payment for referrals

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# Sunshine Act

- Federally mandated reporting of expenditures by life science companies to health care providers including physicians and teaching hospitals.
  - Pharma
  - Medical devices
  - Biologicals
- Expenditures include:
  - Certain payments
  - Items of value
  - Certain ownership interests held by physicians and their immediate family members
- Manufacturers are required to collect and track payment, transfer and ownership information beginning 8/1/13.
  - Reports must be submitted to CMS annually.
  - The majority of the information in the reports will be posted on a public, searchable website.
  - Physicians have the right to review their reports and challenge reports that are false, inaccurate or misleading.
- Equivalent to Freedom of Information laws
  - Promotes transparency

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# THANK YOU



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