

Tips for Relationships with Drug and Device Companies

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December 7, 2018



Typical Drug/Device Deals

- Honorarium.
- Gifts.
- Intellectual Property.
- Grants.
- Sponsorships.
- Distributorships.
- Research Payments.

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Medicare Antikickback Statute

- It is illegal to offer, solicit, make or receive any payment intended to influence referrals under a federal health care program.
- The government applies the “one purpose” test. If one purpose of the payment is to influence referrals, the payment is illegal.

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Antikickback Statute

- Intent is everything. The question: Is the payment intended to induce a favor?
- If the payment is “bait” to get you to listen, you have a defense. If the gift is to get you to act, take cover immediately.
- “Why” is always the operative question

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Antikickback Protection

- Safe harbors exist, but will probably not protect any type of gift.
- They will cover payments for services as long as the payment is reasonable for the work done.
- Common sense takes you a long way with the antikickback law. Remember, you don't need to fit in a safe harbor.
- Beware of bad advice: "There is no favorable Advisory Opinion, suggesting this is illegal."

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Advisory Opinions

- Must be a serious proposal.
- Must disclose parties and facts.
- Must pay government's costs.
- OIG will not analyze fair market value.
- Only binding for the parties involved.
- Generally, advisory opinions do not give you much security.

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Stark

- A physician may not make a referral to an entity for the furnishing of designated health services if the physician (or an immediate family member) has a financial relationship with the entity.
- An entity may not bill for designated health services furnished under a prohibited referral.
- Never forget "referral" really means plan of care.
- The penalties only apply when a bill is submitted, but beware of licensing boards.

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Stark

- Stark will very rarely affect device-related payments.
- Unless there is a hospital involved in the relationship, you can generally focus on antikickback issues.
- When a hospital is involved, both Stark and Tax Exemption are relevant.

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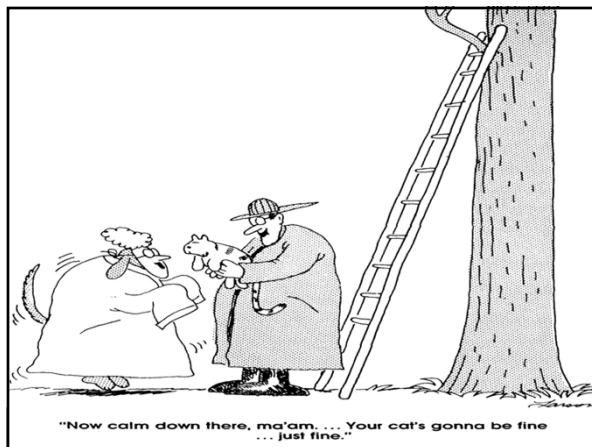
Device Advice


- Device reps can be really good.
- But there's a but...

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Office of Audit Services
Region 1
John F. Kennedy Federal Building
Boston, MA 02100
(617) 565-2464

Dear Dr. *Letter*

The Office of Inspector General of the Department of Health and Human Services is currently conducting an audit of payments for clinical laboratory services under the Medicare program. In this regard, we need your assistance to confirm that you (1) requested the services provided and billed to the Medicare program by a laboratory and (2) received and considered the test results in the treatment of your patient. Your response will be vital in assisting our efforts to ensure that Medicare dollars are appropriately spent on deserving beneficiaries.

As part of this audit, we are reviewing Medicare payments to laboratories for additional automated hemogram indices that were billed with hematology profiles (CBCs or other hematology profiles). Examples of additional automated hemogram indices include red cell distribution width (RDW), mean platelet volume (MPV), red blood cell histogram, platelet histogram and white blood cell histogram. These indices are in addition to the "standard" indices which are part of a CBC: the mean corpuscular volume (MCV), the mean corpuscular hemoglobin (MCH), and the mean corpuscular hemoglobin concentration (MCHC).

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The Subpoena

You get a grand jury subpoena from Atlanta that says "The United States Attorney requests that you do not disclose the existence of this subpoena. Any such disclosure would impede the investigation being conducted and thereby interfere with the enforcement of the law."

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Sunshine Act

- All transfers of value (over \$10) from device companies to physicians must be reported.
- Look out for state sunshine laws that extend beyond physicians.

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Neiman Marcus or Marshall's?

- An off-label use of a device greatly helps cardiac patients.
- The company asks your physician to give a speech about the merits of the device.
- Labeling matters!
- Are you required to disclose the off-label status to patients?

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Getting Concrete

- Drug rep really wants a practitioner's advice. Offers to pay \$200/hour if physician will attend a focus group in San Diego.
- Analysis: Stark, Antikickback, ethics.

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Stark Analysis

- Does the drug company bill Medicare or Medicaid for drugs prescribed by the physician?
 - Probably not. Most likely the billing is done by a pharmacy or some other entity, so Stark is inapplicable.

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Antikickback Analysis

- Is there an argument that the drug manufacturer is paying the practitioner to influence referrals paid for by a federal health care program?
 - Yes. The new Medicare Part D program greatly increases the risk of prosecution.

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Antikickback Analysis

- What exactly is the practitioner being paid for?
- Why San Diego? Could the same thing be done in the physician's office? Via teleconference? In Ottumwa?
- "Live from the airport, for Fox Nine News."
- This is also where ethics creep in.

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
State Law Analysis

- Antikickback statute.
- Pharmacy law.
- Watch for new laws; this is a hot topic.

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Getting Concrete

A drug rep offers to pay a physician \$200/hr to listen to their explanation of why their drug is better.

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Getting Concrete Walls

- A drug rep offers to pay a physician \$200/hr to listen to their explanation of why their drug is better.
- Does a physician have a duty to learn about new developments in medical care?

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Upcoming Webcast Will Feature New Breakthrough Data for MS

Bayer HealthCare Pharmaceuticals is pleased to invite you to a live interactive webcast with noted multiple sclerosis (MS) specialist, Dr. Jack Burks.

Dr. Burks will discuss the recent findings presented by Bayer HealthCare at the 59th Annual AAN Meeting held in Boston, MA. This unprecedented data showed that the immediate initiation of Betaseron treatment significantly reduced the risk of permanent disability in MS by 40% over 3 years as compared to delayed treatment.

Program Objectives:



- Discuss the clinical relevance of the 2 and 3 year BENEFIT™ data
- Better understand the Medical Director's perspective of Betaseron's impact on delaying disability
- Gain feedback on how the BENEFIT™ data may affect current and future formulary management decisions

Program date: July 31, 2007
Time: 6:00 - 7:00 pm
Presenters: Jack Burks, MD, University of Nevada School of Medicine
 Robert LeNigro, MD, Tufts Health Plan
Moderator: Robert LeNigro, MD, Tufts Health Plan
Requirements: Simultaneous Internet and telephone access
Honorarium: \$400

To accept this invitation, please reply to this email. Upon receipt of your email, we will send a confirmation of your registration and further webcast instructions, including your user name and password.

Please RSVP to jschachter@radicalgrp.com by July 30, 2007.

*Betaseron is Newly Emerging Multiple Sclerosis For Initial Treatment

Getting Concrete

- A device manufacturer offers to pay \$2,000 to give a speech about your experience using their new implant.

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Getting Concrete

- A device manufacturer offers to pay \$2,000 to give a speech about your experience using their new implant.
- Does it matter if the physician is the number one user of the implant?

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Getting Concrete

- A device manufacturer offers to pay \$2,000 to give a speech about your experience using their new implant.
- Does it matter if the physician is the number one user of the implant?
- Be a reporter.

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Train in Vein

- Device company wants to send physicians to a small Midwestern town to learn how to use the latest cardiac device.
- Group will build a mock cath lab and teach classes. "I'm so excited!"
- Device company's lawyers say a "lease" is risky. Propose a grant. Group thinks this sounds fishy, but they don't want to complain.

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
Train in Vain

- After the group spends \$40,000 making this possible, no physicians ever attend the training.
- Lessons:
 - Appearances matter.
 - Intent is a two way street.

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Beware of Perceptions

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
Food, Fun and Friends

- A drug rep and the hospital purchasing supervisor (or clinic's physician) are good friends. The rep takes the supervisor (physician) to the best restaurant in town to celebrate the supervisor's (physician's) birthday.
- The total bill is \$350.

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Food, Fun, Friends and Felony?

- A drug rep and the hospital purchasing supervisor (or clinic's physician) are good friends. The rep takes the supervisor (physician) to the best restaurant in town to celebrate the supervisor's (physician's) birthday
- The total bill is \$100.
- Drug rep submits the receipt to the company as a promotional expense.

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The Hard Sell

- A new device manufacturer asks a physician to serve as a consultant.

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The Hard Cell

- A new device manufacturer asks a physician to serve as a consultant.
- They explain the doctor “won’t have to do much, but the pay is good.”

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Physician-Owned Distributorships

- A good means to lower device costs?
- Model: Physicians responsible for production or distribution of device.
- Contract with hospitals.
- Several widely distributed legal opinions.

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PODs

- Two well-respected law firms say “these are fine.”
- A firm hired by device companies says “these are illegal.”
- Government has solicited comment.
- Extremely intriguing. Great law exam question.
- Crack out the risk rheostat.

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Gainsharing/Shared Savings

- Goal is reducing waste.
- Savings may be from conservation.
 - Avoiding drug wastage.
 - Avoid using costly service.
- Savings may come from standardization.

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Gainsharing/Shared Savings

- Pharmaceutical or device companies should not help you create the gainsharing agreement.

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Gainsharing: Good Idea Goes Bad

- According to her lawsuit, Kathleen Davis suffered a significant complication after having a Medtronic pacemaker implanted at Methodist in 2004. She said that her cardiologist made a startling confession when she asked what happened to cause a twitching in her abdomen. He told her that she probably would have fared better with another brand of pacemaker,

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A Good Idea Goes Bad

- but that Methodist administrators had leaned on him to install the Medtronic model to help the hospital collect on what he called a kickback deal, the lawsuit said.

Des Moines Register, Feb. 9, 2006.

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Think before you type

- "Frank [the physician] has made no attempt to comply with the contract. . . . I am prepared to reschedule his devices to be in compliance with the contract," wrote Tim Nelson, a hospital manager who has since left the company, in one e-mail obtained from the court file.

• Des Moines Register, Feb. 9, 2006.

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Think before you type

- In another e-mail in the court records, Butz [another administrator] wrote: "Frank did say . . . that he would abide by a contract that paid him money for compliance." In the e-mail, which Butz wrote to Methodist's chief operating officer, David Stark, he said, "Isn't there a joke along these lines — now that we have established what he is, we are simply negotiating over price."

• Des Moines Register, Feb. 9, 2006.

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The PUVA box

A drug company offers you a free light box if you prescribe Drug X 10 times each month. Their legal department writes you that this is fine because the light box is intended to help patients rather than your group and is therefore not considered a kickback.

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The "Patient Care" Myth

- Perhaps the best test of whether something may be a kickback is whether it involves cash, a good or service that the practice would otherwise acquire.
- A gift of \$500 is no different than a \$500 piece of equipment, which is no different than a \$500 "fellowship" to pay a nurse.

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A Deal Too Good to Pass Up?

- You buy devices wholesale and bill insurers for them. The device manufacturer tells you "if you buy 10, they cost \$1,000 each. If you buy 100, they are yours for \$800. For each one you buy after that, there is a \$100 rebate.

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A Deal Too Good to Pass Up?

- This deal will cause most people to blanch. But there is nothing wrong with it unless you:
 - Are paid on a cost basis AND
 - Fail to accurately state the price by disclosing the discount.
- Payor by payor analysis is key.

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What Can You Mark Up?

- Generally, Medicare pays on a fee schedule. (Note exceptions for purchased diagnostic tests.) There are also some radiopharmaceuticals that are paid based on invoice.
- Absent a clear rule/policy, your purchase price is irrelevant.

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Scholarship

- You want to train your nurses on the latest insulin regime. An ADA seminar in Orlando seems perfect. You ask a testing device manufacturer for a grant to pay for the nurse's travel.

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Scholarships

- The ADA obtains 10 scholarships from assorted drug companies to offer them to qualifying practices in rural areas.

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Scholarships

A drug company offers to give you a \$50,000 fellowship so you can hire a new PA.

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Health Screening

- A drug company offers to pay your costs if you will do cholesterol screening at the local mall. The drug company will pay for a marketing campaign that will include ads naming the clinic, hospital, the company and the drug.

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Health Screening

- A drug company offers to supply you with a manometer prominently labeled with their popular drug in exchange for your patient list. They will then mail patients a notice encouraging patients to come in and get a blood pressure check.

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Dr. Frankenstent

- Physicians suggests modifications to an existing device.
- Device manufacturer agrees to pay physician 1% of profits from the device.
- The physician proves to be a big user of the device.

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Breaking Into the Market

DV US has developed several new medical devices that are used to treat post-surgical pain. The devices can be used immediately following surgery, in the hospital, or also in the days following the procedure, in the clinic. The company is convinced that there is a CPT code that describes the device and that is regularly billed for devices used by physicians. Devices dispensed in the hospital are presumed to be part of the DRG. The company is excited, but recognizes that it will have a challenge breaking into the market. At a brainstorming session, the marketing team presents the following ideas:

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Marketing "Schemes?"

- Send a mailing to some large urban hospitals offering to provide them with 100 free devices to try on patients.
- Send a mailing to smaller hospitals, including some critical access hospitals, offering a "buy one, get one free."
- For some of these small hospitals, it will also test an offer of "buy 10 of our Surgical tables, we will toss in 100 devices for free."
- Send a mailing to a select group of physicians offering them 100 free devices to try on patients. The mailing will say "Use code X. You can bill for this service and be reimbursed \$1500 for each device. This means that the 100 devices will be worth \$150,000 to your practice!!!!"

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Using Appeals to Appeal

- A device company has had issues with some third-party payors.
- The company's marketing group proposes to assist clinics and hospitals with appeals when a device is denied.

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Establishing a 501(c)(3)

- It sounds great: free money.
- You can use a foundation to conduct research, provide charity care, promote health, etc.

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Establishing a 501 See Through You

- A sham here will get you in big trouble.
- Is the research real? Is this really just a subsidy of the practice?
- There are headaches. Some people LOVE the foundation. But use it with care.

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QUESTIONS?



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