Session L

DISCOUNTS & PERKS

by

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HEALTH CARE IN THE NEW MILLENNIUM:

Good morning, Mr. Smith. My lawyers and I would like to know how you and your lawyers are feeling today.

You've said enough, Doc.

You can't have to answer that, Mr. Smith.
Overview

- Regulatory Overview
- Pharmaceutical Marketing
- Professional Courtesy
- Discounts
- Hospital Perks
Goals:

• Prevent Overutilization
• Maintain Independent Clinical Judgment
Primary Enforcement Tools:

- Anti-kickback Statute
- Stark II
- False Claims Act
Pharmaceutical Marketing

- Pharmaceutical fraud will be a “special focus area” of fraud and abuse efforts under the DHHS/OIG Fiscal Year 2002 Workplan
- Pharmaceutical industry is “high on the health care fraud watch list” (BNA)
Pharmaceutical Marketing Facts

Because . . .

• The Pharmaceutical Industry spends more than $11 billion annually on promotion and marketing and approximately $6 billion on direct detailing to physicians.

• Drug Makers spend between $8,000 to $13,000 per physician each year on marketing and employ one drug rep for every eleven physicians.

http://www.acponline.org/journals/news/dec01/president.htm
TAP Settlement

- In October 2001, TAP Pharmaceutical Products Inc. agreed to pay $875,000,000 to resolve criminal and civil liabilities in connection with its fraudulent drug pricing and marketing conduct with regard to Lupron.
- 5 physicians were indicted or pleaded guilty to health care fraud

DOJ Press Release, October 3, 2001
TAP Settlement

- $290,000,000 criminal fine
- $560,000,000 to feds for false claims to Medicare and Medicaid
- $25,000,000 to states for false claims and failing to offer Medicaid programs best price

DOJ Press Release, October 3, 2001
TAP Settlement

• Gov’t alleged that TAP set and controlled the amount Medicare reimbursed physicians and other customers for Lupron by reporting an Average Wholesale Price (AWP) that was significantly higher than the average price TAP offered to physicians and other customers, or the price at which wholesalers and distributors sold the drug.

DOJ Press Release, October 3, 2001
TAP Settlement

- Gov’t alleged that TAP concealed true discounted price paid by physicians from Medicare, and falsely advised physicians to report the higher AWP rather than their real discounted price to Medicare.
TAP Settlement

- TAP “marketed the spread” between its discounted prices and the significantly higher Medicare reimbursement (based on reported AWP) as an inducement to physicians to obtain their Lupron business (i.e., “what you’re reimbursed is a lot more than what you have to pay”).

DOJ Press Release, October 3, 2001
Inducements to Physicians by TAP

Indictments alleged that inducements to physicians included:

- free products
- free consulting services
- trips to expensive golf and ski resorts
- money disguised as “educational grants” but used to pay for Christmas parties, cocktail parties, medical equipment, travel expenses;
- bribes to reverse formulary decisions adverse to use of Lupron.

DOJ Press Release, October 3, 2001

Other Marketing Programs

• “Product Conversion” - Drug Companies offering incentives to pharmacists to help persuade physicians to change prescriptions to their products;

• “Frequent Flyer Campaigns” - Physicians given credit toward airline frequent flyer mileage each time the physician completes a questionnaire for a new patient placed on drug company’s product.

Special Fraud Alert, Dec. 19, 1994

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Other Marketing Programs

• “Research grant programs” - Physicians given substantial sums of money for de minimis record keeping tasks.
No More Free Lunches?

• Gifts of nominal value are generally permitted. However, the OIG’s Physician Compliance Program Guidance recommends that physician groups establish clear policies governing gift-giving because such exchanges may be viewed as inducements to influence business decisions or independent judgment.

• Final Stark Rule imposes limit of $300 in the aggregate per year per entity.
Ethical Guidance:

- What would my patients and the public think of this arrangement? What if the media reported it?
- What is the purpose of the industry offer?
- What would my colleagues think of this arrangement? What would I think if my physician accepted this arrangement?

Professional Courtesy

- Studies show that up 97% of physicians offer some type of professional courtesy.¹
- Traditionally refers to the practice of waiving all, or part of, the fee for services provided to staff and employees and/or their family members.
- Important to distinguish between “professional courtesy” and “insurance only” billing.

Professional Courtesy

• Legality of Professional Courtesy often depends on:
  – How recipients are selected; and
  – How the professional courtesy is extended.
Selective Professional Courtesy

• Refers to courtesy extended to individuals that directly or indirectly takes into account their ability to affect past or future referrals
  - ex) Physician B frequently refers patients to Physician A; Physician C makes no referrals to Physician A. Physician A extends courtesy to B, but not to C.

• Extending courtesy only to B, who refer patients to A, gives the appearance that the courtesy is a reward for referrals.
Q: What’s Wrong with Selective Courtesy?

A: Providing free/discounted services to referral sources may be viewed as a form of remuneration (i.e., giving something of value) in return for past or anticipated referrals and may implicate the anti-kickback statute.
• The OIG has determined that routine waiver of coinsurance or deductible ("insurance only" billing) is potentially unlawful because it results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and services paid for by Medicare.

Office of Inspector General, Fraud Alert, “Routine Waiver of Copayments and Deductibles Under Medicare Part B”
Form of Professional Courtesy

• *Insurance Only = False Claim.* Waiving the copayment then submitting a bill to Medicare for the full charge results is a misrepresentation of the actual charge and may be a false claim.

• *Waiver=Kickback violation.* Routinely waiving copayments may be viewed as illegal remuneration or an inducement given to beneficiary to purchase items or services from the provider.

• *Excessive utilization* results when beneficiaries are given “free” care.
Permitted Professional Courtesy

- A physician’s regular and consistent practice of extending professional courtesy by waiving the entire fee for services rendered to a group of persons (including employees, physicians, and/or their family members) may not implicate any of the OIG’s fraud and abuse authorities so long as membership in the group receiving the courtesy is determined in a manner that does not take into account directly or indirectly any group member’s ability to refer to, or otherwise generate Federal health care program business for the physician.

OIG Compliance Program Guidance for Individual and Small Group Physician Practices
Permitted Professional Courtesy

- A physician’s regular waiver of applicable copayments for services rendered to a group of persons (including employees, physicians, and/or their family members), would not implicate the anti-kickback statute so long as membership in the group receiving the courtesy is determined in a manner that does not take into account directly or indirectly any group member’s ability to refer to, or otherwise generate Federal health care program business for the physician — however.
Any waiver of copayment practice, including that described in the preceding slide does implicate the anti-kickback statute if the patient for whom the copayment is waived is a Federal health care program beneficiary who is not financially needy.
Reality Check

- We have yet to see a reported case involving the prosecution of a physician solely for extending traditional professional courtesy to other physicians.

Caveat: This does not mean that it won’t happen!
• The term “discount” means a reduction in the amount a buyer is charged for an item or service based on an arms-length transaction.
Discounts are not specifically named as a prohibited form of remuneration; however, the AKS contains an exemption that protects certain discounts that meet specific requirements - suggesting that discounts that do not meet the requirements may constitute prohibited remuneration.
Discounts do not include:

- cash payments or equivalents
- Bundling arrangements - supplying one good or service without charge or at a reduced charge to induce the purchase of a different good or service
- reduction in price applicable to one payer but not to Medicare or State health care program

Health Care Program Compliance Guide, BNA §1420.10.10
Discounts

- Discounts involving items or services that are paid for by federal health care programs require:
  
  • discount to be made at the time of the sale of good or service or the terms of the rebate to be fixed at the time of and disclosed in writing to the buyer at the time of the initial sale; and
  
  • the buyer must provide, upon request by appropriate agency, information provided by seller relating to the discount (invoice, coupon or statement reflecting discount terms)

42 C.F.R. 1001.952 et seq.
Hospital Perks

- Hospital/Physician relationships are subject to AKS and Stark
- OIG issued a fraud alert analyzing hospital incentives to physicians and identified several suspect arrangements.
Hospital Perks

Suspect Arrangements

- Payment of any sort of incentive to a physician each time physician refers patient to hospital;
- Use of free or significantly discounted office space or equipment;
- Provision of free or significantly discounted billing, nursing, or other staff services;
- Guarantees which provide that if a physician’s income fails to reach a predetermined level, the hospital will supplement the income up to a certain level;
Hospital Perks
Suspect Arrangements

• Providing low-interest or interest free loans, or loans which may be “forgiven” if a physician refers patients to the hospital;
• Payment of costs of physician’s travel and expenses for conferences;
• Coverage on the hospital’s group health plan at inappropriately low cost;
• Payment for services in excess of fair market value.
Hospital Perks

• Preferential and Sham Investment Opportunities
• Sham Personal Service Arrangements
• Sham Leases
• Improper Gratuities
• Improper Recruitment Packages

Problematic Investment Opportunities

• Hospitals only targeting referral sources for partnerships
• Excluding non-referring physicians from investment opportunities
• Distributions to investors based upon patient referrals
Problematic Investment Opportunities (cont.)

• Investment interests with no out of pocket expenses (no risk investments)
  – Fronting investment funds to physicians
  – Deliberate failure to collect note payments for funds “loaned” to physicians
  – Return of charitable donations made by physicians to cover capital contributions
Personal Service Arrangements

- Problematic Agreements include:
  - Directorships for bogus programs
  - Directorships that require no services to be performed
  - Cumulative Directorships (3 people paid to the job of one)
  - P/T positions to physicians already employed F/T
Suspect Lease Agreements (Physician-Lessor)

- February 2000 Fraud Alert:
  - Appropriateness of Rental Agreements (ex., agreements renting consignment closets are suspect)
  - Appropriateness of Rental Amounts
    - rental amounts exceed amounts paid for comparable property rented in arms-length transactions
    - rental amounts for subleases that exceed the rental amounts per square foot in the primary lease
    - rental amounts that are subject to modification more often than annually
    - rental amounts that vary with the number patients or referrals
Suspect Lease Agreements (cont.)

- rental arrangements that set a fixed rental fee per hour, but do not fix the number of hours or the schedule of usage in advance (i.e., “as needed” arrangements)
- rental amounts that are only paid if there are certain number of Federal health care program beneficiaries referred each month
- rental amounts that are conditioned upon supplier’s receipt of payments from a Federal health care program
Suspect Lease Agreements (cont.)

– Time and Space Considerations

• rental amounts for space that is unnecessary or not used
• rental amounts for time when the rented space is not in use by the supplier (ex., ultrasound supplier has enough business to support the use of one examination room for four hours each week but rents for examination room for eight hours)
• non-exclusive occupancy of rented portion of space (ex., physical therapists who moves from room to room treating patients after they have seen physician) may be scrutinized to determine if proration of time and space used to calculate rent is appropriate.
Rent Calculation

Physician Office rent Per Day

Annual rent of primary lease
no. of workdays per year

% of Physician Office Space Rented by Supplier

Sq. ft. exclusively occupied by supplier
total office sq. ft.

% of Each Day Rented by Supplier

4 hours 8 hours

No. of Days Rented by Supplier Per Year

52 days (i.e., 1 day per week)

Supplier’s Annual Rent for Exclusive Space

OIG Special Fraud Alert 2000
Suspect Leases
(Physician-Lessee)

- Below market rents for facilities near hospital
- Below market rent for equipment
- Leased employees (where terms of lease do not accurately portray allocation of time employees provide services to physician)
**Leases**

Should comply with AKS safe harbors and Stark exception requirements:

- In writing and signed;
- specifies premises to be leased;
- specifies exact schedule, length and rent for the intervals that the space is available to lessee;
- not less than one year term;
- aggregate rental charge is set in advance, consistent with FMV, does not take into account volume or value of any referrals or business generated between parties;
- aggregate space does not exceed that which is reasonably necessary to accomplish business purpose of the rental.

42 C.F.R. § 1001.952(b)
Gratuities

- Out of town trips for physicians, their spouses and families as rewards for reaching referral goals
- Expensive hunting and fishing trips
- Free pharmaceuticals
  - for personal use or use by family members
  - for sale to patients
AMA Guidelines on Gratuities

• gifts should primarily benefit patients (e.g., textbooks, drug samples)
• gifts of minimal value are permissible
• Legitimate conferences/meetings should be held at appropriate location where:
  – the gathering is primarily dedicated in time and effort to promoting objective scientific and educational activities and discourse
  – the main incentive for bringing attendees together is to further their knowledge on the topic being presented
AMA Guidelines on Gratuities

- Subsidies to underwrite the costs of CME conferences or professional meetings can contribute to the improvement of patient care and therefore are permissible. Such payments should be made to sponsors rather than directly to physicians since the giving of a subsidy directly to a physician by a company’s representative may create a relationship that could influence the use of the company’s products.
AMA Guidelines on Gratuities

• Subsidies for costs of travel, lodging, or other personal expenses for attending the conference should not be accepted nor should the physician accept subsidies to compensate the physician for time.

• Consultants who provide genuine services to receive reasonable compensation are permitted to accept reimbursement for reasonable travel, lodging, and meal expenses.
AMA Guidelines on Gratuities

• Certain arrangements can be made to provide scholarships to students, residents and fellows to attend carefully selected conferences.

• No gifts with strings attached should be accepted (For example, physicians should not accept gifts if they are given in relation to the physician’s prescribing practices.)
Permissible Benefits

- Stark rules provide that incidental benefits offered by Hospitals to medical staff members are permitted if:
  - offered to all members of the medical staff;
  - offered only during periods staff is performing duties for hospital or its patients;
  - Used by staff on hospital campus;
  - Reasonably related to provision of health care;
  - of low value and consistent with benefits typically offered by comparable hospitals.

- Still need to comply with AKS

42 CFR § 411.357 (m)
THE END