Anti-Kickback Enforcement and Compliance Update

Health Care Compliance Association
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Anti-Kickbacks – Where We’ve Been

- Undisguised Kickbacks
  - Pay $$ in exchange for referrals
    - Often accompanied by false billing for unnecessary services and/or services not provided
    - Participants have no illusion or doubts about illegality
  - “Legitimate” health care organizations avoid these types of arrangements
Anti-Kickbacks – Where We’ve Been

• Space Rentals
  – Organizations renting space from or to referrals sources for above or below FMV
    ▪ Should the parties have known better?
  – Less common today?
Anti-Kickbacks – Where We’ve Been

• The Wild ’90s – 00’s – Blockbuster Drugs and Devices
  – Lavish Entertainment
    ▪ Often little or no business conducted
    ▪ Spouses included (if customer wants)
    ▪ First Class Travel
      o Resorts, resort locations, luxury hotels
        » Europe
        » Hawaii
        » Caribbean
    ▪ Dine and Dash
    ▪ Sporting and entertainment events
      o Skyboxes
    ▪ Breakfast and Lunch for Staff
      o Scheduled
      o Promoted as work “benefit”
Anti-Kickbacks – Where We’ve Been

- The Wild ’90s – 00’s -- Blockbuster Drugs and Devices
  - Marketing the spread
    - “Billable” Samples
  - Consulting, Research, Royalties
    - Payment for services not needed and/or provided
      - Post-market research
        - Rewards for high users
        - Switching mechanism – offered to physicians using competitive products
      - Questionable royalties for minimal contribution
    - Compensation greatly exceeds FMV
      - Little to no effort to determine FMV
    - Return on Investment Selection Criteria
      - Sales and marketing make and/or influence selection
Anti-Kickbacks – Where We’ve Been

• The Wild ’90s - 00’s -- Blockbuster Drugs and Devices
  – Gifts
    ▪ Nothing too expensive or irrelevant to health care
  – Paying physicians to attend product training programs and/or association/society conferences
    ▪ Sometimes under the guise of a consulting agreement
    ▪ Paying for family members travel and meals
    ▪ Recreational activities
  – Generous “giving” programs
    ▪ ROI selection criteria
    ▪ Customers’ favorite charities
    ▪ Providing fundraiser event tickets to customers
Anti-Kickbacks – Why all the Concern

• Remind me why kickbacks are bad.
  – Because …
    ▪ Skew clinical decisions. Decisions not based on best interest of patient
    ▪ Undermine formularies’ clinical integrity
    ▪ Increased/inappropriate utilization
      o Back to patient’s best interest…
      o Increased costs
    ▪ Undermine pricing structure for government programs

• ~$10BB in from health care industry recoveries in last 10 years
  – 3+BB from pharmaceutical industry
  – 19 of top 20 FCA recoveries are from health care organizations
Anti-Kickbacks – In the News

• “The Drug Pushers,” The Atlantic Online, April, 2006
  – “effective selling is all about developing a relationship with a doctor. If a doctor likes a rep, that doctor is going to feel bad about refusing to see the rep, or about taking his lunches and samples but never prescribing his drugs.”
  – “The trick is to give doctors gifts without making them feel that they are being bought. ‘Bribes that aren’t considered bribes … This…is the essence of pharmaceutical gifting.’”
  – “Although most reps agree that the PhRMA code has changed things … Jordan Katz says that things actually got worse after 2002. ‘The companies that tried to follow the guidelines lost a ton of market share, and the ones who didn’t gained it’…”
Anti-Kickbacks – In the News


  – “The charities are typically set up to engage in medical research or education, and the doctors involved defend those efforts as legitimate charitable activities that benefit the public. But …the tax-exempt organizations represent a growing conduit for industry money. They payments, they say, can bias the treatment decisions of physicians, may lead to suspect research findings and at times may even risk running afoul of anti-kickback laws.”

  – “…the charities drawing scrutiny are set up by doctors in private practice and are closely linked to those doctors’ for-profit medical groups.”
Anti-Kickbacks – In the News

• “Hospital Chiefs Get Paid for Advice on Selling,” The New York Times, July 17, 2006
  – “One recent sun-splashed afternoon, executives who run some of America’s leading nonprofit hospitals met at a stately Colorado resort for an unusual mission: to advise companies confidentially on how best to sell their drugs, medical devices and financial services to hospitals.”
  – “[The hospital executives] were …paid thousands of dollars for the advice…”
Anti-Kickbacks – In the News

  – “We got the numbers of what the physicians were prescribing. If I brought in lunch one week, I could see the following week if that lunch had an impact,’ Ms. Slattery-Moschkau said.”
  – “Mr. Carolan said his lunch business – about 30 – 40 orders a day – exploded after the new industry marketing code was adopted in 2002. ‘I got into this business because the feds cracked down on the more extravagant things they were doing: the dinners, courtside N.B.A. games, flying them to the islands.’ Mr. Corolan said.
Anti-Kickbacks – In the News

  – “…pressure is building against the widely reported gifts and other potential conflicts, an effort that took hold last year when a group of influential doctors condemned financial arrangements between doctors and drug companies in The Journal of the American Medical Association.”
Anti-Kickbacks – In the News

• House of Representatives Committee on Oversight and Government Reform
  – Chairman Waxman Requests Research and Marketing Information from Pharmaceutical and Medical Device Companies (Monday, March 5, 2007)
    ▪ As part of the Committee’s oversight of the marketing practices of the pharmaceutical and device industry, Chairman Waxman sent letters (1) to Eli Lilly and AstraZeneca Pharmaceuticals requesting information related to Zyprexa (olanzapine) and Seroquel (quetiapine), drugs used to treat bipolar disease and schizophrenia; (2) to Boston Scientific Corporation and the Cordis Corporation requesting information on the companies’ drug coated stents; and (3) to Cephalon regarding Actiq, a powerful narcotic lollipop, and Fentora, a narcotic lozenge, both approved to treat pain associated with cancer.
Anti-Kickback – Where We Are

- Oversight and Standards
  - Oversight
    - Corporate Integrity Agreements
      - All/most large pharmaceutical companies have entered into settlements and are subject to CIAs that address kickback compliance.
        - Possible many device companies will be subject to CIAs in future
        - Trickle-down kickback compliance for customers. If industry says “no,” then kickback avoided.
        - Unlikely prosecution of solicitation only kickbacks
      - Inevitably restricting payments by organizations subject to CIA to referral sources
        - Increased compliance more likely if have to obtain legal approval, track and report all arrangements with referral sources
Ant-Kickback – Where We Are

• Oversight and Standards
  – PhRMA and AdvaMed Codes
    ▪ Identify permitted customer interactions and limitations on permitted interactions
    ▪ Issues
      o Voluntary
        » Regular allegations about competitor violations
      o Interpretation
        » Different companies have different interpretations about what is permitted/prohibited by Codes
      o High level
        » Do not deal with many of the day-to-day issues faced by staff in the field
        » Companies need own standards/policies to address day-to-day issues
      o May not address relevant risk areas
        » For example, the AdvaMed Code does not address pricing arrangements
Anti-Kickback – Where We Are

- Oversight and Standards
  - Fewer and less blatant senior management sanctioned kickback schemes
    - Rogue employee or department?
    - Bad/unfortunate documentation
      - For example, sales and marketing characterizing legitimate non-sales activity, such as product training, as “Sales Tools” or “Sales Programs”.
        » Does that make the legitimate non-sales activity a kickback or just bad/unfortunate documentation?
  - Is it a kickback or poor controls? – Is there a difference?
    - Needed consulting or research services, but:
      - Inadequate documentation regarding need
      - Inadequate rationale and documentation of FMV
Restrictions on Industry Benefits to Physicians

- States Laws Restricting Industry Gifts, Meals, etc. to Physicians.
  - All but California apply only to pharmaceutical companies
    - California references device manufacturers, but inclusion appears to be a mistake
    - California requires industry to have comprehensive compliance program

- “A Policy Proposal for Academic Medical Centers”
  (JAMA. 2006;295:429-433)
  - “elimination or modification of common practices related to small gifts, pharmaceutical samples, continuing medical education, funds for physician travel, speakers bureaus, ghostwriting, and consulting and research contracts.”
Anti-Kickback – Where We Are

• Restrictions on Industry Benefits to Physicians (cont)
  – NoFreeLunch.org

  ▪ “We are health care providers who believe that pharmaceutical promotion should not guide clinical practice. Our mission is to encourage health care providers to practice medicine on the basis of scientific evidence rather than on the basis of pharmaceutical promotion. We discourage the acceptance of all gifts from industry by health care providers, trainees, and students. Our goal is improved patient care.”

  ▪ “Drug Free Practitioners” Pledge

  ▪ Initially banned from having an exhibit booth at the American Academy of Family Practitioner conference
Anti-Kickback – Provider Resistance

• “Not me -- Industry entertainment and funding do not affect my medical judgment”
  – Resident Survey
    - 60% did not think they were influenced by industry gifts
    - But, only 16% thought other physicians were not affected by industry gifts
  – Numerous studies have demonstrated that physician medical decisions are influenced by meals, gifts, and other items of value provided by the industry, even relatively minor meals or gifts.
    - Influence may be unconscious
    - Accepting gifts can lead to social relationships with real obligations (Chen, Landefeld & Murray, *Doctors, Drug Companies and Gifts*, 262 JAMA 2448 (1989))
      - Natural reaction to reciprocate when receive something
Anti-Kickback – Provider Resistance

• Customer Expectations
  – “AdvaMed is dead”
  – “Your competitors are doing it”
  – “I want a consulting agreement!”
  – “Where’s my grant!”
  – “Why won’t you pay for my wife?”
  – “Where is our pizza?”
  – “Will you pay for my flight and hotel for ABC Association Annual Meeting?”
  – “We are such good customers of yours that we are sure you will want to participate in our fundraiser”

  ▪ Signed by or copied to physicians using vendor’s products
Anti-Kickback – Enforcement Effect

• Limited enforcement against customers (physicians) soliciting or receiving alleged kickbacks after industry settlements:
  – CMPs against 8 “TAP” physicians and 1 “Astra Zeneka” physician who billed for samples
    ▪ Where are the CMP actions against physicians who received “kickbacks” from the other life science companies that have settled with the government?

• Cost-benefit-ratio of prosecuting industry with deep pockets and individual physicians with much smaller pockets
  – Is law enforcement relying on the industry to reign-in customer demands?
    ▪ Maybe …, well probably…, okay, Yes.
Anti-Kickback – Enforcement Effect

- Customers think they are not at risk for soliciting/accepting “kickbacks”
  - Particularly private practice physicians
  - Less of an issue with physicians who are part of larger organization with comprehensive compliance program and/or CIA
  - See next discussion regarding medical group/center Conflict of Interest Policies
• Medical groups and centers adopting new or revised Conflict of Interest Policies that prohibit and/or restrict interactions between staff and the life sciences industry
  – Known to date…
    ▪ Cleveland Clinic
    ▪ Kaiser Permanente Medical Group of Northern California
    ▪ Stanford
    ▪ University of Pennsylvania
    ▪ Yale
Anti-Kickback – COI Policies

• Conflict of Interest Policies
  – Cleveland Clinic
    ▪ After adverse publicity regarding the clinic’s and its staff’s relationships with investment firms and life science industry
    ▪ “Policies on Conflicts of Interest and Consulting”
      o “A Conflict Of Interest may exist when [staff] … has an interest in .. a non-CCF party … that could be reasonably perceived as influencing the Staff member’s or Employee’s action or judgments in patient care, research, administrative decisions, or business transactions for CCF.
      o Several policies addressing different conflict types, i.e., Business Affairs, Research, and Consulting
    ▪ Post-policy, fired a physician for failing to disclose a royalty-based interest in a new product
    ▪ Sponsored “A National Dialogue on Biomedical Conflicts of Interest and Innovation Management”
Anti-Kickback – COI Policies

• Conflict of Interest Policies
  – Permanente Medical Group of Northern California (December, 2004)
    ▪ “Conflict of Interest’ means any personal relationships or interests, including financial interests, which interfere or have the potential to interfere with professional roles, responsibilities or judgments of TPMG physicians, and which place the interests of an individual physician ahead of the interests of TPMG and Kaiser Permanente.”
  ▪ No Food, Fun or Friendships
    o No gifts
    o No food for department meetings or on-site education
    o Consulting arrangements require prior approval and no honoraria
    o No travel and lodging for product training
• Conflict of Interest Policies
  – Stanford
    ▪ “…interactions with industry should be conducted so as to avoid or minimize conflicts of interest. When conflicts do arise they must be addressed appropriately…”
    ▪ Policy Summary
      o Faculty research addressed in another policy
      o Gifts and compensation
        » All gifts are prohibited
        » Compensation for sales pitches and attending CMEs are prohibited
      o Restricted site access by sales and marketing representatives
      o Limitations and requirements for scholarships and other educational funds for students and trainees
      o Required disclosure of industry relationships
      o Conflicts of interest training for students, trainees and staff
        » “All students, residents, trainees, and staff shall receive training regarding potential conflicts of interest in interactions with industry.”
• Conflict of Interest Policies
  – University of Pennsylvania
    ▪ “The purpose of this policy is to protect physician and other medical staff and other health care providers’ efficiency and integrity and to protect patient safety and privacy.”
    ▪ Pharma only policy and separate pharma + device policy
    ▪ Policy Summary
      o Prohibits gifts from both industries
      o Requires pharma rep registration and an appointment.
      o Restricts meeting and detailing areas
      o Prohibits pharma samples or vouchers
      o Limitations on and requirements for educational grants and programs
      o Prohibition against food provided directly by pharma reps. Prohibits hospitality or subsidies from both industries
      o Restrictions on consulting and research
      o Requirements for scholarships for health care professionals in training
Anti-Kickback – COI Policies

• Conflict of Interest Policies
  – Yale
    • “The overriding goal of these Guidelines is to ensure as much as possible that the integrity of clinical decision-making is not compromised by financial or other personal relationships with industry.
    • Applies only to pharmaceutical industry
    • Policy Summary
      o Prohibits all personal gifts
      o Prohibits on-campus industry funded meals
      o Requires FMV compensation for specific, legitimate services provided to industry
      o Sales pitch and attending education compensation prohibited
      o Bans sales reps from patient care areas
      o Limitations and requirements for scholarships and other educational funds for students and trainees
      o Limitations on and requirements for industry sponsorship of educational activities
      o Disclosure requirements
Anti-Kickbacks – Next . . .?

• More Companies Subject to CIAs or Additional CIA Requirements
  – Estimated 180 “pharma” cases in the pipeline
    ▪ Includes medical device cases
      ○ Anti-kickback and off-label promotion?
    ▪ Eight medical device companies have already received U.S. Attorney Office subpoenas regarding relationships with physicians
      ○ How often does a U.S. Attorney Office issue subpoena without resulting settlement and CIA?
    ▪ May include 2\textsuperscript{nd} and 3\textsuperscript{rd} cases against companies with prior settlement agreements and CIAs
• More Companies Subject to CIAs (cont)
  – Fewer gifts, meals, travel, grants, etc.
    ▪ Better and broader compliance with PhRMA and AdvaMed Codes.
    ▪ Lower risk tolerance
      o Less Sales and Marketing control over benefits to customers
      o Reduction and/or elimination of historic funding
    ▪ CIAs prior approval requirements ➔ tighter controls ➔ more legal review ➔ more prohibitions and denials ➔ less and/or different industry funding
      o Re-directed and/or re-balanced funding
      o Increased bureaucracy for grants, i.e., request forms with supporting documentation
      o Lower compensation for consulting, research, etc.
        » Limitations on overhead costs and indirect allocations?
      o Increased formality, i.e., written agreements
• More enforcement against physicians soliciting and/or accepting “kickbacks”?  
  – Perhaps if kickbacks are primary focus of industry cases  
• More and tighter medical group/center Conflict of Interest Policies?  
  – More likely for academic medical centers are larger group practices  
  – Likely if embarrassing and reputation-damaging publicity regarding entity/staff relationships with industry  
  – Less likely for small-to-mid-sized private practices  
    ▪ Private practice physicians will continue to be biggest challenge for industry  
• More state laws?
Questions?