Session 306: Kickback and Stark Developments

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Panel

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Enforcement Trends and Other Recent Developments in Kickback and Stark Law

1. Charitable Contributions
   b. Medco Health Solutions – Defense MSJ upheld on appeal – Jan. 19, 2018

2. Escobar Materiality
Enforcement Trends and Other Recent Developments in Kickback and Stark Law

3. HDL Bankruptcy and Related Litigation
   a. HDL Kickback Settlement – $485 Million (Apr. 9, 2015)
   b. HDL Bankruptcy (filed June 9, 2015)
   c. HDL Bankruptcy Trustee Sues Doctors and Non-Profits to Recover Kickbacks (June 12, 2017)

4. (Stark) Self-Referral Disclosure Protocol (SRDP)

   CMS VOLUNTARY SELF-REFERRAL DISCLOSURE PROTOCOL: CHECKLIST

   Checklist of required items for a complete submission:
   - SRDP Disclosure Form
   - Physician Information Form(s) (one for each physician included in the disclosure who made referrals in violation of section 1877 of the Act)
   - Financial Analysis Worksheet, submitted in Microsoft Excel-compatible format
   - Certification

   The disclosing party may also submit an optional cover letter. All the items listed above (and the optional cover letter, if included) must be submitted electronically to 1877SRDP@hs.gov. In addition, a hard copy of the certification only must be mailed to Division of Technical Payment Policy, ATTN: Provider and Supplier Self-Disclosure, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mailstop C4-25-02, Baltimore, MD 21244-1850.

   Obligation to update: Disclosing parties are reminded of the obligation to update the disclosure if the disclosing party files for bankruptcy, undergoes a change of ownership, or changes its designated representative. The update must be submitted electronically to 1877SRDP@hs.gov within 30 days of the change. Include the word “UPDATE” in the subject line of the e-mail.

What Changes to Expect from the Trump Administration

1. Reduce Regulations
   a. Executive Orders 13771 (Jan. 30, 2017) and 13777 (Feb. 24, 2017)

2. Increased Emphasis on Innovation
   a. Center for Medicare and Medicaid Innovation
   b. Value Based Pricing arrangements

3. Changes in FCA Enforcement
   a. Brand Memo – DOJ civil litigators are prohibited from using agency guidance documents to establish violations of law (Nov. 16, 2017)
   b. Granston Memo – DOJ will consider dismissing FCA actions that lack substantial merit (Jan. 10, 2018)
What Changes to Expect from the Trump Administration

4. Lower Drug Prices
   a. Value based pricing (VBP) may become more common for pharmaceuticals
   b. Industry has expressed concern about AKS, Stark law and Medicaid Best Price in connection with VBP arrangements

Practical Tips for Navigating Kickback and Stark Law Compliance

1. Physician Compensation and Practice Acquisitions
   a. Use kickback employment exception if possible
   b. Relative Value Unit (RVU) based compensation models:
      • Limit to work RVUs (wRVUs) – exclude practice expense and malpractice components
      • wRVU rate should not increase with productivity – may exceed FMV
      • wRVUs should be limited to the physician’s personally performed services
   c. Physician group practices - Follow all 8 requirements for Stark-compliant physician group practices
   d. Get valuations to support FMV for medical directorships and call coverage
Practical Tips for Navigating Kickback and Stark Law Compliance

2. Distinguishing Between FMV and Commercial Reasonableness (CR)
   a. FMV - The value in arm’s length transactions, consistent with the **general market value**
   b. General Market Value -
      • Bona fide bargaining between well-informed buyers and sellers
      • Not in a position to general business for the other party
      • Not determined in a manner that takes into account the volume or value of anticipated or actual referrals
   c. CR – Arrangement would make commercial sense if entered into by a reasonable entity of similar scope and size and a reasonable physician of similar scope and specialty, **even if there were not potential DHS referrals**.
   d. Practice loss theory – FMV and CR?

3. Considerations for Compliance Officers
   a. What new risk areas may impact your organization given recent case law and regulatory developments in kickback and Stark?
   b. Would any new kickback or Stark developments warrant an internal investigation in your organization?
   c. How would the organization calculate the amount of any overpayments received in non-compliant kickback or Stark arrangements?
Practical Tips for Navigating Kickback and Stark Law Compliance

3. Considerations for Compliance Officers
   d. Should the compliance officer recommend new policies or modifications to existing policies for kickback and Stark compliance?
   e. How will your organization be affected by the Trump Administration’s focus on lowering drug prices, reducing regulations and moving away from agency guidance documents?

Questions???
Thank you!