AMERIGROUP

- AMERIGROUP – Who We Are
- Serve 1.6 million members in 11 states nationwide
- The largest publicly traded corporation dedicated exclusively to those on publicly funded programs such as Medicaid and Medicare
- Focus on a unique population
  - The financially vulnerable, seniors and people with disabilities
- We take that role – and responsibility – very seriously
Introduction

Managed care organizations (MCOs) are integral players in Federal and State health care programs

- Both Medicare and Medicaid have adopted managed care models as a means of cost containment
- States continue to expand managed care into their Medicaid programs
- More and more states are adopting mandatory managed care models

Introduction (continued)

- Provider interaction with MCOs is almost guaranteed
- Providers will need to closely examine deals and arrangements, being presented to them by MCOs, for possible anti-kickback statute (AKS) implication
Introduction (continued)

The compliance and legal departments of MCOs should:
- take inventory of and examine business development and cost containment initiatives, strategies, and deals in every functional area
- evaluate the risk that each initiatives, strategies, and deals pose of implication of the AKS

Presentation Overview

- What AKS guidance is there for MCOs?
  - Managed care safe harbors
  - Advisory opinions
  - Enforcement actions
- Potential implication of the AKS in the managed care world
  - Functional areas and strategies
  - Provider and MCO deals
- Practical tips for avoidance of AKS violations
Anti-kickback Statute

The law's main purpose protect patients/members and the federal health care programs from fraud and abuse by reducing the corrupting influence of money on health care decisions, such as:

- Overutilization (expense to government)
- Underutilization (compromise health care to member)
- Medical recommendations not based solely upon the best treatment for the patient (compromise health care to member)
Anti-kickback Statute (continued)

- The law is broad and far-reaching
- The penalties for violations are severe

Safe Harbors

- Because the law is broad, concerns arose in the industry that some relatively innocuous arrangements, in some cases beneficial, are prohibited by the anti-kickback law
- Responding to these concerns, Congress in 1987 authorized the Department of Health and Human Services to promulgate "safe harbor" provisions for various payment and business practices that, potentially prohibited by the law, would not be prosecuted
Safe Harbors (Continued)

- Safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor.
- Safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

Looking for Guidance

- Safe Harbors?
- Advisory Opinions?
- Enforcement Actions?
1st Managed Care Safe Harbor

Applies to MCOs that receive fixed capitated payments from government programs

- The safe harbor recognizes that eligible organizations with risk contracts present little or no risk of overutilization or increased cost to the government
  - Payments are fixed
  - Regulatory oversight is high

1st Managed Care Safe Harbor (continued)

- Limits
  - Only protects remuneration of health care items or services related to providing those services
  - Does not cover marketing services (services before enrollment)
  - Does not cover swapping (offering reduced rate to participate in one product in exchange for opportunity to participate in other less restrictive programs)
  - Only applies to “eligible” managed care organization
2nd Managed Care Safe Harbor

Applies where both the MCO and the subcontractor are at substantial financial risk

- This safe harbor has limited application
- Most MCOs do not place their providers and suppliers at substantial financial risk
- Only applies to “qualified” managed care plans

Advisory Opinions

- Limited in scope to the specific arrangement described in the letter
- May only be used by the requestor of the opinion
- There are not many advisory opinions on managed care arrangements, but we can obtain some small guidance from the rationale used in advisory opinions given to requestors from other sectors
Advisory Opinions

Decisions to seek opinions must be considered carefully, weighing the pros and cons.

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<td>• Obtain protection from sanctions for the arrangement for which the advisory opinion was given</td>
<td>• Cost</td>
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<td>• Does not limit the enforcement authority</td>
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<td>• Limited in scope</td>
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<td>• Advisory opinions may be rescinded</td>
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Enforcement Actions

• No recent anti-kickback action against MCOs
• Very little guidance, therefore we are left to extrapolate guidance from enforcement actions against other health care providers (physicians, device companies and pharmaceutical companies)
Major Anti-kickback Recoveries Against Device Companies

Artificial-joint makers paid $310 million to settle anti-kickback case

- Four device companies allegedly used consulting deals with orthopedic surgeons to induce the purchase of their respective artificial hip and knee products
- Agreed to pay a total of approximately $310 million to resolve allegations of anti-kickback statute and FCA violations

Carefully review all payment arrangements to providers. Bogus consulting deals or those lacking in fair market value may be considered improper kickbacks

Pharmaceutical Major Recoveries

- The Government alleged that Bristol-Myers Squibb Co., among other things, paid various forms of illegal kickbacks to physicians and pharmacies. Bristol-Myers Squibb Co. paid more than $499 million to resolve these allegations.
- Merck & Company paid $361.5 million to resolve allegations that it, among other things, paid kickbacks to health care providers to induce them to prescribe the company’s products.
Pharmaceutical Major Recoveries (continued)

- The Merck & Company law suits alleged that Merck & Company paid kickbacks to physicians, disguised as fees for training, consultation, and market research, to induce them to prescribe its drugs and that Merck provided deep discounts to hospitals to induce them to administer its antacid, Pepcid, as a means to boost sales through continued use after the patient’s discharge.

Again, kickbacks can be disguised as fees for training, consulting, market research, etc. Companies would be well advised to carefully review any form of payment to providers.

Enforcement is Good Business
Enforcement is Good Business

- The expected recoveries resulting from OIG investigative and audit oversight activities averaged $3.41 billion per year for the 3-year period from FY 2006 through FY 2008, exceeded all previous reporting periods and exceeded the prior reporting period by 8.5 percent.

- These results include an average of more than $2.05 billion in investigative receivables and $1.36 million in audit disallowances per year by OIG’s Office of Investigations and Office of Audit Services.

Enforcement is Good Business

- The return on investment for the OIG’s oversight of all programs and operations for the FY 2006 through FY 2008 reporting period was $14.7:$1.

Nearly $15.00 recovered for every dollar spent!
Anti-kickback Statute is an Effective Weapon

- The AKS, along with the False Claims Act and Stark, is one of the government's most effective weapons used to combat fraud.
- AKS enforcement action against only four pharmaceutical companies alone in 2008 yielded nearly $640 to the federal government and an additional $430 million to states.
- Can we expect to see greater enforcement with the use of the AKS?

Anti-kickback Enforcement Involving MCOs

The Current Environment - - - the "Perfect Storm" - - - for Enforcement in the MCO Sector
Anti-kickback Enforcement Involving MCOs - - - the “Perfect Storm”

- Political Environment
  - Health care reform is a top priority of state and federal government
  - Reduction of fraud and abuse in the industry is a top priority

- Economic Environment
  - Federal and state budget crisis
  - Astonishing recoveries through enforcement activities
  - The government is likely to dedicate more resources to enforcement actions – great return on investment (almost 15 to 1)

Anti-kickback Enforcement Involving MCOs - - - the “Perfect Storm” (Continued)

- Business Environment: Managed Care Organizations and Providers
  - Economic crisis triggering the emergence of cost management and cost controls, such as risk, gain and cost sharing arrangements and provider incentive programs
  - Economic challenges spark new and creative ways to grow the business, such as new marketing initiatives, joint ventures and emergence of provider owned MCO
Anti-kickback Enforcement Involving MCOs - - - the “Perfect Storm” (Continued)

- Legal Environment
  - Broad and far reaching law
  - Limited guidance on application to MCO related arrangements
  - Federal funding for prosecution
  - States as willing partners in the legal battles
  - Whistleblower laws

Where to Look for Potential Violations
MCO Functional Areas at Risk

- Medical and Quality Management
- Medical Finance
- Provider Relations
- Sales, Marketing and Retention
- Mergers and Acquisitions

Risk and Gain Sharing Agreements at Risk

- Safe Harbors provide protection for some risk and gain sharing arrangements. However, the arrangement must fall squarely within the requirements
  - Does your arrangement meet the safe harbor requires?
  - Does your MCO meet the definition of “eligible managed care organizations” or “qualified managed care plan”?
Other Provider Incentive Programs at Risk

- **Medical and Quality Management**
  - Provider quality incentive programs tied to panel size

- **Marketing**
  - Offering remuneration in order to encourage providers to steer business to MCO
  - Perks to providers tied to panel size of MCO members or growing of panels, i.e. offering of monthly appreciation lunches for all providers that maintain a MCO panel size of 200 or more members

Other Provider Incentive Programs at Risk

- **Retention Programs**
  - Incentives to providers to assist MCO with retention in MCO’s health plan. i.e. will pay provider office staff $25.00 for each member he/she assist with renewal into MCO health plan
Joint Ventures

- Providers are getting in the managed care business by, individually or via joint ventures, forming managed care organizations, known as provider or hospital owned MCOs

- Providers are also entering into joint ventures with managed care organizations and sometimes third parties

Advisory Opinions Nos. 98-19
(Independent physician association acquiring interest in MCO)

- Illegal remuneration can be disguised as stock options and incentive plans
- Incentive Stock Plan does not violate the anti-kickback statute when the physician receiving the stock is not in a position to refer business to IPA and additional stock is not tied referrals to the managed care organization.

Benefits to Beneficiaries

- Offering beneficiaries incentives to induce a beneficiary to use a particular provider or supplier, for example:
  - A particular physicians group within a network offering incentives to beneficiaries designed to encourage a beneficiary to use one group over another
  - Mailing out information to members with diabetes encouraging them to order diabetic supplies from a particular vendor, induced by a volume discount offered to the MCO by the vendor
Benefits to Beneficiaries (continued)

- Offers directly or indirectly to beneficiaries and potential beneficiaries could run afoul of the AKS

Advisory Opinions Nos. 06 -20
(Offering of free items or services as part of a patient or provider marketing strategy)

DME company sought to provide free home oxygen pending the required oximetry test results required for payment by Medicare. The OIG concluded that arrangement would subject to sanctions because the remuneration would likely influence the beneficiaries choice of suppliers of other good and the physician would have effectively endorsed the DME supplier by ordering the non-reimbursable service.

Community Outreach Marketing

- Community-based and faith-based organizations can also serve as a referral source

- Although deals with community-based and faith-based organizations present very little risk of frustrating the purpose of law, below are examples of activities that could technically implicate the AKS
  - Making charitable contribution or giving sponsorship dollars to organizations in exchange for steering of members to the MCO
  - Providing in-kind services in exchange for the steering of employees, event audiences or members to the MCO organization
Tips for Avoidance of AKS Implications

Take Inventory
- Our legal and compliance departments took inventory of the existing deals and set out to review all of these existing deals. Legal or compliance is now consulted on any deals being negotiated between MCOs and providers, and
- We carefully evaluate the unique facts and circumstances of each arrangement
- We look for language, conduct or arrangements that could be perceived by investigators as violating the law
- We carefully review all forms of compensation to referral sources for:
  - the appropriateness of the payment (fair market value for services, venue for training, modest meals at training)
  - documentation required in the approval process before payments are made,
  - the safeguards in place to ensure policies and guidelines are followed
Tip # 2 for Avoidance of AKS Implications

AMERIGROUP developed solid anti-kickback policies and procedures that clearly outline, among other things, what types of gifts (and dollar limits for those gifts) that are permissible

- What gifts benefit patients/members or serve a genuine educational function
- What donations or grants are permissible
- What payments a company representatives may make for meals, receptions or other hospitality during meetings with physicians
- What gifts may be made to physicians or other decision as good will
- How gift limits are calculated (per provider, per practice group, or per legal entity)
- How gift are tracked and monitored

Tip # 3 for Avoidance of AKS Implications

AMERIGROUP launched a company-wide anti-kickback educational campaign

- Created functional area specific bulletins, computer based training and facilitated training
- Incorporated AKS awareness into mandatory compliance programs training
Tip # 4 for Avoidance of AKS Implications

Consider the pros and cons of seeking advisory opinions for new and existing deals and seek legal advice.

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