HCCA Compliance Institute 2003

CASE STUDY: ANALYZING ANTI-KICKBACK AND STARK LAW ISSUES

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Part I
The Anti-kickback Law
AGENDA

- Purposes
- Elements
- Safe Harbors and Other Guidance
- Mac’s Top Ten Tips
PURPOSES

- Prevent corruption of medical decision-making
- Prevent overutilization
- Prevent increased program costs
- Prevent unfair competition
ELEMENTS

- Remuneration
- Offered, paid, solicited, received
- To induce Federal program referrals
- Knowingly and willfully
REMUNERATION

- Anything of value
- Cash or in-kind
- Direct or indirect
- Examples:
  - Cash, free goods, below market rent, free medical waste disposal, free housecleaning
OFFERED, PAID, SOLICITED, RECEIVED

- Separate intent inquiries for payors and payees
- Payors most commonly prosecuted in the past
- Payees (mostly physicians) becoming more frequently prosecuted (e.g., TAP, Clearwater Clinic)
TO INDUCE FEDERAL REFERRALS

- Any Federal health care program
- “To induce”: a nexus between payment and referrals
- One purpose test
“KNOWINGLY AND WILLFULLY”

- Acting with knowledge and purpose
- Standard varies by circuit
  - 9th circuit: knowledge of anti-kickback statute with specific intent to violate
  - 8th circuit: knowledge that conduct was wrongful
  - 11th circuit: knowledge that conduct was unlawful
PENALTIES

- Criminal
  - prison and/or fines
- Exclusion
- Civil monetary penalties
  - $50,000 plus 3x kickback
EXCEPTIONS AND SAFE HARBOURS

- Immunity available
- Practice must meet all conditions
- Voluntary
STATUTORY EXCEPTIONS

- Discounts
- Payments to employees
- Group purchasing organizations
- Waiver of Part B co-payments by Federally qualified health centers
- “Shared risk” exception
SAFE HARBORS

Investments

- Large entities
- Small entities
- small entities in underserved areas
- ASC’s
- Group practices
SAFE HARBORS

Other

- Employees
- Discounts
- Space rental
- Equipment rental
- Personal services
- Practitioner Recruitment in underserved areas
- Group Purchasing Organizations
- Managed care arrangements
- Shared Risk
- etc.
GUIDANCE

- Advisory opinions
- Fraud Alerts and Special Advisory Bulletins
- Preambles to the safe harbor regulations
- Compliance Guidances
- www.oig.hhs.gov
AREAS OF GOVERNMENT INTEREST

- Medical directorships
- Consultation fees
- Marketing to physicians
- Education/research grants
- Joint ventures
- Below market leases
- Below market loans
MAC’S TOP TEN TIPS

# 10 NICE PERSONAL FAVORS TO REFERRAL SOURCES: END OF AN ERA

- Message of TAP case and proposed Pharmaceutical Guidance
  - No fancy dinners
  - Nothing for spouses
  - No NFL tickets
  - No free computers
  - No unrestricted educational grants, etc.
MAC’S TOP TEN TIPS

# 9  DON’T BE THE “LOW HANGING FRUIT”

- In a period of shrinking investigatory resources, don’t stick out of the crowd.
MAC’S TOP TEN TIPS

# 8 BUT ALSO BE WARY OF BEING IN THE CROWD

- Crowds not to be in (examples)
  - clinical lab ordering in the early 90’s
  - PATH in the mid 90’s
  - pharma marketing in the late 90’s

- Avoid being in the next “national project”

- Ask frankly: “has competition in X area gone to far?”
MAC’S TOP TEN TIPS

#7 ALWAYS START ANALYSIS WITH THE BASIC PURPOSES OF THE STATUTE

- Prevent corruption of medical decision-making
- Prevent overutilization
- Prevent increased program costs
- Prevent unfair competition
MAC’S TOP TEN TIPS

# 6 GET AS CLOSE TO A SAFE HARBOR OR ADVISORY OPINION AS POSSIBLE

- Document business reasons why full compliance with an applicable safe harbor is not possible
- Adopt principles from relevant OIG guidance to extent possible
MAC’S TOP TEN TIPS

# 5  FAIR MARKET VALUE: “THE SAFE UNHARBOR”

- Never will be an official safe harbor, but . . .
- Excellent overall protection if FMV established:
  - for necessary, justifiable services/investment
  - by independent, reliable source
  - using recognized methodology
MAC’S TOP TEN TIPS

# 4 DON’T MUDDY YOUR OWN SHOES

- don’t acquiesce to any fooling around with documents (e.g., shredding, altering, backdating)
- don’t acquiesce to withholding information to the government or to producing literally true but incomplete information (half truth)
- ask for express numeric “odds” on being detected or being prosecuted (Note: it’s OK to assess legal risk generally where law is ambiguous)
# 3 **CHECK COMPLIANCE ON AN ONGOING BASIS**

- Check to see that:
  - deal properly implemented
  - parties fulfilling substantive responsibilities
  - ongoing documentation (if any) properly maintained
MAC’S TOP TEN TIPS

# 2 DOCUMENT! DOCUMENT! DOCUMENT!

**Document:**
- legitimate business purposes
- fair market value
- services to be provided and time spent providing them

**Powerful evidence of good faith and a turn-off to investigators**

**But a two-edged sword if documentation is:**
- inaccurate when created
- not fulfilled going forward
MAC’S TOP TEN TIPS

# 1 “GREED IS GOOD” -- NOT

- #1 red flag to investigators:
  - return on investment that appears excessive
  - compensation that appears excessive
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