




National CME Audioconference

Industry-Supported CME Under Fire: Mitigating Risk and Enhancing Compliance

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Viveca D. Parker
Assistant United States Attorney
615 Chestnut Street, Suite 1250
Philadelphia, PA 19106
Phone: (215) 861-8443
E-mail: viveca.parker@usdoj.gov





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- My own opinions, not DOJ or US Attorney policy





NEW FOCUS

KICKBACKS INVOLVING PAYORS AND MIDDLEMEN

- PAYMENTS TO OBTAIN CONTRACTS
 - PAYMENTS TO RETAIN CONTRACTS
 - PAYMENTS TO OBTAIN FAVORABLE TREATMENT IN CONTRACTS
 - PAYMENTS TO AGENT OR FIDUCIARY FOR EXERCISING DISCRETION ON BEHALF OF PRINCIPAL IN FAVOR OF PAYOR
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CME In the Middle?



- CME provider as middleman between manufacturer and physician




- CME provider being asked to exercise its discretion in favor of the manufacturer





Could It Be A Kickback?


- Violation of state anti-kickback law (e.g., contained in pharmacy, insurance, licensing, or practice acts)
 - Violation of PhARMA Code
 - Violation of industry ethics and standards
 - Violation of fee splitting or referral prohibitions
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Kickbacks As Violations of the False Claims Act


31 USC 3729

● False Claims Act prohibits:

- Knowingly presenting, or causing to be presented, a false or fraudulent claim
 - Knowingly making or using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid
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FCA Theory of Kickbacks

- Compliance with the Anti-Kickback Statute is a prerequisite to payment by the government (an express requirement for Medicare payment 42 CFR 413.24(f)(4)(iv))
 - By seeking payment, applicant is certifying that it has complied
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FCA Theory of Kickbacks (cont'd)

- - Applicant expressly certifies compliance with laws
 - Applicant impliedly certifies compliance if compliance is a prerequisite to payment – look for a nexus between the statute and the government's decision to pay – is compliance with the Anti-Kickback Statute relevant to the government's decision to pay
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FCA – Kickbacks (cont'd)


● Remember:

- no specific intent to defraud required – reckless disregard is enough
- and the one purpose test: if only one purpose of the payment is to induce, it could be a kickback






What If . . . ?

- Sponsoring entity pays CME provider “incentive bonus” for attendees – and some of that is passed on to the attendees
 - Sponsoring entity and CME provider have a relationship: co-ownership, joint venture, lease – does that make the CME program a kickback from the sponsor to the attendee?
 - The CME program is repeated so often it becomes a profit center – does that make the CME program a kickback from the sponsor to the CME provider?
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A Kickback by Any Other Name – Bribery

- Travel Act 18 U.S.C. 1952(b)(2)
Prohibits interstate travel or mail to distribute proceeds of any “unlawful activity”
 - Defines “unlawful activity” as including bribery in violation of laws of state in which committed
 - Can turn a state bribery violation into a federal case
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Public Contract Anti-Kickback Act



41 U.S.C. sections 51 et seq.

- Kickbacks are prohibited in the context of public contracts
 - Kickback is anything of value provided to a prime contractor or subcontractor in exchange for favorable treatment in connection with the prime contract
 - Prime contract is the one with the government – subcontract is one with the prime contractor for materials or services under the prime contract
 - No exception for discounts
 - Civil and criminal penalties
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KICKBACK CASES

- USA v. Merck-Medco Managed Care L.L.C, 336 F. Supp 2d 430 (E.D. Pa. 2004)
 - Public Contracts Anti-Kickback Act, 41 U.S.C. 52- prohibits providing, offering, accepting, or soliciting payments to “induce or reward” “favorable treatment” in connection with a federal contract
 - Motion to dismiss denied
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- PBM/Subcontractor paid health plan/prime contractor with a Medicare contract, and
 - PBM/subcontractor was paid by other entities (manufacturers, etc.)
 - Could be liable even if unaware of the government contract
 - Medicare program involves contractual action that qualifies as a “prime contract” – Medco, 336 F. Supp. 2d 430, Warning, 1994 WL 396432
 - No financial harm necessary to state a claim
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Kickbacks and professional standards

- Vine Street Clinic v. Healthlink, Inc. 856 NE2d 422 (Ill. S. Ct. 2006)
 - Physicians seek declaratory judgment that percentage-based fees for inclusion on preferred-provider network list are violation of Illinois Medical Practice Act
 - Act prohibited payments by physicians for management or other services based upon a percentage of professional/medical income
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Vine Street Clinic (cont'd)

- Physicians paid network administrator 5% of network's rate schedule medical fees paid by payors
 - A form of referral fee – network referred patients to providers – and fee sharing
 - Flat fee for administrative services based upon volume and complexity of administrative services was not prohibited
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Vine Street Clinic (cont'd)

- No return of fees ordered because physicians were in pari delicto
 - Significance: ethical standards and professional standards under licensing laws can be basis for “improper payment” or bribery under Public Contract Anti-Kickback Act, 41 U.S.C. 51, or the Travel Act, 18 U.S.C. 1952(b)(2) (bribery in violation of the laws of the state in which committed)
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Indictment of Dr. Gleason

Licensed psychiatrist gave medical education speeches about a drug indicated for patients with narcolepsy – “date rape” drug

Manufacturer paid tens of thousands of dollars to psychiatrist because of his proven ability to generate off-label sales

Psychiatrist engaged in a scheme to defraud private and public health insurance plans by advising prescribing physicians not to include off-label indications on prescription forms, and by suggesting diagnosis codes

Indicted in April 2006 in EDNY





Another Case

The Zimmer/Premier case: USA ex rel. Schmidt v. Zimmer, 386 F. 3d 235 (3d Cir. 2004)

Manufacturer Zimmer contracts to supply products to purchasing agent Premier's entities

“Conversion incentive” to Premier participants-
price reduction for increased purchases, plus
2% bonus if Zimmer meets market share and
volume purchase goals






Schmidt v. Zimmer, cont'd.

Payments to physicians and orthopedic surgeons from Zimmer and certain Premier entities to induce purchases of Zimmer products

Allegation: Premier entities' Medicare HCFA 2552 certification of costs and compliance was false-because of violation of Stark and Anti-Kickback Acts

Premier entities did not disclose Zimmer contract rewards to Medicare






Schmidt v. Zimmer, cont'd.

Zimmer could be liable under FCA for knowingly assisting in filing a false claim/causing the government to pay a false claim


Premier had clause in contract requiring that “members disclose” discounts and reductions on cost reports

“It thus appears that Zimmer was at least aware that (Premier entity) might file a false claim for more than it paid Zimmer”







Evidence

- Recording physicians' state of mind after the CME program, tracking prescription activity
 - Inappropriately large sales force for topic
 - Amounts paid to CME provider, speakers, locations, repetitions of program
 - Types of locales
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Evidence (cont'd)

- Incomplete disclosure of relationships
 - Involvement of sales and marketing staff
 - One-sided science, no real contribution to improving patient care
 - Inappropriate audience selection
 - Lack of written contract with objective criteria/goals
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THANK YOU

