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**EYE OF THE STORM:  
HOT TOPICS IN FLORIDA HEALTH CARE  
FRAUD AND COMPLIANCE  
SEPTEMBER 23, 2008**




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FOLEY EXECUTIVE BRIEFING SERIES



**Eye of the Storm:  
Hot Topics in Florida  
Health Care Fraud and Compliance**

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FOLEY EXECUTIVE BRIEFING SERIES <sup>2</sup>



**Overview**

- A Regulatory Trifecta: Antikickback Statute, Stark Law and Civil Monetary Penalty for Beneficiary Inducements
- Some Not So Hypothetical Case Studies
- Trends in Florida Enforcement
- DMEPOS Competitive Bidding
- The Next Big Wave: Understanding the Off-Label Cases

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**A Regulatory Trifecta**

- Antikickback Statute
- Stark Law
- Civil Monetary Penalty for Beneficiary Inducements

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## Antikickback Statute

- Receipt of items of value
- In exchange for
- Purchasing, ordering, arranging for
- Items, services paid by Medicaid/Medicare
- Includes referrals
- Covers soliciting, receiving, offering, paying
- Direct/indirect benefits
- One purpose test
- Criminal Statute
- Intent-based

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## Antikickback Statute: Examples

- Side payments by salesman to purchasing agent
- Swap purchase of goods for future unrelated business
- “Freebies”--free computer hardware to run purchased software
- Free training--questionable

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## Anti-Kickback Statute--Carve-Outs

<ul style="list-style-type: none"> <li>■ Type 1: Safe harbors           <ul style="list-style-type: none"> <li>- Zones of protected activity</li> <li>- OIG/CMS studying more</li> <li>- Examples:               <ul style="list-style-type: none"> <li>■ Discounts</li> <li>■ Group purchases</li> <li>■ Employees</li> </ul> </li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>■ Type 2: Advisory opinions           <ul style="list-style-type: none"> <li>- Create case specific safe harbors</li> <li>- Submit to OIG</li> <li>- Full description</li> <li>- All parties and corporations</li> </ul> </li> </ul>
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## Anti-kickback Statute Penalties

- Civil Monetary and Criminal Penalties
- CMP of \$50,000 per violation
- Criminal Penalties: \$25,000 per violation and/or up to 5 years in jail
- Exclusion

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## Antikickback Statute: Advisory Opinions

- Must be actual arrangement
- Planning to enter; attest good faith
- Can be contingent on OIG
- Can't ask about competitor
- 2 certifications
- Include all relevant documents
  - leases, contracts, court documents, employment agreements
- Deal can't be under investigation

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## Antikickback Statute: Advisory Opinions

- OIG not bound to honor
- 60 day response time
- IG will publish summary of request and response
- Internet
- Competitors will know plans
- Only OIG and parties bound
- Impact for public
- OIG can rescind opinion
- If fraud, no sanctions unless material info withheld
- IG opposition

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## Stark Law

- Prohibits referrals for designated health services (“DHS”) to/by physicians who have a financial relationship in the provision of the DHS
- The term “financial relationship” means an (i) ownership or investment interest or (ii) a compensation arrangement between the referring physician (or immediate family member) and the entity furnishing designated health services.

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## Stark Law

- An ownership interest includes any kind of equity or debt arrangement, direct or indirect, secured by the entity’s property or revenue.
- A compensation arrangement means any arrangement involving any remuneration, direct or indirect, between the referring physician and the entity providing the designated health services.

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## Stark Law

- Unlike Anti-Kickback Law, all elements of exception must be met or referral is prohibited.
- Exceptions vary based upon type of relationship between physician and entity.
- New regulations published July 2008.

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## Stark Law

- CMS will deny payment for any designated health services provided by the entity as a result of a prohibited referral.
- CMS will require refunds of all amounts collected as a result of a prohibited referral.
- Civil monetary penalties of up to \$15,000 for each bill or claim and up to \$100,000 for a circumvention scheme (knowing violation).
- Medicare program exclusion.



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## CMP: Beneficiary Inducements (42 U.S.C. § 1320a-7a(a)(5))

- Offer or transfer of “remuneration” to Medicare or State health care program beneficiary.
  - Items or services for free or for other than fair market value.
  - Special rules on waivers of coinsurance and deductibles.
  - Incorporates AKS statutory and regulatory safe harbors
  - Preventive care exception
- Actual knowledge, deliberate ignorance, reckless disregard
- Likely to influence beneficiary to order or receive Medicare or SHCP items or services from particular provider, practitioner, or supplier.



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## CMP: Beneficiary Inducements (cont.)

- Civil Monetary Penalty
  - \$10,000 for each item or service
  - Three times the amount **claimed** for each item or service (not amount received).
  - Exclusion



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**SOME  
NOT-SO HYPOTHETICAL  
CASE STUDIES**

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**Case Study: The Physician Office Brochure**

- Joe Go-Getter, a Sales Manager for Company Y, wants to take out an advertisement in a patient brochure for Doctor Seuss, a head, shoulders, knees, and toes specialist.
- Cost is minimal.
  - FMV? Basis for determining FMV? What if Company Y's ad would entirely underwrite the cost?
- Legal Dept. receives an email from Joe Go-Getter states "This is a great marketing program that Dr. Seuss has started. We're lucky to have been invited. If we don't jump on this, Dr. Seuss told me he's going to get our biggest competitor, Company W, to do it."
  - What if compliance or Joe's boss received Joe's email instead?

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**Case Study: The Physician Office Brochure (cont.)**

- Brochure will be distributed in the community
  - Different answer if only in-office?
- Brochure contains endorsement for Company Y's products from Dr. Seuss.
  - Different answer if no endorsement?
- Distinction between advertisement and brochure content is blurred (and a picture of Company Y's CEO and Dr. Seuss together)
  - Different answer if ad is placed at end and clearly marked as ad?

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## Case Study: The Educational Trip

- Dr. Zhivago, a famous orthopedic surgeon, is invited to Costa Rica to receive training on Company Y's new device.
  - Does it make any difference if the training facility is in rural Iowa?
  - What if it's cheaper for Company Y to have the training facility in Costa Rica than in rural Iowa?
  - What if the training facility is co-located with Company Y's plant in Costa Rica?
  - What if the visit includes a plant tour?
- Does Company Y need to have any type of signed agreement with Dr. Zhivago to provide this training?
- What if the training is for surgeons who've never used your device and Dr. Zhivago has been using it for many, many years and is a top prescriber?

  
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## Case Study: The Educational Trip (cont.)

- Dr. Zhivago wants to bring his wife along. Can she come? Who pays? Who makes the travel arrangements? What if Dr. Zhivago wants to bring his nurse? What if Dr. Zhivago and his nurse also have a personal relationship (and your sales representative knows because he introduced them)?
- What if Dr. Zhivago uses your device primarily for an unapproved/off-label use? What if your sales staff is aware of this since they recommended the off-label use?

  
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## Case Study: The DVD Player

- Dan's DME Supply provides all patients receiving a certain new prosthetic device a coupon redeemable at the local Drugs R Us pharmacy for a free DVD player. The DVD player is valued at \$29.99.
- The purpose of the DVD player is to permit patient to watch a DVD (also provided free of charge to the patients) with information and tips on living with the prosthetic device.
- The manufacturer of the prosthetic device supplies the informational DVDs to the supplier for distribution to its customers.
- Dan's DME Supply pays Drugs R Us \$29.99 for each DVD coupon that is redeemed.

  
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### Case Study: The DVD Player (cont.)

- Does your analysis change if Dan's DME Supply gives the patient the DVD player directly?
- Does your analysis change if the Drugs R Us only charges Dan's DME Supply \$15.99 for each coupon redeemed?
- Does your analysis change if instead of a DVD player, the patient receives a digital video recorder worth \$249.99?
- Does your analysis change if Dan's DME Supply only gives the coupons to low-income patients?
- Does your analysis change if Dan's DME Supply only give the coupons to returning Iraq War Vets? What is the Iraq War Vets are all TRICARE beneficiaries?

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### Case Study: The DVD Player (cont.)

- What if Dan's DME Supply takes out an advertisement in the local newspaper that says: "Get your new Nimbus 3000 prosthetic leg here and receive a free DVD player?" What if the ad has a footnote in very small type at the bottom stating "except Medicare and Medicaid Beneficiaries."
- What if Dan runs out of the manufacturer's free DVDs before Drugs R Us runs out of the DVD players?
- What if the DVD player is proprietary and can only be used to play informational DVDs from this device manufacturer?

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### Trends in Florida Enforcement

- OIG Redraws the Map
- Enforcement Considerations
- Prioritizing Financial Relationships
- Prioritizing DME and Device Investigations
- Prioritizing Medicaid Investigations
- Spinning Off CMPL Investigations
- Recent Florida Enforcement Actions

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## OIG Redraws the Map

- New Florida field office in Miami Lakes (had been managed from Atlanta previously)
- Separate funding
- New Special Agent in Charge (Miami): Christopher Dennis
- New Counsel (Miami): Felicia Heimer



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## Enforcement Considerations

In determining whether to “prosecute” or otherwise pursue an action, DOJ and OIG look at a variety of factors:

- Increased charges or costs reported for items paid by Medicare or Medicaid.
- Possible encouragement of over-utilization or steering.
- Other inappropriate influences on patient treatment.
- Whether there is a legitimate business purpose, which the arrangement is reasonably designed to carryout.

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## Prioritizing Financial Relationships

- Baptist Health South Florida, Inc.
  - Settled May 14, 2008
  - \$7.7 million settlement
  - Voluntary disclosure under Stark Law.
  - Baptist made payments for physics and dosimetry services to community oncology group in excess of FMV.
  - Oncology group source of referrals to hospital
  - Pursuant to 2008 Open Letter, no CIA required.

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## Prioritizing DME and Device Investigations

- Focused primarily on Antikickback Statute allegations
- Enforcement focus on arrangements that include travel, entertainment, consulting, and royalties.
- Multiple arrangements with single physician will be evaluated in the aggregate.
- DOJ and OIG particularly interested in industry/physician financial arrangements they believe may intersect with off-label or other marketing activities or implicate quality issues.
- Both competitors and physicians have been source of qui tam complaints and other allegations



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## Prioritizing Medicaid Investigations

- CMS Medicaid Integrity Program: Headed by David Frank, former criminal AUSA in Miami.
- Dedicated MIP/MMA funding being used to train attorneys, investigators, and auditors on how to perform Medicaid investigations.
- WellCare Health Plans, Inc. (Aug. 18, 2008)
  - Form 8-K filing announcing agreement for initial \$32.5 million payment
  - Payment based on Medicaid behavioral health capitation refunds WellCare Florida allegedly owes to AHCA



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## Spinning Off CMPL Investigations

- OIG strategy first initiated in Clearwater labs investigations in 2001
- Divide and conquer
  - Individual or smaller targeted by OIG under CMPL
  - Larger entities targeted by DOJ under FCA
- Particularly effective in context of kickback investigations
- MedCare Home Health (March 27, 2008)
  - \$178,000 CMPL settlement
  - Alleged kickbacks to coordinators to induce referrals of home health care patients



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## Recent Florida Enforcement Actions

- Acculab Laboratories, Inc. March 17, 2008
  - \$461,000 FCA qui tam settlement
  - Allegations that laboratory services were not ordered, not provided, not medically necessary, improperly bundled.
  - Primary allegation involved falsification of ICD-9 diagnosis codes.
- Dr. Aleyda M. Borge
  - Physician at HIV Infusion Clinic
  - Acquitted in 2007 criminal trial, but co-defendant was convicted.
  - \$6.7 million FCA settlement

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## Recent Florida Enforcement Actions

- University MRI (April 14, 2008)
  - \$7 million FCA qui tam settlement
  - CIA with 11 related entities and company owner
  - Alleged claims for CT scans without contrast that were not performed
  - Alleged claims CT scans and ultrasound tests not ordered and not medically necessary
  - Alleged AKS and Stark violations related to medical directorships, clinical research, employment, facility use, and equipment lease agreements.

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## DMEPOS Competitive Bidding

- April 2, 2007
- Initial Regions: Charlotte-Gastonia-Concord, North and South Carolina; Cincinnati-Middletown, Ohio, Kentucky, and Indiana; Cleveland-Elyria,-Mentor, Ohio; Dallas-Fort Worth-Arlington, Texas; Kansas City, Missouri and Kansas; **Miami-Fort Lauderdale-Miami Beach, Florida;** **Orlando, Florida;** Pittsburgh, Pennsylvania; Riverside-San Bernardino-Ontario, California; San Juan-Caguas-Guaynabo, Puerto Rico

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## DMEPOS Competitive Bidding

- Version 1.1: Would have gone into effect 7/1/2008
- Postponed by Congress
- Version 1.2: Bidding to begin 1/2009. Implementation in 2010
- Accreditation Requirements
  - To be met by 9/1/2009

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## The Next Big Wave: Understanding the Off-Label Cases

- The Threshold Question -- What is 'off-label'?
- The Important Question -- Why do we care?

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## What is a "label"?

- FDCA Section 201(k) – “display of written, printed, or graphic matter upon the immediate container of any article.”
  - Source: 21 U.S.C. § 321(k).
- FDCA Section 201(m) – labels and other written, printed or graphic material (1) upon any article or any of its containers or wrappers; or (2) accompanying such articles.
  - Source: 21 U.S.C. § 321(m).

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## The Package Insert

Information included:

- Contents of the tablet, capsule, or vial
- **The indication of the drug – the conditions approved by the FDA**
  - Literally, what is on the label
- The approved age range
- The Mechanism of Action – how it works
- The pharmacokinetics of the drug – absorption, metabolism, excretion

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## The Package Insert (cont.)

- Serves as a guide for healthcare professionals, pharmacists and patients; mainly intended for healthcare professionals
- Includes summary of the safety and efficacy data submitted to the FDA
- Pharmaceutical Companies required to develop all promotional materials based **only** on information included in the PI
  - Anything else is considered 'off-label'

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## Medicare Overview

- Medicare Part A – hospital, SNF
  - Bundled payments (DRG, OPSS)
- Medicare Part B – suppliers (doctors, labs)
  - Fee-for-Service
- Medicare Part C – managed care
- Medicare Part D – prescription drugs

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## Medical Necessity is the Starting Point

- “[N]o payment may be made...for items or services ...[that] are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”
  - Source: *U.S.C. § 1395y(a)(1)(A) Soc. Sec. Act 1862(a)(1)(A).*
- NOTE: “reasonable and necessary” is still not a defined term

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## Elements of Medicare Coverage

- Regulatory Approval (e.g., FDA-approved for some use)
- Benefit Category Determination (e.g., prescription drugs may fall under Part B or Part D Medicare)
- Not statutorily excluded per *42 U.S.C. § 1395y(a)(2)-(15), Soc. Sec. Act § 862(a)(2)-(15)*
- Coding & Payment Issues (e.g., need a HCPCS code, claim has to be timely, etc.)

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## Part A and Off-label

- Drugs and biologicals should be covered for indications other than those specified on the labeling.
- FDA must not have specified such use as nonapproved.
- Coverage is determined taking into consideration the generally accepted medical practice in the community.
- A hospital stay solely for the purpose of use of a drug or biological that is determined not to be reasonable and necessary is not covered.
- Drugs and biologicals which have not received final marketing approval by the FDA are not covered unless CMS instructs the intermediary to the contrary.

- Source: *42 C.F.R. § 409.13; Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapter 1, Section 30.*

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## Part B and Off-label

- Off-label use of an FDA-approved drug may be approved if the use determined to be “medically accepted,” taking into consideration:
  - the major drug compendia (the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information, other authoritative compendia as identified by the Secretary);
  - authoritative medical literature, and/or
  - accepted standards of medical practice.
- Source: Medicare Benefit Policy Manual (CMS Pub. 100-02), Ch. 15, § 50.4.2

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## Part B, cont.

- Unless *the Secretary* has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia; or
- The carrier determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary.
  - Source: 42 U.S.C. § 1395(t); Soc. Sec. Act § 1861(t).

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## Part D and Off-label

- Drug must be prescribed for a medically accepted indication, including uses:
  - approved by the FDA, or
  - supported by a citation included, or approved for inclusion, in one of the following three compendia: (1) American Hospital Formulary Service Drug Information; (2) United States Pharmacopoeia-Drug Information; or (3) DRUGDEX Information System.
    - Drugs supported in peer-reviewed medical literature but not yet approved by the FDA or reflected in one of these compendia are not “medically accepted” and therefore plans should deny payment.
    - Coverage Question: “Describe how drugs used for off-label indications will be covered under Part D,” available at [http://questions.cms.hhs.gov/cgi-bin/cms/hhs.cgi/fhqs/requser/ftd.plp?fp\\_sid=Vnpoczd/](http://questions.cms.hhs.gov/cgi-bin/cms/hhs.cgi/fhqs/requser/ftd.plp?fp_sid=Vnpoczd/), (Question ID: 5074) (last updated June 23, 2006).

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## Part D

- CMS has indicated in comments in the final Part D Rule that it recognizes that “off-label use is critically important and may be the mainstay of medical practice for successfully managing certain conditions.”
  - Source: 70 Fed. Reg. 4248, 4260-61 (Jan. 28, 2005).
- CMS has concluded that it does not, however, have authority to require that Part D plans cover off-label use. Moreover, if not prescribed for a medically accepted indication, the drug is not a Part D drug, and coverage would not be permitted.
  - Source: 70 Fed. Reg. at 4261.

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## Medicare Non-Covered Off-Label Uses:

- “Less than effective” drugs are not covered by Medicare or Medicaid:
  - Drugs that have been determined by the FDA to lack substantial evidence of effectiveness for all labeled indications;
  - Drugs that have been the subject of a Notice of Opportunity for a Hearing (NOOH) published in the “Federal Register” before being withdrawn from the market, and for which the Secretary has not determined there is a compelling justification for its medically need;
  - Any other drug product that is identical, similar, or related.
  - Source: Medicare Benefit Policy Manual (CMS Pub. 100-02), Ch. 15, § 50.4.6.
- Non-covered uses also include those that are:
  - identified as not indicated by CMS or the FDA;
  - specifically identified as not indicated in one or more of compendia mentioned; or
  - not safe and effective, as determined based on peer reviewed medical literature.
  - Source: Medicare Benefit Policy Manual (CMS Pub. 100-02), Ch. 15, § 50.4.5.

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FOLEY EXECUTIVE BRIEFING SERIES 48

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## Medicaid (Federal Requirements)

- Under the Federal Enabling Statute, the term “covered outpatient drug” does not include “a drug or biological used for a medical indication which is not a medically accepted indication.”
  - Source: 42 U.S.C. § 1396r-8(k)(3), Soc. Sec. Act § 1927(k)(3)

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## Medicaid (Federal Requirements)

- “Medically accepted indication” means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act or the use of which is supported by one or more citations included or approved for inclusion in the compendia.
  - Source: 42 U.S.C. § 1396r-8(k)(6), Soc. Sec. Act § 1927(k)(6)

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## Devices

- CMS has also determined there to be coverage determination issues in the medical device arena.
- Consider, among other factors, whether the device is:
  - Medically necessary for the particular patient and whether the amount, duration, and frequency of use or application of the service are medically appropriate; and
  - Furnished in a setting appropriate to the patient's medical needs and condition.

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## Intersection between Off-Label Promotion and Off-Label Uses

- A vivid example

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## Questions?

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## PROFILES

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Foley & Lardner LLP draws on the experience of attorneys in more than 50 practice areas throughout the United States, Brussels, Shanghai and Tokyo to address your legal and business needs. We have assembled a team of knowledgeable practitioners and have included biographies on the following pages detailing the depth and breadth of their experience.

Heidi A. Sorensen .....	3
Robert E. Slavkin .....	6



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Heidi A. Sorensen is of counsel with Foley & Lardner LLP and is a member of the Health Care and Life Sciences Industry Teams.

Ms. Sorensen has extensive experience in health care fraud and abuse and compliance issues. In particular, Ms. Sorensen has worked with medical device and pharmaceutical manufacturers and corporate health care providers in the negotiation of False Claims Act settlements and corporate integrity agreements, and the resolution of matters under the Civil Monetary Penalties Law and the Office of Inspector General's exclusion authorities.

Prior to joining Foley, Ms. Sorensen was chief in the Administrative & Civil Remedies Branch of the Office of Counsel to the Inspector General (OCIG) at the United States Department of Health and Human Services. Ms. Sorensen served as OCIG's coordinator for the Provider Self-Disclosure Protocol and as coordinator for the Physicians at Teaching Hospitals national project. Ms. Sorensen previously served OCIG as senior counsel and as deputy branch chief.

Ms. Sorensen formerly practiced health care and government contracts law in Washington, D.C. with the law firm of Miller & Chevalier. She has experience litigating disputes related to the Federal Employees Health Benefits Program, with a special focus on federal preemption, cost accounting, and compliance issues. Ms. Sorensen also has served as a legislative assistant and law clerk for the Council of the District of Columbia.

Ms. Sorensen earned her J.D. from Georgetown University Law Center (*cum laude*, 1993). While attending law school, she was a notes & comments editor for *The Georgetown Law Journal*. She earned her bachelor's degree from Colgate University.



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Ms. Sorensen is a member of the District of Columbia and Maryland bars. She is a long-time member of the Women's Bar Association of the District of Columbia, where she has served as co-chair of the Judicial Endorsements Committee, treasurer-elect and treasurer, and co-chair of the Health Law Forum. Ms. Sorensen was the treasurer of the Women's Bar Association Foundation and was also a vice-chair for the Debarment and Suspension Committee of the American Bar Association's Public Contract Law Section. She is admitted to practice before the U.S. Court of Appeals for the Federal Circuit and U.S. Court of Federal Claims.

Ms. Sorensen's speaking engagements include:

- Panel: *The Recovery Audit Contractor Initiative*, Virginia Hospital & Health Care Association (Sept. 17, 2007).
- Panel: *Negotiating False Claims Act Settlements and Living Under Corporate Integrity Agreements*, American Bar Association 17th Annual National Institute on Health Care Fraud (May 16 - 18, 2007).
- Panel: *Effective Use of the OIG Self Disclosure Protocol*, American Health Lawyers Association Institute on Medicare & Medicaid Payment Issues (March 22-23, 2007).
- Panel: *Federal and State Administrative Sanctions*, American Health Lawyers Association/Health Care Compliance Association, Fraud & Compliance Forum (Sept. 26, 2006).
- Panel: *Case Resolution*, Strengthening the Government's Response to Medicaid Fraud Conference, Office of Legal Education, Executive Office for United States Attorneys (Sept. 6, 2006).
- Panel: *Investigative Building Blocks*, Strengthening the Government's Response to Medicaid Fraud Conference, Office of Legal Education, Executive Office for United States Attorneys (Sept. 6, 2006).
- Panel: *Current Trends in Compliance Enforcement*,



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American Health Lawyers Association/Health Care Compliance Association, Fraud & Compliance Forum (Sept. 26, 2005).

- *Partnering with OIG: Compliance & Health Care Billing*, Keynote Address at the Health Care Billing & Management Association Spring Educational Conference (April 23, 2004).
- *OIG Provider Self-Disclosure Protocol*, Benefit Integrity Conference, Centers for Medicare & Medical Services (Aug. 2002).
- *Compliance, Enforcement & Risk In Veteran's Health Administration: Panel Presentation and Conducting Compliance Assessments*, Veteran's Health Administration Compliance And Business Integrity Conference (Aug. 21, 2001).
- Panel: *Have Fraud and Abuse Laws Harmed Health Care?* ABA Business Law Section Spring Meeting (March 24, 2001).





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Robert Slavkin is senior counsel with Foley & Lardner LLP and a member of the firm's Health Care and Life Sciences Industry Teams and its Business Counseling & Technology Practice.

Prior to joining Foley, Mr. Slavkin was corporate counsel and compliance and privacy officer for Priority Healthcare Corporation, where he oversaw the daily activities of the company's legal department. During his tenure, Mr. Slavkin provided detailed analysis and guidance pursuant to both FDA and state pharmacy laws, created and supervised the company's patient privacy program pursuant to HIPAA, provided general counsel regarding Stark and anti-kickback matters, and assisted in the oversight of the company's Sarbanes-Oxley compliance process. He has also worked for Adventist Health System, where he was a senior attorney focusing on home health care management, physician contracting, managed care contracting, landlord/tenant issues, HIPAA matters, fraud and abuse matters, tax issues, and appropriate corporate structures.

Mr. Slavkin recently co-authored the book "Healthcare Compliance Professional's Guide to the False Claims Act," (October 2007).

Mr. Slavkin also has experience representing long-term care providers, including guidance regarding Medicare and Medicaid issues related to billing, reimbursement, compliance, fraud, and abuse. He has extensive experience representing health care providers in reimbursement, licensure, certification and other regulatory matters, as well as provided guidance on formation of corporate entities and mergers and acquisitions. Early in his career, Mr. Slavkin interned with U.S. Senator John Heinz (Pittsburgh, Pa.).

Mr. Slavkin earned his J.D. from University of Pittsburgh School of Law. He also holds a bachelor's degree from



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