Update Regarding OIG and CMS Initiatives

HCCA 2011 North Central Regional Compliance Conference

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Recent Enforcement Initiatives

- Opinions
- Settlements
- Cases
- Compliance Guidance
Insurance-Only Billing, Lodging Assistance, and Transportation Assistance
OIG Advisory Opinion No. 11-01

Network of pediatric charity hospitals that provide free pediatric care for certain catastrophic and intractable injuries and medical conditions planned to:

- Begin billing both public and private third-party payers including Federal health care programs, for services rendered, and waive all cost-sharing amounts without regard to patient's financial need;
- Provide financial need-based lodging assistance; and
- Provide a financial need-based transportation for patients and their families.
Advisory Opinion - FAVORABLE

The insurance-only billing policy might implicate the AKS to the extent it would constitute a waiver of Federal health care program cost-sharing amounts, however, the OIG would not seek to impose administrative sanctions primarily because:

- The network’s policy of providing free care predates Federal health care programs, is applied uniformly, and very few, if any of the network’s patients are Medicare-eligible;
- The highly specialized nature of services offered at network hospitals reduces the risk of unnecessary services;
- The network will bear the cost of the foregone cost-sharing waivers;
- Hospital compensation for employed physicians is fixed; and
- The policy would be discussed with patients only after they are already admitted.

Advisory Opinion (continued)

The OIG would not subject the network hospitals to administrative sanctions in connection with the lodging and transportation assistance programs primarily because:

- A recent amendment to § 1128A of the SSA provides that the beneficiary inducement prohibition does not apply to remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs; and
- Aid would be offered to families of inpatients only in the context of recent spinal cord or burn injuries, during hospital instruction of home care needs, and in situations when the patient’s condition requires family accompaniment.
An acute care hospital that provides outpatient services, planned to provide *complimentary transportation* to patients (and their families) from physicians offices on the hospital’s campus to the hospital, if they required further treatment or admission, and were unable to transport themselves.

**Advisory Opinion - FAVORABLE**

The complimentary transportation potentially implicates the AKS prohibiting inducements to Medicare and state health care program beneficiaries because the transportation could induce beneficiaries to obtain Federally-payable items or services from the hospital. However, the OIG would not subject the hospital to administrative sanctions primarily because:

- The transportation would *not selectively limit eligibility* to targeted populations of Federal health care program beneficiaries;
- The transportation would *only be offered on the hospital’s campus*; and
- The cost of the transportation would neither be claimed, directly or indirectly on any Federal health care program *cost report* or claim, nor otherwise be shifted to any Federal health care program.
Long-term care (LTC) pharmacy that services skilled nursing, intermediate care, assisted living, and residential care facilities, planned to have its employee form a new long-term care pharmacy, that he would own, along with one or more LTC facility owners in the pharmacy’s market area. The LTC pharmacy would manage the operations.

Advisory Opinion - UNFAVORABLE
The proposed joint venture could potentially generate prohibited remuneration under the AKS and the OIG could potentially impose administrative sanctions because:

- The LTC pharmacy is a provider of the same services the new pharmacy would provide and is in a position to directly provide products and services, bill insurers and patients in its own name and retain reimbursements;
- The aggregate payment to the LTC pharmacy would vary with the volume of referrals from the LTC facilities, as would the new pharmacy owner’s income; and
- The LTC pharmacy and the new pharmacy owners would share in the economic benefit of the new pharmacy.
Community hospital and Air Force Medical Group entered into a Training Affiliation Agreement whereby the medical group’s physicians remain full-time military personnel, receiving full salaries and benefits, but are also members of the hospital’s medical staff.

**Advisory Opinion - FAVORABLE**

The agreement would not constitute grounds for the imposition of civil monetary penalties (CMPs). While the agreement could potentially generate prohibited remuneration under the AKS, the OIG will not impose administrative sanctions because:

- The hospital provides Air Force physicians in designated specialties with a setting for training that is not sufficiently available at the Air Force Medical Center;

- The Agreement furthers a vital public interest in ensuring members of the armed services and patients in a community recovering from the aftereffects of Hurricane Katrina receive high quality medical care, from well-trained specialists; and

- Under the Agreement the Air Force Medical Group provides free services to patients, but does not bill Medicare or Medicaid.
Charitable organization proposed:

- A cost-sharing arrangement to provide *copayment assistance* to financially needy individuals, including Medicare and Medicaid beneficiaries, for use in connection with genetic testing services to screen for and assist with the diagnosis of cancer; and

- A *voucher program* for individuals uninsured, or whose insurance does not cover genetic testing.

**Advisory Opinion - FAVORABLE**

The Copayment Assistance would not constitute grounds for CMPs, but could potentially generate prohibited remuneration under the AKS if the intent to induce or reward referrals were present. The OIG would not impose administrative sanctions primarily because:

- *No donor* will have any control over the assistance program, and assistance will be awarded independent of any link between donors and beneficiaries;

- Assistance will be based solely on *financial need* and without regard to applicant’s choice of provider; and

- The assistance will cover the *12 most common tests for cancer* predisposition currently available, so not to steer patients towards particular tests.
Charitable Organization Sponsored Co-Payment Assistance for Genetic Testing Services OIG Advisory Opinion No. 11-05

Advisory Opinion (continued)
The voucher arrangement does not generate remuneration under the AKS, and accordingly the OIG will not impose administrative sanctions primarily because:

- The organization does not provide remuneration to Federal health care program beneficiaries, physicians or genetic counselors because, Federal health care program beneficiaries are not eligible to receive vouchers, and physicians and genetic counselors receive no actual or expected economic or other benefit for alerting or referring patients to the voucher program.

Fee for An Online Referral Service to Receive and Respond to Referral Requests OIG Advisory Opinion No. 11-06

For-profit corporation that operates online referral service proposed to begin charging providers an implementation and monthly fee for the capability to electronically receive and respond to referral requests. Non-paying providers would only receive and be able to respond to referral requests via facsimile.
Advisory Opinion - UNFAVORABLE
The proposed arrangement would likely implicate the AKS, and the OIG could potentially impose administrative sanctions primarily because:

- The corporation would be soliciting and accepting, and providers would be paying remuneration in return for the corporation’s arranging for the furnishing of post-acute care services;
- Providers who can electronically receive and respond to referral requests would have a competitive advantage over providers who did not subscribe;
- The cost to fax referrals would exceed the cost to transmit them electronically; and
- Some providers cannot afford the subscription fees.

Vaccine Reminder Program Operated by Pharmaceutical Manufacturer
OIG Advisory Opinion No. 11-07

Pharmaceutical manufacturer of universally recommended vaccine for children arranges mail and telephone vaccination reminders to parents and guardians of children who have missed a vaccine, or are due for a vaccine on a shot schedule. Manufacturer proposed to expand the program to include health insurers and health care entities that insure and treat patients covered by a fee-for-service Federal health care program.
Advisory Opinion - FAVORABLE

- Regarding parents and guardians, neither the AKS nor the CMP is implicated, because the reminders serve only to inform parents and guardians that their child may have missed a vaccine, or is due for a recommended vaccine.

- Regarding participating entities, the program could potentially generate prohibited remuneration, but the OIG will not impose administrative sanctions, primarily because:
  - Program reminders are sent only to parents and guardians of children who have begun but not completed a course of recommended vaccinations;
  - The program does not target any particular referral source;
  - The vaccine is the standard of care and universally recommended; and
  - The program reminders do not recommend a specific vaccine.

Contracts Between DME Supplier and IDTFs
OIG Advisory Opinion No. 11-08

Durable Medical Equipment Supplier (DME) entered into contracts with Independent Diagnostic Testing Facilities (IDTFs) pursuant to which:

- IDTF staff members perform services, including setting up equipment and educating the patient on behalf of the DME, when a non-Federally insured patient selects the DME as a supplier;

- IDTF staff members are responsible for the equipment consigned to the IDTFs by the DME; and

- In exchange for these services, the DME pays the IDTF a per patient fee.

- DME proposed that contracts will begin to include Federal health care program beneficiaries, and the fees paid to IDTFs would be a flat fee.
Advisory Opinion- UNFAVORABLE

Both the existing contracts and the proposed contracts potentially generate prohibited remuneration under the AKS and the OIG could potentially impose administrative sanctions primarily because:

- IDTFs, through their staffs, could potentially influence Federal health care program beneficiaries to select the DME’s products;
- Physicians who are able to prescribe the DMEs products may have a financial interest in the IDTFs;
- When physicians or staff market items to their patients, patients may be unable to distinguish between medical advice and a sales pitch.

Licensed Medigap policy provider proposed an agreement with PPO network hospitals to discount Medicare inpatient deductibles of provider’s policyholders – an amount for which providers would otherwise be liable. In turn, providers would provide a $100 premium credit to policyholders who utilized a network hospital for an inpatient stay.
**Waivers of Inpatient Deductibles**  
OIG Advisory Opinion No. 11-09

**Determination - FAVORABLE**

Proposed arrangement would not constitute grounds for CMPs and while the arrangement could potentially generate prohibited remuneration under the AKS, the OIG would not impose administrative sanctions, primarily because:

- Waiver of fees for inpatient services is not likely to result in significant increases in utilization;
- The arrangement will not unfairly affect competition among hospitals because membership in the network would be open to any accredited Medicare-certified hospital; and
- There is a **statutory exception** for differentials in coinsurance and deductible amounts as part of a benefit design plan, and while the premium credit is not technically a differential, it would have substantially the same purpose and effect.

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**Pay-for-performance Payments**  
**to Physicians and Dentists**  
OIG Advisory Opinion No. 11-10

A company who provides administrative services to a state’s Medicaid program, proposed to disburse pay-for-performance payments to physicians and dentists participating in the state's Medical Home Program. The payments are funded by the state's Medicaid program, and the company has no discretion to revise the amount of the payments.
Advisory Opinion - FAVORABLE
The OIG would not impose administrative sanctions in connection with the arrangement primarily because:

- The payments are funded by the state's Medicaid Program and not by the company;
- The company is merely acting as an agent of the state and has no discretion or control over the payments issued to the physicians and dentists;
- Reasonable steps have been taken by the parties to lessen any misimpressions that the company is paying the providers for Medicaid referrals because the state indicates on the check that the company is the administrator of the program;
- The state supervises all disbursements and is able to audit company's performance.

In response to a Skilled Nursing Facility’s (SNF) RFP, a medical supplier proposed two arrangements:

1. To furnish items not covered by Medicare below its costs, while billing the SNF the full Medicare Part B rate for Medicare covered services; and

2. Same as above, except that the medical supplier’s owners would form a new company and submit a joint bid to the SNF, whereby one company provides the covered items and the other provides the non-covered items.
Advisory Opinion – UNFAVORABLE

The proposed arrangements could potentially generate prohibited remuneration under the AKS and the OIG could potentially impose administrative sanctions.

- Regarding the first arrangement, it proposes a substantial risk of improper “swapping” of business because a nexus may exist between the below-cost pricing of non-covered items and referrals of other Federal health care program business for three reasons:
  - The SNF is in a position to direct business to the supplier for covered items when the SNF is not the entity paying for the items;
  - A link between covered items and non-covered items is inferred because they are included in the SNF’s single request for proposals; and
  - Both supplier and the SNF have obvious motives for contracting for non-covered items at below-cost.

Advisory Opinion (continued)

- Regarding the second arrangement, it creates a means for the supplier and SNF to swap the below-cost rates on non-covered items for which the supplier bears the business risk in exchange for the profitable non-discounted covered items.

- Although the non-covered items would now be provided by the new company, the OIG stated, "it is the substance, not the form, of an arrangement that governs under the anti-kickback statute."
Non-profit corporation that through its flagship hospital provides nationally-ranked neuroscience care, proposed to enter into arrangements to provide, at its own expense, to certain community hospitals:

- Neuro emergency telemedicine technology;
- Neuro emergency clinical consultations;
- Acceptance of neuro emergency transfers; and
- Neuro emergency clinical protocols, training, and medical education.

Advisory Opinion – FAVORABLE

The arrangement could potentially generate prohibited remuneration under the AKS, however, the OIG would not impose administrative sanctions, primarily because:

- The corporation would likely not generate considerable referrals as neither the participating hospitals nor the physicians would be required or encouraged to refer patients to corporation's hospital and no emergency physician would receive additional compensation under the arrangement;
- Initially, the arrangement would only be available to affiliated hospitals;
- The primary beneficiaries of the arrangement would be stroke patients;
- Neither the corporation nor any participating hospital would be required to engage in any marketing activities and each would be responsible for its own marketing; and
- It is unlikely that the arrangement would result in increased costs to the Federal healthcare programs.
A county that provides emergency medical services ("EMS") transportation through its fire department, proposed to treat revenue received from taxes as payment of otherwise applicable cost-sharing amounts owed by bona fide county residents for EMS transportation to hospitals. The county would accept payment from residents’ insurers, including Federal health care program recipients.

Advisory Opinion – FAVORABLE

The arrangement could not generate prohibited remuneration under the AKS, and accordingly, the OIG would not impose administrative sanctions because there is a special rule for suppliers owned and operated by a state or political subdivision that provides:

“A [government owned] facility which reduces or waives its charges for patients unable to pay, or charges patients only to the extent of their Medicare and other health insurance coverage, is not viewed as furnishing free services and may therefore receive program payment.”

- CMS Medicare Benefit Policy Manual, Chapter 16, section 50.3.1.
In 2010:

- 80% of all fraud recoveries involved health care suppliers and providers (other industries include defense, education, transportation, and the oil and gas industries).
- $15 is repaid for every $1 invested by the government in fraud enforcement.
- 28 states and the District of Columbia have their own versions of the False Claims Act.
- Indiana’s False Claims Act is found at IC § 5-11-5.5, “False Claims and Whistleblower Protection.”

### Top Ten Settlements

<table>
<thead>
<tr>
<th>Company</th>
<th>Amount</th>
<th>Date</th>
<th>Allegation</th>
</tr>
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<tbody>
<tr>
<td>Allergan</td>
<td>$600 million</td>
<td>9/1/2010</td>
<td>Off-label marketing practices involving Botox</td>
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<tr>
<td>Pharmacy</td>
<td>$520 million</td>
<td>4/27/2010</td>
<td>Illegally marketed the anti-psychotic drug Seroquel</td>
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<tr>
<td>Novartis Pharmaceuticals</td>
<td>$422.5 million</td>
<td>9/30/2010</td>
<td>Unapproved promotion of Trileptal</td>
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<tr>
<td>Forest Laboratories</td>
<td>$313 million</td>
<td>9/15/2010</td>
<td>Marketed Levoxithroid without FDA approval and unlawfully promoted Cil you and Lexapro for pediatric use</td>
</tr>
<tr>
<td>Elan Corporation</td>
<td>$203.5 million</td>
<td>7/15/2010</td>
<td>Improperly sold and marketed Zonovarin</td>
</tr>
<tr>
<td>Teva Pharmaceuticals</td>
<td>$169 million</td>
<td>7/26/2010</td>
<td>Inflated prices reported to Medicaid</td>
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<tr>
<td>WellCare Health Plans</td>
<td>$137.6 million</td>
<td>9/6/2010</td>
<td>Defrauded Medicare and Medicaid programs in several states</td>
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<tr>
<td>Mylan, AstraZeneca, and Ortho-McNeil</td>
<td>$124 million</td>
<td>10/19/2009</td>
<td>Companies improperly classified certain drugs to evade rebate obligations</td>
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<tr>
<td>Omnicare and IVAX Pharmaceuticals</td>
<td>$112 million</td>
<td>11/3/2009</td>
<td>Omnicare engaged in kickback schemes with several parties, including IVAX</td>
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<tr>
<td>Health Alliance of Greater Cincinnati and Christ Hospital</td>
<td>$108 million</td>
<td>5/21/2010</td>
<td>Kickbacks to doctors in exchange for referring cardiac patients hospital</td>
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Key Notes Regarding Settlements

- All of the top ten involved **health care**
- 8 of the top ten settlements involved fraud committed by pharmaceutical companies
- For 2010 the top ten cases accounted for $2.7 Billion dollars of the more than $3.6 Billion recovered, or about 85.5% of the total fraud recoveries.

2011 Cases

- **Labcorp.** On August 30, 2011, Labcorp settled a $49.5 million investigation stemming from a lawsuit alleging illegal overcharges to California’s Medicaid program. The *qui tam* suit was filed in 2005 by a whistleblower alleging that Labcorp and other medical laboratories *over charged the Medicaid program* and gave illegal kick-backs in the form of discounted or free testing to doctors, hospitals and clinics that referred Medicaid patients and other business to the labs. Labcorp allegedly charged Medi-Cal *over 5 times* as much as it charged some other customers for certain tests.
- **Quest Diagnostics.** On May 19, 2011, Quest Diagnostics settled a $241 million investigation for alleged illegal overcharges to California’s Medicaid program. The facts are very similar to Labcorp.
- **Par Pharmaceutical.** On August 24, 2011, Par Pharmaceutical settled a $24.4 million investigation with the State of Texas for *inappropriately reporting the wholesale price for drugs.*
2011 Cases
(continued)

- **Nova Nordisk.** On June 10, 2011, Novo Nordisk settled for *off-label promotion of a hemophilia drug* to military and civilian physicians, including providing *unrestricted grant funds, speakers' fees and other kickbacks to encourage doctors to publically support* the use of the hemophilia drug in trauma units to control bleeding among non-hemophiliac patients. Because Medicare, Medicaid, Tri-Care in the Department of Veteran’s Affairs are not authorized to pay or reimburse for off-labeled use, the off-label promotion led to the payments of false claims.

- **Serono Laboratories.** On May 4, 2011, Serono agreed to pay $44.3 million for *allegedly paying health care providers* to induce the providers to promote or prescribe Rebif, and injectable used to treat relapsing forms of multiple sclerosis.

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**Personal Exclusion**

**Howard Sulliman-Forrest Laboratories**

DHHS seeks to exclude Howard Sulliman, CEO, 83 years old, of Forrest Laboratories, from the Medicare program. In September, 2010, Forrest Laboratories plead guilty to criminal charges involving marketing and manufacturing practices, and agreed to pay $313 million to settle criminal and civil allegations that, among other things, it paid illegal kickbacks to pediatricians who prescribed anti-depressants to children. Lewis Morris, Chief Counsel for the OIG, testified before Congress stating that the OIG will use its exclusion authority as “one of the most powerful tools in our arsenal. We intend to use this essential fraud-fighting tool in a broader range of circumstances,” he said, “to hold responsible individuals accountable for corporate misconduct.”
According to Forest Laboratories’ statement, regulators have not accused Solomon of any wrongdoing. Its press release does not indicate whether or not he was aware that Forest's drugs were being illegally marketed.

The government's civil complaint alleged that Forest Laboratories’ senior executives concealed a negative clinical study about Celexa, duped physicians about the drug's clinical trials and encouraged sales reps to pay illegal kickbacks to pediatricians. Solomon, however, was not named individually.

Forest's general counsel, Herschel Weinstein, challenged the government's fairness in a written statement, saying executives of other convicted drug companies had not been targeted. "Numerous other major pharmaceutical companies have plead guilty to much more egregious offenses," he said.

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Wayne County Hospital
Kentucky

- NONCOMPLIANT PAYROLL SERVICES CONTRACTS, LEASES, ON-CALL ARRANGEMENTS AND BILLING/COLLECTION AGREEMENTS

- 12-03-2010 After it self-disclosed conduct to the OIG, Wayne County Hospital (WCH), Kentucky, agreed to pay $110,000 for allegedly violating the Civil Monetary Penalties Law provisions applicable to physician self-referrals and kickbacks.

- The OIG alleged that WCH: paid remuneration to a physician by failing 1) to charge processing fees for payroll services rendered to physician practices; 2) to demand or collect payroll processing fees and payments due for personnel and practice management support services rendered to a physician practice; and 3) to demand repayment of wages and benefits paid to the physicians and their staff.

South Coast Medical Center
California

- NONCOMPLIANT LEASES AND PERSONAL SERVICES CONTRACTS

- 09-03-2010 After it self-disclosed conduct to the OIG, South Coast Medical Center (SCMC), California, agreed to pay $72,637.77 for allegedly violating the Civil Monetary Penalties Law provisions applicable to physician self-referrals and kickbacks.

- The OIG alleged that SCMC entered into multiple lease and personal services arrangements with doctors that raised compliance issues under the Stark Law and Anti-Kickback Statute.
Mercy Medical Center, Inc. Maryland

- NONCOMPLIANT PERSONAL SERVICES CONTRACTS, LEASES, ON-CALL ARRANGEMENTS AND BILLING/COLLECTION AGREEMENTS

- 07-21-2010 After it self-disclosed conduct to the OIG, Mercy Medical Center, Inc. (MMC), Maryland, agreed to pay $195,013.50 for allegedly violating the Civil Monetary Penalties Law provisions applicable to physician self-referrals and kickbacks.

- The OIG alleged that MMC entered into physician service arrangements, lease arrangements, physician on-call arrangements and billing and collection agreements that raised potential issues under the Stark Law and the Anti-Kickback Statute.

Surgical Specialty Center of Baton Rouge, LLC Louisiana

- MISSING WRITTEN AGREEMENTS

- 05-11-2010 After it self-disclosed conduct to the OIG, Surgical Specialty Center of Baton Rouge, LLC (provider), Louisiana, agreed to pay $51,300 for allegedly violating the Civil Monetary Penalties Law provisions applicable to the Stark Law.

- The OIG alleged that the provider entered into several types of financial arrangements with referring physicians without the requisite written agreements in place as required by the Stark Law.
Colorado West HealthCare System

- NONCOMPLIANT PERSONAL SERVICES CONTRACTS, LEASES, ON-CALL ARRANGEMENTS, CME AND DIAGNOSTIC INTERPRETATIONS

- 05-03-2010 After it self-disclosed conduct to the OIG, Colorado West HealthCare System d/b/a Community Hospital and its subsidiary, Doctor’s Clinic Building, Inc. (Colorado West), Colorado, agreed to pay $420,175 for allegedly violating the Civil Monetary Penalties Law provisions applicable to kickbacks and physician self-referrals.

- The OIG alleged that Colorado West entered into six categories of contractual arrangements (i.e., medical director arrangements, emergency room services, office leases, on-call physician arrangements, continuing medical education services, and diagnostic test interpretations) that violated the Stark Law and, in some instances, implicated the Anti-Kickback Statute in connection with physicians’ referrals of Medicare beneficiaries to Colorado West.

St. Elizabeth Hospital and Mercy Medical Center of Oshkosh, Inc. Wisconsin

- NONCOMPLIANT ON-CALL ARRANGEMENTS

- 04-20-2010 After it self-disclosed conduct to the OIG, St. Elizabeth Hospital and Mercy Medical Center of Oshkosh, Inc. (hospitals), Wisconsin, both part of the Affinity Health System, agreed to pay $54,124 for allegedly violating the Civil Monetary Penalties Law provisions applicable to the Stark Law.

- The OIG alleged that the hospitals disclosed payments to three independent psychiatrists who provided behavioral health services at the hospitals’ emergency rooms.

- Specifically, the on-call coverage arrangements between the psychiatrists and hospitals failed to comply with Stark Law requirements.
St. James Healthcare
Montana

- NONCOMPLIANT PERSONAL SERVICES CONTRACTS, SPACE AND EMPLOYEE LEASES

- 03-31-2010 After it self-disclosed conduct to the OIG, St. James Healthcare (SJH), Montana, agreed to pay $275,000 for allegedly violating the Civil Monetary Penalties Law provisions applicable to the Stark Law.

- The OIG alleged that SJH entered into a space lease, an employee lease, and a medical services arrangement with an entity partly owned by SJH that failed to meet Stark Law requirements because they were not set forth in writing and signed by the parties.

- Significant for relationship with partially-owned entity

Liberty HealthCare Systems, Inc.
New Jersey

- NONCOMPLIANT EMPLOYEE BONUS

- 03-01-2010 After it self-disclosed conduct to the OIG, Liberty HealthCare Systems, Inc. (Liberty), New Jersey, agreed to pay $225,000 to resolve its liability for allegedly violating the Civil Monetary Penalties Law provisions applicable to the Stark Law.

- The OIG alleged that Liberty made an improper bonus payment to an employee physician based, in part, on the volume and value of referrals made by the physician.
Verdict: Tuomey

Tuomey Healthcare System (S.C.) was required to repay $44.9 million plus interest in Medicare payments (March 2010)

but jury found no violation of FCA

ISSUE: FMV of % Compensation for Part-Time Employed Physician


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Verdict: Tuomey

- The government and relator alleged that the part-time employment agreements for roughly 18 physicians in various specialties violated the Stark Law and the Anti Kickback Statute
- Because the agreements
  - paid physicians at more than fair market value (FMV),
  - restricted patient referrals to Tuomey,
  - contained inappropriate non-compete clauses, and
  - all referrals from the employed physicians were in violation of the FCA.
- The government’s position is that the compensation paid by Tuomey was in excess of FMV because it exceeded 130 percent of the physicians’ net collections on procedures they performed
- The government also alleged that the compensation varied with the value or volume of referrals because the % compensation for personally performed physician professional services would increase referrals for the technical component of the services
Verdict: Bradford

Bradford Regional Medical Center (Pa) violated federal law by submitting claims to Medicare based upon referrals from physicians with whom the hospital had a prohibited financial relationship (Nov. 12, 2010)

Judge found as a matter of law "that Defendants have violated the Stark Act" on a motion for summary judgment

Damages could be in excess of $20 million plus millions of dollars more in FCA mandatory penalties

Verdict: Bradford

Hospital subleased a nuclear imaging camera from Physician Group, which Physician Group was using to perform diagnostic tests in-house, rather than referring patients to the hospital, which had its own nuclear camera

Hospital agreed to pay Physician Group $23,655 per month, purportedly for certain "noncompete" agreements

Hospital's CEO "expected [Hospital] would get substantial referrals from [the doctors] as a result of the sublease" and stated he entered into sublease arrangement to get referrals.
Verdict: Kosenske

**Kosenske v. Carlisle**, 2010 WL 1390661 (M.D.Pa. 3/31/10)

Cross motions for summary judgments were denied after remand from Third Circuit

U.S. Court of Appeals for the Third Circuit reversed summary judgment granted by the U.S. District Court for the Middle District of Pennsylvania in favor of a hospital and its anesthesia providers who asserted protection under the "personal services" exemption to Federal Stark Law ("Stark") and the Federal Anti-Kickback Statute ("AKS")

Even though arrangements between anesthesiologists and hospitals typically do not raise Stark (or AKS concerns) because anesthesiologists do not refer patients to the hospital, the case continued because the physicians also were seeing patients in a pain management clinic and may refer patients to the hospital for tests or other procedures.

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Verdict: Kosenske

In 1998, Carlisle Hospital built a new stand-alone facility containing an outpatient ambulatory surgery center and a pain clinic, located about three miles from the hospital.

The parties did not amend the 1992 agreement covering the hospital to include this additional facility or new range of responsibility.

The Group provided pain management services to patients in the pain clinic and, in exchange, was given rent-free space and equipment in the pain clinic and support personnel at no charge.
Verdict: Kosenske

For anesthesia services at the hospital and for services at the new pain clinic, the Group’s member physicians submitted claims to Medicare for the professional services performed during Carlisle Hospital’s patients visits, and Carlisle Hospital submitted claims for the facility and technical component of the visits.

Sale of Assets in 2001

Carlisle HMA purchased the hospital, Surgery Center, and certain other assets from CHHS. CHHS, the former owner of then Carlisle Hospital, did not execute a formal written assignment of its contractual rights and obligations under the 1992 agreement for the benefit of Carlisle HMA. Nevertheless, after the sale, Carlisle HMA and the Group conducted their relationship as if the agreement remained in effect.

Verdict: Kosenske

From the *Kosenske* court – setting the stage for requiring independent valuations:

- As a legal matter, a negotiated agreement between interested parties does not by definition reflect fair market value.
- To the contrary, the Stark Act is predicated on the recognition that, where one party is in a position to generate business for the other, negotiated agreements between such parties are often designed to disguise the payment of non-fair-market-value compensation.
**Settlement: Covenant**

- The DOJ alleged that the Covenant physicians—specifically, two orthopedic surgeons, two neurosurgeons, and a gastroenterologist—were reportedly among the highest-paid physicians in the entire U.S., making as much as $2.1 million, despite Covenant’s non-profit status.

- These salaries were three times greater than the compensation being paid to other physicians who referred patients to Covenant, according to the CEO of Cedar Valley Medical Specialists, a competing independent physician group in Waterloo, IA who brought the issue to the attention of the DOJ.

- $4.5 million in response to alleged violations of the Stark Law and the False Claims Act (August 2009).

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**Settlement: Arlington Memorial Hospital**

**Retro Written Agreement Doesn’t Cure Prior Overpayment**

- Longstanding contract with a physician group to interpret arterial blood gas tests potentially violated the Stark Law and Anti-Kickback Statute.

- The hospital through its former president, paid a physician group for ABG tests even though the tests did not require any professional interpretation.

- To correct the compensation, the hospital’s former president agreed to pay the group for uncompensated charity care and oversight of the hospital’s blood gas lab.

**Settlement: $990,509 (January 2010)**
Settlement: DMC

Detroit Medical Center to pay $30 million settlement (December 2010)

DMC brought 2 boxes outlining potentially improper financial relationships with >250 physicians
Asst US Atty declined to describe the range of fines discussed with DMC, but said FCA violations could have tripled amount

Settlement: DMC

The Detroit Medical Center

- Allowed physicians to continue to rent space once leases expired
- Provided free signage and marketing help
- Provided free continuing medical education seminars held most weekends for doctors on the DMC campus
- Provided other perks, including tickets to sporting events
Settlement: Christ Hospital

Health Alliance of Greater Cincinnati, $108 million for paying kickbacks to physicians for referring cardiac patients to hospitals
(Cincinnati 5/21/2010)

- alleged pay to play required referrals of cardiology patients to participate in reading panel
- whistleblower = cardiologist
- Christ Hospital initially declined to enter into acceptable CIA & OIG did not release exclusion authority -- CIA was negotiated later

U.S. v. Center for Diagnostic Imaging, Inc.

Background & Overview

- Center for Diagnostic Imaging, Inc (CDI) is a national radiology and imaging company that operates 54 diagnostic imaging centers in ten states.

- Plaintiffs filed a *qui tam* action based on relator’s claims that CDI violated the False Claims Act (FCA), the Stark Act and the Anti-Kickback Statute (AKS); CDI filed a motion to dismiss all claims.

- The motion was granted in part and denied in part.
Claims

- CDI violated the FCA, the Stark Act and the AKS by:
  - Entering into lease and joint venture agreements with physician groups, and funneling money to the groups in exchange for referrals of government insured patients;
  - Providing free and discounted services to physicians to induce referrals; and
  - Submitting claims for procedures that were not supported by written orders from physicians.

Lease and Joint Venture Agreements

- Plaintiffs claimed CDI violated the FCA and the AKS by entering into certain arrangements with referring physician groups to direct millions of dollars to those groups to induce them to refer patients to CDI.
- Plaintiffs alleged CDI used three types of lease and joint venture agreements:
  - Facility leasing arrangements (or “per-click”);
  - In-office scanner arrangements; and
  - Equipment joint venture arrangements.
U.S. v. Center for Diagnostic Imaging, Inc.

Lease and Joint Venture Agreements

- **Facility Leasing Arrangements**

  - Plaintiffs alleged CDI first identified radiologists in a geographic market that CDI was interested in for purposes of opening diagnostic imaging centers. CDI then established imaging centers near physician groups, provided all capital, office space, equipment and personnel, and diagnostic imaging services.

  - In turn, the physician groups paid CDI a “leasing” fee on a per service or per click-fee basis; for each technical component fee the physician groups collected, the groups paid a portion of that fee back to CDI.

  - The per click fee was not paid for government insured patients, however, CDI required that physicians groups refer their Medicare and Medicaid patients to CDI in order to be eligible for the lease arrangements.

U.S. v. Center for Diagnostic Imaging, Inc.

Lease and Joint Venture Agreements

- **In-Office Scanner Arrangements**

  - Plaintiffs alleged CDI formed LLC partnerships with large physician groups, provided scanners and other equipment in the groups’ offices, and offered to “loan” the groups all of the groups’ portion of the capital investment.

  - CDI then recouped the loan by deducting periodic payments on amounts from ownership dividends paid to the physician groups as co-owners of the LLCs.

  - The physician groups referred its Medicare and privately insured patients to the center. CDI performed the imaging services, and then submitted claims for reimbursement.

  - When the reimbursement was received, CDI retained a portion for its services, and sent the remainder to the LLCs, which in turn paid profits as dividends to the physician groups and CDI.
Lease and Joint Venture Agreements

- **Equipment Joint Venture Arrangements**
  - Plaintiffs alleged CDI and physician groups established and co-owned joint ventures that would purchase and maintain diagnostic equipment. Similar to the scanner arrangements, CDI offered to “loan” the groups’ portion of the investment. CDI then recouped the loan by deducting periodic payments on amounts from ownership dividends paid to the physician groups.
  - CDI executed rental agreements with the joint venture for use of the equipment, paying per click for use of the equipment. CDI then paid the per click fee to the joint venture.
  - The physician groups referred their Medicare and privately insured patients to CDI, CDI performed the imaging services, and then submitted claims for reimbursement.
  - The physician groups earned a referral fee, because the fees paid by CDI were divided among the owners of the joint venture.

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CDI argued the government failed to plead the specifics of the agreements, because the government did not specifically identify the participating physician groups, the dates or amounts billed, or the identity of the patients involved.

The court disagreed and found the government’s evidence of an alleged scheme that CDI offered remuneration in exchange for referrals was sufficient to survive the motion, because the AKS prohibits “willfully offering remuneration to induce the referral of program-related-business, so proof of payment is not required.”

CDI’s motion to dismiss on these claims was denied.
Free and Discounted Services and Procedures Not Supported by Physician's Orders

- Plaintiffs alleged that CDI, based on its own internal protocols, automatically and without written orders, added free or discounted MRAs to ordered MRI exams.
- Plaintiffs contended the free or reduced fee “add-on” services were improper inducements because:
  - The conduct encouraged the overutilization of MRI tests because it was likely physicians might order more MRIs than medically necessary in order to obtain free MRAs; and
  - Because the free MRA test results were given to the referring doctor who was treating the patient, the doctor was receiving a benefit from the free services, and indirect remuneration in exchange for sending his or her MRI and other imaging tests to CDI.

Free and Discounted Services and Procedures Not Supported by Physician's Orders

- The court granted CDI’s motion to dismiss finding:
  - Plaintiffs failed to show a connection between the free or discounted services and inducements for referral of government insured patients, because they failed to allege the referring physicians were even aware that CDI was not charging for the MRAs;
  - Plaintiffs failed to allege that the discounted services were offered for less than fair market value, or that the discounted prices were not commercially reasonable; and
  - If the imaging services were provided for free, then CDI did not bill for them, thus no false claims were submitted.
Compliance Guidance

No new compliance guidance has an issue by the OIG since November 30, 2008. The OIG has issued either original and/or supplemental compliance guidance for the following providers:

- Nursing facilities
- Recipients of research awards from National Institute of Health and U.S. Public Health Service
- Hospitals
- Pharmaceutical manufacturers
- Ambulance Suppliers
- Individual and small group physician practices
- Medicare + Choice organizations
- Hospice
- Durable medical equipment manufacturers
- Third party medical billing companies
- Clinical laboratories
- Home health agencies

Self-Referral Disclosure Protocol
Self-Referral Disclosure Protocol

Overview of Protocol

• Introduction and Discussion of Protocol
• Cooperation with OIG and the Department of Justice
• Instructions Regarding Submission
• Verification
• Payments
• Cooperation and Removal and Timeliness of Disclosure
• Factors Considered in Reducing Amounts Owed

Self-Referral Disclosure Protocol

Introduction and Discussion of Protocol

• Purpose is to resolve actual or potential violations of the physician self-referral law
• Separate from the advisory opinion process
• Disclosure must be made in good faith
• Cannot appeal settlement
• Application of Reopening Rules
Self-Referral Disclosure Protocol

Cooperation with the OIG & DOJ

- Physician Self-Referral Law only violations or potential violations to CMS.
- Physician Self-Referral Law and additional violations or potential violations of other criminal, civil, and administrative laws to OIG.
- The same conduct should not be disclosed under both SRDP and OIG’s Self-Disclosure Protocol.
- Coordination with Law Enforcement.
- Corporate Integrity Agreements.

Instructions Regarding Submission

- Disclosure

- Required information related to the matter disclosed:
  - Description of Actual or Potential Violation(s)
  - Financial Analysis
Self-Referral Disclosure Protocol

Instructions Regarding Submission

- Description of Actual or Potential Violation(s)
  - Identifying Information
  - Description of the nature of the matter being disclosed
  - Duration of violation
  - Disclosing party’s legal analysis of how the matter is a violation
  - Circumstances under which the matter was discovered and measures taken to address the issue and prevent future abuses
  - Statement identifying a history of similar conduct or enforcement action
  - Description of the pre-existing compliance program
  - If applicable, a description of appropriate notices provided to other government agencies
  - Whether the matter is under current inquiry by the government

Self-Referral Disclosure Protocol

Instructions Regarding Submission

- Financial Analysis
  - “Look Back” Period
  - Total amount actually or potentially due and owing
  - Description of the methodology used including estimates
  - Summary of auditing activity and documents used
Quantification of Potential Overpayment

Providers need to:

- Determine commencement and ending of period of time during which financial arrangement fell out of compliance
- Utilize the 6-month holdover period, where applicable (personal services arrangements and rental of space and equipment exceptions)
- If financial arrangement was with a group practice, identify each physician in the group practice
- Determine when any applicable physician “referred” to the DHS entity during the period of disallowance
  - Referring physician
  - Admitting physician
  - Attending physician
  - Consulting physician
- Especially for the consulting category, determine if items or services ordered by “tainted” physician impacted the reimbursement received

Assuming provider diligently quantifies the potential overpayment during the “lookback” period with due diligence, 60-day reporting period does not commence until the amount of the overpayment has been determined.
Quantification of Potential Overpayment

- Due to the complexity of hospital’s financial data bases, especially if a recent conversion has occurred, providers may desire to hire external auditing firms to assist with the quantification process.
- Should the external auditors be hired in a manner to preserve the attorney/client privilege?

CMS Review Process

Collaborative review among multiple CMS components

- Center for Medicare
  - Intake of self-disclosures
  - Policy and legal analysis

- Center for Program Integrity
  - Coordination with law enforcement partners

- Office of Financial Management
Factors Considered, Reducing Amount Due and Owing

CMS may consider the following factors in reducing the amount due and owing:

- Nature and extent of the improper or illegal practice
- Timeliness of the self-disclosure
- Cooperation in providing additional information
- Litigation risk
- Financial position of the disclosing party
- Effectiveness of compliance program, especially if compliance program resulted in discovery of potential Stark infraction

Reducing Amount Due and Owing: Nature and Extent of Improper / Illegal Practice

Some of the sub-factors CMS will weigh include:

- Commercially reasonable? Fair market value?
- Takes into account volume or value of referrals?
- History of program abuse?
- Set in advance?
- Presence, strength of preexisting compliance program?
- Length, pervasiveness of noncompliance?
- Steps taken to correct noncompliance?
SRDP Settlements

- 80+ Self Disclosures have been filed to date
- Only one settlement has been finalized.

On February 10, 2011, CMS announced the first SRDP settlement with Saints Medical Center in Lowell, Massachusetts. SMC settled for $579,000 related to issues regarding night coverage, medical directorships, and stipends. The true nature of the Stark violations have not been released by CMS. A statement released by SMC as well as local media indicated that the potential repayment was between $785,000 and $14.5 million.