STARK, SUNSHINE AND PHYSICIAN COMPLIANCE ISSUES

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Summary
A. Recent Laboratory Enforcement Activity
B. Physician Contracting Cases
   ■ Stark & Anti Kickback
   ■ Toumey & Halifax
C. Physician Payment Sunshine Act

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Laboratory Enforcement
A. Pennsylvania
B. Federal – Special Fraud Alert
A. Health Diagnostic Laboratory, Inc.
B. Pennsylvania Act 122

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A. December 18, 2013
B. Prohibited Acts
   - Fee splitting and kickbacks to referring providers
   - Office space subleases
   - Providing personnel
C. Fair Market Value is not an exception or defense

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A. Provider who operates a laboratory may place provider personnel
B. Referrals between licensed laboratories
C. Laboratories may lease space to providers for FMV
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## Significant Physician Contract Case

A. Halifax Medical Center  
B. Toumey Healthcare System

## HCCA Stark, Sunshine & Compliance

<table>
<thead>
<tr>
<th>AKS</th>
<th>Stark</th>
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<tbody>
<tr>
<td>Criminal</td>
<td>Civil</td>
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<tr>
<td>Intent</td>
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<tr>
<td>Penalties</td>
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<td>$50K</td>
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<td>Treble Damages</td>
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## HCCA Stark, Sunshine & Compliance

<table>
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<th>AKS</th>
<th>Stark</th>
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<tr>
<td>Bona Fide Employment</td>
<td>Set in Advance</td>
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<tr>
<td>Payment for Referrals</td>
<td>One year</td>
</tr>
<tr>
<td>exception rejected in Halifax</td>
<td>FMV</td>
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<td></td>
<td>Unrelated to value/volume of referrals: VVR</td>
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</table>
A. Multiple counts in whistleblower litigation filed June 2009
   - Medically unnecessary
   - Admission vs. short stay
   - Psychiatrist contracts
   - Neurologists contracts
   - Medical oncologists

B. Attorney General intervened in medical oncologists and neurologist issues
   - Medical oncologist: Summary Judgment granted to U.S. and Relator November 13, 2013 and $85 million settlement and CIA by March 10, 2014
   - Neurologist: Summary Judgment denied November 18, 2013

Medical Oncologists Contracts

A. Existence of referral
B. Allocation of incentive pool
C. Summary Judgment issued based on interpretation of contract language
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Halifax
Thus the Court concludes that the claims forms relied on by the Government are evidence of referrals for DHS made by the Medical Oncologists during the time period the Incentive Bonus was in effect, thereby violating Stark Law, 42 U.S.C. § 1395nn(a)(1). By the same token, the claims forms are evidence that Halifax Hospital submitted claims to Medicare for the DHS furnished pursuant to such referrals, also in violation of the Stark Law, 42 U.S.C. § 1395nn(a)(2). The Defendants have not presented any evidence to the contrary. As the Government’s evidence on this point is undisputed, the Government has established that Halifax Hospital violated the Stark Law.

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Neurologists
A. No summary judgment
B. Issue of fact regarding FMV
C. Issues in expert report:
   - Compensation > 90th percentile
   - Extra benefits relative to other physicians (car allowance)
   - Compensation equal to 100% of collections
   - Compensation for all call coverage

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Tuomey
A. Court decision that financial arrangements violated Stark
B. Submission of claims were therefore false claims
C. Jury award: $39,313,065
Financial arrangement – hospital entered into part time employment contract with private practice urologists to perform ambulatory procedures at hospital, and physicians abandoned plans to build ASC.

Hospital took into account the value or volume of referrals via appraisal that valued future procedures.

Advice of counsel defense.

Absence of damages because all claims medically necessary, appropriately coded and properly billed rejected as a defense.

Introduction
A. Statute – Physician Payment Sunshine Act Final Rules implements §6002 of the Affordable Care Act, which added §1128G of the Social Security Act [42 USC §1302a-7(h)].
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Physician Payment Sunshine Act

General Summary
A. Payment Reporting - Applicable Manufacturers of drugs, devices, biologicals, or medical supplies covered by federal healthcare programs and GPOs must file annual reports with HHS regarding payments or transfers of value to Covered Recipients.
B. Ownership Reporting - Applicable Manufacturers and Group Purchasing Organizations (GPOs) must annually report certain physician ownership and investment interests.
C. HHS Publication - HHS required to publish reports on public website.

Covered Recipients
Any physician, except a physician employee of an applicable manufacturer:
- Medicine
- Osteopathy
- Dentist
- Dental surgeon
- Podiatrist
- Optometrist
- Chiropractor
- Excludes residents (Fellows?)

Teaching Hospital Definition
For the purposes of this program, teaching hospitals are defined as hospitals that received a payment(s) Medicare direct graduate medical education (GME), inpatient hospital prospective payment system (IPPS), indirect medical education (IME), or psychiatric hospital IME programs during the most recent calendar year for which such information is available.
Applicable Manufacturer

A. Engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply for sale or distribution in the United States, or in a territory, possession, or commonwealth of the United States; or

B. Under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotions, sale, or distribution of a covered drug, device, biological, or medical supply for sale and distribution in the United States, or in a territory, possession, or commonwealth of the United States.

Applicable Group Purchasing Organization (GPO)

Applicable GPO

- Operates in the United States (meaning that they have a physical location within the U.S. or otherwise conduct activities in the U.S., either directly or through a legally-authorized agent); and
- Purchases, arranges for purchase, or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or organizations that is not solely for use by the purchasing entity itself.

Covered Product

- A Covered Product is any drug, device, biological, or medical supply that is eligible for payment by Medicare, Medicaid, or CHIP either individually or as a part of a bundled payment (such as the inpatient prospective payment system), and requires a prescription to be dispensed (for drugs and biological) or required premarket approval by or premarket notification of the U.S. Food and Drug Administration (FDA) (for devices, including medical supplies that are devices).
Reportable Payments

General Rule - Payments or other transfers of value provided to any covered recipient, including payments to another individual or entity at the request of (or designated on behalf of) a covered recipient, by an applicable manufacturer or a third party (on behalf of an applicable manufacturer) must be reported to CMS by the applicable manufacturer on an annual basis.

Form of Payment - An applicable manufacturer must report each payment or transfer of value, or separable part of that payment or transfer of value, as taking one of the following forms, using the designation that best describes the form of the payment or other transfer of value, or separable part of that payment or other transfer of value. Each of the following terms has its dictionary definition:

- Cash or cash equivalent.
- In-kind items or services.
- Stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment.

Categorization of Payments - Reports will be required to categorize all reportable payments as falling within one of the following natures of payment:

- Consulting fees
- Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program
- Honors
- Gifts
- Entertainment
- Food and beverage
- Travel and lodging
- Education
- Research
- Charitable contributions
- Royalty or license
- Current or prospective ownership or investment interest
- Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program
- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program
- Grants
- Space rent or facility fees (teaching hospital only)
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Physician Payment Sunshine Act
Reportable Payments
Exclusions from Reporting
- $10 CY2012 individual minimum and $100 CY2012 aggregate minimum tied to CPI
- Product samples not intended for sale and intended for patient use
- Educational materials that directly benefit patients or are intended for patient use
- Loans of covered devices not to exceed 90 days to permit evaluation
- Warranty replacements
- When covered recipient is a patient
- Discounts and rebates
- Charity care
- Dividends or ownership distributions from publicly traded securities or mutual funds
- Payments from self-insured health funds
- Payments to recipients for non-medical licensed purposes
- Payments for services with respect to criminal or civil proceedings
- Incidental items and snacks at large scale conferences
- Speaker compensation at accredited programs

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Physician Payment Sunshine Act
Enforcement
A. Failure to report
B. Knowing failure to report
C. Mitigating factors

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Physician Payment Sunshine Act
Enforcement
Failure to Report
- Any applicable manufacturer or applicable group purchasing organization that fails to accurately and completely submit the information required in accordance with the rules established under this subpart in a timely manner is subject to a civil monetary penalty of not less than $1,000 but not more than $10,000 for each payment or other transfer of value or ownership or investment interest not reported.
- The total amount of civil monetary penalties imposed on an applicable manufacturer or applicable group purchasing organization under this subpart with respect to each annual submission of information will not exceed $150,000.
Enforcement

Knowing Failure to Report

- Any applicable manufacturer or applicable group purchasing organization that knowingly fails to accurately and completely submit the information required in accordance with the rules established under this subpart in a timely manner is subject to a civil monetary penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported.
- The total amount of civil monetary penalties imposed on an applicable manufacturer or group purchasing organization for knowing failure to report under this subpart with respect to each annual submission of information will not exceed $1,000,000.

Determinations regarding the amount of civil money penalties

A. In determining the amount of the civil monetary penalty, factors to be considered include, but are not limited to, the following:
   - The length of time the applicable manufacturer or applicable group purchasing organization failed to report, including the length of time the applicable manufacturer and applicable GPO knew of the payment or other transfer of value, or ownership or investment interest.
   - Amount of the payment the applicable manufacturer or applicable group purchasing organization failed to report.
   - Level of culpability.
   - Nature and amount of information reported in error.
   - Degree of diligence exercised in correcting information reported in error.

Administration & Enforcement

A. Maintenance of records
B. Audit
C. Non-limitation other applicable laws
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Physician Payment Sunshine Act

Record Retention and Inspection
A. Applicable manufacturers and GPOs must maintain all books, contracts, records, documents and other evidence sufficient to allow audit, evaluation and inspection
B. 5 years
C. Requirements do not preempt or replace any other requirements.

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Physician Payment Sunshine Act

Review, Dispute & Correction Process
Voluntary
A. Pre-Submission review
B. Register and review on website
   ■ 45 days to review
   ■ 15 days to correct
C. CMS notifies submitter of dispute
D. No “appeal” process; marked disputed

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Physician Payment Sunshine Act

Key Dates
Beginning in 2014 and each year thereafter, data collection occurs between January 1 and end on March 31. Applicable manufacturers and applicable GPOs are required to submit the annual reports to CMS electronically on or before March 31 for data collected during the preceding year.
Physician Participation

Physicians are not required to register with or send any information to Open Payments. However, to make sure we have the right information, we do encourage physicians to:

- Become familiar with the information that will be reported about physicians.
- Keep records of all payments and other transfers of value received from applicable manufacturers or applicable GPOs. Physicians can use the Open Payments Mobile for Physicians app to track payments and other transfers of value they receive from applicable manufacturers and applicable GPOs throughout the year.
- Register with CMS’ Open Payments system and subscribe to the listserve to receive updates regarding the program.
- Look at the information applicable manufacturers and applicable GPOs submit on physician’s behalf.
- Work with applicable manufacturers and applicable GPOs to make sure the information submitted about them is correct.

Internal Compliance Program

- Although physicians have no reporting obligations, they should register to allow review and inspection.
- Exercise caution regarding all industry transactions.
  - Written agreement
  - Preview reports
  - Correction process
- Compliance audits - compare physician consents and disclosures to Open Payments information.
- Conflict of Interest Policy
- Medical staff and employment training and CME

Any Questions?

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