

**THE STARK LAW:
COMING CLEAN, STAYING CLEAN**
October 12, 2012
**HCCA East Central
Regional Annual Conference**
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STARK 101

- A **Physician** may not refer for DHS if there is a non-exempt financial relationship
- **DHS Provider** may not submit claim for DHS if referred by physician with non-exempt financial relationship

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STARK 101

- Is there a **Referral?**
- Made by a **Physician?**
- Does the physician or a family member have a **Financial relationship?**
- Does an **Exception** apply?


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Stark Penalties

- \$1,500 CMP per claim/prohibited referral
- Denial/refund of payment
- \$100,000 civil monetary penalty for “circumvention scheme.”
- ACA establishes that Stark violation = FCA violation
 - FCA penalties include \$11,000 per claim; treble damages; exclusion (“death penalty”)

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Temporary Non-Compliance

- Available if arrangement complied with an applicable exception for at least 180 consecutive calendar days immediately preceding the date on which the financial relationship became noncompliant with the exception;
- (ii) The financial relationship has fallen out of compliance with the exception for reasons beyond the control of the entity, and the entity promptly takes steps to rectify the noncompliance; and
- (iii) The financial relationship does not violate the anti-kickback statute, and the claim or bill otherwise complies with all applicable Federal and State laws, rules, and regulations.
- Applies only during the period of time it takes the entity to rectify the noncompliance, which must not exceed 90 consecutive calendar days.
- May be used by an entity only once every 3 years with respect to the same referring physician.

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Only available if the failure to comply with the signature requirement was—

- (A) Inadvertent and the parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant; or
- (B) Not inadvertent and the parties obtain the required signature(s) within 30 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant.
- May be used by an entity only once every 3 years with respect to the same referring physician.

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Self-Referral Disclosure Protocol

- Required by ACA; released 9-23-2010
- Posted by CMS at http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/downloads/6409_SRDP_Protocol.pdf
- Allows "disclosing parties" to self-disclose actual or potential violations of the Stark Law and potentially settle their financial liability for for less than the maximum amount.

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Self-Referral Disclosure Protocol

- SRDP does not *guarantee* leniency, either with regard to the refund obligations or with regard to any Stark or False Claims Act penalties.
- All disclosures must be made electronically and include the following information:

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Self-Referral Disclosure Protocol

- The name, address, NPIs, CMS Certification Number(s) (CCN) and tax identification number(s) of the disclosing party.
- A description of the nature of the matter being disclosed, including the type of financial relationship(s), parties involved, specific time periods the disclosing party may have been out of compliance; type of designated health service claims at issue; type of transaction or other conduct giving rise to the matter; and the names of entities and individuals believed to be implicated and an explanation of their roles in the matter.
- A statement from the disclosing party regarding why it believes a violation of the physician self-referral law may have occurred, along with a description of the potential causes of the incident or practice (e.g., intentional conduct, lack of internal controls, circumvention of corporate procedures or government regulations).


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Self-Referral Disclosure Protocol

- The circumstances under which the disclosed matter was discovered and the measures taken upon discovery to address the issue and prevent future abuses.
- A statement identifying whether the disclosing party has a history of similar conduct or has any prior criminal, civil and regulatory enforcement actions (including payment suspensions) against it.
- A description of the existence and adequacy of any pre-existing compliance program and the measures or actions taken by the disclosing party to restructure the arrangement or non-compliant relationship.

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Self-Referral Disclosure Protocol

- A description of appropriate notices, if applicable, provided to other government agencies, (e.g., Securities and Exchange Commission and Internal Revenue Service) in connection with the disclosed matter.
- An indication of whether the disclosing party has knowledge the matter is under current inquiry by a government agency or contractor.
- A full financial analysis must also be completed for the applicable "look-back period."

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Self-Referral Disclosure Protocol

- Factors CMS may consider in reducing the amounts otherwise owed include:
 - the nature and extent of the improper or illegal practice;
 - the timeliness of the self-disclosure;
 - the cooperation in providing additional information related to the disclosure;
 - the **"litigation risk"** associated with the matter disclosed; and
 - the financial position of the disclosing party.

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Self-Referral Disclosure Protocol

- CMS makes it clear this protocol is not to be used to elicit advisory opinions about Stark compliance -- Such requests should go through the existing Advisory Opinion process
 - *Caveat:* CMS Stark AO's have been infrequent and rarely address grey areas.

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SRDP and Other Agencies

- Upon receipt of disclosure, CMS will coordinate with the Office of the Inspector General ("OIG") and the Department of Justice ("DOJ").
- May also refer the disclosed matter to law enforcement.
- CMS may use the disclosure to prepare recommendations to OIG and DOJ for resolution of False Claims Act, civil monetary penalty, or other liability.

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SRDP To Date

- Of 150 disclosures made under the SRDP*
- 6 have been resolved through settlement,
 - 51 are currently under review
 - 61 are on hold pending CMS obtaining additional information.
 - *Source: HHS Report to Congress on "Implementation of the Medicare Self-Referral Disclosure Protocol," April 9, 2012

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Providers	
Hospital	125
Community Mental Health Center	2
Suppliers	
Clinical Laboratory	11
Durable Medical Equipment	2
Ambulance Services Company	1
Group Practice	8
Other	
	1
Total	
	150

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Enforcement Trends

- Majority of cases still begin as *qui tam* whistleblower actions.
- Few cases go to trial; few judicial opinions.
- Those opinions that exist may be less than helpful:
 - **United States ex rel. Singh v. Bradford Regional Medical Center, No. 04-186 (W.D. Pa. Nov. 10, 2010).**

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HHS Discretion Under ACA

- ACA grants the Secretary of HHS discretion to reduce the amounts due for Stark violations and directs the Secretary to consider as mitigating factors the nature and extent of the improper or illegal practice; the timeliness of such disclosure; the cooperation in providing additional information related to the disclosure; and such other factors as the Secretary considers appropriate.
 - The CMS protocol adds two more factors: the litigation risk associated with the matter disclosed and the financial position of the disclosing party.


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FERA/ACA "60 Day Rule"

- FERA (amended by ACA) requires disclosure of overpayments within 60 days of discovery
- Failure to disclose = FCA violation
- Stark violation = FCA violation


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"Preventive Care"

- Self-audit physician relationships
- Coordinate all documentation centrally
- Focus on Common Risk Areas:
 - FMV process and documentation
 - Medical Directorships
 - Physician Compensation
 - Practice Acquisition
 - Leases of Space and Equipment
 - Service Agreements
 - Joint Ventures; "Under Arrangements" deals

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