

Davis Wright Tremain LLP 

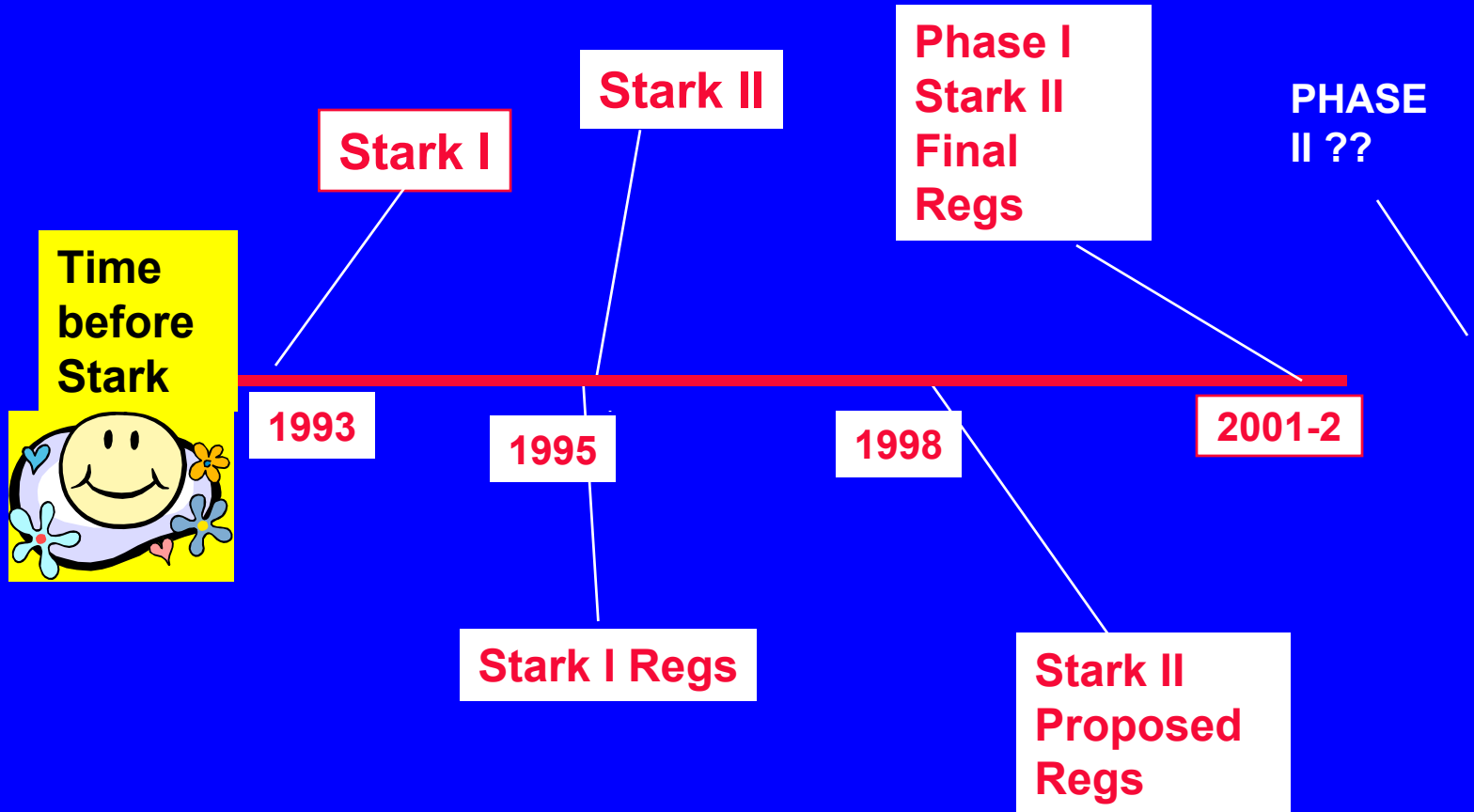
Stark Enforcement

By

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Stark Timeline





Stark II

- Stark prohibits a physician from referring Medicare patients to an entity for designated health services for which Medicare would otherwise pay, if the physician (or an immediate family member of the physician) has a financial relationship with the entity.



Stark Prohibition/Penalties

- **Physician cannot refer Medicare patients; receiving entity cannot bill Program for services provided pursuant to tainted referral**
- **Stark applies to Medicaid by denying FFP for services rendered to Medicaid beneficiary pursuant to tainted referral**
- **Denial of payment; repayment; civil penalties; exclusion**



Final Stark II Rule

- Phase I of a 2 Phase process
- Phase II to be issued “shortly”





Advisory Opinions

- Final regulation establishing advisory opinion process published January 1998-- Law reauthorized January 2001.
- Process similar to OIG advisory opinions on Anti-kickback statute;
- CMS issued two opinions--then deferred accepting any requests pending issuance of final regulations
- None forthcoming-- Reason unclear



Stark Advisory Opinions

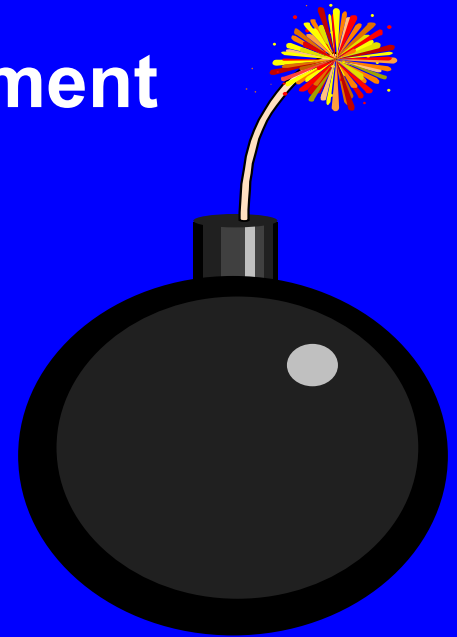
- Badly needed because of the ambiguity of the statute and its potentially draconian consequences
- CMS not responding
- Too Hard?





Stark Enforcement

- CMS has authority to enforce
 - Stark is, in essence, a payment statute
 - Denial of payment
 - Repayment or Recoupment
 - Civil penalties
 - Exclusion





Stark Enforcement : OIG

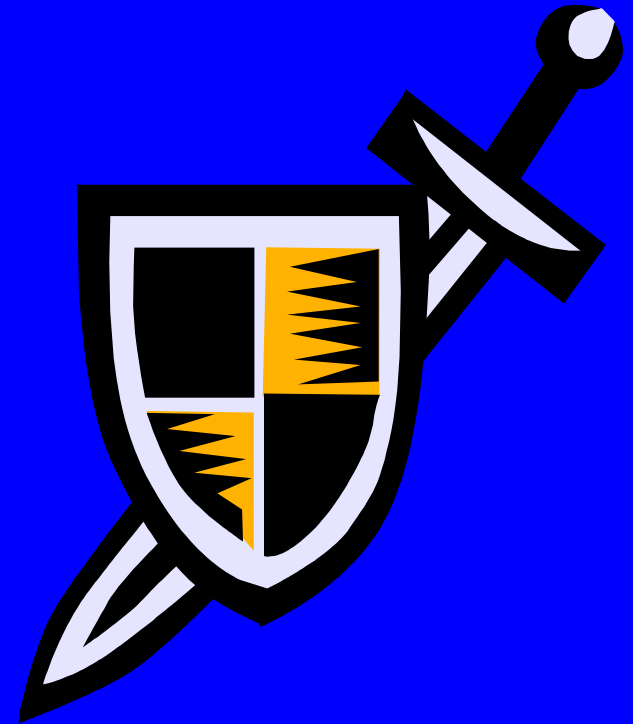
- OIG has indicated its intention to pursue Stark enforcement actions
- New litigation attorneys hired dedicated to Stark/Kickback cases
- New enforcement actions imminent





Stark Case law

- Growing body of cases addressing various aspects of the Stark Law
- Evolving regulations add to the uncertainty
- Stark used as sword and shield with mixed results





The Saga of Lithotripsy

- Phase II Final Rule indicates that Lithotripsy is DHS if provided (billed) by hospital
- Subject of much controversy– Pete Stark letter, legislative history, urologists outcry
- *American Lithotripsy Society v. Thompson* -- D.C. District Court held Lithotripsy not DHS
- Appeal filed by Government
- Is the injunction binding on CMS outside of D.C.???





Stark Case law: Between a Rock and

- *Steele v. St Vincent Hospital*
- Hospital employment agreement with Dr. Steele
 - compensation includes payments for administration of chemotherapy and other medications
- On advice of counsel hospital does not pay the compensation related to chemo drugs based on interpretation of proposed Stark II rules
- Physician files suit under Indiana Wage Payment Statute
- Court holds that there is no good faith exception to Wage Payment Statute
- Physician wins—
 - Awarded approximately \$850,000



Huntsville Hospital v. Alapati

- **Hospital sues physician for failure to repay loan (made in connection with recruitment arrangement)**
- **Physician asserts that loan is illegal under Stark and Kickback laws as enforced because the hospital has not enforced other loan agreements when the physician's referrals are sufficient**
- **Physician seeks discovery of all other physician deals**
- **Discovery denied– No ruling on illegality**



False Claims Act & Stark

- **Federal False Claims Act (FCA) weapon of choice**
- **Permits whistleblowers to file suit on government's behalf – bounty hunters**
- **Recovery includes treble damages, fines of \$5,500 to 11,000 per claim**
- **Some courts have permitted False Claims Act suits based on Stark violations**



US ex rel Thompson v. HCA



- FCA whistleblower case based on HCA's relationships with Physicians
- Both Stark and Kickback allegations as bases for FCA claims
- Decisions to date allow whistleblower to use Stark violations as basis for FCA claims
- Case still pending



U.S. v. Advocate Health

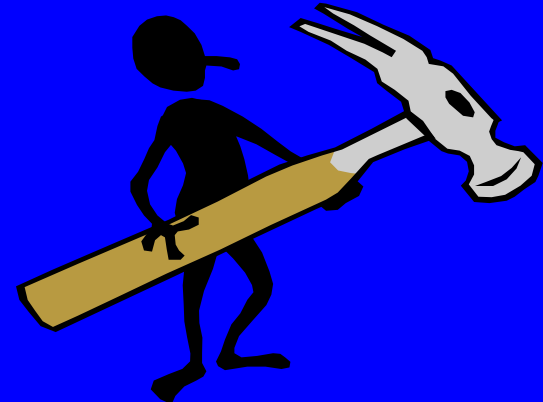
- **FCA case brought against Hospital system alleging practice acquisitions and contract with physicians violated Stark and kickback laws**
- **Dismissed by District Court**
 - **Mandatory referrals by Physician employees– ok**
 - **Percentage arrangements-- ok**





Pastor Medical Associates

- Former partner brings FCA claim based on Stark violations tied to group compensation system
- Group paid members % of income derived from lab tests the physician referred to group's lab
- Pastor settles for \$230,000
- Is it a violation? Were rules clear in 1992?





United States v. McLaren Regional Medical Center

- **Facts: Physician group leased office space to hospital---**
 - **Fair market value?**
- **FCA case filed by whistleblower and government intervened**
- **Discovery regarding negotiations— attorney-client privilege waived**
- **Trial Bifurcated: Limited to issue of FMV**



McLaren (cont)

- Government argued above market lease resulted in false cost report-
- did not argue that all claims pursuant to referrals from group = false claims
- Court found that the lease to the hospital was FMV
- Did the Court Blink?
- Did the lawyer effectively make it into a real estate case?

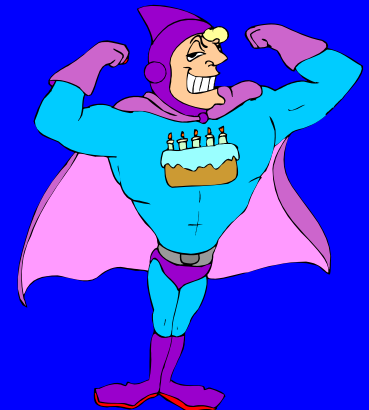




2002 FCA Settlements



- *Rapid City Hospital (S.D.)*
 - Qui Tam case based on Stark violations (below market lease)
 - \$6 million settlement
- *St. Joseph's Hospital (N.D.)*
 - Qui Tam case based on Stark violations (payments to physicians)
 - \$5 million settlement





Future of Stark

- It is not going away
- Phase II will be issued (2003??)
- Regulatory Enforcement is imminent
- Courts will play greater role in shaping law
- CMS will eventually issue Advisory Opinions

