



Sonnenschein

Part II

The Stark Law

Elements

- **Physician**
- **Referral**
- **To**
- **Entity**
- **Financial Relationship**
 - **Ownership/Investment Interest**
 - **Compensation Arrangement**
- **Furnishing**
- **DHS**
- **Medicare**
- **Exceptions**

Policy Objectives

- General. “When physicians have a financial incentive to refer, this incentive can affect utilization, patient choice, and competition.”
- Overutilization. Physicians can “overutilize by ordering items and services for patients that, absent a profit motive, they would not have ordered.”

Policy Objectives

- Choice. Patient choice “can be affected when physicians steer patients to less convenient, lower quality, or more expensive providers . . . just because the physicians are sharing profits with, or receiving remuneration from, the providers.”
- Competition. Where referrals are “controlled by those sharing profits or receiving remuneration, the medical marketplace suffers since new competitors can no longer win business with superior quality, service, or price.”

Chronology

- 1989: Stark I - Lab Services
- 1993: Stark II - DHS
- 1995: Stark I Regulations
- 1998: Proposed Stark II Regulations
- 2001: Stark II Regulations - Phase I
- 2002: Stark II Regulations - Phase I
Effective Date (January 4, 2002)
- (July 2003?): Final Stark II Regulations -
Phase II

Phase I - Overview

- **Phase I Regulations Address:**
 - **General prohibitions**
 - **Definitions used throughout law**
 - **Existing and new exceptions covering both ownership interests and compensation arrangements**
 - **New exceptions covering compensation arrangements**

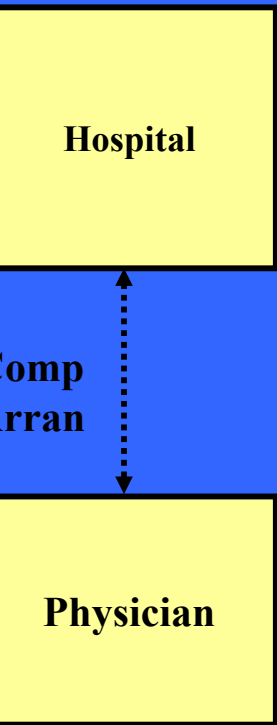
Phase I - Overview

- **Phase I Regulations Do Not Address:**
 - Existing exceptions covering compensation arrangements
 - Existing and new exceptions covering ownership interests
 - Reporting requirements

Phase I - Bottom Line

- **On the one hand . . .**
 - **Fewer referrals are implicated**
 - **More exceptions are available**
 - **Existing exceptions have been liberalized**
- **On the other hand . . .**
 - **The law remains very broad and incredibly complicated**
 - **Litigation underway; likely to increase**

Application



- **Facts**

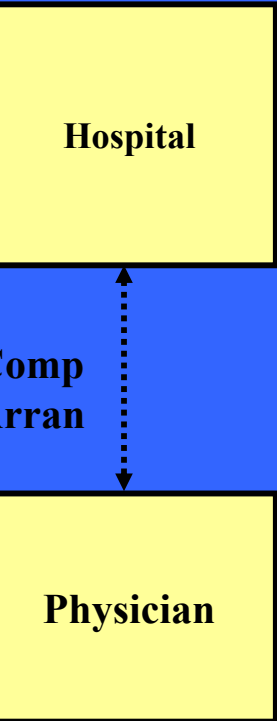
- Hospital creating cancer center
- Hires Physician to furnish consulting services
- Pays physician \$100/hour

- **Conclusion**

- Hospital and Physician have a “financial relationship” in the form of a “compensation arrangement” unless an “exception” applies

Application

- **Exceptions**



- **Personal Services Exception**

- 42 U.S.C. § 1395nn(e)(3)

- 42 C.F.R. § 411.357(d)

- 10 requirements

- May be revised in Phase II regulation

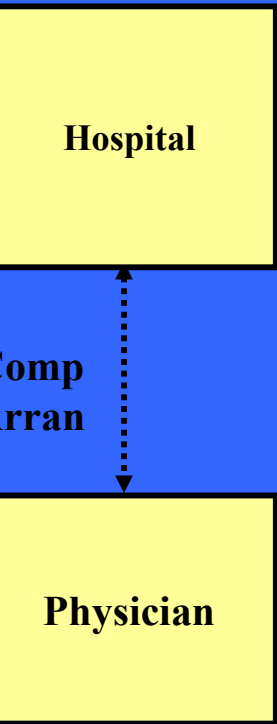
- **Fair Market Value Exception**

- 42 C.F.R. § 411.357(l)

- Effective January 2002

- 11 requirements

Application

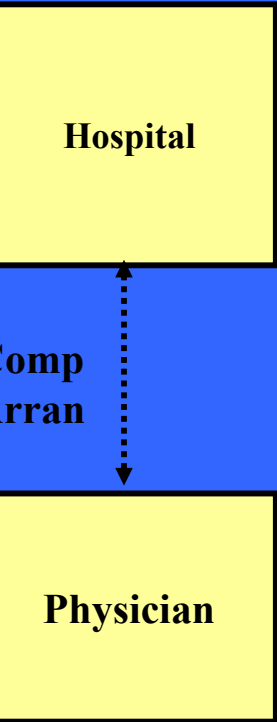


- **Exceptions**

- **Remuneration Unrelated To Provision of DHS**
 - 42 U.S.C. § 1395nn(e)(4)
 - “nexus” test
 - CMS examples

Application

- Facts



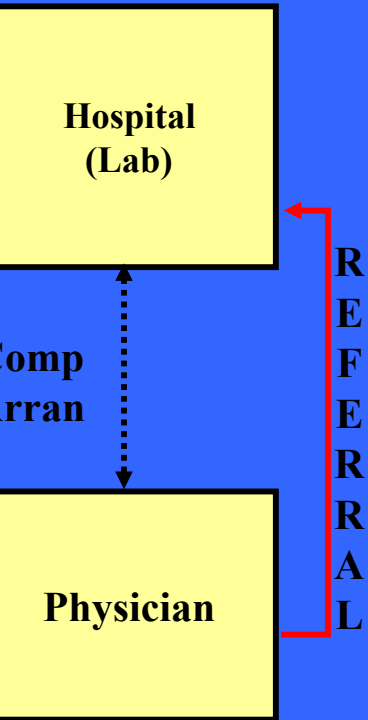
- Assume one requirement not met.
For example:

- Agreement is oral
- One party failed to sign
- Agreement does not sufficiently “specify” covered services
- Agreement for less than 12 mos.
- \$100/hour is more (or less) than “fair market value”

Application

- Facts

- Physician has private practice
- Patient needs lab test
- Physician refers patient to Hospital's outpatient lab



- Stark law violation? Yes.

- “[I]f a physician has a financial relationship with an entity . . . then the physician may not make a referral to th
entity”

- Stark law sanctions? No.

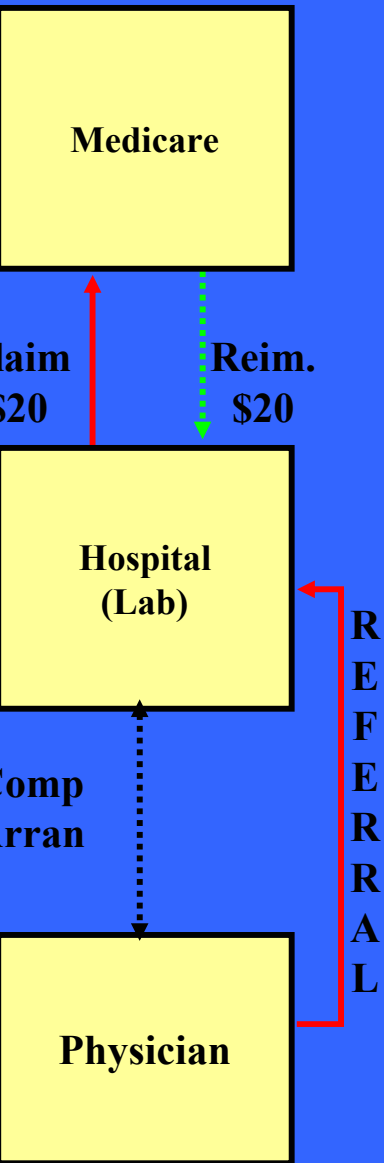
Application

- Facts

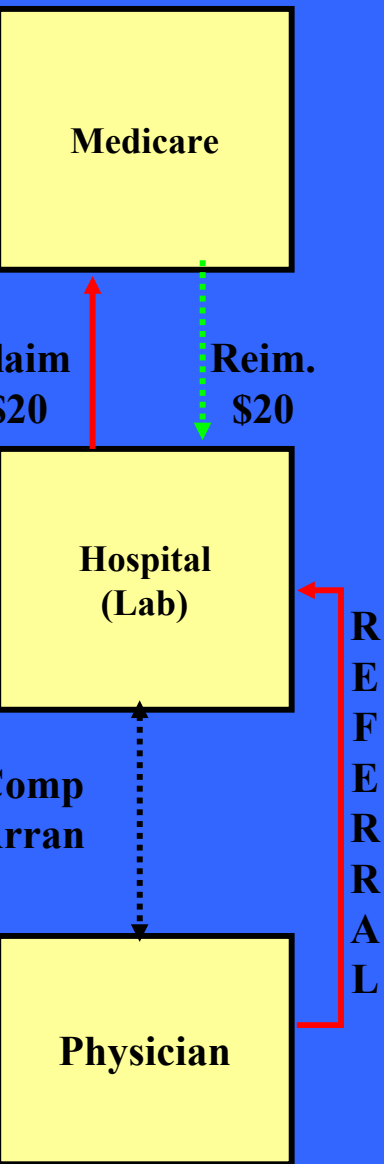
- Hospital furnishes services, submits claim for fee schedule amount (\$20)
- Intermediary reimburses Hospital (\$20)

- Stark law violation? Yes.

- “[I]f a physician has a financial relationship with an entity,” then “the entity may not present . . . a claim” to anyone “for [DHS] furnished pursuant to a [prohibited] referral . . .”

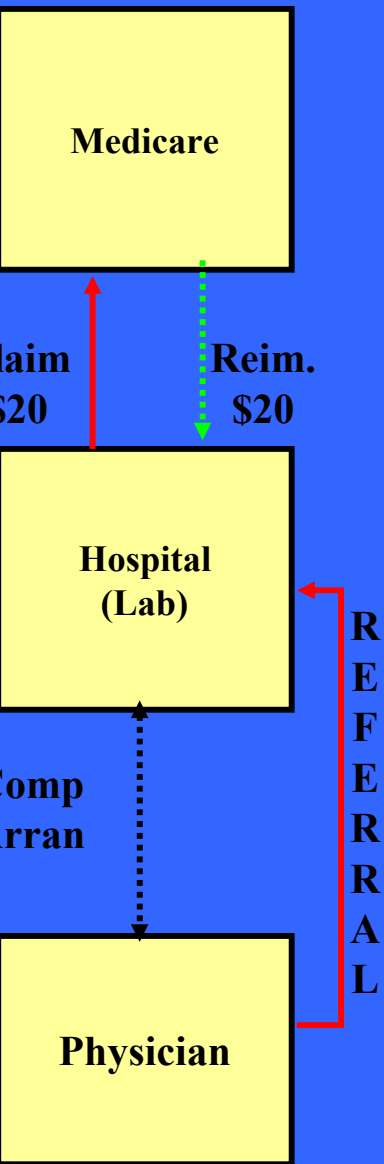


Application



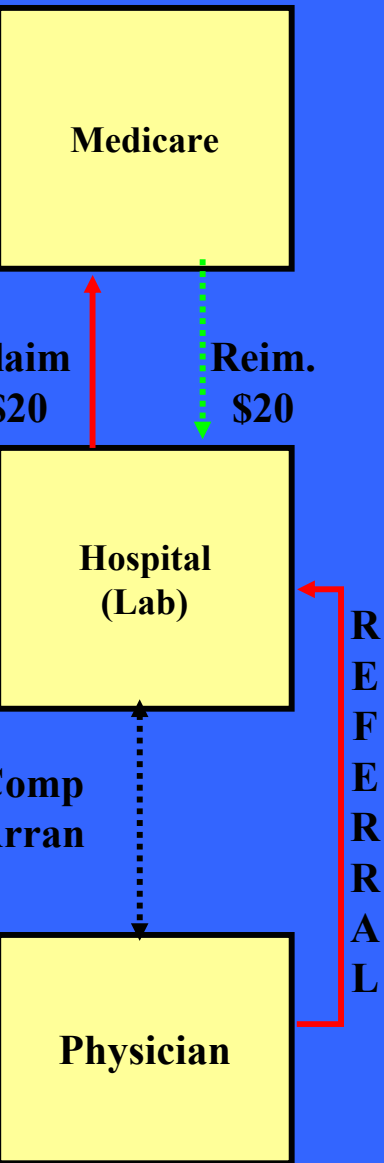
- Stark law sanctions? Probably.
 - Basis. No payment will be made for services furnished pursuant to a prohibited referral.
 - Types. Any person that presents a claim that such person “knows or should know” is for a service for which payment may not be made shall be subject to:
 - \$15,000 CMP per service
 - 3X amount claimed
 - Exclusion

Application



- Can Hospital be sanctioned?
 - Hospital presented claim for service (lab test) for which payment may not be made by Medicare (because it was referred by physician with unexcepted financial arrangement with Hospital).
 - That leaves only the “knows or should know” issue/defense.

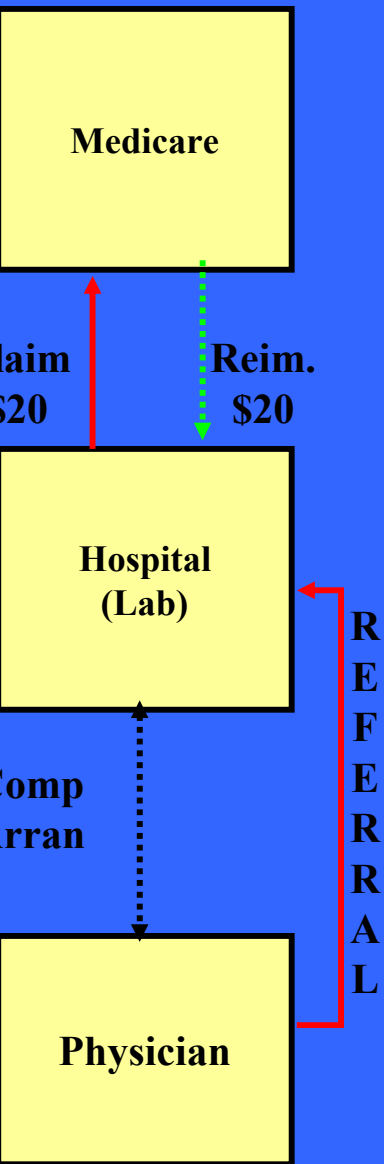
Application



- “should know” means that a person, “with respect to information,” either:

- “acts in deliberate ignorance of the truth or falsity of the information”
or
- “acts in reckless disregard of the truth or falsity of the information”

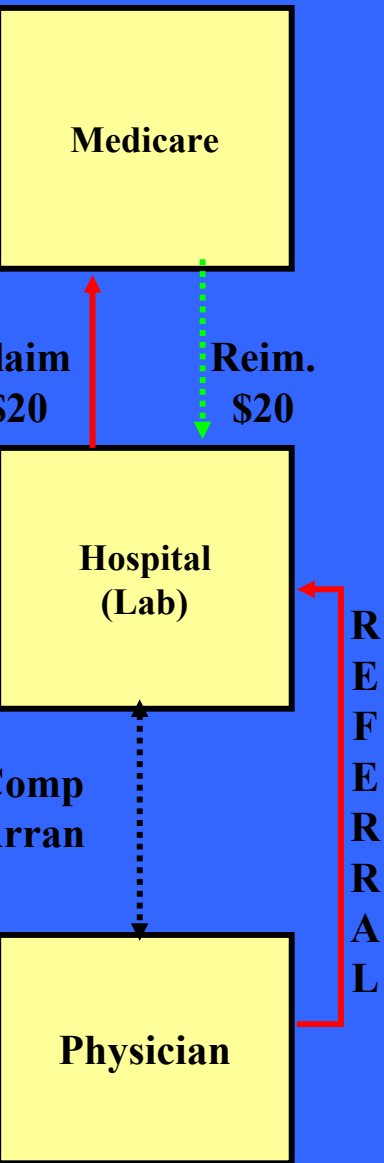
Application



- Did Hospital know that it had a “financial relationship” with Physician?
 - That is, did Hospital know that its payments to Physician constituted a “compensation arrangement” that was not covered by an exception?
- Alternatively, did Hospital act in “reckless disregard” or “deliberate ignorance” of this fact?

Application

● Possible CMS Arguments



- If Hospital (1) aware of arrangement with Physician, (2) examined arrangement, and (3) determined no exception applied, Hospital had actual knowledge
- If Hospital not aware of arrangement or failed to examine it, Hospital acted with reckless disregard/deliberate ignorance
- Either way, Hospital can be sanctioned

Application

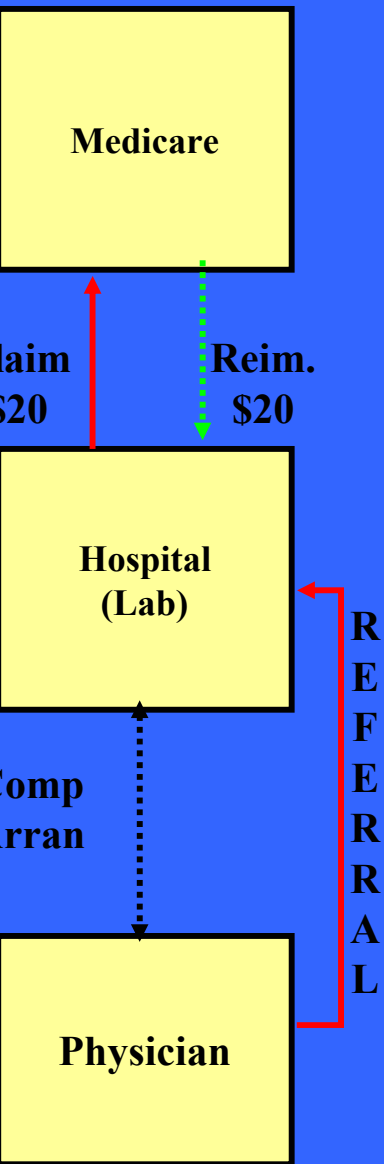
- Bottom Line

- If

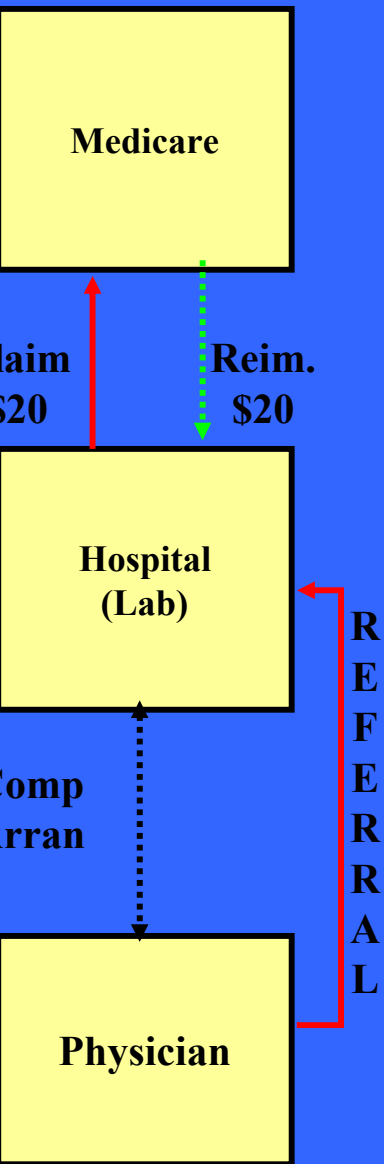
- you furnish DHS,
- you are owned by or give any thing of value to physician,
- physician refers Medicare patients to you, and
- you bill for your services,

- Then

- your arrangement with physician better fit within an exception



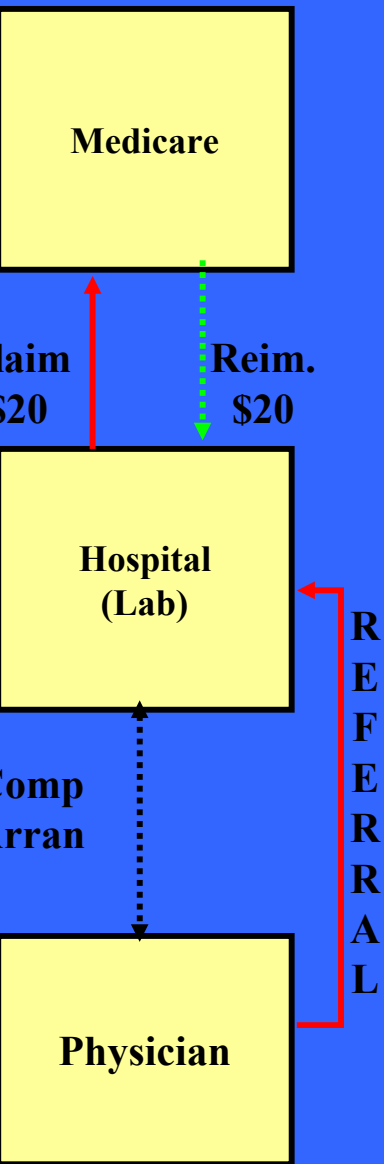
Application



- **CMS Enforcement**

- That CMS may impose sanctions does not mean that it will do so
- Resource issues
- Discretion issues
 - Stark Law very broad; implicates arrangements that do not implicate policy objectives
 - Advisory opinion process

Application

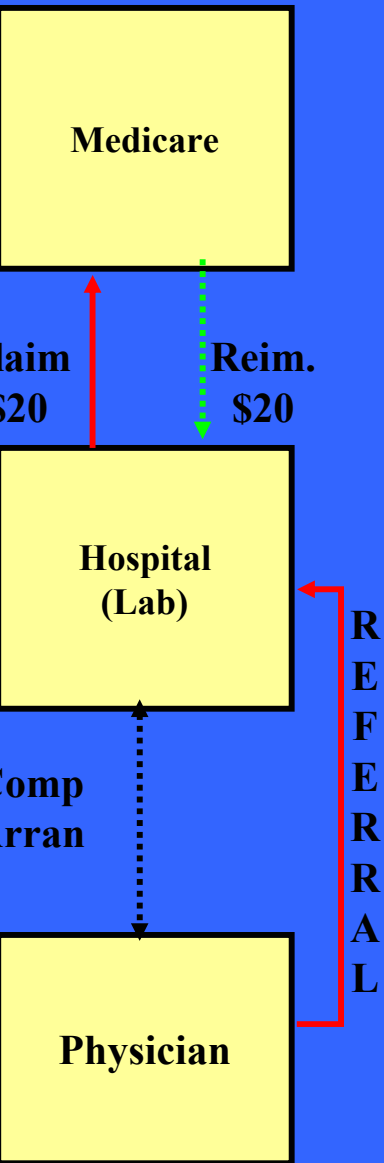


- Discretion issues (cont.)
 - Does arrangement implicate Stark law policy objectives?
 - Overutilization?
 - Steering?
 - Market competition?
 - How far is arrangement from meeting exception?
 - Not FMV?
 - No signature?

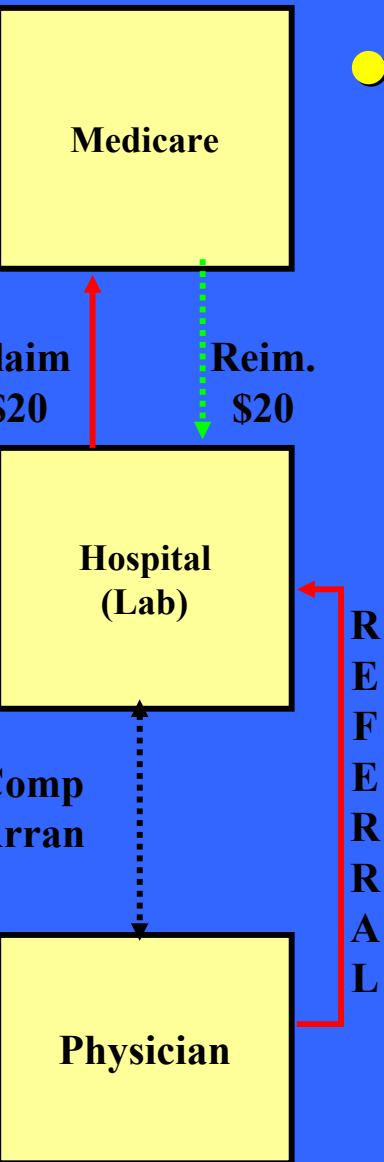
Application

- **Bottom Line**

- **Law is very broad**
- **CMS knows this**
- **Both for reasons relating to resources and public policy, enforcement action may not be taken where law violated**
- **Particularly where arrangement:**
 - **Does not materially implicate law's objectives**
 - **Meets all non-technical exception requirements**



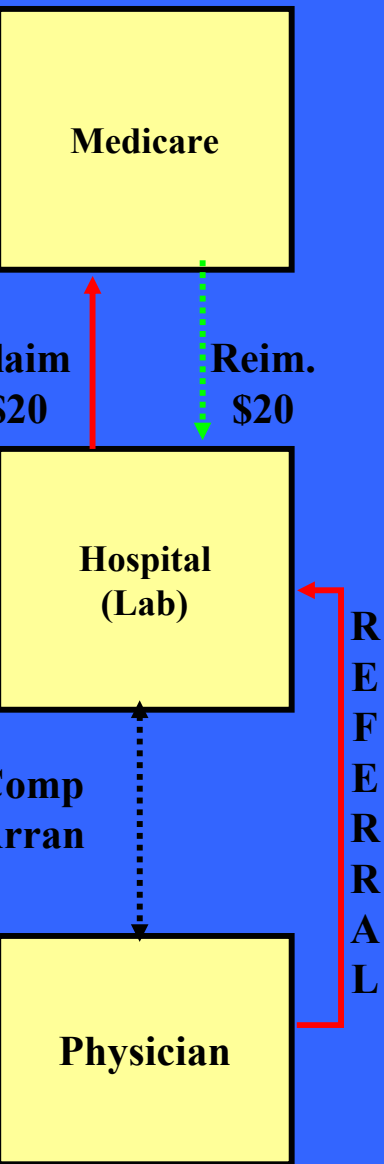
Application



- **False Claims Act Liability**

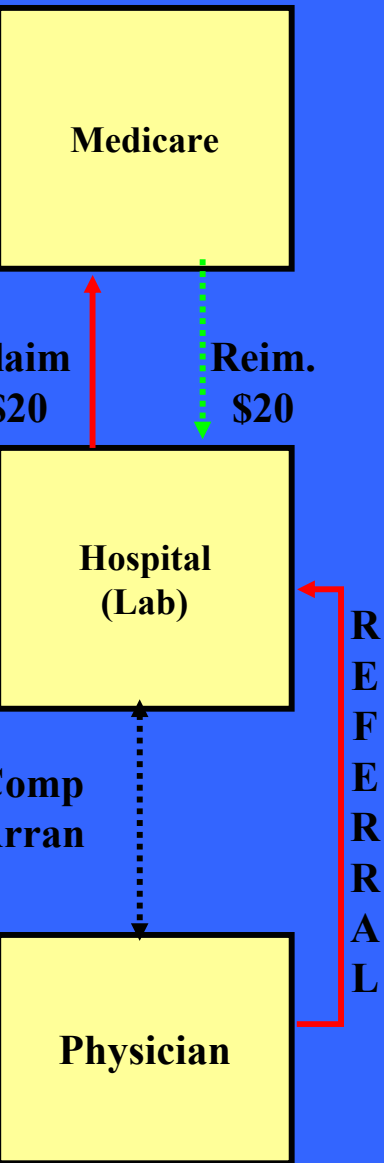
- **By virtue of Stark law violation, is Hospital's submission of claim a "false claim" under civil FCA?**
- **Is so, then CMS resources and discretion are irrelevant**
- **Whether arrangement materially implicates law's policy objectives is irrelevant**
- **Whether arrangement meets all non-technical requirements of an exception is irrelevant**
- **Relators (and their counsel) could care less**

Application



- Basic Rule. Presentation of a claim to the government with knowledge that it's false (with "knowledge" defined as in Stark CMP provision)
- Sanctions
 - Up to \$11,000 per claim
 - Treble damages

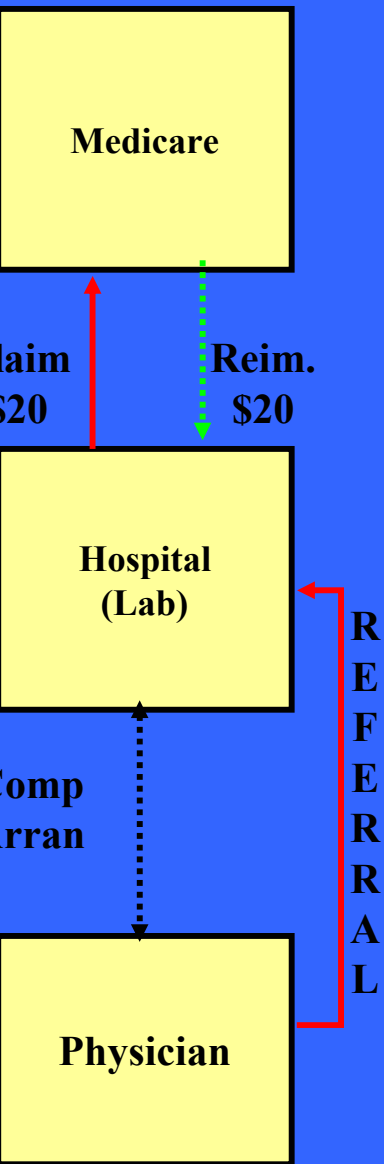
Application



■ DOJ Position

- Stark law violations give rise to FCA violations
 - Tenet (2/01) (non-FMV payments to physician practices)
 - HCA (3/01) (non-FMV rent, non-FMV directorships, etc.)
- If Hospital “knows” that claim not reimbursable under Stark law, this “knowledge” is sufficient for FCA purposes

Application



■ Implications

- Potential increase in DOJ-initiated FCA actions
- Potential explosion of FCA whistleblower actions

■ Defenses

- Law is ambiguous; “knowledge” requirement can’t be met
 - Case by case analysis
- Violating regulatory requirement does not give rise to FCA action
 - Thompson (1998)

Recommendations

- First. DHS Entity should identify all physicians that refer Medicare patients to the entity
- Second. Entity should identify each physician with which it has a direct or indirect financial arrangement

Recommendations

- Third. Entity should determine whether arrangement is covered by an exception
- Fourth. If arrangement is not covered by an exception, the entity should give serious consideration to working with fraud and abuse counsel to restructure the arrangement to fit within an exception or, if that is not possible, to terminate the arrangement

Recommendations

- If entity fails to do this
 - CMS may take enforcement action under Stark law
 - Refund
 - CMP (\$15,000 per service)
 - 3X amount claimed
 - Exclusion
 - DOJ may initiate civil FCA action
 - Relators will initiate civil FCA action

Recommendations

- Moreover, to the extent that the entity had knowledge that it had submitted improper claims, its failure to disclose this fact to the relevant payor (e.g., intermediary, carrier or DMERC) may subject the entity to criminal exposure pursuant to 42 U.S.C. § 1320a-7b(a)(3)

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