Stark Update

The gift that keeps on giving . . .

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The Stark Law

- Prohibits a physician from referring Medicare patients for designated health services (DHS) to entities with which the physician (or an immediate family member) has a financial relationship, unless an exception applies
- Entities are prohibited from billing Medicare for DHS furnished pursuant to tainted referrals

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Overview

- ACA amendments to Stark Whole Hospital and IOAS exception
- ACA Disclosure/Repayment Provisions
- ACA Stark Self Disclosure Protocol
- CMS Implementation of Protocol
- Practical Tips

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Affordable Care Act

- On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Health Care Act ("ACA")
- ACA includes a few notable amendments to the Stark law:
  - Severely restricts the ability of physicians to hold equity interests in hospitals
  - Imposes additional disclosure requirements when certain imaging services are provided by a group practice
  - Establishes a Stark Self Disclosure Protocol

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Stark Whole Hospital Exception

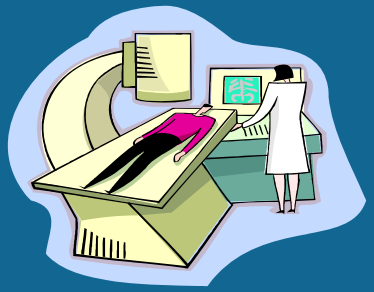
- ACA restricts the ability of physicians to own interests in hospitals to which they refer
- The hospital must have already had physician ownership or investment as of December 31, 2010, and had a provider agreement in effect on such date
- Subject to certain exceptions, the hospital may not increase the number of operating rooms, procedure rooms, or beds for which the hospital is licensed on March 23, 2010
- The hospital must disclose physician ownership and investment interests to the Secretary and the public and must have procedures in place to require referring physicians to disclose their ownership interests in the hospital as well as those of other treating physicians

Whole Hospital Exception

- The percentage of the total value of the ownership or investment interests held by physicians in the aggregate may not exceed the percentage as of March 23, 2010
- Ownership interests cannot be offered on more favorable terms to physicians than to non-physicians
- The hospital, its owners, or investors cannot directly or indirectly provide loans or financing for physician owners or investors
- Hospital cannot limit the physician owners right or ability to purchase or lease business interests or other property under the control of the hospital or other owners or investors

Disclosure Requirements Under IOAS

- Beginning January 1, 2011, physicians who refer patients for in-office MRI, CT and PET services must:
  - inform their patients at the time of the referral, in writing, that the patient is entitled to get MRI, CT and PET services at places other than the physician's office
  - provide the patient with a written list of at least five other MRI, CT and PET suppliers within a 25-mile radius of the physician office
    - The list should include the name, address and telephone number of each supplier



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ACA: Disclosure and Return of Identified Overpayments

- ACA included a new provision that imposes an affirmative obligation to report and return overpayments
- This obligation is imposed on "persons," which are defined to include providers of services, suppliers, Medicaid managed care organizations, Medicare Advantage organizations, or Part D Plan sponsors

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Report and Repayment: Timing

- Under the statute, the reporting and return processes are to be completed by the later of
  - the date which is 60 days after the date on which the overpayment was identified, or
  - the date any corresponding cost report is due, if applicable

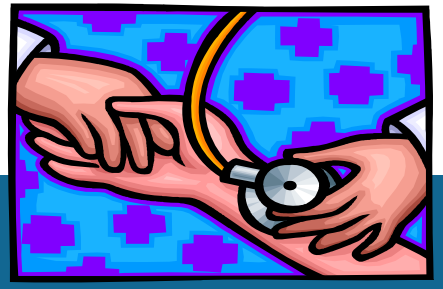
Failure to Return Identified Overpayment --Reverse False Claim

- Failure to report and return the overpayment within the required timeframes is an "obligation" for purposes of the federal False Claims Act (FCA)
- Thus, the failure to return an overpayment in violation of this statute creates a basis for a FCA lawsuit
  - Note: FCA permits whistleblower (*qui tam*) suits

Overpayments arising out of Stark Violations

- An overpayment is defined as “any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled . . .”
- Stark prohibits a provider from billing Medicare for designated health services furnished pursuant to a prohibited referral
- Thus, when a provider discovers a Stark violation and identifies the reimbursement received derived from services provided pursuant to prohibited referrals then it must return the overpayment to the government within 60 days

Open Questions



- When is an overpayment “identified”?
  - When a violation is discovered?
  - When the provider has determined the amount of the overpayment arising out of the violation?
- When is Medicare reimbursement sufficiently related to a prohibited Stark referral that it is an overpayment?

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Stark Self Disclosure Protocol

- ACA directs the CMS to establish a self disclosure process for actual or potential Stark violations and gives the Secretary explicit authority to compromise the amount of the damages resulting from submission of claims prohibited by the Stark law

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Compromise of a Stark Violation

- Under the ACA Congress stated that the circumstances the Secretary may consider in making a determination to compromise include:
  - the nature and extent of the alleged illegal activity
  - the timeliness of the self-disclosure
  - the cooperation of the disclosing entity
  - any other factors deemed appropriate

CMS: Self Disclosure Protocol

- Issued September 23, 2010
- Gives guidance as to disclosure process and what facts should be included in a Disclosure Statement
- Does not provide any guidance as to how CMS will exercise its discretion
  - And CMS is not telling
- Does provide that 60 day period for return of identified overpayments is tolled once the Disclosure Statement is filed

Self Disclosure Protocol: Inside CMS

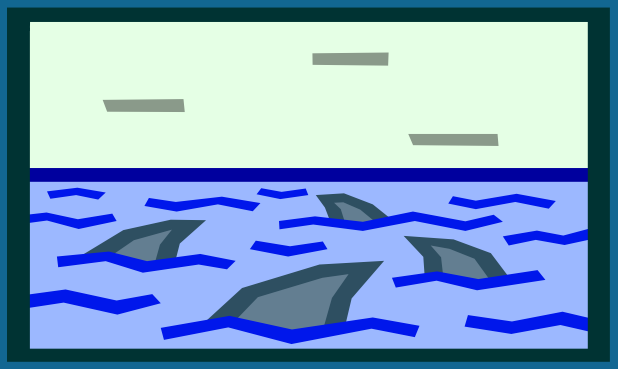
- Once disclosure statement is submitted to the agency, three separate divisions within CMS are involved in processing the disclosure:
  - Office of Technical Payment Policy
  - Office of Program Integrity
  - Office of Financial Management (OFM)
- The relative roles and responsibilities of the three offices are unclear
- Concern is that OFM will make the decision as to how the financial liability arising out of the disclosure will be reduced or compromised

Self Disclosure Protocol: Current Status?

- When the Protocol was announced CMS made no promises to anyone
- In fact, CMS guarded statements about its authority to compromise discouraged many in the industry
- Approximately 50 Disclosure Statements have been submitted to CMS since the Protocol was established last September
- Low number given all the circumstances

Status of Self Disclosure Protocol

- No final settlements arising out of the Disclosure Protocol have been announced
- CMS is sending mixed signals to the parties who have elected to self disclose
  - Probing questions
- Some speculate that CMS is purposely undermining the disclosure protocol because it doesn't want to make the hard decisions about compromising the amount due and owning to the government
- Time will tell . . .



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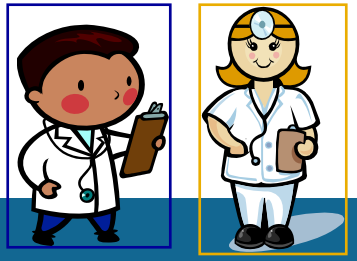
Hypothetical



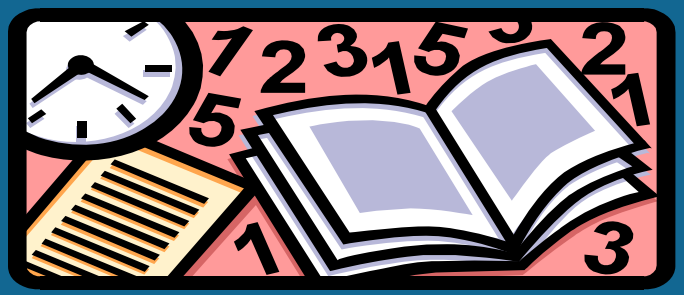
- Regional Health System has offered to purchase St. Somewhere Community Hospital
- In due diligence Regional's lawyers identify 5 historical Medical Director Agreements that were never signed
- The Medical Director agreements all started January 1, 2010 and ended December 31, 2010
- The Medical Director services were provided by the physicians, compensation paid was fair market value and the terms of the agreements were commercially reasonable

Hypothetical

- Is there a Stark violation?
  - Careful review of the specifics of each contract and its circumstances is needed
  - Is the contract with the individual physician or his/her group?
  - Was there a contract in effect at 12/31/09?
- Were claims related to prohibited referrals submitted by St. Somewhere to Medicare?

Hypothetical

- When does the 60 day clock start running?
  - Is there an overpayment?
  - How much is the overpayment?
  - What is the period of disallowance?
  - What APC or DRG payments are affected?
    - All or part?



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Hypothetical

- What should St. Somewhere do?
- What should Regional Health System do?
- Should the parties close the transaction?

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Practical Tips

- Do not over react
- Do not assume that an unsigned agreement or other foible in a document means either that the law has been violated or that an overpayment has been received
- Investigate the facts before making any admissions or accusations

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Practical Tips

- Carefully analyze the parameters of the Stark prohibition and exceptions
  - The law is full of nuances:
    - Alternative method of compliance with signature requirements
    - Hold over provisions in the Lease and PSA exceptions
    - Definition of referral
- Consider state law arguments and creative theories before deciding how to proceed
- Recognize that ignoring the problem creates its own set of risks