













# What does it mean to "identify" an overpayment?

CMS has <u>proposed</u> that a person has "identified" an overpayment if:

- It has actual knowledge of the existence of the overpayment; or
- acts in reckless disregard or deliberate ignorance of the existence of the overpayment.

# Sound familiar?????





# What does it mean to act in reckless disregard or deliberate ignorance?

CMS suggests in the preamble to the proposed rules that failure to "exercise reasonable diligence" could result in a provider being deemed to have identified an overpayment. Particular examples given of exercising reasonable diligence include conducting:

Self-Audits; Compliance checks; and Other additional research.





The Civil Monetary Penalty liability appears to only apply if a provider "knows of" an overpayment and does not report and return it according to the law.

Other CMP provisions specifically read: "knows or should know." The CMP statutes define "should know" as encompassing reckless disregard and deliberate ignorance.

Does the CMP law only apply if the provider has <u>actual</u> <u>knowledge</u> of an overpayment??????





Possibly Relevant CMS Manual Provisions:

Chapter 3, Section 90, of the Medicare Financial Management Manual, states that "a provider is liable for overpayments it received unless it is found to be without fault." It further provides that a provider is not considered at fault if "it exercised reasonable care in billing for, and accepting, the payment; i.e.,

It made full disclosure of all material facts; and

On the basis of the information available to it, including, but not limited to, the Medicare instructions and regulations, it had a reasonable basis for assuming that the payment was correct, or, if it had reason to question the payment; it promptly brought the question to the FI or carrier's attention."

Section 90.1, Example H, outlines a standard that informs whether a provider "should have known about a policy or rule." The standard suggests that the policy or rule should have been known if it is in the provider manual or in Federal regulations. Further, the standard suggests consideration of "all the circumstances, including such factors as whether and to what extent a coverage rule is spelled out in regulations, instructions, or in a CMS notice..."



# Putting it all together

- A provider is liable under the FCA if it "identifies" an "overpayment" and "knowingly conceals or knowingly and improperly avoids" the "obligation" to report/repay after the 60 day window.
- A provider is liable under the CMP statute if it "knows of" an "overpayment" and does not report/repay within 60 days of "identifying" the overpayment.





# **Conditions of Payment vs. Conditions of Participation**

**Conditions of Payment** 

- Conditions that must be satisfied before the government will pay a claim.
- If the conditions of payment are not met, the payment will be an overpayment and must be returned to avoid violation of the FCA.

Conditions of Participation

- Health and safety standards that must be satisfied to participate in a federal health care program.
- Failure to comply does <u>not</u> result in payment denial (unless also a condition of payment).





# Overpayments Under the Stark Law: Background

Two prohibitions under the Stark Law when a physician has a financial relationship with an entity that does not meet an exception:

- The physician may not make a referral to the entity for the furnishing of DHS for which Medicare may make payment
- The entity may not present or cause to be presented a claim to Medicare for DHS provided pursuant to a prohibited referral



# Overpayments Under the Stark Law: Background

# So what would be the amount of an overpayment for a Stark Law violation?



All Medicare payments the entity receives for services provided under a prohibited referral.



# Overpayments under the Stark Law: Pitfalls

Complexity

- Broad prohibition
- Exceptions with multiple, technical elements

Serious Consequences

- Repay to Medicare the collections related to prohibited referrals
- Repay co-payments to Medicare beneficiaries
- Potential CMPs up to \$15,000 per claim
- Potential False Claims Act liability
- Liability can be disproportional to violation



# Overpayments Under the Stark Law: 3 Common Technical Traps

Lack of a signature when a signed document is necessary for a Stark Law exception.



Possible Solution:

Special rule for temporary noncompliance with signature requirement.

- "inadvertent" correct in 90 days
- "not inadvertent" correct in 30 days

# Overpayments Under the Stark Law: 3 Common Technical Traps

BUT, is this really helpful?

- Applies only to lack of signature
- Available only once every 3 years for a physician

What if no signature within the 30 or 90 days?

"We recognize that, in some cases parties may never bring the arrangement back into compliance, such as failing to ever get a missing signature. That is why we proposed, and we adopt as final, a rule that specifies an outside date for the period of disallowance."

CMS, 2009 IPPS Final Rule, 73 Fed. Reg. at 48702



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# Overpayments Under the Stark Law: 3 Common Technical Traps

#### Other Possible Solutions:

- What constitutes a "signature"?
  - Not defined in the Stark regulations
  - Consider state law
    - Connecticut Uniform Electronic Transactions Act (Conn. Gen. Stat. §§ 1-266 to 1-286)
    - "Electronic Signature" means an electronic sound, symbol or process . . . attached to a record with intent to sign
  - Signature on a cancelled check

# Overpayments Under the Stark Law: 3 Common Technical Traps

#### Problem #2:

Small payments without documentation

Examples:

Medical staff leadership stipends paid to referring physicians without a signed written document.

Hospital purchases medical equipment from physician practice.





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# Overpayments Under the Stark Law: 3 Common Technical Traps

#### **Possible Solutions:**

- Would existing documents constitute a "writing"?
  - A "writing" is not defined in the Stark regulations.
  - The writing must describe the arrangement and be signed by the parties.
  - Consider application of state law.
    - Common Law Enforceable contract exists if (1) terms and requirements are definite and certain (even if some terms are missing), and (2) manifestation of mutual assent of the parties.
    - Connecticut Statute of Frauds, Conn. Gen. Stat. § 52-550(a)
  - Consider use of multiple documents or records.



# Overpayments Under the Stark Law: 3 Common Technical Traps

# Possible Solutions:

- Exceptions with No Writing Requirement
  - Isolation Transactions (42 C.F.R. § 411.357(f))
  - Remuneration by a Hospital Unrelated to DHS (42 C.F.R. § 411.357(g))
  - Indirect Compensation Analysis
    - Might apply if relationship is with hospital's captive professional corporation or medical foundation affiliated with hospital.



# Overpayments Under the Stark Law: 3 Common Technical Traps

#### Problem # 3:

Failure to renew a contract

#### Possible Solution:



- Holdover provisions for leases and personal services arrangements
- Temporary Noncompliance (42 C.F.R. § 411.353(f))
  - Complied for at least 180 days before became non-compliant
  - Non-compliance for reasons beyond the control of the entity and fix within 90 days
  - Available only once in 3 years for a physician

# Overpayments Under the Stark Law: Amount of the Overpayment

#### Period of Disallowance (§ 411.353(c))

- Time period during which referrals are prohibited as a result of a financial relationship that fails to satisfy a Stark exception.
- Begins when relationship fails to satisfy exception.
- Ends not later than the date when relationship satisfies an exception.

#### Applied literally, this means:

- Missing signature? Until the parties sign.
- Lack of written document? Until a written contract is created and signed.
- Lease term expired and not renewed? Starts after the 6 month holdover until written renewal is signed.



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# **Overpayments Under the Stark Law:** Self-Referral Disclosure Protocol

Self-referral Disclosure Protocol established by § 6409(a) of PPACA

- Purpose was to provide a process for healthcare providers and suppliers to self-disclose actual or potential violations of the physician self-referral statute.
- Secretary is authorized to reduce amounts due and owing for all violations under Section 1877 of the Social Security Act.

#### Self-Disclosure Considerations:

- After investigation of facts, is it legally required?
- If not legally required, is it tactically wise?



# **Overpayments Under the Stark Law:** Self-Referral Disclosure Protocol

- Requires detailed submission facts, claims affected and legal analysis
- Requires concession that a violation occurred
- E-mail confirming receipt from CMS tolls the 60 day clock
- CMS will consider various mitigating factors in reducing amounts otherwise owed
- Outcome is subject to uncertainty
  - CMS not required to reduce liability
  - No opportunity to negotiate the settlement

# Anti-kickback Statute – Conditions of Payment(?)

- CMS states in the preamble to the proposed overpayment rules that "compliance with the anti-kickback statute is a condition of payment," meaning CMS believes if there is a kickback scheme, the payment will be an overpayment and must be returned to avoid violation of the FCA.
- This is also supported by applicable FCA case law that appears to have prompted legislative change.
- The amended AKS statute, however, appears only to make an item or service billed pursuant to an illegal kickback scheme a false claim.
  - Thus, until there is a Manual provision or regulation, this may leave open a very small window of interpretation that a provider may still be entitled to the funds, and hence not in receipt of an overpayment, but subject to the FCA penalties.



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Provider-Based Billing – Conditions of Payment

For a provider to bill a facility as providerbased, the facility must meet <u>all</u> the regulatory requirements.

The overpayment would be the difference between the amount of the provider-based payment rate and the freestanding facility payment rate.





