Stark Law Overpayments and False Claims Act Implications

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What Is An “Overpayment”? 

“Medicare funds a provider, supplier, an individual, or other entity, including a [MCO] contracting with CMS... has received in excess of amounts payable under the Medicare statute and regulations.” 67 Fed. Reg. 3665 (Jan. 25, 2002) (proposed rule) 

Overpayments can be caused by:

– Lack of Medicare eligibility
– Medicare improperly pays as the primary insurer
– Services not statutorily covered
– Services not medically necessary
– Payment amount is incorrect and excessive
Stark Law Violations *Can* Lead to Overpayments

- The **two** Stark Law prohibitions: if a physician has an ‘un- excepted’ financial relationship with an entity, then:
  1. The **physician** may not make a **referral** to the entity for the furnishing of DHS for which Medicare may make payment; and
  2. The **entity** may not present or cause to be presented a **claim** to Medicare or bill to any individual, third party payor, or other entity for DHS furnished pursuant to a prohibited referral

- If the entity violates the Stark Law, and receives payment, an overpayment has occurred

- How much of the payment received is considered an overpayment? All of it.
The Stark Law’s Refund Provisions

- Statute: “If a person collects any amounts that were billed in violation of [the Stark Law], the person shall be liable to the individual for, and shall refund on a timely basis to the individual, any amounts so collected” (emphases added). 42 U.S.C. §1395nn(g)(2)

- Regulation: “An entity that collects payment for [DHS] that was performed pursuant to a prohibited referral must refund all collected amounts on a timely basis” (emphasis added). 42 C.F.R. §411.353(d)
Penalty Provisions and the Stark Law

- Penalty provisions for physicians’ violations of the referral prohibition
  - No statutory or regulatory penalty

- Penalty provisions for entities’ violations of the claims prohibition?
  - Statute: “Any person that presents or causes to be presented a bill or a claim for a service that such person knows or should know is for a service for which payment may not be made under [the Stark Law]… shall be subject to a civil money penalty of not more than $15,000 for each such service” (emphasis added). 42 U.S.C. §1395nn(g)(3).
Penalty Provisions and the Stark Law, cont.

- Regulation: “The OIG may impose a penalty and assessment against any person whom it determines… has knowingly presented, or caused to be presented, a claim which is for… [a] payment that such person knows, or should know, may not be made under [42 C.F.R. §411.353].” 42 C.F.R. §1003.102(a)(5).
  - Penalty of no more than $15,000 per item or service
  - Assessment of no more than three times the amount of each item or service “wrongfully” claimed
  - Completeness and timeliness of any refund will be considered in determining penalties and assessments
- Regulatory exclusion also possible, if CMPs imposed for violation of claims prohibition. 42 C.F.R. §1003.105(a)(1)(i)
Penalty Provisions and the Stark Law, cont.

- Penalty provisions for not fulfilling the refund requirement?
  - No statutory penalty
  - Regulation: “The OIG may impose a penalty, and where authorized, an assessment against any person… whom it determines… [h]as not refunded on a timely basis… amounts collected as the result of billing an individual, third party payer or other entity for a [DHS] that was provided in accordance with a prohibited referral as described in [42 C.F.R. §411.353].” 42 C.F.R. §1003.102(b)(9).
    - Penalty of no more than $15,000 per item or service
    - Assessment of no more than three times the amount of each item or service “wrongfully” claimed
    - Completeness and timeliness of any refund will be considered in determining penalties and assessments
  - Failure to refund is neither a statutory nor regulatory basis for exclusion
Stark Law Uncertainties

- When are the Stark Law referral and claims prohibitions, and its refund provisions, triggered?

- Stark Law uncertainties may include:
  - Indirect compensation arrangement… and available exceptions
  - Physician organization
  - “Performing” DHS
  - Falling out of compliance for “reasons beyond the control of the entity”
  - Fair market value
  - Commercially reasonable
  - Set in advance / payments and performance inconsistent with arrangement
  - “Set forth in writing”
  - “Does not violate the anti-kickback statute”
Connecting the Stark Law to the False Claims Act (Before May 20, 2009)

- Hospital cost report certification (CMS Form 2552)
  - “I further certify that I am familiar with the laws and regulations regarding the provision of health care services and that the services identified in this cost report were provided in compliance with such laws and regulations.”
  - Is compliance with the Stark Law a condition of payment?

- ‘False’ hospital cost report certifications could lead to liability under then-31 USC §§3729(a)(1) and (a)(2)

- Numerous and high dollar settlements continue, e.g.:
  - United States ex rel. Reimche v. Tulare Local Healthcare District, No. CV 08-00543 CAS (C.D. Cal. 7/27/09) (debt forgiveness, below market rent).

- Reverse false claim provision (then-31 U.S.C. §3729(a)(7))

- **Old** reverse false claim provision, 31 U.S.C. §3729(a)(7)
  - “Any person who… knowingly makes, uses, or caused to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government….”

- On and after May 20, 2009 (enactment of FERA):
  - **New** reverse false claim provision, 31 U.S.C. §3729(a)(1)(G)
    - “Any person who… knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government…” (emphases added).
Key Defined and Undefined Terms

- “Material” 31 U.S.C. §3729(b)(4)
  - “having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.”

  - “an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment…” (emphases added).

- Undefined Terms:
  - “Established duty… arising from”
  - “Overpayment”
Unpacking §3729(a)(1)(G)’s Three Actionable Offenses

- First: ‘knowingly makes or uses a false record or statement [that has a natural tendency to influence or is capable of influencing the payment]… of an [established duty] to pay the Government’
  - Interpretation and application will be difficult
  - Make / use false record or statement to what end?
    - Previously: to “conceal, avoid, decrease”
    - Elsewhere: “for payment or approval”, “to defraud”, “to get”
    - Now? To do anything? For any end? Any making or use?
Unpacking §3729(a)(1)(G)’s Three Actionable Offenses, cont.

- Second: ‘knowingly conceals an [established duty] to pay or transmit money or property to the Government’
  - Expansion: actionable without making / using false record or false statement
  - What does ‘conceal’ mean in absence of false record / statement?
Unpacking §3729(a)(1)(G)’s Three Actionable Offenses, cont.

- Third: ‘knowingly and improperly avoids or decreases an [established duty] to pay or transmit money or property to the Government’
  - Expansion: actionable *without* use of record or statement
  - Expansion: actionable *without* falsity
  - Expansion: actionable *without* actus reus
What Was An “Obligation” Under Old (a)(7)?

“Obligation” was an operative term under (a)(7), but defined only by the courts, e.g.:

- **U.S. ex rel. Prawer v. Verrill & Dana, 946 F.Supp. 87 (D. Me. 1996)** (‘obligation’ does not include potential liabilities, only current liabilities)

- **U.S. v. Q Int’l Courier, Inc., 121 F.3d 770 (8th Cir. 1997)** (‘obligation’ does not include penalties due to undeclared violations of laws/regulations, or instances where administrative or prosecutorial discretion could interfere, or where selection of various applicable penalties and sanctions has not been made)

- **American Textile Mfrs. Inst. v. The Limited, Inc., 190 F.3d 729 (6th Cir. 1999)** (‘obligation’ does include acknowledgement of indebtedness, court judgment, administrative judgment, contractual duty… but not “contingent” obligations, i.e., those “that will arise only after the exercise of discretion by government actors”)


- Consistent with previous, (a)(7) jurisprudence?
- “Obligation” now defined by statute as an “established duty… arising from” any one of eight prescribed sources:
  - Express contractual relationship
  - Implied contractual relationship
  - Grantor-grantee relationship
  - Licensor-licensee relationship
  - Fee-based or similar relationship
  - Statute
  - Regulation
  - Retention of overpayment
Potential Sources of Stark Law “Obligations” / “Established Duties”

- Contractual Relationships, e.g.:
  - Enrollment agreement (CMS Form 855)
  - EDI agreement, §5? (CMS Form 8275)
  - Corporate Integrity & Certification of Compliance Agreements
Potential Sources of Stark Law “Obligations” / “Established Duties”, cont.

- Statutes, e.g.:
  - 42 U.S.C. §1320a-7b(a)(3)
  - 42 U.S.C. §1395nn(g)(2)
    - Requires refunds, but only to individuals
  - 42 U.S.C. §1320a-7b(b)
    - At best, implies that claims would not have been paid had violation been known…. Insufficient.
  - 18 U.S.C. §§669, 1347
    - USAO assertions that these give rise to “obligations” under (a)(7)
Potential Sources of Stark Law “Obligations” / “Established Duties”, cont.

- Regulations, e.g.:
  - 42 C.F.R. §411.353(d)
    - Requires refunds to Medicare program
    - Beyond scope of APA rulemaking authority?
  - 42 C.F.R. §1003.102(b)(9)
    - CMP for failure to refund in accordance with §411.353(d)
    - Contractors can be debarred for failing to disclose significant overpayments
Potential Sources of Stark Law “Obligations” / “Established Duties”, cont.

- Sub-regulatory guidance, e.g.:
    - “Report overpayments and establish the timeframe and process for making those reports.”
    - “Obligation to… return overpayments is derived from 42 U.S.C. §1395gg”
  - CMS’ Suggested Overpayment Refund Form (to FIs)
    - 17 “reason codes” for source of overpayment
    - Constitutional, APA rulemaking concerns

- When does (can?) an “established duty” to pay the Government “arise from” a mere retention of an overpayment?
  - Equitable theories of recovery?
Other §3729(a)(1)(G) Issues

- “Avoiding”
  - Is simply not repaying an overpayment enough? Or is more required?
- “Improperly” / Timing
  - “Improperly”: clear intent to protect hospitals’ retention of “overpayments” during cost report year / reconciliation period
  - Does this mean overpayments to hospitals can occur only after final cost report is finally closed out?
  - Does this mean all other overpayments retained by all other payees must be repaid instantly? Implications for Stark Law violations?
  - What if an appeal has been filed?
- Overpayments made before May 20, 2009 (FERA) can be actionable if knowingly retained today….
  - New and old Stark Law violations now actionable in and of themselves and under FCA without falsity / false certification theory
- How does the FCA penalty provision apply?
New Source of Stark Law “Obligation” / “Established Duty”…?

- “(d) REPORTING AND RETURNING OVERPAYMENTS.—
  - (1) IN GENERAL.-- If a person has received an overpayment, the person shall —
    - (A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address, and
    - (B) notify the Secretary, the State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
  - (2) DEADLINE FOR REPORTING AND RETURNING OVERPAYMENTS.—An overpayment must be reported and returned under paragraph (1) by the later of---
    - (A) The date which is 60 days after the date on which the overpayment was identified; or
    - (B) The date any corresponding cost report is due, if applicable.
  - (3) ENFORCEMENT.--Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31 of the United States Code) for purposes of section 3729 of such title…” (emphases added).
Connecting the Stark Law to the False Claims Act as of March 23, 2010...

- 31 U.S.C. §§3729(a)(1)(A) and (B): ‘traditional’ false claims and false statements
  - Hospital cost report certification

- 31 U.S.C. §3729(a)(1)(G): ‘traditional’ reverse false claims and ‘avoidance of obligations / established duties to pay the government,’ including duties arising from…:
  - Agreements with government?
  - Statute (the Stark Law itself)?
  - Regulation (42 C.F.R. §411.353(d))?
  - Mere retention of overpayment???
  - *New statutory provision… (per H.R. 3590, §6402)*
Mitigating The Risk of FCA Liability Based on “Identified” Stark Law Violations

- **Self-disclosure?**
  - OIG Open Letters to Health Care Providers
    - 2006: “lower end of damages continuum”
    - 2008: presumption against CIA or CCA
    - 2009: “OIG will no longer accept disclosure of a matter that involves only liability under the physician self-referral law in the absence of a colorable anti-kickback statute violation.”
  - But see *United States ex rel. Beecham v. Rush University Medical Center, et al*, Civ. Act. No. 04C 4584 (N.D. Ill 3/4/10) (where hospital had remedied non-compliant office space leases prior to knowledge of government investigation, *qui tam* settlement included treble the remuneration provided to referring physicians and no CIA or CCA).
Mitigating The Risk of FCA Liability Based on “Identified” Stark Law Violations, cont.

- New self-disclosure protocol on the horizon
  - H.R. 3590, §6409, “Medicare Self-Referral Disclosure Protocol”: HHS, in conjunction with HHS-OIG, must establish a self-disclosure protocol for ‘pure’ Stark Law violations that will detail:
    - Instruction on who self-disclosures will have to be made to
    - Implications that self-disclosures will have on CIAs and CCAs
    - How HHS will consider repayment in amounts less than claims made, based on:
      - Nature and extent of improper or illegal practice
      - Timeliness of self-disclosure
      - Cooperation in providing information related to self-disclosure
      - Other factors
Questions?

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