

The Self-Referral Disclosure Protocol: Settlement and Enforcement Trends

Emily H. Wein, Ober | Kaler, Baltimore, Maryland
ehwein@ober.com



OIG's Self Disclosure Protocol

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- Established in 1998 by the Office of Inspector General (OIG)
- Open and cooperative process for health care providers' resolution of potential fraud (anti-kickback)
- Technical payment errors are outside scope of protocol
- Demonstrates diligence and good faith
- Lesser sanctions expected
- No Corporate Integrity Agreement (CIA)
- No settlements less than \$50,000 for anti-kickback violations
- 2009 – no longer accepted disclosures of only potential Stark violations – will accept if connected to anti-kickback issues



CMS Voluntary Self-Referral Disclosure Protocol

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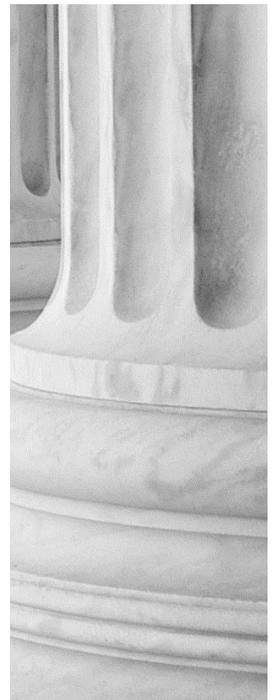
- In 2010, the Patient Protection and Affordable Care Act (“ACA”) passed
- Section 6409 of the ACA required the establishment of a self-referral disclosure protocol ("SRDP") for Stark violations
- Section 6402 of the ACA established a deadline for reporting and returning overpayments within 60 days after the overpayment was identified
- Submission through the SRDP tolls the 60-day repayment obligation



SRDP Disclosures

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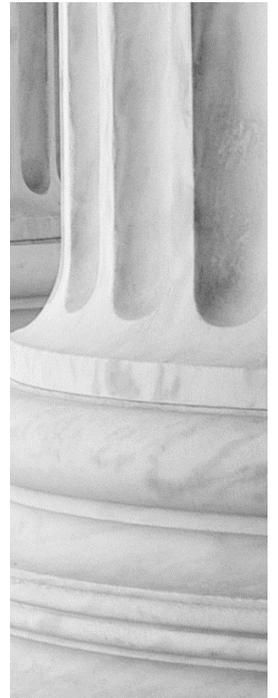
- ACA also gave CMS authority to compromise on repayment amount for Stark violations
- Sufficient supporting information and documentation
- Disclosures should be organized
- SRDP is not for purposes of determining whether there is a violation
- Avoid referring to violations as “technical” – “routine” is better received



SRDP Disclosures

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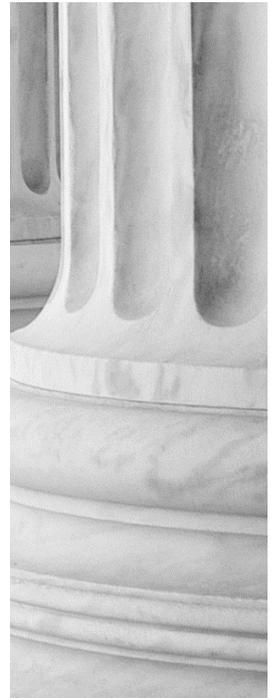
- Complete legal and financial analysis including a certification to a violation
- “Look Back” Period v. “Reopening Period”
–42 C.F.R. § 405.980(b)
- Mitigating factors



SRDP Settlements

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- Estimated over 400 disclosures submitted; 41 published settlements
 - Settling faster, but still slow
 - Staffing and “calendar/timing” constraints
- Underlying facts not available from settlements
- Majority relate to personal service arrangements, leases, recruitment agreements and nonmonetary compensation
- Range from \$60 - \$579,000 (currently)



Impetus for Disclosures

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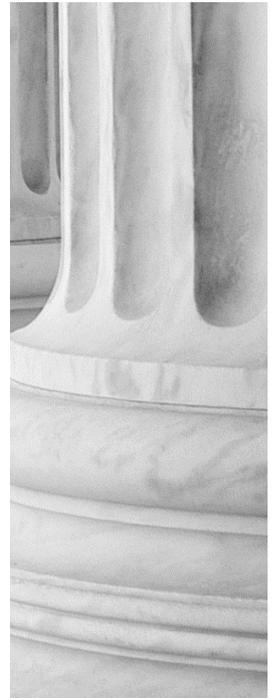
- Change in Compliance Program
 - Creation
 - New Leadership
- Corporate Restructuring
- Sales
 - Real Estate
 - Practice
- Acquisitions



Sales/Mergers/Acquisitions and Disclosures

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- Both purchaser and seller have interests
- Why disclose?
 - Ideal time
 - Illustrates proper due diligence, compliance efforts
 - Availability of personnel with historical knowledge
- Who discloses?
 - Prior to acquisition, Seller discloses
 - After acquisition, Purchaser discloses if assignment of provider agreement accepted



Sales/Mergers/Acquisitions and Disclosures

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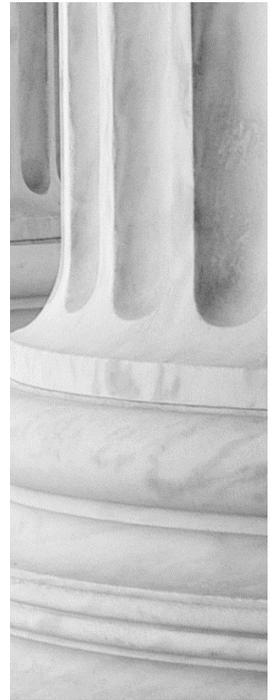
- What is disclosed?
 - Who decides?
 - Who is involved in preparing disclosure?
- When disclosed?
 - Before/after acquisition?
- How is investigation conducted?
 - Is non-disclosing party involved?



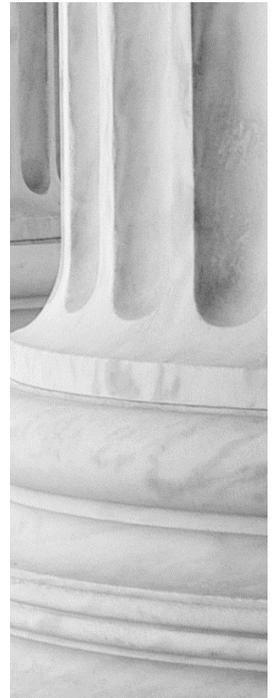
Sales/Mergers/Acquisitions and Disclosures

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- Reserves
 - Relationship between potential overpayments and settlement amounts are unknown
 - Range is known
- Indemnification/Release
 - How long should they continue?
- Corrective Actions
 - Who is involved in this process?



Stark and Medicaid



Stark Statute Language re: Medicare

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- “. . . no payment shall be made to a State ... for expenditures for ... a designated health service ... furnished to an individual on the basis of a referral that would result in the denial of payment for the service under [Medicare] ... , and subsections (f) and (g)(5) of [the Stark reporting provisions] shall apply to a provider of such a designated health service ...”.

- 42 U.S.C. § 1396b(s)



Stark Regulatory Discussion

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- “[42 U.S.C. § 1395nn(s)] does not, for the most part, make the provisions in [Stark] that govern the actions of Medicare physicians and providers of designated health services apply directly to Medicaid physicians and providers. As such, these individuals and entities are not precluded from referring Medicaid patients or from billing for designated health services. A state may pay for these services, but cannot receive FFP for them.”

- 53 Fed. Reg. 1659, 1704 (January 9, 1998)
(emphasis added).

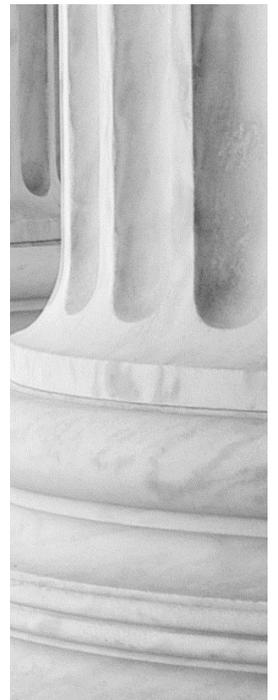


Stark Regulatory Discussion

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- We had intended to address in this Phase II rulemaking section 1903(s) of the Act, which applies section 1877 of the Act to referrals for Medicaid covered services which we However, in the interest of expediting publication of these rules, we are reserving the Medicaid issue for a future rulemaking”

- 69 Fed. Reg. 16054, 16055 (March 26, 2004).



United States ex rel. Baklid-Kunz v. Halifax Hosp. Med. Center

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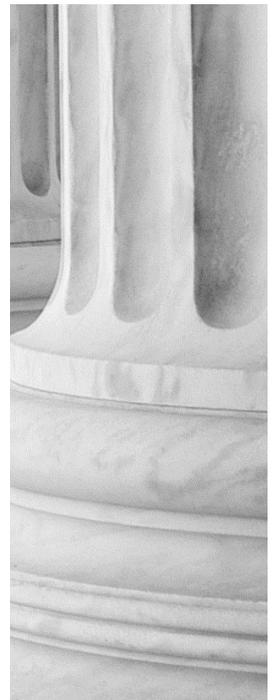
- The government argued that because the state was not entitled to claim FFP from the federal government based upon the allegedly prohibited referrals, Halifax had “caused” a false FFP claim to be submitted by the Medicaid program
- Here the “false claim” was not submitted by the provider to CMS, but by the Medicaid program to the federal government
- The Court agreed in the context of denying a motion to dismiss



Current Status re: Stark and Medicaid

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- Still an absence of Stark liability for Medicaid claims.
- Medicaid payments are not part of the required SRDP elements
- However, providers on notice that, of DOJ's theory Keep watching this area.
 - Could changes come in the form of a new DOJ policy?
 - Will there be changes to the Stark regulations?



CHANGES ON THE HORIZON?



Proposed Expedited Protocol

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- May 2nd, CMS published a request for comment regarding its intent to revise the SRDP's information collection process, 79 Fed. Reg. 25, 133 (May 2, 2014)
- Comments were due on June 2, 2014
- Proposed an optional expedited SRDP
 - More streamlined approach
 - Submission contains certifications and brief narrative summaries



Proposed Expedited Protocol

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- Arrangements eligible for Expedited Protocol include those that:
 - Have no indicia of fraud
 - Involve common arrangements, e.g., leasing and personal services arrangements; and
 - Meet certain requirements
 - Submissions contain all supporting documentation
 - Disclosing party requests expedited review



Proposed Expedited Protocol

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- Arrangements not eligible for optional protocol
 - Present complex questions of law or fact
 - Ownership arrangements



Questions?

Emily H. Wein

Principal, Ober | Kaler

ehwein@ober.com

