

O B E R | K A L E R
Attorneys at Law



Deciphering the Self-Disclosure Puzzle

ABA Health Law Section
Emerging Issues in Healthcare Law

Bill Mathias | 410.347.7667 | wtmathias@ober.com
Lisa Ohrin | 410.786.8852 | Lisa.Ohrin1@cms.hhs.gov

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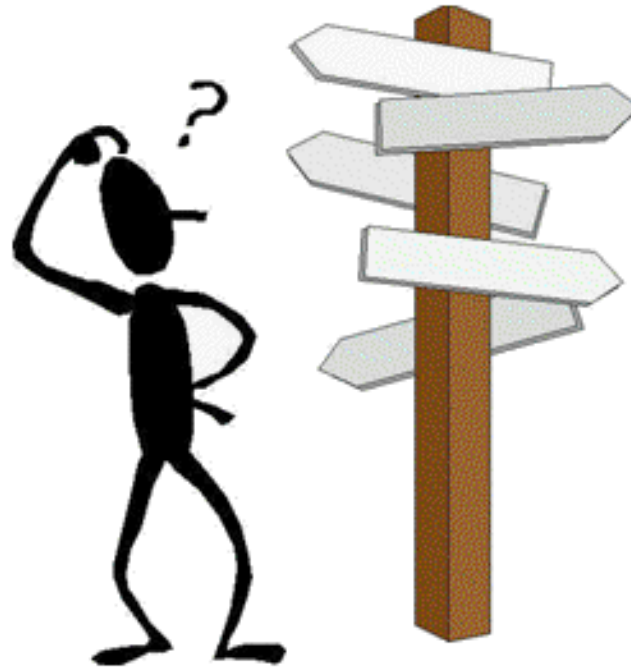
Agenda

- Current Enforcement Climate
- Internal Investigations
- Disclosure Calculus
- OIG Self-Disclosure Protocol
- CMS Self-Referral Disclosure Protocol
- U.S. Attorney's Office Disclosure
- Q&A

Current Enforcement Environment

Some Things Don't Change

- Medicare and Medicaid regulations remain incredibly complex



“There can be no doubt but that the statutes and provisions in question, involving the financing of Medicare and Medicaid, are among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of matters addressed merely a passing phase.”

Chief Judge Ervin

United States Court of Appeals for the
Fourth Circuit in *Rehabilitation Association
of Virginia v. Kozlowski*

42 F. 3d 1444, 1450 (4th Circuit 1994)

The Cost of Medicare

**Each
working
day**

- Medicare pays over 4.4 million claims
- To 1.5 million providers
- Worth \$1.1 billion

Each month

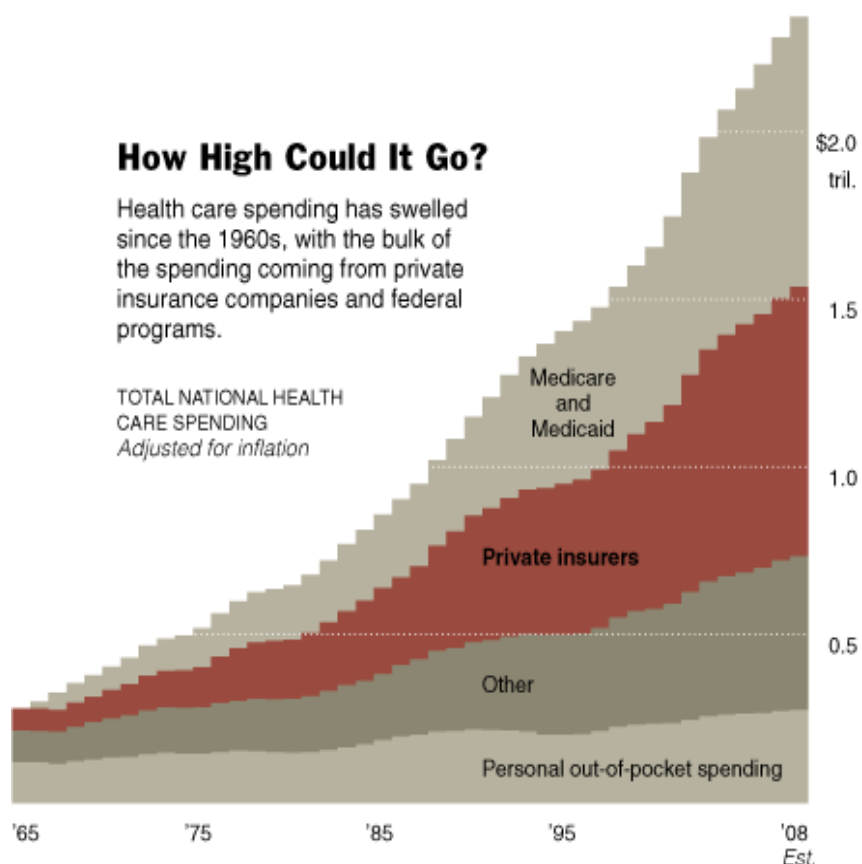
- Medicare receives almost 19,000 provider enrollment applications

Each year

- Medicare pays over \$430 billion for more than 45 million beneficiaries

Annual Health Care Spending in U.S.

- Health care spending in 2020 is projected to reach \$4.64 trillion, accounting for 19.8% of GDP.
- Lost to fraud: 3% - 10% (\$69 billion - \$230 billion).



Out-of-pocket spending includes co-payments and deductibles. Other includes spending for the Department of Defense, Veterans Affairs, children's health and other programs.

Source: Centers for Medicare and Medicaid Services, Office of the Actuary

THE NEW YORK TIMES

Enforcement Remains Aggressive

OIG Report for FY 2012

- \$6.9 Billion in expected recoveries
 - \$923.8 million in audit receivables
 - \$6 billion in investigative receivables
- \$8.5 billion in estimated savings from OIG recommendations
- 3,131 individuals and entities excluded
- 778 criminal actions
- 367 civil actions



Fighting Fraud is a Good Investment

The return-on-investment (ROI) for Health Care Fraud and Abuse Control (HCFAC) program

- Since 1997, \$4.9 returned for every \$1.0 expended.
- 3-year average (2008-2010), \$6.8 returned for every \$1.0 expended



Coordinated Enforcement Efforts

CMS Opened Program Integrity Command Center in Baltimore

- \$3.6 million facility equipped with dozens of computer workstations, giant screens and new computerized detection systems.



Growing Use of Data Analytics

Fraud Prevention System

- Computer program that uses predictive analytics to identify and prevent improper claims.
- In first year, “stopped, prevented or identified” \$115 million in fraudulent payments.
- Flags from the system helped to initiate 536 new investigations.

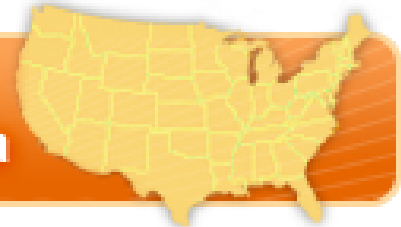
Have You Seen the OIG's Website Lately?

OIG
★
**MOST WANTED
FUGITIVES**



REPORT FRAUD

**HEAT Task Force
in Your Area**



Internal Investigations

When Must You Investigate?

Any time there is:

- An allegation of a violation of law.
- A suggestion of improper conduct.
- A potential for an overpayment by the government.
- A potential for a significant overpayment by a commercial insurer or other third-party payor.
- A potential for whistleblower activity.

How Much Must You Investigate?

- Depends on the facts.
- Initially, need to investigate enough to gauge the credibility of the allegation.
 - Believable on its face
 - Documentary evidence exists
 - Depends on the facts.
- Dollar amount of potential exposure impacts practical decisions regarding scope, depth, and personnel involved in investigation.

Who Should Investigate?

- Depends on the type of issue:
 - Human resources issues (such as sexual harassment or discrimination) – investigated by HR Department and/or employment counsel.
 - Other general issues (non-criminal in nature, unlikely to result in substantial civil liability) – initially investigated in-house.
 - Consider whether attorney-client privilege may be important? If so, involve counsel (in house or outside).

Who Should Investigate?

- Criminal issues or issues likely to result in significant civil liability (whistleblower situations, high dollar overpayments, systemic problems) – shouldn't be investigated without legal counsel.
- Attorney-client privilege important – may want outside counsel involved to strengthen argument supporting attorney-client privilege.

Conduct Your Investigation



Results of Your Investigation

- No problem ⇒ Done!!!



- Problem ⇒ Fix it???



Fix The Problem

- Take corrective action
- Assess existing compliance process and policies to identify shortfalls
- Discipline responsible employees, as appropriate
- Add policies, procedures, or reporting layers as necessary to prevent reoccurrence

Disclosure Puzzle

Now What?

Need to discuss with client:

- Whether there is a legal obligation to disclose?
- Whether disclosure should be made?
 - Balance legal obligations & business risks

Moving Line on Legal Obligation to Disclose

2009 FERA Amendments

- FCA imposes liability on both concealing overpayments and failure to repay identified overpayments
 - Codification of “reverse false claims” provision

Moving Line on Legal Obligation to Disclose

Affordable Care Act – 60-day Rule

- Section 6402 of ACA establishes a deadline for reporting and returning overpayments
- “Identified” overpayments must be reported and returned within 60 days
- Failure to repay within 60 days constitutes an “obligation” under reverse false claims provisions of FCA



Disclosure Calculus

- Decision to disclose is a business decision
 - weighing potential risks and benefits.
 - Where available, disclosure offers protections too significant to pass up
 - Useful for substantial violations of law
 - More difficult question for more minor or isolated violations – time + expense
 - Continuing focus on compliance programs, good faith cooperation, and prompt disclosure

What Gets Disclosed Where?

- To OIG – only “potential fraud against the Federal health care programs, rather than merely an overpayment.”
 - “Potential fraud” does not include Stark only violations – must be at least a “colorable” AKS violation
- To CMS – Stark only violation
- To Contractor – “merely an overpayment”
- To U.S. Attorney’s Officer – depends
- To State – depends on state laws

OIG Self-Disclosure Protocol (SDP)



History of SDP

- SDP establishes a process for voluntarily identifying, disclosing, and resolving violations of OIG's civil money penalty (CMP) authority
- Original SDP adopted October 1998
 - [63 Reg. Reg. 58,399]
- Supplemented by Open Letters in 2006, 2008, and 2009
- Updated SDP issued April 17, 2013

Updated SDP Changes

- Express acknowledgment of NO CIA
- Disclosing party must acknowledge that conduct is potential violation of law
- Requires internal investigation to be completed within 90-days of disclosure
- New guidelines for submissions involving false billing, excluded persons, and AKS and Stark violations.
- Lower multiplier (usually 1.5 times single damages)

Updated SDP Changes

- Updated minimum settlement amount for non-AKS violations
- Clarification that disclosing party must waive statute of limitations, laches, and similar defenses in subsequent OIG administrative action.
- Clarification that OIG will coordinate with DOJ and CMS in resolving criminal and civil liability.
- Greater information about eligibility, general requirements for disclosures, and specific requirements for disclosures under false billings, excluded persons, and liability under AKS and Stark

SDP Statistics

- First 14 years of SDP
 - Over 800 disclosures
 - Over \$280 million returned to Federal health care programs
- Average length of time in SDP
 - 2008 = over 18 months
 - 2011 = roughly 10 months
- Most frequent subject matter of disclosures in recent years has been excluded providers

SDP Benefits

- Lower multiplier
- No CIA
- More timely resolution
- Avoid Government-initiated investigation
- May address 60-day rule liability

SDP Requirements

What is Not Eligible

- Errors or overpayments where no potential violation
- Requests for opinion on whether there is a potential violation
- Stark-only conduct

Damages Calculation

Damages Calculation

- All claims or statistically valid random sample
- Use point estimate
- Simplified audit protocol

SDP Tips

- Carefully review the protocol
- Submit all of the information required by the protocol
- Do not disclose too early – limited time to complete audit
- Need to identify the fraud law at issue
- Prepare client that SDP settlement will involve a multiplier
- Full cooperation is essential

CMS Self-Referral Disclosure Protocol (SRDP)



Stark Self-Referral Disclosure Protocol

- CMS statutory authority to compromise amounts due and owing under Stark law
- Disclosures should be organized with complete legal and financial analysis and sufficient supporting information and documentation
- New practical tips on Stark self-disclosure protocol from AHLA Public Interest
www.healthlawyers.org/hlresources/PI/Documents/StarkSDP_4Pager_FINAL.pdf

SRDP

- Separate from the advisory opinion process
- Disclosure must be made in good faith
- New FAQs on CMS website at www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQsPhysSelfRef.pdf

SRDP – Required Elements of Submission

Description of Actual or Potential Violation(s)

- Identifying Information of party disclosing
- Description of the nature of the matter being disclosed
- Duration of violation
- Disclosing party's legal analysis of how the matter is a violation
 - Specify Stark exception AND which elements are/are not met.

SRDP – Required Elements of Submission

- Circumstances under which the matter was discovered and measures taken to address the issue and prevent future abuses.
- Statement identifying a history of similar conduct or enforcement action.
- Description of any compliance program
- If applicable, a description of appropriate notices provided to other government agencies.
- Whether the matter is under current inquiry by the government

SRDP – Required Elements of Submission

Legal/Compliance Analysis

- SRDP requires that parties identify the requirements of an exception with which their arrangement complies AND requirements with which it does not comply.
 - This analysis could lead to a conclusion of technical compliance with ALL elements of an exception.
- Must provide CMS with your legal analysis
 - CMS may not agree with your assessment.
- Consider all available exceptions and applicable rules before determining that you have a noncompliant arrangement.

SRDP – Required Elements of Submission

Financial Elements of Submission

- “Look Back” Period
 - Total time arrangement was non-compliant
- Time period to calculate amount physician received is limited to period in reopening rules.
 - 42 CFR 405.980 (reopening rules)
 - » Can use these rules until proposed repayment rules finalized
- Time period to calculate amount of claims is limited to reopening rules.

SRDP – Required Elements of Submission

Financial Elements of Submission (cont.)

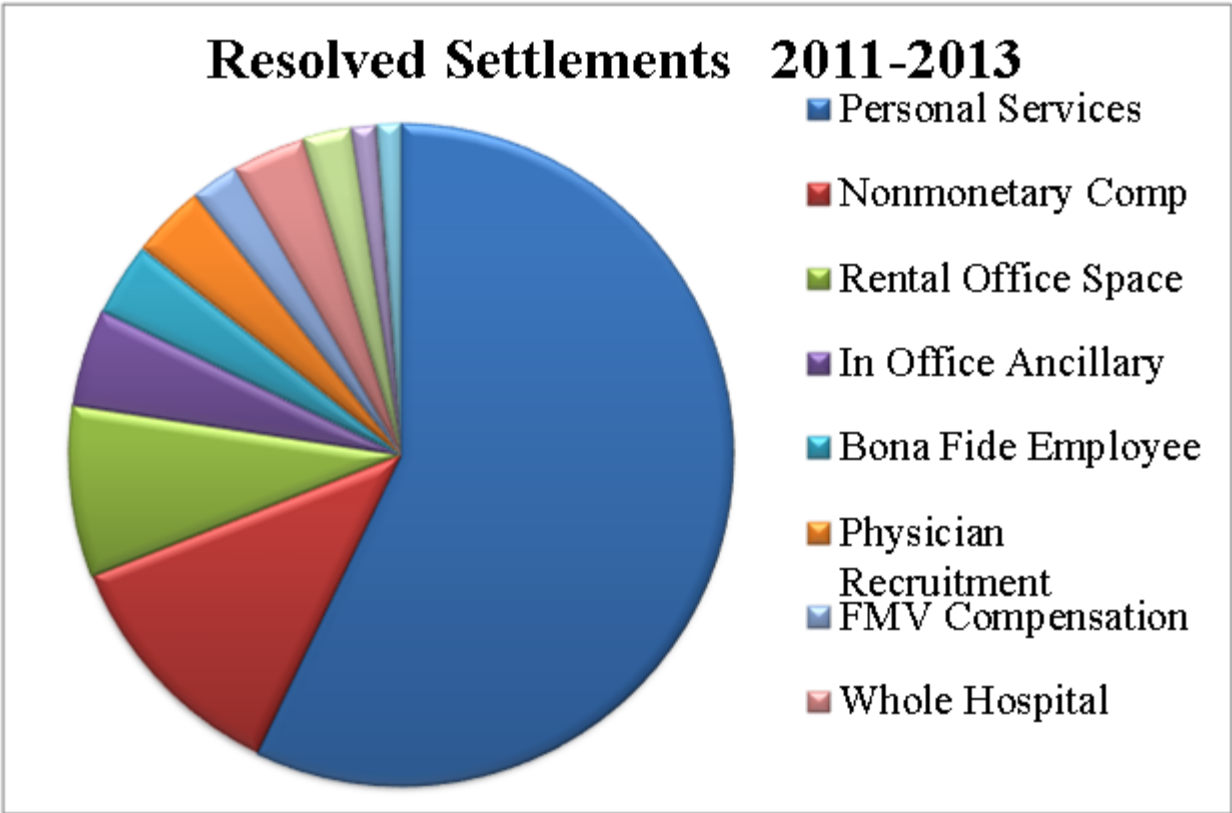
- Total amount actually or potentially due and owing (limited by reopening rules).
- Description of the methodology used including estimates.
- Summary of auditing activity and documents used.
- Requires payback to beneficiaries
 - How to do this?

SRDP – Compromising Overpayments

Factors considered in compromising overpayments

- Nature and extent of the improper or illegal practice
- Timeliness of the self-disclosure
- Cooperation in providing additional information
- Litigation risk to CMS
- Ability to pay

SRDP Statistics



SRDP Tips and Updates on the Process

- Carefully review the protocol
- Submit all of the information required by the protocol
- Must acknowledge potential violation of the law
- Prepare client that Offer of Settlement is not negotiable
- Explain to client what is required to make successful ability to pay argument
- Full cooperation is essential
- Future changes

U.S. Attorney's Office (USAO) Disclosure



Background – USAO Disclosure

- Same matters that can be disclosed to OIG can be disclosed to USAO
- Only DOJ/USAO can offer release from FCA liability
- USAO frequently handle self-disclosures

Advantages – USAO Disclosure

- FCA release
- Potentially more timely resolution
- Potential flexibility in structuring settlement

Disadvantages – USAO Disclosure

- Potential lack of flexibility in structuring settlement
- 2-times multiplier
 - But against what base?
- Investigation creep
- Lack of defined protocol
- Lack of predictability

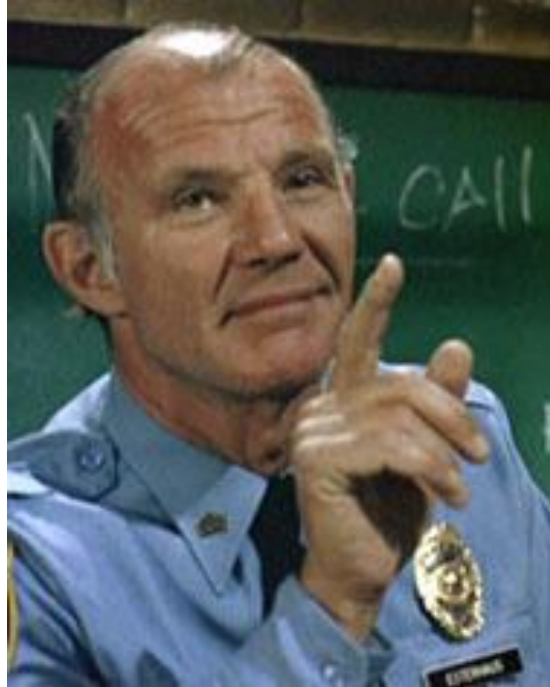
USAO Tips

- Learn counsel's relationship/reputation with USAO
- Try to gauge client's relationship/reputation with USAO
- Gather intelligence on USAO handling of past disclosures
- Complete thorough investigation before approaching USAO
- Truthful cooperation is essential

Practical Considerations for Self-Disclosure

- Disclosure calculus = balance legal obligations & business risks
- Be realistic with your client about timing.
- How big a deal is no CIA?
- Understand collateral risks and limitations of disclosure

Final Words of Advice



“Be careful out there”

Questions?



Lisa Ohrin

CMS

410.786.8852

Lisa.Ohrin1@cms.hhs.gov

Bill Mathias

Ober|Kaler

410.347.7667

wtmathias@ober.com