

TACKLING THE SELF-DISCLOSURE PUZZLE

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Kenneth Kraft, Senior Counsel, HHS OIG
William Mathias, Shareholder, Baker Ober Health Law
Lisa Noller, Partner, Foley & Lardner

Agenda

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

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CURRENT ENFORCEMENT ENVIRONMENT





Medicare is Complicated

“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)

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Some Things Don't Change

- Medicare and Medicaid regulations remain incredibly complex



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Size of Medicare

Physician (and other practitioners)	• 1.25 million
Hospitals	• 6,123
Labs	• 258,473
DMEPOS Suppliers	• 85,297

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Cost of Medicare

Each working day

- Medicare pays out nearly **\$2.6 billion**

Each year

- Medicare pays over **\$672 billion** for nearly **60 million beneficiaries**

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Annual Health Care Spending in U.S.


- 2016
 - \$3.337 trillion
 - 17.9% of GDP
 - \$10,348 per capita
- Projection Growth (2017-2026) = 5.5% per year
- 2026
 - \$5.7 trillion
 - 19.7% of GDP

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Estimate of Health Care Fraud

- Estimate Percent of Health Care Spending Lost to Fraud
 - 3% to 10%
- 2016: \$100 billion to \$334 billion
- 2026: \$171 billion to \$570 billion


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Enforcement Remains Aggressive

OIG Report for FY 2017

- \$2.4 billion in health care fraud judgments and settlements
- DOJ opened 967 new criminal health care fraud investigations
- DOJ filed criminal charges in 439 cases involving 720 defendants
- DOJ opened 948 new civil health care fraud investigations
- HHS-OIG excluded 3,244 individuals




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Fighting Fraud is Good Investment

- Return-on-investment (ROI) for Health Care Fraud and Abuse Control (HCFA) program
 - 3-year average (2015-2017) = \$4.20 returned for every \$1.00 expended






Coordinated Enforcement Efforts

- CMS Program Integrity Command Center
 - \$3.6 million facility in Baltimore equipped with dozens of computer workstations, giant screens and new computerized detection systems



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Growing Use of Data Analytics

Fraud Prevention System (FPS)

- Computer program that uses predictive analytics to identify and prevent improper claims
- Launched in 2011
- Next generation system (FPS 2.0) implemented in 2017

FY 2016 Statistics

- Identified or prevented \$527.1 million in inappropriate payments
- Generated 688 leads for ZPICs
- Resulted in 476 new investigations


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Have You Seen OIG's Website Lately?




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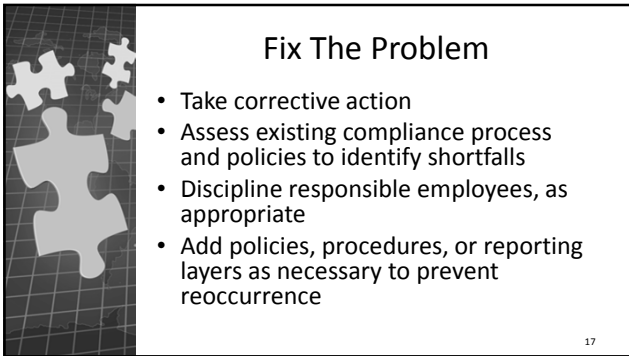
DOJ Memorandum on Individual Accountability for Corporate Wrongdoing

- September 9, 2015
- Largely formalization of prior public statements
- Why
 - Deters future illegal activity
 - Incentivizes changes in corporate behavior
 - Ensures that proper parties are held responsible
 - Promotes public confidence in judicial system



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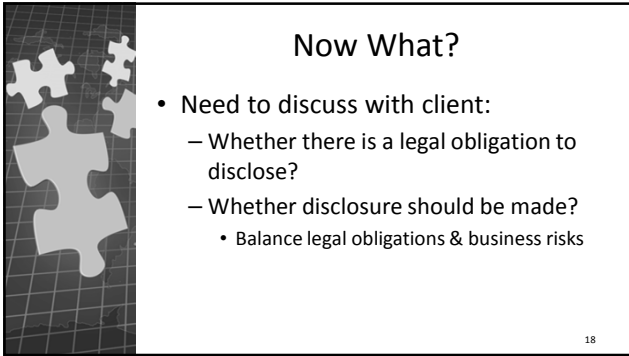




Fix The Problem

- 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

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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

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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

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Moving Line on Legal Obligation to Disclose (cont.)

- 60-day Rule
 - ACA created 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



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Voluntary Disclosures

- Potential Risks and Benefits:
 - Potential to avoid criminal liability
 - Potential to minimize civil exposure
 - Potential to avoid Corporate Integrity Agreements
 - Potential to neutralize qui tam suits

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Voluntary Disclosures

- Potential Risks and Benefits:
 - May invite more scrutiny
 - May encourage government to require additional investigation
 - May result in penalties for conduct that would have remained undiscovered
 - May not include an FCA release

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Disclosure Calculus

- Decision to disclose is a legal and business decision – weighing potential risks and benefits
 - Where available, disclosure offers protections too significant to pass up
 - Continuing focus on compliance programs, good faith cooperation, and prompt disclosure


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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 Office – depends
- To State – depends on state laws

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OIG SELF-DISCLOSURE PROTOCOL (SDP)






OIG/SDP: Background




- Created 1998, Updated 2013
- Receive about 100 submissions a year
- What for? Potential violations of federal criminal, civil, or administrative law for which CMPs are authorized
- Who for? Physicians, Hospitals, Pharmaceutical/Device manufacturers, SNFs...all providers/suppliers/individuals subject to CMPs are eligible for SDP
 - Civil Monetary Penalties Law (CMP)
 - § 1128A of the Social Security Act (42 U.S.C. § 1320a-7a)

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OIG/SDP: Resolutions



- Not admitting liability
- Benchmark 1.5 multiplier (x single damages)
 - False Claims Calculation
 - All claims or statistical sample of 100 claims minimum
 - Use point estimate (not lower bound)
 - Excluded persons – salary and benefits-based
 - AKS – remuneration-based
- Presumption of no CIA
- Six-year statute of limitations
- Tolling of the 60-day period after submission
- No FCA release, but can help limit exposure, including 60-day issues
- More predictable process, but DOJ may become involved


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OIG/SDP: CMP Case Types


- Billing while employing excluded individuals
- Kickbacks and Physician self-referral (“Stark”) violations
- False or Fraudulent Claims
- Failure to Return Overpayments
- About 40 other OIG CMPs
 - 42 C.F.R. § 1003.102 catalogues available CMPs
 - 42 C.F.R. § 1003.103 catalogues the amount of penalty and assessment available for each CMP

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OIG/SDP: Ineligible Submissions

- What is not eligible for OIG’s SDP?
 - Errors or overpayments with no potential violation of CMPL
 - Requests for opinion on whether there is a potential violation
 - Settlement less than \$10,000 (\$50,000 for AKS)
 - Stark-only conduct




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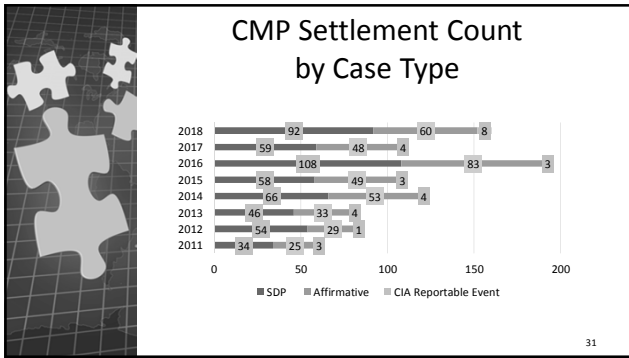


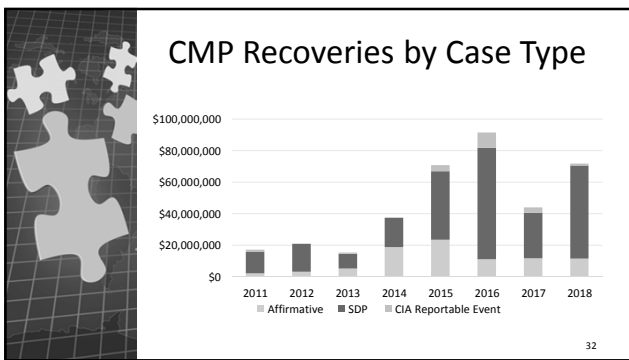
OIG/SDP: Common Mistakes Providers Make

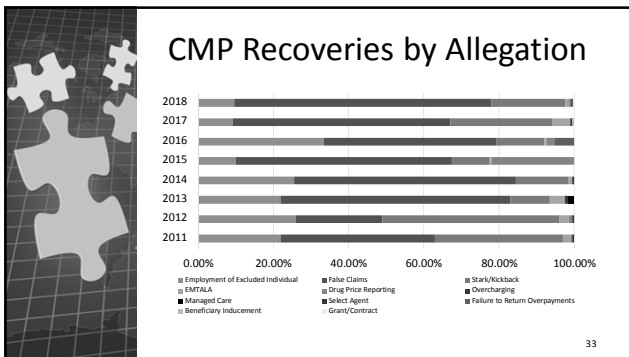
- Denying liability: No admission required, but ... No potential liability = No release
- Does not identify potential laws violated
- Discloses the conduct too early (before determining potential liability)
- No plan to quantify damages
- Refuses to pay a multiplier
- Lack of cooperation
- Argues damages should be calculated in a manner contrary to the revised SDP




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SDP Tips

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


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CMS SELF-REFERRAL DISCLOSURE PROTOCOL (SRDP)



CENTERS for MEDICARE & MEDICAID SERVICES



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

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SRDP

- Separate from the advisory opinion process
- Disclosure must be made in good faith
- FAQs on CMS website at <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf>

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SRDP – Required Elements of Submission

- Description of Actual or Potential Violation(s)
 - Identifying Information of party disclosing
 - Description of nature of matter being disclosed
 - Duration of violation
 - Disclosing party's legal analysis of how matter is a violation
 - Specify Stark exception AND which elements are/are not met


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SRDP – Required Elements of Submission (cont.)

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


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SRDP – Required Elements of Submission (cont.)

- 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
 - Analysis could lead to conclusion of technical compliance with ALL elements of 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


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SRDP – Required Elements of Submission (cont.)

- 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 C.F.R. § 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


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SRDP – Required Elements of Submission (cont.)

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


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SRDP – Compromising Overpayments

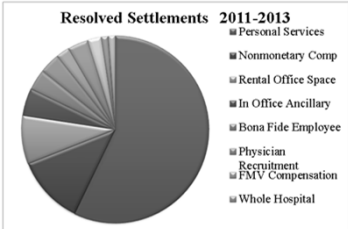
- Factors considered in compromising overpayments
- Nature and extent of improper or illegal practice
- Timeliness of self-disclosure
- Cooperation in providing additional information
- Litigation risk to CMS
- Ability to pay

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SRDP Statistics

Resolved Settlements 2011-2013



- Personal Services
- Nonmonetary Comp
- Rental Office Space
- In Office Ancillary
- Bona Fide Employee
- Physician Recruitment
- FMV Compensation
- Whole Hospital


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SRDP Tips


- Carefully review protocol
- Submit all information required by protocol
- Use CMS forms
- Must acknowledge potential violation of 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

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**U.S. ATTORNEY'S OFFICE (USAO)
DISCLOSURE**






Background – USAO Disclosure

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


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Advantages – USAO Disclosure

- FCA release
- Potentially more timely resolution
- Potential flexibility in structuring settlement
- Different knowledge base
- Amount thresholds may keep matter local


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Disadvantages – USAO Disclosure

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

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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

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FINAL THOUGHTS



**Practical Considerations
for Self-Disclosure**

- Disclosure calculus = balance legal obligations & business risks
- Be realistic with your client about timing
- Integrity Obligations
- Understand collateral risks and limitations of disclosure


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TIME FOR...

QUESTIONS





Thank You

Kenneth Kraft, Esq.
Office of Counsel to the Inspector General
U.S. Department of Health and Human Services

Bill Mathias, Esq.
Baker Ober Health Law
410-862-1067, bmathias@bakerdonelson.com

Lisa Noller, Esq.
Foley & Lardner
312-832-4363, LNoller@foley.com

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