

TACKLING THE SELF-DISCLOSURE PUZZLE

4th Annual Healthcare Enforcement Compliance Conference
November 5, 2018
Washington, DC

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Agenda

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



CURRENT ENFORCEMENT ENVIRONMENT



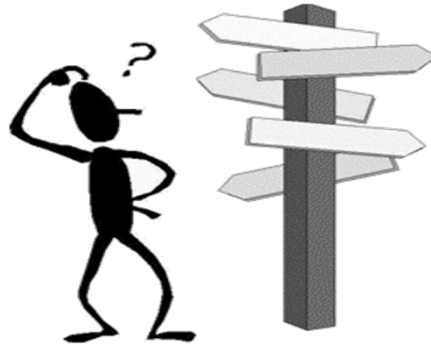
Medicare is Complicated

“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)

Some Things Don't Change

- Medicare and Medicaid regulations remain incredibly complex



5

Size of Medicare

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

6



Cost of Medicare

Each working day

- Medicare pays out nearly \$2.6 billion

Each year

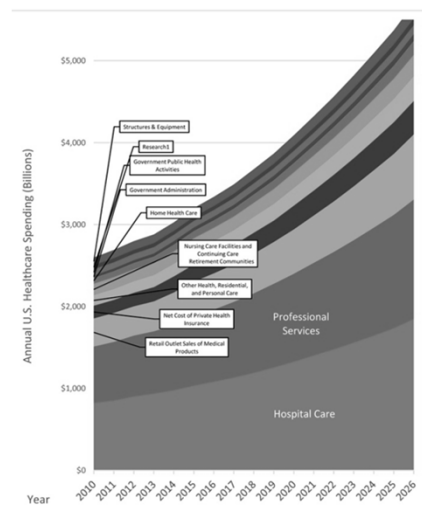
- Medicare pays over \$672 billion for nearly 60 million beneficiaries

7

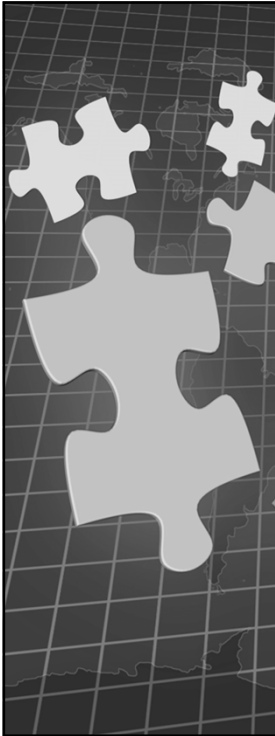


Annual Health Care Spending in U.S.

- 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



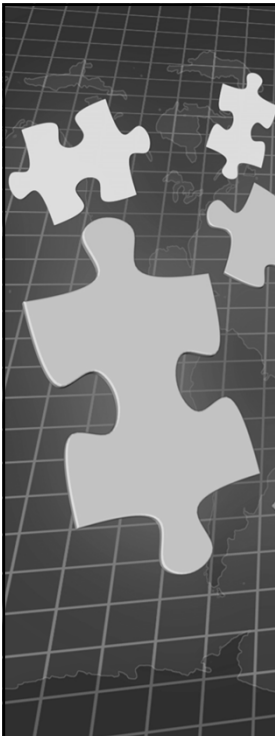
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Estimate of Health Care Fraud

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

9



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



10



Fighting Fraud is Good Investment

- Return-on-investment (ROI) for Health Care Fraud and Abuse Control (HCFAC) 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



12

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

13

Have You Seen OIG's Website Lately?

OIG
★
MOST WANTED FUGITIVES



14



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



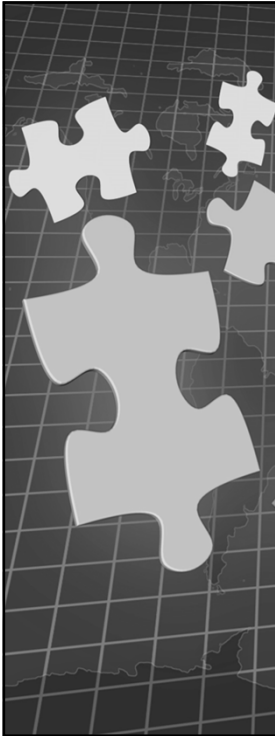
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DISCLOSURE PUZZLE



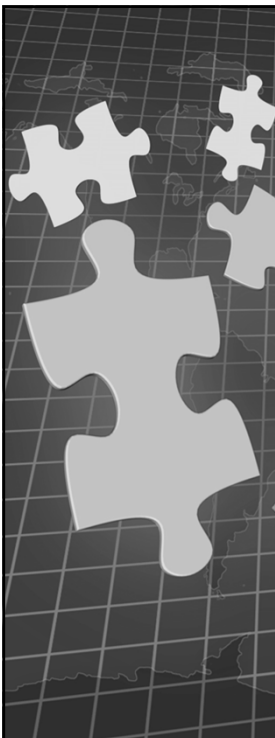
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Fix The Problem

- 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

17



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

18



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

19



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



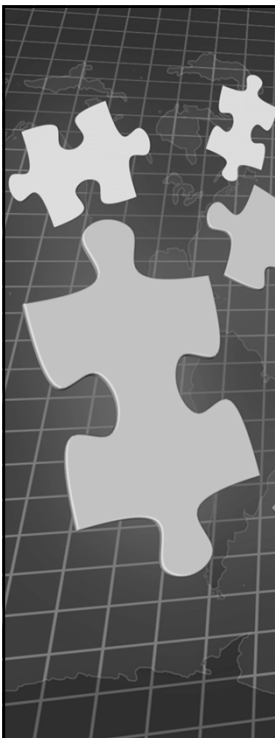
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Voluntary Disclosures

- 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

21



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

22



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

23



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


24



OIG SELF-DISCLOSURE PROTOCOL (SDP)



OIG/SDP: Background

- 
- The seal is circular with an eagle in the center. The text "OFFICE OF INSPECTOR GENERAL" is written around the eagle. The letters "OIG" are prominently displayed in the center of the seal.
- 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)



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



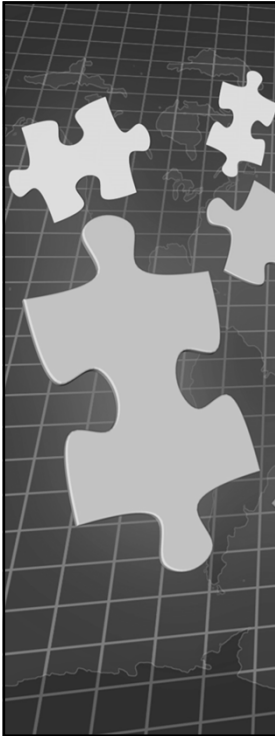
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OIG/SDP: CMP Case Types

- 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

28

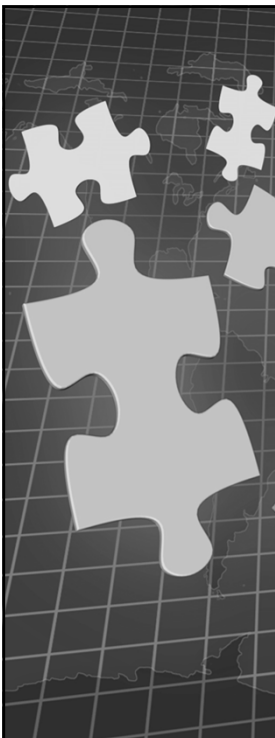


OIG/SDP: Ineligible Submissions

- 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



29



OIG/SDP: Common Mistakes Providers Make

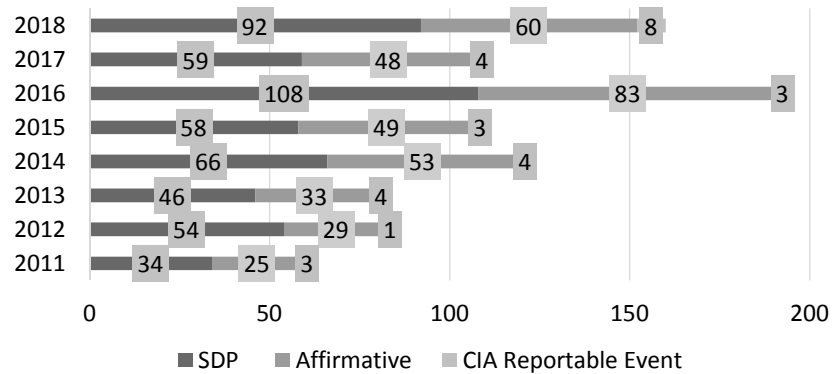
- Denying liability: No admission required, but ... No potential liability = No release
- Does not identify potential laws violated
- Discloses the conduct too early (before determining potential liability)
- No plan to quantify damages
- Refuses to pay a multiplier
- Lack of cooperation
- Argues damages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



30



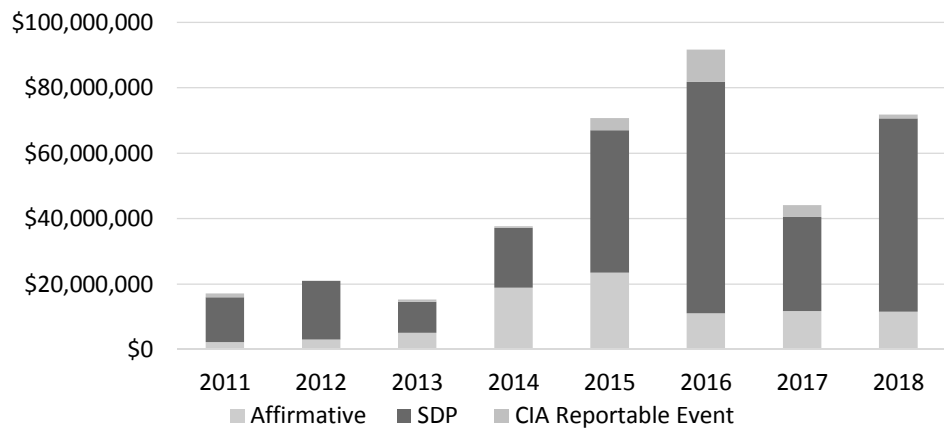
CMP Settlement Count by Case Type



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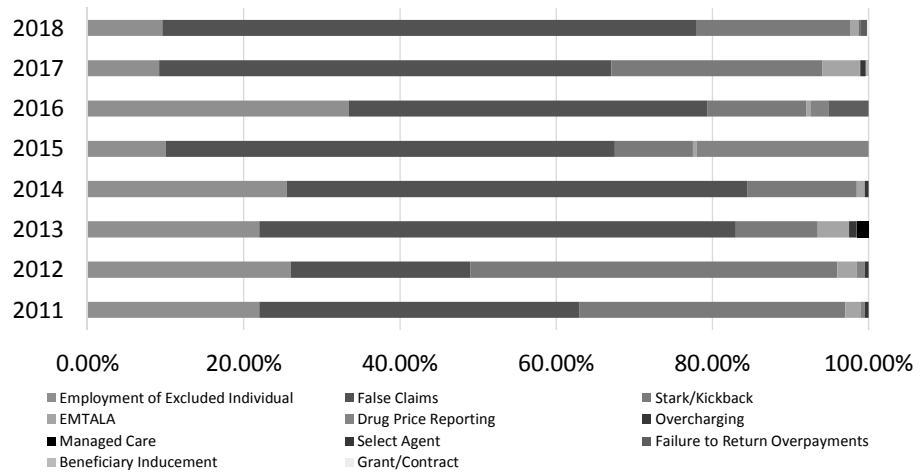
CMP Recoveries by Case Type



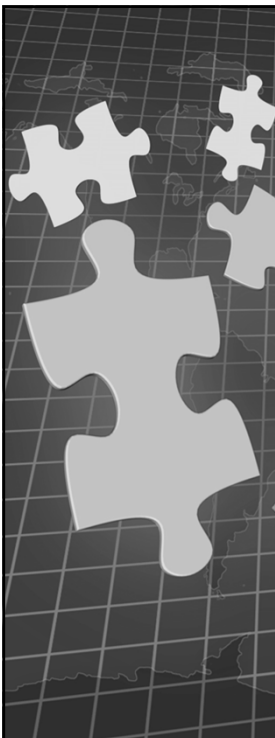
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CMP Recoveries by Allegation



33



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

34



CMS SELF-REFERRAL DISCLOSURE PROTOCOL (SRDP)



Stark Self-Referral Disclosure Protocol

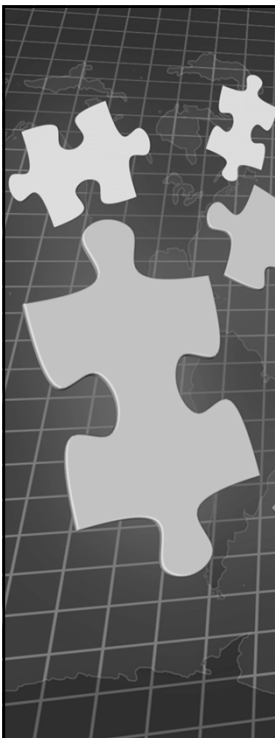
- CMS statutory authority to compromise amounts due and owing under Stark law
- Disclosures should be organized with complete legal and financial analysis and sufficient supporting information and documentation



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>

37



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

38



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

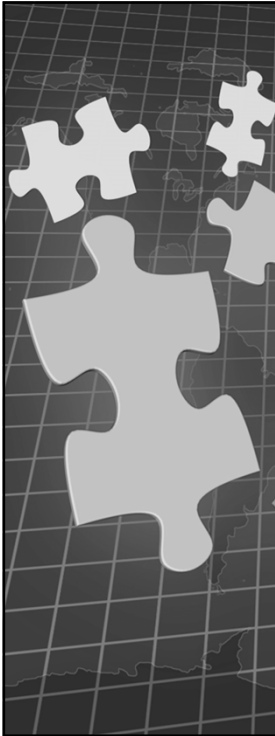
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SRDP – Required Elements of Submission (cont.)

- 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

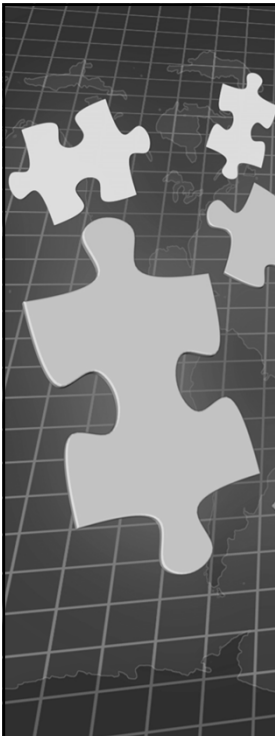
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SRDP – Required Elements of Submission (cont.)

- 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

41



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?

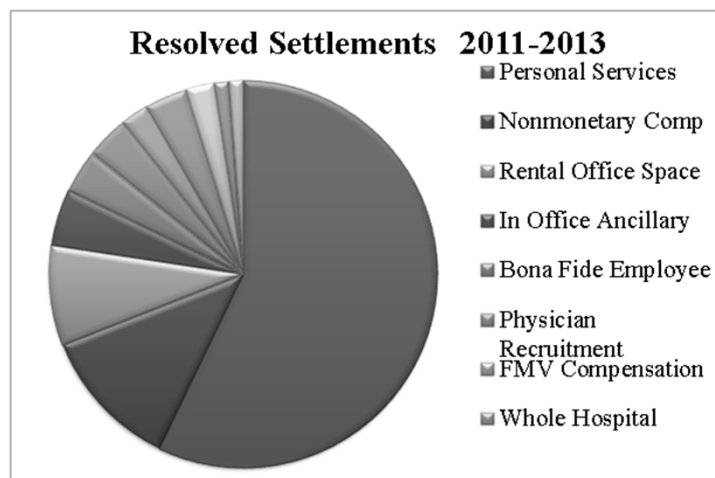
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SRDP – Compromising Overpayments

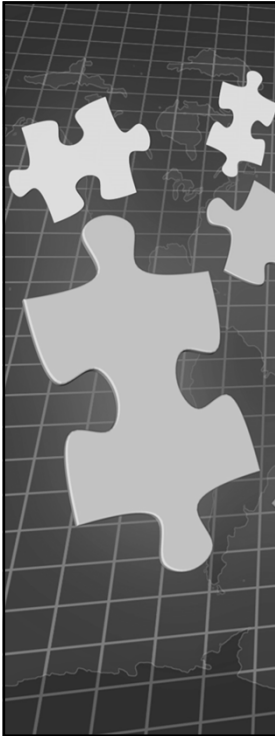
- Factors considered in compromising overpayments
- Nature and extent of improper or illegal practice
- Timeliness of self-disclosure
- Cooperation in providing additional information
- Litigation risk to CMS
- Ability to pay

43

SRDP Statistics



44



SRDP Tips

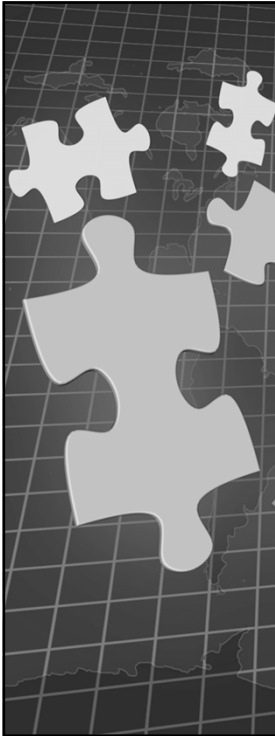
- Carefully review protocol
- Submit all information required by protocol
- Use CMS forms
- Must acknowledge potential violation of law
- Prepare client that Offer of Settlement is not negotiable
- Explain to client what is required to make successful ability to pay argument
- Full cooperation is essential

45



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

47



Advantages – USAO Disclosure

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

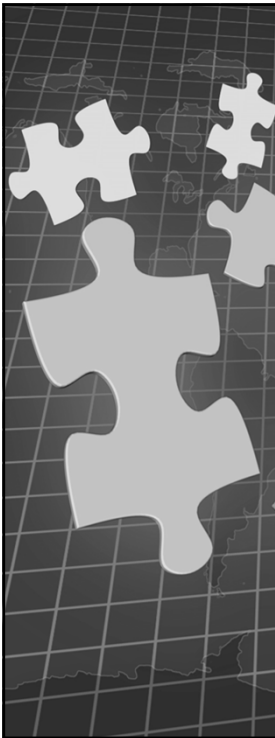
48



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

49



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

50



FINAL THOUGHTS



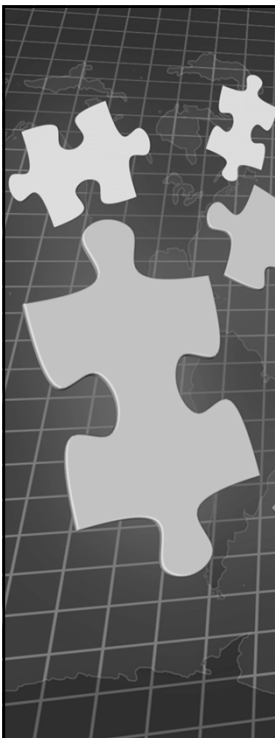
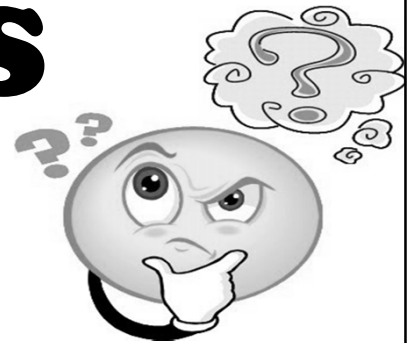
Practical Considerations for Self-Disclosure

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



TIME FOR...

QUESTIONS



Thank You

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