It's Here:

The Final 60-Day Overpayment Rule

(What it means for you and your clients)

November 12, 2016

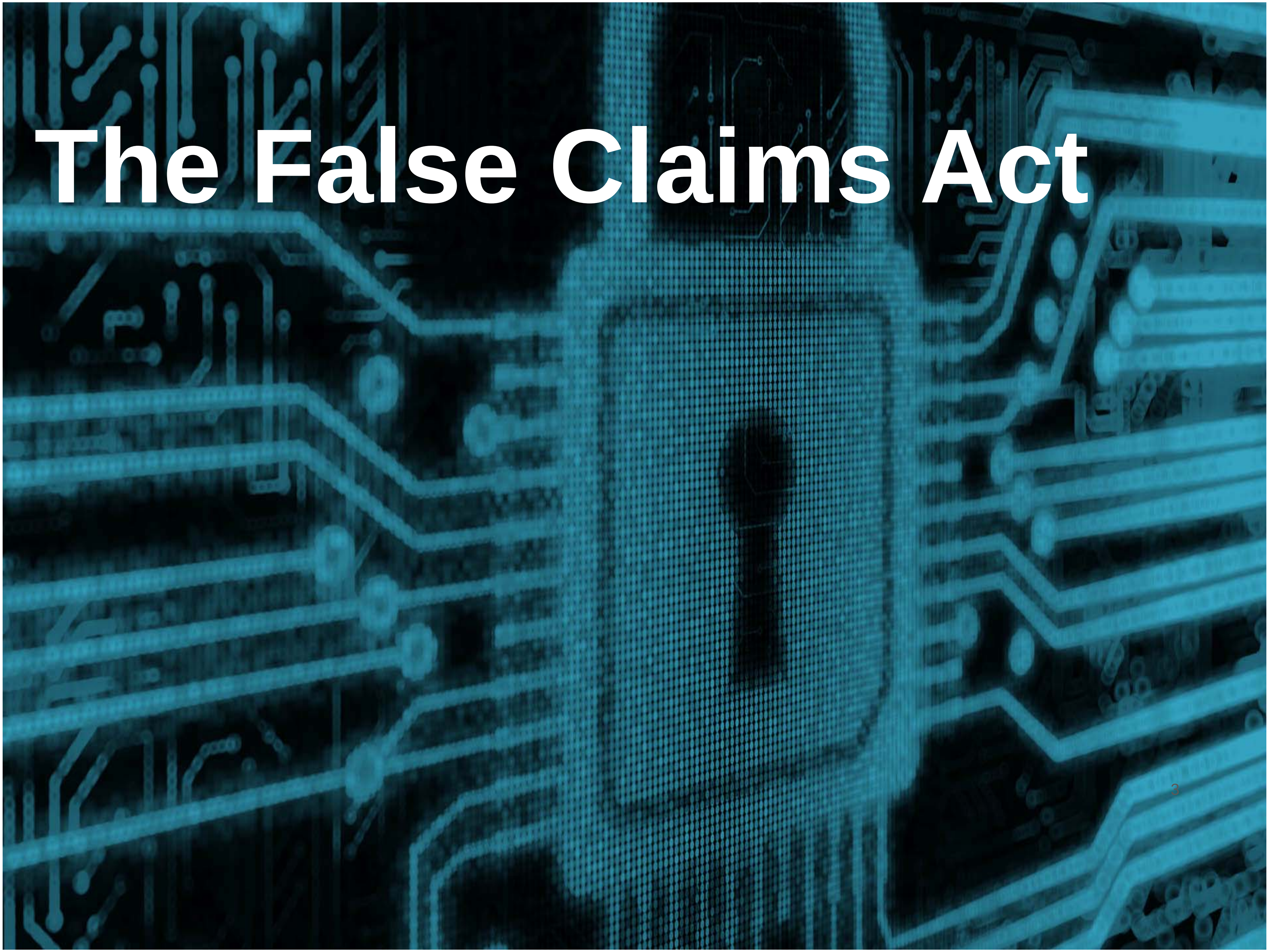
Hillary M. Stemple, Esq.
Associate
Arent Fox LLP
Washington, DC 20006
hillary.stemple@arentfox.com

Smart in your world®
Arent Fox

Overview

- **The False Claims Act**
- **The 60 Day Repayment Rule**
  - Creation of the Rule-the Affordable Care Act
  - The 60 Day Rule
  - Options for Reporting/Returning Overpayments
- **60 Day Rule Enforcement**
- **How to Structure Your Compliance Program**
- **Self-Disclosure**
  - Pros & Cons of Self-Disclosure
  - The Self-Disclosure Process and Options

The False Claims Act



Smart in your world®
Arent Fox

The False Claims Act – 31 U.S.C. § 3729

- **Prohibitions include:**
  - Knowingly submitting or causing to be submitted false or fraudulent claims
  - Knowingly making, using, or causing to be made or used, false records or statements material to a false or fraudulent claim
- **“Reverse” False Claims Prohibition**
  - Knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government

Smart in your world®
Arent Fox

The False Claims Act - 31 U.S.C. § 3729

- **Penalties**
  - Treble damages
  - Penalties recently doubled for violations occurring after Nov. 2, 2015
  - $10,800 - $22,000 per false claim

- **Many cases brought by qui tam relators (whistleblowers) who receive a percentage of the recovery**

- **Number of cases and recovery amounts increasing**

The 60 Day Repayment Rule

Creation of the 60 Day Repayment Requirement

- The Affordable Care Act requires providers to report and return any overpayment within 60 days after identification (or the date any corresponding cost report is due), whichever is later ("the 60 Day Rule") -- Section 1128J(d) of the Social Security Act
- "Overpayment" is defined as any funds that a person receives or retains from Medicare or Medicaid to which the person, after any applicable reconciliation, is not entitled
- Overpayments include payments received for claims submitted in violation of the Stark Law or the Anti-Kickback Statute
- Any overpayment retained after the repayment deadline is considered an obligation for purposes of the False Claims Act

The 60 Day Rule

- **Final regulations for the 60 Day Rule (Medicare Parts A & B) published on February 12, 2016 (81 Fed. Reg. 7654).** The regulations:
  - Clarify when an overpayment is identified
  - Establish a six-year lookback period
  - Describe options for reporting and returning identified overpayments

- **There is no minimum monetary threshold; all identified overpayments must be returned**

The 60 Day Rule

- "[A] person has **identified** an overpayment when the person has or should have, through the exercise of reasonable diligence, determined that **the person has received an overpayment *and quantified* the amount of the overpayment**." (emphasis added)
- "Reasonable diligence" includes both (1) proactive compliance activities and (2) reactive investigations conducted in a timely manner in response to credible information of a potential overpayment
  - "Minimal" compliance activities to monitor the appropriateness and accuracy of claims would be a failure to exercise reasonable diligence
  - Identification of a single overpaid claim requires further investigation
- "Part of identification is quantifying the amount, which requires a reasonably diligent investigation."

The 60 Day Rule

- The 60 day time period for reporting/returning begins when either:
  – The reasonable diligence is completed; or
  – On the day the provider received credible information of a potential overpayment (if the provider fails to conduct reasonable diligence)

- For an investigation to be conducted in a “timely” manner, providers typically must complete the investigation within 6 months from receipt of credible information indicating there may be an overpayment
  – 6-month timeframe may potentially be extended under “extraordinary circumstances”
  – *8 months generally the maximum total time to return overpayments*

- The government recommends that providers maintain records documenting “reasonable diligence”

Smart in your world®
Arent Fox

The 60 Day Rule

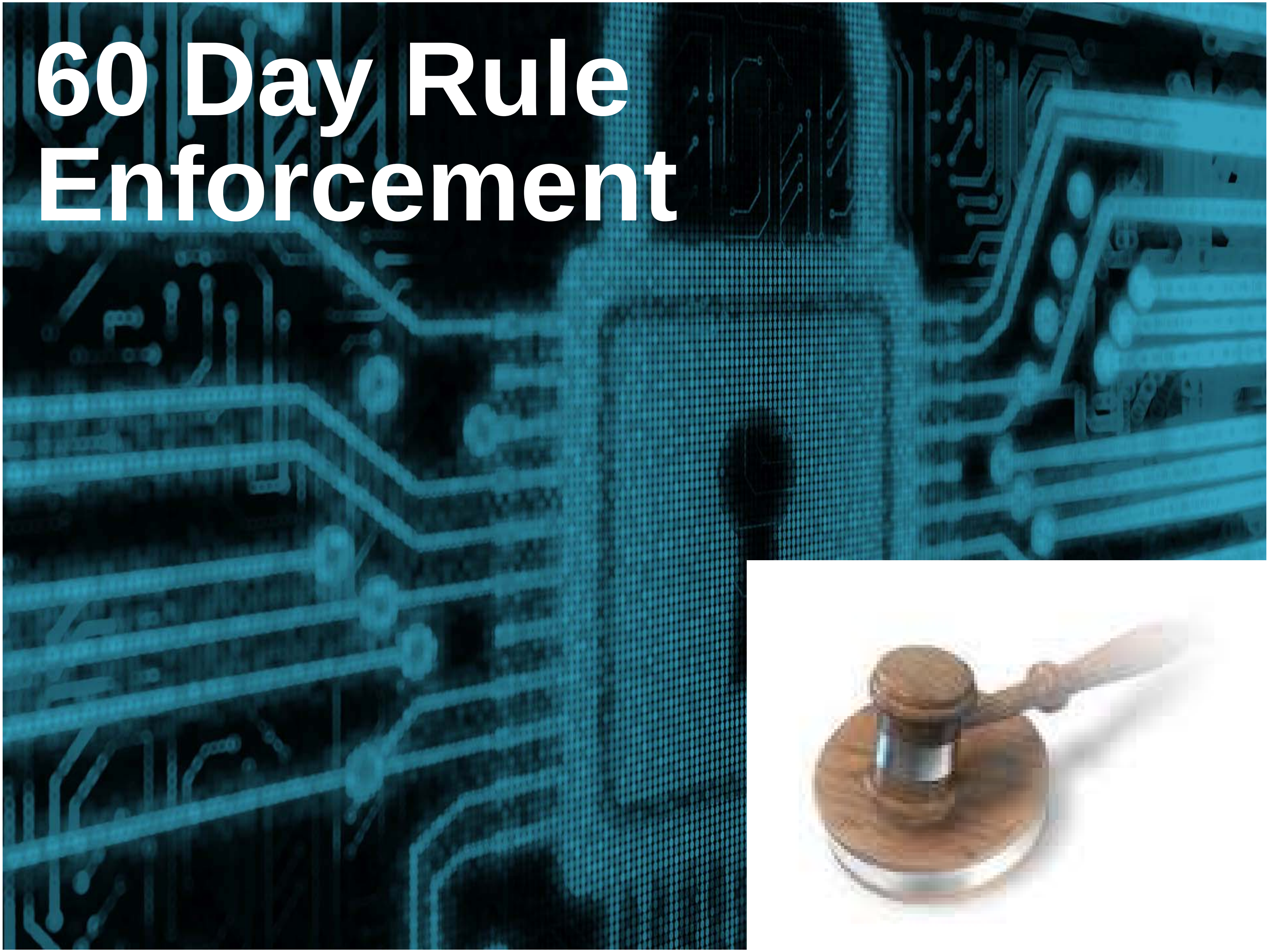
- **Six-year lookback period**
  - Sometimes possible to use a shorter period depending on the facts at issue
- **Amount to be repaid**
  - May vary depending on the method used to report/return, e.g., Medicare administrative contractor (“MAC”) v. self-disclosure
- **Overpayment notification**
  - After receiving an overpayment notification from the government, you should investigate for related overpayments, e.g., other time periods

Smart in your world®
Arent Fox

Options for Reporting/Returning Overpayments

- **MAC reporting process**
- **Self-disclosure protocols**
  - – A submission to the OIG or CMS protocols suspends the 60-day requirement for returning overpayments until a settlement agreement is entered
    - – OIG's Self-Disclosure Protocol (SDP)
    - – CMS Voluntary Self-Referral Disclosure Protocol (SRDP)
  - – Self-disclosures to other agencies do not suspend the repayment deadline
    - – E.g., Department of Justice, U.S. Attorneys' Office, Medicaid Fraud Control Unit

60 Day Rule Enforcement



60-Day Rule Enforcement

- *Kane v. Healthfirst, Inc.,* 120 F. Supp. 3d 370 (S.D. NY. 2015)
  - District Court interpreted "identified:"
    - Providers "identify" overpayments when they are *"put on notice of a potential overpayment*, rather than the moment when an overpayment is conclusively ascertained…"
  - Holding likely limited by facts at issue and, to some extent, by new regulations
  - Parties settled in August 2016 for $2.95M (treble damages, but no per claim penalties)
- Pediatric Services of America ("PSA") – DOJ Settlement (Aug. 2015)
  - PSA and related entities agreed to pay $6.88 million to resolve allegations that it failed to report and return overpayments it received from Medicare & Medicaid
- Enforcement likely to increase in light of new regulations

How to Structure Your Compliance Program

Facilitating Compliance With the 60-Day Rule

- Implement appropriate policies and procedures
- Implement periodic billing and coding audits to proactively identify overpayments
- Utilize publicly available government resources to guide audit efforts
- Promptly investigate any suspected incidence of non-compliance with federal health care program requirements

Smart in your world®
Arent Fox

Facilitating Compliance With the 60-Day Rule

- Engage counsel and other experts to complete a thorough investigation (including quantification)
- Understand the various risks, benefits and methods for reporting and returning overpayments, including which method is appropriate for which type of overpayment
- Document the diligence performed as part of your inquiry

Self-Disclosure

Is Self-Disclosure Appropriate?

- **Is the matter a potential violation of the law**?
- **Is there an alternative to disclosure?**
  - Matters exclusively involving overpayments that do not involve violations of law should be brought to the attention of the MAC
- **Is the provider already operating under a Corporate Integrity Agreement?**

Smart in your world®
Arent Fox

Potential Benefits

- The amount to be re-paid to the government likely will be lower than if the government identifies the issue
- The government is unlikely to impose a costly Corporate Integrity Agreement (CIA)
- Depending on the disclosure, the provider likely will receive one or more releases, protecting against certain types of liability
- If a self-disclosure is well-structured, the government is less likely to conduct its own, more intrusive investigation that could expand to other types of issues as well
- May provide better protection for individuals

Smart in your world®
Arent Fox

Potential Risks

- The government may not limit its review to the facts and issues disclosed, which could lead to expanded exposure
  – If the government identifies overpayments or issues not identified in the self-disclosure, questions could be raised about the provider's intent
- Protocols provide no guarantees of leniency, immunity, or specific benefits
- Providers may not be accepted into the OIG or CMS protocols
- Self-disclosure to one agency may not resolve potential liability to another
- Impact of self-disclosures on *qui tam* complaints filed under the federal FCA also is unclear

Smart in your world®
Arent Fox

Potential Risks

- Certain types of self-disclosure may take a significant amount of time to resolve

- Complexity of the fraud and abuse laws may lead to unnecessary disclosure and liability

Smart in your world®
Arent Fox

Yates Memorandum and Self-Disclosure

- DOJ memo emphasizes increased enforcement against individuals as part of corporate investigations (9/9/2015)
- Includes steps DOJ will take to strengthen pursuit of individuals in the context of corporate wrongdoing:
  - To get “credit” for cooperation, corporations must provide relevant facts relating to individuals responsible for the misconduct
  - Criminal and civil attorneys handling the investigation will coordinate
  - DOJ will not typically release culpable individuals from civil or criminal liability when resolving matters with a corporation
  - No resolution of corporate cases without a plan to resolve related individual cases
  - Civil attorneys directed to focus investigations on individuals as well as the company
- Self-disclosure is likely to decrease exposure for individuals

The Self-Disclosure Process

Engaging outside counsel/consultants

- Once a compliance concern is raised, providers must conduct a thorough investigation of the issue
- Having the investigation directed by counsel can create privilege
  - Privilege more likely to be respected when outside counsel is involved
- Experienced outside counsel and/or consultants provide additional credibility and can help:
  - Evaluate complex legal questions or issues (e.g., analyze whether there has been a violation of the Stark Law)
  - Analyze the facts
  - Assess the amount of overpayment liability (e.g., determine the appropriate look-back period and/or perform extrapolation, as appropriate)

Smart in your world®
Arent Fox

Potential Avenues of Disclosure

- **Choosing the appropriate disclosure process depends on factors including**:
  - The underlying facts (Overcoding issue? Stark-only issue? Stark and AKS issue? Number of claims at issue? Improper intent? etc.)
  - The type of release wanted

- **Regardless of the type of disclosure, providers should:**
  - Identify the laws that were potentially violated, the timeframes during which the potential violation occurred, and acknowledge the potential violation
  - Take corrective action to end the non-compliant practice, arrangement, etc. and prevent its recurrence
  - Cooperate fully during the agency's investigation

Choice of Agency

- **OIG - Self-Disclosure Protocol**
  - Conduct involving false billing
  - Conduct involving excluded persons
  - Conduct involving the Anti-Kickback Statute (including conduct that violates both the AKS and Stark Law)
- **CMS – Self-Referral Disclosure Protocol**
  - Conduct involving only violations of the Stark Law
- **DOJ**
  - May be appropriate when provider believes a FCA release is necessary
- **Other – e.g., the MAC**
  - Usually best for relatively simple overpayment returns

Smart in your world®
Arent Fox

Disclosure to the OIG

- **The OIG Self-Disclosure Protocol ("SDP")**
  - Providers are required to:
    - Explicitly identify the laws that were potentially violated and acknowledge the potential violations
    - Take corrective action and end the potential conduct at issue within 90 days of submission to the SDP
    - Perform an initial investigation and damages audit within 3 months of acceptance into the SDP
  - Minimum settlement amounts of at least $50,000 for kick-back related submissions, and at least $10,000 for all other disclosures
  - SDP requirements available at: http://www.oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf,

Smart in your world®
Arent Fox

Benefits and Limitations of the SDP

Benefits

- The OIG can provide a release from exposure under the CMP law, and permissive exclusion
- Lower multiplier on single damages (often 1.5) and other potential damages likely reduced
- Tolls 60-day report/return obligation
- Expedited resolution

Limitations

- No release for potential FCA liability without DOJ involvement
- DOJ participation often results in higher settlement amounts
- Costs more than returning money to the MAC

Disclosures to CMS

- The SRDP is open to all health care providers and suppliers, but it is used **exclusively** to report actual or potential violations of the Stark Law
  - See: https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/self_referral_disclosure_protocol.html.
  - There is an abbreviated protocol solely for certain Stark Law violations related to physician-owned hospitals
  - A new form for all disclosures was recently *proposed* by CMS

Smart in your world®
Arent Fox

Benefits and Limitations of the SRDP

Benefits

- CMS has discretion in determining settlement amounts (often based on excess remuneration paid; not reimbursement received)
- CMS may release disclosing party from certain limited administrative liabilities and claims
- 60-day report/return obligation tolled

Limitations

- Disclosure can involve *only* actual or potential violations of the Stark Law
- Limited scope release – CMS only releases overpayment liability under Section 1877(g)(1) of the Social Security Act
- CMS may coordinate with the OIG and/or DOJ for additional releases, although the settlement amount likely would increase
- SRDP process can be extremely slow

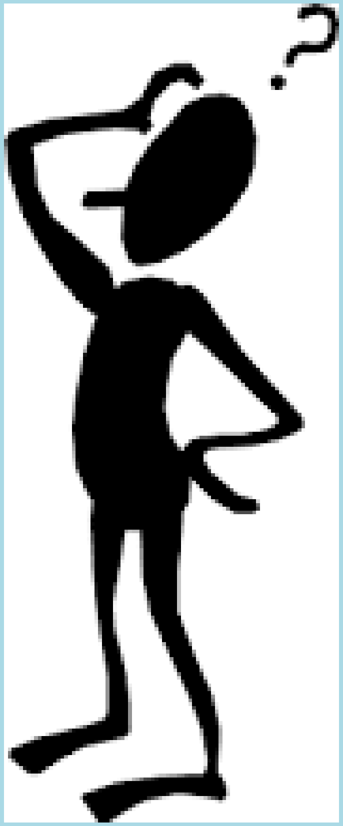
Smart in your world®
Arent Fox

Other Avenues of Disclosure

- **DOJ**
  - Typically through local US Attorney's office (USAO)
  - No formal guidance or protocol
  - Beneficial to providers that require an FCA release
  - No guaranteed settlement formula, and anecdotal reports that some USAOs will not settle for less than double damages
  - Does not toll 60 day report/return requirement

- **Medicare Administrative Contractors (MACs)**
  - Best for simple overpayment matters (e.g., improper coding)
  - No release given but usually least costly approach

Questions?



This material is intended for informational purposes and should not be taken as legal advice. Please consult appropriate advisors for guidance applicable to your individual circumstances.