Should I Disclose? Risks and Benefits of OIG Voluntary Disclosure

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Introduction

- OIG Published Provider Self-Disclosure Protocol (SDP) in 1998 at 63 Fed. Reg. 58399 (October 30, 1998) to establish a process for health care providers to voluntarily identify, disclose, and resolve instances of potential fraud involving the Federal health care programs.
- OIG has resolved approximately 900 disclosures resulting in recoveries
- OIG also issued three (3) Open Letters in 2006, 2008, and 2009 to provide additional guidance to health care providers with respect to voluntary disclosures
- 2013 OIG SDP supersedes and replaces all prior guidance and the 1998 protocol.

Benefits of Disclosure

- **Release from False Claims Act:** DOJ Civil settlement releasing organization from liability under the False Claims Act.
- **FCA Statute of Limitations (SOL):** SOL begins running on any potential *qui tam* action pursuant to the False Claims Act once disclosure is made to OIG
- **Avoid Exclusion**.
- **Integrity Agreement**. Potentially avoid the requirement of an Integrity or Corporate Integrity Agreement.
- **1.5 Multiplier**: Presumption of a 1.5 multiplier for damages opposed to treble damages pursuant to a *qui tam* action.
- **Suspension of Overpayment Reporting Obligation**. Participation in SDP suspends a disclosing party's obligation to report an overpayment to Medicare or Medicaid.
- **Factor Considered by DOJ Criminal Division and Federal Sentencing Guidelines.** Disclosure and cooperation are factors which directly influence prosecutorial decision making with respect to the criminal prosecution of individuals and business organizations. *See* Federal Sentencing Guidelines, 8C2.5(g); *see* Department of Justice Principles of Federal Prosecution, Section 9-27.620; *see* Department of Justice, Principles of Federal Prosecution of Business Organizations, Section 9-28.700.

Benefits of Disclosure – Possible Release Under the False Claims Act

- **Page 13 of OIG SDP states**: *"In some cases, disclosing parties may request release under the FCA, and in other cases, DOJ may choose to participate in the settlement of the matters. If DOJ participates in the settlement, the matter will be resolved as DOJ determines is appropriate consistent with the resolution of its FCA cases, which could include a calculation of the damages resulting from violations of the AKS based on paid claims. OIG will advocate that the disclosing party receive a benefit from the disclosure under the SDP and the matter be resolved consistent with OIG's approach in similar cases. However, DOJ determines the approach in cases in which it is involved."*
- **Practice Points:**
  - DOJ Civil might defer to the recommendations made by OIG to release the organization/individual from FCA liability based on a disclosure under the SDP.
  - DOJ might decline intervention in cases where a relator's complaint includes many of the allegations or transactions previously disclosed by virtue of OIG's SDP.
  - DOJ might determine that a resolution with a 1.5 multiplier is an appropriate multiplier for damages as part of a settlement and a release under the FCA.
- **Question:** But, even if DOJ participates in an FCA settlement and grants a release will that preclude a relator, as a matter of law, from prevailing in a subsequent *qui tam* action based on allegations or transactions previously disclosed via the SDP?

Benefits of Disclosure – SOL Begins Running on *Qui Tam* Actions

- Once a disclosure is submitted, the party submitting the disclosure should be able to argue that "facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances" in which case a disclosure via SDP should trigger the 3 year statute of limitations for any potential *qui tam* action.
- **Practice Point**: But, SOL is tricky. SOL states that no cause of action pursuant to the FCA may be brought:
  - more than **6 years** after the violation is committed;
  - more than **3 years** after the date that "facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances";
  - *But*, in no event more than **10 years** after the date on which the violation is committed, *whichever occurs last.*

  ***See* 31 U.S.C. Section 3130(b)(1)-(2).**
- **Question:** Last false claim submitted on 2005. A voluntary disclosure is made in 2012. A complaint is then filed in 2015. Has the SOL expired?

Benefits of Disclosure-Exclusion and Integrity Agreements

- OIG has now instituted a "presumption" against requiring integrity agreement obligations in exchange for a release of OIG's permissive exclusion authorities.
- For many organizations, a multi-year ban (e.g. 3-10 years) from participating in federal health care programs is a death sentence. Thus, the financial consequences of *not* disclosing potential violations might ultimately outweigh the risks attendant to any disclosure.
- A disclosing organization might avoid the requirement of a Corporate Integrity Agreement (CIA) with rigorous reporting, auditing, and continuing compliance obligations.

Benefits of Disclosure -1.5 Multiplier

- Pursuant to the SDP, OIG's general practice in Civil Monetary Penalty (CMP) settlements is to require a minimum of a 1.5 multiplier.
- **$50,00.00** is the minimum settlement amount for any violation of the Anti Kickback Statute (AKS) which is disclosed.
- OIG believed that individual or entities that cooperate and disclose violations through the SDP "deserve to pay a lower multiplier on single damages" as opposed to a multiplier of 3 which would normally be required in a government initiated investigation into violations of the FCA.
- **Practice Points:** OIG will determine on a case by case basis whether a higher multiplier is appropriate **and** OIG, in practice, might be unwilling to sufficiently articulate the reasons underlying the application of a multiplier.

Benefits of Disclosure - Suspension of Overpayments Reporting

- Pursuant to 77 Fed. Reg. 9179-9187 (Feb. 16, 2012), CMS proposed to suspend the obligation for reporting "overpayments" when OIG has acknowledged the receipt of a submission into the SDP.
- CMS also proposed to suspend the obligation to return overpayments until a settlement agreement is entered into, or the disclosing party withdraws or is removed from the SDP.
- Suspension of these obligations is significant because:
  - **60 days.** Normally, a provider or supplier has **60 days after the date on which the overpayment is "identified"** to **return and report** the overpayment to the Medicare Administrative Contractor (MAC). ***See* 42 U.S.C. Section 1320a-7k(d)(2).**
  - **"Identified."** An overpayment is "identified at the time that a person acts with actual knowledge of, in deliberate ignorance of, or in reckless disregard to the overpayment's existence." *See* 77 Fed. Reg. 9182.
    - There are varying interpretations and opinions concerning this definition.
    - The vague and somewhat broad definition demonstrates that there might be significant affirmative obligations for providers.
    - **EXAMPLE**: If an overpayment were identified at the commencement of the investigation, then a provider would have 60 days to report and return the overpayment *prior to* the conclusion of any internal investigation.

Benefits of Disclosure – Factor Considered by DOJ Manual and Federal Sentencing Guidelines

- **DOJ Manual**
  - Federal Principles of Prosecution of Business Organizations encourages disclosure and cooperation
  - Federal Principles of Prosecution emphasize the importance of disclosure.
- **Federal Sentencing Guidelines**
  - Disclosure may lead to a reduced sentence for individuals
  - Disclosure and cooperation are significant factors considered by the Sentencing Guidelines in computing an organization's culpability score

Benefits of Disclosure - Organizations

- **DPA or Non-Prosecution**
- "The corporation's timely and voluntary disclosure of wrong-doing *and* its willingness to cooperate in the investigation of its agents" is a factor in the department's prosecutorial decision-making. *See* Department of Justice, Principles of Federal Prosecution of Business Organizations, Section 9-28.700.
- **Lower Culpability Score.**
  - Sentencing Guidelines establish certain multipliers associated with certain culpability scores to establish the range of the fine that the organization is required to pay.
  - **Section 8C2.5(g)(1)** of the Federal Sentencing Guidelines permits an organization to subtract **5 points** from its Culpability Score which impacts, among other things, the fine paid by the organization.
  - To benefit from the 5 point reduction, the organization must:
    - Report the offense to appropriate governmental authorities, fully cooperate in the investigation; and
    - Clearly demonstrate and affirmatively accept responsibility for its criminal conduct *prior to* an imminent threat of disclosure or government investigation *and* within a reasonable time after becoming aware of the offense
- **Avoid Exclusion from Medicare, Medicaid, or Tricare**
  - A declination of prosecution may permit an individual to avoid exclusion.
  - An individual may avoid mandatory exclusion and/or may be able to negotiate an Integrity Agreement as part of any global settlement with OIG and DOJ to avoid permissive exclusion. ***See* 42 C.F.R. Section 1001.**

Benefits of Disclosure- Individuals

- **Possible Declination or NPA**
  - A person's willingness to cooperate in the investigation or prosecution of others is an appropriate consideration in deciding whether to recommend prosecution. *See* Department of Justice, Principles of Federal Prosecution of Business Organizations, Section 9-27.230.
  - Availability of a non-criminal alternative is a factor that the Government considers in recommending prosecution. In weighing the adequacy of the non-criminal alternative, the Government weighs the nature and severity of the sanctions that could be imposed, the likelihood that they would be imposed, and the impact of a non-criminal disposition on federal law enforcement interests. *See* Department of Justice, Principles of Federal Prosecution of Business Organizations, Section 9-27.250.
  - **A non-prosecution agreement** may be available if the individual offers substantial cooperation in the prosecution or investigation of others. *See* Department of Justice, Principles of Federal Prosecution of Business Organizations, Section 9-27.260.
- **Charge Bargaining**
  - If the conduct is disclosed well in advance of any government investigation or prosecution, then an individual may have an opportunity to charge-bargain and to avoid a plea to a count that involves mandatory exclusion and may avoid a lengthy period of incarceration (e.g. probation).
  - *See United States v. Dennis Aponte*, Case No. 13-CR-00464 (D. N.J., July 17, 2013) (DE-4) – physician receiving kickbacks from laboratory for Medicare referrals permitted to enter into a One Count Information to Travel Act violation (18 USC Section 1952) and was sentenced pursuant to 2B4.1.
- **Sentencing Guidelines**
  - Pursuant to Federal Sentencing Guidelines, **Section 3E1.1**, a voluntary disclosure and admission of the applicable violation should form the basis for an acceptance of responsibility, which might, where applicable, reduce the individual's potential term of incarceration.
  - Disclosure and cooperation may also form grounds for a downward departures pursuant to **Section 5K1.1** depending on the completeness and timeliness of the disclosure and/or cooperation.
- **Avoid Exclusion from Medicare, Medicaid, or Tricare**
  - A declination of prosecution may permit an individual to avoid exclusion.
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Issues to Consider

- Eligibility Concerns
- Immediate Risks Associated with Disclosure
  - Acknowledgment of Liability
  - 90 Day Shot Clock for Conducting an Internal Investigation
  - Non Binding Recommendations from DOJ Civil and DOJ Criminal
- Will Client fully Cooperate with OIG?
- Will a voluntary disclosure bar a filing of a subsequent qui tam?
- Overpayment Reporting Obligations
- Physician Payment Sunshine Act Reporting Obligations
- FOIA

Eligibility Concerns

- **What Types of Violations may be disclosed via SDP?**
  - AKS violations only, not Stark.
  - False Billing
  - Hiring of an Excluded Individual.
- **Are we Ineligible if we discovered the violation based on any of the following:**
  - Civil Investigative Demand (CID)
  - Government initiated audit (e.g., ZPIC audit)
  - Grand jury subpoena
  - Execution of Search warrant
- **Automatic Ineligibility based on ongoing Government inquiry?**
  - According to OIG, disclosing parties already subject to a Government inquiry, audit, investigation, or "other oversight activities" are not automatically precluded from making a disclosure. But, disclosure must be made in "good faith" and not for the purpose of circumventing an ongoing inquiry.

Immediate Risks Associated with Disclosure

- **Acknowledgement of Liability.** A self-disclosing party must acknowledge that the conduct is a potential violation of the Anti Kickback Statute, which is a federal criminal statute.
- **90 Days.** A disclosing party must conduct an internal investigation and report the findings to OIG or certify that it will complete the investigation within **90 days.**
- **Non-Binding Recommendations from DOJ Civil and Criminal.**
  - **DOJ Civil.** DOJ Civil determines the resolution of the case consistent with its approach in past cases notwithstanding the fact that OIG may make a non-binding recommendation to DOJ Civil.
  - **DOJ Criminal**.
    - OIG is required to refer criminal conduct to DOJ.
    - Although OIG "will advocate that the disclosing parties receive a benefit from disclosure under the SDP," there are no guarantees.

DOJ Criminal Concerns

- A submission *via* the SDP *may* result in a non-binding recommendation from OIG to DOJ Criminal.
- A disclosure will not exonerate a disclosing party or protect a disclosing party against prosecution.
- Furthermore, OIG has no power or authority to enter into a non-prosecution agreement (NPA) or a deferred prosecution agreement (DPA).
- **Question:** Based on the following, should a disclosing party consider the benefits of making a disclosure to OIG ***and*** DOJ if the disclosing party is truly concerned with future actions by DOJ Criminal? Is such a step premature and potentially detrimental to the client?

Requirement of Cooperation

- Voluntary disclosure requires cooperation
- **OIG-SDP** states that the benefits of self-disclosure depend on the disclosing party's "willingness to work cooperatively with OIG throughout the process."
- Cooperation includes:
  - Conducting a thorough investigation
  - Communicating through a consistent point of contact
  - Responding to OIG requests for information.
  - Paying the multiplier determined by OIG.
  - Note that "a disclosing party may removed from SDP if a party fails to cooperate with OIG in good faith."

What is Adequate Cooperation?

"Most companies now understand the benefits of voluntarily disclosing the misconduct before we come asking, and the benefits of conducting an internal investigation and providing facts about the misconduct to the government. But companies all too often tout what they view as strong cooperation, while ignoring that prosecutors specifically consider 'the company's willingness to cooperate in the investigation of its agents.' Corporations do not act, but for the actions of individuals. In all but a few cases, an individual or group of individuals is responsible for the corporation's criminal conduct. The prosecution of culpable individuals – including corporate executives – for their criminal wrongdoing continues to be a high priority for the department.

For a company to receive full cooperation credit following a self-report, it must root out the misconduct and identify the individuals responsible, even if they are senior executives. We are not asking that you become surrogate FBI agents or prosecutors, or that you use law enforcement tactics like body wires. And we do not need to hear you say that executive A violated a particular criminal law. All we are saying is that we expect you to provide us with facts. We will take it from there. But a company that interviews its employees in an effort to whitewash the facts or spread the company's narrative spin risks receiving any cooperation credit. Additionally, for a company to receive full cooperation credit, the company must provide relevant documents and evidence, and should do so in a timely fashion. …"

Leslie Caldwell, Assistant Attorney General, 22nd Annual Ethics and Compliance Conference in Atlanta, Georgia, (October 1, 2014)

Conducting Internal Investigations

- **Who is the Client?**
  - Who hired you for the engagement?
  - Counsel should include a written retainer confirming whom you represent and whom you do *not* represent
  - Retainer should be confirmed and signed by General Counsel (GC) and should contain a statement that GC understands who client is and understands who may claim attorney-client privilege pursuant to the agreement
- **What is the Purpose of the Investigation?**
  - To respond to an internal suggestion of wrongdoing
  - To respond to a government inquiry
  - To respond to an inquiry from a fiscal intermediary (MAC) or Zone Program Integrity Contractor (ZPIC)
- **Employee Interviews**
  - Conducted by Whom?
    - In house counsel or external legal counsel?
    - Is the investigation truly independent?
    - What if certain employees refuse to be interviewed and direct you to their attorney?
    - Can you ask a particularly disgruntled employee if they have filed a *qui tam?*
- ***Upjohn* Warnings?**
  - What warnings should be given to employees?

Conducting Internal Investigations

- **What Steps Should Be Taken Internally <u>After</u> the Investigation?**
  - Analyze whether a voluntary disclosure is appropriate
  - Discipline employees
  - Recalibrate or remodel any existing compliance program
  - Disclose facts and/or investigative findings related to the internal investigation to OIG/DOJ
  - Disclose attorney client communications to OIG/DOJ

Conducting Internal Investigations –Attorney Client Privilege

- ***United States, ex rel Baklid Kunz v. Halifax Hospital Medical Center,* 2012 WL 5415108, No. 09-cv-01002-GAP (M.D. Fla. Nov. 6, 2012)** (finding that communications seeking "compliance advice" and the compliance log documenting corrective actions and concerns were not protected and were subject to disclosure). The log was also maintained to facilitate discussions between general counsel and the Legal Department.
- ***Gruss v. Zwirn,* 09-cv-06441- (S.D.N.Y. Nov.20, 2013) (DE-67)** (ordering defendants to produce notes of attorney interviews with 21 employees conducted pursuant to an internal investigation for *in camera* inspection after attorneys for defendants included and referenced the interviews in a power point presentation before the SEC). Court also rejected defendants' argument that Gibson Dunn had a "core privacy interest" in the attorney notes prepared by Gibson associates.
- ***United States v. ISS Marine Services,* 2012 WL 5873682 (D.D.C. 2012)** (internal audit report created by external auditor after defendant retained Arnold & Porter was subject to disclosure despite the fact that defendant argued that auditor sent internal audit report to A&P for purpose of seeking legal advice).
- ***In Re Kellogg Brown & Root, Inc, No.* 14-CV-5055 (D.C. Cir. June 27, 2014).** KBR conducted an internal investigation pursuant to its Code of Conduct which was overseen by the company's legal department.
  - Company conducted the investigation to gather facts and to ensure compliance with the law after being informed of potential misconduct.
  - Court found that the company investigation was "materially indistinguishable" from the investigation in *Upjohn and emphasized:* "[i]n the context of an internal investigation, if one of the significant purposes of the internal investigation was to obtain or provide legal advice, the privilege will apply. That is true regardless of whether an internal investigation was conducted pursuant to a company compliance program require by statute or regulation or was otherwise conducted pursuant to company policy."

Will a Voluntary Disclosure Bar a Subsequent Qui Tam Filed by a Relator?

- **31 U.S.C. 3730(e)(3)** of the False Claims Act specifically states that "in no event may a person bring an action under subsection (b) which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil penalty proceeding in which the Government is already a party."
- **31 U.S.C. Section 3730(e)(4)(A)(ii)** of the False Claims Act states "the court shall *dismiss* an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed…. in a congressional, GAO, or other Federal report, hearing, audit, or investigation…"
- **Practice Point:** Thus, focusing on the plain language of the FCA, a voluntary disclosure does not appear to bar a relator from filing a *qui tam* action after a disclosure is made.

Will a Voluntary Disclosure Bar a Subsequent Qui Tam Filed by a Relator?

- A voluntary disclosure is not an "administrative civil penalty proceeding in which the Government is already a party."
- But, are the allegations or transactions contained in the voluntary disclosure allegations or transactions that were "publicly disclosed in.. a Federal hearing, audit, or investigation?"
- **Question:** If DOJ Civil is already aware of the voluntary disclosure and has agreed to release the organization from FCA liability, then, in practice, barring extraordinary circumstances, is the Government likely to intervene in a subsequent *qui tam* action?

United States ex rel. Rost v. Pfizer, 507 F.3d 720, 728-29 (1st Cir. 2007)

Our case turns on the "public disclosure" language of § 3730(e)(4)(A). **Pfizer asserts that its self-disclosure to HHS and DOJ, the appropriate investigative bodies, constitutes "public disclosure of allegations" in an appropriate government investigation setting under § 3730(e)(4)(A) and thus bars the action**.

Analysis of § 3730(e)(4)(A) requires several inquiries: (1) whether there has been public disclosure of the allegations or transactions in the relator's complaint; (2) if so, whether the public disclosure occurred in the manner specified in the statute; (3) if so, whether the relator's suit is "based upon" those publicly disclosed allegations or transactions; and (4) if the answers to these questions are in the affirmative, whether the relator falls within the "original source" exception as defined in § 3730(e)(4)(B). We reach only the first question. Our case law has not previously defined the term "public disclosure."

The question here is whether self-disclosure made by a private party only to government agencies, without further disclosure, is "public disclosure." In our view, a "public disclosure" requires that there be some act of disclosure to the public outside of the government. The mere fact that the disclosures are contained in government files someplace, or even that the government is conducting an investigation behind the scenes, does not itself constitute public disclosure. Our construction of the term "public disclosure" does not turn on the fact that Pfizer requested or assumed that its disclosures to the investigating agencies would be held confidential. The United States has taken the litigation position in this action that "public disclosure" does not include the disclosure from Pfizer to the government that occurred here.

Pfizer's reading is inconsistent with our understanding of the language, structure, and history of the Act. The plain language of the statute cuts against Pfizer's interpretation of the public disclosure bar for several reasons. This court has already held that "the logical reading is that the [public disclosure] subsection serves to prohibit courts from hearing *qui tam* actions based on information made available to the public during the course of a government hearing, investigation or audit or from the news media." *United States ex rel. LeBlanc v. Raytheon Co.*, 913 F.2d 17, 20 (1st Cir.1990). **What Pfizer did was to make confidential disclosures to the government, which triggered an investigation. But the statute does not bar jurisdiction over qui tam actions based on disclosures of allegations or transactions to the government; it does so only for actions based on qualifying disclosures made to the public**. If providing information to the government were enough to trigger the bar, the phrase "public disclosure" would be superfluous.

Compare United States ex rel. Reagan v. East Texas Medical Center, 384 F.3d 168, 174-75 (5th Cir. 2004)

- In *United States ex rel. Reagan v. East Texas Medical Center*, 384 F.3d 168, 174-75 (5th Cir. 2004), the court held that relator "publicly disclosed" allegations when she provided information to HCFA and BCBS prior to filing a *qui tam*.
- In *Reagan*, the Court specifically found:

> *Reagan's argument is, in essence, that no disclosure to the government by the relator should be considered a public disclosure. Her reasoning is not fully clear to us. The best translation of her argument, however, is that a relator is hoisted on her own petard, if the relator, acting in good faith to remedy the fraud, discloses to the government the fraudulent activity, and then, based on that disclosure, is barred from bringing suit. This argument fails wholly to take into account the original source exception under the statute: if the relator is the original source of such disclosure to the government, the "public disclosure bar" does not apply. Here, for example, if Reagan had been the original source of the disclosure to the government — i.e., if she had "direct and independent knowledge" of the information publicly disclosed to BCBS and HCFA — she would not be barred from bringing suit.*

Reagan, 384 F.3d at 175, n.9.

Additional Cases

- *Whipple v. Chattanooga-Hamilton County Hospital Authority*, No. 3-11-0206 (M.D. Tenn. 2013). District court accepted Defendants argument that Plaintiff's *qui tam* action barred by public disclosure bar because Plaintiffs allegations were publicly disclosed to more than just the government. Allegations were previously raised and made public in connection with an audit and investigation involving OIG, Program Integrity Contractors, the USAO, consultants, and attorneys in connection with their investigation of wrongdoing. The Court also concluded that because the disclosure was sufficient to put the government on notice of an allegation of fraud it constituted a public disclosure.
- *United States ex rel. Poteet v. Medtronic, Inc.*, 552 F.3d 503, 512-13 (6th Cir. 2009) (finding that state court complaint was a public disclosure that barred relator's subsequent qui tam action based upon same allegations of fraud). Court also noted that the "FCA clarifies that a prior disclosure of fraud is public if it appears in 'the news media" or is made "in a criminal, civil, or administrative hearing, [or] in a congressional, administrative, or Government Accounting Office report, audit, or investigation." 31 U.S.C. § 3730(e)(4)(A).'").
- *United States ex rel. Lancaster v. Boeing Co.*, 778 F.Supp.2d 1231, 1244 (N.D. Okla. 2011) (disclosure of information to a competent public official about an alleged false claim against the government is "public disclosure" within the meaning of the Public Disclosure Bar when the official is authorized to act for or to represent the community on behalf of government.)

FOIA Issues

- If a voluntary disclosure is submitted to OIG, then a FOIA requestor might be able to obtain some of the information included in the disclosure unless a FOIA exemption applies.
- A FOIA requestor may also obtain information about the facts underlying the SDP for the purpose of buttressing his claims against the disclosing party in a *separate* cause of action (*e.g.* unfair competition, unjust enrichment, common law fraud, etc.).
- Disclosing parties should therefore identify the portions of the disclosure which they believe are:
  - Confidential or privileged
  - Trade secrets
  - Confidential financial or commercial information
  - **Questions/Concerns**:
    - When information is disclosed to a relator pursuant to a FOIA request, is that a "public disclosure" of any of the information contemplated under 31 U.S.C. Section 3731(e)(4)(A)?
      - *United States ex rel Mistick v. Housing Auth. of the City of Pittsburgh*, 186 F. 3d 376 (3d Cir. 1999) (YES)
      - *United States ex rel. Reagan v. East Texas Medical Center*, 384 F.3d 168, 175-76 (5th Cir. 2004) (YES)
    - Can a FOIA requestor claim that "original source" status if the requestor obtains information via FOIA which materially adds to the requestor's personal knowledge regarding a potential qui tam action?

Physician Payment Sunshine Act (PPSA) Issues

- PPSA is codified at **42 C.F.R. Sections 403.900-403.915; 78 Fed. Reg. 9458 (Feb 8, 2013)**
- PPSA requires that "applicable manufacturers" report payments they made to physicians through CMS' Open Payments.
- While physicians are not legally required to report, the intent of Open Payments is to enhance transparency with respect to physicians and anything of value they might have received from applicable manufacturers.
- **Questions:**
  - Has the disclosing party received anything of value from an "applicable manufacturer" pursuant to the PPSA?
  - If so, what, if any, payments received by the disclosing party will also be included in a disclosure made by an "applicable manufacturer" via Open Payments pursuant to the PPSA?
  - How will this impact a decision to submit a disclosure via SDP?
  - Is there any way to effectively streamline this process? Will the filing of 2 reports be necessary, e.g., one through Open Payments and one via OIG-SDP?

Summary

1. Is the disclosing party eligible for SDP?
2. What are the immediate risks associated with disclosure?
3. What are the defined benefits of disclosure to OIG-HHS?
4. Can the disclosing party afford to pay a 1.5 multiplier? Can the disclosing party afford to hire a third party consultant (e.g. forensic auditor) to evaluate damages?
5. Is the disclosing party willing to cooperate, and if so, is the disclosing party willing to waive attorney-client privilege as part of cooperation?
6. Has the disclosing party conducted a thorough investigation?
7. If so, is the disclosing party willing to take substantial corrective actions internally after determining the nature of the violation (e.g. discipline, enhancement of compliance program)?
8. What are some of the other consequences associated with disclosure (e.g. FOIA and Physician Payment Sunshine Act)?

Questions

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