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by Winston Y. Chan and Emily C. Aldridge

Healthcare providers' False Claims Act self-disclosure "discount"

» The government has introduced incentives to healthcare providers that voluntarily disclose potential False Claims Act violations.

» It remains unclear whether there is any discernible financial "discount" to self-disclosing entities.

» Although the OIG states that self-disclosers may not face treble damages, it has not offered any indication of what multiplier it uses.

» The government generally does not impose certification of compliance agreements (CCAs) and corporate integrity agreements (CIAs) in self-disclosure cases.

» This alone may be a sufficient predictable benefit to warrant self-disclosure for healthcare providers.

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In recent years, the government has introduced incentives to entities that self-disclose potential False Claims Act (FCA) violations to the government. This can be particularly attractive to healthcare providers, which are often the focus of government FCA investigations and prosecutions. It remains unclear, however, whether there is any discernible financial "discount" to those that voluntarily disclose FCA violations. The Updated Self-Disclosure Protocol of 2013, published by the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS), promises that participants may not face the treble damages that they might otherwise be required to pay, but neither the OIG nor federal prosecutors offer information that can be used to peg what multiplier they actually tend to use. However, it is apparent that the government generally has imposed certification of compliance agreements (CCAs) and corporate integrity agreements (CIAs) in only a handful of self-disclosure cases, and this alone may be a sufficient predictable benefit to warrant self-disclosure for many healthcare providers, given the burden and associated expense of such agreements.

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The current guidelines

The False Claims Act, (31 U.S.C. §§ 3729-33), enacted in 1863, provides that any person who knowingly submits false claims to the government is liable for the government's damages, increased by a multiplier, plus an added penalty for each false claim. The statute has been amended a number of times, raising penalties to their present levels: a treble damages multiplier (raised from double damages) and a penalty of $5,500 to $11,000, depending on the type of claim. The statute imposes liability for those who knowingly submit a false claim to the government, those who improperly avoid the payment of money to the government, and

those who conspire to violate the FCA. The statute requires that guilty parties have knowledge of the falsity of their actions—defined as "actual knowledge," "deliberate ignorance of the truth," and "reckless disregard for the truth or falsity of the information."

Enforcement agencies are allowed to discount penalties for parties who voluntarily disclose their wrongdoing to the government. The question before us specifically focuses on the nature of this discount in the healthcare context, and whether recent government statements and settlement trends can help hospitals and other providers predict the savings they might earn from self-disclosure.

The answer to this question becomes increasingly important as the federal government turns up the heat on its FCA enforcement. In 2014 alone, it recovered a record $5.69 billion in settlements and judgments under the FCA and related legislation. It was the first time the government recovered more than $5 billion in cases under the FCA and brought total recoveries from January 2009 to the end of Fiscal Year 2014 to $22.75 billion, which a press release characterized as "more than half the recoveries since Congress amended the False Claims Act 28 years ago to strengthen the statute and increase the incentives for whistleblowers to file suit."[1]

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Part of the explanation for this rise in enforcement activity may be the FCA's *qui tam* provisions, which invite whistleblowers or relators to sue on the government's behalf with the potential of collecting up to 30% of the monies recovered. In 2014, whistleblowers initiated more than 700 FCA cases, exceeding 700 for the second year in a row. Recoveries in *qui tam* cases during FY 2014 totaled nearly $3 billion, with whistleblowers receiving $435 million. If federal action were not enough, the 2005 Federal Deficit Reduction Act (DRA), [42 U.S.C. § 1396(h)], included incentives designed to encourage states to adopt false claims act laws of their own and collect an additional 10% of any federal Medicaid funds recovered through a state action.

However, another explanation is the government's prioritization of pursuing FCA claims in specific industries where the impact of the fraud is acute and the cost recovery is therefore greatest as well—for example, healthcare. These claims typically involve fraud alleged against federal healthcare programs such as Medicare, Medicaid, and TRICARE federal health coverage for the armed services. Since January 2009, the Department of Justice (DOJ) has recovered $14.5 billion in federal healthcare fraud. In 2014 alone, it recovered $2.3 billion, marking the fifth straight year that the DOJ has recovered more than $2 billion in cases involving false claims against federal healthcare programs. To coordinate this effort, the government relies not only on the Civil Division of the DOJ, but also the OIG. In May 2009, HHS and the DOJ created the Health Care Fraud Prevention and Enforcement Action Team (HEAT) to coordinate these efforts. The government has also launched a public-private partnership to allow an insider perspective to inform best practices and offer insight into where to direct investigations most effectively.

The False Claims Act operates with particular force in the healthcare industry because it operates alongside additional anti-fraud

legislation that targets specific prohibitions. The Social Security Act authorizes the Secretary of HHS to pursue civil monetary penalties (CMPs) under separate authority, and many of these duties have been delegated to the OIG. Many of these CMPs are enumerated in the Civil Monetary Penalties Law (CMPL) (prohibiting false claims for federal healthcare funds), the Anti-Kickback Statute (prohibiting offering or seeking remuneration for patient referrals), and the Stark Law (prohibiting physician self-referrals). Each of these carries the same treble damages and per-violation penalties. Depending on their conduct, healthcare providers can face potential liability under a number of these statutes, as well as the FCA, for a single transaction or occurrence.

Parties under FCA scrutiny face not only triple damages and per-violation fines, but also non-monetary sanctions like CIAs and CCAs, whereby they must promise to implement enhanced and expensive safeguards.

Self-reporting guidelines and specific recommendations

Both the OIG and CMS have published recommended self-disclosure protocols (SDPs)—guidelines for healthcare companies and providers to self-report potential fraud in return for leniency. The two independent processes are described below.

The OIG self-disclosure protocols

The OIG has published SDPs since 1998. When a healthcare provider self-discloses potentially fraudulent conduct, the OIG alleges it takes the self-disclosure and the provider's level of cooperation into account when deciding on settlement terms. From the time of the OIG's original Provider Self-Disclosure Protocol in 1998 to its update in April 2013, the SDP reporting mechanisms resulted in more than 800 settlements totaling $280 million.[2]

On April 17, 2013, the OIG officially updated its SDP, comprehensively incorporating ad hoc changes that had been announced in earlier years and responding to feedback it had solicited from the healthcare industry. The 2013 SDP highlights three particular rewards that disclosing parties can expect to receive in exchange for their cooperation:

- A presumption against requiring disclosing parties to sign CIAs, promising specific prophylactic compliance efforts, in exchange for their continued participation in federal programs;
- The reduction of damages to a lower multiplier, at minimum 1.5 times the single damages, to be determined on a case-by-case basis; and
- A promise that timely disclosure to the OIG will not require duplicate submissions to CMS and other authorities, and disclosing parties will not be required to return overpayments until a settlement has been agreed upon.

Additionally, the OIG streamlined its internal processes to reduce the time for which a case is pending to 12 months. The updated SDP reiterates that the OIG demands minimum settlement levels: $50,000 for Anti-Kickback Statute violations and $10,000 for all other violations.

For a submission to satisfy the OIG's SDP, a disclosing party must take several steps:

1. Acknowledge the conduct is a potential violation by explicitly identifying the specific laws at issue.
2. Take corrective action and end the potential conduct at issue within 90 days of submission to the SDP.
3. Perform an initial investigation and damages audit within three months of acceptance by the OIG.
4. A proper disclosure includes: (a) complete information on the healthcare provider;

(b) an organizational chart, if the entity is owned or part of a network or system; (c) identification of the party's designated representative handling the claim; (d) a statement describing all relevant details of the conduct at issue; (e) the federal healthcare programs affected; (f) an estimate of the damages derived using SDP estimation methodology; (g) a description of the disclosing party's corrective action; (h) a statement regarding whether the disclosing party knows of any concurrent or pending investigation or action taken by the government in this matter, even by another department or enforcement agency; (i) the name of the party authorized to enter into a settlement agreement; and (j) certification of the truth of all disclosed information.

The guidelines also include specific methodology for estimating damages for false billing claims, claims involving the hiring of a person or entity excluded from federal programs, and claims involving allegations under the Anti-Kickback or Stark Statute.

Significantly, this process tolls the statute of limitations on related criminal or regulatory action that could result from the same behavior—meaning that while the disclosure review takes place, the statute of limitations on government prosecution is paused and cannot run out.

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CMS self-disclosure protocols

The OIG's SDP process does not allow for violations of the Stark Law that do not also contain a colorable kickback allegation. In other words, if physician self-referral is the only allegation leveled at the party, they cannot avail themselves of the favorable self-disclosure remedies available through the OIG's office.

For this reason, the Affordable Care Act, enacted on March 23, 2010, empowered the Centers for Medicare & Medicaid Services (CMS) to develop its own protocol for handling self-referred disclosures of potential Stark Law violations.[3] The Self-Referral Disclosure Protocol (SRDP) is similar in many ways to the OIG's process. CMS will engage the OIG and DOJ as needed to ensure the disclosing party's review is comprehensive and that the government's response is coordinated. Furthermore, the elements of an appropriate disclosure are nearly identical, with few material differences. CMS is explicit about the five factors under consideration in its review:

- The nature of the allegedly violating behavior;
- The timeliness of the disclosure;
- The party's cooperation during review;
- The risk of litigation; and
- The financial position of the disclosing party.

However, the SRDP differs from the OIG's process in that it is not a settlement itself, but instead results in an Advisory Opinion of recommendations for CMS penalties. This opinion may be the basis for a settlement, but CMS is not bound by its determination, and the disclosing party can appeal its decision. As a result, the CMS process may be more discretionary and, therefore, more flexible than the OIG's. There is no discussion of minimum penalties or multipliers of damages, which could indicate that the CMS has more authority to downwardly depart from precedent. On the other hand, it could indicate that the system has potential to

be more punitive. For example, there are several mentions of CCAs that suggest that CMS still relies on using those as sanctions, even against voluntary disclosures. Disclosing parties should consider these possible outcomes when choosing whether to commit to the OIG or CMS self-disclosure avenue.

Self-disclosure from the government's point of view

It is difficult to find truly revelatory statements from policymakers regarding self-disclosure and healthcare providers. One might expect the Attorney General or the Secretary of HHS to indicate more clearly the penalty discount that parties can expect from voluntary disclosure, much like occurs in the context of antitrust violations.

Here, we highlight two types of statements. The first are statements made by policymakers and analysts discussing the voluntary disclosure protocols and anti-fraud measures more generally. The second are statements made by policy and law enforcement officials in the context of publicized settlements. The latter are particularly important, as they reveal the careful efforts by many to signal to other healthcare providers what the standards of the government's settlement review may be.

Policymakers' comments

The OIG Provider Self-Disclosure Protocol, most recently updated in April 2013, describes four primary benefits of self-disclosure. First, there is "a presumption against requiring integrity agreement obligations in exchange for a release of OIG's permissive exclusion authorities in resolving an SDP matter."[4] Second, the government will use "a lower multiplier on single damages than would normally be required" in a government-initiated investigation. Ultimately, however, the OIG generally requires a minimum multiplier of 1.5 times the single damages and has the discretion to choose the exact multiplier. Third, the OIG suggests that use of the SDP "may mitigate potential exposure under section 1128J(d) of the Social Security Act, 42 U.S.C. 1320a-7k(d)," which requires the reporting and returning of overpayments 60 days after the date on which the overpayment was identified. Fourth and finally, the OIG offers the somewhat vague promise that it will commit to working with entities using the SDP, and that it expects SDP cases to be resolved in fewer than 12 months.

The government has made few other public statements encouraging self-disclosure of FCA violations in the recent past, but in 2012, Acting Assistant Attorney General Stuart F. Delery said this at the American Bar Association's Ninth National Institute on the Civil False Claims Act and Qui Tam Enforcement:

> Most defendants in FCA matters have come to recognize that there is an enormous benefit to be gained by avoiding what will likely be costly and protracted discovery, trial, and the mandatory treble damages and penalties that will be assessed if the government prevails. The more thorough and effective the job defense counsel do investigating the case and presenting their clients' views of the applicable facts and law, the more likely it is that we will find these defenses persuasive, and the more credit your clients will get from the federal government in negotiated resolutions. And, I might add, because disclosure and cooperation show a sincere interest in cleaning house—and ensuring a culture of doing the right thing—they can help companies demonstrate the necessary responsibility to continue participating in government programs and contracts. There are legal requirements, policies, and practices in place that encourage businesses to combat

> fraud on their own. For example, as many of you may know, under the False Claims Act, self-disclosure of violations can mean a reduction in potential damages—either in litigation or during settlement. So, a decision to come in promptly and work with the government to resolve any liability that may arise from past wrongdoing is more than the right litigation decision. It is a good economic decision.[5]

Settlement-related comments

By and large, prosecutors and policymakers have been reluctant to discuss the formulae by which they determine damages and penalties for FCA violations, voluntary disclosure or otherwise. However, the public statements related to some of the higher profile settlements of this kind reveal how careful the government is to signal that it values early action, cooperation, and good faith. Voluntary self-disclosure that fails to meet any of these criteria may be viewed less favorably and be subject to harsher penalties and consequences than it might have otherwise.

For example, in October of last year, the United States Attorney's Office for the Northern District of New York stated in a press release regarding the resolution of False Claims Act liability:

> Due in large part to Lourdes's decision to self-disclose these issues and its cooperation throughout the government's investigation, the hospital was required to pay far less than the treble damages and penalties that the United States is authorized to seek under the False Claims Act.... United States Attorney [Richard S.] Hartunian said: 'Today's settlement is an excellent example of how voluntary self-disclosure benefits both the integrity of healthcare programs and providers who discover and report evidence of improper billing in their organization. Lourdes should be commended for the manner in which it handled the disclosure.'[6]

A 2014 press release regarding a FCA settlement in the Northern District of Ohio included a quote that Inspector General Daniel R. Levinson was "pleased that Memorial [Hospital] stepped forward to disclose these improper financial relationships and is working to avoid future occurrences."[7]

Similarly, in a 2013 settlement press release out of the District of Utah, Derrick L. Jackson, Special Agent in Charge at the U.S. Department of Health and Human Services, Office of Inspector General in Atlanta, encouraged self-disclosure and stated:

> This case is an excellent example of collaboration between the healthcare community and the law enforcement community coming together to serve the American taxpayer. When this hospital realized it had received inappropriate Medicare payments, it brought the matter to the attention of the U.S. Attorney's Office and refunded the money to the Medicare Trust Fund. We certainly hope that other healthcare providers will do the same when they realize they have been overpaid.[8]

Another 2013 press release "applaud[ed] Intermountain [Healthcare] for recognizing their liability and coming forward to self-disclose these violations."[9]

The Middle District of Tennessee was especially effusive in a 2012 press release, in which U.S. Attorney Jerry E. Martin stated:

> Maury Regional is to be commended for the manner in which the hospital handled the disclosure of these billing issues once the issues came to light through the hospital's compliance program. After notifying

this office that the billing issues had been discovered, Maury Regional outlined its plan to determine the scope of these issues, followed through on that plan, and worked closely with us to bring this matter to resolution. Self-disclosure by providers is critical to the protection of the integrity of the federal healthcare system and this office is committed to bringing voluntary disclosures to resolution as quickly and as efficiently as is reasonably possible.[10]

Another official continued, "Maury Regional was transparent in their disclosure to the government and ultimately saved the taxpayers the cost associated with a federal investigation. OIG and the United States Attorney's Office will continue to work with healthcare providers to return substantial dollars back to Medicare."

Trends evident in recent FCA self-disclosure settlements

Government press releases may point to cases that the government thinks are particularly illustrative of the kinds of settlement process they hope to encourage with the SDP. For example, the case involving Maury Regional Hospital in Tennessee was, by insiders' accounts, amicable, cooperative, and efficient for all parties involved. The fact that the government and private parties worked together so effectively prompted this case to become a model case-study for the procedure by others. The case was also the first time a healthcare company in Tennessee self-reported violations to the False Claims Act, and its publicity may have been a result of law enforcement hoping to encourage others to follow suit.

The government has been incredibly consistent across these cases. In nearly every case, it was careful to signal that the financial penalties, no matter how large the number, were tailored more narrowly in recognition of the disclosing party's cooperation. It was particularly voluble on this count where the dollar figure imposed was in the millions.[11]

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The government has also been clear in its intention not to impose soft penalties, such as CIAs, CCAs, or other compliance measures on self-disclosing parties. CIAs typically last three to five years and require the healthcare provider to institute a corporate integrity program, which could include employee training, annual audits reported to the OIG, and new written compliance policies. In only a very few self-disclosure cases has the OIG asked the party to sign a CIA or CCA. This relieves the healthcare provider of the costs of fulfilling such agreements, which can range from tens of thousands of dollars to cover the cost of auditors to many millions of dollars, depending on the extent of the CIA.

Case study: A repeat player

Healthcare providers that have experienced settlement after both self-disclosure and after

a government-initiated investigation demonstrate potential differences in treatment, the key of which is the imposition of a CIA or CCA in the absence of self-disclosure.

In May 2000, Community Health Systems (CHS) agreed to pay $31 million to resolve allegations that it submitted false claims for reimbursement to Medicare, Medicaid, and TRICARE. CHS had disclosed four years of "upcoding" (i.e., the improper assignment of diagnostic codes to hospital inpatient discharges for the purpose of increasing reimbursement amounts) at its hospitals after the government informed CHS that it was investigating several of CHS's hospitals. In the press release announcing the settlement, Department of Health and Human Services Inspector General June Brown Gibbs remarked, "This case is a good example of the value of compliance programs and provider self-disclosure. Through its voluntary compliance program, Community Health Systems identified a Medicare billing abuse and then self-disclosed the problem to the government."[12] The settlement included a corporate compliance agreement, but as Gibbs stated, "Because of the self-disclosure, we have significantly modified the company's obligations under the corporate compliance agreement that is part of the settlement."

In August 2014, CHS again settled False Claims Act allegations with the government. This time, CHS had not participated in self-disclosure. Instead, a government investigation initiated by several *qui tam* lawsuits revealed that "from 2005 through 2010, CHS [allegedly] engaged in a deliberate corporate-driven scheme to increase inpatient admissions" of Medicare, Medicaid, and TRICARE program beneficiaries who were admitted through the Emergency Department for medically unnecessary care. In addition, Laredo Medical Center, a CHS hospital, was alleged to have submitted false claims to Medicare from 2005 through 2010 for inpatient medical procedures that should have been performed more cheaply as outpatient procedures, and to have violated the Stark Law. CHS paid $89.15 million to resolve the inpatient scheme allegations and $9 million to resolve the Laredo Medical Center allegations. It was the largest FCA settlement in the history of the Middle District of Tennessee. The press release was sternly worded and offered such admonitions as, "Put simply, these types of fraudulent practices will not be tolerated and the investigation and resolution of such claims will continue to be a high priority of this office." It continued, "Health care providers should make treatment decisions based on patients' medical needs, not profit margins. We will not allow this type of misconduct to compromise the integrity of our health care system."[13]

Moreover, the terms of the settlement required CHS to enter into a "a rigorous multi-year Corporate Integrity Agreement" with the OIG under which it is required to retain independent review organizations to review the accuracy of the company's claims for inpatient services furnished to federal healthcare program beneficiaries for five years.[14]

CHS's example could therefore demonstrate at least a few benefits to self-disclosure. The differences between these two settlements are stark. It is true that the facts of the alleged false claims differ. At a minimum, the 2014 alleged violations took place over six years as compared to four, and the alleged illegal acts were not the same. Both sets of violations, however, involved the same company, the same law, the same federal healthcare programs, and, for the most part, behavior that took place throughout the chain. The principal difference between the settlements is that the first involved self-disclosed violations and the second did not, so they are worth comparing. Although the difference between the settlements is huge—$67 million—the key measure

of a settlement is the discount the government applied to a provider's actual damages to reach a settlement amount. Because the government does not disclose those figures, however, it is impossible to compare the discount percentage between self-disclosure settlements and settlements of government-initiated investigations.

Nevertheless, CHS appears to have benefitted greatly from its self-disclosure. First, the tones of the two press releases could not be more unlike. The 2000 press release is mostly free of chastisement of the company, touts the value of self-disclosure, and is spare on detail. The 2014 press release, on the other hand, explains the company's wrongdoing and the harsh terms of the settlement in detail, quoting no less than five government officials. If the press releases are any indication of the tone of the two investigations, CHS likely had an easier time during the first investigation. Second and more importantly for our purposes, CHS's obligations under the terms of its first CIA were "significantly modified" and likely less costly and inconvenient.

Although the 2000 CIA is not available publicly, the 2014 CIA is, and the obligations contained in the CIA's 60 pages are onerous. For five years, CHS must, among other duties, maintain a compliance program; develop and distribute a written code of conduct and policies and procedures, to be updated annually; provide various trainings to employees; create procedures to ensure that new arrangements with physicians do not violate the Anti-Kickback Statute or the Stark Law; hire an independent auditor to perform numerous reviews; maintain a disclosure program for employee whistleblowers; and report any possible overpayments and FCA violations to the OIG.[15] These are fairly common in other non-self-disclosure cases. It seems likely that CHS could have avoided at least some of these burdensome obligations through self-disclosure.

Conclusion

Although the government has announced that it is predisposed to apply only the 1.5 times damages multiplier (as opposed to treble damages) to self-disclosing healthcare providers, it has not released any information that would allow parties to predict the penalties they will have to pay. Although it is impossible to determine whether the government gives any financial "discount" to self-disclosing healthcare providers, there does appear to be a "discount" for CIAs and CCAs usually imposed during FCA settlements. Self-disclosing parties can expect the potential for lesser collateral obligations, thus reducing the ultimate cost of settlement.

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10. U.S. Attorney's Office, Middle District of Tennessee, press release: "Maury Regional Hospital To Pay $3.59 Million To Settle False Claims Act Allegations." June 29, 2012. Available at http://bit.ly/18LrLpi
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14. CMS, OIG: Corporate Integrity Agreement with Community Health Systems, July 28, 2014. Available at http://1.usa.gov/1DAUHNs
15. *Id.*