Catching Flies With Vinegar: A Critique of the Centers for Medicare and Medicaid Self-Disclosure Program

Jean W Veilleux, Prof., Charlotte School of Law
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Jean Wright Veilleux, J.D., LL.M.*

Abstract
The article argues that the current approach of the Department of Health and Human Services and the Centers for Medicare and Medicaid Services (CMS) to enforcement of the Ethics in Patient Referrals Act (the “Stark Law”) is unnecessarily punitive and discourages health care providers from self-disclosing even very minor violations of the Stark Law. The article suggests a number of specific changes to encourage provider self-disclosure and proposes that CMS create a demonstration project under the authority of the Patient Protection and Affordable Care Act to test the reforms. A demonstration project provides the perfect vehicle to prove that increased self-disclosure protocols for the Stark Law can decrease the government’s costs of enforcement, improve program integrity, and encourage providers to deal responsibly with the inevitable minor lapses in compliance that arise in such an enormous government program as Medicare.

Introduction

Benjamin Franklin, that astute observer of nature and humanity, once described his approach to making difficult decisions in terms that sound quite modern. He said that when he had a difficult decision to make, “To get over [any uncertainty] . . . my way is to divide half a sheet of paper by a line into two columns; writing over the one ‘Pro,’ and the other ‘Con.’” Then

*The author is Assistant Professor of Law at the Charlotte School of Law. Prior to joining the faculty, Prof. Veilleux had a private practice specializing in health care fraud and abuse. She also served as General Counsel to Presbyterian Healthcare from 1997 to 2003.

Prof. Veilleux would like to thank Cynthia Simmons, Charlotte School of Law Class of 2012, for her diligence and insight in compiling the research for this article and Mary Susan Lucas, research librarian at the Charlotte School of Law, for her unfailing willingness to help.
. . . I put down under the different heads short hints of the different motives . . . for and against the measure . . . .”¹ Mr. Franklin further opined that other people using a similar approach are more likely to take a particular action once they see clearly how they would benefit from taking the action. Before the complexity of the formulas, graphs, and charts of modern cost-benefit analysis, Franklin summed it up quite simply: “[A] spoonful of honey will catch more flies than a gallon of vinegar.”²

This article argues that the Department of Health and Human Services (“HHS”) and its constituent agency, the Centers for Medicare and Medicaid Services (“CMS”), are using vinegar instead of honey in CMS’s current approach to enforcement of the Ethics in Patient Referrals Act of 1988, Section 1877 of the Social Security Act, commonly referred to as “the Stark Law” in honor of its author, Representative Pete Stark.³ The Stark Law prohibits physicians from referring Medicare patients for certain services to entities in which the physician has a financial interest unless an exception applies.⁴ Stark is extremely detailed and does not require the element of intent to violate the law. As a result, it is quite easy for health care providers to unwittingly run afoul of the law, leaving them liable to repay fees earned for the care of the patient, in addition to liability for civil penalties.

¹ Letter from Benjamin Franklin to Joseph Priestley (Sept. 19, 1772) (on file with Library of Congress).
² Benjamin Franklin, Poor Richard’s Almanack, 1744 (on file with Yale University Library).
³ Limitation on Certain Physician Self-Referrals (Stark Law), 42 U.S.C. § 1395nn (2010). The Stark Law and supporting regulations have been modified significantly over the years to add or expand covered designated health services and exceptions. This article refers to the laws and regulations collectively as “Stark” or “the Stark Law” unless otherwise noted.
⁴ Prohibition on Certain Referrals by Physicians (Stark Regulations), 42 C.F.R § 411.353-.389 (2010). Some of the more commonly relied upon exceptions include those for services performed personally by or under the personal supervision of the a physician in the same group practice as the referring physician; services provided ancillary to the physician’s or group’s own professional services; personal services arrangements meeting specific requirements; isolated transactions such as the sale of a practice; and fair market value compensation documented in a specific manner proscribed by the regulations.
The Patient Protection and Affordable Care Act of 2010 (“PPACA”) required CMS to develop a procedure by which health care providers could self-disclose violations of the Stark Law. The statute also explicitly gave CMS the authority to reduce the amount due for violations of self-referral law as a way to encourage providers to self-disclose violations. Congress included these provisions in PPACA in response to providers’ requests. Indeed, before the self-disclosure protocol was released, many in the health care provider community were hopeful CMS would create a protocol that would provide relief from the draconian penalties that can result from very minor infractions of the Stark Law. For example, the American Hospital Association (“AHA”) wrote a letter to HHS Secretary Kathleen Sebelius urging that HHS use the discretion given it under PPACA to “…offer providers a clear and understandable process for presenting and resolving disclosed issues—a framework that is fair; adjusts repayments to the harm, if any, to patients and the program; takes the financial condition of the provider into account; and offers reasonable certainty or predictability of outcomes.”

In September 2010, CMS released its Self-Referral Disclosure Protocol (“SRDP”), with a slightly revised version released on May 6, 2011. Unfortunately, the SRDP is so punitive and difficult to navigate that very few health care providers have made disclosures, despite specific legal requirements to do so. As will be detailed in this article, the program takes a harder line and offers less guidance or incentives to use the protocol than similar self-disclosure protocols.

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6 Id. § 6409 (to be codified at 42 U.S.C. § 1395nn note).
7 Id.
8 Letter from Rick Pollack, Executive Vice President, American Hospital Association, to Kathleen Sebelius, Secretary, Department of Health and Human Services 1, 3 (July 16, 2010), http://www.aha.org/aha/letter/2010/100716-cl-ppaca.pdf [hereinafter AHA Letter].
9 CMS VOLUNTARY SELF-REFERRAL DISCLOSURE PROTOCOL (SRDP), OMB Control Number 0938-1106 (September 23, 2010). The SRDP was revised on May, 6, 2011 and is available at http://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf [hereinafter SRDP].
such as HHS’s Office of Inspector General self-disclosure protocol for the Anti-Kickback Statute and the New York State Medicaid self-disclosure program.\textsuperscript{10}

As of July, 2011, only eighty providers have taken advantage of the SRDP.\textsuperscript{11} CMS has stated that it is pleased with the numbers to date.\textsuperscript{12} However, when those eighty disclosures are viewed in the context of the Medicare program as a whole, it is difficult to understand why CMS would be happy with those numbers. There are over 6100 hospitals and 932,700 physicians participating in the Medicare program.\textsuperscript{13} Hospitals are the focus of this discussion, as physicians are rarely prosecuted under Stark.\textsuperscript{14}

Consider the number of potential Stark issues possible at those 6100 hospitals. Even the smallest hospital has numerous contracts with physicians that create potential Stark issues.\textsuperscript{15} But assume for a moment that each hospital has a few hundred to a thousand or more such arrangements. Kevin McAnaney, a former CMS official now in private practice, has estimated that ninety-five percent of hospitals have “technical” violations of Stark arising out of their

\begin{footnotesize}
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\item Katherine A. Lauer & Robert L. Roth, Medicare Repayments and Disclosures, AM. HEALTH LAWYERS ASS’N Webinar Presentation, at 23 (June 16, 2011), http://www.healthlawyers.org/Events/Webinars/2011/Pages/MedicareRepaymentsDisclosures.aspx [hereinafter Lauer & Roth].
\item CMS DATA COMPENDIUM (2010), https://www.cms.gov/DataCompendium/14_2010_Data_Compendiump.asp#TopOfPage (follow “Providers and Suppliers” hyperlink; the select “ProvidersTableVI.1 & VI.6) (over 95% of physicians are Medicare program participants).
\item See infra § I(A).
\item CMS Postpones Hospital Reporting of Disclosure of Financial Relationships Report (DFRR), https://www.cms.gov/PhysicianSelfReferral/70_Disclosure.asp#TopOfPage (last visited July 25, 2011) [hereinafter DFRR]. DFRR, initially proposed in 2008, would have required hospitals to document and disclose to CMS all financial relationships with physicians. After multiple CMS modifications of timeline and cost estimates, DFRR reporting was delayed pending implementation of new hospital disclosure requirements under PPACA § 6001.
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arrangements with physicians.\textsuperscript{16} Mr. McAnaney does not define a technical” as opposed to a substantive violation. It is likely he is referring to a violation relating to compliance with the specifications in the regulations concerning exactly how an arrangement can comply with a Stark exception. For example, a major issue in any Stark case is always whether a payment by an entity to which a physician makes referrals, such as a hospital, can qualify as a payment at fair market value and thus fall within an exception to the Stark prohibition on payments to referral sources.\textsuperscript{17} For an arrangement to jump that hurdle, it must meet several procedural requirements, including that the arrangement be set out in a written document signed by the parties, and specifying the compensation in advance.\textsuperscript{18} Failure by one party to sign an employment agreement or allowing an agreement to lapse while continuing to honor the substantive terms of the agreement is an example of a procedural or “technical” violation.

Even if Mr. McAnaney’s estimate is largely hyperbole, it becomes clear that thousands of hospitals with thousands of physician relationships should generate many more than eighty self-disclosures of at least minor procedural violations. The former New York State Medicaid Inspector General, James Sheehan, has said that he considers the number and extent of disclosures a good outcome measure of his own agency’s effectiveness in running the New York State Medicaid self-disclosure program.\textsuperscript{19} If that measure is applied to the CMS program, it is a dismal failure.

\textsuperscript{16} OIG ‘Open Letter’ to Industry Cites Kickbacks in Self-Disclosure Protocol, 13 HEALTH CARE FRAUD REPORT (BNA) 258 (April 8, 2009) [hereinafter McAnaney].

\textsuperscript{17} 42 U.S.C. § 1395nn(h)(3). Fair market value is broadly considered to be the value of arms’ length transactions, consistent with general market value. Where applicable, fair market value also factors in the value of rental property for general commercial use, less any value for proximity or convenience as a potential source of patient referrals.

\textsuperscript{18} E.g., 42 U.S.C. § 1395nn(e)(1) (rental of office space or equipment);  § 1395nn(e)(3) (personal services arrangements).

\textsuperscript{19} James Sheehan, NY State Medicaid Inspector General, Self-Disclosures by Medicaid Providers, NY OFFICE OF MEDICAID INSPECTOR GENERAL, Webinar Presentation 1, 38 (September 14, 2010),
The fact that providers are, by and large, not choosing to self-disclose to CMS, despite the enormous penalties they face if the government discovers any overpayments they have not self-disclosed, should cause CMS to rethink the current SRDP. Providers do have other options within the government for self-disclosure of various fraud and abuse issues. These include: simple refunds to the appropriate fiscal intermediary; a self-disclosure of an issue involving the Anti-Kickback Statute to the HHS Office of the Inspector General (“OIG”); or, for the most serious matters, a report to the Department of Justice through the local Assistant U.S. Attorney. For pure Stark issues, however, CMS has stated providers should use its protocol. If providers choose not to take advantage of this opportunity to come forward voluntarily, the government fails to recover money the Medicare program is owed, costs of enforcement are unnecessarily high, and providers who might voluntarily return overpayments if the incentives were properly aligned choose instead to roll the dice and hope they do not get caught.

HHS is under tremendous pressure to recover program dollars lost to fraud. The National Health Care Anti-Fraud Association, an organization of private insurers and public agencies, conservatively estimates that some $60 billion (about 3% of total annual health care spending) is lost to fraud every year. During the congressional debate on PPACA, proponents of the bill touted fraud recovery as an important source of funding to counterbalance the costs of covering millions of new people. During fiscal year 2010, the federal government won or negotiated approximately $2.5 billion in health care fraud judgments and settlements and attained additional


See infra § II.


administrative settlements or penalties.\textsuperscript{23} In an attempt to raise that number even higher, PPACA increased the budget of the Health Care Fraud and Abuse Control Program by $10 million a year for 2011 through 2019, and increased funding for the OIG, FBI, and Medicare Integrity Program by the rate of increase in the urban Consumer Price Index over the previous year for 2011-2019.\textsuperscript{24}

However, as Professor Joan Krause pointed out in a recent article, while billions of dollars in fraud recovery may seem like a lot of money, it pales in comparison to estimates of money lost each year to fraud.\textsuperscript{25} Krause also makes the point that more resources allocated to prosecution are not necessarily going to result in increased fraud recovery.

If it were really that easy to recover hundreds of billions of dollars through anti-fraud efforts, chances are we would have made more progress by now. It is easy to blame our failure on the refusal to invest sufficient resources, or our blind adherence to outdated detection strategies. But that doesn’t account for the fact that legions of very bright, dedicated, well-intentioned policymakers and prosecutors have been doing the best they can for many years, with only limited success. Assuming that now we will be able to find the key to health care fraud enforcement—and that the recoveries will be enough to fund a large chunk of the health care reform effort—simply strains credulity.\textsuperscript{26}

While it is undoubtedly important for CMS to protect the public fisc generally and the tremendously expensive Medicare program in particular, this article argues that more provider-friendly rules and procedures would encourage health care provider self-disclosure of improper practices, thus improving the government’s recovery of health care program dollars more effectively than pouring larger and larger amounts of money into increasing enforcement efforts.

\textsuperscript{23} HHS AND DOJ HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FY 2010 (Jan. 2011) at 8.
\textsuperscript{24} PPACA, supra note 5, § 6402(i), amended by Health Care and Education Reconciliation Act of 2010, § 1303 (to be codified at 42 U.S.C. § 1395(i)(k)).
\textsuperscript{25} Joan H. Krause, Following the Money in Health Care Fraud: Reflections On a Modern-Day Yellow Brick Road, 36 AM. J.L. & MED. 343, 355 (2010) (discussing difficulties with calculating the amount of money attributed to fraud).
\textsuperscript{26} Id. at 364.
This article sets out in Section I an overview of the Stark Law, explaining how it applies to physicians, hospitals and other health care entities. Section II summarizes the SRDP requirements and process for disclosure of Stark issues, as well as results of the SRDP to date. Section III details why certain SRDP provisions make it difficult for providers to self-disclose even minor violations of Stark without paying large fines and/or risking possible exclusion from the Medicare or Medicaid program. Finally, section IV proposes a demonstration project to test possible improvements to the SRDP.

HHS has used demonstration or pilot projects in the past, and PPACA specifically directs HHS to create projects that offer the possibility of reducing Medicare and Medicaid expenditures while preserving or enhancing the quality of care provided in the programs.\textsuperscript{27} Using the demonstration project format to test changes to the SRDP in a few sample states will allow CMS to determine whether it could relax the protocol’s current requirements, making it more “provider friendly” without increased risk of abuse. If the test is successful in terms of revenue raised and increased provider compliance with the law, CMS could then revise the SRDP through the normal regulatory process. A demonstration project provides the perfect vehicle to prove that improved self-disclosure protocols for the Stark Law can decrease the government’s costs of enforcement, improve program integrity, and encourage providers to deal responsibly with the inevitable minor lapses in compliance that arise in such an enormous government program as Medicare.

I. Background on the Stark Law

A. Basic Provision

\textsuperscript{27} See PPACA, \textit{supra} note 5, § 3021(a) (to be codified at 42 U.S.C. § 1315(a))(creating the Center for Medicare and Medicaid Innovation).
The Stark Law limits a physician’s ability to refer patients for certain services to entities in which the physician or an immediate family member has a financial interest unless an exception applies.\textsuperscript{28} It was originally enacted to curb rampant Medicare program abuse by physicians and hospitals, particularly in the 1980’s. Physicians would refer patients to facilities they owned or otherwise had a financial interest in, regardless of whether patients actually needed the x-ray or medical equipment for which they were being referred.\textsuperscript{29} The purpose of the law, as its author Rep. Stark described it, was threefold: 1) assure that physicians refer patients to the highest quality provider available rather than to a provider with whom the physician has a financial relationship; 2) prevent overutilization of Medicare and Medicaid; and 3) promote legitimate competition among providers.\textsuperscript{30} Rep. Stark hoped the law would provide a “bright line rule” and “unequivocal guidance” for providers.\textsuperscript{31}

The Stark Law prohibits physician referrals to an entity for “designated health services” if the physician (or a member of the physician’s immediate family) has a “financial relationship” with that entity.\textsuperscript{32} The term “financial relationship” is defined very broadly. It includes ownership and any type of compensation.\textsuperscript{33} “Designated health services” include: lab, radiology, inpatient, and outpatient hospital services, among others.\textsuperscript{34} Stark prohibits any entity from billing government payment programs such as Medicare for services provided pursuant to a noncompliant referral during the “period of disallowance,”\textsuperscript{35} defined as starting on the date the financial relationship is first noncompliant and lasting until no later than (1) the date on which

\textsuperscript{28} 42 U.S.C. § 1395nn(b)-(e); 42 C.F.R. § 411.353(a).
\textsuperscript{30} Id.
\textsuperscript{31} Id.
\textsuperscript{32} 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. § 411.353(a).
\textsuperscript{33} 42 U.S.C. § 1395nn(a)(2); 42 C.F.R. § 411.354(a).
\textsuperscript{34} 42 U.S.C. § 1395nn(h)(6); 42 C.F.R. § 411.354(b)-(d).
\textsuperscript{35} 42 C.F.R. § 411.353(c).
the financial relationship satisfies an exception; (2) the date on which all excess compensation is returned to the party that paid it; or (3) the date on which all additional required compensation is paid to the party to which it is owed.\textsuperscript{36}

The Stark Law applies to both Medicare and Medicaid;\textsuperscript{37} however, due to hospitals’ and physicians’ particular dependence on Medicare as a source of revenue, most commentators refer to Stark only in connection with Medicare. Additionally, although the Stark Law refers to physician referrals, enforcement of the statute has generally focused on hospitals’ submissions of claims resulting from physician referral because actions against hospitals are seen as having “deeper pockets” than physicians.\textsuperscript{38} As the American Health Lawyers Association (“AHLA”) White Paper on Stark Enforcement stated, “Stark enforcement against physicians is almost nonexistent and there is little reason to believe that will change. Given this, it is not surprising the physicians often view Stark compliance as the hospital’s problem.”\textsuperscript{39} So as not to contribute to this perception, this article uses the term “provider” to include physicians, hospitals, nursing homes, laboratories, medical device manufacturers, pharmaceutical companies and any other provider of health care services to recipients of federal government health care program benefits.

B. Application of the Stark Law

Some of the common practices and arrangements that implicate Stark are: referrals within a group practice; medical director agreements; investment interests in a hospital or

\textsuperscript{36} \textit{Id.} § 411.353(c)(1)(i)-(iii) (emphasis added). Because the regulation used “no later than,” rather than “the latter of,” the regulation could be seen as extending the period of disallowance beyond the date on which the financial relationship is technically cured to the state on which any excess compensation is finally returned or money is due. \textit{See} Leslie Reynolds & Ben Koplin, \textit{Overpayment Liability and Self-Disclosure Under the New CMS Protocol}, 13 J. HEALTH CARE COMPLIANCE 23, 24 (May-June, 2011) [hereinafter Reynolds & Koplin].

\textsuperscript{37} 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. § 411.353(a).


\textsuperscript{39} \textit{Id.} at 10.
ambulatory surgical center; arrangements between physicians and other designated health service providers such as clinical laboratories, diagnostic imaging centers, physical therapy companies or durable medical equipment companies; physician part-time employment or independent contractor agreements; lease agreements for space or equipment; hospital-physician recruitment agreements; marketing agreements with entities owned by physician or hospital investors that do not reflect fair market value payments for necessary services; and practice compensation programs that reward shareholders or employee physicians based on orders of designated health services.

The reason these practices and arrangements often pass muster under the law is that Stark contains numerous exceptions, covering the most common types of financial relationships between hospitals and physicians. Among the most often used exceptions are ones for fair market value compensation, employment agreements, personal services arrangements, and office space rental. There are also numerous exceptions applicable to physicians practicing in groups, such as the exception for services personally performed by a physician. Each of these exceptions has very specific requirements and failure to meet those requirements causes a physician or hospital to run afoul of the Stark Law. For example, the employment exception requires that there be a written agreement with a term of at least one year that is signed by both parties. The agreement must set out the compensation formula, which cannot change during the term of the agreement. The compensation must be at fair market value and may not be determined in a manner that takes into account the volume or value of referrals generated by the physician.

40 42 U.S.C. § 1395nn(e)(1)-(8); 42 C.F.R. § 411.357.
41 42 U.S.C. § 1395nn(e)(7); 42 C.F.R. § 411.357(h).
42 42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(c).
An example will illustrate the interplay of these various provisions. Suppose the fictional infectious disease specialist, Dr. Gregory House of television fame, has a thriving private practice in addition to his employment at the also fictional Princeton-Plainsboro Teaching Hospital (the “Hospital”). He refers many patients to the Hospital each year for inpatient admission or for various diagnostic or treatment services. Absent an exception in the Stark Law, Dr. House’s employment relationship with the Hospital would “taint” his referrals to the Hospital. However, there is a Stark exception for written employment agreements signed by both parties, with a term of at least one year and compensation paid at fair market value.\textsuperscript{43} As long as the Hospital and Dr. Stark meet all the technical requirements of the exception, Dr. House can refer to the Hospital without any Stark issues.

C. Stark and Intent

The Stark Law overlaps significantly the criminal Anti-Kickback Statute\textsuperscript{44} ("Anti-Kickback Statute"), which prohibits the \textit{knowing} offering of any remuneration in order to secure referrals to federal health care programs, including Medicare.\textsuperscript{45} Similar to Stark, the Anti-Kickback Statute was aimed at financial relationships that potentially influenced physicians to refer patients inappropriately for their own financial gain.\textsuperscript{46} So why was Stark necessary? Rep. Stark described it this way.

Perhaps the most serious shortcoming of [the Anti-Anti-Kickback Statute] is the enormous difficulty involved in proving to the satisfaction of a judge in a criminal or civil enforcement action that a particular arrangement is deliberately structured to induce referrals. A successful prosecution requires a lengthy investigation of the business records to prove unequivocally that dividend payments to physicians were intended as disguised payment of a referral fee. The enforcement resources simply aren’t there. There is no way that the Inspector General—with fewer than 500 investigators

\textsuperscript{43} \textit{Id.}
\textsuperscript{44} Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (2010).
\textsuperscript{45} \textit{Id.}
nationwide, can adequately police the complex business arrangements that underpin the $100 billion a year Medicare program.\textsuperscript{47}

While the lack of any intent requirement certainly achieves Rep. Stark’s goal of making a Stark violation easier to prove than a violation of the Anti-Kickback Statute, it also has the effect of making it very easy for providers to unintentionally or even unknowingly run afoul of the statute. In fact, it is so easy that the Stark Law is often referred to as a “strict liability” statute.\textsuperscript{48} To extend upon the example above, if Dr. House forgot to sign the employment contract between himself and the Hospital, any referrals he made to the Hospital would be improper, regardless of whether the failure to sign was a mere oversight. This would be true even if the Hospital signed the agreement, paid Dr. House according to its terms and at fair market value as required by the Stark Law, and made sure that Dr. House performed the duties set out in the contract. Dr. House and the Hospital would also be liable for Stark violations if both parties had properly signed the agreement but its initial term had lapsed and the parties inadvertently failed to renew the agreement but continued to perform according to its terms.

The lack of an intent requirement and the complexity of the law have caused Stark to be criticized as inflexible and excessively punitive almost since its passage.\textsuperscript{49} Numerous amendments and HHS regulatory changes have only made the Stark Law more difficult for providers to interpret and follow.\textsuperscript{50} The American Hospital Association (“AHA”) recently described the Stark Laws as “…increasingly complex, confusing and continually changing.…”\textsuperscript{51}

\textsuperscript{47} Id.
\textsuperscript{48} Richard Lower & Robert D. Stone, Off With Their Heads! Summary Execution For Technical Stark Violations – and a Proposal To Commute the Sentence, 3 J. HEALTH & LIFE SCI. L. 112, 147 (discussing the strict liability nature of Stark violations despite no intent and no harm brought to patients or the public) [hereinafter Lower & Stone]; Reynolds & Koplin, supra note 34, at 24 (no showing of intent required under Stark).
\textsuperscript{50} White Paper, supra note 36, at 6.
\textsuperscript{51} AHA Letter, supra note 8, at 1.
The AHA had originally supported the Stark Law when it was introduced by Rep. Stark, but as CMS was preparing to release the SRDP, AHA asked CMS for changes and clarifications in the proposed protocol because AHA had seen the “unintended consequences of the current rules” and wanted CMS to “restore fairness” to the law.52

D. Penalties under Stark

If the penalties under Stark were inconsequential, the strict liability aspect of the law would not be very significant. As it is, however, Stark can, in the words of a former government official, result in “ruinous liability.”53 Penalties include: denial of payment of claims submitted as a result of a relationship that violates the Law,54 refunds of amounts collected in violation,55 and fines assessed by the Office of the Inspector General of HHS (“OIG”).56 The total penalty amounts in Stark cases are often in the millions of dollars.57

If providers exhibit intent to violate Stark, they can be liable for additional fines through the application of civil monetary penalties (“CMPs”). HHS has the authority to impose these administrative penalties of up to $15,000 for each bill or claim, depending on the specifics of the offense, and up to $100,000 for each arrangement or scheme which the physician or entity knows or should know has a principal purpose of assuring referrals which, if directly made, would be in violation of the Law.58 Providers may also be excluded from participation in federal health care

52 Id. at 3.
54 42 U.S.C. § 1395nn(g)(1); 42 C.F.R. § 411.353(b).
55 42 U.S.C. § 1395nn(g)(2); 42 C.F.R. § 411.353(d).
56 Civil Monetary Penalties, 42 U.S.C. § 1320a-7 (2010); 42 C.F.R. § 1003.102(b) (2010). A CMP is an administrative remedy that gives providers very limited rights to review in the courts.
57 See, e.g., Dept. of Justice press release, Aug. 25, 2009 (Covenant Medical Center settlement of $4.5 million); Dept. of Justice press release, Oct. 20, 2006 (Northside Hospital settlement of $5.72 million); Dept. of Justice press release Nov. 9, 2010 (St. Joseph’s Hospital settlement of $22.5 million on Stark, Anti-Kickback and False Claims grounds).
58 Id.
programs. The effect of exclusion is that no items or services furnished by an excluded person are reimbursable under federal healthcare programs. Furthermore, other providers may not employ or contract with excluded providers.\textsuperscript{59} PPACA extended possible liability under the CMPs to a person who “knows of an overpayment . . . [and] . . . does not report and return the overpayment . . . .”\textsuperscript{60}

A Stark violation can also trigger the application of the False Claims Act (“FCA”). The FCA is not specifically a health care statute. The statute prohibits the knowing submission of “false or fraudulent” claims for payment to the federal government.\textsuperscript{61} Violations of the FCA are punishable by up to treble damages and an $11,500 per claim penalty.\textsuperscript{62} Prior to the 2009 passage of the Fraud Enforcement and Recovery Act (“FERA”), the government could allege that a Stark violation triggered the application of the FCA if a provider submitted claims for payment that had arisen out of an illegal financial relationship under Stark. The FCA stated that any person who “knowingly makes, uses or caused to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the US government” had violated the FCA.\textsuperscript{63} Providers had to engage in an affirmative act intended to avoid or conceal the obligation to repay.\textsuperscript{64}

With the passage of FERA, providers became liable not only for affirmative acts that conceal overpayments but also for the failure to repay an identified overpayment.\textsuperscript{65} No attempt to conceal is required. Simply avoiding the obligation to repay under a “knew or should have

\textsuperscript{59} 64 Fed. Reg. 52,791 (Sept. 30, 1999).
\textsuperscript{60}  PPACA, supra note 5, § 6402(d) (to be codified at 42 U.S.C. § 1320a-7a(a)).
\textsuperscript{62}  Id. § 3729(a)(1), (b)(2).
known” standard is enough to trigger the FCA. “Any person who …knowingly makes, uses or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government…” has violated the FCA.66

In addition to creating an affirmative obligation for providers to “report and return” overpayments, PPACA made another significant change in the FCA. It established a sixty day window within which an “identified” overpayment must be reported and returned to the government.67 The deadline is measured by the date on which the claim is submitted or that on which any corresponding cost report is due, whichever is later.68 Prior to PPACA, HHS regulations had used sixty days as the definition of a “prompt refund” required for proper handling of incorrect collections.69 PPACA applied that time limit to the FCA.

E. Qui Tam Actions and the Stark Law

The FCA rewards whistleblowers who report suspected violations of the FCA to the government. These whistleblowers can file suit as a “qui tam” relator. If the government decides to intervene in the qui tam action and ultimately settles for a cash settlement or prevails in court, the qui tam relator can receive up to one-third of the government’s recovery as a reward for alerting the government to the false claims.70 Qui tam relators have every incentive to push for prosecution of even the most minor Stark violation. They lack the mitigating policy concerns

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66 Id.
67 PPACA, supra note 5, § 6402(a) (to be codified at 42 U.S.C. § 1320a-7(k)(d)(2)).
68 Id.
that normally encourage prosecutors to exercise their discretion in situations where the
government has not truly been harmed by an inadvertent violation.\footnote{See Joan H. Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 203 (Fall, 2001) (discussing concerns that prosecutorial discretion is undermined when the DOJ is forced to allocate significant resources to reviewing numerous qui tam filings); cf. Dayna Bowen Matthew, *The Moral Hazard Problem With Privatization Of Public Enforcement: The Case Of Pharmaceutical Fraud*, 40 U. MICH. J.L. REFORM 281, 297-98 (Winter 2007) (recognizing prosecutorial discretion is minimized by qui tam filings, though the Government may have economic incentive to allow them to proceed to litigation) [hereinafter Matthew].}

Most Stark-related legal action arises in the form of suits by *qui tam* relators rather than prosecutors.\footnote{White Paper, supra note 36, at 3.} Between 1986 and 2008, sixty-two percent of FCA cases were initiated and filed by *qui tam* relators.\footnote{Robert T. Rhoad & Matthew F. Fornataro, *A Gathering Storm: The New False Claims Act Amendments and Their Impact On Healthcare Fraud Enforcement*, 21 No. 6 HEALTH LAW 14, 16 (Aug. 2009) (discussing the use of False Claims Act *qui tam* cases in healthcare fraud enforcement).} These relators have no incentive to take a provider’s record of overall compliance with Medicare’s intent into consideration and every incentive to get the penalties as high as possible. Other authors have discussed at length the fact that the heavy role of *qui tam* relators in health care fraud cases has led to a situation where much Stark enforcement is not based on governmental assessments of the seriousness of an offense or even a prioritization of prosecutorial resources.\footnote{See Lower & Stone, supra note 46, at 122-25; see also Matthew, supra note 68, at 297-98 (although this article discusses FCA *qui tam* enforcement, the author’s premise is likely applicable to the increased role of *qui tam* relators in health care fraud generally).}

The linkage of Stark and the FCA provides most of the teeth for Stark enforcement. Consider our example involving Dr. House and his unsigned or lapsed employment agreement. Assume the unsigned or signed but lapsed agreement was not discovered for several years after the omission occurred. All claims Dr. House or the Hospital made to government payers such as Medicare for services provided by either party over the year in which the agreement was in place are overpayments. This is true regardless of whether the patients needed the services or the services were provided appropriately. Even if the Hospital was not aware of the oversight, the
strict liability aspect of Stark means that, under the Stark Law, the Hospital and Dr. House are now liable for repayment of all the claims made for care of patients Dr. House admitted to the hospital or otherwise referred there for services.

In addition, the Hospital and Dr. House are liable for penalties under the CMPs and FCA if they become aware of the overpayments and do not repay them within sixty days. These penalties generally consist of a per-claim penalty of $11,500 plus two to three times the amount of the overpayment (the total value of referrals made in the case of a Stark violation).75 Depending on how many referrals Dr. House has sent to the Hospital during the applicable time period, the amount of the potential penalties could add up to millions of dollars - all for a lapsed agreement with no harm to the government or patients.

It is important to note that due to the strict liability nature of Stark, with the exception of penalties requiring actual or constructive knowledge, most of the penalties that could be assessed against a provider in a situation such as the one involving Dr. House would be identical to the penalties in a situation in which Dr. House and the Hospital entered into a covert scheme to pay the physician kickbacks for referring patients to the Hospital. The obligation to return overpayments resulting from a relationship that violated Stark would be the same in both situations. If the government took the position that the providers had “identified” the overpayments and failed to return them, the additional penalties possible under the CMP statute and FCA penalties for failure to return those when discovered would also be the same.76 To add to Dr. House and the Hospital’s woes, a disgruntled clerk who learns of Dr. House’s failure to sign the agreement can also pursue a *qui tam* action against Dr. House and the Hospital.

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76 42 U.S.C. § 1395nn(g)(4). A Stark CMP of up to $100,000 per arrangement may be assessed against a physician or entity for participation in an “arrangement or scheme” which the party knows or should know has the principle purpose of securing referrals.
The stringent penalties possible under Stark are exacerbated by the possibility that *qui tam* relators can use the facts revealed by providers in self-disclosures to the government as the basis for their *qui tam* action. Providers may actually be giving *qui tam* relators ammunition against them when the providers voluntarily step forward to acknowledge violations of the law that would have otherwise been unknown to the relators or the government. The FCA generally bars private parties from bringing *qui tam* suits based on the public disclosure of allegations or transactions in a criminal, civil or administration hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media.\(^{77}\) Some courts have taken the position that voluntary disclosures made to the government on a party’s own initiative rather than in response to a government inquiry do not constitute a “public disclosure.” For example, in *United States ex rel. Liotine v. CDW Gov’t Inc.*, the court determined the Plaintiff’s *qui tam* allegation was not “publically disclosed” by the Defendant’s voluntary disclosure of similar information to the government, when that information was uncovered by the Defendant’s internal audit and not as a result of an audit “instigated or undertaken by an authorized government official with an official purpose.”\(^{78}\) Other courts have held that voluntary disclosure does bar an FCA *qui tam* action. For example, a district court in *United States ex rel. Cosens v. Yale-New Haven Hosp.* held that statements to Medicare investigators were a “public disclosure.”\(^{79}\) Although this question is beyond the scope of this article, these cases suffice to illustrate the point that providers have reason to be concerned that their voluntary disclosures may be used against them by *qui tam* plaintiffs.


\(^{78}\) *United States ex rel. Liotine v. CDW Gov’t Inc.*, No. 05-33-DRH, 2009 WL 3156704, at *7 (S.D.Ill. Sept. 29, 2009); see also *United States ex. rel. Rost v. Pfizer Inc.*, 507 F. 3d 720, 730 (1st Cir. 2007) (rejecting the notion that voluntary disclosure to the government can constitute a public disclosure).

F. “Technical” v. “Substantive” Stark Issues

As noted earlier, Rep. Stark’s purpose in enacting Stark was to target intentional activity without having to saddle administrative agencies with the difficulties of proving intent. While it makes sense to relax the standard of proof in order to assure that providers cannot easily avoid the purpose of the statute, if the statute is blindly applied without any consideration for proportionality between the violation and punishment, the public policy rationale behind the statute may be undermined. This problem is especially acute in situations of so-called “technical” violations of Stark. Providers contend that these “technical” violations should be treated differently from substantive violations, both in terms of the process the government uses to resolve overpayment issues and the penalties assessed.

Kevin McAnaney, Chief of the OIG’s Industry Guidance Branch from its creation in 1997 until May 2003, stated recently that most of the issues under Stark are technical violations. “The Stark statute is so potentially unfair—the rules have gotten increasingly more technical and penalties are draconian—and even though CMS has never gone after hospitals, the potential liability is a Damocles sword over them.” 80 Mr. McAnaney’s sentiments were echoed in the AHLA White Paper on the Stark Law, based on two Convener Sessions held on April 24, 2009 and June 30, 2009. 81 The participants in the sessions included in-house counsel to health care providers, academics, attorneys in firms representing providers and qui tam relators, and former government attorneys. Attorneys currently serving the government observed but did not participate in the sessions. The White Paper concluded that “innocent or highly technical

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80 McAnaney, supra note 16; see also AHA Letter, supra note 8, at 3 (Stark’s increased complexities make it difficult for compliance by even the best intentioned providers, leaving open the possibility of disproportionately large liability in relation to the conduct giving rise to the violation).
81 AHA Letter, supra note 8.
violations [of the Stark law] can result in ruinous liability” and “technical violations that cause no harm to the federal program can trigger huge penalties.”82

Two practitioners recently noted that, because of the Stark law, the health care industry is in a particularly difficult situation when simple mistakes are made.

Such mistakes occur in every corner of every industry of a modern, fast-paced economy. But in every other industry, the law provides the parties with options to resolve compliance problems uncovered from their internal reviews—to execute contract amendments or new contracts with retroactive effective dates, to enter into repayment arrangements, or to reform their contracts based on the doctrines of mutual mistake or course of dealing. If they uncover minor compliance violations, they have a means of fixing them and putting them to rest. This is not the case for healthcare providers trapped by the highly technical requirements of the Stark law.83

In 2007, CMS seemed on the verge of recognizing that some types of Stark violations are less serious than others. Proposed regulations published in 2007 created new criteria by which providers could satisfy Stark exceptions in situations where the failure to satisfy the exception was merely “procedural.”84 The proposed regulations stated that a relationship would be deemed to have met an exception regarding financial arrangements if: (1) the facts and circumstances of the relationship were self-disclosed to CMS; (2) CMS determined the relationship satisfied all but the prescribed procedural requirements of the exception; (3) the failure to meet the procedural requirement was inadvertent; (4) no referrals or claims were made by parties to an arrangement knowing of the non-compliance; (5) the relationship was brought into compliance as soon as possible after discovery of the non-compliance; (6) the relationship did not pose a risk of program or patient abuse; (7) no more than a yet-to-be determined period of time passed since the period of the original non-compliance; and (8) the relationship involved

82 Id. at 3, 6, 10-11, 16.
83 Lower & Stone, supra note 46, at 118 n.8 (discussing the CMS position that state law contract doctrines are not available to remedy technical violations of Stark, citing 73 Fed. Reg. 48434, 48703 (Aug. 19, 2008)).
was not subject to an on-going federal investigation or proceeding. CMS specified that the alternative method was not intended to be used in situations where there was a question of whether the compensation was at fair market value, not related to volume or value of referrals or set in advance. This alternative method of meeting an exception was to be reserved for procedural issues such as a missing signature or an expired agreement still being followed by the parties.

CMS received thousands of comments about the proposed regulation. While most of the comments applauded CMS’s goal of setting aside non-substantive violations, many were skeptical of the regulations’ approach. They expressed concern about the amount of discretion CMS would have under the proposal to assess a provider’s motivation. CMS had specified that it retained sole discretion to determine whether the relationship met the terms of the exception. Parties had no right to an administrative or judicial review.

Rather than decrease the scope of the agency’s discretion in response to these concerns, CMS chose instead to greatly narrow the scope of the exception. The final exception that resulted was limited to situations in which providers comply with all Stark requirements other than the signature requirement, and only for very limited time periods. In its final rule, CMS elected not to adopt most of the eight criteria originally proposed, including the requirements that parties self-disclose a non-compliant relationship and that CMS determine the relationship satisfactory in all areas but the procedural criteria. Instead, CMS chose to allow providers to

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85 Id.
86 Id.
87 Id. Consideration of an alternative method of Stark compliance for these types of technical violations has been supported by a number of providers, their counsel, and interest groups. See infra § V(D).
89 72 Fed. Reg. at 38185.
90 73 Fed. Reg. at 48706.
take advantage of the alternative policy for compliance only when the relationship in question fulfills all criteria of an exception except for the signature requirement.91

Unfortunately, those limitations are so narrow that they make the exception practically irrelevant for most providers. The real problem for a provider is a lapsed agreement or a missing signature that goes undiscovered for years, racking up huge possible CMP and FCA penalties. Some have argued for a new Stark exception for procedural violations as a means of mitigating Stark’s harshness in this regard,92 but CMS does not seem to be considering any such exception.

G. CMS’s Authority to Settle Cases

Prior to the enactment of PPACA, CMS had little or no authority to compromise or waive any claims liability for Stark or other statutes.93 Thus, the usual “prosecutorial discretion” was not available. OIG, by contrast, did not have this limitation. When OIG announced it would no longer take Stark only disclosures so that it could focus on criminal activity under other statutes, providers lost their best avenue for negotiating settlements. However, as noted above, this situation was remedied by PPACA’s explicit grant of authority to CMS to compromise penalty amounts in Stark cases,94 creating significant opportunities for improving the administration of the Stark Law, as will be discussed below.95

II. The Self-Disclosure Protocol

A. Providers’ Legal Obligation to Self-Disclose

When providers discover a Stark violation that has resulted in overpayments as defined by FERA and the FCA, the clock begins ticking on the provider’s obligation to report and return

91 Id. at 48706.
92 See Lower & Stone, supra note 46 (proposing a Technical Deficiency Exception to Stark; White Paper, supra note 36, at 15 (suggesting a Technical Violation Exception).
93 Prior to PPACA, 42 CFR § 405.376 did not include Stark claims among those that could be compromised by CMS.
94 PPACA, supra note 5, § 6409(b) (to be codified at 42. U.S.C. § 1395nn note).
95 See infra § III.
the overpayment to the government within sixty days.\textsuperscript{96} An overpayment retained past the deadline is an “obligation” for purposes of the reverse false claims provision of the False Claims Act.\textsuperscript{97} Self-disclosure under SRDP tolls the sixty day requirement.\textsuperscript{98} Also, the provider may be eligible for a potential reduction in penalties if the overpayment is self-reported rather than discovered by the government in some other manner.\textsuperscript{99}

A protocol had been in place since 1998 for self-disclosure of Anti-Kickback Statute or mixed Anti-Kickback Statute and Stark issues.\textsuperscript{100} The OIG SDP is based on a Department of Defense self-disclosure program from the 1980’s. It requires that the provider describe the problem, including the scope and results of its internal investigation into the issue, an assessment of the issue’s financial impact on government health programs, and an explanation of the likely cause of the problem.\textsuperscript{101} The SDP is administered by the HHS OIG’s office, which has jurisdiction over the Anti-Kickback Statute.

Originally, providers were expected to report Stark violations using the OIG SDP. However, in 2009, due to the large volume of disclosures it was receiving and its limited resources to process the disclosures, the OIG decided to focus on the more serious Anti-Kickback Statute situations and stop accepting disclosures of “Stark only” violations.\textsuperscript{102} The PPACA provision requiring CMS to develop a protocol was the Congressional response to providers’ complaints about the lack of good options for Stark-only self-disclosures.

B. Self-Referral Disclosure Protocol Basics

\textsuperscript{96} \textit{PPACA}, supra note 5, § 6402(a) (to be codified at 42 U.S.C. § 1320a-7k(d)(2)).
\textsuperscript{97} 42 U.S.C. § 3729(b)(3).
\textsuperscript{98} \textit{SRDP}, supra note 9, at 1.
\textsuperscript{99} \textit{Id.}
\textsuperscript{101} \textit{Id.}
The SRDP provides that the disclosure must identify the disclosing provider\(^{103}\) and describe the issue being disclosed, including: the type of transaction or conduct giving rise to the issue; entities and/or individuals believed to be implicated and an explanation of their roles; financial relationship(s) involved, including specific periods during which the provider may have been out of compliance; any applicable date(s) by which the conduct was cured; and any type of designated health service claims involved.\(^{104}\)

The disclosure must also include a complete legal analysis as to why the disclosing party believes a violation of the Stark law may have occurred, the application of Stark to the conduct, including any exceptions that may apply to the conduct; a description of the potential causes of the incident;\(^{105}\) the circumstances surrounding the discovery of the matter and measures taken to address the issue and prevent future abuses;\(^{106}\) and a statement concerning any history of similar conduct, or any prior criminal, civil and regulatory enforcement actions against the disclosing provider.\(^{107}\)

The provider must describe the existence and adequacy of a pre-existing compliance program and all actions taken by the disclosing provider to prevent a recurrence of the incident or practice, including any measures taken to restructure the non-compliant relationship or arrangement;\(^{108}\) as well as describe any and all other Federal health care program investigations the provider may currently be under, including any other disclosures made by the provider to other Government entities.\(^{109}\)

The provider must also set out a full financial analysis, including: a total amount, itemized by year, that is actually or potentially owing, back to the start of the “look back period,” which CMS defines as the date of the initial non-compliance;\(^{110}\) along with the methodology used to calculate the amount

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\(^{103}\) SRDP, supra note 9, at 3.
\(^{104}\) Id.
\(^{105}\) Id. at 4.
\(^{106}\) Id.
\(^{107}\) Id.
\(^{108}\) Id.
\(^{109}\) Id.
\(^{110}\) Id. at 5.
actually or potentially due or owing and an explanation of any estimates used.\textsuperscript{111} The SRDP requires the provider include in the financial analysis the total amount of remuneration the physician(s) received as a result of an actual or potential violation, based on the applicable “look back period”.\textsuperscript{112} Finally, the provider must include a certification of the truthfulness of the information, based on a good faith effort to resolve disclosed potential liabilities as they relate to Stark.\textsuperscript{113}

After receiving the disclosure, CMS will verify the facts asserted in the disclosure.\textsuperscript{114} The extent of CMS’s verification effort will depend, in large part, upon the quality and thoroughness of the submission received.\textsuperscript{115} Matters uncovered during the verification process, which are outside the scope of the matter disclosed to CMS, may be treated as new matters outside the scope of the SRDP.\textsuperscript{116}

In the normal course of verification, CMS will not request production of written communications subject to the attorney-client privilege.\textsuperscript{117} If there are documents that may be covered by the attorney work product doctrine, but which CMS believes are critical to resolving the disclosure, CMS says it is prepared to work with the disclosing party’s counsel to gain access to the underlying information without the need to waive an appropriately asserted claim of privilege.\textsuperscript{118} CMS’s receipt of the submission will trigger the tolling of the sixty day repayment period, pending settlement, withdrawal, or removal from the SRDP.\textsuperscript{119}

Before any repayment is made, the disclosing party must acknowledge in writing that the acceptance of such a payment by CMS does not constitute the Government’s agreement as to the amount of losses suffered by the programs as a result of the disclosed matter, and does not

\textsuperscript{111} Id.
\textsuperscript{112} Id.
\textsuperscript{113} Id.
\textsuperscript{114} Id. at 5-6.
\textsuperscript{115} Id. at 5.
\textsuperscript{116} Id.
\textsuperscript{117} Id.
\textsuperscript{118} Id.
\textsuperscript{119} Id.
relieve the disclosing party of any criminal, civil, or civil monetary penalty, nor does it offer a
defense to any further administrative, civil, or criminal actions against the disclosing party.\textsuperscript{120}

The disclosing party’s good faith cooperation throughout the entire process is essential.\textsuperscript{121} CMS expects to receive documents and materials from the disclosing provider without the need to resort to compulsory methods.\textsuperscript{122} Any lack of good faith or cooperation on the party of the provider will be considered when CMS assesses the appropriate resolution of the matter.\textsuperscript{123} The intentional submission of false or otherwise untruthful information or the intentional omission of relevant information will be referred to DOJ or other appropriate Federal agencies and may result in additional criminal and/or civil sanctions, as well as exclusion from participation in Federal health care programs.\textsuperscript{124}

CMS is not bound by any conclusions made by the disclosing party under this protocol.\textsuperscript{125} Furthermore, it is not obligated to resolve the matter disclosed in any particular manner and has no obligation to reduce any amounts due and owing.\textsuperscript{126} No appeal rights attach to claims relating to the disclosed conduct if resolved through a settlement agreement.\textsuperscript{127} If a provider is denied acceptance, is removed, or withdraws from the SRDP, the provider may appeal any overpayment demand letter.\textsuperscript{128} However, CMS reserves the right to reopen a hospital’s previously filed Medicare cost report relating to the provider’s operations from the date of its initial disclosure to CMS.\textsuperscript{129}

C. Revisions of the SRDP

\textsuperscript{120} \textit{Id.} at 5-6.
\textsuperscript{121} \textit{Id.} at 6.
\textsuperscript{122} \textit{Id.}
\textsuperscript{123} \textit{Id.}
\textsuperscript{124} \textit{Id.}
\textsuperscript{125} \textit{Id.}
\textsuperscript{126} \textit{Id.}
\textsuperscript{127} \textit{Id.}
\textsuperscript{128} \textit{Id.}
\textsuperscript{129} \textit{Id.}
After the initial release of the SRDP, CMS appears to have received informal comments from providers and their counsel regarding unclear provisions. Agency representatives have informally commented that they have learned about some items that needed clarification after reviewing the first submissions under the protocol.\textsuperscript{130} In May, 2011, CMS released the latest version of the SRDP. This version specified that all physician charges related to a noncompliant arrangement needed to be calculated as part of the disclosing provider’s financial analysis.\textsuperscript{131} More recently, Lewis Morris, Chief Counsel to the Inspector General of HHS, announced that the agency is preparing to release additional guidance regarding self-disclosure, although the agency has not announced specifically what the guidance will cover.\textsuperscript{132} However, there is no indication that CMS is considering the type of significant changes in the SRDP proposed in this article.

D. Results of the SRDP to Date

PPACA included a provision requiring CMS to report back to Congress on the number of disclosures made under the SRDP, the amount collected, and the types of violations. The deadline for the full report is March, 2012.\textsuperscript{133} The report will include the number of health care providers or suppliers making disclosures, the amounts collected, and the types of violations reported.\textsuperscript{134} CMS representatives have described some of the disclosures to date in very general terms but CMS has not issued any summaries in writing.\textsuperscript{135} OIG’s website offers some detail on


\textsuperscript{131} SRDP, supra note 9, at 5.

\textsuperscript{132} Gregg Blesch, \textit{Lawyer Warns On Overpayment Disclosures}, \textit{Healthcare Business News}, June 27, 2011, HTTP://WWW.MODERNHEALTHCARE.COM/ARTICLE/20110627/NEWS/306279945/ [hereinafter Blesch]. Mr. Morris was co-addressing a meeting of in-house counsel assembled for the American Health Lawyers Association annual meeting with Robert Homchick, partner, Davis Wright Tremaine LLP.

\textsuperscript{133} PPACA, supra note 5, § 6409(c) (to be codified 42 U.S.C. § 1395nn note).

\textsuperscript{134} Id.

\textsuperscript{135} Kass & Paddock, supra note12 (discussing Saints Medical Center settlement).
its settlements, such as the general nature of the issue and the amount of the settlement.\textsuperscript{136} Presumably, CMS’s upcoming report to Congress will include similar information.

Recently, one hospital that had self-disclosed to CMS prior to the release of the SRDP announced that it had settled on favorable terms, although it would not release the details of the settlement.\textsuperscript{137} That case involved Saints Medical Center in Lowell, Massachusetts (“Saints”). The settlement was for $579,000, an amount Saints’ press release said was lower than the hospitals’ attorneys’ lowest estimate of potential obligation.\textsuperscript{138} Attorneys for the hospital said that they had not been given the opportunity to negotiate the settlement at all; nonetheless, they were pleased with the amount in light of potential penalties.\textsuperscript{139}

\section*{III. The Honey and the Vinegar: Incentives and Disincentives to Disclosure in the SRDP}

\textbf{A. Importance of Incentives in a Decision to Disclose}

CMS’s position on the SRDP seems to be that since the law requires self-disclosure, the agency does not need the “honey” of positive incentives to self-disclose.\textsuperscript{140} However, very low numbers of disclosures to date as compared to the large number of potential issues that should be disclosed\textsuperscript{141} indicate that a legal requirement to disclose is not enough to make providers do the right thing. Most providers will not state for the record whether and if so, why, they have decided not to disclose issues which they are legally required to disclose. Some attorneys report

\begin{itemize}
\item \textsuperscript{136}\textsuperscript{136} OIG, HHS, \textit{SELECTED PROVIDER SELF-DISCLOSURE SETTLEMENTS}, http://www.oig.hhs.gov/fraud/enforcement/cmp/self_disclosure.asp (last visited July 31, 2011).
\item \textsuperscript{138} Id.
\item \textsuperscript{139} \textit{Kass & Paddock, supra} note 12 (discussion of Saints Medical disclosure by Saints’ attorney Christine Savage, Choate Hall & Stewart).
\item \textsuperscript{140} Interview by Gregg Blesch, News Editor, Modern Healthcare, with Lewis Morris, Chief Counsel to the Inspector General of HHS, in Boston, Mass. (June 27, 2011), http://www.modernhealthcare.com/article/20110627/VIDEO/306279890. Mr. Morris comments on PPACA, specifying that the law provides an “affirmative statutory obligation to repay money that does not belong to the provider.”
\item \textsuperscript{141} \textit{See supra} Introduction.
\end{itemize}
that their provider clients are waiting to see how CMS administers the protocol before they
decide whether to use it.\textsuperscript{142} In other cases, providers simply do not believe that the benefits of
disclosure outweigh the risks. Attorneys report that their clients “…tend to lean toward crossing
their fingers and hoping no one finds out rather than opening their books to the government and
inviting a certain financial consequence in exchange for possible leniency.”\textsuperscript{143}

We can gain some insight into the reasoning of these providers by analyzing data and
comments by health care attorneys responding to an American Health Lawyers’ Association
(“AHLA”) survey on self-disclosure in 2008 about the attorneys’ experiences with the OIG self-
disclosure protocol.\textsuperscript{144} Although the survey deals with a different protocol and predates
PPACA’s requirement to self-disclose violations, it offers some helpful glimpses into the
advantages and disadvantages of self-disclosure from the provider’s perspective.

The survey asked AHLA members to describe their experience with the then-new OIG
SDP.\textsuperscript{145} One hundred ninety-five attorneys responded. Most of the disclosures related to billing
or coding errors, but twenty-eight percent related to either Anti-Kickback or Stark law
disclosures.\textsuperscript{146} In approximately forty-six percent of the cases in which respondents self-
disclosed, the government settled for a simple repayment of the overpayment in question.\textsuperscript{147} In
eighteen percent, the government negotiated a settled with interest, while in twenty-two percent

\textsuperscript{142} Lauer & Roth, supra note 11; see Christ et al., supra note 105, at 5 (concluding that given uncertainty regarding
a number of SRDP provisions, some providers may elect to wait before evaluating the merits of the protocol until
after CMS responds to initial disclosures in its March 2012 report to Congress).

\textsuperscript{143} Blesch, supra note 136 (comments by Robert Homchick).

\textsuperscript{144} Fraud & Abuse Practice Group, AHLA, 2007-2008 Voluntary Disclosure Survey (June 17, 2008),
results) [hereinafter AHLA Survey].

\textsuperscript{145} Id.

\textsuperscript{146} Id. § 2.

\textsuperscript{147} Id. § 6.
of the cases the case was negotiated without interest.\textsuperscript{148} Six percent involved some type of regulatory penalty, while seven percent resulted in a civil monetary penalty or other administrative monetary sanction for individuals or the company.\textsuperscript{149} In eight percent of the cases, there was an FCA settlement with a multiplier of the overpayment.\textsuperscript{150} Twelve percent of the cases resulted in a corporate integrity agreement.\textsuperscript{151}

The survey did not ask what factors were most important in persuading a provider to self-disclose. However, responses to the open-ended response section of the survey provided candid comments on the advantages and disadvantages of disclosure from the provider’s point of view and the thought process of providers about self-disclosure. For example, one attorney said, “My clients have consistently chosen not to make voluntary disclosures.”\textsuperscript{152} Another stated that, “In the few instances where voluntary disclosure was discussed with the client, the decision was made not to voluntarily disclose because the medical practice did not have all of its compliance ducks in a row and was worried about what else the government might uncover if they came onsite to investigate.”\textsuperscript{153} One respondent cautioned, “The FI’s (fiscal intermediary’s) fraud unit and the OIG eventually got involved and demonstrated a real inability to understand the provider’s side of the issue. Eventually, the AUSA and OIG forced an interest payment that was absolutely incorrect and unjust, on top of a two times False Claims Act settlement. The entire experience removed any illusion that the federal government is interested in fairness.”\textsuperscript{154}

\begin{itemize}
\item \textsuperscript{148} Id.
\item \textsuperscript{149} Id.
\item \textsuperscript{150} Id.
\item \textsuperscript{151} Id.
\item \textsuperscript{152} Id. § 11 (follow “View 65 Responses” hyperlink; 3).
\item \textsuperscript{153} Id. at 6.
\item \textsuperscript{154} Id. at 42.
\end{itemize}
Some of the providers reported positive experiences with self-disclosure. “The process worked very well for us. The OIG rep worked with us for a fair resolution and noted our cooperative nature and self-disclosure. She accepted our proposed exposure and waived any interest or fines.”155 Other commentators echoed that comment.156 For example, one said, “I find the process to be fair and balanced, unlike the early reports of overkill in the last decade of the 20th century. If credible, experienced resources are used and the disclosure is professionally prepared and handled, the result is often satisfactory for both provider and enforcer.”157

B. Incentives to Disclosure under the SRDP

If one accepts the premise that providers compare the amounts of honey and vinegar when deciding whether to disclose, it becomes important to identify the reasons providers would choose to disclose or not. The most important reason to disclose a Stark violation is that it is required under PPACA and other statutes.158 If providers considered only this fact, CMS would have far more disclosures than the eighty or so it has received to date. This article’s main thesis is that a legal requirement alone is not the only factor providers consider in determining behavior. Indeed, if that were the case, presumably providers would have far fewer compliance issues to disclose in the first place since they would not have allowed any consideration to trump their need to obey the Stark Statute.

155 Id. at 7.
156 Id. at 41.
157 Id. at 53.
158 PPACA, supra note 5, § 6402(d) (to be codified 42 U.S.C. § 1330a-7k(d)(1); see also 42 U.S.C. § 1395nn(g)(2) (“If a person collects any amounts . . . billed in violation of [Stark] . . . , the person shall be liable to the individual for, and shall refund on a timely basis . . . amounts collected.”); 42 C.F.R. § 411.353(d) (an entity collecting payments for services provided pursuant to a Stark violation “must refund [payments] on a timely basis”); 31 U.S.C. § 3729(a)(1)(G) (“knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government” is subject to False Claim liability).
The SRDP states that while CMS is not obligated to reduce any amounts due and owing as a result of a Stark violation, it will consider doing so based on the facts and circumstances of each disclosed actual or potential violation.\textsuperscript{159} In the only Stark disclosure made to CMS that has been made public to date, it does appear that the hospital received a substantial discount in the settlement from the amount that it might have owed under a worst case scenario.\textsuperscript{160} As previously mentioned, that case involved Saints Hospital in Massachusetts. The attorneys for Saints stated for the Saints annual audit that liability was as much as $14 million and yet the penalty in that case was $579,000.\textsuperscript{161} Since CMS did not provide any reasons as to how it calculated the amount in the case, providers have not learned a great deal from the case about what CMS’s position is likely to be in other cases.

The SRDP further states that if CMS accepts a disclosure into the protocol, the disclosure stops the “ticking of the clock” on the provider’s obligation to repay the overpayment under section 6402 of the ACA.\textsuperscript{162} Thus, a provider avoids interest and potentially some penalties by making a disclosure.

While there are no criminal penalties for Stark violations, a provider may nonetheless view creating prosecutorial good will as a valuable outcome of a Stark self-disclosure. The SRDP itself notes that a prosecutor will not pursue a criminal action against a provider that voluntarily discloses non-compliance, especially when the provider has cooperated fully, taken any necessary personnel actions and taken action to assure the problem will not recur.\textsuperscript{163} As Silver and Wisner point out,

\begin{footnotesize}
\begin{enumerate}
\item\textsuperscript{159} SRDP, supra note 9, at 6.
\item\textsuperscript{160} Saints Press Release, supra note 141.
\item\textsuperscript{161} Kass & Paddock, supra note 12 (discussion of Saints Medical disclosure by Saints’ attorney Christine Savage, Choate Hall & Stewart).
\item\textsuperscript{162} SDRP, supra note 9, at 1.
\item\textsuperscript{163} Am. Health Lawyers Ass’n, Healthcare Compliance Legal Issues Manual 106 (Harry R. Silver & Cynthia F. Wisner eds., 3d ed. 2011) [hereinafter Silver and Wisner].
\end{enumerate}
\end{footnotesize}
Additional benefits of self-disclosure include the ability to more fully frame the issues, complete a thorough internal investigation, develop an improved and less-adversarial relationship with law enforcement officials, and demonstrate that the organization is ready and willing to act responsibly. In addition, providers and entities that voluntarily disclose may reduce the likelihood of receiving subpoenas or search warrants.\textsuperscript{164}

Another benefit of self-disclosure is possible avoidance of a corporate integrity agreement ("CIA"). In situations where the government is concerned about a recurrence of a compliance issue, the agency involved often insists upon a CIA as a part of any settlement. Such agreements impose continuing investigative and reporting obligations on providers, sometimes for a number of years. The HHS Office of Inspector General negotiates CIAs with health care providers and other entities as part of the settlement of federal health care program investigations arising under a variety of civil false claims statutes. Providers or entities agree to the obligations and, in exchange, the OIG agrees not to seek their exclusion from participation in Medicare, Medicaid or other federal health care programs.

According to the OIG, "CIAs have many common elements, but each one addresses the specific facts at issue and often attempts to accommodate and recognize many of the elements of preexisting voluntary compliance programs."\textsuperscript{165} The OIG says that a typical CIA lasts 5 years and includes the following requirements:

- A compliance officer and compliance committee;
- written standards and policies;
- a comprehensive employee training program;
- annual reviews by an independent review organization;
- a hotline or similar confidential disclosure program;

\textsuperscript{164} Id.
• a program to prevent employment of persons with a history of compliance issues;

• reports of overpayments and other compliance issues as they arise; and

• annual reports to OIG on the status of the entity's compliance program. 166

Aside from avoidance of a CIA, a provider might generally seek to establish that it has a good compliance program by self-disclosing a Stark violation. The United States Sentencing Guidelines ("Guidelines") provide significant incentives for an organization to self-disclose in the form of a reduction in possible criminal penalties. The Guidelines give a provider credit for an “effective” compliance plan,167 and state that an effective compliance and ethics program must demonstrate that the organization exercises due diligence to prevent and detect criminal conduct; and otherwise “…promote[s] an organizational culture that encourages ethical conduct and a commitment to compliance with the law.”168 They specify that the program should be “generally effective;” failure to prevent or detect the particular offense at issue does not necessarily mean that the program is not “generally effective.”169 Thus, providers hope that by disclosing a compliance issue, they are demonstrating the effectiveness of their compliance program overall in the event of future investigations.

Self-disclosure also allows a provider to frame the issues and thus minimize the impact of any whistleblower action under the FCA.170 As discussed above in Section I(D), qui tam actions are the major driver in Stark actions. Any opportunity to cut off those suits is therefore extremely valuable to a provider. However, as also noted above, that ability is limited by the

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166 Id.
167 FEDERAL SENTENCING GUIDELINES MANUAL, § 8B2.1 (2010), available at http://www.ussc.gov/guidelines/2010_guidelines/Manual_PDF/Chapter_8.pdf. An effective compliance plan may potentially decrease an organization’s point values when calculating its Culpability Score (§ 8C2.5(f)), which in turn is used to determine minimum and maximum fine multipliers (§ 8C2.5.6).
168 Id. § 8B2.1.
169 Id.
170 Silver & Wisner, supra note 167, at 107.
split in the circuits on the issue of whether a self-disclosure forecloses *qui tam* actions based on that disclosure.\footnote{See infra notes 70, 71.}

C. Disincentives to Disclosure in the SRDP

There are a number of reasons providers might choose to “roll the dice” of possible investigation or prosecution rather than self-disclose under the current version of the SRDP. The most important of these are 1) the difficulty in identifying an overpayment as required in the protocol; 2) CMS’s resistance to settling claims for less than two times the overpayment involved; 3) CMS’s failure to distinguish between procedural and substantive violations; 4) the short amount of time within which a disclosure must be made; 5) the difficulty in determining whether disclosure should be to CMS or another agency; 6) the length of the “look back” period; 7) the waiver of attorney-client privilege; 8) the required statement about past conduct; 9) the lack of appeal rights; and 10) implications for the provider’s compliance plan. Each of these issues is set out in detail below.

1. Identification of an Overpayment

The term “identified” is not defined in PPACA and so providers may not always know whether they have met that threshold requirement for the repayment obligation.\footnote{See e.g., Lauer & Roth, supra note 11, at 16.} The SRDP does not define the term either. It does require providers to explain to CMS “… [t]he circumstances under which the disclosed matter was discovered and the measures taken upon discovery to address the actual or potential violation and prevent future instances of noncompliance.”\footnote{SRDP, supra note 9, at 4.} Furthermore, the SRDP requires that parties identify the “specific time periods the disclosing party may have been out of compliance (and if applicable, the dates or a...
range of dates whereby the conduct was cured)…” The SRDP does not mention what could be a lengthy period in which the provider investigates a possible overpayment to determine whether it is in indeed an overpayment.

Former New York Medicaid Inspector General James Sheehan once stated that it was his agency’s position that a call to a hospital’s complaint hotline triggers the sixty day period. However, providers argue that they receive many unsubstantiated claims that, upon investigation, prove to be false. Therefore, they argue, no overpayment has been “discovered” until an alleged overpayment has been brought to the attention of the correct person within the provider’s organization, investigated properly, and shown to actually be an overpayment.

The SRDP states that CMS will take into account the “timeliness of the disclosure” as a factor it will consider in determining the penalty applied in a particular disclosure. It also cautions that the extent of its verification will depend on the quality and thoroughness of the submission received. The disclosure must be complete and no further information should be submitted to augment an initial disclosure after it is submitted to CMS. Therefore, providers must choose between submitting the disclosure as soon as possible and making sure it is complete enough to pass muster with CMS. Recently, a CMS representative criticized the disclosures CMS has received thus far under the SRDP, saying that the main problem CMS is seeing with the disclosures is that providers are not giving CMS enough information when they do make a disclosure. Providers must walk a difficult line between disclosing quickly enough to be timely, but not so quickly as to be deemed incomplete.

2. CMS’s Position on Financial Settlements

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174 Id.
175 NY OMIG Webinar, supra note 17, at 26, cited in Lauer & Roth, supra note 11, at 18.
176 SRDP, supra note 9, at 6.
177 SRDP, supra note 9, at 5.
178 Carlson, supra note 134.
The Congressional mandate in PPACA authorized, but did not require, CMS to reduce the amount of penalties due under the Stark Law below a full repayment.\textsuperscript{179} Congress listed three factors CMS should consider when assessing penalties: the nature and extent of the improper or illegal practice; the timeliness of the self-disclosure; and cooperation in providing additional information related to the disclosure.\textsuperscript{180} CMS added additional factors it would consider when it released the SRDP: the litigation risk associated with the matter disclosed; the amounts owed; the financial position of the disclosing party, and other factors as the HHS Secretary deems appropriate.\textsuperscript{181}

Unlike the OIG, CMS has not publicly announced its willingness to decrease Stark penalties below the “face value” of the penalties available. The OIG’s protocol states that, “…subject to the facts and circumstances of the case, [it] will generally settle SDP matters for …a multiplier of the value of the \textit{financial benefit conferred by the hospital upon the physicians(s)}.\textsuperscript{182} Thus, the OIG appears to focus on improper financial benefit rather than on the maximum possible penalty available under the applicable law.

Prior to the SRDP’s release, the American Hospital Association had urged CMS to consider additional factors such as:

\begin{quote}
…whether the parties’ failure to meet all the prescribed criteria of an applicable exception was due to an innocent or unintentional mistake; the corrective action taken by the parties; whether the services provided were reasonable and medically necessary; whether access to a physician’s services was required in an emergency situation; whether the Medicare program suffered any harm beyond the statutory disallowance.\textsuperscript{183}
\end{quote}

\textsuperscript{179} PPACA, \textit{supra} note 5, at § 6409(b) (to be codified at 42 U.S.C. § 1395nn note).
\textsuperscript{180} Id.
\textsuperscript{181} SRDP, \textit{supra} note 9, at 1, 6.
\textsuperscript{183} AHA Letter, \textit{supra} note 8, at 3.
While CMS’s “litigation risk” criteria might arguably include some of the AHA’s suggested factors, CMS declined to openly embrace any of the AHA factors. CMS did not offer any explanations as to why it rejected these ideas.

CMS representatives have informally signaled their willingness to reduce amounts owed in a recent American Health Lawyers Association webinar for health care attorneys. In the webinar, the presenters representing the government listed several “subfactors” CMS considers in settlements: 1) whether the arrangement was commercially reasonable and/or at fair market value; 2) whether the arrangement takes into account the volume or value of referrals; 3) whether there is a history of program abuse; 4) whether the amount in question was set in advance; 5) the presence and strength of the preexisting compliance program; 6) the length and pervasiveness of the noncompliance; and 7) the steps taken to correct the non-compliance. These factors have not been released in any official pronouncement. Notably absent from the list is any consideration of whether patients or the program actually suffered any harm as a result of the arrangement and whether the violation resulted from a mistake or so-called “technical” error.

Leaving aside those considerations, the SRDP does not specify how CMS will determine the dollar amount of the claims made pursuant to the financial relationship. Will it be based on the number of patients admitted by the admitting physician? Sometimes there are multiple physicians involved in one admission. If Dr. House admits a patient but other physicians or providers such as physical therapists or medical equipment providers also bill the government for services as a result of the initial hospital admission, will the value of those products and services be considered part of the basis for the penalty?

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For example, in the Saints case settled this year under the SRDP, CMS could say that the amounts billed to the Medicare program for all services provided to all patients treated by the physician involved in the financial relationship is the sole basis for determining the value of the government’s claim against Saints Hospital. CMS apparently did not take that position since the hospitals’ attorneys said they were very pleased with the amount of the settlement relative to what CMS could have demanded, but we do not know what the basis was for CMS’s calculation of the penalty since CMS did not release that information. We do not know whether the penalty was lower than the Saints attorneys had feared it might be because CMS decided the situation did not really harm the Medicare program, or because the physicians involved simply had not admitted many patients who cost the Medicare program significant amounts of money. In other words, is CMS discounting the value of its claim based on equitable factors that it did not wish to specify either to the party involved or to the public?

The OIG, in contrast to CMS, demonstrated its willingness to settle cases for less than their face value in several cases settled by the OIG before the OIG announced it would not take “Stark only” settlements in the SDP. One case involved Cushing Memorial Hospital’s failure to have a rental agreement with a physician using space in the hospital’s medical office building. OIG settled for $50,000 there despite the fact that the physician’s referrals had resulted in millions of dollars in claims. OIG could have insisted on repayment of all of those claims and possibly argued for penalties under the CMP or FCA that were a multiplier of the amount of the claims.

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185 Hospital Settles CMP Case After OIG Discovers No Problem In Referral Pattern, 18 REPORT ON MEDICARE COMPLIANCE 2 (Oct. 19, 2009).
In another case, Memorial Hospital of Union County in Ohio paid $31,000 in CMPs for exceeding by $3,000 the $355 Stark cap on nonmonetary compensation of physicians. The penalty would have potentially been enormous if the OIG had focused on the value of referrals made by the physicians involved rather than on the minimal financial benefit the hospital had actually conferred upon the physicians. When these settlements were announced, an attorney representing a number of hospitals and physicians hailed these settlements as possible “…cornerstone cases with respect to the application of Stark and repayments. They show there is a substantial ability to negotiate a reasonable amount.” However, the OIG’s subsequent closure of its program to Stark-only disclosures put an end to this short-lived optimism in the provider community regarding Stark enforcement.

The CMS protocol also contrasts with New York State’s Medicaid self-disclosure program in terms of its willingness to publicly offer a reduction in penalties as a reward for self-disclosure. The New York OMIG released its Provider Self-Disclosure Guidance in March 2009. The OMIG states that its program is aimed at encouraging providers to find problems within their own organization, reveal those issues to the OMIG, and return inappropriate payments. The disclosure protocol is written in general terms and includes all program integrity issues rather than the specific statutes that the CMS and OIG protocols cover. The OMIG states that providers who self-disclose overpayments will typically have a better outcome.

186 Id.
187 Id. (discussing attorney Robert Wade’s comments regarding OIG’s willingness to set lower CMPs for hospitals who voluntarily disclose alleged Stark violations).
188 See Levinson supra n.104.
190 Id. at 1.
191 Id.
than if OMIG had discovered the matter independently.\textsuperscript{192} The specific benefits to self-disclosure that OMIG cites in its protocol are: 1) forgiveness or reduction of interest payments; 2) extended repayment terms; 3) waiver of penalties and/or sanctions; 4) recognition of the effectiveness of the provider’s compliance program; 5) a decrease in the likelihood of imposition of an OMIG Corporate Integrity Program, and 6) possible preclusion of subsequently filed New York State False Claims Act \textit{qui tam} actions based on the disclosed matters.\textsuperscript{193}

3. Failure to Distinguish Between Procedural and Substantive Violations

While many of the disadvantages to using the SRDP discussed in this article apply to all disclosures under the SRDP, the disadvantages are particular acute when one considers situations in which the underlying violation of the law is procedural rather than substantive. As discussed above, CMS considered and ultimately rejected any distinction between procedural and substantive violations in the Stark regulations themselves, except under the very narrow ninety and thirty day windows approved in the 2008 regulations revision for missing signatures.\textsuperscript{194}

The SRDP does not make any distinction between minor violations that do not affect the integrity of government health care programs and violations that go to the heart of why the legislation was enacted. Presumably, a procedural violation would fare well in consideration of the “nature and extent of the improper or illegal practice,” but CMS has not said so directly. Attorneys Katherine Lauer and Robert Roth, speaking to an AHLA webinar audience in June 2011, stated that they had heard that CMS may be considering referring matters that are not simply “technical” issues to the OIG.\textsuperscript{195} That would leave only the technical or procedural issues to be dealt with under the CMS SRDP. If CMS were to remove all substantive issues from the

\textsuperscript{192} \textit{Id.} at 2.
\textsuperscript{193} \textit{Id.}
\textsuperscript{194} \textit{See supra} § I(E).
\textsuperscript{195} \textit{Lauer & Roth, supra} note 11.
SRDP, it would only serve to sharpen providers’ complaints that the SRDP as currently structured is unnecessarily punitive and unfair to providers who have simply failed to sign an agreement or have allowed a signed agreement to lapse.

4. Deadline for Disclosure

The SRDP requires the disclosing provider to act quickly, yet quite comprehensively. Some practitioners have stated that the sixty day requirement for repayment of overpayments under PPACA means that providers must disclose within sixty days to be able to take advantage of the SRDP. As some attorneys have noted:

Sixty days is a short time frame to conduct a thorough internal review of potential noncompliance, come to conclusions about whether a violation has occurred, assemble descriptions of the potential causes of the incident or practice at issue, draft descriptions of any similar conduct and of the compliance program, design remedial actions and describe them, conduct an accurate financial analysis of the potential repayment and present all these materials to the compliance committee and/or governing body for review/approval for filing with CMS. The timetable for this process raises serious questions as to whether the SRDP process is a meaningful opportunity for providers to resolve significant or complex legal areas of potential noncompliance.

The information that must be provided in that short amount of time is actually more comprehensive and definitive that that required in the OIG SDP. The OIG SDP allows the provider to conduct its internal review after the initial disclosure to the government. The OIG agrees not to investigate on its own while the provider conducts its internal review according to the OIG’s guidelines as laid out in the SDP. The CMS SRDP has no similar process for allowing incremental submission of information by providers. In fact, under the SRDP, the provider must conduct a “complete legal analysis,” including identification of the specific requirements of all exceptions under Stark and explanations as to why the organization fails to

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196 Christ et al., supra note 105, at 3.
197 Id. at 4.
198 OIG SDP, supra note 103, at 58401.
meet them. Presumably a disclosure will need to include a memorandum of law by legal counsel in order to fulfill this requirement.

If CMS determines that the information the provider has given to CMS is not sufficient, CMS may decide not to accept a disclosure into the SRDP. Attorney Robert Wade represents five of the providers who have applied to resolve Stark problems through the CMS self-referral disclosure protocol. He reports that in two cases, CMS accepted the submissions but asked for more documentation; in two other cases, CMS asked for additional information, but he has not been notified as to whether CMS will accept the submission. CMS has not yet responded to the fifth disclosure.

5. Determining To Which Agency Disclosure Is Best Made

The SRDP states that parties should not disclose the same behavior to both OIG and CMS. Due to the fact that most situations that raise Stark issues also raise Anti-Kickback issues, providers often face a dilemma when deciding which disclosure protocol to use. Providers should prefer to use the “Stark-only” SRDP when possible, rather than take the position they may have violated the criminal Anti-Kickback statute, which is necessary to use the OIG SDP. Another advantage of using the SRDP is that disclosure to CMS offers the potential for a release of Stark liability, whereas OIG does not have authority to release liability under that statute.

Despite these advantages, providers often prefer to try to walk the line of stating that there is a colorable Kickback claim in their situation so they can disclose to the OIG rather than CMS. In the words of one attorney who advises healthcare providers, the OIG’s “clear guidance

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199 SRDP, supra note 9, at 4.
200 Nina Youngstrom, First Stark Case Is Resolved Through CMS Self-Disclosure; Is the OIG Option Gone?, 20 REPORT ON MEDICARE COMPLIANCE 2 (Feb. 21, 2011) [hereinafter Youngstrom].
201 SRDP, supra note 9, at 2.
202 PPACA, supra note 5, § 6409(d) (to be codified at 42 U.S.C. § 1395nn note).
and reasoned approach to penalty determination” makes disclosure to the OIG preferable to disclosure to CMS.\(^{203}\) Also, if a provider decides to go the Stark-only route and discloses to CMS but the agency decides in the course of its investigation that there is a colorable Anti-Kickback claim, CMS may then refer the matter to the OIG and the Department of Justice.\(^{204}\) Indeed, the SRDP warns that CMS may use material in the disclosure itself as evidence against the provider in its decision to make a referral to the OIG or Department of Justice.\(^{205}\) In that situation, the provider will not have the opportunity for any leniency under the OIG SDP. So, providers will do well to heed CMS’s advice in the SRDP that “the disclosing party’s initial decision of where to disclose at matter…should be made carefully.”\(^{206}\)

6. The “Look Back” Period

One of the most significant issues for providers in a self-disclosure is the length of time CMS will “look back” from the date of the disclosure itself to determine the extent of the illegal conduct. If the financial relationship at issue was in place for an extended period of time, the look back period can be a major determinant of the total overpayment and penalties that will be due. Many of the financial relationships between hospitals and physicians, such as medical directorships of departments within a hospital, can extend for decades, creating a major problem for an entity seeking closure on a lapsed contract, for example.

\(^{203}\) Larry C. Conn, *Navigating CMS’ Channel For Stark Disclosures*, 13 J. HEALTH CARE COMPLIANCE 25, 28 (Jan.-Feb. 2011) [hereinafter Conn]; see also Michelle C. Gabriel McGovern, *Medicare Physician Self-Referral Disclosure Protocol: Will the Truth Set You Free?*, 13 J. HEALTH CARE COMPLIANCE 59 (Jan.-Feb. 2011), (comparing the OIG and CMS disclosure protocols and concluding that absent further clarification by CMS, its SRDP offers no significant additional benefits to disclosing providers)

\(^{204}\) SRDP, supra note 9, at 2-3.

\(^{205}\) Id. at 3.

\(^{206}\) Id.
The SRDP requires a disclosing party to state the total amount that is actually or potentially due and owing based on the “applicable look back” period.”

The SRDP defines the look back period in a disclosure as the length of the time during which the disclosing party may not have been in compliance with the physician self-referral law. When the protocol was first published, many commentators raised concerns regarding the open-ended nature of this definition. The definition conceivably extends the look back period for which a provider is liable under a self-disclosure beyond that for which the provider would be liable if the government learned of the conduct through means other than self-disclosure.

A government contractor reviewing a hospital’s claims may reopen an initial determination or redetermination only up to four years from the date of the initial determination or redetermination and only when “good cause” exists. “Good cause” is said to exist when, “There is “new and material evidence that was not available or known at the time of the determination or decision and may result in a different conclusion, or; the evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.”

Even in the most serious of cases, the government contractor may only reopen a claim for four years after the initial determination or redetermination. This limitation is designed to prevent the government from reopening claims indefinitely and to ensure that the contractor reviews claims in a timely manner.

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207 Id. at 5.
208 Id.
209 See Goel & Melvin, supra note 51, at 3-4 (recognizing that although the SRDP refers to regulatory time limitations on look back periods, neither the protocol nor CMS has indicated how they may be applied in a self-disclosure); see also Youngstrom, supra note 203, at 2 (a provider’s documentation of an entire look back period can be “fairly extensive . . . and can be burdensome,” quoting attorney Kevin McAnaney, former chief OIG’s Industry Guidance Branch).
210 42 CFR 405.980(b)(2). The government may reopen a claim at any time if “reliable evidence”, as defined in 42 CFR §405.902, exists that the initial determination was procured by fraud. Presumably that section would not apply in most “pure Stark” cases, particularly in those cases involving only procedural violations of the statute.
Stark violations where the False Claims Act is implicated, the statute of limitations is six years.\textsuperscript{212}

CMS representatives recently stated that the agency did indeed intend to create an open-ended look back period for the SRDP.\textsuperscript{213} Thus, self-disclosure under the SRDP potentially exposes the provider to more liability than would be allowable under law in the event the non-compliance was discovered by the government in some manner other than self-disclosure. In contrast, the New York OMIG takes an alternative approach, providing a clear six year look back period with limited exceptions.\textsuperscript{214}

7. Waiver of Attorney Client Privilege

Once a provider enters into the SRDP, the provider must provide CMS access to “all financial statements, notes, disclosures, and other supporting documents without the assertion of privileges or limitations.”\textsuperscript{215} Though CMS has specified it will not request written material subject to attorney-client privilege, the agency does state that if there are documents or other materials which it believes are critical to resolving the disclosure, CMS will discuss with a disclosing party’s counsel “…ways to gain access to the underlying information without waiver of protections provided by an appropriately asserted claim of privilege.”\textsuperscript{216}

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\textsuperscript{212} 31 U.S.C. § 3731(b).
\textsuperscript{213} Carlson, supra note 134 and accompanying text (“The CMS will request to see the entire amount of questionable remuneration, regardless of any statute of limitations that would apply in a court process,” reporting on comments made by Troy Barsky at AHLA annual meeting).
\textsuperscript{214} NY OMIG Webinar, supra note 17, at 31 (“OMIG will not require or expect providers to look back more than six years from the date of disclosure unless the disclosure involves a base year cost report, or OMIG determines that there is a basis to suspect fraud.”).
\textsuperscript{215} SRDP, supra note 9, at 5.
\textsuperscript{216} Id.
\end{footnotesize}
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concerned that a disclosure might lead to a situation where they could be forced to waive the privilege as a result of a self-disclosure.\(^{217}\)

8. Statement Regarding Past Conduct

The protocol requires participants to include a statement “…identifying whether the disclosing party has a history of similar conduct or has any prior criminal, civil and regulatory enforcement actions against it.” There doesn’t appear to be any time limitation on this requirement. The language “a history of similar conduct” is quite ambiguous. Does “similar” refer to specific issue such as failure to obtain a signature or does it consider all the facts and circumstances of the particular disclosure? For example, consider again Dr. House’s situation in which the Hospital failed to obtain Dr. House’s signature on an agreement that would otherwise comply with a Stark exception. If neither party noticed the lack of a signature for five years, is that “similar” to another situation in which the hospital failed to obtain a signature but discovered it after five weeks? Suppose that in the first scenario, the Hospital had a transition of personnel so that the department head responsible for the agreement left the Hospital. By the time of the second incident, the Hospital had implemented a new contract management system and that system caught the lack of a signature. The Hospital’s overall compliance program has improved significantly between the time of the two incidents and yet CMS may consider the two situations “similar” and expect disclosure of the second incident even though it meets the CMS exception for self-correction of a missing signature.\(^{218}\)

The requirement for determining whether the hospital has had a “similar” situation exacerbates the time pressure on providers who need time to compare different situations before

\(^{217}\) See Christ et al., supra note 105, at 5 (concluding the potential waiver of privilege is an uncertainty in the SRDP process which is a “critically important consideration that disclosing parties should weigh carefully”); Conn, supra note 206, at 29 (“CMS may insist on review of materials that may be covered by the work product doctrine.”).

\(^{218}\) See supra § I(F).
making a conclusion about their similarity. The OIG SDP allows providers to provide additional information after the initial disclosure,\[^{219}\] which gives a provider the chance to amend any initial statements about the provider’s historical compliance if the provider’s investigation uncovers a previously unrecognized pattern of similar conduct. The SRDP does not allow amendment after submission.

9. Lack of Appeal Rights

There are no appeal rights from a CMS resolution of a self-disclosure.\[^{220}\] By contrast, if a provider’s compliance issues were discovered in an investigation or through some other means, the provider would have full rights to appeal from any administrative penalty assessment or court decision unless the provider waived those rights in a settlement. The protocol does state that if an entity does not enter into a satisfactory resolution with CMS through the protocol, CMS may issue overpayment determinations. The provider would then be able to appeal those determinations through the normal administrative processes.\[^{221}\] So, providers have at least some leverage on this point since they can simply threaten to walk away from the disclosure if they are concerned that CMS does not seem to be coming to a resolution that will be favorable for the provider. If they choose this option, of course CMS will likely turn the matter over to OIG or DOJ for investigation and prosecution.\[^{222}\]

Of course, that may not always be apparent. In the Saints Medical Center disclosure discussed above, the hospital’s counsel reported that they had no idea how CMS came to the settlement amount it did.\[^{223}\] While Saints’ counsel said they were pleased with the settlement,
had they not been, they would have had to choose to waste the time and money they had already
invested in the disclosure process and roll the dice of appealing a CMS overpayment
determination or other legal action had the provider chosen to pull out of the disclosure process
before CMS’s determination of the final amount.

10. Implications for the Provider’s Compliance Plan

Finally, it is unclear what the implications of a self-disclosure are for the disclosing
provider’s compliance plan. The SRDP requires providers to provide “…a description of the
potential causes of the incident or practice (e.g., intentional conduct, lack of internal controls,
circumvention of corporate procedures or Government regulations).”224 It goes on to state that
the provider must provide:

…a description of the existence and adequacy of a pre-existing compliance program that
the disclosing party had, and all efforts by the disclosing party to prevent a recurrence of
the incident or practice in the affected division as well as in any related health care
entities (e.g., new accounting or internal control procedures, new training programs,
increased internal audit efforts, increased supervision by higher management).225

In light of these requirements, providers question whether CMS views a disclosure as
evidence of the effectiveness or lack of effectiveness of a compliance plan. This ambiguity
contrasts with the explicit statement of the New York OMIG that a disclosure will be taken as
evidence that the provider’s compliance plan is effective.226

IV. A Proposal for A Demonstration Project to Test Modifications

A. Benefits of a Demonstration Project

The central question raised in this article is whether there are changes that could be made
in the SRDP to encourage providers to disclose more violations without risks to the Medicare
program from providers abusing simpler procedures and less governmental scrutiny. Prior to the

224 SRDP, supra note 9, at 4.
225 Id.
226 NY OMIG SDG, supra note 192, at 2.
release of the current SRDP, other authors suggested more provider friendly procedures than were ultimately adopted by CMS. Since the agency did not explain why it did not include any of these ideas in the SRDP, we can only guess as to its reasons. Presumably, CMS was concerned that the Medicare program’s integrity would be compromised if providers took undue advantage of the flexibility or limited penalties embodied in these suggestions. A demonstration project offers an opportunity to test these ideas without risking the integrity of the entire Medicare system. If any of the ideas prove too fraught with difficulties in administration or result in providers’ failing to fully and truthfully describe their situations in disclosures, the risks to the Medicare program will have been limited to the test state or states.

A more provider-friendly demonstration protocol offers an opportunity to gain several important insights. First, CMS would learn whether providers would respond by significantly increasing the number of disclosures and the amount the government recovers for the Medicare Trust Fund. Second, CMS would learn which protocol provisions are most significant in providers’ decisions concerning whether to disclose. Third, CMS would learn a great deal about how hospitals contract with physicians, including what provisions in those contracts are typical of the industry as a whole, and which are more unusual and possibly more problematic.

Finally, CMS would also learn about providers’ recordkeeping practices and approaches to documentation of fair market value. CMS has demonstrated its interest in this type of information. In 2008, the agency launched a program to gather data on physicians’ relationships with hospitals. Ultimately the program was halted because CMS determined that PPACA’s disclosure requirements may provide duplicative information. However, CMS stated “[it] remain[s] interested in analyzing physicians’ compensation relationships.”

227 See DFRR, supra note 15 and accompanying text.
If the information CMS gleaned from the project supported CMS’s concerns about significant provider abuses, the agency could use the information to craft better enforcement programs and tighter regulations overall or to target particular industry segments where problems are more rampant. CMS would have a more accurate profile of providers likely to be engaged in more significant misconduct. If, on the other hand, the information gathered showed that current Stark regulations are overly restrictive compared to the money recovered, the agency could relax Stark enforcement and shift the resources to other parts of the health care industry or to other health care statutes. At a minimum, a more provider-friendly protocol with simpler, faster resolution of issues would avoid the expense of complex investigations and negotiations with providers whose violations are less serious, allowing attention to be focused on providers with more serious violations.

For providers in the demonstration project states, it would offer opportunities including lower costs of settlement and decreased risk of penalties, particularly for technical violations. The pilot program would make the cost benefit analysis for self-disclosure less lopsided so that doing the right thing would not put a provider in financial or legal peril. If CMS were to ultimately use the results of the project to make the SRDP more provider-friendly, providers in all states would reap the benefits.

B. Past Demonstration Projects

1. CMS Projects

HHS has conducted numerous demonstration projects related to Medicare. PPACA gives HHS broad authority to create demonstration projects that test various ideas for decreasing the costs of or improving care delivery in federal health care programs.\(^\text{228}\) While some

\(^{228}\) *PPACA, supra* note 5, § 3021(a) (to be codified at 42 U.S.C. § 1315(a)) (creating the Center for Medicare and Medicaid Innovation).
demonstration project recommendations are outlined in the legislation. HHS also has general authority to develop or demonstrate improved methods for the investigation and prosecution of fraud in federal health care programs. Some carried out by CMS in the past include: 1) a value-based purchasing initiative designed to tie Medicare payments to performance on quality and efficiency; 2) the Hospital Quality Incentive Demonstration; 3) the Physician Group Practice Demonstration to improve care of patients with chronic illnesses or requiring preventive care; and 4) the Medicare Care Management Performance Demonstration.

CMS is currently involved in two demonstration projects with implications for fraud and abuse regulations. These projects concern “gainsharing” between hospitals and physicians. Gainsharing programs involve hospitals paying physicians a share of savings resulting from collaborative efforts between the hospital and the physician to improve quality and efficiency in care delivery. Gainsharing implicates two specific fraud and abuse statutes: 1) the civil monetary penalty law, which prohibits a hospital from knowingly making a payment, directly or indirectly, to a physician as an inducement to reduce or limit items or services furnished to Medicare or Medicaid beneficiaries, and 2) the Anti-Kickback Statute if one purpose of the cost-savings payment is to influence referrals of federal health care program business by the physicians.

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229 Id. Twenty project models are specifically recommended, including the promotion of broad payment and practice reform in primary care, and provision of payment to providers for using patient decision-support tools that improve individual understanding of medical treatment options.


234 42 U.S.C. § 1320a-7a(b)(1).

235 42 U.S.C. § 1320a-7b(b)(2).
The New Jersey Hospital Association initially proposed a gainsharing demonstration in 2004, but at that time, CMS did not have the statutory authority to waive gainsharing restrictions in the law. The Deficit Reduction Act, Section 5007, gave CMS the necessary authority for the first project, while Title XVIII of the Social Security Act, as amended by section 646 of the Medicare Prescription Drug, Improvement, and Modernization Act, authorized the other. Both demonstrations included various restrictions to protect the Medicare program, such as a requirement that payments to physicians could not be payments for referrals that would violate the Anti-Kickback Statute.

CMS has not yet released results of the project that ended in 2009, but Jonathan Blum, director of the CMS’ Center for Medicare Management and acting director of the Center for Health Plan Choices, stated in 2009, “What we learn from the various Medicare demonstrations help to achieve the Administration’s goals of paying for high quality and efficient health care in America. Building on these findings, we will aggressively test new demonstration concepts to continue to meet these goals.”

2. OIG Pilot Project on Self-Disclosure

The HHS OIG has applied the demonstration program concept in the area of provider self-disclosure. In 1995, OIG launched a program called “Operation Restore Trust” (“ORT”) to

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respond to a surge of fraud, waste and abuse in the Medicare and Medicaid programs.\textsuperscript{240} One of the initiatives included in ORT was a two year pilot program on a voluntary self-disclosure program, targeting home health and nursing facility suppliers and providers in five states. Together, the five states accounted for forty percent of Medicare and Medicaid beneficiaries.\textsuperscript{241} The program was based on an approach taken by the Department of Defense starting in 1986 for self-disclosed incidents of fraud by defense contractors.\textsuperscript{242}

OIG’s main purpose in developing the program was to increase industry participation in the detection and prevention of Medicare and Medicaid fraud and abuse. From OIG’s perspective, the program offered providers a way to decrease potential costs from governmental audits and investigations and avoid possible exclusion from the program. For the government, the program offered insight for the OIG into industry patterns and practices.\textsuperscript{243} The OIG learned from the program and then used that knowledge to refine the program before releasing its current self-disclosure protocol nationwide in 1998.\textsuperscript{244}

C. Proposed Provisions of a Stark Self-Disclosure Demonstration Project

Just as CMS is learning about various parts of the health care industry today through its many demonstration projects, and as OIG first piloted to a few industries and states a then-novel approach to self-disclosure, so should CMS today use the opportunity afforded by PPACA to experiment with ways to make its SRDP more effective. Some of the specific provisions any

\begin{footnotes}
\item[241] Id.
\item[243] Operation Restore Trust, supra note 240, at 34.
\item[244] OIG SDP, supra note 103, at 58400 (OIG’s current protocol eliminated a number of provisions found in the pilot program, including: predisclosure requirements and preliminary qualifying characteristics, disclosures limited to particular healthcare industries, and automatic preclusion of providers from disclosure if already subject to a government inquiry).
\end{footnotes}
demonstration project on Stark self-disclosure should contain are: a two track process, a flat penalty for procedural violations, and an explicit statement of tangible benefits in the SRDP.

1. Two-Track Process

Prior to the release of the SRDP, the AHA suggested a two-track system for disclosures that offers an excellent framework for a demonstration project. Under the AHA proposal, Track I would allow for expedited reviews, similar to “desk audits” at many agencies. This type of review would be for the disclosure of situations that can be resolved on the basis of evidence provided by the disclosing party. The agency would verify the data provided but would not conduct a full-scale investigation.245 The AHA offered missing signatures, mistaken payments, mistaken non-collection of payment, and holdover leases as examples of matters that could be handled on an expedited basis.246 Track Two would be for more complex matters that need a detailed review by CMS. AHA identified arrangements with “complex payment methodologies” or situations where “the extent to which the self-referral law applies is unclear” as examples.247 The AHA emphasized that CMS should be flexible in administering the two tiers and encouraged that “the SRDP should not attempt to define the circumstances or categories of arrangements for which the protocol is available. To do so would limit its utility and the ability of the agency to appropriately address complex situations that must be evaluated on a case-by-case basis.”248

CMS did not publicly explain why it rejected AHA’s two-track proposal. However, CMS’s comments in response to public comments on the 2008 regulations revisions may provide a clue. There, CMS rejected a proposal to allow parties who inadvertently failed to conform to a procedural requirement the opportunity to “self-correct,” or in other words, fix the problem

245 AHA Letter, supra note 8, at 4.
246 Id. at 2.
247 Id. at 3.
248 Id.
going forward and not disclose the problem. CMS stated that it did not believe that this type of proposal would meet the “no risk of program or patient abuse” standard.249

A demonstration project offers the possibility of using the AHA two-track framework while addressing CMS’s concern as well. For simple matters such as the AHA examples of missing signatures or non-collection of payment, providers could be required to disclose the violation to CMS but be subject only to a desk audit rather than a full investigation, as is the situation under the current SRDP. If any facts came to light during the desk audit that cause CMS to be concerned that the provider had not fully disclosed all the issues, CMS could move the matter to Track II and conduct a full investigation. For most simple matters, neither CMS nor providers would have to worry about a full blown, time-consuming, and expensive investigation. This process would address provider concerns raised in the AHLA survey on OIG disclosures that many of the disclosures resulted in investigations that dragged on for many months or even years.250

2. Flat Penalty for Procedural Violations

In situations where there is no allegation of intent to steer referrals to a provider, providers argue that CMS should, for purposes of determining any penalty assessed, exercise its discretion to sever the link entirely between the Stark violation and the value of so-called “tainted” referrals.251 According to advocates of this position, if the service in question was necessary and provided properly, neither the government nor any patient has been harmed. The dollar value of that claim should be irrelevant to the penalty calculation. Furthermore, the conduct to be punished should be the failure to document the arrangement. Whether the

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249 73 Fed. Reg. at 48707.
250 AHLA Survey, supra note 148, § 11 (free response comments, including “process is very slow” and “took a long, long, time”).
251 Letter from Robert Homchick, Craig Holden, Beth Schermer, & Sanford Teplitzky, attorneys, to Kathleen Sebelius, Secretary, Department of Health and Human Services 1, http://www.healthlawyers.org/Events/Programs/Materials/Documents/AM10/holden_proposal.pdf.
physician involved bills millions of dollars or only a few dollars to the Medicare program is irrelevant to the penalty assessed for the conduct. 252

Four prominent health care attorneys whose practices include a significant amount of Stark work have used this notion as the basis for a proposal they made in 2010 to CMS prior to its release of the SRDP. In their letter, the attorneys proposed that CMS establish a flat $5,000 penalty for procedural Stark violations. They lobbied CMS for the idea and discussed it with other health care attorneys in an attempt to create popular support for it. The letter (“Homchick Letter”) suggested that the category of arrangements that would qualify for summary disposition should include arrangements in which (1) the compensation is at fair market value and does not vary with referrals; 2) the failure to fit within an exception is due to the lack of an adequate writing; 3) the entity can prove by parole evidence that the compensation for the arrangement was set in advance; and 4) the failure to have a sufficient writing was inadvertent (i.e., the failure was attributable to negligence rather than a knowing violation of the Stark requirements). 253 They proposed that the penalty would be assessed per arrangement, and added that, “…in our experience, non-compliant arrangements rarely occur in isolation.” 254 This proposal addressed the same type of violation as the AHA two-track proposal, but went further than the AHA proposal in suggesting the notion of a flat penalty. It also expressly limited the desk audit track to procedural violations, something the AHA resisted doing.

In support of the proposal, the attorneys argued that the proposal:

would allow CMS to focus enforcement resources in areas where Stark law violations present real concern and damage to the Medicare program. The proposal would encourage self-disclosure, create a pathway for the fair and equitable resolution of the

252 Id. at 2.
253 Id.
254 Id.
hundreds, if not thousands of technical violations in the provider community and avoid
the waste of enforcement resources on these technical violations.\(^{255}\)

At the same time that the AHA proposed the two track process described above, it also
suggested a penalty scheme similar to that suggested by the Homchick Letter. The AHA
proposed stipulated damages “for categories of violations posing the least risk of harm to the
program or its beneficiaries” in amounts ranging up to $10,000. The AHA cited agreements with
missing signatures or situations where an arrangement was otherwise compliant with an
exception but had not been documented as examples of situations where the stipulated penalties
would apply. The AHA suggested this provision should be applicable regardless of whether a
situation qualified for expedited review or not under its two-track proposal.\(^{256}\)

CMS did not comment publicly on either the AHA and Homchick proposals or on the
general idea of a procedural/substantive distinction. Some high-profile cases have offered CMS
and the Department of Justice the opportunity to make that type of statement as part of an
explanation the government’s reasoning behind penalty calculation. For example, the
Department of Justice settled with Detroit Medical Center (“DMC”) for $30 million in a case
involving a mixture of procedural and substantive issues.\(^{257}\) Rather than categorize the unsigned
leases that were not below fair market value separately from the other agreements that arguably
were, the DOJ press release simply treated all of the infractions as equally serious, stating simply
that “improper financial relationships between health care providers and their referral sources
can corrupt a physician’s judgment about the patient’s true healthcare needs.”\(^{258}\) Also, if the
DOJ settlement amount reflected any discount on the penalties in recognition of DMC having

\(^{255}\) Id. at 3.

\(^{256}\) AHA Letter, supra note 8, at 3.

\(^{257}\) Press Release, U.S. Dep’t Justice, Detroit Medical Center Pays U.S. $30 Million to Settle False Claims Act

\(^{258}\) Id. (quoting Tony West, Assistant Attorney General for the DOJ Civil Division).
voluntarily disclosed the problems, the press release made no mention of it. This lack of a distinction leaves providers with no confidence that inadvertent errors will be treated more leniently than intentional attempts to defraud the government. A demonstration project offers the opportunity to make the important distinction between intentional actions and innocent errors.

3. Explicit Statements Offering Tangible Benefits for Self-Disclosure

The simplest improvement CMS could make in the SRDP is for the agency to make the kinds of statements about the SRDP that the OIG and New York OMIG have made about their protocols. Whether the differences between the CMS, OIG and New York OMIG protocols truly signal a different attitude or are merely oversights, they have certainly been interpreted by the provider community as significant. The contrast between the agencies is especially striking in light of the fact that the OIG protocol deals with potential criminal issues under the Anti-Kickback statute while CMS deals with a civil statute. CMS could add clarity and consistency to the government’s handling of health care providers’ self-disclosures by simply making a statement similar to the OIG’s or New York OIMG’s concerning their apparent willingness to at least sometimes settle a claim for less than the face amount of the potential penalties.

CMS should also expand the list of factors it will consider in mitigating penalties to include some of those suggested by the AHA before CMS released the SRDP: 1) whether the parties’ failure to meet all of the prescribed criteria in an applicable exception was due to an inadvertent error or an intentional act; 2) the corrective action taken by the parties; 3) whether the services provided were reasonable and medically necessary; 4) whether the care was sought in an

259 See Conn, supra note 206, at 1 (analogizing provider navigation between multiple disclosure protocols with ancient Greek sailors navigating between two mythological sea monsters, Scylla and Charybdis, poised to devour sailors).
emergency situation; and 5) whether the Medicare program or any beneficiaries suffered any harm from the provider’s actions.\textsuperscript{260}

D. Measuring Results of a Demonstration Project

As part of each of its previous demonstration projects, CMS developed criteria for determining the success of the project as part of the project. The CMS staff is best positioned to determine specific measures that would be most helpful in evaluating any project. CMS would, at a minimum, want to consider the amount of money recovered during the demonstration period, along with the number of providers participating, as compared to SRDP results to date. It would be important to choose states for the project that include a variety of demographics, including hospitals in rural, urban and suburban settings. As CMS consulted with trade groups, providers’ counsel and others in the development of previous demonstration projects,\textsuperscript{261} CMS should include similar stakeholders when developing this project. In fact, PPACA mandates that CMS consult with such groups in the development of any demonstration project.\textsuperscript{262} Since the AHA and the AHLA, among many other groups and individuals, have been very active to date on self-disclosure issues, it is likely those groups would be willing to assist in the development of a good demonstration project model.

Conclusion

The stakes for health reform are enormous. Health care accounts for approximately seventeen percent of the United States’ gross domestic product.\textsuperscript{263} PPACA’s inclusion of demonstration projects reflects the need for HHS and CMS to be open to new ways of doing

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\item \textsuperscript{260} AHA Letter, supra note 8, at 3.
\item \textsuperscript{261} See Press Release, NJ Hospital Ass’n, Medicare Picks NJ To Test Innovative Incentive System (Aug. 18, 2009), http://www.njha.com/press/PressRelease.aspx?id=7575 (NJ Hospital Ass’n spearheaded effort to win waiver from CMS to test Gainsharing initiative, aimed at reducing healthcare costs while maintain quality of care).
\item \textsuperscript{262} PPACA, supra note 5, § 3021(a) (to be codified 42 U.S.C. 1315(a)(3)).
\item \textsuperscript{263} OFFICE OF THE ACTUARY, CMS, NATIONAL HEALTH EXPENDITURE DATA HIGHLIGHTS 1 (2009), http://www.cms.gov/NationalHealthExpendData/downloads/highlights.pdf (national expenditure for health care was 17.3\% of GDP for 2009).
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business if we are to continue to provide high quality care to our citizens without bankrupting the country.

A revised self-disclosure protocol offers the opportunity to increase return of overpayments to the Medicare Trust Fund, improve respect for and compliance with the law, and encourage generally law-abiding providers to work with regulators so that regulators can focus their limited resources on investigating and prosecuting providers who seek to intentionally defraud government health care programs. Since vinegar does not seem to be attracting providers’ disclosures, it is time for CMS to try a little honey in the controlled environment of a demonstration project. If the experiment proves out Ben Franklin’s aphorism, taxpayers and health care providers alike will benefit.