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

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CATCHING FLIES WITH VINEGAR: A CRITIQUE OF THE CENTERS FOR MEDICARE AND MEDICAID SELF- DISCLOSURE PROGRAM

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ABSTRACT

This 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. This 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.

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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, “[t]o 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 . . . 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] [g]allon of [v]inegar.”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, commonly referred to as the “Stark Law,” or simply “Stark,” 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 trigger legal liability. 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 patient care, in addition to civil penalties.

¹ Letter from Benjamin Franklin to Joseph Priestley (Sept. 19, 1772) (emphasis in original) (on file with the Library of Congress).

² RICHARD SAUNDERS, POOR RICHARD, AN ALMANACK (1744) (quoting Benjamin Franklin) (on file with Yale University Library).

³ Limitation on Certain Physician Referrals (Stark Law), 42 U.S.C. § 1395nn (2006). 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. §§ 411.353-411.389 (2010). Some of the more commonly relied upon exceptions include those for services performed personally by or under the personal supervision of 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 prescribed by the regulations.

The Affordable Care Act of 2010 (ACA)⁵ required CMS to develop a procedure by which health-care providers could self-disclose violations of the Stark Law.⁶ The statute also explicitly gave CMS the authority to reduce the financial penalties for Stark violations as a way to encourage providers to self-disclose violations.⁷ Congress included these provisions in the ACA in response to providers' requests. Indeed, before the self-disclosure protocol was released, many health-care providers were hopeful that 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 the ACA 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."⁸

In September 2010, CMS released its Self-Referral Disclosure Protocol (SRDP), with a slightly revised version released on May 6, 2011.⁹ 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, provides less guidance, and offers fewer incentives to use the protocol than similar self-disclosure protocols, such as those employed by HHS's Office of Inspector General for the Anti-Kickback Statute and by New York State for its Medicaid program.¹⁰

⁵ Patient Protection and Affordable Care Act, Pub. L. No. 111–148, 124 Stat. 119 (2010), *amended by* Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111–152, 123 Stat. 1029 (2010) (to be codified as amended at various sections of Title 42 of the United States Code).

⁵ *Id.* § 6409 (to be codified at 42 U.S.C. § 1395nn note).

⁶ *Id.*

⁷ *See id.*

⁸ Letter from Rick Pollack, Exec. Vice President, Am. Hosp. Ass'n, to Kathleen Sebelius, Sec'y, Dep't of Health & Human Serv's 3 (July 16, 2010) [hereinafter AHA Letter], <http://www.aha.org/aha/letter/2010/100716-cl-ppaca.pdf>.

⁹ *See CMS Voluntary Self-Referral Disclosure Protocol*, CMS.GOV (revised May 6, 2011) [hereinafter *SRDP*], http://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf.

¹⁰ *See infra* Part III.

As of July 2011, only seventy providers had taken advantage of the SRDP.¹¹ CMS has stated that it is pleased with the numbers to date.¹² However, when those seventy disclosures are viewed in the context of the Medicare program as a whole, it is difficult to understand why CMS is happy with those numbers. There are over 6,100 hospitals and 932,700 physicians participating in the Medicare program.¹³ Hospitals are the focus of this Article, as physicians are rarely prosecuted under Stark.¹⁴

Consider the number of potential Stark issues at those 6,100 hospitals. Even the smallest hospital has numerous contracts with physicians that create potential Stark issues.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 95 percent of hospitals have “technical” violations of Stark arising out of their arrangements with physicians.¹⁶ McAnaney did not define a “technical,” as opposed to a substantive, violation. It is likely he was referring to a violation of the regulations that specify exactly how an arrangement can fall under a Stark exception. For example, one exception to Stark permits self-referrals by physicians if the remuneration is at fair market value.¹⁷ For an ar-

¹¹ Katherine A. Lauer & Robert L. Roth, Am. Health Lawyers Ass’n Webinar Presentation, *Medicare Repayments and Disclosures*, at 23 (June 16, 2011) (on file with author).

¹² Julie E. Kass et al., *Seven Months Later: An Interactive Dialogue Regarding Initial Experiences and Practical Advice in Dealing with CMS’ Self-Referral Disclosure Protocol*, AM. HEALTH LAWYERS ASS’N (Apr. 11, 2011) http://www.healthlawyers.org/Events/Webinars/RoundtableDiscussions/2011/Documents/roundtable_discussion_recording_041111.mp3.

¹³ *2010 Edition: Data Compendium*, CMS.GOV (2010), <https://www.cms.gov/DataCompendium/downloads/2010ProvidersSupp.zip> (according to Providers Table VI.1 & VI.6, over 95 percent of physicians are Medicare program participants).

¹⁴ See *infra* Part I.A.

¹⁵ *CMS Postpones Hospital Reporting of Disclosure of Financial Relationships Report (DFRR)*, CMS.GOV [hereinafter *DFRR*], https://www.cms.gov/PhysicianSelfReferral/70_Disclosure.asp#TopOfPage (last visited July 25, 2011). DFRR, initially proposed in 2008, would have required hospitals to document and disclose to CMS all financial relationships with physicians. *Id.* After multiple CMS modifications of timeline and cost estimates, DFRR reporting was delayed pending implementation of new hospital disclosure requirements under PPACA § 6001. *Id.*

¹⁶ *OIG ‘Open Letter’ to Industry Cites Kickbacks in Self-Disclosure Protocol*, 13 HEALTH CARE FRAUD REP. (BNA) 258 (2009).

¹⁷ 42 U.S.C. § 1395nn(h)(3) (2006). 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

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 specify the compensation in advance.¹⁸ Failure to follow those steps probably constitutes the sort of “technical” violation to which McAnaney refers.

Even if McAnaney’s estimate is largely hyperbole, it is clear that thousands of hospitals, each with thousands of physician relationships, should generate many more than seventy self-disclosures. The former New York State Medicaid Inspector General, James Sheehan, said that he considers the number and extent of disclosures a good outcome measure of his agency’s effectiveness in running the New York State Medicaid self-disclosure program.¹⁹ Applying that measure to the CMS program, it is a dismal failure.

The fact that providers are, by and large, not choosing to self-disclose Stark violations to CMS, despite the enormous penalties for nondisclosure,²⁰ should cause CMS to rethink the current SRDP. Providers do have other options for self-disclosure of various fraud and abuse issues. These include (1) simple refunds to the appropriate fiscal intermediary, (2) 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, (3) a report to the Department of Justice (DOJ) through the local Assistant U.S. Attorney. For Stark-only issues, however, CMS has stated that providers should use its protocol, the SRDP. If providers choose not to take advantage of this opportunity to come forward voluntarily, the government fails to recover money that the Medicare program is owed. Costs of enforcement are then 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 percent of total annual health-

general commercial use, less any value for proximity or convenience as a potential source of patient referrals. *Id.*

¹⁸ *See, e.g.*, 42 U.S.C. § 1395nn(e)(1)(A) (rental of office space or equipment); *id.* § 1395nn(e)(3) (personal services arrangements).

¹⁹ James Sheehan, & Robert Hussar, *Self-Disclosures by Medicaid Providers*, N.Y. OFF. OF MEDICAID INSPECTOR GEN. 38 (Sept. 14, 2010), http://www.omig.ny.gov/data/images/stories/Webinar/9-14-10_omig_self_disclosure_webinar.pdf.

²⁰ *See infra* Part II.

care spending) is lost to fraud every year.²¹ During the congressional debate on the ACA, proponents of the bill touted fraud recovery as an important source of funding to counterbalance the costs of extending insurance coverage to millions of new people.²² During fiscal year 2010, the federal government won or negotiated approximately \$2.5 billion in health-care fraud judgments and settlements, and attained additional administrative settlements or penalties.²³ In an attempt to raise that number even higher, the ACA increased the budget of the Health Care Fraud and Abuse Control Program by \$10 million per year for 2011–2019, and increased funding for the OIG, FBI, and Medicare Integrity Program by the rate of increase in the Consumer Price Index over the previous year for 2011–2019.²⁴

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.²⁵ Krause also makes the point that more resources allocated to prosecution will not necessarily 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

²¹ Vicki Lee Parker, *Treasure Might be Buried in Medical Bills*, NAT'L HEALTH CARE ANTI-FRAUD ASS'N (Apr. 12, 2007, 7:15 AM), http://www.nhcaa.org/eweb/dynamicPage.aspx?webcode=about_nhcaa&wpscode=Treasuremightbeburiedinmedicalbills.

²² John K. Iglehart, *Finding Money for Health Care Reform – Rooting Out Waste, Fraud, and Abuse*, 361 NEW ENG. J. MED. 229, 229-31 (2009) (discussing governmental efforts to strengthen antifraud measures to increase recoupment of improper payments).

²³ DEP'T OF HEALTH & HUMAN SERV'S. & DEP'T OF JUSTICE, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FISCAL YEAR 2010 8 (2011), available at <http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2010.pdf>.

²⁴ Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 6402(i), 124 Stat. 119, 760 (2010) (to be codified at 42 U.S.C. § 1395(i)(k)).

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, 355–56 (2010) (discussing difficulties with calculating the amount of money attributed to fraud).

will be enough to fund a large chunk of the health care reform effort—simply strains credulity.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 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.

This Article sets out in Part I an overview of the Stark Law, explaining how it applies to physicians, hospitals, and other health-care entities. Part II summarizes the SRDP requirements and process for disclosure of Stark issues, and the results of the SRDP to date. Part 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 exclusion from the Medicare or Medicaid program. Finally, Part IV proposes a demonstration project to test possible improvements to the SRDP.

HHS has used demonstration or pilot projects in the past, and the ACA 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.²⁷ Using the demonstration project format to test changes to the SRDP in a few 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 enforcement costs, improve program integrity, and encourage providers to deal responsibly with the minor lapses in compliance that inevitably arise in such an enormous government program as Medicare.

²⁶ *Id.* at 364.

²⁷ *See* § 3021(a), 124 Stat. at 389 (creating the Center for Medicare and Medicaid Innovation).

I. BACKGROUND ON THE STARK LAW

A. Basic Provisions

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.²⁸ It was originally enacted to curb rampant Medicare abuse by physicians and hospitals, particularly in the 1980s. Physicians referred patients to facilities they owned or otherwise had a financial interest in, regardless of whether patients actually needed the tests or services for which they were being referred.²⁹ The purpose of the law, as 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.³⁰ Rep. Stark hoped that the law would provide a "bright line rule" and "unequivocal guidance" for providers.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.³² The term "financial relationship" is defined very broadly. It includes ownership and any type of compensation arrangement.³³ "Designated health services" include lab, radiology, inpatient, and outpatient hospital services, among other things.³⁴ The Stark Law prohibits any entity from billing government payment programs, such as Medicare, for services provided pursuant to a noncompliant referral during the "period of disallowance."³⁵

²⁸ 42 U.S.C. §§ 1395nn(b)-(e) (2006); 42 C.F.R. §§ 411.353(a), (e) (2010).

²⁹ 135 CONG. REC. 2035 (1989) (statement of Rep. Pete Stark, introducing the Ethics in Patient Referrals Act of 1988).

³⁰ *Id.*

³¹ *Id.*

³² 42 U.S.C. § 1395nn(a)(1); 42 C.F.R. §§ 411.353(a), (c)(1).

³³ 42 U.S.C. § 1395nn(a)(2); 42 C.F.R. § 411.354(a).

³⁴ 42 U.S.C. § 1395nn(h)(6); 42 C.F.R. § 411.351.

³⁵ 42 C.F.R. § 411.353(c). This period is defined as "starting on the date the financial relationship is first noncompliant and lasting until *no later than* (1) the date on which 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." Lesley Reynolds & Ben Koplin, *Overpayment Liability and Self-Disclosure Under the New CMS Protocol*, J. HEALTH CARE COMPLIANCE, May-June 2011, at 23, 24. 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 the financial relation-

The Stark Law applies to both Medicare³⁶ and Medicaid,³⁷ however, due to hospitals' and physicians' particular dependence on Medicare as a source of revenue, most commentators refer to the Stark Law's application only in connection with Medicare. Additionally, although the Stark Law addresses physician referrals, enforcement of the statute has generally focused on hospitals' submissions of claims resulting from physician referral because hospitals are seen as having "deeper pockets" than physicians.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."³⁹ So as not to contribute to this misperception, this Article uses the term "provider" to reference 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 and physician part-time employment or independent contractor agreements.⁴⁰ Other situations in which Stark issues arise are physician investment in hospitals or ambulatory surgical centers, and arrangements between physicians and other designated health service providers such as clinical laboratories, diagnostic imaging centers, physical therapy companies, durable medical equipment companies, and lease agreements for space or equipment.⁴¹ Other types of agreements that raise Stark issues are hospital-physician recruitment agreements, marketing agreements with entities owned by physician

ship is technically cured to the date on which any excess compensation is finally returned or money due is finally paid." *Id.*

³⁶ 42 U.S.C. § 1395nn.

³⁷ 42 C.F.R. § 411.353(a).

³⁸ AM. HEALTH LAWYERS ASS'N, PUB. INTEREST COMM., A PUBLIC POLICY DISCUSSION: TAKING THE MEASURE OF THE STARK LAW 5 (2009) [hereinafter WHITE PAPER], <http://www.healthlawyers.org/hlresources/PI/Policy/Documents/Stark%20White%20Paper.pdf>.

³⁹ *Id.* at 10.

⁴⁰ 42 U.S.C. §§ 1395nn(b), (e)(2), (e)(4); 42 C.F.R. §§ 411.355, 411.357(c), (g), (h).

⁴¹ 42 U.S.C. §§ 1395nn(e)(1), (8); 42 C.F.R. §§ 411.357(a), (b), (i), (k), (l), (p).

or hospital investors that do not reflect fair market value for necessary services, and practice compensation programs that reward shareholders or employee-physicians based on orders of designated health services.⁴²

The reason that these practices and arrangements often pass muster is that Stark contains numerous exceptions, covering the most common types of financial relationships between hospitals and physicians. For example, exceptions are made for fair market value compensation, employment agreements, personal services arrangements, and office space rental.⁴³ There are also numerous exceptions applicable to physicians practicing in groups,⁴⁴ as well as an exception for services personally performed by a physician.⁴⁵ Each of these exceptions has very specific requirements, and failure to meet those requirements will result in a Stark violation. For example, the employment exception requires that there be a written agreement for 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.⁴⁶

An example will help illustrate the interplay of these various provisions. Suppose the fictional infectious disease specialist, Dr. Gregory House,⁴⁷ has a thriving private practice in addition to his employment at the Princeton-Plainsboro Teaching 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, as long as the hospital and Dr. House meet all the technical requirements of the employment exception, Dr. House can refer patients to the hospital without triggering either the referral or billing prohibitions of the Stark law.

(p). ⁴² 42 U.S.C. §§ 1395nn(e)(3)(B), (e)(5); 42 C.F.R. §§ 411.357(e), (i), (k), (l),

⁴³ 42 U.S.C. § 1395nn (e); 42 C.F.R. § 411.357.

⁴⁴ 42 U.S.C. § 1395nn(b); 42 C.F.R. § 411.355.

⁴⁵ 42 U.S.C. § 1395nn(e)(3)(A); 42 C.F.R. § 411.357(d).

⁴⁶ 42 U.S.C. § 1395nn(e)(2); 42 C.F.R. § 411.357(e).

⁴⁷ *House* (FOX Broadcasting Co. Nov. 16, 2004).

C. Stark and Intent

The Stark Law overlaps significantly the Anti-Kickback Statute,⁴⁸ a criminal law which prohibits the *knowing* offering of any remuneration in order to secure referrals to federal health-care programs, including Medicare.⁴⁹ Similar to Stark, the Anti-Kickback Statute is aimed at financial relationships that potentially influence physicians to refer patients inappropriately for the physicians' own financial gain.⁵⁰ So why was the Stark law necessary? Rep. Stark described it this way:

One of the most serious shortcoming[s] of current law 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 nationwide, can adequately police the complex business arrangements that underpin the \$100 billion a year Medicare program.⁵¹

While the lack of an 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 makes it very easy for providers to unintentionally, or even unknowingly, run afoul of the statute. In fact, it is so easy to do so that the Stark Law is often referred to as a "strict liability" statute.⁵² For example, if Dr. House forgot to sign the employment contract between himself and Princeton-Plainsboro, any referrals he made to the hospital would be improper, even if the failure to sign was merely an oversight. This would be true even if the hospital signed the agreement, paid Dr. House accord-

⁴⁸ Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (2011).

⁴⁹ *Id.*

⁵⁰ 135 CONG. REC. 2035 (1989).

⁵¹ *Id.*

⁵² Richard Lower & Robert D. Stone, *Off with Their Heads! Summary Execution for Technical Stark Violations – and a Proposal to Commute the Sentence*, J. HEALTH & LIFE SCI. L., Apr. 2010, at 112, 147 (discussing the strict liability nature of Stark violations despite no intent and no harm brought to patients or the public); Reynolds & Koplin, *supra* note 35, at 24 (no showing of intent required under Stark).

ing to its terms at fair market value, 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 coupled with the complexity of the law has caused Stark to be criticized as inflexible and excessively punitive almost since its passage.⁵³ Numerous amendments and HHS regulatory changes have only made the Stark Law more difficult for providers to interpret and follow.⁵⁴ The AHA recently described the Stark Laws as “increasingly complex, confusing and continually changing”⁵⁵ Though the AHA had originally supported the Stark Law when it was introduced by Rep. Stark, as CMS was preparing to release the SRDP, it asked CMS for changes and clarifications in the proposed disclosure protocol, because it had seen the “unintended consequences of the current rules” and wanted CMS to “restore fairness” to the law.⁵⁶

D. Penalties under Stark

If the penalties under Stark were inconsequential, the strict liability aspect of the law would not be so significant. As it is, however, Stark can result in “ruinous financial liability.”⁵⁷ Penalties include denial of payment for claims submitted as a result of an unlawful relationship,⁵⁸ mandated refunds of amounts collected in violation of Stark,⁵⁹ and fines assessed by the OIG.⁶⁰ The total penalty amounts in Stark cases are often in the millions of dollars.⁶¹

⁵³ See Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 *LAW & PSYCHOL. REV.* 1, 22-24 (2003) (citing commentators’ descriptions of Stark as “confusing,” “complicated,” “over-reaching, too complex and intrusive,” “antiquated,” among many others).

⁵⁴ WHITE PAPER, *supra* note 38, at 6.

⁵⁵ AHA Letter, *supra* note 8, at 1.

⁵⁶ *Id.* at 4.

⁵⁷ Ankur J. Goel & Daniel H. Melvin, *New CMS Self-Disclosure Protocol Fundamentally Changes the Landscape For Stark Law Compliance and Enforcement*, 14 *HEALTH CARE FRAUD REP.* (BNA) 862 (2010).

⁵⁸ 42 U.S.C. § 1395nn(g)(1) (2006); 42 C.F.R. § 411.353(b) (2010).

⁵⁹ 42 U.S.C. § 1395nn(g)(2); 42 C.F.R. § 411.353(d).

⁶⁰ Civil Monetary Penalties, 42 U.S.C. §§ 1320a-7a (2011); 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.

⁶¹ See, e.g., Press Release, Dept. of Justice, *Covenant Medical Center to Pay U.S. \$4.5 Million to Resolve False Claims Act Allegations* (Aug. 25, 2009), *available*

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 CMPs up to \$15,000 per claim, depending on the specifics of the offense, and up to \$100,000 per arrangement which the physician or entity knew or should have known had the principal purpose of assuring referrals which, if made directly, would violate the Stark Law.⁶² Providers may also be permanently excluded from participation in federal health-care programs, meaning that no goods or services furnished by an excluded provider are reimbursable under federal health-care programs. Furthermore, other providers may not employ or contract with excluded providers.⁶³ The ACA extended CMPs to any person who “knows of an overpayment . . . [and] does not report and return the overpayment”⁶⁴

A Stark violation can also trigger the application of the False Claims Act (FCA). The FCA is not specifically a health-care statute; instead, it prohibits the knowing submission of “false or fraudulent” claims for payment to the federal government.⁶⁵ Violations of the FCA are punishable by up to treble damages and an \$11,000 per-claim penalty.⁶⁶ Prior to the 2009 passage of the Fraud Enforcement and Recovery Act (FERA), a Stark violation would trigger 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 causes 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 [g]overnment” had violated the

at <http://www.justice.gov/opa/pr/2009/August/09-civ-849.html>; Press Release, Dept. of Justice, Northside Hospital and Doctors' Groups Pay \$6.37 Million to U.S. to Settle False Claims Act Suit (Oct. 20, 2006), *available at* <http://www.justice.gov/usao/gan/press/2006/10-20-06b.pdf>; Press Release, Dept. of Justice, St. Joseph Medical Center in Maryland to Pay U.S. \$22 Million to Resolve False Claims Act Allegations (Nov. 9, 2010), *available at* <http://www.justice.gov/opa/pr/2010/November/10-civ-1271.html>.

⁶² 42 U.S.C. §§ 1395nn(g)(3)-(4) (2011).

⁶³ Publication of the OIG Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs, 64 Fed. Reg. 52,791, 52,792 (Sept. 30, 1999).

⁶⁴ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402(d)(2)(A)(iii), 124 Stat. 119, 758 (2010) (to be codified at 42 U.S.C. §§ 1320a-7a(a)).

⁶⁵ False Claims Act, 31 U.S.C. §§ 3729(a)(1)(A)-(G) (Supp. III 2010).

⁶⁶ *Id.* § 3729(a)(1). The original \$10,000 per claim penalty was adjusted upward for inflation. 28 C.F.R. §§ 85.3, (a)(9) (2008).

FCA.⁶⁷ Providers had to engage in an *affirmative act* intended to avoid or conceal the obligation to repay.⁶⁸

With the passage of the FERA, providers became liable not only for affirmative acts that conceal overpayments, but also for the failure to repay an identified overpayment.⁶⁹ No attempt to conceal is required. Simply avoiding the obligation to repay is enough to trigger the FCA. Anyone 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.⁷⁰

In addition to creating an affirmative obligation for providers to “report and return” overpayments, the ACA made another significant change to the FCA. It established a sixty-day window within which an “identified” overpayment must be reported and returned to the government.⁷¹ The statute starts tolling on either the day that the claim is submitted or the day that a corresponding cost report is due, whichever is later.⁷² Prior to the ACA, HHS regulations had used sixty days as the definition of a “prompt refund” required for proper handling of incorrect collections.⁷³ The ACA simply 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. A whistleblower can file suit as a qui tam relator.⁷⁴ If the government decides to intervene in the qui tam action and ultimately reaches a cash settlement or prevails in court, the qui tam relator can receive up to one-fourth of the government’s recovery as a reward for

⁶⁷ False Claims Act 31 U.S.C. § 3729(a)(7) (2006).

⁶⁸ *Id.*

⁶⁹ False Claims Act, 31 U.S.C. § 3729(a)(1)(G) (Supp. III 2010).

⁷⁰ *Id.*; *see generally id.* § 3729(b)(1) (stating that “knowingly” means that a person either has “actual knowledge of the information,” “acts in deliberate ignorance of the truth...of the information,” or “acts in reckless disregard of the truth...of the information,” regardless of a lack of specific intent to defraud).

⁷¹ Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 6402(a), 124 Stat. 119, 755 (2010) (to be codified at 42 U.S.C. § 1320a-7k(d)(2)).

⁷² *Id.*

⁷³ Timing and Methods of Handling, 42 C.F.R. § 489.41 (2010).

⁷⁴ Under the FCA, a qui tam relator is a private individual who brings an allegation of fraud or abuse to the government. False Claims Act, 31 U.S.C. § 3730(b)(1) (2006).

alerting the government to the false claims.⁷⁵ Qui tam relators therefore have every incentive to push for prosecution of even the most minor Stark violation. In addition, relators are unaffected by the counterbalancing policy concerns that normally restrain prosecutors in situations where the government has not truly been harmed by an inadvertent violation.⁷⁶

Most Stark-related legal action arises in the form of suits by qui tam relators rather than prosecutors.⁷⁷ Between 1986 and 2008, 62 percent of FCA cases were initiated and filed by qui tam relators.⁷⁸ These relators have no incentive to take a provider's record of overall compliance with Medicare into consideration, and every incentive to seek the maximum penalty. The prominent role of qui tam relators in health-care fraud cases has led to a situation where many Stark enforcement actions fail to assess the seriousness of an offense or prioritize prosecutorial resources.⁷⁹

The linkage between Stark and the FCA provides most of the teeth for Stark enforcement. Consider our example involving Dr. House and his unsigned agreement. Assume the unsigned agreement was not discovered for several years after the omission occurred. All claims that 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 or not the patients needed the services or the services were provided appropriately. The government's position is that the contract between the doctor and the hospital was improper. As a result, all services provided under that contract were improperly

⁷⁵ *Id.* § 3730(d)(1)-(2).

⁷⁶ 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 (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 (2007) (recognizing prosecutorial discretion is minimized by qui tam filings, though the government may have economic incentive to allow them to proceed to litigation).

⁷⁷ WHITE PAPER, *supra* note 38, at 3.

⁷⁸ Robert T. Rhoad & Matthew F. Fornataro, *A Gathering Storm: The New False Claims Act Amendments and Their Impact on Healthcare Fraud Enforcement*, 21 HEALTH LAWYER 14, 16 (Aug. 2009) (discussing the use of False Claims Act qui tam cases in healthcare fraud enforcement).

⁷⁹ See Lower & Stone, *supra* note 52, at 122-25; see also Matthew, *supra* note 76, at 297-98 (discussing FCA qui tam enforcement, although the author's premise is likely applicable to the increased role of qui tam relators in health care fraud generally).

provided. Therefore, any money the government paid on any of the claims constitutes an overpayment that must be repaid. Even if the hospital was not aware of the oversight, the strict liability aspect of Stark means that the hospital and Dr. House are now liable for repayment of all the claims made for care of patients that Dr. House admitted to the hospital or otherwise referred there for services.

In addition, the hospital and Dr. House are liable for CMPs under the 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 \$11,000 plus three times the amount of the overpayment (in other words, the total value of referrals made in the case of a Stark violation).⁸⁰ 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, 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 Dr. House kickbacks for referring patients to the hospital (with the exception of penalties requiring actual or constructive knowledge). 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.⁸¹ 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.

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 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 that is part

⁸⁰ False Claims Act, 31 U.S.C. § 3729(a)(1) (Supp. III 2010).

⁸¹ 42 U.S.C. § 1395nn(g)(4) (2006). 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. *Id.*

of a criminal, civil or administration hearing; a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation; or from the news media.⁸²

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 that 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 "undertaken by authorized government officials with official purposes."⁸³

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 Hospital* held that statements to Medicare investigators were a "public disclosure."⁸⁴ 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 subsequently be used against them by qui tam plaintiffs.

F. "Technical" v. "Substantive" Stark Issues

As noted earlier, Rep. Stark's purpose in proposing this law was to target intentional activity without saddling 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 viola-

⁸² False Claims Act, 31 U.S.C. § 3730(e)(4)(A) (2006).

⁸³ *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) (quoting *United States ex rel. Mathews v. Bank of Farmington*, 166 F.3d 853, 862 (7th Cir. 1999); 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).

⁸⁴ *United States ex rel. Cosens v. Yale-New Haven Hosp.*, 233 F. Supp. 2d 319, 327 (D. Conn. 2002).

tions, both in terms of the process the government uses to resolve overpayment issues and the penalties assessed.

Most issues that arise under Stark are matters relating to compliance with the specific requirements for meeting the language of various exceptions rather than any more substantive problem. Strict enforcement of technical violations with application of the same penalties as are used for more serious issues produces potentially unjust penalties. Kevin McAnaney, Chief of the OIG's Industry Guidance Branch from its creation in 1997 until May 2003, has stated that most of the issues under Stark relate to these technical violations rather than anything more substantive. He has written that "[t]he 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."⁸⁵ McAnaney's sentiments were echoed in the AHLA White Paper on the Stark Law, which was based on two Convener Sessions held in April and June 2009.⁸⁶ 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 AHLA White Paper concluded that "innocent or highly technical 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."⁸⁷

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

⁸⁵ OIG 'Open Letter' to Industry Cites Kickbacks in Self-Disclosure Protocol, *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).

⁸⁶ WHITE PAPER, *supra* note 38, at 1.

⁸⁷ *Id.* at 3, 6.

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.⁸⁸

Social science research supports the notion that if providers believe the law punishes minor procedural failings in the same way as it punishes intentional attempts to improperly influence referral patterns, the providers will be less likely to comply with the law. Professor Paul Robinson has written about the importance of the government having “moral credibility” when attempting to convince people to obey the law.⁸⁹ He argues that simply enacting a statute is not enough to persuade individuals and companies to obey the law. People must see the law as having moral credibility. Robinson goes on to define “moral credibility” as the law’s reputation for punishing those who deserve it, under rules perceived as just. Furthermore, he says, the law must protect from punishment those who do not deserve punishment and assure that any punishment levied is in the amount deserved—“no more and no less.”⁹⁰ In his book, *Why People Obey the Law*, sociologist Tom Tyler states, in a similar vein, that “[i]t is interesting that people appear to connect the obligations of authorities to issues of fair procedure, not to outcomes. It is being unfairly treated that disrupts the relationship of legitimacy to compliance, not receiving poor outcomes.”⁹¹

In 2007, CMS seemed on the verge of recognizing that some types of Stark violations are less serious than others. CMS proposed regulations that would create new criteria by which providers could satisfy Stark exceptions in situations where the failure to satisfy the exception was merely “procedural.”⁹²

The alternative method for compliance with the physician self-referral prohibition would provide that, if an arrangement does not meet all of the existing pre-

⁸⁸ Lower & Stone, *supra* note 52, at 118 (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)).

⁸⁹ See generally Paul H. Robinson, *Moral Credibility and Crime: Why People Obey the Law*, CURRENT, June 1995, at 10.

⁹⁰ *Id.* at 12.

⁹¹ TOM R. TYLER, WHY PEOPLE OBEY THE LAW 172 (2006).

⁹² Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, 72 Fed. Reg. 38,122, 38,185 (proposed July 12, 2007).

scribed criteria of an exception, the arrangement nevertheless would meet the exception if: (1) The facts and circumstances of the arrangement are self-disclosed by the parties to us; (2) we determine that the arrangement satisfied all but the prescribed procedural or “form” requirements of the exception at the time of the referral for DHS at issue and at the time of the claim for such DHS; (3) the failure to meet all the prescribed criteria of the exception was inadvertent; (4) the referral for DHS and the claim for DHS were not made with knowledge that one or more of the prescribed criteria of the exception were not met (consistent with other exceptions, we would apply the same knowledge standard as that applicable under the False Claims Act); (5) the parties have brought (or will bring as soon as possible) the arrangement into complete compliance with the prescribed criteria of the exception or have terminated (or will terminate as soon as possible) the financial relationship between or among them; (6) the arrangement did not pose a risk of program or patient abuse; (7) no more than a set amount of time had passed since the time of the original non-compliance with the prescribed criteria; and (8) the arrangement at issue is not the subject of an ongoing Federal investigation or other proceeding (including, but not limited to, an enforcement matter.⁹³

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.”⁹⁴ This sort of exception was to be reserved for procedural issues such as a missing signature or an expired employment agreement still being followed by the parties.⁹⁵

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 approach. Commenters expressed concern about the amount of discretion CMS

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ *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* Part IV.D.

would have to assess a provider's motivation.⁹⁶ CMS specified that it would retain sole discretion to determine whether the relationship met the terms of the exception. Parties had no right to an administrative or judicial review of this determination.⁹⁷

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 version was limited to situations in which providers comply with all Stark requirements other than the signature requirement, and only for very limited time periods.⁹⁸ The final rule eliminated most of the eight criteria originally proposed, including the requirements that parties self-disclose a noncompliant relationship, and that CMS determine the relationship satisfactory in all areas but the procedural criteria. Instead, CMS chose to allow providers to take advantage of this alternative policy for compliance only when the relationship in question fulfills all criteria of an exception except for the signature requirement.⁹⁹

Unfortunately, those limitations are so narrow as to 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, potentially racking up huge 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,¹⁰⁰ but CMS does not seem to be considering any such exception.

G. CMS's Authority to Settle Cases

Prior to the enactment of the ACA, CMS had little or no authority to compromise or waive any claims liability under Stark or other statutes.¹⁰¹ Thus, "prosecutorial discretion" was simply not available. OIG, by contrast, did not have this limitation. When OIG announced that it would no longer take Stark-only disclosures so that it could

⁹⁶ Alternative Method for Compliance with Signature Requirements in Certain Exceptions, 73 Fed. Reg. 48,705 (Aug. 19, 2008) (codified at 42 C.F.R. § 411.353(g)).

⁹⁷ Medicare Program; Proposed Revisions to Payment Policies under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008, 72 Fed. Reg. at 38,185.

⁹⁸ Alternative Method for Compliance with Signature Requirements in Certain Exceptions, 73 Fed. Reg. at 48,706.

⁹⁹ *Id.*

¹⁰⁰ See Lower & Stone, *supra* note 52 (proposing a Technical Deficiency Exception to Stark; WHITE PAPER, *supra* note 38, at 15 (suggesting a Technical Violation Exception)).

¹⁰¹ Prior to PPACA, 42 C.F.R. § 405.376 did not include Stark claims among those that could be compromised by CMS. 42 C.F.R. § 405.376(d) (2010).

focus on criminal activity under other statutes, providers lost their best avenue for negotiating settlements. However, as noted above, this situation was remedied by the ACA's explicit grant of authority to CMS to compromise on penalty amounts in Stark cases,¹⁰² creating significant opportunities for improving the administration of the Stark Law, as will be discussed below.¹⁰³

II. THE SELF-DISCLOSURE PROTOCOL

A. Providers' Legal Obligation to Self-Disclose

When a provider discovers 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 the overpayment to the government within sixty days.¹⁰⁴ An overpayment retained past the deadline is an "obligation" for purposes of the reverse false claims provision of the FCA.¹⁰⁵ Self-disclosure under SRDP tolls the sixty-day requirement.¹⁰⁶ Also, a provider may be eligible for a reduction in penalties if the overpayment is self-reported rather than discovered by the government in some other manner.¹⁰⁷

A protocol has been in place since 1998 for self-disclosure of issues related to Stark and the Anti-Kickback Statute.¹⁰⁸ The OIG Self-Disclosure Protocol (SDP) is based on a Department of Defense self-disclosure program from the 1980s.¹⁰⁹ The SDP requires that the provider describe the problem, including the scope and results of its internal investigation, an assessment of the financial impact on government health programs, and an explanation of the likely cause of the problem.¹¹⁰ The SDP is administered by the OIG, which has jurisdiction over actions arising under the Anti-Kickback Statute.

¹⁰² Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6409(b), 124 Stat. 119, 772 (2010) (to be codified at 42 U.S.C. § 1395nn note).

¹⁰³ See *infra* Part III.

¹⁰⁴ PPACA § 6402(a), 124 Stat. at 755.

¹⁰⁵ See False Claims Act, 31 U.S.C. § 3729(b)(3) (Supp. III 2010).

¹⁰⁶ *SRDP*, *supra* note 9, at 1.

¹⁰⁷ *Id.*

¹⁰⁸ See Publication of the OIG's Provider Self-Disclosure Protocol, 63 Fed. Reg. 58,399, 58,399 (Oct. 30, 1998) [hereinafter OIG's Provider Self-Disclosure Protocol].

¹⁰⁹ See generally INSPECTOR GEN., DEP'T OF DEF., THE DEPARTMENT OF DEFENSE VOLUNTARY DISCLOSURE PROGRAM (Apr. 1990) [hereinafter DEPARTMENT OF DEFENSE VOLUNTARY DISCLOSURE PROGRAM], available at <http://www.dodig.mil/iginformation/archives/vdguidelines.pdf>.

¹¹⁰ *Id.* at 6, 12.

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.¹¹¹ As a result, providers complained about the lack of good options for Stark-only self-disclosures. Congress responded with the ACA provision requiring CMS to develop a protocol.¹¹²

B. Self-Referral Disclosure Protocol Basics

The SRDP provides that the disclosure must identify the disclosing provider¹¹³ and describe the issue being disclosed, including the type of transaction or conduct giving rise to the issue; entities and/or individuals 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.¹¹⁴

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;¹¹⁵ the circumstances surrounding the discovery of the matter and measures taken to address the issue and prevent future abuses;¹¹⁶ and a statement concerning any history of similar conduct, or any prior criminal, civil and regulatory enforcement actions against the disclosing provider.¹¹⁷

The provider must describe the existence and adequacy of a pre-existing compliance program and all actions taken to prevent a recurrence of the incident or practice, including any measures taken to restructure the noncompliant relationship or arrangement.¹¹⁸ The pro-

¹¹¹ Open Letter from Daniel R. Levinson, Inspector Gen., Dep't of Health & Human Serv's, to Health Care Providers, OFF. OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERV'S (Mar. 24, 2009), <http://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf>.

¹¹² Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6409, 124 Stat. 119, 772-73 (2010) (to be codified at 42 U.S.C. § 1395nn note).

¹¹³ *SRDP*, *supra* note 9, at 3.

¹¹⁴ *Id.* at 4.

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*

vider must also describe any other federal health-care program investigations to which the provider is currently subject, including any other disclosures made by the provider to other government entities.¹¹⁹

The provider must also set out a full financial analysis, including a total amount, itemized by year, that is actually or potentially owed, back to the date of the initial noncompliance (or “look-back period”),¹²⁰ along with an explanation of the methodology used to calculate the amount.¹²¹ The SRDP requires that 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”.¹²² Finally, the provider must include a certification of the truthfulness of the information, based on a good faith effort to resolve the disclosed potential liabilities under Stark.¹²³

After receiving the disclosure, CMS verifies the facts asserted in the disclosure.¹²⁴ The extent of CMS’s verification effort depends, in large part, upon the quality and thoroughness of the submission received.¹²⁵ 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 and thus proper subjects for governmental investigation and possible prosecution.¹²⁶

Generally, CMS will not request information subject to the attorney-client privilege.¹²⁷ 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 waiving privilege.¹²⁸

Before any repayment is made, the disclosing party must acknowledge in writing that CMS’s acceptance of the payment is not an agreement as to the amount of losses suffered by the government, and “does not 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.”¹²⁹

¹¹⁹ *Id.*

¹²⁰ *Id.* at 5.

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*

¹²⁴ *Id.* at 5-6.

¹²⁵ *Id.* at 5.

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.* at 6.

The disclosing party must exhibit good faith and full cooperation with CMS during the disclosure process.¹³⁰ This cooperation includes the provision of documents and materials without CMS having to resort to “compulsory methods.”¹³¹ CMS will consider a lack of good-faith cooperation on the part of the provider when it determines the appropriate resolution of the matter.¹³² The intentional submission of false information, or the intentional omission of relevant information, will be referred to the DOJ or other appropriate federal agencies and may result in additional criminal and/or civil sanctions and exclusion from participation in federal health-care programs.¹³³

CMS is not bound by any conclusions made by the disclosing party under the SRDP.¹³⁴ Furthermore, it is not obligated to resolve the matter disclosed in any particular manner and has no obligation to reduce any amounts owed.¹³⁵ A disclosing provider has no right of appeal for matters resolved through a settlement agreement.¹³⁶ If a provider’s SRDP submission is denied acceptance, is removed, or withdrawn, the provider may appeal any overpayment demand letter.¹³⁷ However, CMS reserves the right to reopen any Medicare cost reports filed since the initial disclosure of Stark violations.¹³⁸

C. Revisions of the SRDP

Since the initial release of the SRDP, CMS has received informal comments from providers and attorneys regarding unclear provisions. Agency representatives have informally commented that they learned about some items that needed clarification after reviewing the first SRDP submissions.¹³⁹ In May 2011, CMS released the latest version of the SRDP. This version specified that all physician fees related to a noncompliant arrangement needed to be calculated as part of the disclosing provider’s financial analysis.¹⁴⁰ More recently, Lewis Morris,

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

¹³⁴ *Id.* at 2.

¹³⁵ *Id.* at 2, 6.

¹³⁶ *Id.* at 2.

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ Joe Carlson, *Few Details Emerge on CMS Self-Disclosure Process*, MODERN HEALTHCARE (June 29, 2011), <http://www.modernhealthcare.com/article/20110629/NEWS/306299963/> (“We’re in a learning process.” (quoting Troy Barsky, Director, CMS Technical Payment Policy Division, speaking at the 2011 AHLA annual meeting)).

¹⁴⁰ *SRDP*, *supra* note 9, at 5.

Chief Counsel at OIG, announced that the agency is preparing to release additional guidance regarding self-disclosure, although it has not announced specifically what that guidance will cover.¹⁴¹ However, there is no indication that CMS is considering the type of significant changes to the SRDP proposed in this Article.

D. Results of the SRDP to Date

The ACA included a provision requiring CMS to report to Congress regarding disclosures by March 2012.¹⁴² The report will include the number of health-care providers or suppliers making disclosures, the dollar amounts collected, and the types of violations reported.¹⁴³ CMS representatives have described some of the disclosures to date in very general terms, but have not issued any summaries in writing.¹⁴⁴ OIG's website provides information about its settlements, such as the general nature of the issue and the amount of the settlement.¹⁴⁵ Presumably, CMS's upcoming report to Congress will include similar information.

One hospital has been willing to publicly discuss the results of its self-disclosure to CMS. The settlement occurred prior to the release of the revised SRDP, but it at least provides some guidance as to how CMS conducts negotiations in these matters and on what terms it will settle.¹⁴⁶ That case involved Saints Medical Center in Lowell, Massachusetts. The settlement was for \$579,000, an amount lower than the hospital's attorneys' lowest estimate of potential obligation.¹⁴⁷ Attorneys for the hospital said that they had not been given the opportunity

¹⁴¹ Gregg Blesch, *Lawyer Warns on Overpayment Disclosures*, MODERN HEALTHCARE (June 27, 2011), <http://www.modernhealthcare.com/article/20110627/NEWS/306279945/>. 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.

¹⁴² See Patient Protection and Affordable Care Act, Pub. L. no. 111-148, § 6409(c), 124 Stat. 119, 773 (2010) (to be codified 42 U.S.C. § 1395nn note).

¹⁴³ *Id.*

¹⁴⁴ Kass et al., *supra* note 12, at 29:45 (discussing the Saints Medical Center settlement).

¹⁴⁵ *Selected Provider Self-disclosure Protocol Settlements*, OFF. OF THE INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERV'S, http://www.oig.hhs.gov/fraud/enforcement/cmp/self_disclosure.asp (last visited July 31, 2011).

¹⁴⁶ See Press Release, Saints Medical Center, Saints Medical Center Resolves Medicare Billing Compliance Issue (Feb. 10, 2011) [hereinafter Saints Press Release], available at <http://www.saintsmedicalcenter.com/news/CMS/>.

¹⁴⁷ *Id.*

to negotiate the settlement at all; nonetheless, they were pleased with the amount in light of potential penalties.¹⁴⁸

III. THE HONEY AND THE VINEGAR: INCENTIVES AND DISINCENTIVES TO DISCLOSURE IN THE SRDP

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.¹⁴⁹ However, the dearth of disclosures to date, compared to the multitude of potential issues requiring disclosure,¹⁵⁰ indicates that a legal requirement to disclose is simply not enough to make providers do the right thing. Most providers will not state for the record whether and why they have decided not to disclose issues which they are legally required to disclose. Some attorneys report that clients are waiting to see how CMS administers the protocol before they decide whether to use it.¹⁵¹ 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."¹⁵²

We can gain some insight into the reasoning of these providers by analyzing data and comments by health-care attorneys responding to a 2008 AHLA survey on the OIG self-disclosure protocol.¹⁵³ Although the survey deals with a different protocol and predates the ACA's

¹⁴⁸ Kass et al., *supra* note 12, at 23:35 (discussing disclosure by Saints' attorney Christine Savage).

¹⁴⁹ *Video News: Live@AHLA 2011 Interview with OIG Chief Counsel Lewis Morris*, MODERN HEALTHCARE (June 27, 2011, 5:00 PM), <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." *Id.*

¹⁵⁰ See *supra* notes 12-14 and accompanying text.

¹⁵¹ Lauer & Roth, *supra* note 11; see Jason Christ et al., *CMS Opens its Doors by Creating the Stark Voluntary Self-Referral Disclosure Protocol—But Enter at Your Own Risk*, 19 HEALTH LAW REP. (BNA) 1400 (2010) (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).

¹⁵² Blesch, *supra* note 141 (discussing comments by Robert Homchick).

¹⁵³ *2007-08 Voluntary Disclosure Survey*, ZOOMERANG.COM [hereinafter *Voluntary Disclosure Survey*], <http://www.zoomerang.com/Shared/SharedResultsSurveyResultsPage.aspx?ID=L235XLG2T5DX> (last visited Oct. 29, 2011) (complete survey results).

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 AHHA members to describe their experience with the then-new OIG SDP.¹⁵⁴ One hundred ninety-five attorneys responded. Most of the disclosures related to billing or coding errors, but 28 percent related to either Anti-Kickback or Stark disclosures.¹⁵⁵ In approximately 46 percent of the cases in which respondents self-disclosed, the government settled for a simple repayment of the overpayment in question.¹⁵⁶ In 18 percent, the government negotiated an amount to be repaid plus simple interest, while 22 percent negotiated settlements but were not required to pay interest.¹⁵⁷ Six percent involved some type of regulatory penalty, while 7 percent resulted in a civil monetary penalty or other administrative monetary sanction for individuals or the company.¹⁵⁸ In 8 percent of the cases, there was an FCA settlement with a multiplier of the overpayment.¹⁵⁹ Twelve percent of the cases resulted in a corporate integrity agreement.¹⁶⁰

The survey did not ask what factors were most important in persuading the provider to self-disclose. However, the open-ended response section of the survey provided a platform for candid comments on the advantages and disadvantages of self-disclosure from the provider's point of view. For example, one attorney said, "[m]y clients have consistently chosen not to make voluntary disclosures."¹⁶¹ Another stated that, "[i]n 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."¹⁶² 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.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Id.* (follow "View 65 Responses" hyperlink to Response 3 for Question 11).

¹⁶² *Id.* (follow "View 65 Responses" hyperlink to Response 6 for Question 11).

Eventually, the AUSA [Associate U.S. Attorney] 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.¹⁶³

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.”¹⁶⁴ Other commenters echoed that sentiment,¹⁶⁵ stating that the attorney found the process “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.”¹⁶⁶

B. Incentives to Disclosure under the SRDP

Providers clearly weigh the honey and vinegar of self-disclosure when deciding whether to proceed. Therefore, one must identify the reasons providers would choose to disclose or not. The most obvious reason to disclose a Stark violation is that it is required by the ACA and other statutes.¹⁶⁷ If the requirement alone were enough to motivate providers, CMS would have far more disclosures than the seventy or so it has received to date. This Article’s main thesis is that

¹⁶³ *Id.* (follow “View 65 Responses” hyperlink to Response 42 for Question 11).

¹⁶⁴ *Id.* (follow “View 65 Responses” hyperlink to Response 7 for Question 11).

¹⁶⁵ *Id.* (follow “View 65 Responses” hyperlink to Response 41 for Question 11).

¹⁶⁶ *Id.* (follow “View 65 Responses” hyperlink to Response 53 for Question 11).

¹⁶⁷ Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 6402(a), 124 Stat. 119, 755 (2010) (to be codified 42 U.S.C. § 1330a-7k(d)(1)); *see also* 42 U.S.C. § 1395nn(g)(2) (2006) (“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) (2010) (an entity collecting payments for services provided pursuant to a Stark violation “must refund [payments] on a timely basis”); False Claims Act, 31 U.S.C. § 3729(a)(1)(G) (Supp. III 2010) (stating that an entity that “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).

many other factors besides the legal requirement determine the behavior of providers. If providers were primarily focused on the legal requirement, there would be far fewer compliance issues to disclose in the first place, since they would not have allowed any other consideration to trump their need to obey the Stark Law.

The SRDP states that while CMS is not obligated to reduce any amounts owed as a result of a Stark violation, it will consider doing so based on the facts and circumstances of each actual or potential violation disclosed.¹⁶⁸ In the only Stark disclosure 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 in a worst-case scenario.¹⁶⁹ As previously mentioned, that case involved Saints Hospital in Massachusetts. The hospital's attorneys stated for the annual audit that liability could be as much as \$14 million, but the penalty in that case was only \$579,000.¹⁷⁰ Since CMS did not provide any rationale for the final penalty, providers have not learned a great deal 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.¹⁷¹ Thus, a provider can avoid interest, and potentially some penalties, by making a disclosure. CMS, however, is not bound to accept any conclusions by disclosing parties and is not obligated to resolve the matter in any particular manner.¹⁷²

While there are no criminal penalties for Stark violations, a provider may nonetheless view creating prosecutorial goodwill 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 noncompliance, especially when the provider has cooperated fully, taken any necessary personnel actions, and taken action to assure the problem will not recur.¹⁷³ As Silver and Wisner point out:

¹⁶⁸ *SRDP*, *supra* note 9, at 6.

¹⁶⁹ *See* Saints Press Release, *supra* note 146.

¹⁷⁰ Kass et al., *supra* note 12, at 35:00, 34:45 (discussing Saints Medical disclosure by Saints' attorney Christine Savage).

¹⁷¹ *SRDP*, *supra* note 9, at 1.

¹⁷² *Id.* at 2.

¹⁷³ AM. HEALTH LAWYERS ASS'N, HEALTHCARE COMPLIANCE LEGAL ISSUES MANUAL 106 (Harry R. Silver & Cynthia F. Wisner eds., 3d ed. 2011) [hereinafter Silver & Wisner].

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.¹⁷⁴

Another benefit of self-disclosure is possible avoidance of a corporate integrity agreement (CIA). In situations where the government is concerned about a recurring 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 OIG routinely 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.¹⁷⁵ Providers or other entities agree to the obligations, and, in exchange, the OIG agrees not to exclude them from participation in Medicare, Medicaid, or other federal health-care programs.¹⁷⁶

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.”¹⁷⁷ The OIG states further that a typical CIA lasts five 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;
- a program to prevent employment of persons with a history of compliance issues;

¹⁷⁴ *Id.*

¹⁷⁵ *Corporate Integrity Agreements*, OFF. OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERV'S, <http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp> (last visited Aug. 1, 2011).

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

- reports of overpayments and other compliance issues as they arise; and
- annual reports to OIG on the status of the entity's compliance program.¹⁷⁸

Aside from avoidance of a CIA, a provider might 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 self-disclosure in the form of reduced criminal penalties. The Guidelines give a provider credit for an “effective” compliance plan.¹⁷⁹ An effective compliance and ethics program is one which demonstrates that the organization “exercise[s] 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.”¹⁸⁰ The Guidelines specify that the program should be “generally effective,” but “failure to prevent or detect . . . [an] offense does not necessarily mean that the program is not generally effective.”¹⁸¹ Thus, providers hope that by disclosing a compliance issue, they will demonstrate the effectiveness of their compliance program, and reap benefits 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.¹⁸² As discussed above in Part I.D, *qui tam* actions are the major driver of Stark enforcement. Any opportunity to cut off such suits is therefore extremely valuable to a provider. However, as also noted above, that ability may be limited if a voluntary disclosure does not foreclose a *qui tam* action.¹⁸³

C. Disincentives to Disclosure in the SRDP

There are a number of reasons providers might choose to “roll the dice” and risk investigation or prosecution rather than self-disclose under the current version of the SRDP. The most of important are as

¹⁷⁸ *Id.*

¹⁷⁹ U.S. 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. *Id.* § 8C2.5(f). The Culpability Score is then used to determine minimum and maximum fine multipliers. *Id.* § 8C2.6.

¹⁸⁰ *Id.* § 8B2.1.

¹⁸¹ *Id.*

¹⁸² Silver & Wisner, *supra* note 173, at 107.

¹⁸³ *See supra* Part I.E.

follows: (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 the ACA, and so providers may not always know whether they have met that threshold requirement for the repayment obligation.¹⁸⁴ 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."¹⁸⁵ 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)"¹⁸⁶

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 within which the provider must report an overpayment.¹⁸⁷ However, providers point out that they receive many unsubstantiated claims that, upon investigation, prove to be false. Therefore, they argue, no overpayment has been identified 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" in determining the appropriate penalty.¹⁸⁸ It also cautions that the extent of verification will depend on the quality and thoroughness of the submission received. The disclosure must be

¹⁸⁴ See e.g., Lauer & Roth, *supra* note 11, at 15-16.

¹⁸⁵ SRDP, *supra* note 9, at 4.

¹⁸⁶ *Id.*

¹⁸⁷ Sheehan & Hussar, *supra* note 19, at 26 (cited in Lauer & Roth, *supra* note 11, at 18).

¹⁸⁸ SRDP, *supra* note 9, at 6.

complete, and no further information should be submitted to augment an initial disclosure after it is submitted to CMS.¹⁸⁹ 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 received thus far under the SRDP, saying that the main problem is that providers are not giving CMS enough information when they do make a disclosure.¹⁹⁰ 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

The congressional mandate in the ACA authorized, but did not require, CMS to reduce the penalties due under the Stark Law.¹⁹¹ Congress listed three factors that CMS should consider when assessing penalties: (1) “[t]he nature and extent of the improper or illegal practice,” (2) “[t]he timeliness of the self-disclosure,” and (3) “cooperation in providing additional information related to the disclosure.”¹⁹² CMS added additional factors it would consider when it released the SRDP: (4) the litigation risk associated with the matter disclosed, (5) the amounts owed, (6) the financial position of the disclosing party, and (7) other factors as the HHS Secretary deems appropriate.¹⁹³

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 *financial benefit conferred by the hospital upon the physician(s)*.”¹⁹⁴ Thus, the OIG appears to focus on improper financial benefit rather than the maximum penalty available under the applicable law.

¹⁸⁹ *Id.* at 5.

¹⁹⁰ Carlson, *supra* note 139.

¹⁹¹ Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 6409(b), 124 Stat. 119, 772 (2010) (to be codified at 42 U.S.C. § 1395nn note).

¹⁹² § 6409(b), 124 Stat. at 773.

¹⁹³ *SRDP*, *supra* note 9, at 1, 6.

¹⁹⁴ Open Letter from Daniel R. Levinson, Inspector General, Dep’t of Health & Human Serv’s, to Health Care Providers (Apr. 24, 2006), <http://www.oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf> (emphasis added); *see also* Open Letter from Daniel R. Levinson, Inspector General, Dep’t of Health & Human Serv’s, to Health Care Providers (Apr. 15, 2008), <http://www.oig.hhs.gov/fraud/docs/openletters/OpenLetter4-15-08.pdf> (“OIG has . . . committed to settling liability . . . generally for . . . a multiplier of the value of the financial benefit conferred.”).

Prior to the SRDP's release, the American Hospital Association (AHA) urged CMS to consider additional factors such as:

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.¹⁹⁵

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 explanation as to why it rejected these ideas.

CMS representatives have informally signaled their willingness to reduce amounts owed in a recent AHLA webinar for health-care attorneys. In the webinar, the presenters representing the government listed several "subfactors" that CMS considers in settlements: (1) whether the arrangement was commercially reasonable and/or at fair market value, (2) whether the arrangement took into account the volume or value of referrals, (3) whether there was a history of program abuse, (4) whether the amount in question was set in advance, (5) the presence and strength of a preexisting compliance program, (6) the length and pervasiveness of the noncompliance, and (7) the steps taken to correct the noncompliance.¹⁹⁶ These factors have not been released in any official pronouncement.¹⁹⁷ 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 an innocent 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 a noncompliant financial relationship. Will it be based on the number of patients admitted by the 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

¹⁹⁵ AHA Letter, *supra* note 8, at 3.

¹⁹⁶ Troy Barsky & Roy Albert, Ctr. for Medicare & Medicaid Services, Am. Health Lawyers Ass'n Webinar Presentation, *The New Reality of Stark Self-Disclosures: What to Do and Not Do*, at 14 (Nov. 19, 2010) (on file with author).

¹⁹⁷ *Id.*

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?

For example, in the above-mentioned Saints Medical Center case,¹⁹⁸ CMS could base the government's claim on the amounts billed to the Medicare program for all services provided to all patients treated by the physician involved in the noncompliant financial relationship. Clearly, CMS did not take that position, since the hospital's attorneys were very pleased with the settlement relative to what it could have been. But we do not know what the basis was for CMS's calculation of the penalty, since it did not release that information. The penalty might have been lowered 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 provider or to the public?

The OIG, in contrast to CMS, demonstrated its willingness to settle for less than the face value of the claim in several cases settled prior to the OIG's announcement that it would not accept "Stark-only" settlements in the SDP. For instance, the failure of Cushing Memorial Hospital in Leavenworth, Kansas to have a rental agreement with a physician using space in the hospital's medical office building resulted in a Stark violation.¹⁹⁹ The OIG settled for \$50,000, despite the fact that the physician's referrals had resulted in millions of dollars in claims.²⁰⁰ The OIG could have insisted on repayment of all of those claims and possibly even CMPs or penalties under the FCA that are a multiplier of the amount of the claims.

In another case, Memorial Hospital of Union County in Marysville, Ohio paid \$31,000 in CMPs. The hospital had exceeded by \$3,000 the \$355 Stark cap on nonmonetary compensation of physicians.²⁰¹ The penalty would have been enormous if the OIG had focused on the value of referrals made by the physicians, rather than the minimal financial benefit the hospital had actually conferred upon those physicians. When these settlements were announced, an attorney representing a number of hospitals and physicians hailed the settlements as possible "cornerstone cases with respect to the application of Stark and repayments. They show there is a substantial ability to

¹⁹⁸ See *supra* Part III.B.

¹⁹⁹ *Hospital Settles CMP Case After OIG Discovers No Problem in Referral Pattern*, REP. ON MEDICARE COMPLIANCE, Oct. 2009.

²⁰⁰ *Id.* at 2.

²⁰¹ *Id.*

negotiate a reasonable amount.”²⁰² 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.²⁰³

The CMS disclosure protocol also contrasts with New York State’s Medicaid self-disclosure program in terms of its willingness to offer a reduction in penalties as a reward for self-disclosure. The New York Office of the Medicaid Inspector General (OMIG) released its Self-Disclosure Guidance in March 2009.²⁰⁴ The OMIG’s guidance 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.²⁰⁵ The OMIG 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.²⁰⁶ The OMIG disclosure protocol states that providers who self-disclose overpayments will typically have a better outcome than if the OMIG had discovered the matter independently.²⁰⁷ The specific benefits to self-disclosure that the OMIG cites in its protocol include:

- forgiveness or reduction of interest payments;
- extended repayment terms;
- waiver of penalties and/or sanctions;
- recognition of the effectiveness of the provider’s compliance program;
- a decrease in the likelihood of imposition of an OMIG Corporate Integrity Program; and
- possible preclusion of subsequently filed New York State False Claims Act *qui tam* actions based on the disclosed matters.²⁰⁸

²⁰² *Id.* (discussing attorney Robert Wade’s comments regarding OIG’s willingness to set lower CMPs for hospitals who voluntarily disclose alleged Stark violations).

²⁰³ See Open Letter from Daniel R. Levinson, *supra* note 111.

²⁰⁴ STATE OF N.Y. OFFICE OF THE MEDICAID INSPECTOR GEN., SELF-DISCLOSURE GUIDANCE (Mar. 12, 2009) [hereinafter N.Y. SELF-DISCLOSURE GUIDANCE], http://www.omig.state.ny.us/data/images/stories/self_disclosure/omig_provider_self_disclosure_guidance.pdf.

²⁰⁵ *Id.* at 1.

²⁰⁶ *Id.* at 3. Disclosures may include substantial routine errors and patterns of errors, as well as issues implicating potential violations of fraud and abuse laws.

²⁰⁷ *Id.* at 2.

²⁰⁸ *Id.*

3. *Failure to Distinguish Between Procedural and Substantive Violations*

While many of the disadvantages of using the SRDP apply to all SRDP disclosures, the disadvantages are particularly acute when 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 the very narrow exception provided for missing signatures.²⁰⁹

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,”²¹⁰ 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.²¹¹ That would leave only the technical or procedural issues to be dealt with under the SRDP. If CMS were to remove all substantive issues from the 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 the ACA means that providers must disclose within sixty days to be able to take advantage of the SRDP.²¹² 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

²⁰⁹ See *supra* Part I.E.

²¹⁰ *SRDP*, *supra* note 9, at 6.

²¹¹ Lauer & Roth, *supra* note 11, at 25.

²¹² Christ et al., *supra* note 151.

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.²¹³

The information that must be provided in that short amount of time is actually more comprehensive and definitive than that required in the OIG SDP. The 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.²¹⁴ 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 meet them.²¹⁵ Presumably, a disclosure needs to include a legal memorandum by an attorney in order to fulfill this requirement.

If CMS determines that the information given by the provider is not sufficient, CMS may decide not to accept a disclosure into the SRDP. Attorney Robert Wade represents five providers who applied to resolve Stark problems through the SRDP. He reported that in two cases, CMS accepted the submissions but asked for more documentation before it accepted the submissions; in two other cases, CMS asked for additional information, but has not yet notified as to whether it will accept the submissions. CMS has not yet responded to the fifth disclosure.²¹⁶

²¹³ *Id.*

²¹⁴ OIG's Provider Self-Disclosure Protocol, *supra* note 108, at 58,401.

²¹⁵ SRDP, *supra* note 9, at 4.

²¹⁶ Nina Youngstrom, *First Stark Case is Resolved Through CMS Self-Disclosure; is the OIG Option Gone?*, REP. ON MEDICARE COMPLIANCE, Feb. 2011, at 2.

5. *Determining To Which Agency Disclosure Is Best Made*

The SRDP states that parties should not disclose the same behavior to both the OIG and CMS.²¹⁷ 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 conceivably prefer to use the “Stark-only” SRDP when possible, rather than admit that they may have violated the criminal Anti-Kickback statute, which requires the OIG SDP. Another advantage to using the SRDP is that CMS has the authority to release providers from Stark liability,²¹⁸ whereas the OIG does not.

Despite these advantages, providers often prefer to disclose that there is a colorable Anti-Kickback claim so that they can work with the OIG rather than the CMS. In the words of one attorney who advises health-care providers, the OIG’s “clear guidance and reasoned approach to penalty determination” makes disclosure to the OIG preferable to disclosure to CMS.²¹⁹ Also, if a provider decides to go the Stark-only route and discloses to CMS, the agency may refer the matter to the OIG or DOJ if it decides during the course of its investigation that there is a colorable Anti-Kickback claim.²²⁰ 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 DOJ.²²¹ In that situation, the provider will not have the opportunity for any leniency under the OIG SDP. So, providers would do well to heed CMS’s advice in the SRDP that “the disclosing party’s initial decision of where to disclose a matter . . . should be made carefully.”²²²

²¹⁷ *SRDP*, *supra* note 9, at 2.

²¹⁸ See Patient Protection and Affordable Care Act, Pub. L. No. 111–148, § 6409(b), 124 Stat. 119, 772 (2010) (to be codified at 42 U.S.C. § 1395nn note).

²¹⁹ Larry C. Conn, *Navigating CMS’ Channel for Stark Disclosures*, J. HEALTH CARE COMPLIANCE, Jan.–Feb. 2011, at 25, 28; see also Michelle C. Gabriel McGovern, *Medicare Physician Self-Referral Disclosure Protocol: Will the Truth Set You Free?*, J. HEALTH CARE COMPLIANCE, Jan.–Feb. 2011, at 59, 60 (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).

²²⁰ *SRDP*, *supra* note 9, at 2–3.

²²¹ *Id.* at 3.

²²² *Id.*

6. The “Look-Back” Period

One of the most significant issues for self-disclosing providers is the length of time CMS will “look-back” from the date of the disclosure to determine the extent of the illegal conduct. The “look-back” period is a major determinant of the total overpayment and penalties that will be due. Many of the financial relationships between hospitals and physicians, such as departmental directorships, can extend for decades, creating a major problem for an entity seeking closure on a lapsed contract, for example.

The SRDP requires a disclosing party to state the total amount that is actually or potentially owed based on the applicable “look-back” period.²²³ The SRDP defines the “look-back” period as the length of the time during which the disclosing party may not have been in compliance with the provider self-referral law.²²⁴ When the protocol was first published, many commentators raised concerns regarding the open-ended nature of this definition.²²⁵ The definition conceivably extends the “look-back” period beyond that for which the provider would be liable if the government learned of the conduct through means other than self-disclosure.

Normally, HHS may reopen a hospital’s filed claims for up to four years from the date of the initial determination or redetermination when “good cause” to reopen the claim exists.²²⁶ 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 [t]he evidence that was considered in making the determination or decision clearly shows on its face that an obvious error

²²³ *Id.* at 5.

²²⁴ *Id.*

²²⁵ See Goel & Melvin, *supra* note 57 (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 216, 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).

²²⁶ 42 C.F.R. § 405.980(b)(2) (2010). The government may reopen a claim at any time if “reliable evidence,” as defined in 42 C.F.R. § 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. *Id.*

was made at the time of the determination or decision.²²⁷

Even in the most serious of Stark violations where the FCA is implicated, the statute of limitations is six years.²²⁸

Thus, the effect of CMS's look-back period is to extend what would otherwise be a shorter statute of limitations. CMS representatives recently stated that the agency did indeed intend to create an open-ended look-back period for the SRDP.²²⁹ Thus, self-disclosure under the SRDP potentially exposes the provider to more liability than would be allowable under law in the event the noncompliance 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.²³⁰

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. . . ."²³¹ Although CMS has specified that it will not request written material that is subject to attorney-client privilege, it also states that if there are documents or other materials which it believes are critical, it 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."²³² Providers remain concerned that a self-disclosure might result in waiving the privilege.²³³

²²⁷ CMS, MEDICARE CLAIMS PROCESSING MANUAL: CHAPTER 34 - AEOPENING AND REVISION OF CLAIM DETERMINATIONS AND DECISIONS §10.11 (revised June 17, 2011), available at <https://www.cms.gov/manuals/downloads/clm104c34.pdf>.

²²⁸ False Claims Act, 31 U.S.C. § 3731(b)(1) (2006).

²²⁹ Carlson, *supra* note 130 ("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.").

²³⁰ Sheehan & Hussar, *supra* note 19, 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.").

²³¹ SRDP, *supra* note 9, at 5.

²³² *Id.*

²³³ See Christ et al., *supra* note 151 (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 219, at 69

8. *Statement Regarding Past Conduct*

The SRDP 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.”²³⁴ There doesn’t appear to be any time limitation on this requirement. The phrase “a history of similar conduct” is quite ambiguous. Does “similar” refer to a specific type of 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 failure to sign his agreement that otherwise complied with a Stark exception. If neither party noticed the lack of a signature for five years, is that “similar” to a future situation in which the hospital failed to obtain a signature but discovered it after five weeks? Suppose that in the first instance, the hospital had a change of personnel and 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. Clearly, the hospital’s overall compliance program had improved significantly between the two incidents, and yet CMS may consider the two situations “similar” and expect disclosure of the second incident even though it meets the SRDP exception for self-correction of a missing signature.²³⁵

The requirement for determining whether the hospital has had a “similar” situation exacerbates the time pressure on providers who need to compare different situations before making a conclusion about their similarity. The OIG SDP allows providers to supply additional information after the initial disclosure,²³⁶ which gives the provider a chance to amend any initial statements about the provider’s historical compliance if its investigation uncovers a previously unrecognized pattern of similar conduct. The SRDP does not allow amendment after submission.

(“CMS may insist on review of materials that may be covered by the work product doctrine.”).

²³⁴ See *supra* note 9, at 4.

²³⁵ See *supra* Part I.F.

²³⁶ See N.Y. SELF-DISCLOSURE GUIDANCE, *supra* note 204, at 4.

9. *Lack of Appeal Rights*

There is no right of appeal from a voluntary settlement agreement with CMS resolving a self-disclosed violation.²³⁷ 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 any administrative penalty or court decision unless the provider waived those rights in a settlement. The SRDP does state that if an entity does not satisfactorily resolve the issue with CMS through the protocol and ultimately withdraws from the process, CMS has the authority to issue overpayment determinations based on the information it gained from the self-disclosure. The provider would then be able to appeal those determinations through the normal administrative processes.²³⁸ So, providers have at least some leverage on this point, since they can simply threaten to walk away from the self-disclosure resolution process if they are concerned that CMS will not reach an acceptable conclusion. If they choose this option, CMS will likely turn the matter over to the OIG or the DOJ for investigation and prosecution.²³⁹

Of course, the outcome may not always be readily apparent. In the Saints Medical Center disclosure discussed in Part III.B, the hospital's counsel reported that they had no idea how CMS came to the settlement amount it did.²⁴⁰ While Saints' counsel was pleased with the settlement, had they not been, they would have had to choose to roll the dice on an appeal after investing significant time and money in the self-disclosure process.

10. *Implications for the Provider's Compliance Plan*

Finally, it is unclear what the implications of self-disclosure are for the provider's compliance plan. The SRDP requires providers to supply "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)."²⁴¹ It goes on to state that the provider must also supply:

²³⁷ *SRDP*, *supra* note 9, at 2.

²³⁸ *Id.*

²³⁹ *Id.* at 2-3, 6 (discussing cooperation between CMS, OIG, and the DOJ when considering a provider's "lack of cooperation" in determining an "appropriate resolution to the [disclosed] matter").

²⁴⁰ Kass et al., *supra* note 12, at 37:54 (discussing Saints Medical disclosure by Saints' attorney Christine Savage).

²⁴¹ *SRDP*, *supra* note 9, at 4.

[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).²⁴²

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.²⁴³

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 to the SRDP to encourage providers to disclose more violations, while also avoiding the risk of Medicare program abuse by providers due to simpler procedures and less governmental scrutiny. Prior to the release of the current SRDP, other authors suggested more provider-friendly procedures than were ultimately adopted by CMS.²⁴⁴ 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 integrity of Medicare would be compromised if providers took undue advantage of the flexibility or limited penalties embodied in these suggestions. A demonstration project would offer 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 region.

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 num-

²⁴² *Id.*

²⁴³ N.Y. SELF-DISCLOSURE GUIDANCE, *supra* note 204, at 2.

²⁴⁴ *See infra* Part I.F.

ber of disclosures and therefore the amount of money the government recovers for the Medicare Trust Fund.²⁴⁵ Second, CMS would learn which protocol provisions are most significant in provider self-disclosure decisions. 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 the ACA's disclosure requirements may result in duplicative information. However, CMS stated that "[it] remain[s] interested in analyzing physicians' compensation relationships."²⁴⁶

If the information CMS gleaned from the project supported its concerns about significant provider abuses, the agency could use the information to craft better enforcement programs and tighter regulations, or to target particular industry segments where problems are more rampant. CMS would gain a more accurate understanding of which providers are likely to be engaged in significant misconduct. If, on the other hand, the information gathered showed that current Stark regulations are overly restrictive and ineffective at recovering funds, 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 of and negotiations with providers whose violations are less serious. Instead, CMS could focus on more serious violators.

Providers in the demonstration project region could take advantage of 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 decided to use the results of the project to make the SRDP more provider-friendly, providers across the United States would reap the benefits.

²⁴⁵ The Medicare Trust Fund collectively refers to the Federal Hospital Insurance Trust Fund (Medicare Part A) and the Federal Supplementary Medical Insurance Trust Fund (Medicare Parts B and D). Costs for beneficiaries under these programs are paid out of the Medicare Trust Fund. See 42 U.S.C. §§ 1395i, 1395t (2006).

²⁴⁶ See *DFRR*, *supra* note 15, and accompanying text.

B. Past Demonstration Projects

1. CMS Projects

HHS has conducted numerous demonstration projects related to Medicare. The ACA gives HHS broad authority to create demonstration projects that test various ideas for decreasing costs or improving care delivery in federal health-care programs.²⁴⁷ While some demonstration project recommendations are outlined in the legislation,²⁴⁸ HHS also has general authority to develop or demonstrate improved methods for the investigation and prosecution of fraud in federal health-care programs.²⁴⁹ 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.²⁵⁰

CMS is currently involved in two demonstration projects with implications for fraud and abuse regulations.²⁵¹ These projects concern “gainsharing” between hospitals and physicians. Gainsharing programs involve hospitals paying physicians a share of the savings that result from collaborative efforts between the hospital and the physician to improve quality and efficiency in care delivery.²⁵² Gainshar-

²⁴⁷ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3021(a), 124 Stat. 119, 389 (2010) (to be codified at 42 U.S.C. § 1315(a)) (creating the Center for Medicare and Medicaid Innovation).

²⁴⁸ § 6409(a), 124 Stat. at 390-92 (recommending twenty project models, 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).

²⁴⁹ 42 U.S.C. § 1395b-1(a)(1)(J) (2006).

²⁵⁰ *Master Demonstration, Evaluation, and Research Studies for ORDI System of Record 09-70-0591: List of Projects*, CMS.GOV, 5-8, <http://www.cms.gov/DemoProjectsEvalRpts/downloads/MasterSORList.pdf> (last visited Nov. 8, 2011).

²⁵¹ *DRA 5007 Medicare Hospital Gainsharing Demonstration*, CMS.GOV (2006), <https://www.cms.gov/demoprojectevalrpts/md/itemdetail.asp?itemid=CMS1186805>; *MMA Section 646 Physician Hospital Collaboration Demonstration*, CMS.GOV (2006), <https://www.cms.gov/demoprojectevalrpts/md/itemdetail.asp?itemid=CMS1186653>.

²⁵² *DRA 5007 Medicare Hospital Gainsharing Demonstration*, CMS.GOV, 1, http://www.cms.gov/DemoProjectsEvalRpts/downloads/DRA5007_Solicitation.pdf (last visited Nov. 8, 2011).

ing 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;²⁵³ 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.²⁵⁴

The New Jersey Hospital Association initially proposed a gain-sharing demonstration project in 2004, but at that time, CMS did not have the statutory authority to waive gainsharing restrictions.²⁵⁵ The Deficit Reduction Act and amendments to the Social Security Act subsequently gave CMS the necessary authority.²⁵⁶ CMS's two gain-sharing 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.²⁵⁷

CMS has not yet released results of the project that ended in 2009, but Jonathan Blum, director of CMS's Center for Medicare Management and acting director of the Center for Health Plan Choices, stated in 2009, "[w]hat we learn from the various Medicare demonstrations help [sic] 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."²⁵⁸

2. *OIG Pilot Project on Self-Disclosure*

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

²⁵³ 42 U.S.C. § 1320a-7a(b)(1).

²⁵⁴ *Id.* § 1320a-7b(b)(2).

²⁵⁵ Cinda Becker, *Pilot Crashes*, MODERN HEALTHCARE (Apr. 19, 2004), <http://www.modernhealthcare.com/article/20040419/NEWS/404190321/>.

²⁵⁶ 42 U.S.C. § 1395ww (2011); Medicare Program: Solicitation for Proposals to Participate in the Medicare Hospital Gainsharing Demonstration Program Under Section 5007 of the Deficit Reduction Act, 71 Fed. Reg. 54,664, 54,664 (Sept. 18, 2006); 42 U.S.C. § 1395cc-3 (2011).

²⁵⁷ *DRA 5007 Medicare Hospital Gainsharing Demonstration*, *supra* note 252, at 4, 6.

²⁵⁸ *Medicare Says Demonstration Projects Proving Paying For Quality Health Care Pays Off*, SENIOR JOURNAL (Aug. 26, 2009), <http://seniorjournal.com/NEWS/Medicare/2009/20090826-MedicareSaysDemonstration.htm> (quoting Jonathan Blum, Director of CMS Center for Medicare Management and Acting Director for Center for Health Plan Choices).

fraud, waste, and abuse in the Medicare and Medicaid programs.²⁵⁹ One of the initiatives included in ORT was a two-year pilot of a voluntary self-disclosure program, targeting home health and nursing facility suppliers and providers in five states. Together, the five states accounted for 40 percent of Medicare and Medicaid beneficiaries.²⁶⁰ 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.²⁶¹

The 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 the OIG's perspective, the program offered providers a way to decrease potential costs from governmental audits and investigations and avoid possible exclusion from Medicare and Medicaid. In addition, the program offered insight into industry patterns and practices.²⁶² The OIG learned from the program, and then used that knowledge to refine its approach before releasing its current self-disclosure protocol nationwide in 1998.²⁶³

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

Just as CMS is currently using demonstration projects to learn about various parts of the health-care industry, and just as the OIG piloted a novel approach to self-disclosure several years ago, so CMS should now use the opportunity afforded by the ACA to experiment with ways to make the SRDP more effective. CMS should specifically include the following in a new Stark self-disclosure demonstration project: (1) a two-track process, (2) a flat penalty for procedural violations, and (3) an explicit statement of tangible benefits in the SRDP.

²⁵⁹ OFF. OF INSPECTOR GEN., DEP'T OF HEALTH AND HUMAN SERV., OPERATION RESTORE TRUST ACTIVITIES 1 (Nov. 1995) [hereinafter OPERATION RESTORE TRUST], <http://oig.hhs.gov/oei/reports/oei-12-96-00020.pdf>.

²⁶⁰ *Id.*

²⁶¹ See generally DEPARTMENT OF DEFENSE VOLUNTARY DISCLOSURE PROGRAM, *supra* note 109, at 1.

²⁶² OPERATION RESTORE TRUST, *supra* note 259, at 34.

²⁶³ OIG's Provider Self-Disclosure Protocol, *supra* note 108, at 58,399-400 (establishing that OIG's current protocol eliminated a number of provisions found in the pilot program, including: pre-disclosure requirements and preliminary qualifying characteristics, disclosures limited to particular health-care industries, and automatic preclusion of providers from disclosure if already subject to a government inquiry).

1. *Two-Track Process*

Prior to the release of the current 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.²⁶⁴ This type of review would facilitate 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.²⁶⁵ 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.²⁶⁶ Track II would be for more complex matters that need a detailed review by CMS. The AHA identified arrangements with “complex payment methodologies” or situations where “the extent to which the self-referral law applies is unclear” as good candidates for Track II review.²⁶⁷ The AHA emphasized that CMS should be flexible in administering the two tiers and that “[t]he 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.”²⁶⁸

CMS did not publicly explain why it rejected the AHA’s two-track proposal. However, CMS’s response to public comments on the 2008 proposed rulemaking may provide a clue. 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 going forward and not disclose the problem. CMS stated that it did not believe that this proposal met the “no risk of program or patient abuse” standard.²⁶⁹

²⁶⁴ A desk audit, or review, is conducted by an agency based on correspondence or phone interviews with the subject of the review rather than an on-site visit by the agency. For example, CMS Medicare contractors conduct desk reviews of health-care provider cost reports to determine whether the report can be settled without completion of a full audit. CMS, MEDICARE FINANCIAL MANAGEMENT MANUAL, ch. 8 § 20, available at <https://www.cms.gov/manuals/downloads/fin106c08.pdf> (last reviewed June 12, 2009).

²⁶⁵ AHA Letter, *supra* note 8, at 2.

²⁶⁶ *Id.*

²⁶⁷ *Id.* at 3.

²⁶⁸ *Id.*

²⁶⁹ Alternative Method for Compliance with Signature Requirements in Certain Exceptions, 73 Fed. Reg. 48,434, 48,707 (Aug. 19, 2008) (codified at 42 C.F.R. § 411.353(g)).

A demonstration project could incorporate the AHA two-track framework while still addressing CMS's concern. For simple matters, such as missing signatures or non-collection of payment, CMS could require providers to disclose the violation, but only require a desk audit rather than a full investigation. If any facts came to light during the desk audit that caused 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 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.²⁷⁰

2. Flat Penalty for Procedural Violations

In situations where the government does not allege any intent to steer referrals to a provider, CMS should exercise its discretion to sever the link entirely between Stark violations and the value of so-called "tainted" referrals.²⁷¹ If the service in question was necessary and provided properly, neither the government nor any patient has been harmed. The dollar value of the service should be irrelevant to the penalty calculation. Furthermore, the conduct to be punished should be the failure to document the arrangement. Whether the physician billed millions of dollars or only a few dollars to the Medicare program should be irrelevant to the penalty assessed for the conduct.²⁷²

Four prominent health-care attorneys whose practices include a significant amount of Stark work²⁷³ have used this notion as the basis

²⁷⁰ *Voluntary Disclosure Survey*, *supra* note 153, §11 (follow "View 65 Responses" hyperlink to Responses 27 and 58 for Question 11 which state: "very slow process" and "[t]ook a long, long, long time").

²⁷¹ See *A Proposal for Resolving Technical Stark Violations*, AM. HEALTH LAWYERS ASS'N 1, http://www.healthlawyers.org/Events/Programs/Materials/Documents/AM10/holden_proposal.pdf (last visited Nov. 8, 2011).

²⁷² *Id.* at 2.

²⁷³ The authors are Robert Homchick, Sanford Teplitzsky, Beth Schermer and Craig Holden. Robert Homchick is a partner with Davis, Wright, Tremaine LLP and a past member of the American Health Lawyers Board of Directors. *Robert G. (Bob) Homchick*, DAVIS, WRIGHT, TREMAINE LLP, <http://www.dwt.com/People/RobertGHomchick> (last visited Jan. 11, 2012). Sanford Teplitzky is a partner with Ober Kaler and a former Department of Health, Education and Welfare counsel. *Sanford Teplitzky*, OBER KALER, <http://www.ober.com/attorneys/sanford-teplitzky> (last visited Jan. 11, 2012). Beth

for a proposal they made in 2010 to CMS prior to its release of the SRDP.²⁷⁴ In their proposal (Homchick Proposal), the attorneys suggested that CMS establish a flat \$5,000 penalty for procedural Stark violations. They lobbied CMS and discussed the idea with other health-care attorneys in an attempt to create popular support for it. The Homchick Proposal stated that:

[t]he 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 [written agreement]; (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 [written agreement] was inadvertent (i.e.,] the failure was attributable to negligence [rather than] a knowing violation of the Stark requirements).²⁷⁵

They suggested that the penalty be assessed per arrangement, and commented that, “in our experience, noncompliant arrangements rarely occur in isolation.”²⁷⁶ This proposal addressed the same type of violations 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 availability of a desk audit to procedural violations, something the AHA resisted doing.

In support of their proposal, the attorneys argued that it

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

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²⁷⁴ Robert Homchick, *Proposed Stark Technical Violation Fix*, AM. HEALTH LAWYERS ASS'N (May 3, 2010, 11:06 AM) (on file with author).

²⁷⁵ *A Proposal for Resolving Technical Stark Violations*, *supra* note 271, at 2.

²⁷⁶ *Id.*

resolution of the hundreds, if not thousands, of technical violations in the provider community and avoid the waste of enforcement resources on these technical violations.²⁷⁷

The AHA also suggested a penalty scheme similar to that suggested by the Homchick Proposal. 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 \$10,000.²⁷⁸ The AHA cited agreements with missing signatures or situations where an arrangement was otherwise compliant with an exception but had not been documented in the manner specified in the regulations, as examples of situations where the stipulated penalties would apply. The AHA suggested that this provision should be applicable regardless of whether the situation qualified for expedited review or not under its two-track proposal.²⁷⁹

CMS did not comment publicly on either the AHA/Homchick proposal or the general idea of a procedural/substantive distinction. Some high-profile cases have offered CMS and the DOJ the opportunity to incorporate that distinction into their rationale for the penalty calculation. For example, the DOJ settled with Detroit Medical Center (DMC) for \$30 million in a case involving a mixture of procedural and substantive issues.²⁸⁰ 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 lumped all of the infractions together, 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.”²⁸¹ Also, if the DOJ settlement amount reflected any discount on the penalties in recognition of DMC’s voluntary disclosure, 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.

²⁷⁷ *Id.* at 3.

²⁷⁸ AHA Letter, *supra* note 8, at 3.

²⁷⁹ *Id.*

²⁸⁰ Press Release, U.S. Dep’t Justice, Detroit Medical Center Pays U.S. \$30 Million to Settle False Claims Act Allegations (Dec. 30, 2010), *available at* <http://www.justice.gov/opa/pr/2010/December/10-civ-1484.html>.

²⁸¹ *Id.* (quoting Tony West, Assistant Attorney General for the DOJ Civil Division).

3. *Explicit Statements Offering Tangible Benefits for Self-Disclosure*

The simplest improvement CMS could make to the SRDP is 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 approach or are merely an oversight, they have certainly been interpreted by the provider community as significant.²⁸² The contrast between the agencies is especially striking in light of the fact that the OIG protocol deals with potential criminal liability 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 stating their willingness to settle a claim for less than the face value of the penalties.

CMS should also expand the list of mitigating factors that it will consider to include some of those suggested by the AHA:

- 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,
- whether corrective action was taken by the parties,
- whether the services provided were reasonable and medically necessary,
- whether the care was sought in an emergency situation, and
- whether the Medicare program or any beneficiaries suffered any harm from the provider's actions.²⁸³

D. Measuring the Results of a Demonstration Project

As part of each of its previous demonstration projects, CMS developed criteria for determining the success of the project. The CMS staff is best positioned to determine specific measures that would be most helpful in evaluating any project. CMS should, at a minimum, consider the amount of money recovered during the demonstration period, along with the number of providers participating, as compared to SRDP results to date. CMS should choose states for the project

²⁸² See Conn, *supra* note 219, at 25 (analogizing provider navigation between multiple disclosure protocols with ancient Greek sailors navigating between two mythological sea monsters, Scylla and Charybdis, poised to devour sailors).

²⁸³ AHA Letter, *supra* note 8, at 3.

that include a variety of demographics, including hospitals in rural, urban, and suburban settings. Just as CMS consulted with trade groups, providers' counsel, and others in the development of previous demonstration projects,²⁸⁴ it should include similar stakeholders when developing this project. In fact, the ACA mandates that CMS consult with such groups in the development of any demonstration project.²⁸⁵ 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 that those groups would be willing to assist in the development of a good demonstration project model.

CONCLUSION

CMS's approach to provider self-disclosure of failure to comply with the Stark Law appears to be based on an assumption by the government that providers will disclose merely because the law says they must. However, providers do consider the advantages and disadvantages of compliance with laws. In the case of Stark self-disclosure, there are few advantages for providers, and a great many significant disadvantages. The CMS self-disclosure protocol punishes health-care providers heavily who disclose even very minor violations of the Stark Law. It also fails to distinguish between simple procedural failings and more significant noncompliance. Furthermore, use of the SRDP invites virtually unlimited government scrutiny, a dangerous prospect at best for any provider.

CMS would do well to heed Benjamin Franklin's advice about using honey rather than vinegar to catch flies. The self-disclosure protocol should be revised to establish a two-track system for disclosure that distinguishes between procedural and substantive violations of the Stark Law and a flat penalty for procedural violations. The government does not have the resources to police how every dollar of the enormous Medicare program budget is spent. Therefore, it should do everything possible to encourage health-care providers to police themselves. Self-disclosure of minor procedural violations of the Stark law would improve recovery of federal program dollars, encourage provider integrity, and avoid unnecessary expenditures for enforcement.

²⁸⁴ See Press Release, NJ Hospital Ass'n, Medicare Picks NJ to Test Innovative Incentive System (Aug. 18, 2009), *available at* <http://www.njha.com/press/PressRelease.aspx?id=7575> (NJ Hospital Ass'n spearheaded efforts to win waiver from CMS to test a gainsharing initiative, aimed at reducing health-care costs while maintaining quality of care).

²⁸⁵ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3021(a), 124 Stat. 119, 389 (2010) (to be codified 42 U.S.C. 1315(a)(3)).

A revised self-disclosure protocol offers the opportunity for providers to become partners with the government in assuring program integrity, at least with respect to the large number of minor violations of the Stark law. This change would enable regulators to focus their limited resources on investigating and prosecuting providers who seek to intentionally defraud government health-care programs.

The ACA's emphasis on using demonstration projects to test new ideas for improving the federal health-care programs offers CMS an opportunity to establish a demonstration project to test these reforms. The demonstration project model would limit potential dangers to program integrity. It would also enable government officials to learn a great deal about common Stark issues that providers encounter. If the demonstration project reveals issues that should be investigated, the government would then be in a better position to do so.

The fact that fewer than one hundred providers have taken advantage of the Stark self-disclosure protocol shows that vinegar is not attracting providers' disclosures. It is time for CMS to try a little honey in the controlled environment of a demonstration project. If the disclosure project proves out Ben Franklin's aphorism as predicted here, taxpayers and health-care providers alike will benefit.