DISCLOSURE FOR CLOSURE? WHY THE SELF-REFERRAL DISCLOSURE PROTOCOL PROCESS PAIRED WITH THE 60-DAY OVERPAYMENT RULE CREATES MORE HEADACHES THAN SOLUTIONS

I. INTRODUCTION

The history of health care includes many dates that cannot be ignored. The institution of Medicare in 1965, the passage of the Health Insurance Portability and Accountability Act (HIPAA) in 1996, and the passage of the Affordable Care Act (ACA) in 2010. Each law transformed the health care landscape, posing questions to be answered and presenting problems to be solved. Each act hoped to change health care for the better and each made health care more complicated. Those complications have increased the need for health care compliance departments and legal counsel.

Much of a health care compliance department's focus is on prevention of regulatory violations. Those violations vary from HIPAA privacy violations, antitrust agreement violations, or physician self-referral violations. The avenues through which providers disclosed violations prior to the passage of the ACA were overlapping and convoluted.[1] The Office of the Inspector General (OIG) for the Department of Health and Human Services (HHS) and Department of Justice (DOJ) have disclosure protocols; however, providers were not always confident which agency to report to. The Centers for Medicare and Medicaid Services (CMS) issue advisory opinions on various violations, most prevalently Stark Law violations, adding one more avenue for providers to contemplate.[2] Providers submit details of a potentially law-violating situation looking for an advisory opinion response on whether it is a violation and to seek a settlement agreement. Prior to understanding the disclosure process, it is important to understand the nature of the violations themselves.

Since 2009, three important laws passed, dramatically impacting how providers disclose various violations.[3] This paper will argue that the three laws passed, as they stand, impose unreasonably difficult standards on providers to

1. Stephen Chananie et al., *Disclosing and Refunding Overpayments in Healthcare Cases*, HEALTH LAW., Feb. 2012, at 16, 16.

2. 42 C.F.R. § 411.370(b) (2013).

3. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 6409(a)(1), (b), 6402, 124 Stat. 772 (2010); Medicare Program; Reporting and Returning of Overpayments, 77 Fed. Reg. 9179, 9187 (proposed Feb. 16, 2012) [hereinafter Proposed Rule].

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return and disclose overpayments and violations. Section II will describe the needed background to understand how and why the laws were passed. Section III will navigate, from a provider's perspective, the various difficult decisions and legal challenges faced when addressing an actual or potential Stark Law violation. It will begin with characterization of the violation, and address the disclosure process, determining potential liabilities and the benefits and risks involved in utilizing the Self-Referral Disclosure Protocol (SRDP). Section IV will further analyze the interaction of the three laws and provide a solution that is best suited for both providers and government actors.

II. BACKGROUND

Health care providers have many laws and regulations to navigate in order to operate a successful practice or hospital. Before addressing the issues in the event of an actual or potential violation, it is necessary to understand the history of the violations and how and why they were passed. This section will begin with the most prevalent fraud and abuse laws and move toward the more recent laws that have presented the legal issue posed in this paper.

A. History of the Stark Law and Anti-Kickback Statute

The government discovered many years ago that physicians could potentially take advantage of or abuse the Medicare payment system for their own financial gain. The financial gain came in forms such as compensation from a hospital to a doctor for referring a patient to that hospital, from a device manufacturer to a physician for influencing the use of a particular product, or by a physician referring a test or service to an entity the provider owns. Congress saw the potential for abuse in these relationships and the effects of the abuse such as providers not putting the Medicare beneficiaries' interests first. Initially, Congress passed the Anti-Kickback Statute (AKS) to combat these inappropriate relationships. However, the AKS was not broad enough to combat all fraud and abuse and led to the subsequent passage of the Stark Law.[4]

In 1972, Congress passed the AKS,[5] which imposes criminal and civil penalties on anyone who *knowingly* and *willfully* receives or pays anything of value to influence the referral of federal health care program business.[6] Such a violation can result in a felony conviction with violations punishable by up to five years in prison, criminal fines of $25,000, civil monetary penalties up to $50,000, and exclusion from participation in federal health care programs, such

4. *See generally* 42 U.S.C. § 1320a-7b(b) (2012); 42 U.S.C. § 1395nn (2012).
5. Social Security Amendments of 1972, Pub. L. No. 92-603, § 242, 86 Stat. 1329, 1419.
6. 42 U.S.C. § 1320a-7b(b).

as Medicare and Medicaid.[7] While the rule is hard and fast, it contains a number of safe harbors that make particular arrangements, which on their face violate the law, legal.[8]

In spite of the AKS, in the late 1980s, a series of reports to Congress showed that higher utilization of various medical services occurred when physicians had a financial interest in those services.[9] Not enough intentional receiving or paying of value occurred to impose criminal penalties, but the business arrangements did not feel right. Physicians received both direct and indirect value for referring services for patients to entities with whom they had a financial relationship. Following the studies, Congress enacted the Federal Physician Self-Referral Statute,[10] also known as the Ethics in Patient Referrals Act, or most commonly the "Stark Law."[11]

The Stark Law passed in two phases, the first effective in 1992 ("Stark I") followed by the second in 1995 ("Stark II").[12] Stark I focused mostly on the financial relationship between physicians and clinical laboratories while Stark II extended to eleven designated health services (DHS). The wide array of DHS include clinical laboratory services, physical therapy services, occupational therapy, speech pathology, radiology and imaging services, radiation therapy services, durable medical equipment, parenteral and enteral nutrients and equipment, prosthetics and orthotics, home health services, prescription drugs, and inpatient and outpatient hospital services.[13]

The statute made it illegal for a physician to refer DHS to an entity if the physician or someone related to the physician has a financial interest in the entity, and Medicare would typically make payment to the entity for the DHS. The result was various penalties at CMS' discretion including, but not limited to, civil monetary penalties or exclusion from the Medicare program.[14] No penalty would occur if the physician or entity complied with one of the many exceptions included in the law.

The Stark Law's broad nature left many questions unanswered. CMS published regulations addressing the new coverage under Stark II in three

7. 42 U.S.C. § 1320a-7b(b)(1)(B), (2)(B).

8. 42 U.S.C. §1320a-7b(b)(3).

9. OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., NO. OAI-12–88– 01410, FINANCIAL ARRANGEMENTS BETWEEN PHYSICIANS AND HEALTH CARE BUSINESSES ii-iii (1989).

10. 42 U.S.C. § 1395nn(a)(1) (2012).

11. Called the Stark Law because its primary sponsor was Congressman Fortney "Pete" Stark (D-CA), the law aimed at removing the financial incentive of physicians in making medical decisions. *See* Andrew B. Wachler & Adrienne Dresevic, *Stark II Phase III – "The Full Picture"*, HEALTH LAW., Sept. 2007, at 1, 3.

12. *Id.*

13. 42 U.S.C. § 1395nn(h)(6).

14. *Id.*

separate phases beginning in 2001[15] and ending in 2007.[16] The phases sought to clarify many of the uncertainties in the original law. Each of the phases introduced new definitions, explaining what various terms in the law meant, and added new regulatory exceptions as the Secretary of HHS deemed fit. The law, upon completion of the final phase, became a living creature molding and conforming to various market and political pressures.

B. Provider Voluntary Self-Disclosure Process and the New Self-Referral Disclosure Protocol

When a Stark Law violation exists, providers are expected to disclose the violation to CMS and either repay the money with the possibility of penalties, lose future access to Medicare Participation, or reach a settlement for less than the amount owed.[17] Many issues arose throughout the early disclosure process, particularly with the OIG's Self-Disclosure Protocol.[18] Specifically, the OIG required disclosures to be for "knowing violations."[19] This alienated some violators because they were reporting solely Stark Law violations, which is a strict liability statute, resulting in many unknowingly committed Stark Law violations. Providers sought to resolve their uncertainty in an inefficient way: by seeking advisory opinions and submitting settlements directly to the DOJ.[20]

In response to the underdeveloped resolution process for Stark Law violations offered by the government, Congress created the SRPD in Section 6409 of the ACA.[21] In creating the SRDP, Congress authorized HHS to create a disclosure process, separate from advisory opinions and the existing Self-Disclosure Protocol with the OIG, to resolve Stark Law violations.[22] The SRDP authorizes HHS, and consequently CMS, to reduce amounts owed to the government based on a variety of factors.[23] Additionally, CMS is required to

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15. Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856 (Jan. 4, 2001); Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16,054 (Mar. 26, 2004).

16. Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-Kickback Statute, 71 Fed. Reg. 45,110 (Aug. 8, 2006).

17. 42 U.S.C. § 1395nn(g).

18. Chananie et al., *supra* note 1, at 19.

19. OFFICE OF INSPECTOR GEN., DEP'T HEALTH & HUMAN SERV'S, UPDATED PROVIDER SELF-DISCLOSURE PROTOCOL (Apr. 17, 2013) [hereinafter OIG PROTOCOL], *available at* http://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf.

20. Chananie et al., *supra* note 1, at 20.

21. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6409(a)(1), (b) (2010).

22. *Id.*

23. Factors include (1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; (3) the cooperation in providing additional information related to

publish all settlements online to inform other actual or potential violators of the law.[24]

When submitting a report pursuant to the SRDP, it is required that various complicated analyses are submitted along with it. The SRDP requires some simple information, such as the National Provider Information number, tax identification number, and the type of DHS provided.[25] The SRDP also requires more complicated information including a legal analysis, financial analysis, financial relationship definitions, statements regarding the adequacy of any pre-existing compliance program, and a history of any similar violations.[26]

The legal analysis requirement of the SRDP is to be presented as a statement from the disclosing party. Specifically, the disclosing party must write which Stark Law exception the provider was trying to meet, and why the provider failed to meet the exception.[27] The disclosing party must break down the elements of the exception and explain which elements were met and which were not.[28] Additionally, the disclosing party must provide an explanation for why they violated the law, whether it was a lack of compliance, intentional conduct, or changing corporate procedures.[29]

The SRDP's financial analysis requirement is slightly more ambiguous and difficult to complete than the legal analysis. The disclosing provider must define the "look-back" period in its financial analysis.[30] To define the "look-back" period the provider must identify the entire period of noncompliance and find the total dollar amount that is actually or potentially due to CMS.[31] In addition to defining the "look-back" period, the provider must explain its rationale for defining such period, set forth the total amount of remuneration received in violation of the law, and a summary of any auditing activities.[32]

the disclosure; (4) the litigation risk associated with the matter disclosed; and (5) the financial position of the disclosing party. *Id.*

24. *Id.*

25. CTRS. FOR MEDICARE & MEDICAID SERVS., OMB CONTROL NO. 0930-1106, CMS VOLUNTARY SELF-REFERRAL DISCLOSURE PROTOCOL 3 (revised May 6, 2011) [hereinafter SELF-REFERRAL DISCLOSURE PROTOCOL].

26. *Id.* at 4-5.

27. *Id.* at 4.

28. *Id*.

29. CTRS. FOR MEDICARE & MEDICAID SERVS., FREQUENTLY ASKED QUESTIONS: VOLUNTARY SELF-REFERRAL DISCLOSURE PROTOCOL (Oct. 21, 2013) [hereinafter FREQUENTLY ASKED QUESTIONS].

30. SELF-REFERRAL DISCLOSURE PROTOCOL, *supra* note 25, at 5.

31. *Id*.

32. *Id.*

Once instituted, CMS received many SRDP submissions from providers.[33] The volume of submissions created an administrative backlog and slow settlement turnarounds.[34] In its statutorily mandated Report to Congress in 2012, CMS reported that 150 submissions had been made with only fifteen resolved: six fully settled and nine withdrawn.[35] Providers most-likely hesitated to self-disclose not knowing how generous CMS would be, or how similarly situated providers would be rewarded for self-disclosing. CMS publicized through its website the initial case settlements and any new disclosures.[36] Since the initial backlog and a strongly worded letter from the lead author of Section 6409 of the ACA,[37] CMS began to catch up on its settlement proceedings.[38]

Despite some minor recent success, the SRDP still works much slower than the OIG Self-Disclosure Protocol, which typically produces a settlement agreement in a year or less.[39] The slower turnaround time is somewhat puzzling since the OIG disclosure covers a wide array of violations, including Stark Law violations paired with other categories of fraudulent violations. The SRDP is limited exclusively to Stark Law violations.[40] If a provider believes a Stark Law violation occurred with other non-Stark Law violations, CMS advises to use the OIG Self-Disclosure Protocol, not the SRDP.[41] Therefore, OIG Self-Disclosure Protocol cannot include violations consisting solely of Stark Law violations. The slow turnaround for the SRDP exemplifies the truly complicated nature of Stark Law violations.

33. *See* DEP'T OF HEALTH & HUMAN SERVS., REPORT TO THE CONGRESS: IMPLEMENTATION OF THE MEDICARE SELF-REFERRAL DISCLOSURE PROTOCOL (Mar. 23, 2012) [hereinafter REPORT TO THE CONGRESS].

34. Letter from Jim McDermott to Marilyn Tavenner, Administrator of Ctrs. for Medicare & Medicaid Servs. (Aug. 13, 2013) [hereinafter McDermott Letter] (highlighting the poor implementation of the Self-Referral Disclosure Protocol and backlog of settlements occurring as a result of the poor implementation), *available at* http://op.bna.com/hl.nsf/id/stee-9ajr5w/$File/mcdermottstark.pdf.

35. REPORT TO THE CONGRESS, *supra* note 33, at 10.

36. *Self-Referral Disclosure Protocol Settlements*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 9, 2014, 11:34 PM), http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.html.

37. McDermott Letter, *supra* note 34.

38. *See Self-Referral Disclosure Protocol Settlements, supra* note 36 (settling three cases in 2011, fourteen in 2012, and 24 in 2013); *see also* McDermott Letter, *supra* note 34.

39. *See generally* REPORT TO THE CONGRESS, *supra* note 33.

40. *See* SELF-REFERRAL DISCLOSURE PROTOCOL, *supra* note 25, at 2; *see also* OIG PROTOCOL, *supra* note 19, at 4.

41. FREQUENTLY ASKED QUESTIONS, *supra* note 29, at 6.

C. *Section 6402 of the ACA: The 60-Day-Rule*

Submission of a report pursuant to the SRDP must be made in conjunction with other applicable laws, a feat more easily said than done. In Section 6402 of the ACA, Congress created a deadline for returning overpayments.[42] Providers overpaid by a federal health care program must return the overpayment within sixty days of identification (hereinafter the "60-day-rule").[43] Overpayments, as defined by CMS in its Proposed Rule, consist of any remuneration paid to a provider by Medicare (or any other federal health care program) where the provider discovers, after applicable reconciliation, it was not entitled to the payment.[44] This includes payments to providers for services billed for but not rendered, double payment for a single service, or payment to a provider not in compliance with valid federal law (such as the Stark Law). Therefore, when a provider identifies she was not in compliance with the Stark Law, she must return the payment within sixty days. If payment is not returned in sixty days, she automatically violates the False Claims Act (FCA), creating exposure to a large array of additional penalties.[45]

Along with the sixty-day time requirement, the violating provider must include a written report to be processed by the appropriate agency.[46] The reporting requirement replaces an already existing reporting requirement in the CMS Medicare Financial Management Manual.[47] The reporting requirement, for many purposes, serves as the only reporting the violating provider must do. For some violations, however, providers must also submit a self-disclosure to the appropriate agency to avoid additional penalties, such as the FCA or Civil Monetary Penalty Law.[48] Submissions made to CMS using the SRDP must also include a written report of overpayment to the OIG to satisfy Section 6402 of the ACA.[49]

Due to the complicated nature of most Stark Law violations, it can take providers a long time to calculate the "look-back" period, or period of noncompliance, and the money paid by Medicare during that time. Therefore, it is very likely providers need more than sixty days to calculate and furnish

42. 42 U.S.C. § 1320a-7k(d)) (2012).

43. *Id.*

44. Proposed Rule, *supra* note 3, at 9180.

45. 42 U.S.C. § 1320a-7k(d)(3) (2012).

46. Many providers experience minor overpayments by a Medicare payment contractor and refund them automatically through their computer system. Providers are concerned that writing a report to CMS for every overpayment, no matter how minor, can be administratively costly and time consuming. CMS has yet to issue guidance on a threshold, but some jurisdictions have taken action to limit the amount of reports, like New York who set the threshold required to be met to write a report at $5,000 overpayment. *See* Chananie et al., *supra* note 1, at 18.

47. Proposed Rule, *supra* note 3, at 9181.

48. FREQUENTLY ASKED QUESTIONS, *supra* note 29, at 3.

49. 42 U.S.C. § 1320a-7k(d)(1).

payment to CMS. Seeking to resolve this issue, CMS "pauses" the 60-day-rule upon receipt of the SRDP.[50] While seemingly resolving the issue, CMS created many more legal issues for actual or potential Stark Law violators, which will be discussed further in this paper.

So far, there have been no reported instances of the OIG enforcing the 60-day-rule. It is likely that the OIG will wait until CMS' Final Rule on the 60-day-rule is issued before engaging in any enforcement. In its revised version of the Self-Disclosure Protocol published in April of 2013, the OIG states it will address how the 60-day-rule will affect its Self-Disclosure Protocol after CMS issues a final rule on the matter.[51] However, delayed enforcement does not address the legal problems engrained in the statutory language.

Following publication of the Proposed Rule to the 60-day-rule in February 2012, many providers worried about how the rule would affect them. The American Hospital Association (AHA) described the law and its proposed rules as another "confusing, onerous, and legally risky set of expectations."[52] Section 6402 of the ACA starts the clock when the provider "identifies" the overpayment.[53] "Identifies" is defined by CMS as having actual knowledge or having no knowledge due to deliberate ignorance or reckless disregard.[54] The standard presents potential legal issues for providers and what the AHA calls a "diversion of resources" towards compliance departments and educational programs to ensure legal execution of health care services under the "unreasonable and often impossible timeframes."[55]

D. Fraud Enforcement and Recovery Act of 2009

The Fraud Enforcement and Recovery Act (FERA) passed in 2009, amending an important government tool, the FCA.[56] The FCA is a civil and criminal law that prevents the knowing submission of false or fraudulent claims to a federal health care program.[57] Prior to 2009, there was an issue many called the "reverse false claims" problem.[58] The problem was that smaller damages were imposed on a provider that submitted a claim the provider believed to be legal, but later discovered was a false claim. Doing a

50. FREQUENTLY ASKED QUESTIONS, *supra* note 29, at 4.

51. OIG PROTOCOL, *supra* note 19, at 2.

52. Letter from Rick Pollack, Exec. Vice President Am. Hosp. Ass'n., to Marilyn Tavenner, Acting Adm'r, Ctrs. for Medicare & Medicaid Servs. (Apr. 12, 2012) [hereinafter AHA Letter] *available at* http://www.aha.org/advocacy-issues/letter/2012/120416-cl-CMS60037-p.pdf.

53. 42 U.S.C. § 1320a-7k(d).

54. Proposed Rule, *supra* note 3, at 9182.

55. AHA Letter, *supra* note 52, at 2.

56. Chananie et al., *supra* note 1, at 16.

57. 31 U.S.C. § 3729(a) (2012).

58. Chananie et al., *supra* note 1, at 16

cost-benefit analysis would lead the provider not to disclose the false claim, because even if it was discovered later, the smaller damage would apply.

FERA included an amendment to the FCA that extended the same penalties to any provider who knowingly retained payment to which it was not entitled.[59] Therefore, a provider was liable for just as many damages if it knowingly submitted a false claim as if it discovered after the submission it was a false claim and did not come forward to remedy the situation. FERA also increased HHS' authority to investigate various forms of fraud and abuse, increasing the likelihood that violating providers that do not voluntarily self-disclose are caught.[60]

III. STARK LAW VIOLATION ROADMAP

Stark Law violations occur in many circumstances. Many times the provider commits the violation unknowingly due to the complicated nature of the law. For example, a physician is in violation of the Stark Law if a lease and subsequent holdover period expire on the physician's office in a building owned by an entity to which the physician refers DHS.[61] It is easy for a physician to forget to sign a new lease and let the previous lease carry over, but due to the strict liability of the Stark Law, the physician is in noncompliance. Applying CMS' proposed definition of an overpayment, any payments made by Medicare to the physician during the period of the expired lease is considered an overpayment and subject to the 60-day-rule.[62] A simple misstep by a provider could result in a violation of the Stark Law and consequently, subject the provider to the 60-day-rule, increasing the penalties and repayments to Medicare through the FCA.[63] Therefore, application of the proper legal analysis is imperative when a violation or potential violation is discovered.

A. *Identification and Characterization of the Violation*

Violations, or potential violations, can manifest themselves in a wide variety of ways. For developed health systems, an existing compliance department may receive tips from its anonymous hotline. For physician offices, knowledge of a violation could be discovered in the course of legal assistance on an unrelated matter. When discovered, it is very important to ask a variety of questions to identify the issue and determine the severity of the violation and extent of the providers' potential liability.

59. Proposed Rule, *supra* note 3, at 9187.
60. Fraud Enforcement and Recovery Act, Pub. L. No. 111-21, § 4, 123 Stat. 1622 (2009).
61. 42 U.S.C. § 1395nn(e)(1) (2012).
62. Proposed Rule, *supra* note 3, at 9181.
63. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402, 124 Stat. 755 (2010).

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1. What Kind of Violation? Is the Violation Systemic or Singularly Occurring?

One of the most important questions surrounding any potential Stark Law violation is whether the violation occurred on a systemic basis or as an isolated incident. A systemic violation does not necessarily mean higher penalties or larger liability, but the scope of the investigation can usually be determined based on the violation being systemic or singularly occurring.

A common Stark Law violation occurs with arrangements claiming the Bona Fide Employment Exception.[64] Often, hospitals hire a physician as an employee and have the physician sign an employment agreement. For the purposes of Stark, that physician now has a financial relationship with the hospital (i.e., the hospital is paying her a salary). Under the Bona Fide Employment Exception to Stark, that physician may make referrals to the hospital and entities owned by the hospital so long as the appropriate measures have been taken.[65] Failure to meet the Stark Law exception occurs if it is determined that the agreed compensation amount was more than fair market value.[66] If the hospital is large and has many employment agreements, asking whether the compensation arrangement is systemic can determine liability exposure. Many hospitals offer standard contracts that vary minimally for similarly situated positions, and it is very possible that the exposure to Stark Law penalties is not limited to just this physician's arrangement.

Understanding the violation, whether just a Stark Law violation or both a Stark Law and an AKS violation, is important for the self-disclosure process. Prior to 2009, providers reported Stark Law violations directly to the DOJ, to CMS through advisory opinions, and most often reported violations to the OIG following the Self-Disclosure Protocol.[67] However, in an Open Letter from the Inspector General in 2009, the OIG narrowed its focus on matters just involving AKS and FCA issues.[68] The OIG still accepts disclosure for Stark Law violations, but it must be paired with a "colorable violation" of the AKS or FCA.[69] The Letter also set a minimum settlement amount required for self-disclosure at $50,000.[70] No such minimum is required for any Stark Law

64. 42 U.S.C. § 1395nn(e)(2).

65. *Id.* To meet the requirements of the exception, (A) the employment must be for identifiable services, (B) the amount paid to the physician must be consistent with fair market value of the services and does not take into account the volume or value of referrals, and (C) the employment must be pursuant to a commercially reasonable agreement. *Id.*

66. 42 U.S.C. § 1395nn(e)(2)(B)(i).

67. Chananie et al., *supra* note 1, at 18.

68. DANIEL LEVINSON, DEP'T OF HEALTH & HUMAN SERVS., AN OPEN LETTER TO HEALTH CARE PROVIDERS (2009), *available at* http://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf.

69. *Id.*

70. *Id.*

violation disclosure pursuant to the SRDP. A violator could jeopardize its settlement proceeding by incorrectly identifying the violation and incorrectly disclosing information to the wrong agency.

2. When Was the Violation Identified?

Identification of the violation seems like a straightforward issue; however, with the current complex system of compliance programs, nature of various physician arrangements, and myriad complex rules and regulations governing the Stark Law, pinpointing the date of identification of a Stark Law violation may not be simple. Understanding when the violation was identified is important, especially with the presence of Section 6402 of the ACA: the 60-day-rule.[71] Some Stark Law violations, in the knowing or intentional manner they are violated, implicate violations of the FCA on their own.[72] However, with the implication of Section 6402 of the ACA, any overpayment held past sixty days of identification automatically violates the FCA and as noted above, results in larger penalties for the violating provider.[73]

In the legal world, "identification" means many things and could result in potential noncompliance for lack of understanding. CMS, in an attempt to clear up any confusion, issued Proposed Rules, which defined identification as "knowing" or "knowingly" in the manner defined in the FCA.[74] "Knowing" is defined in the FCA as: (1) actual knowledge of the information; (2) acting in deliberate ignorance of the truth or falsity of the information; or (3) acting in reckless disregard of the truth or falsity of the information.[75] By including provisions beyond actual knowledge, CMS hoped to give providers an "incentive to exercise reasonable diligence to determine whether an overpayment exists."[76] However, it put the onus on providers to adequately supervise their system to ensure compliance when no current guidance identifies adequate supervision.

Identifying overpayment is simple for various forms of overpayments. If a physician accidentally double bills for services rendered and identifies it two weeks later, she has identified the overpayment and has sixty days to repay the government. This is generally done by automatic payment through the electronic payment system set up with the physician and Medicare

71. 42 U.S.C. § 1320a-7k(d)(2) (2013).

72. *See generally* U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., Inc., 675 F.3d 394 (4th Cir. 2012).

73. 31 U.S.C. § 3729(a)(1) (2013). Specifically, violation of the False Claims Act can result in payment of three times what the overpayment owed to the government is, as well as civil monetary penalties. *Id.*

74. Proposed Rule, *supra* note 3, at 9182.

75. 31 U.S.C. § 3729(b)(1).

76. Proposed Rule, *supra* note 3, at 9182.

Administrative Contractor (MAC).[77] Identification becomes much more difficult involving Stark Law violations. A Stark Law violation that lasts for one month could impose liability for each of the billed Medicare beneficiaries the physician saw in that month. That one month of noncompliance is considered by CMS as the "look-back" period, mentioned above.[78] Going back and calculating all payments made by Medicare for one month could prove both costly in dollars and time and often cannot be done in the sixty day window. The "look-back" period, set by CMS in its Proposed Rule, can go back as far as ten years.[79] Because providers cannot risk owing ten years worth of FCA penalties, they must then diligently ensure that the "look-back" period for each particular violation does not extend back to that time, dramatically increasing the cost of compliance.

Because clear guidance has not been issued on how the 60-day-rule will be applied to the Stark Law, legal discrepancies exist for providers that affect liability. Identification of a Stark Law violation occurs after a provider is notified or discovers a potential violation and conducts a reasonable inquiry.[80] How CMS defines a reasonable inquiry is still unknown to providers. A provider does not know when the 60-day-rule begins throughout its investigation process. It is also unclear if the rule applies to any related violations, or to the full extent of the "look-back" period discovered after investigation.

An alternative method of interpretation is the 60-day-rule starts over for each material piece of information discovered, information that changes the severity of the liability. For example, if a provider identifies a Stark Law violation and believes the "look-back" period is only for the month of May, applying the language of the statute, it follows that the 60-day-rule begins upon that discovery. However, if the provider discovers after thirty days of investigation that the actual "look-back" period also included March and April, does the rule's clock start over altogether, do the new months of payments get added to the already existing clock, or does a second clock begin for March and April while the May clock still runs? It is possible providers could be required to pay Medicare for overpayments in reverse chronological order, depending on how CMS applies the language in the statute. Also, providers are unsure of when to disclose because CMS could interpret the reasonable inquiry to start the clock after the discovery of the May violation, where the provider believes it starts after the full investigation.

77. Chananie et al., *supra* note 1, at 17.
78. SELF-REFERRAL DISCLOSURE PROTOCOL, *supra* note 25, at 6.
79. Proposed Rule, *supra* note 3, at 9187.
80. *Id.* at 9182.

CMS aims to incentivize providers to exercise reasonable diligence in determining whether an overpayment or Stark Law violation occurred.[81] Without defining diligent (or reasonable inquiry), providers could incur large, unnecessary costs. A cautious institutional provider could incur large costs by investing large amounts of capital into an oversized compliance department as opposed to more targeted services that could increase efficient, high quality care. Would having any compliance department satisfy the diligence standard set by CMS or does the department need to be a certain size based on some quantifiable factor such as how many beds the institution has? Cautious providers of all sizes could end up incurring large legal costs over issues not necessarily needing outside legal counsel. On the other hand, a risk-taking institution may not invest in a large compliance department and just do what it believes to be an adequate job, but potentially incur large penalties due to a lack of diligence. CMS will not penalize with FCA penalties for expiration of the 60-day-rule when no identification occurs because of mere negligence,[82] but without clear guidance on how reckless disregard and deliberate ignorance standards apply to Stark Law cases, providers could be on the hook for very large penalties.

Working in concert with the 60-day-rule and identification of a violation is FERA. The extent of FERA's broadness lies with the broadness of the FCA's definition of "knowing" or "knowingly."[83] Congress sought to improve enforcement for the recovery of funds lost to frauds related to federal assistance programs and relief programs, such as Medicare.[84] In doing so, Congress amended the FCA and made it a violation to knowingly retain funds not properly obtained from the Medicare program and granted greater authorization for investigating potential fraud.[85] It seems as though FERA's battle against reverse false claims makes illegal any retention of overpayments, even those that fall within the 60-day-rule, but this will be addressed in Section IV of this paper.

3. Can the Provider Calculate the Overpayment in 60 Days?

While briefly touched on in the previous section, whether overpayment can be calculated in sixty days is very important in determining the course of remedial action. As previously mentioned, some fraud and abuse issues can be resolved very quickly. Providers can easily calculate the difference in overpayment in simple situations such as when a provider enters an incorrect

81. *Id.*
82. Chananie et al., *supra* note 1, at 17.
83. *See generally* Fraud Enforcement and Recovery Act, Pub. L. No. 111-21, 123 Stat. 1616 (2009).
84. Fraud Enforcement and Recovery Act § 4(a)(1).
85. Fraud Enforcement and Recovery Act § 4(b)(1).

code for a singular incident. The overpayment is just the difference in payment of the appropriate code from the entered code. Stark Law problems are generally larger, more complex, and more difficult to sort out. To resolve that issue, Congress created the SRDP, which contains a pause button for the 60-day-rule. Once an SRDP is electronically submitted, the 60-day-rule is suspended and the provider is not in violation of the FCA and has as much time as necessary to settle with CMS.[86] The provider goes through the procedure set forth by CMS to settle any overpayments and potential penalties for its violation.

B. Self-Referral Disclosure Protocol and the Remedial Process

When a provider determines that it may or may not have committed a violation and needs to take remedial action, there are various ways the provider may do so. One way is through a process established long before the institution of the SRDP. If a provider believes that its action could constitute a violation, it can submit a request for an advisory opinion pursuant to 42 C.F.R. §§ 411.370 through 411.389.[87] However, the advisory opinion process does not pertain to providers who are looking for answers regarding what fair market value is (a concept included in most Stark Law exceptions) and other aspects of specific exceptions.[88] As mentioned in Section II, however, the advisory opinions can take a long time and do not always yield desirable results.

The SRDP was created to fill the void the advisory opinions created. In fact, in the SRDP publication, CMS clearly states that providers may not file both an SRDP and an advisory opinion simultaneously.[89] Providers are incentivized to participate in the voluntary self-disclosure process with the reduction of payment provision[90] and the anticipated amount paid out for similarly situated providers freely available to the public.[91] While the intentions are good, Congress left too much for CMS to define and the clarity that the SRDP was supposed to bring now creates larger clouds of confusion.

One particular area of confusion surrounds criminal liability. If a provider deems itself a violator of a colorable AKS offense, it may participate in the OIG's Self-Disclosure Protocol.[92] Participation in that self-disclosure results in collaboration between the OIG and the DOJ, which often results in waiver of criminal liability, or, at the very least, a clearer understanding of potential

86. SELF-REFERRAL DISCLOSURE PROTOCOL, *supra* note 25, at 1.

87. 42 C.F.R. §§ 411.370-411.389 (2014).

88. 42 C.F.R. § 411.370(c).

89. SELF-REFERRAL DISCLOSURE PROTOCOL, *supra* note 25, at 1.

90. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6409(b), 124 Stat. 722-723 (2010).

91. Patient Protection and Affordable Care Act § 6409(a)(2).

92. LEVINSON, *supra* note 68.

criminal liability. The OIG and DOJ work together and, if any unanticipated discoveries arise, they are handled accordingly.

The SRDP process does not contain a waiver of criminal liability. In fact, while the SRDP is specific to the Stark Law, CMS does not guarantee that the disclosure is not turned over to the DOJ for criminal prosecution.[93] The investigative process undertaken by CMS is not as closely connected to the DOJ's work and so potential criminal investigation is a strong consideration for a provider deciding whether or not to submit a disclosure pursuant to the SRDP or the OIG's Self-Disclosure Protocol. Also, because the disclosure processes between the OIG and CMS differ regarding AKS disclosure and Stark Law disclosure, it is possible the government could receive multiple overpayments by way of multiple disclosures.[94] While CMS recommends that the provider identify any additional disclosures in its SRDP,[95] the recommendation could fall on deaf ears and the uncertain provider could self-disclose to multiple agencies.

The settlement procedure has taken CMS longer than anticipated, potentially creating more hesitancy in self-disclosing to CMS. OIG set a one-year deadline for reaching settlement agreements pursuant to its Self-Disclosure Protocol.[96] Out of hundreds of submissions to the SRDP since 2010, only thirty-nine settlement agreements have been published on CMS' website.[97] CMS sped up the process of review, settling only seventeen cases in the first two years of establishment and twenty-two in the last year.[98] The sped up process, however, still gives providers an inadequate amount of information to make an informed decision as to its own self-disclosure process. The published cases on CMS' website vaguely identify what kind of provider and what Stark Law provision were in violation.[99]

The SRDP gives no indication as to how much liability a provider could incur, and only mildly assists a provider in determining if it should report using SRDP, which itself is not a clear process. The government generally just wants the overpayment to be returned. Therefore it is not always necessary to inform the "correct" agency. But which agency is chosen could affect how much the payment is reduced in the settlement process, what additional penalties could occur, and how efficient the process is. Therefore, for each potential violation, the provider should carefully assess which agency will provide the best opportunity for favorable outcomes.

93. SELF-REFERRAL DISCLOSURE PROTOCOL, *supra* note 25, at 3.
94. FREQUENTLY ASKED QUESTIONS, *supra* note 29, at 7.
95. *Id.* at 6.
96. OIG PROTOCOL, *supra* note 19.
97. *Self-Referral Disclosure Protocol Settlements*, *supra* note 36.
98. *Id.*
99. *Id.*

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If the provider believes that it is in violation of the AKS, it should most likely submit its disclosure to the OIG. The OIG will work in concert with the DOJ to work out any potential criminal charges. If it is solely a Stark Law violation, submitting an SRDP would generally best suit the provider. CMS has not historically worked as closely with the DOJ, so there are instances when a provider may want to report directly to the DOJ for a strictly Stark Law violation if criminal charges are likely.[100] Often, providers or counsel will have working relationships with U.S. Attorneys in their region and know what to expect in a disclosure process if they choose to work out the disclosure with that U.S. Attorney.

As part of the SRDP, the provider must submit a full financial and legal analysis of why it violated the Stark Law.[101] A cause of the delay in settlement proceedings has been that many of the disclosures by providers have not included an adequate enough financial analysis.[102] A legal analysis means that the provider must submit detailed information regarding the Stark Law exception it aimed to meet, and why the provider failed to meet that exception in an element-by-element break down.[103]

One explanation for the inadequate financial analyses is that providers believed they adequately provided the right financial information but misunderstood how much was required. In this instance, the providers voluntarily submitted legal analysis of why they did not meet the Stark Law without the understanding of how much information they would be required to report. At first glance, it looks as if providers were making decisions to voluntarily report without knowing their full potential liability. This has almost no impact on providers whose situations are clear-cut violations. But for providers who are reporting a potential violation, their initial financial analysis could result in serious miscalculations of liability prior to submission. Of course, the submission may be withdrawn,[104] but it is likely the potential for CMS investigation or audit procedures under FERA could rise significantly and the provider flagged itself as an audit target.

Another possibility surrounding the number of reports with inadequate financial analyses revisits issues with the 60-day-rule. One possible reason many disclosures have inadequate financial analysis is that providers are scared they will be in violation of the 60-day-rule and prematurely report. Providers may look at their financial situation, specifically the "look-back" period, and with the sixty-day time limit approaching any FCA liability would significantly increase their potential liability. Providers would submit the

100. SELF-REFERRAL DISCLOSURE PROTOCOL, *supra* note 25, at 3.
101. *Id.* at 5.
102. REPORT TO THE CONGRESS, *supra* note 33, at 8-9.
103. SELF-REFERRAL DISCLOSURE PROTOCOL, *supra* note 25, at 4.
104. *Id*. at 5.

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electronic SRDP with as much financial information as they have and pause the 60-day-rule. The fear is that the providers did not move with enough "deliberate speed" and did not make a reasonable enough inquiry.[105] At the time of submission the violation might not be colorable and therefore the providers submitted a voluntary self-disclosure prematurely. If not under the pressure of the 60-day-rule, the providers could have made the reasonable inquiry without the added pressure and discovered they did not need to submit. At that point, the providers would withdraw their SRDP but like the previous scenario, the providers may unnecessarily put themselves on CMS' list for potential future audits.

IV. WHY CONGRESS AND CMS SHOULD CHANGE THE REPORTING AND DISCLOSURE RULES AND PROVIDERS SHOULD BE CAUTIOUS IN SELF-DISCLOSING UNTIL IT DOES

Congress aimed to crackdown on fraud and abuse on the Medicare system and to make a clear avenue for self-reporting by providers in the recent health care law changes. By implementing the SRDP, strengthening FERA's investigative powers, and implementing the 60-day-rule, Congress gave CMS the upper hand in fraud and abuse prosecution. However, Congress also put providers in a predicament that could result in outcomes less desirable than intended. A few of the ultimate goals of the ACA were to reduce fraud and abuse, recover money that CMS paid to providers not entitled, and to improve the quality of care of the Medicare beneficiaries. The problems presented to providers through these particular provisions of the ACA and guidance issued, create a cloud of confusion surrounding the self-reporting process.

The legal determination for how the 60-day-rule applies to Stark Law violations, or lack of one, is insufficient in providing the guidance necessary to make an informed decision about self-disclosure. CMS proposes that if, after applicable reconciliation, the provider identifies overpayment, it is to report that overpayment. According to the commentary, if a report has already been made on the initial discovery, an additional report should be made to the appropriate agency as a separate self-disclosure, only referencing its connection to the first report.[106] Providers, out of fear of violating the 60-day-rule, will report a simple overpayment to the OIG through Section 6402, and continue to conduct their reasonable inquiry. Providers may discover a self-referral violation in connection to the original overpayment report and file a subsequent SRDP with CMS.

105. Proposed Rule, *supra* note 3, at 9182.

106. *Id.* at 9184. Language of the commentary implies that HHS wants to shy away from "supplemental" reports to the initial report. *Id.* CMS most likely does not want providers submitting initial reports to OIG covering the bare bones requirements and then supplementing these reports with the actual information causing review of the report twice.

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The confusion not only makes decisions difficult for providers in how to best resolve any actual or potential violations, it creates inefficiencies for all parties. From the government's perspective, there is potential that double or even triple review for the same violation could occur. The 60-day-rule applies pressure to the provider to disclose before ready. The pressure could force providers to disclose the overpayment or violation to the wrong agency. In its Report to Congress, CMS stated that it would work in concert with the other agencies (namely OIG and DOJ) to resolve issues.[107] However, submissions that would not normally be reviewed by all three agencies could potentially be reviewed by all three because of the providers' fear of violation of the 60-day-rule.

From the provider's perspective, the increased enforcement could actually slow down the reporting process. Congress aimed to create an avenue that helped resolve Stark Law violations in a much clearer manner. The avenue it created, passed in conjunction with FERA and the 60-day-rule, makes it harder for providers to figure out where to report. As mentioned previously, providers may have to submit multiple disclosures for one violation if they prematurely report and discover more about the violation. Additionally, in order to meet the reasonable inquiry standard, providers may take more time forming compliance departments or seeking assistance of legal counsel for some violations or overpayments when simple reporting via Section 6402 would suffice.

One issue not addressed yet is how the health care law puts a heavy burden on institutional providers. According to the Report to Congress, of the first 150 submissions using the SRDP, 125 of the submissions were from hospitals.[108] Of course, hospitals generally have the money to start, or already have institutional compliance departments, and catching violations is generally easier. Additionally, hospitals contain a high concentration of physicians and other providers in one area and hold the upper hand (and often reporting responsibility) in contracts with outside physicians.

If one goal of adding FERA, the SRDP, and 60-day-rule is to increase quality of care for Medicare beneficiaries, a large number of providers are falling out of the spotlight. A recent study conducted by the American Medical Association (AMA) found that 53.5 percent of physicians surveyed were self-employed, twenty-three percent worked in practices at least partly owned by a hospital, and only 5.6 percent of respondents stated they were hospital employees.[109] It would be inappropriate to directly correlate the AMA study

107. REPORT TO THE CONGRESS, *supra* note 33, at 6-7.

108. *Id.* at 8-9.

109. CAROL K. KANE & DAVID W. EMMONS, NEW DATA ON PHYSICIAN PRACTICE ARRANGEMENTS: PRIVATE PRACTICE REMAINS STRONG DESPITE SHIFTS TOWARD HOSPITAL

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percentages to the number of SRDPs because often hospitals have a more complicated series of arrangements, trying to meet more Stark Law exceptions. Hospitals generally have a larger dependence on Medicare payment and so even if over half of physicians are in private practice, many of those practices could be in specialties that do not require Medicare payment (i.e., pediatrics, elective plastic surgery) and some of them may choose not to take Medicare payment at all. But it cannot be ignored that the new rules, the same rules forcing hospitals to beef up their compliance departments, put a heavier burden on institutional providers.

The AHA, in their strongly worded comments to CMS regarding the Proposed Rule on overpayments in February 2012, reiterates this exact point. The AHA identifies the provisions calling for reasonable inquiry (or "duty to investigate") and extension of the "look-back" period to ten years the "two most concerning aspects of the proposed rule."[110] The AHA argues that hanging ten years of FCA violations over the head of an institutional provider creates an impossible standard where a hospital "would effectively have to guarantee that its bills and reviews were 100 percent accurate 100 percent of the time."[111] In addition to accuracy, the AHA argues that the Proposed Rule puts too strong an emphasis on speed, stating that sixty days to return an overpayment is an unreasonable amount of time with large institutions and allows for meritless cases to be brought by whistleblowers within the institution on the premise that the hospital should have known of the overpayment sooner.[112] The AHA reiterates the point made earlier in this paper that a focus is put on institutions and their compliance departments and such a focus minimizes their already good faith efforts to comply with various regulations and puts a near impossible burden on them.[113]

The heavy burden on institutional providers could have many unintended consequences hurting the aims of the health care laws. For a savvy private practice physician wanting to ensure a compliant provision of care to patients, the additional burdens (and resulting legal and administrative expenses) could discourage the physician from renewing her Medicare Participating Provider Agreement. A decline in Medicare reimbursement in general combined with the number of expenses (even if no violations are discovered) added would make moving to only commercial payors a potentially smart business move.

EMPLOYMENT 8 (2013), *available at* https://download.ama-assn.org/resources/doc/health-policy/x-pub/prp-physician-practice-arrangements.pdf.

110. AHA Letter, *supra* note 52, at 6.

111. *Id.* at 7.

112. *Id.* at 7-8.

113. *Id.* at 8-9.

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The implementation of the rules as they stand could add to the existing problem of physicians retreating from Medicare.[114]

As a solution to the large problems of the overlap of FERA, the SRDP, and 60-day-rule, CMS should only apply the 60-day-rule to a category of overpayments titled "simple overpayments." CMS defines any money paid to a provider that, after applicable reconciliation, the provider is not entitled to as an "overpayment" for the purposes of the 60-day-rule.[115] An exception should be created for Stark Law and AKS violations thereby creating the overpayments required to comply with the 60-day-rule as "simple overpayments." The "simple overpayments" include examples already given by CMS such as: (1) when a provider reviews payment records and discovers one was incorrectly coded; (2) discovery that patient death occurred prior to a submitted bill for services; and (3) services billed for were conducted by an unlicensed professional.[116] These suggestions are just to give an idea of what a "simple overpayment" would entail and is not an exhaustive list. The key point is that "simple overpayments" do not include violations of the Stark Law and AKS and include those that can be discovered fairly quickly and remediated easily.

As expressed previously in this paper, the government currently has an overlap of laws. One discussed in less detail is the overlap of FERA provisions and the 60-day-rule. The FERA provision makes changes to the FCA stating that if a provider knowingly retains an overpayment, it is an FCA violation.[117] The 60-day-rule holds that once an overpayment is identified, the provider has sixty days to return the overpayment.[118] Technically, during those sixty days (or until the provider returns the overpayment) the provider is knowingly retaining the overpayment, violating FERA. The OIG is not likely to enforce FERA this way because such an interpretation would make the 60-day-rule moot and would extend FERA beyond the scope intended. Both FERA and the 60-day-rule impose FCA violations to previously unaffected overpayments or violations.

Defining overpayment for the purposes of the 60-day-rule as a "simple overpayment" would ease the burden placed on providers and the government would still accomplish its fraud and abuse goals. Providers' burden would ease by removing the seemingly arbitrary sixty day deadline acting like a gun to their heads. Providers would not be bound by the "duty to investigate" or reasonable inquiry standards with the sixty day deadline approaching. Of

114. *See* Julie Connelly, *Doctors Are Opting Out of Medicare*, N.Y. TIMES (Apr. 1, 2009), http://www.nytimes.com/2009/04/02/business/retirementspecial/02health.html?r=0.

115. Proposed Rule, *supra* note 3, at 9181.

116. *Id.* at 9182.

117. *Id.* at 9185.

118. 42 U.S.C. § 1320a-7k(d)(2) (2013).

course, the same "knowing" standard applies to FERA and so providers would need to ensure that their retention of overpayments was not made with deliberate ignorance or reckless disregard. Congress could accomplish its fraud and abuse goals by using FERA to replace the FCA penalties on providers who knowingly retain overpayments in cases where the FCA penalties would be removed with the 60-day-rule. The point of adding the FCA violations was to incentivize providers to remain accountable for what they bill for and how they conduct business. That point is not lost in removing the 60-day-rule for Stark Law and AKS violations because providers would still need to ensure they do not hide behind ignorance or reckless disregard without the threat of FCA violations. It just gives providers the room necessary to operate their compliance programs and confer with legal counsel without the frantic aspects of the 60-day-rule.

Removing the 60-day-rule's application to the Stark Law and AKS will ultimately result in more disclosures due to efficiencies in the system. Providers, in discovering an overpayment, will preliminarily identify the category of overpayment. If at first glance the overpayment looks like a "simple overpayment," the provider will work to submit a report pursuant to Section 6402 to OIG and repay the overpayment within sixty days, most likely directly to the MAC. If, after further investigation, the provider realizes the overpayment was tied to a series of Stark Law violations, the provider will have as much time as necessary to investigate the violation and apply the appropriate financial and legal analysis without triggering the 60-day-rule. A more complete SRDP will be submitted to CMS and there will be less intra-agency conferring because the report will be more complete. The complete report will result in less time waiting on document submission and quicker review turnaround time. Quicker turnaround time will result in more settlement postings and more faith in the system from providers that not only will their submissions result in reduction of payments, but they will be resolved quickly. Ultimately, the number of submissions will increase and the number of dollars recovered will increase.

Problems will still exist with the system, but many of them will not change because of the nature of the Stark Law itself. There will still be situations where providers are unsure whether there is an AKS issue and a Stark Law issue, or if it is just one or the other. The providers will need to decide whether the SRDP or the OIG Self-Disclosure Protocol is appropriate. There will still also need to be an increase in compliance departments around the country for institutional and large group providers. Lack of adequate knowledge and investigation could result in FCA violations if no system for detecting and investigating potential overpayments and violations exists. However, by removing the 60-day-rule from the Stark Law and AKS analysis, a provider

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will not be held to the impossible standards of having "to guarantee that its bills and reviews were 100 percent accurate 100 percent of the time."[119]

IV. CONCLUSION

Congress intended to create an open channel of communication between providers and CMS when it created the SRDP. Providers, feeling threatened to disclose potentially damaging information without knowing the outcome, can hinder that channel of communication. That channel of communication could be damaged by not addressing different problems in different manners. The Stark Law presents a unique problem that results in Medicare overpayments, as currently defined, that are much different than many other overpayments. Giving providers extra time to appropriately investigate their potential violations without the fear of FCA prosecutions will result in not only more disclosures, but more thorough disclosures. Because the disclosures will be more thorough, there will be less administrative time devoted by CMS in fact finding and information requests, resulting in quicker settlement turnarounds and fewer agency dollars spent in administrative review for each disclosure.

CMS changing its definition of "overpayment" when publishing its Final Rule on the Section 6402 of the ACA would grant providers the necessary extra time. Overpayment should be defined as is in the Proposed Rule in February 2012, with a new exemption for Stark Law and AKS violations. This definition would apply the 60-day-rule only to "simple overpayments." Any lost enforcement capabilities from the change in definition would be made up by FERA's already existing "reverse false claim" provision prohibiting the knowing retention of payments the provider is not entitled to.

Whether the Final Rule applies principles in the Proposed Rule or not, providers will need to increase their compliance departments. The impetus of potential FCA violations, which would apply through either FERA or the 60-day-rule, is too large a concern to not address with added compliance programs. But if the 60-day-rule does not apply to Stark Law and AKS violations, providers will not be held to impossible standards of investigation. Providers will be able to adequately investigate and research violations so a more appropriate analysis can be applied and a more complete SRDP can be filed. Appropriate legal and financial analyses are key to a complete SRDP, which is key to successful communication between CMS and the disclosing

119. AHA Letter, *supra* note 52, at 7.

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providers. Successful communication will benefit both the providers and the government and assist in accomplishing overarching societal goals of improving health care in the United States.

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