

NOTE

“STARK” RAVING MAD: MAKING THE SELF-REFERRAL DISCLOSURE PROTOCOL BETTER, FASTER, STRONGER

I. INTRODUCTION

“Stark Law” is the popular name for section 1877 of the Social Security Act,¹ which prohibits physician self-referrals of Medicare patients. Congress enacted the law in 1989 due to concern over the increasing rate of Medicare patients referred for testing services at facilities in which the referring physicians have an ownership interest.² Stark Law is enforced, overseen, and regulated primarily by the Centers for Medicare and Medicaid Services (“CMS”).³ The vast majority of Stark Law claims, however, are filed as qui tam suits by relators (private persons)⁴ pursuant to the False Claims Act (“FCA”).⁵ When a relator brings a suit, the U.S. Department of Justice (“DOJ”) decides whether to intervene or to let the relator proceed on his own.⁶ The harsh reality of a

1. 42 U.S.C. § 1395nn (2012).

2. See *About Stark Law*, STARK L., http://starklaw.org/stark_law.htm (last visited Apr. 10, 2017); *Physician Self Referral*, CMS.GOV, <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/PhysicianSelfReferral> (last visited Apr. 10, 2017).

3. Marc S. Raspanti & Sarah R. Lavelle, *Who Is Enforcing the Stark Law of the United States*, AHLA CONNECTIONS, Sept. 2012, at 24, 25.

4. See Paula Tironi, *The “Stark” Reality: Is the Federal Physician Self-Referral Law Bad for the Health Care Industry?*, 19 ANNALS HEALTH L. 235, 239 (2010); Press Release, Office of Pub. Affairs, U.S. Dep’t of Justice, Justice Department Recovers \$3.8 Billion from False Claims Act Cases in Fiscal Year 2013 (Dec. 20, 2013), <http://www.justice.gov/opa/pr/justice-department-recovers-38-billion-false-claims-act-cases-fiscal-year-2013.pdf>. Qui tam comes from the Latin word for “who as well,” and refers to a lawsuit brought by a whistleblower “against a person or company who is believed to have violated the law in the performance of a contract with the government.” *Qui Tam Action*, LAW.COM, <http://dictionary.law.com/default.aspx?selected=1709> (last visited Apr. 10, 2017).

5. Press Release, Office of Pub. Affairs, U.S. Dep’t of Justice, Justice Department Recovers Nearly \$6 Billion from False Claims Act Cases in Fiscal Year 2014 (Nov. 20, 2014), www.justice.gov/opa/pr/justice-department-recovers-nearly-6-billion-false-claims-act-cases-fiscal-year-2014.

6. Jonathan T. Brollier, Note, *Mutiny of the Bounty: A Moderate Change in the Incentive Structure of Qui Tam Actions Brought Under the False Claims Act*, 67 OHIO ST. L.J. 693, 703

Stark Law violation coupled with a colorable claim under the FCA can clearly be seen in the case of *Tuomey Healthcare System, Inc.*⁷ In July of 2015, Tuomey incurred civil monetary penalties levied in excess of \$237 million as a result of a *qui tam* suit.⁸ In his concurring opinion, Judge James Wynn described the “troubling picture the case paints: An impenetrably complex set of laws and regulations that will result in a likely death sentence for a community hospital in an already medically underserved area.”⁹

In the United States, “Medicare is the federal health insurance program for people who are 65 or older, certain younger people with disabilities, and people with End-Stage Renal Disease.”¹⁰ In 2014, there

(2006). A false claim is made by “any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.” 31 U.S.C. § 3729(a)(1)(A) (2012). The FCA carries civil penalties ranging between \$5000 to \$10,000 per claim and three times (treble) the amount of damages sustained by the government. *Id.* § 3729(a)(1)(G). CMS has not historically sought enforcement of Stark Law, policing it themselves. PUB. INTEREST COMM., AM. HEALTH LAWYERS ASS’N, A PUBLIC POLICY DISCUSSION: TAKING THE MEASURE OF THE STARK LAW 11, <https://www.healthlawyers.org/hlresources/PI/ConvenerSessions/Documents/Stark%20White%20Paper.pdf> (last visited Apr. 10, 2017). Rather, it relies on relators bringing actions under the FCA. *Id.* at 3. Further, there is “[t]he risk of a hospital facing disproportional penalties for an innocent Stark violation, however, is exacerbated to the extent that prosecutorial discretion has been effectively abdicated to whistleblowers under the *qui tam* provisions of the FCA.” *Id.* at 11. Additionally, “the industry has viewed Stark enforcement as akin to lightning striking - unpredictable but deadly.” *Id.*

7. Press Release, Office of Pub. Affairs, U.S. Dep’t of Justice, United States Resolves \$237 Million False Claims Act Judgment against South Carolina Hospital that Made Illegal Payments to Referring Physicians (Oct. 16, 2015), <http://www.justice.gov/opa/pr/united-states-resolves-237-million-false-claims-act-judgment-against-south-carolina-hospital>. Tuomey Healthcare System is a 301 bed medical facility located in South Carolina. *History*, PALMETTO HEALTH TUOMEY, <http://www.tuomey.com/about/history.aspx> (last visited Apr. 10, 2017).

8. United States *ex rel* Drakeford v. Tuomey, 792 F.3d 364, 387, 389-90 (4th Cir. 2015). As of October 16, 2015, Tuomey entered into a settlement with the DOJ to reduce its civil monetary penalty to \$72.4 million, and will be sold to Palmetto Health, a multi-hospital conglomerate. Press Release, Office of Pub. Affairs, *supra* note 7. While the settlement drastically reduced the damages award, Tuomey’s penalty is still a “death sentence” as Judge Wynn noted in his concurring opinion. *Tuomey*, 792 F.3d at 390 (Wynn, J., concurring).

9. *Tuomey*, 792 F.3d at 390. Judge Wynn also stated, “Ironically, the Stark law was actually intended to simplify life by creating ‘bright lines’ between what would be permitted and what would be disallowed, and creating certainty by removing intent from the equation.” *Id.* at 393. Instead, Stark “has become a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the False Claims Act.” *Id.* at 395. A medically underserved area is established by the Health Resources and Services Administration (“HRSA”). *Medically Underserved Area/Population (MUA/P) Application Process*, HEALTH RESOURCES & SERVICES ADMIN., <http://www.hrsa.gov/shortage/mua/imutables.html> (last visited Apr. 10, 2017). HRSA establishes what is a medically underserved area based on four metrics: (1) percentage of the population below the poverty line; (2) percentage of the population over the age sixty-five; (3) the infant mortality rate for the area; and (4) the ratio of primary care physicians per 1000 people. *Id.* The four individual scores are then tabulated and if the score adds up to less than sixty-two, the area is deemed medically underserved. *Id.*

10. *What’s Medicare?*, MEDICARE.GOV, <https://www.medicare.gov/sign-up-change-plans/decide-how-to-get-medicare/whats-medicare/what-is-medicare.html> (last visited Apr. 10, 2017).

were an estimated fifty-four million people enrolled in Medicare programs.¹¹ Despite the increase in Medicare enrollees since 1990, the number of inpatient hospital beds¹² has decreased by forty-five percent.¹³ As part of its initial mandate, CMS stated that Medicare did not "authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided or over the selection, tenure, or compensation . . . of any institution, agency, or person providing health services."¹⁴

Therefore, with fewer and fewer Medicare dedicated beds and enrollment expected to reach 64.3 million subscribers by 2020,¹⁵ medical facilities should not be forced to bear heavier regulatory burdens.¹⁶ The government has an interest in settling claims faster, in order to receive penalties and Medicare overpayments in a more timely fashion.¹⁷ A quicker disclosure process would allow Stark Law to better self-police the health care industry and expedite large claims that the DOJ has grown accustomed to collecting as a result of health care entities entering into self-dealing contracts with physicians.¹⁸

Over the years, in response to various abuses, Congress has been forced to legislate against its original mandate to ensure that Medicare provides its authorized function of supplying necessary health coverage.¹⁹ One of these legislative acts was Stark Law.²⁰ Stark Law

Medicare has four distinct parts (Parts A to D). *Id.* "Part A covers inpatient hospital stays, care in a skilled nursing facility, hospice care, and some home health care" (hospital coverage). *Id.* "Part B covers certain doctors' services, outpatient care, medical supplies, and preventive services" (medical insurance). *Id.* Part C is "[a] type of Medicare health plan offered by a private company that contracts with Medicare to provide you with all your Part A and Part B benefits" (Medicare Advantage plans) and Part D adds prescription drug coverage. *Id.* (stating that Medicare additionally covers some younger people with disabilities, and people with End-Stage Renal Disease).

11. U.S. DEP'T OF HEALTH & HUMAN SERVS., 2014 CMS STATISTICS 6 (2014), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/CMS_Stats_2014_final.pdf. Medicare enrollment has increased 183% to 54 million subscribers, up from 1966 when it was only 19.1 million subscribers. *Id.* at 1.

12. *Id.* at 2.

13. *Id.* The number of inpatient beds has decreased from 32.8 beds per 1000 enrolled in 1990 to 18.1 per 1000 in 2013. *Id.*

14. Social Security Amendments of 1965, Pub. L. No. 89-97, § 1802, 79 Stat. 291 (1965) (codified as amended at 42 U.S.C. § 1395nn (2012)).

15. *Projected Change in Medicare Enrollment, 2000-2050*, KAISER FAM. FOUND., <http://kff.org/medicare/slide/projected-change-in-medicare-enrollment-2000-2050> (last visited Apr. 10, 2017).

16. See discussion *infra* Part IV.A.

17. See discussion *infra* Part IV.A.

18. See discussion *infra* Part IV.A.

19. See 42 U.S.C. § 1320a-7b(b) (2012). In 1972, Congress enacted 42 U.S.C. § 1320a-7b, commonly known as the "Anti-Kickback Statute," to prohibit any person or entity from making or

aims to prevent doctors and health care entities from entering into agreements where the physician has a financial interest, be it ownership or a referral-based compensation arrangement.²¹ Stark Law has taken a long time from enactment to utilization, going through numerous phases to mutate from a prohibition placed on doctors referring patients for blood lab work, to a statute comprised of two pages of definitions and prohibitions and an additional nine pages of exceptions.²²

Since 1998, the main avenue for a non-compliant entity to disclose a Stark Law violation was through the Office of Inspector General's ("OIG") Self-Disclosure Protocol ("SDP").²³ In 2010, as part of the Patient Protection and Affordable Care Act ("ACA"), Congress mandated that CMS create its own self-disclosure protocol for Stark Law violations.²⁴ The Self-Referral Disclosure Protocol ("SRDP") has been heavily criticized since its inception in 2010,²⁵ with few disclosures and even fewer resolutions.²⁶ In March 2015, five years after its inception, CMS had only settled sixty-nine self-disclosures through the SRDP and had a queue of over 300 disclosures.²⁷

accepting payment to induce or reward any person "for referring, recommending, or arranging the purchase of any item for which payment may be made under a federally-funded health care program." *Id.* § 1320a-7b(b)(1)(A); see *Federal Anti-Kickback Law and Regulatory Safe Harbors*, OFF. INSPECTOR GEN. (Nov. 1999), <https://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm>. In 1986, Congress expanded the FCA to cover health care entities in an effort to curb false claims made for reimbursement through Medicare. See H.R. REP. NO. 99-660, pt. 1, at 21 (1986) ("[T]he new definition clearly covers false claims for reimbursement under the Medicare, Medicaid, or similar programs."). Finally, in 1989, Stark Law was created to prevent physicians from referring patients for clinical lab services in which they had an ownership interest. *About Stark Law*, *supra* note 2.

20. *About Stark Law*, *supra* note 2.

21. *Id.* Many people have criticized the practice, alleging "an inherent conflict of interest, given the physician's position to benefit from the referral." *Id.* Further, "[t]hey suggest that such arrangements may encourage over-utilization of services, in turn driving up health care costs." *Id.*

22. Patrick A. Sutton, *The Stark Law in Retrospect*, 20 ANNALS HEALTH L. 15, 23-25, 31 (2011).

23. Publication of the OIG's Provider Self-Disclosure Protocol, 63 Fed Reg. 58,399, 58,400 (Oct. 23, 1998); see also U.S. DEP'T OF HEALTH & HUMAN SERVS., REPORT TO CONGRESS: IMPLEMENTATION OF THE MEDICARE SELF-REFERRAL DISCLOSURE PROTOCOL 3 (2012), <https://www.cms.gov/medicare/fraud-and-abuse/physiciansselfreferral/downloads/CMS-SRDP-Report-to-Congress.pdf> ("The SDP was first displayed in the Federal Register in 1998, after being created out of a pilot program operated by [the] OIG and DOJ.").

24. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6407, 124 Stat. 772 (2010) (codified at 42 U.S.C. § 1395nn (2012)).

25. Letter from Jim McDermott, Congressman, U.S. House of Representatives, to Marilyn Tavenner, Adm'r, Ctrs. for Medicare & Medicaid Servs. (Aug. 13, 2013) (on file with author).

26. See Tony Maida, *Disclosure Smart: Strategic Considerations in Making a Government Disclosure*, AHLA WKLY. (Mar. 13, 2015), https://www.mwe.com/~media/files/thought-leadership/publications/2015/03/disclose-smart-strategic-considerations-in-makin_/files/ahlaweekly031315/fileattachment/ahlaweekly031315.pdf.

27. *Id.*

Many exceptions are contained in Stark Law, and they make an already complex statute even less user-friendly.²⁸ Health care entities can easily run afoul of Stark Law and fall vulnerable to heavy civil penalties.²⁹ This Note focuses on streamlining the SRDP process to limit the amount of time health care entities spend waiting for a resolution from CMS.³⁰ Further, this Note posits a set of guidelines that CMS can transmit to ensure entities have a clearer roadmap for utilizing the SRDP process.³¹

Part II of this Note offers background information and the moving parts of Stark Law,³² including the SRDP and the various alterations it has undergone through the years.³³ Part III discusses the various problems facing the SRDP since its inception,³⁴ including the slow pace of claim settlements,³⁵ the need for a separate disclosure process for technical and substantive violations,³⁶ and the lack of clear penalty guidelines.³⁷ Part IV provides solutions to these problems, including speeding up the disclosure process by CMS for processing disclosures via the SRDP,³⁸ creating a separate disclosure for technical and substantive disclosures,³⁹ providing clearer guidelines,⁴⁰ and improving the way CMS publishes disclosures on its website.⁴¹

II. A "STARK" HISTORY

Stark Law began as a way to combat the abuse of doctors referring patients to clinics for unnecessary tests solely for personal, financial benefit.⁴² Today, it primarily deals with the hospital level and is complied with through the use of qui tam lawsuits brought by private citizens.⁴³ Subpart A lays out the creation of Stark Law; the initial statute and the many implementation phases and alterations it has gone through

28. See Sutton, *supra* note 22, at 31 (stating that Stark Law consists of two pages of provisions and an exhaustive nine pages of exceptions).

29. *Id.*

30. See *infra* Part IV.A.

31. See *infra* Part IV.C.

32. See *infra* Part II.A.

33. See *infra* Part II.B–D.

34. See *infra* Part III.

35. See *infra* Part III.A.

36. See *infra* Part III.B.

37. See *infra* Part III.C.

38. See *infra* Part IV.A.

39. See *infra* Part IV.B.

40. See *infra* Part IV.C.1.

41. See *infra* Part IV.C.2.

42. *About Stark Law*, *supra* note 2.

43. *Id.*

in its more than twenty-five year history.⁴⁴ Subpart B sets out some basic definitions necessary to understand the various elements of a Stark Law violation.⁴⁵ Subpart C gives a basic overview of the many Stark Law exceptions.⁴⁶ Finally, Subpart D gives an introduction to the brief history of the SRDP.⁴⁷

A. Stark Law: “What a Long, Strange Trip It’s Been”

Stark Law was originally enacted in 1989 as a response to doctors referring patients to lab clinics in which the doctors had an ownership interest.⁴⁸ The law’s namesake, U.S. Congressman Pete Stark, created the statute to prevent physician self-referral to a medical facility in which he or she has a financial interest—whether it be “ownership, investment, or a structured compensation arrangement.”⁴⁹ The law has been expanded since its inception to cover a host of designated health services (“DHS”)⁵⁰ that make compliance necessary for a myriad of health care entities.⁵¹ It is believed that doctors entering into these referral-based compensation arrangements encourages overutilization of services, thus increasing the cost of health care.⁵² Congressman Stark wanted to promote “self-enforcement” by making a statute that was clear, with substantial penalties.⁵³ The statute has undergone many changes, covering more services and carving out exceptions to others.⁵⁴

Prior to the enactment of Stark Law, abuses of Medicare were prosecuted under the “Anti-Kickback Statute,”⁵⁵ and a violating entity was subject to civil fines and criminal prosecution.⁵⁶ Congressman Stark

44. See *infra* Part II.A.

45. See *infra* Part II.B.

46. See *infra* Part II.C.

47. See *infra* Part II.D.

48. See *About Stark Law*, *supra* note 2.

49. *Id.*

50. See 42 C.F.R. § 411.351 (2009); see also *infra* note 76 and accompanying text (providing a DHS list).

51. *About Stark Law*, *supra* note 2.

52. *Id.*

53. See Jennifer A. Hanson, Note, *The Academic Medical Center Exception to the Stark Law: Compliance by Teaching Hospitals*, 61 ALA. L. REV. 373, 374-75 (2010) (noting that Stark Law imposes a strict liability standard).

54. See Tironi, *supra* note 4, at 238 (“Given the highly detailed and technical nature of the Stark Law exceptions, a seemingly minor oversight, such as neglecting to obtain a party’s signature on an agreement, can trigger disproportionately severe consequences for a physician or DHS entity . . .”).

55. 42 U.S.C. § 1320a-7b (2012).

56. CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP’T OF HEALTH & HUMAN SERVS., LAWS AGAINST HEALTH CARE FRAUD RESOURCE GUIDE 2 (2015), <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/fwa->

was upset with the "severe and inflexible intent element of the Anti-Kickback Statute."⁵⁷ In pertinent part, the statute prohibits a physician from referring a patient to a DHS⁵⁸ in which the physician, or an immediate family member, has a financial interest, unless an exception applies.⁵⁹ The Omnibus Budget Reconciliation Act of 1993 later expanded Stark Law to include a variety of additional health services and applied it to Medicare and Medicaid.⁶⁰ In 1997, Stark Law was revised to allow the Secretary of CMS to issue advisory opinions on whether a referral relating to a DHS is prohibited by the law.⁶¹

Next, came what is known as the phases of Stark, starting in 2001 with Phase I.⁶² Phase I addresses basic statutory definitions, general prohibitions, and explanations of what constitutes a financial relationship between a physician and a health care entity providing DHS.⁶³ Phase II deals with the regulatory exceptions, reporting requirements, and public comments pertaining to Phase I.⁶⁴ Finally, Phase III regulations were published in September of 2007 and largely address comments made after publication of the Phase II regulations.⁶⁵ Phase III not only creates clarity with additional explanation but also reduces the regulatory burden imposed on the health care industry by modifying many of the exceptions related to financial relationships between physicians and DHS entities where there is little risk of abuse to the patient or Medicare programs.⁶⁶

Violations of Stark Law can come at a hefty price.⁶⁷ The statute provides for the following sanctions on claims submitted for DHS in violation of Stark: (1) denial of payment;⁶⁸ (2) requiring refund of funds received;⁶⁹ (3) civil penalties up to \$15,000 per service;⁷⁰ and

laws-resourceguide.pdf.

57. Hanson, *supra* note 53, at 374-75. There is a knowledge requirement under the Anti-Kickback Statute. 42 U.S.C. § 1320a-7b(b)(1) (2012).

58. See 42 U.S.C. § 1395nn(h)(6)(A)-(L); *infra* note 77 and accompanying text (listing the DHSs covered by the statute).

59. See 42 U.S.C. § 1395nn(a)(1)(A).

60. *About Stark Law*, *supra* note 2. For the purpose of this Note, Stark Law is examined primarily from the perspective of how it is applied to Medicare. See *supra* Part I.

61. 42 U.S.C. § 1395nn(g)(6)(A); see *About Stark Law*, *supra* note 2.

62. See Sutton, *supra* note 22, at 24 (explaining that the Stark phases would be revisions to Stark II).

63. *Id.*

64. *Id.*

65. *Id.* at 25.

66. *Id.*

67. See *infra* notes 69-72.

68. 42 U.S.C. § 1395nn(g)(1) (2012).

69. *Id.* § 1395nn(g)(2).

70. *Id.* § 1395nn(g)(3).

(4) exclusion from Medicare or Medicaid programs, where a physician or entity knowingly enters into an improper cross-referral arrangement or scheme in order to avoid the self-referral ban.⁷¹

Additionally, a violation of Stark Law can trigger the FCA because Medicare providers must certify, as a condition precedent to submitting a claim, that they are in compliance with federal law, including Stark Law.⁷² Under the FCA, a claim is false if any person “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.”⁷³ A violation of the FCA carries a penalty of three times the amount paid by the government and a civil monetary penalty of between \$5000 and \$10,000 per claim.⁷⁴ Most penalties under the FCA come as a result of qui tam relator suits.⁷⁵

B. Definitions and Terms for Stark Law

The operation of Stark Law rests heavily upon the three definitions listed below.⁷⁶ A physician under Stark Law is defined as “a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor.”⁷⁷ A “referral” is any request, in any form, by a physician for a DHS for which payment may be made under Medicare Part B; a request for a consultation with another physician; any test arising out of that consultation; and the establishment of a plan of care that includes a DHS.⁷⁸ A “designated health service” is any (1) clinical laboratory service (covered by the 1989 enactment); (2) physical therapy; (3) occupational therapy; (4) outpatient speech-language pathology services; (5) radiology and certain imaging services; (6) radiation therapy services and supplies; (7) durable medical equipment and supplies; (8) parenteral and enteral nutrients, equipment, and supplies; (9) prosthetics, orthotics, and prosthetic devices and supplies; (10) home

71. *Id.* § 1395nn(g)(4).

72. Sutton, *supra* note 22, at 33.

73. 31 U.S.C. § 3729(a)(1)(A) (2012).

74. *Id.* § 3729(a).

75. See Press Release, Office of Pub. Affairs, *supra* note 4. Qui tam relator suits have been the driving force behind FCA enforcement. *Id.* The number of qui tams has increased since 2009, especially for violations of Stark Law, with the DOJ collecting over seventeen billion dollars, comprising nearly half of the total FCA civil penalties paid out since the FCA was amended in 1986. See *id.*

76. See *infra* notes 78-89 and accompanying text.

77. 42 C.F.R. § 411.351 (2009).

78. *Id.*

health services; (11) outpatient prescription drugs; and (12) inpatient and outpatient hospital services.⁷⁹

Additionally, under Stark Law a financial relationship exists between the physician and the entity if (1) there is an ownership interest; (2) an investment interest; or (3) a compensation arrangement between the physician (or an immediate family member) and the entity.⁸⁰ Further, the regulations state that a financial relationship, with respect to ownership, investment, or a compensation arrangement may be either direct or indirect.⁸¹ A financial relationship is direct if "remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities between the entity furnishing DHS and the referring physician (or a member of his or her immediate family)."⁸² A physician is said to have a direct compensation arrangement with an entity if the only intervening entity is his or her physician organization.⁸³

Indirect financial relationships are intricate, especially indirect compensation agreements.⁸⁴ Under the regulations, an indirect ownership or investment interest exists if there is an unbroken chain of owners between the physician and the entity furnishing DHS, and the entity has actual knowledge (or acts in reckless disregard or deliberate ignorance) of the fact that the referring physician has some ownership or investment interest in the furnishing entity.⁸⁵ For an indirect compensation arrangement, three conditions must be satisfied: (1) there must be an unbroken chain of persons or entities that have a financial relationship between the referring physician and the entity furnishing DHS;⁸⁶ (2) the referring physician receives aggregate compensation "that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the DHS entity";⁸⁷ and (3) the DHS entity must have actual knowledge (or act in reckless disregard or in deliberate ignorance) of the fact that the

79. *Id.*

80. 42 U.S.C. § 1395nn(a)(2) (2012).

81. 42 C.F.R. § 411.354(a)(1)(i) (2011).

82. *Id.* § 411.354(a)(2)(i).

83. Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships, 72 Fed. Reg. 51,012, 51,028 (Sept. 5, 2007) (to be codified at 42 C.F.R. pts. 411 and 424).

84. Sutton, *supra* note 22, at 28.

85. 42 C.F.R. § 411.354(b)(5)(i)(A)–(B).

86. *Id.* § 411.354(c)(2)(i).

87. *Id.* § 411.354(c)(2)(ii) (specifying that the physician's compensation correlates to the amount of business he or she refers to the DHS entity).

physician's aggregate compensation varies based on the volume or value of referrals.⁸⁸

C. "Stark" Exceptions

The various exceptions under Stark Law are divided into three broad categories: "(1) all-purpose exceptions, which apply to both ownership and compensation arrangements; (2) ownership and investment exceptions; and (3) direct and indirect compensation arrangement exceptions."⁸⁹ The regulations that govern the exceptions require considerable time and energy to analyze issues, such as, whether physicians in a group practice spend the necessary number of hours with patients per week providing non-DHS services;⁹⁰ whether the volume of space rented or leased surpasses the sum "reasonable and necessary" to qualify as a legitimate business purpose;⁹¹ and, lastly, whether any amount of remuneration⁹² exceeds "fair market value."⁹³

As the statute provides, "[t]he general exceptions include: physician services where referrals are between members of the same group practice;⁹⁴ certain secondary services performed within the same office of a group practice;⁹⁵ and certain prepaid health plans, such as [health maintenance organizations]."⁹⁶ Additionally, for physician groups, the "in-office ancillary services exception" is the most widely used Stark Law exception and also one of the most wide-ranging exceptions available.⁹⁷ To qualify for this exception, the physician must belong to an eligible "group practice"⁹⁸ and meet requirements concerning the supervision of the physician administering services,⁹⁹ the physical location of the building housing the practice as well as its characteristics,¹⁰⁰ and how the practice bills.¹⁰¹ If these regulatory requirements are met, physicians are allowed to provide certain DHS in

88. *Id.* § 411.354(c)(2)(iii).

89. Sutton, *supra* note 22, at 30.

90. See 42 C.F.R. § 411.355(b)(2)(A)(2) (2009); Sutton, *supra* note 22, at 30.

91. 42 C.F.R. § 411.357(a)(3); see Sutton, *supra* note 22, at 30.

92. See 42 C.F.R. § 411.351; Sutton, *supra* note 22, at 30.

93. Sutton, *supra* note 22, at 30; see 42 C.F.R. § 411.357(c)(2)(i).

94. 42 U.S.C. § 1395nn(b)(1) (2012).

95. *Id.* § 1395nn(b)(2).

96. Sutton, *supra* note 22, at 30; see § 1395nn(b)(3).

97. Sutton, *supra* note 22, at 30.

98. 42 C.F.R. § 411.352 (2009); see Sutton, *supra* note 22, at 30.

99. See 42 C.F.R. § 411.355(b)(1) (dealing with the physicians referring a patient to another physician through a referral); Sutton, *supra* note 22, at 30.

100. 42 C.F.R. § 411.355(b)(2); Sutton, *supra* note 22, at 30.

101. 42 C.F.R. § 411.355(b)(3); Sutton, *supra* note 22, at 30.

the group's office without initiating the Stark Law prohibition on self-referral.¹⁰²

Other categories of exceptions pertain to ownership or investment interests including those interests in publicly traded securities or mutual funds.¹⁰³ Also, exceptions correspond to ownership and investment interests in DHS furnished in rural areas.¹⁰⁴ Another exception pertains specifically to health care facilities located in Puerto Rico.¹⁰⁵ And lastly, an exception relates to ownership and investment interests in hospitals meeting certain requirements.¹⁰⁶

Finally, there are exceptions for other types of direct and indirect compensation arrangements, including rental of office space and equipment,¹⁰⁷ bona fide employment relationships,¹⁰⁸ personal services arrangements (used when physicians are independent contractors rather than employees),¹⁰⁹ remuneration unrelated to the provision of DHS,¹¹⁰ physician recruitment,¹¹¹ isolated transactions (for example, the one-time sale of a practice),¹¹² group practice arrangements,¹¹³ and payments by physicians for certain items and services.¹¹⁴

The many exceptions listed above collectively serve as a major point of contention in the debate over Stark Law's effectiveness, with some critics arguing that the exceptions limit the prohibition's efficacy and provide too many loopholes, which providers can use to avoid Stark Law by entering into indirect arrangements.¹¹⁵ Alternatively, it has been argued that the exceptions make the law too complex to comprehend.¹¹⁶ Furthermore, the ACA significantly limits the ability of physicians to invest in hospital facilities by prohibiting hospitals from increasing the total percentage of the total value of ownership interests held in a

102. Sutton, *supra* note 22, at 30-31; *see* 42 C.F.R. § 411.355(b).

103. 42 U.S.C. § 1395nn(c) (2012).

104. *Id.* § 1395nn(d)(2).

105. *Id.* § 1395nn(d)(1).

106. *Id.* § 1395nn(d)(3); Sutton, *supra* note 22, at 31.

107. 42 U.S.C. § 1395nn(e)(1).

108. *Id.* § 1395nn(e)(2).

109. *Id.* § 1395nn(e)(3); *see* Sutton, *supra* note 22, at 31.

110. 42 U.S.C. § 1395nn(e)(4).

111. *Id.* § 1395nn(e)(5).

112. *Id.* § 1395nn(e)(6); *see* Sutton, *supra* note 22, at 31.

113. 42 U.S.C. § 1395nn(e)(7).

114. *Id.* § 1395nn(e)(8).

115. *See, e.g.,* Anne W. Morrison, *An Analysis of Anti-Kickback and Self-Referral Law in Modern Healthcare*, 21 J. LEGAL MED. 351, 378 (2000); Sutton, *supra* note 22, at 31.

116. *See* Morrison, *supra* note 115; Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 LAW & PSYCHOL. REV. 1, 22-23 (2003).

hospital by physicians, as well as subjecting physician owners to a multitude of new requirements.¹¹⁷

D. Enactment of the Self-Referral Disclosure Protocol: Giving Stark Its Own Disclosure Protocol

In 2010, through former President Barack Obama's promotion, the United States enacted the ACA in an effort to ensure that all Americans have secure access to health care coverage.¹¹⁸ As part of the ACA, Congress directed the Secretary of the U.S. Department of Health and Human Services ("HHS") to develop and implement a disclosure process for Stark Law violations.¹¹⁹ Prior to this, all Stark Law violations were disclosed through the OIG's SDP. As a result, the HHS and the CMS created the SRDP to foster the resolution of potential or actual violations of Stark.¹²⁰ This Part gives an in depth look at disclosures prior to SRDP, its enactment, and the important developments in its brief existence.¹²¹

1. Disclosures Prior to the Self-Referral Disclosure Protocol

Prior to the enactment of the SDP and the SRDP, providers "had the option to make unsolicited or voluntary refunds to Medicare administrative contractors who process claims and issue payments on behalf of CMS."¹²² In general, these refunds came in the form of an adjusted bill or check.¹²³ Entities could also request an advisory opinion from CMS to resolve violations.¹²⁴ For CMS to consider an advisory opinion, the requester must be a party to the existing agreement; the requestor is the only individual or entity that may rely on that opinion.¹²⁵

117. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6001, 124 Stat. 685 (2010) (codified as amended at 42 U.S.C. § 1395nn (2012)).

118. See Cheryl Gay Stolberg & Robert Pear, *A Stroke of a Pen, Make That 20, and It's Official*, N.Y. TIMES, Mar. 24, 2010, at A19.

119. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6407, 124 Stat. 772 (2010) (codified at 42 U.S.C. § 1395nn).

120. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 23, at 1.

121. See *infra* Part II.D.1-2.

122. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 23, at 2.

123. *Id.*

124. See 42 C.F.R. § 411.370(a)-(b) (2010). This has seldom been done. See *Advisory Opinions*, CMS.GOV, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html (last visited Apr. 10, 2017). At the time of the ACA, CMS had only issued eight advisory opinions. *Id.*

125. 42 C.F.R. § 411.370(b)(1)-(2); see *Advisory Opinions*, *supra* note 124. Advisory opinions are now considered separately from the SRDP. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 23, at 4-5. Advisory opinions are not retrospective and are a means to inform entities if a violation may occur or is occurring; it is not a means of resolving an actual or potential Stark Law violation. *Id.* at 3.

Also, starting in 1998, entities could make disclosures through the OIG under its SDP.¹²⁶ Today, a Stark Law violation may still be disclosed through the SDP, but only if it is coupled with a violation of the Anti-Kickback Statute.¹²⁷ The SDP is available to all health care providers, whether individuals or entities.¹²⁸ It is intended to facilitate resolution of matters that, in the provider's reasonable assessment, potentially violate federal criminal, civil, or administrative laws.¹²⁹ In March 2009, the OIG issued an open letter limiting the "scope" of the SDP.¹³⁰ No longer would the OIG accept disclosure of matters that only involved Stark Law liability.¹³¹

A third path for disclosing a Stark Law violation is through the DOJ or U.S. Attorney's Office.¹³² The DOJ has the authority to resolve improper disbursements under common law theories of payment by mistake or unjust enrichment¹³³ and the authority to dismiss providers from any civil or administrative claim under the FCA.¹³⁴

2. The Self-Referral Disclosure Protocol

On March 23, 2010, Congress required CMS to add a disclosure protocol for Stark Law violations as part of the ACA.¹³⁵ CMS enacted the SRDP in September of that same year.¹³⁶ Additionally, the Secretary of HHS was given the discretion to reduce the amount due for all Stark

126. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 23, at 3. This protocol was enacted in 1998 by the OIG of the HHS to establish a process for providers to voluntarily identify, disclose, and resolve instances of potential fraud involving federal health care programs (defined by section 1128B(f) of the Social Security Act). As of April 2013, the OIG has received over 800 self-disclosures and recovered over \$280 million for federal health care programs. U.S. DEP'T OF HEALTH & HUMAN SERVS., UPDATED OIG'S PROVIDER SELF-DISCLOSURE PROTOCOL 1 (Apr. 17, 2013), <http://oig.hhs.gov/compliance/self-disclosure-info/files/provider-self-disclosure-Protocol.pdf>.

127. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 23, at 3. This most commonly occurs when a health care provider is in violation of both Stark Law and the Anti-Kickback Statute. *Id.*

128. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 126, at 3 ("The SDP is not limited to any particular industry, medical specialty, or type of service.").

129. Publication of the OIG's Provider Self-Disclosure Protocol, 63 Fed Reg. 58,399, 58,400 (Oct. 23, 1998).

130. See Daniel R. Levinson, *An Open Letter to Health Care Providers*, U.S. DEP'T HEALTH & HUM. SERVICES (Mar. 24, 2009), <http://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf>.

131. *Id.*

132. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 23, at 4.

133. *Id.*

134. *Id.*

135. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6407, 124 Stat. 772 (2010) (codified at 42 U.S.C. § 1395nn (2012)). Congress gave CMS six months to enact a disclosure protocol. *Id.*

136. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 126, at 4. The SRDP was placed on the CMS website. *Id.*

Law violations, based on an assessment of the conduct disclosed through the SRDP.¹³⁷

In evaluating a disclosure under the SRDP, CMS *may* take into account (1) the nature and degree of the improper or illegal practice;¹³⁸ (2) the timeliness of the self-disclosure;¹³⁹ (3) the cooperation in providing additional information associated with the disclosure;¹⁴⁰ and (4) any “other factors as the Secretary considers appropriate.”¹⁴¹ The ACA also established a deadline for reporting and returning overpayments if one is received by a health care entity.¹⁴²

A party utilizing the SRDP must submit its disclosure both electronically and in hard copy.¹⁴³ Once the disclosure is received, CMS sends an automated e-mail response acknowledging the disclosure.¹⁴⁴ The significance of the acknowledgement e-mail is that it temporarily suspends the disclosing party’s obligation under the ACA to return any overpayments.¹⁴⁵ In order to establish a full disclosure, the party must submit the following information to CMS:

- (1) identifying information of disclosing party;
- (2) a description of the nature of the matter being disclosed;
- (3) duration of violation (look back period);
- (4) circumstances under which the matter was discovered and measures taken to address the issue and prevent future abuses;
- (5) a statement identifying a history of similar conduct or enforcement action;
- (6) a description of any compliance program;
- (7) if applicable, a description of appropriate notices provided to other government agencies; and
- (8) whether the matter is under current inquiry by the government.¹⁴⁶

In addition, the SRDP requires a party to submit a legal analysis of how the disclosed matter violated Stark Law, by identifying which elements

137. *Id.*

138. *Id.*

139. *Id.*

140. *Id.*

141. *Id.*

142. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1128J, 124 Stat. 753 (2010) (codified as amended at 42 U.S.C. § 1320a-7k (2012)). Entities now have sixty days to return overpayments, thus placing an impetus on the disclosing party to quickly submit a claim to the SRDP. *Id.* Entities are now forced to turn around reports within two months, and this is a main factor contributing to incomplete SRDP disclosures. See Peter J. Eggers, Comment, *Disclosure for Closure? Why the Self-Referral Disclosure Protocol Process Paired with the 60-Day Overpayment Rule Creates More Headaches Than Solutions*, 8 ST. LOUIS U. J. HEALTH L. & POL’Y 189, 206 (“The 60-day-rule applies pressure to the provider to disclose before ready.”).

143. U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 23, at 5.

144. *Id.*

145. *Id.*

146. *Id.*

of any applicable exceptions were and were not satisfied under the arrangement.¹⁴⁷ Disclosing entities must also provide an in depth financial analysis of the potential amount owed, a description of the methodology used to determine that amount, the potential amount that physician(s) received as a result of the actual or potential Stark violation and the audit activity and documentation used.¹⁴⁸

III. WHAT IS WRONG WITH THE SELF-REFERRAL DISCLOSURE PROTOCOL

The SRDP has been criticized by many for its slow pace of resolving disclosures and CMS's lack of clear guidelines for the disclosure process as a whole.¹⁴⁹ Health care entities lack anything that would resemble a clear set of guidelines on either of these issues.¹⁵⁰ Subpart A discusses how the SRDP has failed to settle disclosures in a timely fashion as compared to its counterpart at the OIG.¹⁵¹ Next, Subpart B addresses the lack of a separate disclosure method for substantive versus technical violations.¹⁵² Finally, Subpart C focuses on the lack of guidelines for disclosing parties.¹⁵³

A. *The Self-Referral Disclosure Protocol Moves at a Sloth-Like Pace*

A requirement of creating the SRDP was the generation of a report by CMS.¹⁵⁴ In 2010, CMS, in cooperation with HHS, issued a report of the effectiveness of the SRDP's implementation.¹⁵⁵ The data was

147. *Id.*

148. *Id.* at 6.

149. See Letter from Jim McDermott, Congressman, U.S. House of Representatives, to Marilyn Tavenner, Adm'r, Ctrs. for Medicare & Medicaid Servs., *supra* note 25. In 2013, Congressman Jim McDermott, ranking member of the Ways and Means Subcommittee on Health and one of the drafters of the SRDP, sent a letter to Marilyn Tavenner, then-Administrator of CMS, voicing his displeasure with the slow pace of the SRDP process. *Id.* In his letter, he posits five suggestions for improving the SRDP process: (1) revising the protocol to include guidance on time parameters to give disclosing entities some level of certainty; (2) modifying the internal deliberative process on how monetary penalties are calculated; (3) making the internal deliberative process public much like the OIG's SDP (referring to the advisory opinion issued by the OIG in 2012); (4) transferring cases that do not fit within the SRDP out to the DOJ and OIG when there are FCA or Anti-Kickback violations involved; and (5) punishing entities that fail to provide all the information required by the SRDP (in effect sending non-compliant entities to the "back of the line"). *Id.*

150. See *infra* Part III.A–C.

151. See *infra* Part III.A.

152. See *infra* Part III.B.

153. See *infra* Part III.C.

154. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 6409, 124 Stat. 772 (2010) (codified at 42 U.S.C. § 1395nn (2012)).

155. See U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 23, at i.

collected from September 23, 2010, through March 9, 2012.¹⁵⁶ The data revealed that the 151 submissions submitted to CMS through the SRDP, encompassed many different categories of violations, and that CMS settled only six of the disclosures.¹⁵⁷ CMS blamed the low number of settlements on a myriad of reasons.¹⁵⁸

B. Lack of a Separate Disclosure for Technical Versus Substantive Stark Law Violations

Stark Law violations fall under one of two categories—either a technical or a substantive violation.¹⁵⁹ A technical violation is one where the physician and the entity have a contract lacking a signature or have an otherwise compliant contract that has lapsed.¹⁶⁰ These violations render an otherwise Stark Law compliant contract between a physician and a health care entity in violation of the Act, “result[ing] in ruinous liability.”¹⁶¹ In today’s health care environment, entities maintain hundreds of contracts, and large health care systems can have thousands, “making it easy to overlook missing signatures and lapsed expirations.”¹⁶² These technical violations can rapidly turn into “million-dollar headaches.”¹⁶³

156. *Id.* at 8. The data collected shows that during this time 148 various health care entities (comprised of 125 hospitals, 11 clinical laboratories, 8 physician group practices, 2 community mental health centers, 1 ambulance services company, and 2 durable medical equipment suppliers) submitted 150 different claims (two entities submitted multiple claims). *Id.* at 7-8. Of those 150 submissions CMS had received, only six had been settled at the time of the report. *Id.* at 8, n.19. Of the 144 outstanding disclosures, 20 had been placed on administrative hold (for reasons including, pending bankruptcy proceedings and ongoing law enforcement activities), 61 were awaiting requested additional information, 3 had been referred to law enforcement for resolution, 51 were still under CMS review, and 9 were withdrawn by the disclosing party after consultation with CMS. *Id.* at 10.

157. *See id.* at 11. The majority of disclosed violations involved failure to comply with various Stark Law exceptions including: the personal service arrangements exception (42 C.F.R. § 411.357(d) (2009)); the nonmonetary compensation exception (42 C.F.R. § 411.357(k)); the rental office space exception (42 C.F.R. § 411.357(a)); and the physician recruitment arrangements exception (42 C.F.R. § 411.357(e)). *Id.*

158. *See id.* at 12. Some of those reasons include, the wide variation in the complexity and number of violations disclosed takes significant time to understand. *Id.* Also, missing documents and inadequate legal analysis of claims significantly slows down the agency. *Id.*

159. Jean Wright Veilleux, *Catching Flies with Vinegar: A Critique of the Centers for Medicare and Medicaid Self-Disclosure Program*, 22 HEALTH MATRIX 169, 186-87 (2012).

160. *See* Joe Carlson, *Curing Technical Violations: Stark Law Exception Would Let Hospitals Disclose, Resolve Paperwork Infractions*, MOD. HEALTHCARE (June 22, 2013), <http://www.modernhealthcare.com/article/20130622/MAGAZINE/306229970> (stating that other forms of technical violations exist, but these two are the predominant examples of a technical Stark Law violation considering the hundreds of contracts maintained by hospitals).

161. PUB. INTEREST COMM., AM. HEALTH LAWYERS ASS’N, *supra* note 6, at 6.

162. Carlson, *supra* note 160.

163. *Id.*

In 2007, CMS proposed regulations to remedy failure of Stark Law to differentiate between substantive and technical violations.¹⁶⁴ The proposed regulation would provide a new means for satisfying a Stark Law exception in the following circumstances:

(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 noncompliance 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).¹⁶⁵

This alternative was not to be used where there existed a question of whether the compensation was of fair market value, related to the volume or value of referrals, or set in advance.¹⁶⁶ Rather, it would only be reserved for technical issues resulting from missing signatures or expired, compliant contracts still being utilized by the parties.¹⁶⁷

Most commenters were in favor of the rule, applauding CMS's goal of technical violations, while others were skeptical of this approach.¹⁶⁸ The final rule eliminated most of the eight criteria and only pertains to circumstances in which the providers comply with all Stark Law obligations other than the signature requirement, and only for a very short period of time.¹⁶⁹ The narrow, final rule made the exception

164. See 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, 38,184-85 (proposed July 12, 2007).

165. *Id.*

166. *Id.*

167. *Id.*

168. Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 48,434, 48,707 (Aug. 19, 2008) (codified at 42 C.F.R. § 411.353(g) (2009)).

169. *Id.*

irrelevant for most entities.¹⁷⁰ With no exception for missing signatures and lapse contracts that are unnoticed for years, health care providers can “potentially rack up huge [Stark Law] and FCA penalties.”¹⁷¹

In 2015, CMS only settled forty-nine self-disclosures through the SRDP¹⁷² and had a backlog of over 400 disclosures, some of which had been waiting over four years for resolution.¹⁷³ In February of 2015, Congressman Charles W. Boustany, along with eight co-sponsors, introduced a bill entitled the Stark Administrative Simplification Act of 2015 (“SASA”).¹⁷⁴ The proposed legislation calls for the implementation of a separate disclosure protocol for technical violations under Stark Law.¹⁷⁵ It would also include a cap on the civil monetary penalty for self-disclosed “technical” Stark Law violations.¹⁷⁶

Furthermore, SASA would speed up the disclosure process for technical violations through the SRDP because under SASA, if an entity discloses a technical Stark Law violation, CMS then has ninety days to determine if the disclosure is appropriate.¹⁷⁷ If CMS does not reject the disclosure within ninety days, it is deemed accepted.¹⁷⁸ This would make one track for technical violations and another for substantive claims.¹⁷⁹

This two-track process would be similar to the one that was recommended by the American Hospital Association (“AHA”) in 2010 when CMS was implementing the SRDP.¹⁸⁰ Under the model proposed by the AHA, disclosures would fall into one of two categories: (1) expedited review for technical violations and (2) a detailed review

170. Veilleux, *supra* note 159, at 190.

171. *Id.*

172. *Self-Referral Disclosure Protocol Settlements*, CMS.GOV, <https://www.cms.gov/medicare/fraud-and-abuse/physiciansselfreferral/self-referral-Disclosure-protocol-settlements.html> (last visited Apr. 10, 2017).

173. Letter from Charles W. Boustany, Jr. & Ron Kind, Congressmen, U.S. House of Representatives, to Andy Slavitt, Adm’r, Ctrs. for Medicare & Medicaid Servs. (Sept. 21, 2015), <http://strategiehealthcare.net/wp-content/uploads/2015/09/092515-Self-Referral-Letter-Reps.-Boustany-Kind-.pdf>.

174. Stark Administrative Simplification Act of 2015, H.R. 776, 114th Cong. § 2 (2015).

175. *Id.*

176. *See id.* (stating that where the violation is disclosed within one year of noncompliance the fine will not exceed \$5000 and where the disclosure is after one year the fine will not exceed \$10,000).

177. *See id.* (stating that CMS may reject any voluntary disclosure within ninety days if it determines that the disclosure does not conform to the requirements described in the SASA).

178. *Id.*

179. Letter from Charles W. Boustany, Jr. & Ron Kind, Congressmen, U.S. House of Representatives, to Andy Slavitt, Adm’r, Ctrs. for Medicare & Medicaid Servs., *supra* note 173.

180. Letter from Rick Pollack, Exec. Vice President, Am. Hosp. Ass’n, to Kathleen Sebelius, Sec’y, U.S. Dep’t of Health & Human Servs. (July 16, 2010), <http://www.aha.org/advocacy-issues/letter/2010/100716-cl-ppaca.pdf>.

for an actual or potential violation.¹⁸¹ CMS ultimately did not adopt the AHA’s two-track proposal—most likely because it had previously rejected a proposal that would afford parties who inadvertently failed to conform to a procedural requirement the opportunity to “self-correct.”¹⁸²

*C. Lack of Centers for Medicare and Medicaid Services
Penalty Guidelines*

Since its inception, CMS has done little to publicize how it will settle disclosures made through the SRDP.¹⁸³ Further, the disclosure statements listed on the CMS website give no indication of how the agency reached its settlement or the area of the statute that the disclosing party has violated.¹⁸⁴ In fact the disclosures have gotten shorter over the past two years, looking like form letters, where CMS simply fills in the state where the offense occurred, the type of entity disclosing, and the dollar amount of the final settlement.¹⁸⁵

A January 2015 settlement appeared as follows:

<i>Date</i>	2015-01-07
<i>Description</i>	CMS settled a violation of the physician self-referral law disclosed under the SRDP by a hospital (the Hospital) located in Minnesota.

On December 22, 2014, CMS settled a violation of the physician self-referral law disclosed under the SRDP by a hospital (the Hospital)

181. *See id.* The expedited process would involve circumstances that can be resolved without significant additional evidence, while the detailed review would require a more involved description or analysis. *Id.* Further, the detailed review would be reserved for more complex matters that need a detailed review by CMS. *Id.* 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 detailed review. *Id.* A two-track process would serve both the interests of CMS and of providers, allowing resources to be allocated efficiently. *Id.*

182. Veilleux, *supra* note 159, at 219. In 2008, CMS stated the statute allows a party lacking a signature, who acts in good faith, to obtain a signature within ninety days and, therefore, is reluctant to provide an alternative means for curing what could be considered technical violations. Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 48,434, 48,707 (Aug. 19, 2008) (codified at 42 C.F.R. § 411.353(g) (2009)).

183. Veilleux, *supra* note 159, at 223. CMS has not publicly disclosed guidelines on its website or issued any open letters similar to the OIG’s procedures. *Id.*

184. *See Self-Referral Disclosure Protocol Settlements*, *supra* note 172. Settlements are listed in the aggregate amount for the very reason that actual or potential violations of the SRDP are often confidential information. *Id.*

185. *See, e.g., Details for Title: 2015-01-07*, CMS.GOV (Jan. 7, 2015), <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements-Items/2015-01-07-mn.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending>; *Details for Title: 2013-06-05*, CMS.GOV (June 6, 2013), <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements-Items/2013-06-05-Settlement.html?DLPage=5&DLEntries=10&DLSort=0&DLSortDir=descending>.

located in Minnesota. The hospital disclosed that it may have violated the physician self-referral law, because arrangements with certain physicians failed to satisfy the requirements of an applicable exception.

The disclosed violation was settled for \$231,981.¹⁸⁶

This disclosure provides little help to a facility considering whether to utilize the SRDP.¹⁸⁷ In at least the first two-and-a-half years, CMS provided the exception that the entity had violated.¹⁸⁸ Ironically, this came at the time when Congressman Jim McDermott was calling for CMS to publicly release information related to its internal deliberative process.¹⁸⁹ Oddly, at this same time, CMS decided to shorten its settlement statements to exclude the exception the entity violated.¹⁹⁰

Another problem faced by a potentially disclosing entity is CMS's refusal to publicly release any information about how it intends to resolve disclosures.¹⁹¹ In 2013, the OIG released an updated version of the SDP.¹⁹² At the time of the release, the OIG had already resolved over 800 disclosures through the SDP.¹⁹³ The OIG saw the

186. *Details for Title: 2015-01-07*, *supra* note 185.

187. *See supra* notes 185-86 and accompanying text.

188. *See Details for Title: 2011-02-10*, CMS.GOV (Feb. 10, 2011) <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements-Items/CMS1249488.html?DLPage=7&DLEntries=10&DLSort=0&DLSortDir=descending>. At the time of its initial disclosure in February 2011, until August 2013, CMS provided the actual exception that the disclosing entity failed to satisfy. *See id.* ("The Hospital disclosed under the SRDP that it violated the physician self-referral statute by (1) failing to satisfy the requirements of the personal services arrangements exception for arrangements with certain hospital department chiefs and the medical staff for leadership services, and (2) failing to satisfy the requirements of the personal services arrangements exception for arrangements with certain physician groups for on-site overnight coverage for patients at the Hospital.").

189. Letter from Jim McDermott, Congressman, U.S. House of Representatives, to Marilyn Tavenner, Adm'r, Ctrs. for Medicare & Medicaid Servs., *supra* note 25. Congressman McDermott said that this would be "akin" to the steps taken by the OIG to alter its own disclosure protocol. *Id.* The OIG amended its SDP to include penalty and time frame guidelines to disclosing entities for violations of the Anti-Kickback Statute. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 126, at 2-3, 14.

190. *See Details for Title: 2013-06-05*, *supra* note 185 (marking the first time CMS did not disclose the requirements of the exception the disclosing entity failed to satisfy).

191. *See Veilleux*, *supra* note 159, at 223.

192. *See* U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 126. The revised protocol arose from the OIG's notice for comments in June 2012. Solicitation of Information and Recommendations for Revising OIG's Provider Self-Disclosure Protocol, 77 Fed. Reg. 36,281, 36,281 (June 18, 2012).

193. Solicitation of Information and Recommendations for Revising OIG's Provider Self-Disclosure Protocol, 77 Fed. Reg. at 36,281. This represented the number of disclosures by the SDP from October 1998 through the updated SDP release in April 2013 (an average of fifty-three resolutions per year). U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 126, at 1.

opportunity to provide simple, yet straightforward guidelines for entities considering disclosure.¹⁹⁴

As part of the updated SDP, the OIG listed a number of guidelines it had used and would use going forward for potential violations of the Anti-Kickback Statute.¹⁹⁵ Generally, the OIG stated it will apply a 1.5 damages multiplier to disclosing parties.¹⁹⁶ Also, the OIG has given entities a clear picture of what it will require of a disclosing entity.¹⁹⁷ Further, a disclosing party must state what section of the Anti-Kickback Statute it has violated.¹⁹⁸ Also, a disclosing entity utilizing the SDP must certify that its internal investigation is complete within ninety days of its submission.¹⁹⁹ Further, the OIG will advocate to the DOJ on behalf of a disclosing party.²⁰⁰ Finally, the OIG has set a minimum monetary penalty for a disclosing party.²⁰¹

IV. CHANGES TO THE SELF-REFERRAL DISCLOSURE PROTOCOL TO PROMOTE MORE DISCLOSURES, SPEED-UP THE PROCESS, AND AVOID THE MADNESS

There are currently many disincentives to disclosing under the SRDP.²⁰² A health care entity may choose to "roll the dice" and risk discovery through investigation, prosecution, or a qui tam suit.²⁰³

194. See U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 126, at 1.

195. See *id.* at 3-15 ("This section explains the eligibility criteria for the SDP, including who may use the SDP and what conduct is and is not eligible for acceptance into the SDP.").

196. *Id.* at 2. The OIG states that settlement matters will require a minimum multiplier of 1.5 times the single damages (based on what is actually paid to the entity and not what is actually billed), although, they may determine whether a higher multiplier is warranted. *Id.*

197. Laurence Freedman, *10 Things to Know About OIG's Self-Disclosure Protocol*, LAW360 (May 2, 2013, 12:23 PM), <http://www.law360.com/articles/437385/10-things-to-know-about-oig-s-self-disclosure-protocol>.

198. See U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 126, at 3-4.

199. Freedman, *supra* note 197. A disclosing entity may ask for an extension if a matter is overly complex or for other reasonable circumstances. *Id.*

200. See *id.* ("[T]he OIG states that in coordinating with the DOJ in both civil and criminal matters, it will 'advocate' that disclosing parties should receive a benefit from disclosing under the SDP.").

201. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 126, at 14. Also, the updated SDP provides that for all other matters the minimum settlement amount will be \$10,000. See Freedman, *supra* note 197.

202. See *supra* Part.III.A-C.

203. Veilleux, *supra* note 159, at 201. Reasons for avoidance include as 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 [technical] 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

Changes can be made to speed up the SRDP process to eliminate many of the over 400 disclosures awaiting resolution, as well as create an incentive for entities to come forward when the Stark Law violation is merely technical.²⁰⁴ The SRDP process and backlog can be greatly reduced by creating separate channels for technical and substantive violations of Stark Law.²⁰⁵ One way to encourage disclosure is to establish clear guidelines for disclosing entities utilizing the SRDP.²⁰⁶ Further, CMS must improve its reporting of disclosures, via the SRDP, on its website.²⁰⁷

A. *No More Long Lines (Faster)*

The OIG has maintained a commitment to keeping the time of claim settlement to less than one year.²⁰⁸ Currently, there are many SRDP disclosures that have been in various stages of the process for over four years.²⁰⁹ Additionally, legislation has been proposed that would eliminate some of the lesser “technical violations.”²¹⁰ CMS must commit to streamlining its process in order to settle claims, so that disclosing entities are not held in a virtual limbo.²¹¹

When the OIG revamped its disclosure process in 2013, it made a commitment to settling claims in under twelve months.²¹² This sped-up process has a two-fold benefit: (1) the entity has the benefit of resolution, of knowing what its punishment for violating Stark Law will entail,²¹³ and (2) the government gets its remuneration faster—alleviating the backlog of unsettled disclosures that the CMS currently has.²¹⁴ In its updated SDP, the OIG has stated that “[a]s part of this commitment, we streamlined our internal process to reduce the average time a case is pending with OIG to less than 12 months from acceptance

statement about past conduct, (9) the lack of appeal rights, and (10) implications for the provider’s compliance plan.

Id. at 201-02.

204. *See infra* Part IV.A–B.

205. *See infra* Part IV.B.

206. *See infra* Part IV.C.

207. *See infra* Part IV.C.2.

208. U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 126, at 3.

209. Letter from Charles W. Boustany, Jr. & Ron Kind, Congressmen, U.S. House of Representatives, to Andy Slavitt, Adm’r, Ctrs. for Medicare & Medicaid Servs., *supra* note 173.

210. *See supra* notes 175-79 and accompanying text.

211. *See supra* notes 172-73 and accompanying text.

212. U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 126, at 3.

213. *See* Letter from Charles W. Boustany, Jr. & Ron Kind, Congressmen, U.S. House of Representatives, to Andy Slavitt, Adm’r, Ctrs. for Medicare & Medicaid Servs., *supra* note 173.

214. *Id.*

into the SDP.”²¹⁵ Further, the OIG has stated that it has sped up its process for submission of its own internal findings, from ninety days from the date of concluding its internal investigation, to ninety days from the date of submission.²¹⁶ By adopting a faster internal process similar to that of the OIG, CMS can effectuate faster outcomes giving resolution to health care entities and also can collect fines and overpayments on a timelier schedule.²¹⁷

B. Self-Referral Disclosure Protocol Two-Step: Creating Separate Modes of Disclosure for Technical and Substantive Violations (Stronger)

In his 2010 letter, Rick Pollack of the AHA asked CMS to create a two-track process for disclosing parties utilizing the SRDP.²¹⁸ Track one would entail an “expedited review” and be reserved for admissions not necessitating further disclosure of material facts.²¹⁹ The second track would service disclosures resulting from an actual or potential violation of Stark and require a “detailed review.”²²⁰ A separate track for deeper review into a possible substantive review would enable CMS to deal with entities that have violated the spirit of what Stark aims at combatting—physician referrals that are generated from volume based compensation and non-compliant ownership interests in referring entities.²²¹ The CMS refrained from separating technical and substantive violations, instead opting to keep all claims on a one-track system, which has greatly resulted in the stagnation of claims that exists today.²²²

By creating a separate disclosure method for technical violations CMS could decrease the amount of time claims spend waiting for resolution.²²³ In September 2015, Congressmen Charles Boustany and Ron Kind introduced legislation to the SASA committee.²²⁴ This legislation proposes to have a set deadline of ninety days and to have a

215. U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 126, at 3.

216. *Id.*

217. *See supra* notes 208-16 and accompanying text.

218. Letter from Rick Pollack, Exec. Vice President, Am. Hosp. Ass’n, to Kathleen Sebelius, Sec’y, U.S. Dep’t of Health & Human Servs., *supra* note 180.

219. *Id.* Here, entities could easily prove that they have committed a technical violation and that there is no need for further review. *Id.*

220. *Id.* at 3.

221. *See id.*

222. *See supra* notes 173-77 and accompanying text.

223. *See* Letter from Rick Pollack, Exec. Vice President, Am. Hosp. Ass’n, to Kathleen Sebelius, Sec’y, U.S. Dep’t of Health & Human Servs., *supra* note 180.

224. Stark Administrative Simplification Act of 2015, H.R. 776, 114th Cong. § 2 (2015).

fixed penalty for technical violations of Stark Law.²²⁵ Once an entity has disclosed a technical violation, CMS would then have ninety days to determine if the violation is in fact a technical violation, and if CMS fails to respond within the ninety-day window, the disclosure would be deemed accepted.²²⁶ Accepted disclosures would be subject to a \$5000 penalty if the disclosure occurs within one year of the initial date of non-compliance and subject to a \$10,000 fine where the disclosure is after one year.²²⁷

C. Establishing Penalty Guidelines and Providing Better Information to Parties Disclosing via Self-Referral Disclosure Protocol (Clearer)

Unlike its counter-part in the OIG, CMS has declined to provide clear guidelines for how it arrives at its penalty determinations and for how it arrives at its settlements with entities utilizing the SRDP.²²⁸ Along with providing a timeline, the OIG has given disclosing entities insight into how it will arrive at the penalties for disclosing entities that violate the Anti-Kickback Statute.²²⁹ Further, CMS has failed to provide an adequate reporting of how it has arrived at the settlements it has made with disclosing entities to date on its website.²³⁰ Establishing a set of guidelines will give disclosing entities an awareness of how much utilizing the SRDP could stand to cost.²³¹ Additionally, improving the way CMS records settlements on its website will enable a disclosing entity to know how much it will be penalized, by seeing what penalties those entities that have already settled have paid.²³²

1. Providing Clear Penalty Guidelines

Penalties under the SDP have a baseline penalty multiplier of 1.5.²³³ The OIG has specifically stated that their “general practice . . . is to require a minimum multiplier of 1.5 times the single damages, although [they] determine in each individual case whether a higher multiplier may be warranted.”²³⁴ The OIG maintains that it may adjust this number based on the severity of the disclosure.²³⁵ However, this provides

225. *Id.*

226. *Id.*

227. *Id.*

228. *See supra* Part III.C.

229. *See supra* Part III.C.

230. *See Self-Referral Disclosure Protocol Settlements, supra* note 172.

231. *See infra* Part IV.C.1.

232. *See infra* Part IV.C.2.

233. U.S. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 126, at 2.

234. *Id.*

235. *Id.* at 2, 14 (“As a general practice . . . OIG applies this multiplier to the amount paid by

disclosing entities with some measure of certainty, knowing the penalties it may face when disclosing a violation of the Anti-Kickback Statute.²³⁶ In 2013, when the OIG released the updated SDP, it had already settled over 800 disclosures since its origination in 1998.²³⁷ CMS has the opportunity to learn from the data that the OIG has compiled in the seventeen plus years that it has been accepting disclosures (eleven of which they accepted Stark Law disclosures).²³⁸

2. Reformatting the Display of Settled Disclosures on the Centers for Medicare and Medicaid Services Website

CMS has settled a number of disclosures through the SRDP and all of them can be viewed on its website.²³⁹ Those that are displayed provide little information for an entity contemplating utilization of the SRDP.²⁴⁰ This information, along with the above-mentioned guidelines, would provide an entity considering the SRDP with even more information to determine what settlement it may hope to achieve through the process.²⁴¹

First, in adopting a two-track process, CMS should divide the listed disclosures into two categories; one for settled technical disclosures and one for settled substantive disclosures.²⁴² This would allow a disclosing entity to eliminate any disclosures not pertaining to substantive or actual Stark violations.²⁴³ Next, in addition to the existing chart, CMS should list the number of violations that the disclosing entity has divulged through the SRDP and the penalty amount settled upon by CMS and the party.²⁴⁴ By providing this information, subsequent disclosing entities can better determine how CMS arrived at the penalty through simple arithmetic. Hence, if there are similar circumstances between the already settled entity and the one considering the SRDP, the considering entity can better determine what penalties it may incur.²⁴⁵

Federal health care programs, not the amount claimed.”).

236. *See id.* at 2.

237. *Id.* at 1. These 800 disclosures represent over \$280 million recovered for federal health care programs. *Id.*

238. *See supra* Part II.D.1.

239. *Self-Referral Disclosure Protocol Settlements*, *supra* note 172.

240. *See supra* note 187 and accompanying text.

241. *See supra* Part IV.C.1.

242. *See supra* notes 219-23 and accompanying text.

243. *See* Letter from Rick Pollack, Exec. Vice President, Am. Hosp. Ass’n, to Kathleen Sebelius, Sec’y, U.S. Dep’t of Health & Human Servs., *supra* note 180.

244. *See Self-Referral Disclosure Protocol Settlements*, *supra* note 172.

245. *See id.* In providing these numbers, entities can formulate a game plan for how to proceed with a disclosure. *See id.* They can confer with counsel and also this could speed up the entities own deliberative process, thus effectuating more thorough and timely disclosures. *See id.*

Information that may be pertinent would include the type of Stark Law violation that the entity had violated.²⁴⁶ This should include if the violation was substantive or technical.²⁴⁷ Coupled with the above-mentioned two-track process, the entity could better find settlements on the CMS website that have Stark Law violations that are similar in scope.²⁴⁸

V. CONCLUSION

No health care entity should face a \$237 million fine.²⁴⁹ As the number of qui tam suits increases, health care entities are becoming more and more exposed to FCA suits as a result of having Stark noncompliant contracts with physicians.²⁵⁰ The government has taken strides to create the avenues to self-disclose Stark Law violations.²⁵¹ However, these steps have not done enough to alleviate an entities' exposure to harsh penalties.²⁵²

CMS needs to publish clear guidelines that give disclosing entities the information necessary to assess the SRDP process.²⁵³ Adopting guidelines similar to the OIG would give disclosing entities an idea of the penalties they may face ahead of making a disclosure.²⁵⁴ CMS also should streamline its process, like that of the OIG, to ensure that claims do not languish in the disclosure process for years.²⁵⁵ Further, CMS should adopt different procedures for disclosing parties based on whether there is a technical or a substantive violation in order to add expediency in claim processing and to better serve the spirit of why Stark was created in the first place.²⁵⁶

246. See Letter from Rick Pollack, Exec. Vice President, Am. Hosp. Ass'n, to Kathleen Sebelius, Sec'y, U.S. Dep't of Health & Human Servs., *supra* note 180.

247. *Id.*

248. *Id.*

249. See *supra* notes 7-8 and accompanying text.

250. See *supra* notes 4-5 and accompanying text.

251. See *supra* Part II.D.2.

252. See Letter from Charles W. Boustany, Jr. & Ron Kind, Congressmen, U.S. House of Representatives, to Andy Slavitt, Adm'r, Ctrs. for Medicare & Medicaid Servs., *supra* note 173 (“[W]e are concerned about the disproportionate nature of the penalties providers face when disclosing technical violations of [Stark Law] and the amount of time it takes for CMS to resolve a disclosure under the Self-Referral Disclosure Protocol.”).

253. See *supra* Part IV.

254. See *supra* Part IV.C.

255. See Letter from Jim McDermott, Congressman, U.S. House of Representatives, to Marilyn Tavenner, Adm'r, Ctrs. for Medicare & Medicaid Servs., *supra* note 25; see also Letter from Charles W. Boustany, Jr. & Ron Kind, Congressmen, U.S. House of Representatives, to Andy Slavitt, Adm'r, Ctrs. for Medicare & Medicaid Servs., *supra* note 173 (stating that, as of 2015, many disclosures had been awaiting resolution for over four years).

256. See *supra* Part IV.B.

The government has legislated to protect Medicare and shield it from people that would attempt to pillage the public coffers.²⁵⁷ However, in the new regime of public health care, it should also strive to ensure that there is a level playing field.²⁵⁸ Stark Law was created in an effort to protect Medicare and the public from abuse of physician referrals, but it was also seen as a means of self-policing by the industry as a whole.²⁵⁹ By implementing the above measures, CMS can avoid the madness—ensuring compliance and giving entities a better means of disclosing violations and providing future compliance industry-wide.²⁶⁰

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257. See *supra* note 19 and accompanying text.

258. See *supra* note 17 and accompanying text.

259. See *supra* notes 19-22 and accompanying text.

260. See *supra* Part IV.

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