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MACRA and Stark: Strange Bedfellows at the Heart of Health Care Reform

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MACRA AND STARK: STRANGE BEDFELLOWS AT THE HEART OF HEALTH CARE REFORM

REBECCA OLAVARRIA[†]

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*“... even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure...”*¹

Judge James A. Wynn

United States Court of Appeals for the Fourth Circuit

The United States health care industry is at a crossroads. Pressures from an aging baby boomer population, unsustainable increases in health care costs, and relatively poor patient care outcomes are interrupting the traditional ways patients are cared for and health care providers are paid.² Over the years, the federal government has grappled with how to manage its Medicare³ and Medicaid⁴ programs in light of these pressures. In 2011, the federal government expended a total of \$545 billion for Medicare⁵ and \$256 billion for Medicaid,⁶ totaling 5.4% of the nation's

1. United States ex rel. Drakeford v. Tuomey, 792 F.3d 364, 395 (4th Cir. 2015) (Wynn, J., concurring).

2. Technological advances and new market entrants are also considered disruptors in the health care industry. See Tony Herrling, *\$2.8 Trillion U.S. Health Care Market Threatened By Disruptive New Entrants Like Those That Reshaped Retail, Banking and Travel, According To PwC's Health Research Institute*, PRICEWATERHOUSE COOPERS (Apr. 2014), <http://www.pwc.com/us/en/press-releases/2014/health-care-market-threatened-by-disruptive-new-entrants.html>; Ellen Lee, *5 Ways Technology is Transforming Health Care*, FORBES (Jan. 2013), <http://www.forbes.com/sites/bmoharrisbank/2013/01/24/5-ways-technology-is-transforming-health-care/#130cc87c1e26>.

3. Medicare is a federal health insurance program instituted in 1965 for persons sixty-five and over. In 1972, it was expanded to cover persons under sixty-five who have permanent disabilities. It provides for hospital and skilled nursing facility stays as well as home health visits and hospice care, limited prescription drug coverage, physician visits, and outpatient services. See *Issue Brief: An Overview of Medicare*, KAISER FAMILY FOUND. (Apr. 1, 2016), <http://kff.org/medicare/issue-brief/an-overview-of-medicare/>.

4. Medicaid is a federal health insurance program instituted in 1965 by the same federal legislation that instituted Medicare. Medicaid provides health care coverage to low-income persons, pregnant women, and people with disabilities. Because it is a program funded by the federal government but administered by the States, the scope of services available varies from state to state so as to allow each State to tailor its Medicaid program to the needs of each individual state. See *CMS' Program History: Medicare and Medicaid*, CTRS. FOR MEDICARE AND MEDICAID SERVS., <https://www.cms.gov/About-CMS/Agency-Information/History/index.html?redirect=History/> (last visited Aug. 18, 2016).

5. *National Health Expenditures by Type of Service and Source of Funds: Calendar Years 1960-2014*, CTRS. FOR MEDICARE AND MEDICAID SERVS., <http://go.usa.gov/jmGY> (last visited Aug. 18, 2016).

6. *Id.* This figure includes federal expenditure on the Children's Health Insurance Program (CHIP), which was not in existence in 1970. CHIP provides health care services to the children of families who do not qualify for Medicaid but who, ordinarily, would otherwise remain uninsured. In some states, CHIP covers pregnant women, too. As with

gross domestic product.⁷ Most recently, in 2015, the federal government expended a total of \$634 billion for Medicare and \$350 billion for Medicaid, representing 5.8% of the nation's gross domestic product.⁸

Unfortunately, there is no end in sight to these rising costs. For 2016, the Congressional Budget Office (CBO) projects spending on federal health programs and subsidies for health insurance purchased through the Affordable Care Act's marketplaces⁹ to rise to \$1.1 trillion, or 6.2% of the nation's gross domestic product.¹⁰ By the end of 2026, the CBO further projects these costs will nearly double to \$2 trillion, or 7.4% of the nation's gross domestic product.¹¹

The main reason health care costs are escalating is the current fee-for-service payment model that rewards health care providers for the volume of their services and not their value.¹² Health care providers seeking reimbursement under Medicare's fee-for-service system (also known as a prospective payment system) are paid for services based on predetermined rates for each service set by the Centers and Medicare and Medicaid (CMS),¹³ without regard for whether the service is the most cost-effective under the circumstances or whether it will contribute to better patient health outcomes. Over the years, this payment system has been criticized for rewarding health care providers for the volume of services without regard for the cost or quality of those services.¹⁴ As a

Medicaid, each state offers CHIP coverage based on the needs existent in their community. See *CHIP Eligibility Standards*, <http://www.medicaid.gov/chip/eligibilitystandards/chip-eligibility-standards.html> (last visited Aug. 18, 2016).

7. Mindy R. Levit, D. Andrew Austin & Jeffrey M. Stupak, *Mandatory Spending Since 1962*, 7-5700, 13, CONG. RES. SERV., (2015).

8. *The Budget and Economic Outlook: 2015 to 2026*, CONG. BUDGET OFF. (Jan. 26, 2016), https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/reports/51129-2016Outlook_OneCol-2.pdf.

9. Since the passage of the Patient Protection and Affordable Care Act in 2010 (42 U.S.C. § 18001 *et seq.*), the federal government also provides subsidies to persons who enroll in a health insurance program either through the federal health insurance marketplace or a state-administered health insurance marketplace.

10. CONG. BUDGET OFF., *supra* note 8, at 65.

11. *Id.*

12. Missouri Hospital Association, *CBO Releases Its Budget and Economic Outlook: 2016-2026*, FEDERAL BRIEF ISSUE 1, 3 (2016), http://web.mhanet.com/Issue%20Briefs/Issue%20Brief_CBO%20Releases%20Its%20Budget%20and%20Economic%20Outlook-2016%20to%202026_%20012616.pdf.

13. See Office of Inspector General, Oei-09-00-00200, *Medicare Hospital Prospective Payment System: How DRG Rates Are Calculated and Updated* (2001).

14. Amy M. Lishko, *Physician Payment Reform: A Review and Updates of the Models*, TUFTS UNIV. SCH. OF MED. 10, [http://www.massmed.org/News-and-Publications/Research-and-Studies/Physician-Payment-Models-MMS-Review-and-Update-\(pdf\)/](http://www.massmed.org/News-and-Publications/Research-and-Studies/Physician-Payment-Models-MMS-Review-and-Update-(pdf)/) (last visited Aug. 18, 2016).

consequence, many argue that it rewards over-utilization and results in increased costs.¹⁵

Despite the large amount of money invested in health care, the United States has relatively poor health outcomes. Currently, it “ranks last overall among [eleven] industrialized countries on measures of health system quality, efficiency, access to care, equity, and healthy lives.”¹⁶ Yet, the United States spends more on health care than any other developed country.¹⁷ In 2010, “the United States spent over \$2.6 trillion on health care, representing roughly 18 percent of gross domestic product (GDP).”¹⁸ Based on this figure, “health spending in the U.S. [was] far higher than the United Kingdom (9.6 percent of GDP), Germany (11.6 percent) or Japan (9.5 percent).”¹⁹ Notwithstanding the amounts of money invested in the U.S. health care system, U.S. patient care outcomes are poor when compared to these other countries. As noted in a bipartisan report, “[t]his discrepancy indicates opportunities to reduce spending while improving care, and the need to carefully examine the structural aspects of our health care system that contribute to inefficiency and wasteful spending.”²⁰

In an attempt to change the trajectory of the United States health care system, the federal government has made a concerted effort to test new payment models that reward quality of care and control costs. As a result of CMS’s success with many of these models,²¹ in 2015, Congress

15. *Id.*

16. See *U.S. Health System Ranks Last Among Eleven Countries on Measures of Access, Equity, Quality, Efficiency, and Healthy Lives*, THE COMMONWEALTH FUND (June 16, 2014), <http://www.commonwealthfund.org/publications/press-releases/2014/jun/us-health-system-ranks-last>.

17. Ashley C. Allen, *Countries Spending the Most on Health Care*, USA TODAY (July 7, 2014), <http://www.usatoday.com/story/money/business/2014/07/07/countries-spending-most-health-care/12282577/>.

18. Paul Ginsburg, Meredith Hughes & Loren Adler, *What is Driving US Health Care Spending: America’s Unsustainable Health Care Cost Growth*, BIPARTISAN POLICY CTR. (Sept. 20, 2012), <http://bipartisanpolicy.org/library/what-driving-us-health-care-spending-americas-unsustainable-health-care-cost-growth/>.

19. *Id.* at 4.

20. *Id.*

21. Medicare’s Pioneer Accountable Care Organization (ACO) saved over \$96 million over a two year period and improved quality of care by 19 percent. Medicare’s Shared Savings Program, ACO, has also shown great success by saving the federal government \$383 million in just one year and achieving improvement in quality of care in 30 out of 33 quality measures. See *Medicare ACOs Continue to Succeed in Improving Care, Lowering Cost Growth*, CTRS. FOR MEDICARE AND MEDICAID SERVS. (Nov. 10, 2014), [https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-11-](https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-11-10.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending)

10.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending.

enacted the Medicare Access and CHIP Reauthorization Act (MACRA).²² Under MACRA, all U.S. health care providers must participate in one of two new payment models.²³ Implementation of MACRA will begin in January 2017,²⁴ with full implementation expected in 2019.²⁵ Because all health care professionals will be required to participate in MACRA, the traditional fee-for-service model will soon be a thing of the past.²⁶ MACRA's new payment models are intended to reward health care providers for value, both in lowering costs and delivering quality care.²⁷ To achieve this, MACRA will require health care providers to work with each other in a coordinated and integrated manner—the opposite of how health care professionals have been working under the traditional fee-for-service model.²⁸

With the imminent transition to MACRA, health care providers find themselves at a crossroads between the old ways of the fee-for-service world and the new ways of the new payment models. A major area of concern is the current misalignment between the federal prohibition against physician self-referral, known as the Stark Law (Stark),²⁹ and MACRA.³⁰ Stark prohibits a physician from referring Medicare patients for designated health services to an entity in which the physician (or immediate family member) has an ownership interest, an investment

Another alternative payment model is Medicare's Bundled Payments for Care Improvement (BPCI) Initiative in which reimbursements are made for a group of highly coordinated services or bundle of services known as an "episode of care." Although official results of the BPCI Initiative are not due until 2018, preliminary reports show that the BPCI Initiative is achieving success in increasing quality of care, decreasing readmission rates, and reducing costs. See *Bundled Payments for Care Improvement Initiative: General Information*, CTRS. FOR MEDICARE AND MEDICAID SERVS., <https://innovation.cms.gov/initiatives/bundled-payments/> (last visited Aug. 18, 2016).

22. Medicare Access and CHIP Authorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87 (2015).

23. *Notice of Proposed Rulemaking Re MACRA's Quality Payment Program*, CTRS. FOR MEDICARE AND MEDICAID SERVS. 1–3, <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/NPRM-QPP-Fact-Sheet.pdf> (last visited Aug. 18, 2016).

24. *Id.*

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.*

29. 42 U.S.C. § 1395nn (2010).

30. Vera Gruessner, *AHA Claims Stark Law Harms Value-Based Care Reimbursement*, HEALTH PAYER INTELLIGENCE (Feb. 2016), <http://healthpayerintelligence.com/news/aha-claims-stark-law-harms-value-based-care-reimbursement>.

interest, or a compensation relationship.³¹ The overall essence of Stark's prohibitions is to discourage cooperation and encourage physicians to work independently and at arm's length from other health care providers, including the very entities that employ them.³² In contrast, MACRA's new payment models require physicians to actively collaborate with other health care providers during all stages of a patient's care to achieve better patient outcomes, reduce costs, and eliminate duplication of services.³³

One of the hallmarks of MACRA's new payment models is to provide economic incentives to health care providers so as to drive cooperative behaviors.³⁴ The problem is that such incentive payments may be deemed improper referral fees under Stark's physician compensation provisions.³⁵ Consequently, this leaves physicians and hospitals wondering how to comply with a new payment model that appears to be in direct conflict with existing law.³⁶

In a post-MACRA world, Stark's regulation of physician compensation is an impediment to payment reform and unnecessary in light of the modern-day, more robust Anti-Kickback Statute. In support of this premise, Section I will provide an overview of the Anti-Kickback Statute and the parallel evolution of Stark. Section II will discuss the nature of the new payment models and the enactment of MACRA. Section III will address the misalignment between Stark and MACRA. Lastly, Section IV will address how best to harmonize Stark with MACRA given the need, amongst all stakeholders, for MACRA to succeed.

31. *Id.*; 42 C.F.R. Subpart J, § 411.354(a)(1) (defining "financial relationship" under Stark to include "a direct or indirect ownership or investment interest" or "a direct or indirect compensation arrangement").

32. *The Stark Law: Opportunities to Address Barriers to Clinical Integration*, THE HOSP. AND HEALTH SYS. OF PA., 2 (Jan. 29, 2016), https://www.haponline.org/Portals/0/docs/Initiatives/Integrating_Care/Stark-Law-Memo-1-26-14.pdf.

33. *Better Care, Smarter Spending, Healthier People: Paying Providers for Value, Not Volume*, CTRS. FOR MEDICARE AND MEDICAID SERVS. (Jan. 26, 2015), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-01-26-3.html>.

34. Gruessner, *supra* note 30.

35. 42 U.S.C. § 1395nn (2010).

36. Although the Stark Law enumerates several exceptions that permit physicians to have certain financial relationships with other providers and CMS has created waivers for select alternative payment models, these exceptions and waivers do not apply to MACRA's alternative payment models. See 42 U.S.C. § 1395nn (2016); *Fraud and Abuse Waivers for Select CMS Models and Programs*, CTRS. FOR MEDICARE AND MEDICAID SERVS. (Dec. 2015), <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html>.

I. THE ANTI-KICKBACK STATUTE AND PARALLEL EVOLUTION OF STARK

There have been numerous instances in the history of the United States of private individuals attempting to profit from the federal government when taxpayer monies are used for a public purpose. In the health care industry, although it was long suspected that many health care providers were over-utilizing Medicare, it was not until the late 1980's and 1990's that studies were conducted to corroborate what was already known in practice: that providers were more likely to have their patients over-utilize a service if the provider had a financial interest in the service prescribed.³⁷ During this time, the Anti-Kickback Statute³⁸ was a tool already in existence in the federal government's arsenal to combat fraud and abuse. However, these findings compelled Congress to enact a law that specifically targeted physician self-referrals and which we know today as the Stark Law.³⁹ A brief history of these two laws is detailed below.

A. *The Anti-Kickback Statute*

1. *The Anti-Kickback's Infancy*

When the first Anti-Kickback Act was passed in 1934,⁴⁰ it was passed for reasons that had nothing to do with health care. At the time, the Davis-Bacon Act required contractors to provide their employees "prevailing rates" on public works.⁴¹ However, to get around this law and keep wages artificially low, many contractors demanded that their employees return or "kick back" part of their wages, or else risk losing

37. See Council on Ethical and Judicial Affairs, American Medical Association, *Conflicts of Interest: Physician Ownership of Medical Facilities*, 267 J. AM. MED. ASS'N. 2366, 2367 (1992); Statement of Janet L. Shikles, *Medicare: Physicians Who Invest in Imaging Centers Refer More Patients for More Costly Services*, Testimony Before the Subcommittee on Health, Committee on Ways and Means, House of Representatives (Apr. 1993); Melissa Ahern & Elton Scott, *Regional and Individual Differences in Physician Practices for Joint-Ventured versus Non-Joint-Ventured*, 28 HEALTH SERVS. RESEARCH 6 (Feb. 1994).

38. 42 U.S.C. § 1320a-7b(b) (2010).

39. *Id.* at § 1395nn.

40. Copeland Anti-Kickback Act of 1935, 48 Stat. 948, 73rd Cong., Sess. 2 (1934) (amending and further fortifying the Davis-Bacon Act of 1931).

41. Davis-Bacon Act of 1931, 40 U.S.C. §§ 276a-276a-5 (1931) (defining 'prevailing rates' as the prevailing or the most common wages received by other laborers performing similar duties on projects of similar character in the same locality. Now re-codified as 40 U.S.C. §§ 3141-3148).

their jobs.⁴² In response to this behavior, Congress enacted the Anti-Kickback Act, imposing a fine and/or imprisonment on anyone that required an employee on a public works project "to give up any part of the compensation to which [he was] entitled to under . . . contract."⁴³ By further amendment in 1935, a contractor who failed to pay 'prevailing wages' could also become ineligible to bid on public works projects for a period of up to three years.⁴⁴ In 1960, Congress further expanded the reach of the Anti-Kickback Act to cover all negotiated contracts entered into with any agency or department of the United States.⁴⁵

2. Adapting to Medicare and Medicaid – The 1970's

In 1965, Congress created the Medicare and Medicaid programs.⁴⁶ Instead of creating both programs as government-run national health insurance programs similar to those in Europe, President Lyndon B. Johnson's administration and Congress opted to create them with an infrastructure similar to private insurance companies of that time.⁴⁷ Both Medicare and Medicaid were "to replicate the reimbursement mechanisms of traditional third-party insurance."⁴⁸ As such, both plans "allowed health care providers . . . to nominate private companies as go-betweens in dealing with the Social Security Administration."⁴⁹ These private companies became depositories of federal monies earmarked for these programs and were then tasked to make payments to each participating health care provider on a fee-for-service basis.⁵⁰ As a result, "the federal government surrendered direct control of [Medicare and Medicaid] and [their associated] costs."⁵¹

42. *Investigation of the Relationship Existing Between Certain Contractors and Their Employees in the United States Before S. Comm. on Educ. and Labor*, 73rd Cong. 3 (1934).

43. Copeland Anti-Kickback Act, 18 U.S.C. § 874 (1934).

44. An Act Relating to Rate of Wages for Laborers and Mechanics Employed on Public Buildings, Pub. L. No. 403 § 1, 74th Cong. Sess. 3303 (1935) (amending Davis-Bacon Act).

45. 41 U.S.C. §§ 51–54 (1960).

46. Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965).

47. J. STUART SHOWALTER, *THE LAW OF HEALTHCARE ADMINISTRATION* 41 (Health Administration Press, 7th ed. 2015).

48. Tamsen Douglass Love, Note, Toward a Fair and Practical Definition of "Willfully" in the Medicare/Medicaid AntiKickback Statute, 50 VAND. L. REV. 1029, 1034 (1997) (citing PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE*, 375 (Basic Books 1982)).

49. National Health Expenditures, *supra* note 5.

50. *Id.*

51. *Id.* at 42.

With Medicare and Medicaid up and running, Congress soon realized that Anti-Kickback measures tailored specifically to health care needed to be put in place to coalesce with both programs. In 1972, Congress introduced Anti-Kickback legislation as part of several amendments made to the Social Security Act.⁵² This new Anti-Kickback Statute prohibited a person from:

[F]urnish[ing] items or services to an individual for which payment is or may be made under this title and who solicits, offers, or receives any—(1) kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment, or (2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services[.]⁵³

In addition, the Statute provided for penalties in the form of a misdemeanor with imprisonment for up to a year and/or fines not to exceed \$10,000.⁵⁴ At that time, Congress clearly stated that the purpose of the Anti-Kickback Statute was to curtail unethical behavior in the health care industry and reduce costs to both the Medicare and Medicaid programs.⁵⁵

Thereafter, in 1977, Congress soon realized that the statute required further improvements, as confusion over what constituted a “bribe” or a “kickback” arose in the courts.⁵⁶ The Senate and House of Representatives committee reports show that improvements were needed to “clarify and restructure [existing] provisions . . . which define the types of financial arrangements and conduct to be classified as illegal,” because the prior provisions had “not proved [to be] adequate deterrents.”⁵⁷ As a consequence, Congress reinforced the Anti-Kickback Statute by enacting three important changes. First, instead of forbidding ‘kickbacks,’ ‘bribes,’ or ‘rebates,’ Congress expanded its language to prohibit any and all ‘remuneration’ that is given in exchange for a

52. Social Security Amendments of 1972, Pub. L. No. 92-603, 242(b), 86 Stat. 1329, 1419 (1972).

53. *Id.*

54. *Id.*

55. H.R. REP. NO. 92-231 (1971), *reprinted in* 1972 U.S.C.C.A.N. 4989, 5093.

56. *See United States v. Porter*, 591 F.2d 1048, 1053–54 (5th Cir. 1979) (reversing the defendants’ convictions because the referral fees a lab paid doctors were not deemed to be bribes or kickbacks, as there was no showing of corruption or misapplied government funds under the Anti-Kickback Statute).

57. H.R. REP. NO. 95-393 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3088; *see also* S. REP. NO. 453 (1977).

referral.⁵⁸ The use of this more generalized language, coupled with language immediately following stating that it applied to transactions "directly or indirectly, overtly or covertly, in cash or in kind,"⁵⁹ shows Congress's intent for the statute to be far-reaching and applicable to a greater number of incidences. Second, due to the fraudulent activity already taking place within the Medicare and Medicaid programs, Congress enacted stiffer penalties by upgrading all violations to felonies punishable by a fine, not to exceed \$25,000, and/or imprisonment, not to exceed five years.⁶⁰ Third, Congress provided for an additional remedy by disallowing participation in Medicare or Medicaid if a health care provider was found guilty of violating any of its provisions.⁶¹

Another interesting feature of this amendment is what is seen by some as the beginnings of a carving-out of exceptions in response to the broad application of the statute. Specifically, the 1977 amendment provided for two exceptions. The statute did not apply when "a discount or other reduction in price [was] obtained by a provider of services or other entity . . . if the reduction in price was properly disclosed and appropriately reflected in the costs claimed or charges made."⁶² The statute also was not applicable to "any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services."⁶³

3. Further Building Blocks: Mens Rea and Safe Harbors – The 1980's

Now that the Anti-Kickback Statute was more expansive in its reach, many health care providers complained of inadvertently violating the Anti-Kickback Statute.⁶⁴ To address these concerns, Congress enacted the Omnibus Reconciliation Act of 1980.⁶⁵ In the Act, "Congress actually narrowed the scope of the Anti-Kickback Statute by adding a mens rea requirement that changed the law from a strict liability

58. Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. No. 95-142, 91 Stat. 1183 (1977).

59. *Id.*

60. *Id.*

61. *Id.*

62. *Id.*

63. *Id.*

64. TIMOTHY STOLTZ JOST & SHARON L. DAVIES, *THE LAW OF MEDICARE AND MEDICAID FRAUD AND ABUSE* 100, 114-15 (2001-02 ed. 2000).

65. Omnibus Reconciliation Act of 1980, H.R. REP. NO. 96-1167 (1980), *reprinted in* 1980 U.S.C.C. A.N. 5526, 5572.

provision to one requiring proof that defendants acted ‘knowingly and willingly’ to impose liability.”⁶⁶ On its face, this amendment appeared to balance out the otherwise harsh aspects of the 1977 amendment.

Nevertheless, health care providers continued to complain about the Anti-Kickback Statute, arguing that the terms ‘knowingly and willfully’ were ambiguous.⁶⁷ Congress appeared to have listened. In a Senate Report, Congress stated that “the breath of . . . statutory language [had] created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed.”⁶⁸ As a consequence, Congress made further amendments by enacting the Medicare and Medicaid Patient and Program Protection Act of 1987.⁶⁹ In the statute, Congress empowered the Office of Inspector General (OIG) of the Health and Human Services Department to impose civil administrative penalties in addition to the criminal penalties already in existence.⁷⁰ It also carved out two additional exceptions that helped define acts that were not considered a violation of the statute. First, it mandated that the Secretary of Health and Human Services, in conjunction with the Attorney General, “promulgate final regulations, specifying payment practices that shall not be treated as a criminal offense.”⁷¹ This mandate led to the birth of “safe harbors” which would inform providers about the types of conduct that would be permissible under the statute.⁷² Second, the statute created another exception for “any amount paid by a vendor . . . to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if the person has a written contract [and] . . . specifies the amount to be paid.”⁷³

66. Dayna Bowen Matthew, *Tainted Prosecution of Tainted Claims: The Law, Economics, and Ethics of Fighting Medical Fraud Under the Civil False Claims Act*, 76 IND. L.J. 525, 569 (2001).

67. See Corbin Santo, Note, *Walking a Tightrope: Regulating Medicare Fraud and Abuse and the Transition to Value-Based Payment*, 64 CASE W. RES. 1377, 1387 (2014) (noting ambiguity caused health care providers to be hesitant about “forming new business and payment arrangements out of fear that they would face criminal liability or exclusion from Medicare”).

68. S. REP. NO. 100-109 (1987), reprinted in 1987 U.S.C.C.A.N. 682, 707–08.

69. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, §§ 4 & 14, 101 Stat. 680, 688–89, 697–98 (1987) (codified as amended at 42 U.S.C. § 1320a-7b (1995)).

70. *Id.* at § 3.

71. *Id.* at § 14.

72. *Id.*

73. *Id.* at § 4.

4. *The Birth of the Advisory Opinion – The 1990's*

By 1996, health care providers continued to lodge complaints regarding the Anti-Kickback Statute's lack of clarity. In a House of Representative Report, even Congress admitted to the continuing problem by stating:

Providers want to comply with the fraud and abuse statute, but many are unsure of how the statute affects them. These providers should be able to receive guidance from the government regarding financial arrangements. Little or no guidance is currently provided because there are no regulations and only insufficient safe harbors. Without this ability, a chilling effect is placed on legitimate arrangements[.]⁷⁴

Thus, this same year, Congress enacted the Health Insurance Portability and Accountability Act of 1996 (HIPAA).⁷⁵ Although the primary goal of HIPAA was to institute safeguards "to protect the confidentiality, integrity, and availability of electronic protected health information"⁷⁶ and "ensure that individuals who are already sick can keep insurance even if they lose or leave jobs,"⁷⁷ it also made important changes to the fraud and abuse laws. Through its enactment, HIPAA: 1) gave the OIG the ability to impose intermediate sanctions,⁷⁸ 2) increased funding to OIG and the FBI for fraud enforcement,⁷⁹ 3) expanded sanctions for fraud and abuse,⁸⁰ and 4) made the Anti-Kickback Statute applicable to all federal programs.⁸¹ In addition, HIPAA directed the Secretary of the Department of Health and Human Services to establish a 'risk-sharing arrangements' exception taking into account, amongst other

74. H.R. REP. NO. 104-496, at 84–85 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1865, 18884–85.

75. Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

76. U.S. Department of Health and Human Services, Health Information Privacy, *Q & A: Why is the HIPAA Security Rule Needed and What is the Purpose of the Security Standards?*, <http://www.hhs.gov/hipaa/for-professionals/faq/2000/why-is-hipaa-needed-and-what-is-the-purpose-of-security-standards/index.html> (last visited Aug. 18, 2016).

77. Kennedy, Kassebaum Steer Insurance Bill to Safety, 54 Cong. Q. 2197 (Aug. 3, 1996).

78. 42 U.S.C. § 1395mm(i)(1) (2016).

79. Health Insurance Portability and Accountability Act of 1996, 110 Stat. 1936, Title II—Preventing Health Care Fraud and Abuse; Administrative Simplification; Medical Liability Reform, § 201, 110 Stat. at 1994 (1996).

80. *Id.* at §§ 211–18 (1996).

81. *Id.* at § 204 (1999).

factors, the extent to which risk-sharing arrangements provide incentives to control the cost and quality of health care services.⁸²

Notwithstanding these changes, many would argue that the most important change brought about by the 1996 amendment to the Anti-Kickback Statute was the mandate for advisory opinions.⁸³ According to the amendment, the Secretary of the Department of Health and Human Services, along with the Attorney General, shall issue advisory opinions regarding what constitutes a prohibited remuneration, whether an arrangement is a prohibited arrangement, what constitutes an inducement to reduce or limit services to beneficiaries, and whether any activity constitutes grounds for the imposition of sanctions.⁸⁴ The amendment clearly stated what topics were not subject to advisory opinions, such as the fair market value of a good, service, or property; and whether an individual was a bona fide employee.⁸⁵ The amendment also stated that advisory opinions would only be binding on the Secretary of the Department of Health and Human Services and on the party or parties requesting the opinion.⁸⁶

Lastly, the amendment called for the Inspector General to issue "special fraud alerts" for the purpose of notifying the public of practices believed to be suspect or of particular concern regarding the administration of the Medicare or Medicaid programs.⁸⁷ All special fraud alerts are to be published in the Federal Registrar and warn of the consequences of any of the actions that were the subject of the alert.⁸⁸

By 1999, twelve years after the 1987 amendments to the Anti-Kickback Statute mandated the creation of safe harbors, the OIG published final regulations clarifying the safe harbors initially promulgated and creating an additional eight safe harbor provisions.⁸⁹ By 1999, there were "a total of 23 Anti-Kickback safe harbors consolidated in the Code of Federal Regulations."⁹⁰ At first glance, the existence of twenty-three safe harbors may have led many to believe that the Office of Inspector General was providing valuable and significant input

82. *Id.* at § 216, 110 Stat. at 2007-08 (1996).

83. *Id.* at § 205(b)(1), 110 Stat. at 2001 (1996).

84. *Id.*

85. *Id.* at § 205(b)(3), 110 Stat. at 2002 (1996).

86. *Id.*

87. *Id.* at § 205(c), 110 Stat. at 2003 (1996).

88. *Id.*

89. Dept. of Health and Human Services, Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518 (Nov. 19, 1999).

90. *Id.*

regarding permissible activities under the Anti-Kickback Statute.⁹¹ However, critics claim that, because the safe harbors are narrowly drawn and strictly construed, “very few arrangements will be completely protected.”⁹²

5. The Affordable Care Act’s Much Needed “Shot in the Arm” – The 2000’s

The passage of the Patient Protection and Affordable Care Act (ACA) in 2010 resulted in significant changes, further strengthening the Anti-Kickback Statute.⁹³ First, the ACA amended the Anti-Kickback Statute by stating that “claims submitted in violation of the [Anti-Kickback] statute automatically constitute false claims for purposes of the False Claims Act.”⁹⁴ To ensure that health care providers will not claim that they unknowingly violated the law, they are required to certify that they comply with all applicable laws, including the Anti-Kickback Statute, before receiving reimbursements from Medicare and Medicaid.⁹⁵ CMS has made it very clear that the Anti-Kickback Statute was “designed to prevent or ameliorate fraud, waste and abuse.”⁹⁶ Federal regulations require providers to file cost reports on an annual basis on or before the last day of the fifth month following the close of the period covered by the cost report.⁹⁷ In these reports, providers are to certify that they are “familiar with the laws and regulations regarding the provision

91. Timothy J. Aspinwall, *The Anti-Kickback Statute Standards of Intent: The Case for a Rule of Reason Analysis*, 9 ANN. HEALTH L. 155, 163 (2000) (citing Scott J. Kelly, Comment, *The Health Insurance Portability and Accountability Act of 1996: A Medicare Advisory Opinion Mandate Sends the Inspector General “Shopping for Hats”*, 59 OHIO ST. L.J. 303, 313 (1998) (citing Hugh E. Aaron, *Application of the Medicare and Medicaid Anti-Kickback Statute to Business Arrangements Between Hospitals and Hospital-Based Physicians*, 1 ANNALS HEALTH L. 53, 63 (1992)).

92. *Id.*

93. Patient Protection and Affordable Health Act, Pub. L. No. 111-148 (2010).

94. 42 U.S.C. § 1320a-7b(g) (2016); *see also* Scott Oswald and David Scher, *Health Care Law Expands False Claims Act Under the Anti-Kickback Statute* (May 2012), employmentlawgroupblog.com/up-content/Anti-Kickback-statute-false-claims-lawyers.pdf.

95. 42 C.F.R. § 424.516(a)(1) (2016):

CMS enrolls and maintains an active enrollment status for a provider or supplier when that provider or supplier certifies that it meets, and continues to meet, and CMS verifies that it meets, and continues to meet, . . . [c]ompliance with title XVIII of the [Social Security] Act and applicable Medicare regulations.

Id.

96. 42 C.F.R. § 422.504(h) (2016).

97. *Id.* at § 413.24(f) (2016).

of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.”⁹⁸

Unfortunately, what the 1987 amendment to the Anti-Kickback Statute gave (the addition of the “knowingly and willfully” intent requirement to prove a violation), the ACA stripped away. Prior to the passage of the ACA, a widespread disagreement existed amongst the courts regarding the meaning of the term “knowingly and willfully.” The Eleventh Circuit promulgated an expansive and traditional interpretation of the “knowingly and willfully” standard by holding that ignorance of the law is not a defense, and that all that had to be proven is knowledge that the conduct was unlawful.⁹⁹ In contrast, the Ninth Circuit took a more narrow approach by holding that the “knowingly and willfully” standard was met if a defendant knew his conduct was a violation of the Anti-Kickback Statute and participated in the conduct with the “specific intent” to violate the statute.¹⁰⁰ Ultimately, the ACA clarified the court split and sided with the Eleventh Circuit.¹⁰¹ Federal prosecutors no longer need to prove that a health care provider specifically intended to violate the Anti-Kickback Statute.¹⁰² Instead, they only need to prove that the health care provider intended to violate the law.¹⁰³ Specifically, the ACA states “a person need not have actual knowledge of . . . or specific intent to commit a violation of [the Anti-Kickback Statute.]”¹⁰⁴ This definition of what constitutes intent under the Anti-Kickback Statute effectively lowers the threshold of proof. Some argue that “[t]his new standard will impact transactions and arrangements counseling and could potentially create significant criminal and civil fraud exposure for transactions and arrangements where there is no intent to violate the

98. *Id.* at § 413.24(f)(4) (2016).

99. *United States v. Starks*, 157 F.3d 833, 838–39 (11th Cir. 1998) (citing in support *Bryan v. United States*, 524 U.S. 184 (1998)).

100. *Hanlester Network v. Shalala*, 51 F.3d 1390, 1399–1400 (9th Cir. 1995).

101. 442 U.S.C. § 1320a-7b(h) (2016).

102. *Id.*

103. *Id.*

104. *Id.*

statute.”¹⁰⁵ Others argue that, in all practically, it eliminates the mens rea requirement,¹⁰⁶ returning the Anti-Kickback Statute to its pre-1987 state.

Lastly, the ACA further strengthened the Anti-Kickback Statute by increasing the type of sentences violators of the statute receive. The ACA mandated that the Federal Sentencing Guidelines be amended “to provide that the aggregate dollar amount of fraudulent bills submitted to the Government health care program shall constitute prima facie evidence of the amount of the intended loss by the defendant.”¹⁰⁷ It also mandated that the Federal Sentencing Guidelines provide for the following enhanced health care fraud sentences: “if . . . [a] defendant [is] convicted of a Federal health care offense involving a Government health care program and . . . the loss [is] more than \$1,000,000, increase by 2 levels; more than \$7,000,000, increase by 3 levels; or more than \$20,000,000, increase by 4 levels.”¹⁰⁸

6. From Humble Beginnings to a Power House Statute – The Anti-Kickback Statute Today

Due to the numerous amendments that have broadened its application and increased penalties for its violation, the Anti-Kickback Statute has proven to be a valuable tool in the fight against fraud and abuse. Today, the statute reads as follows:

Whoever knowingly and willfully solicits or receives any remuneration [and knowingly and willfully offers or pays remuneration] (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind (A) for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) . . . for purchasing, leasing, ordering, or arranging for or

105. Elizabeth R. Sheyden, *Toward a Specific Intent Requirement in White Collar Crime Statutes: How the Patient Protection and Affordable Care Act of 2010 Sheds Light on the “General Intent Revolution”*, 64 FLA. L. REV. 449, 465 (2012) (citing Kathleen McDermott et al., *New Health care Fraud and Abuse and Program Integrity Provisions: Let’s Fasten Our Seat Belts for the Bumpy Ride*, AHLA CONNECTIONS, at 13 (May 2010), available at www.healthlawyers.org/News/Connections/CurrentIssue/Documents/2010%20Features/Feature_May10.pdf).

106. *Id.*

107. Patient Protection and Affordable Health Act, Pub. L. No. 111-148 § 10606 (2010).

108. U.S. SENTENCING GUIDELINES MANUAL § 2B1.1.b.8 (U.S. SENTENCING COMM’N 2011).

recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.¹⁰⁹

To assist health care providers in its application, a total of twenty-five safe harbors have been issued by the Secretary of the Department of Health and Human Services to date.¹¹⁰ In addition, The Office of Inspector General has issued a total of 369 advisory opinions.¹¹¹ Most of these advisory opinions are new opinions,¹¹² while others are modifications to or terminations of prior opinions.¹¹³ The Office of Inspector General has also issued a total of thirty-two special fraud alerts.¹¹⁴

Numerous awards or settlements have been obtained by the government from individuals and entities in violation of the Anti-Kickback Statute and, consequently, the False Claims Act. For example, in *United States ex rel. Gale v. Omnicare*, the defendant agreed to pay over \$120 million for providing illegal discounts to Medicare patients.¹¹⁵ In *United States ex rel. Darita v. C.R.Bard, Inc.*, the defendant agreed to pay \$48.26 million to settle claims it was paying off health care providers if they prescribed a specific radiation therapy that was ultimately paid for by Medicare.¹¹⁶ In *United States ex rel. Bingham v. Hospital Corp. of America*, the defendant agreed to pay \$16.5 million to dismiss charges that it paid money and other valuable consideration to physicians in exchange for patient referrals.¹¹⁷ Similarly, in *United States*

109. 42 U.S.C. § 1320a-7b(b) (2016) (emphasis added).

110. 42 C.F.R. § 1001.952 (2016).

111. Advisory Opinions, Office of Inspector General, U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, <http://oig.hhs.gov/compliance/advisory-opinions/index.asp> (last visited Aug. 21, 2016).

112. *See id.*

113. *See id.*

114. Special Fraud Alerts, Office of the Inspector General, U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, <http://oig.hhs.gov/compliance/alerts/guidance/index.asp> (last visited Aug. 18, 2016).

115. *United States ex rel. Donald Gale v. Omnicare, Inc.*, No. 1:10CV127, 2013 WL 3822152, (N.D. Ohio Sept. 26, 2012).

116. Office of Public Affairs, Department of Justice, *C. R. Bard, Inc. To Pay U.S. \$48.26 Million To Resolve False Claim Act Claims* (May 13, 2013), <https://www.justice.gov/opa/pr/cr-bard-inc-pay-us-4826-million-resolve-false-claims-act-claims>.

117. Office of Public Affairs, Department of Justice, *Hospital Chain HCA Inc. Pays \$16.5 Million to Settle False Claims Act Allegations Regarding Chattanooga, Tenn.*,

ex rel. Health Dimensions Rehabilitation v. RehabCare Group, the defendant paid \$30 million to dismiss a lawsuit that alleged the defendant made payments with the intent of inducing use of its therapy services.¹¹⁸ These cases are just a representative sample of the type of abuse and fraud the federal government has been able to combat by virtue of the Anti-Kickback Statute. Even though critics of the Anti-Kickback Statute claim it is too broad and far reaching, with an intent requirement that has, for all practical purposes, been eradicated by the ACA, it does beg the question, what would be the current state of fraud and abuse in the health care industry if the Anti-Kickback Statute did not exist?

B. The Stark Law

1. An Additional Tool in Fighting Fraud and Abuse – “Stark I”

The Ethics in Patient Referrals Act of 1989 (Stark I) was introduced in the House of Representatives by Representative Fortney H. “Pete” Stark from California.¹¹⁹ It subsequently was enacted by Congress and included in the Omnibus Budget Reconciliation Act of 1989.¹²⁰ Stark I barred a physician from referring patients to a clinical laboratory in which the physician had an interest if the costs of the laboratory services were to be paid by the Medicare program.¹²¹ It became effective in 1992.¹²² Final regulations were not released until August of 1995.¹²³

Prior to the passage of Stark I, several Congressional hearings took place detailing numerous accounts of physician self-referrals financed by Medicare. For example, a 1983 study was introduced in Congress that compared the price and usage of twenty doctor-owned labs and twenty independent labs.¹²⁴ In this study, the average payment made to the

Hospital (Sept. 19, 2012), <https://www.justice.gov/opa/pr/hospital-chain-hca-inc-pays-165-million-settle-false-claims-act-allegations-regarding>.

118. Office of Public Affairs, Department of Justice, *Nationwide Contract Therapy Providers to Pay \$30 Million to Resolve False Claims Act Allegations* (Jan. 17, 2014), <https://www.justice.gov/opa/pr/nationwide-contract-therapy-providers-pay-30-million-resolve-false-claims-act-allegations>.

119. Ethics in Patient Referrals Act of 1989, H.R. 939, 101st Cong. (1989).

120. Omnibus Budget Reconciliation Act of 1989, H.R. 3299, 101st Cong. (1989).

121. *Id.*

122. Andrew B. Wachler & Adrienne Dresevic, *Stark II Phase III – “The Full Picture”*, THE HEALTH LAWYER, ABA HEALTH LAW SECTION 3 (Sept. 2007), http://www.thehealthlawpartners.com/files/stark2_phase3_thefullpicture.pdf.

123. 60 Fed. Reg. 41923 (1995).

124. Physician Self-Referral Problem: The Evidence Increases, 135 CONG. REC. e610, (1989).

doctor-owned labs was \$44.82 and the average number of tests performed per patient was 6.23.¹²⁵ Conversely, in the independent labs, the average payment made to the lab was \$25.48 and the average number of tests performed per patient was 3.76.¹²⁶ Further, anecdotal evidence was introduced showing how physicians were acquiring joint venture interests in laboratories and substantially profiting by making referrals to them.¹²⁷ While “[t]he American Medical Association [stated] only about 7% of American physicians are involved in such ventures, [o]ther health care authorities estimate[d] it [was] closer to 25%.”¹²⁸ Testimony was presented which showed that, in the end, “physicians [held] shares or limited-partnership interests in medical facilities that provide ‘tens of billions of dollars’ a year in services.”¹²⁹

Moreover, in May of 1989, the Office of the Inspector General issued a report regarding the inter-relationship between physician joint ventures and the already escalating costs in the Medicare program.¹³⁰ Amongst the report’s findings was the fact that “patients of referring physicians who own or invest in independent clinical laboratories received 45 percent more clinical laboratory services” than Medicare patients whose physicians did not own or invest in clinical laboratories.¹³¹ As a consequence of these staggering figures, physician self-referral appeared in the headlines of several major news outlets.¹³² There was a sense of urgency at the time. Ultimately, the purpose in enacting Stark I was two-fold: to stop over-utilization of medical services and to remove the conflict of interest inherent in physician self-referral.¹³³

125. *Id.*

126. *Id.*

127. *Id.*

128. *Id.*

129. *Id.*

130. Office of the Inspector General, U.S. Department of Health and Human Services, *Financial Arrangements Between Physicians and Health Care Businesses*, OAI-12-88-01410 (May 1989).

131. *Id.*

132. Robert P. Hey & Barbara Bradley, *\$450 Billion Industry Spawns Fraud, Abuse*, CHRISTIAN SCI. MONITOR, Dec. 7, 1988; Robert P. Hey & Barbara Bradley, *MD’s Investments Reap Controversial Profits*, CHRISTIAN SCI. MONITOR, Dec. 8, 1988; Robert P. Hey & Barbara Bradley, *Patient Care vs. Physicians’ Investments*, CHRISTIAN SCI. MONITOR, Dec. 12, 1988; Michael Waldholz & Walt Bogdanich, *Doctor-Owned Labs Earn Lavish Profits in a Captive Market*, WALL ST. J., Mar. 1, 1989; Robert Pear & Erik Eckholm, *When Healers Are Entrepreneurs: A Debate Over Costs and Ethics*, N.Y. TIMES, June 2, 1991, at A1.

133. SHOWALTER, *supra* note 47, at 538.

When enacted in 1989, Stark I only prohibited a physician from referring Medicare patients to clinical laboratories in which the physician had a financial relationship.¹³⁴ Specifically, it stated:

[I]f a physician (or immediate family member of such physician) has a financial relationship with an entity, the physician may not make a referral to the entity for the furnishing of clinical laboratory services for which payment otherwise may be made under this title, and . . . the entity may not present or cause to be presented a claim under this title . . . for clinical laboratory services furnished pursuant to a [prohibited referral].¹³⁵

It provided four exceptions; namely, Stark I did not apply: 1) if a referral was made by a physician to another physician in the same group practice; 2) if a referral was made for in-office ancillary services; 3) if a referral was made within a pre-paid plan; and 4) in any other financial relationship that the Secretary of Health and Human Services believes does not pose a risk of harm to the Medicare program or to the patient.¹³⁶

It is important to note that, from the outset, Stark I emerged as a strict liability law. This means that “a health care provider’s good faith intent to comply with the law, and any lengths the provider may go to attempt to comply, are irrelevant.”¹³⁷ In other words, “regardless of how analytically difficult a Stark issue may be, and regardless [of] how many reputable law firm opinions a health care provider may obtain, a Stark violation is a Stark violation.”¹³⁸

In addition, the magnitude of a violation is irrelevant. Stark makes no distinction between minor or technical violations (such as “unintentional acts, like forgetting to sign a contract, allowing a contract to expire without renewal, or unintentionally omitting an element of an exception from the agreement”¹³⁹), and more substantive violations the law was designed to prevent (such as “failure to have certain financial

134. *Physician Self-Referral*, CTRS. FOR MEDICARE AND MEDICAID SERVS., <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html> (last visited Aug. 18, 2016).

135. Omnibus and Reconciliation Act of 1989, 101 Pub. L. No. 239, 103 Stat. 2106 (1989).

136. *Id.*

137. Alan Rumph, *Why Stark Answers?*, STARK ANSWERS.COM, <http://www.starkanswers.com/Why-StarkAnswers.html> (last visited Aug. 21, 2016).

138. *Id.*

139. Holly Carnell & Anna Timmerman, *Expensive Mistakes: Preventing Technical Violations Of The Stark Law*, E-Briefings, 11 THE GOVERNANCE INSTITUTE 2 (May 2014), available at <https://www.mcguirewoods.com/news-resources/publications/Expensive-Mistakes-Preventing-Violations-Stark-Law.pdf>.

relationships with physicians memorialized pursuant to a written agreement, calculating a physician's salary or bonus based on referral volume, or leasing office space to a physician below fair market value"¹⁴⁰). Thus, the magnitude of the violation does not matter as "even 'technical' violations can result in large penalties for providers."¹⁴¹

Many commentators have had the opportunity to discuss the reasons Congress found it imperative to enact Stark I notwithstanding the fact that the Anti-Kickback Statute had been in existence for more than seventeen years. Some critics claim that:

At the time Stark [I] was enacted, the government's ability to use the Anti-Kickback statute to regulate inappropriate influences on a physician's referrals was limited by several factors. At that time, there was no civil liability for Anti-Kickback violations under the Civil Money Penalty (CMP) statute, and the government was not sure that it could use an Anti-Kickback violation as a predicate for a Federal Claims Act case. Government enforcement agencies were looking for a non-intent based statute and [Stark I] filled that need.¹⁴²

As will be shown later in this paper, many of the reasons why Stark was initially enacted no longer exist.

2. The Advent of a Bigger and Better Stark – "Stark II"

After the enactment of Stark I, Congress remained interested in monitoring physicians and their investment interests as well as the increased costs to the Medicare program. Several reports were written and testimonies were given in Congress further detailing the magnitude of the problem. In a 1993 report, the United States General Accounting Office provided testimony and supporting data regarding the impact of physician referrals to imaging centers physicians either owned or had an interest in.¹⁴³ The report noted, with great detail, that "physician owners of Florida diagnostic imaging facilities had higher referral rates for all

140. *Id.*

141. *Id.*

142. *A Public Policy Discussion: Taking the Measure of The Stark Law*, AM. HEALTH LAWYERS ASS'N PUB. INTEREST COMM. 8 (2009), available at <https://www.healthlawyers.org/hlresources/PI/ConvenerSessions/Documents/Stark%20White%20Paper.pdf>.

143. U.S. GEN. ACCOUNTABILITY. OFF., GAO/T-HRD-93-14, PHYSICIANS WHO INVEST IN IMAGING CENTERS REFER MORE PATIENTS FOR MOST COSTLY SERVICES 3-7 (1993).

types of imaging services than [non-owners].”¹⁴⁴ Specifically, the report found “the differences in referral rates were greatest for costly, high technology imaging services: . . . [physician] owners had 54 percent higher referral rates for MRI scans, 28 percent higher referral rates for computed tomography (CT) scans, and 25 percent higher referral rates for ultrasound and echocardiography.”¹⁴⁵ Ultimately, because the findings of the study were significant, the report went on to state that the General Accounting Office believed this new information was important to Congress “as it considers legislation to extend current restrictions on physician self-referral.”¹⁴⁶

With data of this magnitude in the hands of Congress, it is not surprising that the wheels were put in motion to further expand Stark I with the passage of Stark II as part of The Omnibus Budget Reconciliation Act of 1993.¹⁴⁷ Stark II expanded the physician self-referral prohibition to a number of health services other than clinical laboratories.¹⁴⁸ Specifically, Stark II prohibited physicians (and members of their immediate family) from referring Medicare and Medicaid patients for “designated health services” to entities in which they had a financial relationship.¹⁴⁹ The term “designated health services” was new to the statute and it included a rather long list of services to which this prohibition applied (i.e., clinical laboratory services; physical therapy services; occupational therapy services; radiology services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospitalization services).¹⁵⁰ As in Stark I, Stark II also prohibited submitting a claim for payment if the services furnished were pursuant to a prohibited Stark II referral.¹⁵¹ It further expanded its reach by making itself applicable to the Medicaid program, too.¹⁵² Lastly, it made some important refinements to the overall wording of Stark I and its exceptions.¹⁵³

144. *Id.*

145. *Id.*

146. *Id.*

147. Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 312 (1993).

148. *See id.*

149. *Id.*

150. *Id.*

151. *Id.*

152. *See id.*

153. *Id.*

Interestingly, regulations for Stark I were not published until August 14, 1995,¹⁵⁴ two years after the enactment of Stark II. Even though “the Stark I final rule technically applied only to referrals for clinical laboratory services . . . , it was assumed [by health care providers] to apply in large part to [the] other [designated health care services]”¹⁵⁵ already designated in Stark II.

3. *The Many Moons of “Stark II”*

Regulations for Stark II were released in three principal phases known as Phase I, Phase II, and Phase III. After much public comment, Phase I of the regulations (known as Stark II, Phase I) was released on January 4, 2001.¹⁵⁶ Phase I “revise[d] the definition of referral, clarifie[d] what constitutes an indirect financial relationship, [and] add[ed] an exception for indirect compensation arrangements and exempts entities who do not know the identity of the referring physician.”¹⁵⁷ It also clarified the definition of several key terms such as “physician,” “referring physician,” “entity,” “immediate family member,” “referral,” and “consultation, amongst others.”¹⁵⁸ Defining these key terms, whether advertently or inadvertently, gave CMS the opportunity to further expand the reach of Stark II. Phase I also created “new general exceptions for academic medical centers; implants in ambulatory surgery centers; certain drugs furnished in or by an end-stage renal disease facility; preventive screening tests and immunizations; and eyeglasses and contact lenses following cataract surgery.”¹⁵⁹

The final regulations for Stark II, Phase II were released on March 26, 2004.¹⁶⁰ When Stark II, Phase II was released, it merged with Stark II, Phase I and, together, superseded the prior Stark I regulations.¹⁶¹ The Phase II final rule “provide[d] some limited relief for ‘technical violations’” by creating new exceptions for temporary lapses in compliance, professional courtesy, community information systems, intra-family referrals, Anti-Kickback safe harbors, and charitable

154. 60 Fed. Reg. 41923 (1995).

155. Wachler, *supra* note 122, at 3.

156. 66 Fed. Reg. 856 (2001).

157. Andrew B. Wachler & Adrienne Dresevic, *Stark II Final Rule-Phase I: A Kinder and Gentler Stark?*, THE HEALTH LAWYER, ABA HEALTH LAW SECTION (Jan. 2001).

158. *Id.*

159. *Id.*

160. 69 Fed. Reg. 16054 (2004).

161. Andrew B. Wachler, Adrienne Dresevic & Karen K. Harris, *Stark II Phase II – The Final Voyage*, THE HEALTH LAWYER, ABA HEALTH LAW SECTION (Apr. 2004), http://www.wachler.com/files/stark_ii_phase_ii_the_final_voyage.pdf.

donations.¹⁶² It broadened the exception for academic centers and permissible compensation arrangements.¹⁶³ It also revised the physician recruitment exception and the in-office ancillary services exception.¹⁶⁴

The Stark II, Phase III final rule was released on September 5, 2007¹⁶⁵ and, with it, the rule-making process for the regulations that would interpret and implement Stark II was over. In Phase III, further limited relief was provided for technical violations.¹⁶⁶ The physician recruitment exception was relaxed and the definition of “physician in group practice” was narrowed.¹⁶⁷ Additionally, in determining whether a physician has a *financial relationship* with an entity, the final rule stated that the physician will stand in the shoes of his physician organization.¹⁶⁸ Moreover, several definitions and exceptions were also clarified based on the public comment received prior to the rules release.¹⁶⁹ According to CMS, Phase I, II, and III would now be read together as a unified whole.¹⁷⁰

To assist with the complexities of all three phases of the Stark final regulations, the Centers for Medicare and Medicaid Services (CMS) is empowered to issue written advisory opinions.¹⁷¹ Specifically, CMS shall “issue written advisory opinions concerning whether a referral relating to designated health services (other than clinical laboratory services) is prohibited under this section.”¹⁷² Similar to the advisory opinions available to those with questions about the Anti-Kickback Statute, each advisory opinion regarding application of Stark shall be “issued by the Secretary [and] shall be binding as to the Secretary and the party or parties requesting the opinion.”¹⁷³ Presently, CMS has issued a total of thirty advisory opinions pursuant to this provision.¹⁷⁴ Half of those

162. See Carnell, *supra* note 139, at 2.

163. See 69 Fed. Reg. 16054 (2004).

164. See *id.*

165. 72 Fed. Reg. 51012 (2007).

166. See Carnell, *supra* note 139, at 3.

167. *Id.*; see also Patricia S. Hofstra & Neville M. Bilimoria, *The New Stark Rules: What Does Stark II, Phase III Mean for Health care Providers*, MEDICAL PRACTICE MANAGEMENT (Mar./Apr. 2008), <http://www.duanemorris.com/articles/static/medpracmgmt0508.pdf>.

168. See Hofstra, *supra* note 167, at 300.

169. *Id.*

170. Wachler, *supra* note 122, at 3. The final rules are codified at 42 C.F.R. § 411.350-411.389 (2007).

171. Social Security Act § 1877(g)(6), 42 U.S.C. § 1395 (2016).

172. *Id.*

173. *Id.*

174. *Physician Self-Referral Advisory Opinions*, CTRS. FOR MEDICARE AND MEDICAID SERVS., https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html (last visited Aug. 18, 2016).

opinions pertain to the application of Stark to unique facts and circumstances that have emerged within the health care industry.¹⁷⁵ The other half of the opinions apply to the specialty hospital moratorium that took place from December 2003 to June 2005.¹⁷⁶

Since the release of Stark II, Phase III, there have not been any further rulemaking procedures to amend Stark. However, CMS has found a different way to amend Stark as health care reform continues to move forward. For the first time ever, in August of 2006, CMS made use of its annual update to the Physician Fee Schedule to address Stark's in-office ancillary services exception.¹⁷⁷ Amending Stark through the Physician Fee Schedule "allows the agency to avoid the cumbersome process of omnibus rulemaking."¹⁷⁸ Consequently, since the 2006 Physician Fee Schedule, CMS has introduced changes to Stark in almost every subsequent yearly update.¹⁷⁹ Thus, based on this recent history, it is reasonable to anticipate that future amendments to Stark will continue to be made in this manner.

Few would disagree that Stark has become increasingly complex over the years. It seems that with Congress's good faith attempt to clarify the statute via amendment, new ambiguities and complexities have been created. Even former Representative Fortney "Pete" Stark has been quoted as saying that "he would favor repealing the law as it currently exists and getting back to the law's initial intent."¹⁸⁰ Mr. Stark laments the current complexities of the statute and claims "those complications were added by high-priced lawyers who tried to build loopholes for their clients."¹⁸¹ Instead, Mr. Stark reiterates that the law was meant to go after people "who are soliciting referrals, and offering kickbacks and special rates."¹⁸²

Unfortunately, the current Stark Law does more than just go after those "who are soliciting referrals and offering kickbacks and special rates." It reads as follows:

175. *Id.*

176. *Id.*

177. Robert C. Homchick & Kim Harvey Looney, *Back to the Drafting Table: How Stark Has Changed Contracting Risks*, AM. HEALTH LAWYERS ASS'N 3, https://www.healthlawyers.org/events/programs/materials/documents/phy12/papers/o_homchick_looney.pdf (last visited Aug. 20, 2016).

178. *Id.*

179. *Id.*

180. Joe Carlson, *Pete Stark: Repeal the Stark Law*, VITAL SIGNS (Aug. 2, 2013), <http://www.modernhealthcare.com/article/20130802/blog/308029995>.

181. *Id.*

182. *Id.*

(1). . . [I]f a physician (or an immediate family member of such physician) has a *financial relationship* with an entity . . . , then—

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a [prohibited]referral . . . (2)For purposes of this section, a *financial relationship* of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is—

(A) . . . an ownership or investment interest in the entity, or

(B) . . . a compensation arrangement between the physician (or an immediate family member of such physician) and the entity.¹⁸³

On its face, it goes beyond its original intent of punishing physicians who have an ownership or interest in an entity to which it refers Medicare and Medicaid patients by delving into the physician compensation arena. By inserting physician compensation arrangements into the statute's definition of "financial relationship," some critics argue that Congress went beyond the scope of the statute's original intent.¹⁸⁴ On the other hand, other critics state that this compensation arrangement prohibition was meant "to prevent the law from being circumvented by contractual structures that did not involve equity but gave physicians the benefits of ownership."¹⁸⁵ Whether outside the scope or not, at the very least, inclusion of the compensation arrangement prohibition is proof of the federal government's distrust of physicians.

Although there is a bona fide employment relationship exception that allows physician compensation arrangements, the exception is laced with complexity. It reads as follows:

183. 42 U.S.C. § 1395nn(a) (2010) (emphasis added).

184. SENATE FINANCE COMM. MAJORITY STAFF REP., *Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models* 4 (June 2016), <http://www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff%20063016.pdf>.

185. *Id.*

Any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for the provision of services if—

- (A) the employment is for *identifiable services*,
- (B) the amount of the *remuneration* under the employment—
 - (i) is consistent with the fair market value of the services, and
 - (ii) *is not determined* in a manner that takes into account (directly or indirectly) the *volume or value of any referrals* by the referring physician,
- (C) the remuneration is provided pursuant to an agreement which would be *commercially reasonable* even if no referrals were made to the employer, and
- (D) the employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.¹⁸⁶

As written, the physician compensation arrangement exception is dependent on a myriad of fact-dependent elements. Terms such as “fair market value,” “not determined [by] the volume or value of any referral,” and “commercially reasonable” require that “parties . . . prove that their arrangement fits into the exception at trial” as questions of fact cannot be resolved in a motion for summary judgment or a motion to dismiss.¹⁸⁷ This fact-dependent exception places a burden on hospitals, as litigation is extremely costly and leads to unpredictable outcomes.¹⁸⁸ Legal practitioners and hospital administrators may feel that they are constantly walking on minefields each time they enter into a compensation agreement with a physician because of the degree of ambiguity found in such terms.

Although CMS would probably never admit to it, its relaxed enforcement of Stark may be indicative that it finds Stark as unreasonably complex, ambiguous, and daunting as others in the health care industry. It may also be indicative that it “lacks the resources to

186. 42 U.S.C. § 1395nn(b)(e)(2) (2010) (emphasis added).

187. SENATE FINANCE COMM. MAJORITY STAFF REP., *supra* note 184, at 5.

188. *Id.* at 17.

enforce Stark more aggressively.”¹⁸⁹ Since 1998, CMS has only issued twenty-eight advisory opinions, with fifteen of these relating to specialty hospital moratoriums.¹⁹⁰ A substantial majority of Stark enforcement actions are not initiated by CMS, but private whistleblowers.¹⁹¹ From a random “review of approximately 100 public legal actions involving allegations of Stark violations, all but two were either initiated or filed by whistleblowers.”¹⁹² In addition, CMS has lagged in addressing Stark violations via its self-disclosure protocol. By January 12, 2015, for example, it had “received 529 disclosures” but only resolved 128 of them.¹⁹³ These facts combined point to CMS’ limited ability to enforce a very complex law.

4. *Comparisons Between the Anti-Kickback Statute and Stark*

Many comparisons can be made between the Anti-Kickback Statute and Stark. When Stark was originally enacted, the Anti-Kickback Statute’s ability to effectively target physician self-referral was questioned.¹⁹⁴ Representative Stark believed that “the Anti-Kickback Statute, which . . . require[d] a showing of intent, was too weak to adequately regulate self-referrals.”¹⁹⁵ However, the Anti-Kickback Statute is now more sophisticated than it was in 1989.

Although the table below provides a comparison between the Anti-Kickback Statute and Stark, several features of the Anti-Kickback Statute are worth highlighting. First, the Anti-Kickback Statute is applicable to all federal health care programs,¹⁹⁶ whereas Stark is only applicable to the Medicare and Medicaid programs.¹⁹⁷ Second, the Anti-Kickback

189. Mark S. Raspani & Sarah R. Lavelle, *Who is Enforcing the Stark Law of the United States?*, AHLA CONNECTIONS 24, 26 (Sept. 2012), http://www.falseclaimsact.com/wp-content/uploads/2013/02/feature_sept20121.pdf.

190. *Advisory Opinions*, CTRS. FOR MEDICARE AND MEDICAID SERVS., https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html (last visited Aug. 21, 2016).

191. Raspani, *supra* note 189, at 25.

192. *Id.* at 28.

193. Martin Merritt, *CMS Self-Disclosure Protocol: Good Intent, Bad Process*, PHYSICIANS PRACTICE (March 29, 2015), <http://www.physicianspractice.com/blog/cms-self-disclosure-protocol-good-intent-bad-process>.

194. See generally Irwin “Ham” Wagner, *The Difficulty of Doing Business with Stark in an Ever-Changing and Overly Complex Regulatory Environment: After Twenty Years, Where Are We Heading?*, 19 ANNALS HEALTH L. 241, 243–44 (2010).

195. Nicholas J. Diamond, *Giving Disclosure Its Due: Proposal For Reforming The Stark Law*, 16 DEPAUL J. HEALTH CARE L. 1, 8 (2014).

196. 42 U.S.C. § 1320a-7b(b) (2010).

197. *Id.* at § 1395nn (2016).

Statute's "knowing and willful" intent requirement has been relaxed.¹⁹⁸ It is now sufficient to prove that defendant "knowingly and willfully" intended to violate the law; not that defendant "knowingly and willfully" intended to violate the Anti-Kickback Statute.¹⁹⁹ This lowering of the "knowing and willful" standard has increased the Anti-Kickback Statute's reach. Third, civil penalties are now available under the Anti-Kickback Statute in addition to the original criminal penalties.²⁰⁰ Fourth, violations of the Anti-Kickback Statute can now be prosecuted under the False Claim Act.²⁰¹ Lastly, because the Anti-Kickback Statute prohibits "offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate federal health care program business,"²⁰² the physician compensation arm of Stark appears redundant as any remuneration that is tied to the value or volume of business is already an illegal remuneration under the Anti-Kickback Statute.²⁰³

198. *Id.* at § 1320a-7b(h) (2010).

199. *Id.* (noting that "[w]ith respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.").

200. See Social Security Act § 1128A(a)(7) (2010), 42 U.S.C. § 1320a-7a (2015); see also § 1128B(b), 42 U.S.C. § 1320a-7b (2015). Under the Civil Monetary Penalties provision, the Office of Inspector General may impose civil penalties for violations of the Anti-Kickback Statute. The penalties are up to \$50,000 per violation plus three times the amount of the remuneration. Violation of the Anti-Kickback Statute may also lead to exclusion from Federal health care programs.

201. See False Claims Act, 31 U.S.C. §§ 3729-3733 (2010).

202. 42 U.S.C. § 1320a-7b (2015).

203. See *Special Fraud Alert: Laboratory Payments to Referring Physician*, OFF. OF THE INSPECTOR GEN. (June 25, 2014), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG_SFA_Laboratory_Payments_06252014.pdf.

Comparison of the Anti-Kickback Statute and Stark Law²⁰⁴

	Anti-Kickback Statute	Stark
Prohibition	Prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal health care program business	<ul style="list-style-type: none"> Prohibits a physician from referring Medicare patients for designated health services to an entity with which the physician (or immediate family member) has a financial relationship, unless an exception applies Prohibits the designated health services entity from submitting claims to Medicare for those services resulting from a prohibited referral
Referrals	Referrals from anyone	Referrals from a physician
Items/Service	Any items or services	Designated health services
Intent	Intent must be proven (knowing and willful)	<ul style="list-style-type: none"> No intent standard for overpayment (strict liability) Intent required for civil monetary penalties for knowing violations
Penalties	<u>Criminal:</u> <ul style="list-style-type: none"> Fines up to \$25,000 per violation Up to a 5 year prison term per violation <u>Civil/Administrative:</u> <ul style="list-style-type: none"> False Claims Act liability Civil monetary penalties and program exclusion Potential \$50,000 CMP per violation Civil assessment of up to three times amount of kickback 	<u>Civil:</u> <ul style="list-style-type: none"> Overpayment/refund obligation False Claims Act liability Civil monetary penalties and program exclusion for knowing violations Potential \$15,000 civil monetary penalties for each service Civil assessment of up to three times the amount claimed
Federal Health Care Programs	All	Medicare/Medicaid ²⁰⁵

204. This table is taken directly, and adapted only in part, from the Office of Inspector General's Health Care Fraud Prevention and Enforcement Action Team (HEAT). OFF. OF THE INSPECTOR GEN., <https://oig.hhs.gov/compliance/provider-compliance/training/files/StarkandAKSChartHandout508.pdf> (last visited Aug. 21, 2016).

205. *Id.*

An important aspect to note regarding the comparison chart above is that existing penalties under Stark have the potential to be more draconian than they are under the Anti-Kickback Statute. For example, “if a hospital has a non-compliant financial arrangement with a physician, all Medicare payments . . . from that physician are ‘overpayments’ and must be returned, regardless of the amount of the ‘tainted’ transaction, or nature of the payment.”²⁰⁶ In contrast, an application of the Anti-Kickback Statute to the same scenario would yield to liability “resulting from” the kickback, and thus, arguably more commensurate to the degree of violation.²⁰⁷ Although this may be perceived as an argument in support of retaining the compensation arm of Stark, the opposite is true. It is impossible for health care providers to comply with a law that is unpredictable in its application and draconian in its enforcement. Under Stark, well-meaning health care providers are exposed to a degree of liability that goes beyond the scope of the statute’s original intent. In contrast, the Anti-Kickback Statute is the better tool in protecting against prohibited referrals because, in addition to yielding penalties that are more commensurate with violations, it allows for criminal penalties, too²⁰⁸—something that Stark is unable to do. In addition, the Anti-Kickback Statute can result in civil monetary damages of up to \$50,000 per violation, whereas Stark can only result in civil monetary damages of up to \$15,000 per violation.²⁰⁹

As of late, the Office of Inspector General (OIG) has taken a keen interest in physician compensation arrangements. In June of 2015, the OIG published a fraud alert targeting them.²¹⁰ The alert specifically states that “a compensation arrangement may violate the Anti-Kickback statute if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business” and that serious criminal, civil, and administrative penalties will follow “[t]hose who commit fraud involving Federal health care programs.”²¹¹ This alert brings to the forefront two important realities. First, the OIG is intent on spending time and resources investigating physicians and their compensation agreements. Because the alert makes

206. SENATE FINANCE COMM. MAJORITY STAFF REP., *supra* note 184, at 5.

207. *Id.*

208. Table, *supra* note 204.

209. *Id.*

210. Office of the Inspector General, *Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability*, U.S. DEPT. OF HEALTH AND HUMAN SERVICES (June 9, 2015), http://oig.hhs.gov/compliance/alerts/guidance/Fraud_Alert_Physician_Compensation_06092015.pdf.

211. *Id.*

reference to the OIG reaching settlements with twelve physicians who were found to be receiving improper remuneration, it is clear that physician compensation will continue to be a matter of great scrutiny by the federal government.²¹² Second, the compensation received by the twelve physicians highlighted in the alert was deemed an illegal remuneration under the Anti-Kickback Statute,²¹³ not Stark. There would have been no additional need to apply Stark inasmuch as violations of the Anti-Kickback Statute trigger application of the False Claim Act.²¹⁴ In this instance, it appears the federal government chose the Anti-Kickback Statute as its tool of choice because it provides for a wider array of penalties than Stark. In this case, Stark was duplicative and unnecessary.

II. THE NATURE OF ALTERNATIVE PAYMENT MODELS AND MACRA

The American health care system's fee-for-service model has fostered certain unwanted behaviors while failing to foster other more desirable ones. First, in a fee-for-service world, health care providers are encouraged to deliver more services as long as the payment received for each service exceeds the provider's cost of delivery.²¹⁵ The practice of "defensive medicine" has further contributed to this pre-disposition as health care providers feel forced to deliver more services, not less, as a shield against lawsuits.²¹⁶ Compounding this lack of control in the volume of services delivered is the fact that the fee-for-service model lacks built-in mechanisms to counteract this behavior and discourage the delivery of unnecessary services.²¹⁷ Second, the propensity towards providing more services fosters an individualistic approach to the practice of medicine and does not encourage collaboration between health care professionals.²¹⁸ In fact, collaboration is usually avoided in the fee-for-service world as it may decrease the volume of services any

212. *Id.*

213. *Id.*

214. 42 U.S.C. § 1320a-7b(g) (2016).

215. Simon Stevens, *Farewell to Fee-For-Service? A "Real World" Strategy for Health Care Payment Reform*, UNITED HEALTH CTR. FOR HEALTH REFORM & MODERNIZATION 6 (Dec. 2012).

216. Julie Barnes, *Moving Away from Fee-For-Service*, THE ATLANTIC (May 7, 2012), <http://www.theatlantic.com/health/archive/2012/05/moving-away-from-fee-for-service/256755/>.

217. *Id.*

218. *Why Incentives Matter: Fee for Service*, HEALTH CARE INCENTIVES IMPROVEMENT INST., <http://www.hci3.org/thought-leadership/why-incentives-matter/fee-for-service> (last visited Aug. 18, 2016).

given health care professional provides.²¹⁹ Third, in a fee-for-service model, paying separate fees to different providers for each individual service leads to service gaps, duplication of services, and numerous other service inefficiencies due to the fragmented and uncoordinated nature of the system.²²⁰ Lastly, payment for health care services is not tied to the quality of those services.²²¹ In the fee-for-service system, the payment for a service remains the same regardless of the quality of the service.²²² Thus, health care providers are not held accountable to the original source of their compensation (i.e. Medicare, Medicaid, private insurance companies) for the quality, or lack thereof, of the services they provide. In CMS's own words, under a traditional fee-for-service system "... many Medicare payments to providers [are] tied only to volume, rewarding providers based on how many tests they ran, how many patients they saw, or how many procedures they did, for example, regardless of whether these services helped (or harmed) the patient."²²³

With a mounting body of evidence over the years showing that the traditional fee-for-service model no longer works, CMS has, in its own words, poised itself as "[beginning] to transform itself from a passive payer of services into an active purchaser of higher quality, affordable care."²²⁴ As a consequence, during the last decade, CMS has been experimenting with several alternative payment models and testing them in different markets across the country. Namely, CMS has instituted the Medicare Shared Savings (MSSP) Accountable Care Organizations (ACO), Bundled Payments for Care Improvement (BPCI) Initiative, Comprehensive Care for Joint Replacement Model (CJR), Oncology Care Model (OCM), End-Stage Renal Disease (ESRD) Quality Incentive Program (QIO), Pioneer Accountable Care Organization (ACO) Model, Next Generation ACO Model, and Health Care Innovation Awards Round Two Demonstration Program, amongst others.²²⁵ Although each program has its own unique aspects, the one denominator they all have in

219. *Id.*

220. Stevens, *supra* note 215, at 6.

221. *Id.*

222. *Id.*

223. CTRS. FOR MEDICARE AND MEDICAID SERVS., *supra* note 33.

224. *Roadmap for Implementing Value-Driven Health care in the Traditional Medicare Fee-for-Service Program*, CTRS. FOR MEDICARE AND MEDICAID SERVS. 1, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/VBPRoadmap_OEA_1-16_508.pdf (last visited Aug. 20, 2016).

225. *Overview of Select Alternative Payment Models*, CTRS. FOR MEDICARE AND MEDICAID SERVS., <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-03.html> (last visited Aug. 18, 2016).

common is that payments are directly tied to the following two outcomes: quality of care and lower costs.²²⁶

While many of these alternative payment models have not been fully tested, to date, CMS reports several significant results. For example, “in 2014 alone, Medicare ACOs improved quality and patient experience markedly over previous years and saved over \$411 million for the program.”²²⁷ In addition, “the Independence at Home Demonstration improved quality of care . . . and saved \$3,000 per Medicare beneficiary on average.”²²⁸ Moreover, the Comprehensive Care for Joint Replacement Model is on track to provide a combined savings of \$153 million over five years.²²⁹ These are just a few of the many positive outcomes that voluntary alternative payment plans have the potential to achieve. Consequently, the positive results of these programs led the way, at least in part, to the passage of an across-the-board bill making quality of care and lower costs factors inextricably tied to all Medicare payments: the Medicare Access and CHIP Reauthorization Act of 2015²³⁰ (MACRA).

Although the passage of MACRA was well-received by a substantial majority of health care professional groups,²³¹ it was not well-received

226. *Id.*

227. CTRS. FOR MEDICARE AND MEDICAID SERVS., *supra* note 33.

228. *Id.*

229. McDermott & Consulting LLC, *Medicare Announces First Mandatory Bundled Payment Model: Comprehensive Care for Joint Replacement*, INSIGHTS (July 14, 2015), <http://www.mcdermottplus.com/news/medicare-announces-first-mandatory-bundled-payment-model-comprehensive-care-for-joint-replacement>.

230. Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 116-10, 129 Stat. 87 (2015).

231. Greg Phillips, *Statement by AARP CEO on Senate Passage of Medicare and CHIP Reauthorization Act of 2015*, AARP (Apr. 15, 2015), <http://www.aarp.org/about-aarp/press-center/info-04-2015/medicare-and-chip-reauthorization-act-of-2015.html>; Robert Wergin, *Family Physicians Applaud Passage Of Medicare Access and CHIP Reauthorization Act*, AM. ACAD. OF FAMILY PHYSICIANS (Apr. 14, 2015), <http://www.aafp.org/media-center/releases-statements/all/2015/statement-medicare-access-chip-reauthorization-act.html>; *ACOG Statement on Senate Passage of the Medicare Access and CHIP Reauthorization Act*, AM. CONG. OF OBSTETRICIANS AND GYNECOLOGISTS (Apr. 15, 2015), <https://www.acog.org/About-ACOG/News-Room/Statements/2015/ACOG-Statement-on-Senate-Passage-of-the-Medicare-Access-and-CHIP-Reauthorization-Act>; *ADA Applauds Passage of the Medicare Access and CHIP Reauthorization Act*, ACAD. OF DOCTORS OF AUDIOLOGY <http://www.audiologist.org/latest-news-archive/1403-ada-applauds-passage-of-the-medicare-access-and-chip> (last visited Aug. 18, 2016); *Statement on Passage of Medicare and CHIP Reauthorization Act of 2015*, PREMIER INC. (Apr. 15, 2015), <https://www.premierinc.com/statement-on-passage-of-medicare-access-and-chip-reauthorization-act-of-2015/>; *Statement by Rich Umbdenstock, President and CEO of the American Hospital Association*, AM. HOSP. ASSN. (Apr. 15, 2015),

by all.²³² Nevertheless, it was historic to witness more than 750 physician membership organizations subscribe to the repeal of the SGR growth rate and endorse the new payment models outlined in MACRA with the goal of aligning payments with value.²³³ It was also historic to have the bill pass overwhelmingly in both the House of Representatives with a 392–37 vote²³⁴ and the Senate with a 92–8 vote.²³⁵ After signing the bill into law, President Obama stated that MACRA “more directly rewards providers for better-quality care [and] . . . creates incentives to encourage physicians to participate in new, innovative payment models that could further reduce the growth in Medicare spending while preserving access to care.”²³⁶

According to CMS, MACRA allows for a flexible payment system that enables health care providers to choose from two different methods of payment: the Merit-Based Incentive Payment System (MIPS) and the Advanced Alternative Payments Models (APMs).²³⁷ Eligible professionals under the MIPS program will be measured based on four factors: quality of service provided, resource use, clinical practice improvement activities, and meaningful use of certified Medicare Electronic Health Record Technology.²³⁸ Physicians who choose MIPS must report their performance measures to CMS.²³⁹ Based on their total scores, physicians who score low will be paid a reduced fee.²⁴⁰ Those who score high will be rewarded with a bonus.²⁴¹ There will

http://www.aha.org/presscenter/pressrel/2015/150415-pr-reauthorization.shtml?ref=rss_presscenter.

232. *American Society of Plastic Surgeons Responds to Medicare and CHIP Reauthorization Act* (Apr. 15, 2015), <http://www.plasticsurgery.org/news/2015/american-society-of-plastic-surgeons-responds-to-the-passage-of-hr2.html>.

233. Bob Doherty, *SGR Repeal and MACRA: Here's Why it is Remarkable*, MEDPAGE TODAY'S KEVIN MD (Apr. 16, 2015), <http://www.kevinmd.com/blog/2015/04/sgr-repeal-and-macra-heres-why-its-remarkable.html>.

234. 161 CONG. REC. H51 (daily ed. Mar. 26, 2015) (regarding the consideration of H.R.2, Medicare Access and CHIP Reauthorization Act of 2015).

235. 161 CONG. REC. S52 (daily ed. Apr. 14, 2015).

236. Press Release, The White House Office of the Press Sec'y, Statement by the President on the Passage of a Permanent Fix to the Medicare Physician Payment System, (Apr. 14, 2015) (on file with author).

237. *Quality Payment Program: Delivery System Reform, Medicare Payment Reform, & MACRA*, CTBS. FOR MEDICARE AND MEDICAID SERVS., <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html> (last visited Aug. 18, 2016).

238. *Id.*

239. Steven Findlay, *Medicare's New Physician Payment System: A 2015 Law has the Potential to Transform How Medicare Pays Physicians*, HEALTH AFFAIRS 3 (Apr. 21, 2016), http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_156.pdf.

240. *Id.*

be a limit as to how high or low a bonus can be with maximum bonuses and penalties set at “4 percent in 2019, 5 percent in 2020, 7 percent in 2021, and 9 percent in 2022 and beyond.”²⁴²

Alternatively, physicians may choose to be paid for their services based on an APMs model.²⁴³ Some examples of approved APMs under MACRA are: accountable care organizations (ACOs), patient centered medical homes, and bundled payments models.²⁴⁴ Regardless of which model is chosen, a physician’s services need to be measured based on the quality of care provided and overall spending.²⁴⁵ Physicians participating in APMs “may be eligible for an annual lump-sum bonus payment equal to 5 percent of their prior year’s payments for [their] professional services.”²⁴⁶ Additional benefits for APM participants include “exemption from the MIPS [program] and, beginning in 2026, receipt of a higher annual payment update under the Medicare Physician Fee Schedule than those clinicians who do not significantly participate in an Advanced APM (0.75 percent vs. 0.25 percent).”²⁴⁷

Proposed regulations for MACRA were published by CMS in April 28, 2016.²⁴⁸ A final rule is expected by November 1, 2016.²⁴⁹ Because final regulations are pending, the MIPS and APMs payment models have not yet been implemented. Instead, “[b]etween 2016 and 2019, MACRA will give physicians a fee increase of 0.5 percent per year.”²⁵⁰ Thereafter, starting in 2020, these systematic fee increases will be eliminated and physicians will be asked to choose which MACRA payment model they wish to participate in.²⁵¹ However, physicians participating in MIPS need to keep track and submit their performance measures to CMS starting in January 2017.²⁵² Payments for those measures will take place in 2019.²⁵³

241. *Id.*

242. *Id.*

243. Quality Payment Program, *supra* note 237.

244. *Id.*

245. *Id.*

246. Robert F. Atlas, David B. Tatge & Lesley R. Yeung, *All About APMs: What Will It Take for Physicians to Earn the APM Bonus Under MACRA?*, EPSTEIN, BECKER & GREEN 1 (June 2016), <http://www.ebglaw.com/content/uploads/2016/06/HCLS-Client-Alert-All-About-APMs.pdf>.

247. *Id.* at 2.

248. 42 C.F.R. §§ 414, 495 (2016).

249. *Physician Payment Reform Under MACRA*, ISSUE BRIEF 1 (July 15, 2016), <http://www.aha.org/content/16/16macraissuebrief.pdf>.

250. Findlay, *supra* note 239, at 3.

251. *Id.*

252. *Notice of Proposed Rule-Making, Quality Payment Program, Medicare Access and CHIP Reauthorization Act*, CTRS. FOR MEDICARE AND MEDICAID SERVS., <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment->

III. THE PRESENT MISALIGNMENT BETWEEN STARK AND MACRA

The federal government's challenge is to find a way to harmonize new laws born out of the present payment reform movement, such as MACRA, and entrenched laws born out of the more antiquated and constrained fee-for-service world, such as Stark's physician compensation prohibitions. To date, all of the alternative payment models that have preceded MACRA have been issued a CMS waiver that frees them from the constraints of Stark.²⁵⁴ In contrast, neither MACRA nor CMS's proposed MACRA regulations provide any additional waivers to Stark enforcement. Yet, the existing waivers "do not protect all of the APMs under MACRA nor do they protect APMs that are implemented by commercial payers."²⁵⁵ Instead, MACRA mandates that the Secretary of the Department of Health and Human Services conduct a study and prepare a report on fraud and abuse within the Medicare program and how it relates to MACRA's alternative payment models.²⁵⁶ The study is to "identify aspects of [MACRA's] alternative payment models that are vulnerable to fraudulent activity and consider the implications of waivers of federal fraud prevention laws in support of such alternative payment models."²⁵⁷ More importantly, the report is to make recommendations regarding suggested changes to federal fraud and abuse laws to enable the proper implementation of MACRA's alternative payment models.²⁵⁸ This report is due to Congress on April 15, 2017—two years after MACRA's enactment.²⁵⁹

A. Stark and MACRA: Why They Don't Get Along

For years, the health care industry has been clamoring for changes to Stark. In 2009, the Public Interest Committee of the American Health

Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/NPRM-QPP-Fact-Sheet.pdf (last visited Aug. 20, 2016).

253. *Id.*

254. *See, e.g.*, Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. 66725 (Oct. 29, 2015) (to be codified at 42 C.F.R.).

255. Rodney L. Whitlock, Laurence J. Freedman & Jordan T. Cohen, *Senate Committee Releases Report on Potential Stark Law Changes, Hearing Scheduled*, MINTZ LEVIN COHN FERRIS GLOVSKY AND POPEO (July 7, 2016), <http://www.lexology.com/library/detail.aspx?g=3bdcd8f-ed66-4673-a4ae-bf0f65b19a8d>.

256. Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, § 101(e)(7), 129 Stat. 128 (2015).

257. *Id.*

258. *Id.*

259. *Id.*

Lawyers Association convened to discuss Stark and its effects on the health care industry as a whole.²⁶⁰ Referred to as a "Convener on Stark Law," participants from a cross-section of the health care community were asked to address three areas of inquiry: (1) whether Stark was working as originally intended; (2) Stark's impact on the industry and the benefits and challenges it has brought forth; and (3) ways to improve Stark.²⁶¹ While Convener participants lauded Stark for contributing to the development of corporate compliance programs and restricting physician investment in health care enterprises, they enumerated a series of unintended consequences that appeared to be doing more harm than good.²⁶² Even though Stark was intended to provide a bright line test limiting physician self-referral,²⁶³ Convener participants agreed that Stark's application has "yielded few bright lines."²⁶⁴ Stark's "vast array of exceptions . . . have driven the restructuring of the healthcare delivery system and in some cases created either an unlevel playing field or unclear boundaries."²⁶⁵ In addition, "[a]rrangements such as pay-for-performance, shared savings and bundled payments are frequently problematic under the Stark law because they may not fit squarely within any existing exception."²⁶⁶ Convener participants went on to state that non-compliance under Stark is unavoidable as even the most well-intended health care provider is unable to wrap her head around its many complexities and draconian strict liability provisions.²⁶⁷ Lastly, regardless of whether a Stark violation is technical or non-technical, the resulting liability, when coupled with the might of the False Claims Act, leads to penalties that are substantially disproportional to the prohibited conduct.²⁶⁸

At a time when MACRA "encourages providers to create larger organizations that can coordinate care in pursuit of greater quality and

260. AM. HEALTH LAWYERS ASS'N PUB. INTEREST COMM., *supra* note 142, at 1:

The purpose of the Convener Session was to provide a forum for a candid discussion of the efficacy of the federal physician self-referral statute or Stark Law and to consider what, if any, changes to the Law might be beneficial in light of both the current structure of the healthcare delivery system and pending healthcare reform proposal.

Id.

261. *Id.* at 1-2.

262. *Id.* at 2-3.

263. See 135 CONG. REC. H240-01 (daily ed. Feb. 9, 1989) (statement of Rep. Stark); 66 Fed. Reg. 856, 860 (Jan. 4, 2008).

264. AM. HEALTH LAWYERS ASS'N PUB. INTEREST COMM., *supra* note 142, at 3.

265. *Id.*

266. *Id.*

267. *Id.*

268. *Id.*

efficiency.”²⁶⁹ Stark holds health care providers back with a blanket prohibition of physician financial relationships unless a physician relationship fits perfectly within one of its exceptions.²⁷⁰ Though the exceptions are numerous, they are subject to complex criteria and significant regulatory interpretation. Some characterize the exceptions as illusory because each exception is dependent on factual determinations that would ultimately have to be proven at trial.²⁷¹ Because many of the terms used in the exceptions—such as “fair market value” and “commercially reasonable”—are ambiguous, a determination as to whether or not the facts of any given financial relationship meet the criteria of an exception leads to many inconsistent and unpredictable results.²⁷² As a consequence, Stark discourages innovation in health care due to fears of potential non-compliance. This fear of entering into a prohibited financial relationship has the effect of encouraging health care providers to work separately and not in a coordinated, patient-centered manner as required by MACRA.

B. The Health Care Industry Stakeholders Speak-Up

The Senate Finance Committee and the House Committee on Ways and Means has taken a keen interest on the needed steps, if any, towards reforming Stark. On December 10, 2015, both Committees hosted a roundtable composed of health care industry leaders to discuss Stark in light of the new alternative payment models under the Affordable Care Act and MACRA.²⁷³ Thereafter, the Committees extended an invitation to all health care industry stakeholders to submit written comments regarding Stark’s challenges and suggested changes.²⁷⁴ In response to this request for comment, the Committees received almost fifty responses suggesting numerous changes to Stark.²⁷⁵ A representative cross-section of the recommendations received are categorized as follows:

269. Joe Carlson, *Pulled in Two Directions: Providers Pursuing Coordinated Care Confused by Antitrust Actions*, 42 (51) MODERN HEALTHCARE 1, 6, 7, 16 (Dec. 15, 2012).

270. See 42 C.F.R. Subpart J, § 411.355 *et seq.* (2016) (providing for ten general exceptions and numerous other exceptions for certain ownership and investment interests and compensation arrangements).

271. SENATE FINANCE COMM. MAJORITY STAFF REP., *supra* note 184, at 5.

272. *Id.*

273. *Id.* at 1.

274. James Swann, *Lawmakers Consider Changes to Physician Self-Referral Law*, BLOOMBERG’S HEALTH CARE DAILY REPORT (Feb. 1, 2016), <http://www.bna.com/lawmakers-consider-changes-n57982066790/>.

275. Press Release, U.S. Senate Comm. on Fin., Hatch Statement on Finance Hearing on the Stark Law (July 12, 2016) (on file with author).

1. Repeal Stark. Several respondents recommended that Stark be repealed in its entirety. The American College of Gastroenterology, for example, described Stark as an antiquated law and stated that it “has run its course and is actually hindering the drive toward better coordinated and cost-effective care.”²⁷⁶ The letter went on to say that its members are “fearful to adopt new and innovative methods of health care delivery as they may trigger some gray areas of this antiquated law.”²⁷⁷ The letter noted that “the fact that the Stark Law is outdated is demonstrated by the ongoing need to continue adding “exceptions” to the rule each time CMS implements a new coordinated-care payment model authorized by Congress.”²⁷⁸ Interestingly, all respondents who suggested Stark be repealed also provided, in the alternative, several non-repeal options, signaling to the reader no hope in a repeal but, at best, only modifications.

2. Repeal the Compensation Arrangement Arm of Stark. Other respondents, such as the American Osteopathic Association (AOA), recommended only a repeal of the physician compensation arrangement arm of Stark, while leaving intact the ownership or investment interest portion of the law.²⁷⁹ The letter refers to Stark as a “complicated legal web” that creates a conundrum for those physicians who find themselves in a blended payment framework wherein a portion of their compensation emanates from a traditional fee-for-service environment while the remaining portion is generated from participation in an APM.²⁸⁰ The question posed by the organization is, “[e]ven if ‘carve-outs’ to Stark restrictions are created for the APM portion of a participating physician’s practice, will his or her remaining fee-for-service arrangement still be subject to the [Stark] law?”²⁸¹ The AOA is vehement about repealing the entire compensation arrangement arm of the law, stating that only modifying it will only add more layers of complexity and uncertainty to an already complex and confusing law.²⁸² The letter ends by arguing that “hav[ing] two sets of requirements for fee-for-service and for APMs under MACRA will be very difficult, and

276. Letter from the Am. Coll. of Gastroenterology to the Senate Comm. on Fin. and the House Comm. on Ways and Means, at 1 (Feb. 3, 2016) (on file with author).

277. *Id.*

278. *Id.* at 2.

279. Letter from the Am. Osteopathic Ass’n to the Senate Comm. on Fin. and the House Comm. on Ways and Means, at 2 (Jan. 29, 2016) (on file with author).

280. *Id.* at 1.

281. *Id.* at 2.

282. *Id.*

could inhibit or dissuade physicians from taking the risk to transition to these new arrangements.”²⁸³

The Medical Group Management Association, another group that favors the repeal of the compensation arrangement arm of Stark, notes in its response that nothing in the last twenty years has given anyone hope that the compensation provisions of Stark can ever be improved.²⁸⁴ In reference to Stark’s prohibition against certain compensation arrangements, it states that “despite countless rule-makings at CMS, each of which identified legitimate problems with the regulations and attempted to fix them, the regulatory scheme has grown in complexity to the point where it is beyond comprehension to the average physician or health care administrator.”²⁸⁵

The American Urological Association (AUA) does not go as far as to request the repeal of the compensation arrangement arm of Stark but does request a significant softening of its limitations.²⁸⁶ Specifically, the AUA asks that physician compensation arrangements that do not violate the Anti-Kickback Statute be deemed a technical violation of Stark and carry no penalties.²⁸⁷ In the alternative, the AUA proposes that physician compensation arrangements that violate Stark, but do not confer a financial benefit on the offending physician, be deemed a technical violation of Stark with no penalties either.²⁸⁸ The underlying theme of the AUA’s letter is that Congress needs to make much-needed changes to the law if it wishes to engage physicians to participate in the new alternative payment models.²⁸⁹

3. Create New Exceptions. Several respondents, including the American Hospital Association (AHA), recommend that Congress create a new exception. Specifically, the AHA asks that “a single, broad exception that cuts across the Stark law, the Anti-Kickback statute, and relevant [Civil Monetary Penalties] for financial relationships designed to foster collaboration in the delivery of health care and incentivize [as well as] reward efficiencies and improvements in care.”²⁹⁰ The AHA goes on to request that this new exception be enacted under the Anti-

283. *Id.*

284. Letter from the Med. Grp. Mgmt. Ass’n to the Senate Comm. on Fin. and the House Comm. on Ways and Means, at 2 (Jan. 28, 2016) (on file with author).

285. *Id.*

286. Letter from the Am. Urological Ass’n to the Senate Comm. on Fin. and the House Comm. on Ways and Means (Feb. 3, 2016) (on file with author).

287. *Id.* at 3.

288. *Id.* at 4.

289. *Id.*

290. Letter from the Am. Hosp. Ass’n to the Senate Comm. on Fin. and the House Comm. on Ways and Means, at 2 (Jan. 29, 2016) (on file with author).

Kickback Statute and that any relationships deemed compliant under this exception be automatically deemed compliant under corresponding provisions of Stark and the Civil Monetary Penalties Act.²⁹¹ The AHA's letter reminds Congress that Stark's "oversight of compensation arrangements is anchored in a fee-for-service world where physicians were self-employed, hospitals were separate entities, and both billed for services on a piecemeal basis."²⁹² As it pertains to enforcement, the AHA emphatically states that Stark should only be enforced when there is actual harm and that the government should take into account mitigating factors when a violation occurs (i.e. ". . . an innocent or unintentional mistake; the corrective action taken by the parties; whether the services provided were reasonably and medically necessary; [or] whether access to a physician's services was required in an emergency situation . . .").²⁹³

4. Broaden Existing Exceptions. Several respondents, including the Hospital and Health System Association of Pennsylvania (HAP), recommend an expansion of existing exceptions.²⁹⁴ In HAP's response, it requests that the existing statutory prepaid plan exception of Stark²⁹⁵ "be broadened so that the prohibition on referrals for designated health services . . . does not apply to services rendered by an entity that has a contract with CMS or its agent and that contemplates the use of payment models alternative to fee-for-service."²⁹⁶ HAP, in its response, echoed a continuing theme amongst all respondents; namely, that "[c]ooperative arrangements among providers will be necessary to improve quality and manage costs and the Stark Law—which is based upon the assumption that cooperative arrangements among health care providers may create incentives for overutilization—is explicitly designed to discourage such relationships."²⁹⁷

5. Expand Current Waivers. Several respondents, such as the American College of Physicians (ACP), recommend expanding the Stark waivers that already exist in the Medicare Shared Savings plan to all programs being tested by the Center for Medicare and Medicaid Innovation as well as to all value-based payment structures, including APMs, under MACRA.²⁹⁸ The ACP emphasized, like so many other

291. *Id.*

292. *Id.* at 3.

293. *Id.* at 6.

294. THE HOSP. AND HEALTH SYS. OF PA., *supra* note 32, at 5.

295. 42 U.S.C. § 1395nn(a)(3) (2016).

296. THE HOSP. AND HEALTH SYS. OF PA., *supra* note 32, at 5.

297. *Id.* at 3.

298. Letter from Wayne J. Riley, President, Am. Coll. of Physicians, to Kim Brandt, Chief Oversight Counsel, U.S. Senate, and Tegan Gelfand, Prof'l Staff Member, U.S. House of Representatives, at 3 (Feb. 3, 2016) (on file with author).

respondents did, that Stark “may impose unnecessary burdens and barriers under the value-based payment pathways, MIPS and APMs, created by MACRA . . . , [and that such] regulatory controls may inhibit approaches and innovation . . . [such as] care integration, care coordination, and patient engagement[.]”²⁹⁹

6. Expand CMS’s Authority. A significant number of respondents also requested that Congress empower CMS to create new exceptions to Stark. For example, in a letter signed by twenty-two health care organizations, it was urged that Congress give CMS the flexibility needed “to refine the regulatory landscape as the health system continues to transform and as payment models continue to evolve.”³⁰⁰ The letter noted that “[j]ust as Congress could not in 1993 foresee what exceptions might be necessary in 2016, this Congress cannot foresee how health care may be delivered years hence.”³⁰¹ In similar fashion, the American Urological Association requests that the CMS advisory opinion process be changed to grant CMS the authority to “permit financial arrangements that may otherwise violate the Stark law, but which would not cause more than a minimal risk of fraud or abuse[.]”³⁰²

7. Change, Expand, or Clarify Existing Statutory Language. A recurring theme in many of the responses is the inherent ambiguity in several terms found in Stark’s statutory language. For example, the American College of Physicians requests that Congress clarify and expand the meaning of “fair market value” under Stark.³⁰³ The Congress of Neurological Surgeons, the Society for Vascular Surgery, and the American College of Rheumatology, to name a few, recommend that Congress remove the terms “value” or “volume” from the definition of “group practice” as “this language . . . creates enormous confusion and opportunities for technical non-compliance.”³⁰⁴ The Federation of American Hospitals (FAH) requests that the “commercially reasonable” standard be eliminated as “[it] is vague and not generally well

299. *Id.*

300. Letter from Am. Acad. of Ophthalmology et al., to Orrin G. Hatch, Chairman, Comm. on Fin. and Kevin Brady, Chairman, Comm. on Ways and Means, at 2 (Feb. 5, 2016) (on file with author).

301. *Id.*

302. *Id.* Letter from Am. Urological Ass’n to Kim Brandt, Chairman, Senate Fin. Comm., and Tegan Gelfand, Chairman, House Comm. on Ways and Means, at 5 (February 3, 2016) (on file with author).

303. Letter from Thomas P. Nickles, Exec. Vice President, Am. Hosp. Ass’n, *supra* note 290, at 3.

304. Letter from Am. Acad. of Ophthalmology et al., *supra* note 300, at 2.

understood or objectively measured.”³⁰⁵ The FAH argues that “[a]ttempting to apply a vague and poorly understood standard such as commercial reasonableness [to the new alternative payment models] creates more uncertainty and is a significant barrier that threatens to chill development and implementation of these new models.”³⁰⁶ The Association of American Medical Colleges is of the mindset that including terms such as “‘fair market value,’ ‘volume or value,’ and ‘other generated business’ standards” as it relates to prohibited compensation arrangements “make[s] it difficult to structure incentive payments that reward physicians for improvements in quality and efficiency.”³⁰⁷

8. Other Relevant Recommendations. There are other recommendations made by respondents that are worth noting. The American College of Physicians requests that Congress formally request the Health and Human Services Secretary to investigate and assess all statutes and regulations that pertain to the integrity of the Medicare program to determine “the potential barriers and unnecessary burdens that these laws and regulations may place on the delivery of value-oriented care” and to make recommendations to eliminate these barriers and burdens.³⁰⁸ Numerous respondents also recommend that Congress make a distinction between technical violations and material violations, noting that technical violations should either carry no penalty or only a penalty commensurate with the harm caused, if any.³⁰⁹ Many also argue that complying with Stark is administratively costly, yet “Medicare reimbursements do not compensate these extra costs which have fundamentally nothing to do with the delivery of quality health care.”³¹⁰ Overall, the unifying theme among all the responses sent to the Senate Committee on Finance and the House Committee on Ways and Means regarding Stark can be summed up in three statements: Stark is unreasonably complex, Stark enforcement is draconian, and Stark is a serious obstacle to the implementation of alternative payment models, including those found in MACRA.

305. Letter from the Fed’n of Am. Hosp. to Orrin Hatch, Chairman, Senate Fin. Comm. and Kevin Brady, Chairman, House Comm. on Ways and Means, at 5 (Feb. 11, 2016) (on file with author).

306. *Id.*

307. Letter from the Ass’n of Am. Med. Colls. to Kim Brandt, Chief Oversight Counsel, U.S. Senate Comm. on Fin. and Tegan Gelfand, Prof’l Staff Member, House Ways and Means Comm., at 2 (Jan. 27, 2016) (on file with author).

308. Letter from Am. Coll. of Physicians, *supra* note 298, at 3.

309. THE HOSP. AND HEALTH SYS. OF PA., *supra* note 32, at 4–5.

310. Letter from the Med. Grp. Mgmt. Ass’n, *supra* note 284, at 4.

IV. HOW TO BEST ALIGN STARK AND MACRA

When determining how to reconcile Stark and MACRA, it is imperative that the principle of “business simplification” be included in the discussion. In the business world, “business simplification” can be defined as “stripping away layers of bureaucracy, letting employees do what do what they do best, and focusing the entire business network on what’s important to customers[.]”³¹¹ One of the many benefits of business simplification is that, all other things remaining equal, it has the effect of improving quality and efficiency, reducing redundancy, and reducing costs.³¹² Each time a process is simplified by the removal of unnecessary complexity, the shortcomings and challenges associated with the complexity also are removed.³¹³

In determining how to best harmonize Stark and MACRA, Congress should be guided by the principle of business simplification. The federal government’s goal should be to strip away any unnecessary layers of regulation, let health care providers do what they do best, and refocus the entire Medicare program on what is in the patients’ best interest. As Daniel A. Levinthal, a management professor at the Wharton School of Business, stated: “[a]s organizations get pulled in different ways [by numerous change agents such as technology, demand, supply, economy, or politics] there’s a natural inclination that causes them to accumulate more complex processes.”³¹⁴ This has occurred in the health care industry as changes in the economy, political landscape, demographics, scientific advancements, and technology are constant agents of change over the years and led the federal government to create more laws and regulations.³¹⁵ Stark expanded over the years via a series of legislative

311. Becky Wieber, *4 Myths, 4 Reasons: Why You Should Pay Attention to Business Simplification Now*, DIGITALIST MAGAZINE (Apr. 6, 2015), <http://www.digitalistmag.com/executive-research/4-myths-4-reasons-why-you-should-pay-attention-to-business-simplification-now>.

312. *Business Simplification 2015: The Unmet Strategic Imperative*, KNOWLEDGE@WHARTON 5 (March 2015), http://www.sap.com/bin/sapcom/en_us/downloadasset.2015-02-feb-13-21.knowledge-wharton-business-simplification-2015-the-unmet-strategic-imperative-pdf.bypassReg.html.

313. *Id.*

314. *Id.*

315. See generally Nicholas P. Vitalari, *A Prospective Analysis of the Future of the U.S. Healthcare Industry*, CTR. FOR DIG. TRANSFORMATION WHITE PAPER SERIES, THE PAUL MERAGE SCH. OF BUS., UNIV. OF CAL., IRVINE, at 1–7, <http://merage.uci.edu/ResearchAndCenters/CDT/Resources/Documents/N%20Vitalari%20A%20Prospective%20Analysis%20of%20the%20Healthcare%20Industry.pdf>; Robert I. Field, *Symposium: A Taxonomy of American Health Care Regulation: Implications for Health Reform*, 17 TEMP. POL. & CIV. RTS. L. REV. 605, 608–12, 615–21 (2008).

amendments and a piling of piecemeal regulations.³¹⁶ This continual layering of rules and regulations have added to Stark's complexity and, with it, created confusion, increased administrative burdens, and dissuaded innovation.³¹⁷ Professor Levinthal explained that, in business, such layering is meant to solve a problem or challenge in the short-term, yet the long-term costs to any system are "foregone efficiencies."³¹⁸ CMS's lax enforcement of Stark, its sizeable backlog of Stark violation self-disclosures, and its failure to provide significant guidance through its advisory opinion authority, may all be signs of a government agency that is spread too thin as it attempts to manage and enforce a law that is too complex.

One recent government action that indicates the federal government has some understanding of the importance of simplification is the administrative simplification provisions as enacted in the Patient Protection and Affordable Care Act (ACA).³¹⁹ Section 1104 of the ACA³²⁰ made significant amendments to the Health Insurance Portability and Accountability Act of 1996.³²¹ The federal government acknowledged that the average physician spends a cumulative total of three weeks per year on billing and insurance related tasks,³²² and that "two-thirds of a full-time employee per physician is necessary to conduct billing and insurance-related tasks."³²³ Thus, the goal of the administrative provisions is to reduce costs and eliminate unnecessary processes as providers, health plans, vendors, and clearinghouses exchange patient and other medical information.³²⁴ Accordingly, the ACA empowered the Secretary of Health and Human Services to create regulations to achieve the goals of the administrative simplification provisions and "to adopt standards for the electronic transmission of

316. See Letter from the Am. Urological Ass'n, *supra* note 286.

317. See AM. HEALTH LAWYERS ASS'N PUB. INTEREST COMM., *supra* note 142, at 4–5.

318. *Id.*

319. The Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 1104, 124 Stat. 119 (2010).

320. *Id.*

321. Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 100 Stat. 1936 (1996).

322. Lawrence P. Casalino et al., *What Does It Cost Physician Practices To Interact with Health Insurance Plans?*, HEALTH AFFAIRS MAGAZINE (2009), <http://content.healthaffairs.org/content/28/4/w533.full>.

323. Julie Ann Sakowski et al., *Peering Into the Black Box: Billing And Insurance Activities In A Medical Group*, HEALTH AFFAIRS MAGAZINE (2009), <http://content.healthaffairs.org/content/28/4/w544.full>.

324. See *What Administrative Simplification Does for You, eHealth*, CTRS. FOR MEDICARE AND MEDICAID SERVS., at 2, https://www.cms.gov/eHealth/downloads/Admin_Simplification_FactSheet.pdf (last visited Aug. 2, 2016).

administrative and financial information throughout the healthcare system.³²⁵

Although it is difficult to determine the exact savings achieved by the passage and implementation of the administrative simplification provisions and their accompanying regulations, it is estimated that it has resulted in a savings anywhere between \$1 billion to \$2.8 billion for the country as a whole per year.³²⁶ Many industry professionals are of the opinion that even greater savings can be achieved with additional changes that have simplification of processes and procedures as its main goal.³²⁷

Notwithstanding this great achievement in the HIPAA arena,³²⁸ the theme of simplification has been otherwise absent in the discussion of improving the quality of health care while improving costs. The legislative approach, thus far, has not been forward-thinking, but instead has consisted of good faith attempts to put a bandage on issues and challenges as they arise. This approach had led to a systematic layering of new rules and procedures to existing laws, including Stark. The most recent input received from the health care industry through the many letters received by the Senate Committee on Finance and the House Committee on Ways and Means sums up the industry's frustration with Stark, as it has gone beyond its original intent and demands substantial manpower to implement with no one individual or organization having certainty of being in compliance.

The concerns expressed by health care professionals in 2009 at the Convener on Stark Law sponsored by the Health Lawyers Association are the same concerns, seven years later, that health care professionals have today.³²⁹ On June 30, 2016, the Senate Committee on Finance published a white paper regarding the current state of Stark.³³⁰ In said publication, the Senate Committee on Finance acknowledged that despite CMS's best efforts to provide guidance, "the Stark law's breadth, complexity, and impenetrability have created a minefield for the health

325. Ninth Report to Congress on the Implementation of the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act of 1996, at 4 (May 11, 2010), <http://www.ncvhs.hhs.gov/wp-content/uploads/2014/05/100511hipaarpt.pdf>.

326. Elizabeth Wikler, Peter Basch, & David Cutler, *Paper Cuts: Reducing Health Care Administrative Costs*, CTR. FOR AM. PROGRESS, at 13 (June 11, 2012), https://cdn.americanprogress.org/wp-content/uploads/issues/2012/06/pdf/paper_cuts_intro.pdf.

327. *Id.* at 1.

328. *Id.* at 7.

329. See Carnell, *supra* note 139, at 3, 5–6.

330. SENATE FINANCE COMM. MAJORITY STAFF REP., *supra* note 184, at 1, 4.

care industry.”³³¹ In addition, the Committee acknowledged that “[t]he Stark law has become increasingly unnecessary for, and a significant impediment to, value-based payment models that Congress, CMS, and commercial health insurers have promoted.”³³² It also acknowledged that the new alternative payment models eliminate the risk of overutilization, which was the main impetus for the passage of Stark back in 1989.³³³

One of the most alarming facts highlighted in the Committee’s document pertains to the recent qui tam lawsuits and the upper hand the federal government has had in such situations.³³⁴ The Committee referred to several False Claim Act settlements in which the government deemed a loss on the profit and loss statement of several hospital-owned physician practices as *ipso facto* evidence that the physicians’ compensation were not at “fair market value” nor “commercially reasonable” and, thus, out of compliance with Stark.³³⁵ Because so many of Stark’s prohibitions are fact-specific,³³⁶ the Committee agrees that health care providers are continually at risk of having to expend an enormous amount of time and money to defend themselves in these lawsuits.³³⁷ Unfortunately, the Committee acknowledged that:

[F]or challenges based on any Stark law exceptions with AKS/Claims Requirements, a hospital would not be able to prevail on a motion to dismiss or a motion for summary judgment because resolving the Stark law claims requires the court to also determine whether the financial relationship at issue satisfies the highly fact-specific AKS/Claims Requirements[.]³³⁸

Resolving the Stark Law claims also requires making factual findings regarding “fair market value, the volume and value of referrals, and commercial reasonableness.”³³⁹ Thus, based on the Committee’s report, it appears that Congress is aware there is a problem. The question now is how to solve it.

331. *Id.* at 2.

332. *Id.*

333. *Id.*

334. *Id.* at 7.

335. *Id.*

336. *Id.*

337. *Id.* at 18.

338. *Id.* at 17.

339. *Id.*

A. Eliminate the Physician Compensation Arrangement Arm of Stark

For several reasons, the best solution in aligning Stark with MACRA's new payment models is to repeal the physician compensation arm of Stark. First, the original intent behind the enactment of Stark was to prevent the documented overutilization and abuse that occurred when physicians referred patients to ancillary service companies in which they had an ownership or investment interest.³⁴⁰ There is no evidence in the Congressional Record that Stark was meant to prohibit anything more.³⁴¹ Stark was supposed to provide a "bright-line" test to prohibit these types of physician self-referrals.³⁴² Yet, the least "bright-line" of all Stark's provisions is the physician compensation arrangement provisions.³⁴³ Time and time again, health care professionals have provided anecdotal evidence showing the complexity and ambiguity of its provisions.³⁴⁴ Terms such as "fair market value," "volume or value of referrals," "commercially reasonable," or "takes into account" have been deemed to be ambiguous, as they are factual and have been interpreted in the different ways depending on the circumstances.³⁴⁵ This inconsistency in results has led to great uncertainty in the health care community, as even the best efforts of any given health care provider does not ensure compliance.³⁴⁶

Second, repealing the physician compensation arrangement arm of Stark would instantly eliminate the corresponding headaches that this provision has caused over the years. Not only would there no longer be debates in or outside of court as to what the terms "fair market value," "volume or value of referrals," "commercially reasonable," or "takes into account" mean,³⁴⁷ but health care administrators would no longer have to invest countless hours in drafting, negotiating, researching, and discussing—most often with the assistance of costly legal counsel—how to draft a "compliant" physician compensation agreement.³⁴⁸ Most would

340. Patrick A. Sutton, *The Stark Law in Retrospect*, 20 ANNALS HEALTH L. 15, 16–18 (2011).

341. *Id.* at 23.

342. *Id.*

343. *See id.* at 33–34.

344. *See id.* at 35.

345. *See Hatch, supra* note 275, at 15.

346. *Id.* at 17.

347. *See id.* at 15.

348. *See id.* at 17; *see also* AM. HEALTH LAWYERS ASS'N PUB. INTEREST COMM., *supra* note 142, at 10–11.

agree that these resources would be best directed to activities that have a direct impact on patient care.

Third, the risk of overutilization as it pertains to physician compensation agreements is substantially eliminated by the new "alternative payment models,"³⁴⁹ such as those in MACRA.³⁵⁰ In the traditional fee-for-service model,³⁵¹ physicians are rewarded for sheer volume of services without regard for the quality of services rendered.³⁵² Under MACRA, volume is no longer part of the equation.³⁵³ Instead, physicians are rewarded for delivering quality care in a cost-efficient manner.³⁵⁴ Under this new framework, the goals of physicians become perfectly aligned with the goals of the federal government.³⁵⁵ As it pertains to physician compensation agreements, there is no longer the danger, for example, that a hospital will nicely pad a physician compensation agreement in exchange for the physician referring patients to other services offered in the hospital.³⁵⁶ In such a situation, under MACRA, a physician is incentivized to make the referral only if it will contribute to that patient's quality of care in a cost efficient manner.³⁵⁷ Under such a scenario, the physician's profit margin is not tied to volume anymore.³⁵⁸ Instead, it is tied to quality of care and cost efficiency.³⁵⁹

Fourth, the Anti-Kickback Statute today is very different from the Anti-Kickback Statute that existed when Stark was initially enacted.³⁶⁰ Presently, the Anti-Kickback Statute already protects against physicians receiving anything of value to induce or reward referrals or generate federal health care program business.³⁶¹ Such a prohibition ensures that physician compensation agreements remain arms-length transactions. In addition, the Anti-Kickback Statute has been expanded to provide for civil enforcement under the False Claims Act³⁶² and Civil Monetary Statute in addition to criminal enforcement mechanisms that already

349. See Hatch, *supra* note 275, at 2.

350. *Id.* at 3.

351. *Id.* at 1.

352. See *supra* text accompanying note 14.

353. See Medicare Access and CHIP Authorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87 (2015).

354. See *supra* text accompanying note 20.

355. See Sutton, *supra* note 340, at 16.

356. See *supra* text accompanying notes 30-33.

357. See *supra* text accompanying note 27.

358. See Hatch, *supra* note 275, at 2.

359. *Id.*

360. See *id.* at 6.

361. See *id.* at 10; see also Sutton, *supra* note 340, at 16 n.8.

362. See *supra* text accompanying note 94.

existed at the time when Stark was enacted.³⁶³ Now, any item or service that is deemed a violation of the Anti-Kickback Statute will automatically constitute a “false or fraudulent claim” under the Federal Claims Act.³⁶⁴ Similarly, violations under the Anti-Kickback Statute can amount to penalties of up to \$50,000 per violation and treble damages under the Civil Monetary Penalties Statute.³⁶⁵

To broaden the reach of the Anti-Kickback Statute, in 2010, the ACA³⁶⁶ made it clear that to satisfy the “knowledge” requirement of the statute it is not necessary to prove that the defendant knew he was violating the Anti-Kickback Statute.³⁶⁷ Instead, the ACA lowered the threshold of proof by stating that to prove the defendant possessed the requisite “knowledge,” it is only necessary to prove that defendant knew he was violating the law.³⁶⁸ In addition, the ACA mandated some changes to the United States Sentencing Commission Guidelines Manual that have led to the further strengthening of the Anti-Kickback Statute.³⁶⁹ In section 10606 of the ACA, the United States Sentencing Commission was mandated to enhance sentences for federal health care offenses based on the amount of loss, as follows: 1) a two-level increase in offense level if the loss is between \$1 million and \$7 million; 2) a three-level increase in offense level if the loss is between \$7 million and \$20 million; and 3) a four-level increase in offense level if the loss equals or exceeds \$20 million.³⁷⁰ In sum, the Anti-Kickback Statute is a much more powerful tool today than it was when Stark as enacted. As such, it has the capability needed to address any concerns or possible abuses that may arise in physician compensation agreements. Hence, the Anti-Kickback Statute has made the physician compensation provisions of Stark irrelevant.

B. Why Repealing Stark in Its Entirety is Not the Answer

Although many health care commentators have argued for the complete repeal of Stark,³⁷¹ this recommendation is ill-advised. The

363. See *supra* text accompanying note 200.

364. 42 U.S.C. § 1320a-7b(g) (2015).

365. *Id.* at § 1320a-7a(a).

366. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1, 124 Stat. 119 (2010).

367. *Id.*

368. *Id.* (stating: “[w]ith respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.”).

369. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 10606, 124 Stat. 1006-1007 (2010).

370. *Id.*

371. See *supra* Part IV.B.1.

ownership and investment interest prohibitions of Stark conform to the original intent of the statute.³⁷² Stark was enacted as a response to the overutilization of federal funds to increase physician profit margins.³⁷³ Back in the 1970's and 1980's, empirical evidence was gathered to show the increased pattern of referrals to entities in which a physician had either an ownership or investment interest.³⁷⁴ If this section of Stark was repealed today, these overutilization patterns would likely repeat themselves.

Some may argue that the Stark prohibition against ownership or investment interest is not needed due to the expansive protections of the Anti-Kickback Statute. However, the reverse is true. Stark's ownership or investment arm has strengths that the Anti-Kickback Statute does not possess. First, Stark is a strict liability statute³⁷⁵ while the Anti-Kickback Statute is not.³⁷⁶ Under the Anti-Kickback Statute, a defendant must knowingly and willfully violate the law,³⁷⁷ while under Stark, intent is irrelevant.³⁷⁸ If this arm of the statute was repealed, it could potentially create a loophole for physicians who engage in a prohibited self-referral, but against whom there is not sufficient evidence to prove the self-referral was knowing and willful.³⁷⁹ Second, when the Stark Law was enacted, the motivation behind making it a strict liability law was to create "bright lines"³⁸⁰ and, thus, dissuade physicians from engaging in self-referrals of any kind.³⁸¹ As a statute specifically targeted to physicians, its existence serves to underscore the problem inherent with self-referral and admonish physicians about the evils of engaging in such conduct.³⁸²

Another reason why Stark's ownership or investment arm need not be repealed is because, unlike Stark's physician compensation arrangement arm, it is not in contravention to the new alternative payment forms, such as those found in MACRA.³⁸³ Also, unlike Stark's physician compensation arrangement arm, it is not rife with ambiguous terms that require factual determinations and lead to inconsistent rulings

372. See *supra* text accompanying note 328.

373. *Id.*

374. See Sutton, *supra* note 340, at 17.

375. See Rumph, *supra* note 137.

376. See *supra* text accompanying note 132.

377. See 492 U.S.C. § 1320a-7b(h) (2015).

378. See *supra* text accompanying note 139.

379. See 492 U.S.C. § 1320a-7b(h) (2015).

380. See *supra* note 260 and text accompanying.

381. See *supra* text accompanying note 30.

382. See *supra* text accompanying note 31.

383. See Medicare Access and Authorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87 (2015).

when such determinations are made.³⁸⁴ This is not the arm of Stark that health care administrators deem as complex, burdensome, and incomprehensible. This is the arm of Stark that was straightforward from the beginning as it is the arm of Stark that was born from the original intent of the statute.

C. Because Time is of the Essence, Bi-Partisan Action is Needed Now

Just as Congress was united in enacting MACRA, so should Congress be united in repealing the compensation arm of Stark. Implementation of MACRA will begin in January 2017 and if these needed changes to Stark are not made, it is more likely than not that there will be weak participation in MACRA's APMs and physicians will have little buy-in into the benefits of alternative payment systems. Repealing the physician compensation arrangement arm of Stark would be an important step toward simplification and increased efficiencies.

384. See *supra* text accompanying note 349.