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The Great American Health Care System and the Dire Need for Change: Stark Law Reform As a Path To a Vital Future of Value-Based Care

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THE GREAT AMERICAN HEALTH CARE SYSTEM AND THE DIRE NEED FOR CHANGE: STARK LAW REFORM AS A PATH TO A VITAL FUTURE OF VALUE-BASED CARE

*By: Marilyn L. Uzdavines**

I.	INTRODUCTION.....	574
II.	THE HEALTH CARE CRISIS MOVES LAWMAKERS TO INCREASE FRAUD AND ABUSE ENFORCEMENT.....	578
III.	ENFORCEMENT OF HEALTH CARE FRAUD AND ABUSE LAWS SAVE BILLIONS OF DOLLARS IN THE MEDICARE AND MEDICAID PROGRAMS	583
	A. <i>The AKS as a Tool to Combat Health Care Fraud..</i>	585
	B. <i>The FCA as a Tool to Combat Health Care Fraud..</i>	587
	C. <i>The Stark Law as a Tool to Combat Health Care Fraud</i>	589
	D. <i>MACRA Reform Highlights the Need for Value- Based Care</i>	592
IV.	PROPOSED CHANGES TO THE STARK LAW WILL ALLOW HOSPITALS AND PROVIDERS THE FREEDOM TO CREATE NEW ARRANGEMENTS AND INFRASTRUCTURE TO SUPPORT VALUE-BASED CARE	595
	A. <i>Finding a Path to Comprehensive Stark Reform</i>	598
	B. <i>CMS Issues a Request for Information on June 25, 2018</i>	599
	C. <i>The Public Responds to CMS’s Request for Information</i>	601
	1. A Call to Amend the Definitions of Key Terms to Provide Clarity.....	601
	2. A Call to Reform the Guidance Process Under the Stark Law	604
	3. A Call to Amend Rules Regarding Technical Noncompliance with the Stark Law.....	605
	4. A Call to Add a New Value-Based Exception to the Stark Law	606

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5. Arguments Against Adding a New Value-Based Exception to the Stark Law 608

D. CMS Confirms Stark Law Reform is Underway 610

V. CONCLUSION 612

*It is health that is real wealth and not pieces of gold and silver.*¹
 – Mahatma Gandhi

I. INTRODUCTION

Health care reform is one of the hottest topics in America. One need look no further than this year’s election cycle to see that health care reform was one of the main platforms for nearly every candidate for the 2020 election.² Why is this the case? Healthcare costs amount to 17.9% of the overall Gross Domestic Product (“GDP”).³ This figure is shockingly high, especially when compared to health care costs of similarly situated countries.⁴ As it currently stands, the United States ranks at the top of per capita health care spending.⁵ Therefore, it should sadden the soul of our nation that our health care outcomes are among the lowest in the world.⁶ In addition to this cost inefficiency and ineffective care, millions of Americans are without affordable health insurance options.⁷ Emergency rooms have become the only option for medical treatment, which has exacerbated the rising costs

1. Mahatma Gandhi

2. *Health Care as a Human Right – Medicare For All*, BERNIE, <https://berniesanders.com/en/issues/medicare-for-all/> (last visited Jan. 12, 2020) [<https://perma.cc/749L-NQVB>]; *Health Care*, KAMALA, <http://kamalaharris.org/issue/health-care/> (last visited Jan. 24, 2020) [<https://perma.cc/YMB3-6M68>]; *Issues*, PETE FOR AMERICA, <https://peteforamerica.com/issues/#Freedom> (last visited Jan. 12, 2020) [<https://perma.cc/SX5C-MV37>]; *Joe’s Vision for America*, JOE BIDEN, <https://joebiden.com/joes-vision/> (last visited Jan. 12, 2020) [<https://perma.cc/2FJR-NC25>].

3. Anne B. Martin et al., *National Health Care Spending in 2017: Growth Slows to Post-Great Recession Rates; Share of GDP Stabilizes*, 38 HEALTH AFF. 96, 96, <https://www.doi.org/10.1377/hlthaff.2018.05085>.

4. Jeffrey Selberg et al., *A Generation of Health Care in the United States: Has Value Improved in the Last 25 Years?*, PETERSON-KAISER HEALTH SYS. TRACKER (Dec. 6, 2018), <https://www.healthsystemtracker.org/brief/a-generation-of-health-care-in-the-united-states-has-value-improved-in-the-last-25-years/> [<https://perma.cc/55HP-39XT>].

5. *Id.*

6. Bradley Sawyer & Daniel McDermott, *How Does the Quality of the U.S. Healthcare System Compare to Other Countries?*, PETERSON-KFF: HEALTH SYS. TRACKER (Mar. 28, 2019), <https://www.healthsystemtracker.org/chart-collection/quality-u-s-healthcare-system-compare-countries/#item-overall-mortality-rate-1980-2015> [<https://perma.cc/3QZ6-E723>].

7. Rachel Garfield et al., *The Uninsured and the ACA: A Primer – Key Facts About Health Insurance and the Uninsured Amidst Changes to the Affordable Care Act*, KAISER FAM. FOUND. (Jan. 25, 2019), <http://www.kff.org/report-section/the-uninsured-and-the-aca-a-primer-key-facts-about-health-insurance-and-the-uninsured-amidst-changes-to-the-affordable-care-act-how-many-people-are-uninsured/> [<https://perma.cc/LC5W-NK97>].

of health care.⁸ Every person, whether directly or indirectly, is affected by health care costs.⁹ Solving this problem will take a multifaceted approach, and there are countless opinions on the best strategy to correct the direction of American health care.

One approach that has gained popularity with health-industry stakeholders and regulators alike is value-based payment reform.¹⁰ Value-based payment models encourage integration and coordination of care across all levels of participation in the care team.¹¹ Instead of a traditional fee-for-service payment model, the value-based payment models incentivize collaboration by the sharing of savings or increased profits with the healthcare team.¹² The healthcare team realizes incentive-based payments only if there is accompanying proof that the patient care is improving while saving the federal program money.¹³ While there have been a handful of limited opportunities for this type of collaboration among providers, this program has not been widely adopted due to regulatory barriers that have impeded this type of reform.¹⁴ Health care fraud and abuse laws are one of the main barriers that limit the business arrangements and financial relationships that exist between hospitals, physicians, and other health care service providers, thus limiting new payment options to support a value-based payment model.¹⁵

8. Sawyer & McDermott, *supra* note 6.

9. See *American Health Care: Health Spending and the Federal Budget*, COMMITTEE FOR RESPONSIBLE FED. BUDGET (May 16, 2018), <https://www.crfb.org/papers/american-health-care-health-spending-and-federal-budget> [<https://perma.cc/DLE8-K2VF>].

10. See THOMAS BODENHEIMER & KEVIN GRUMBACH, *UNDERSTANDING HEALTH POLICY: A CLINICAL APPROACH* § 4.5 (7th ed. 2016).

11. See *Value-Based Insurance Design Model (VBID)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 18, 2019), <http://www.cms.gov/newsroom/fact-sheets/value-based-insurance-design-model-vbid-fact-sheet-cy-2020> [<https://perma.cc/EL5Z-XHGU>].

12. *Value-Based Programs*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs.html> (last visited Nov. 24, 2019) [<https://perma.cc/47LJ-ZMAC>].

13. HOSPITAL VALUE-BASED PURCHASING, CTRS. FOR MEDICARE & MEDICAID SERVS. 2–3 (2017), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Hospital_VBPurchasing_Fact_Sheet_ICN907664.pdf [<https://perma.cc/S5D6-X3T8>].

14. John O’Shea, *Patient-Centered, Value-Based Health Care Is Incompatible With The Current Climate of Excessive Regulation*, HEALTH AFF.: BLOG (Oct. 3, 2018), <https://www.healthaffairs.org/doi/10.1377/hblog20180927.405697/full/> [<https://perma.cc/WG45-6FRR>]. The term “Federal health care program” is defined as “any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government,” or “any State health care program, as defined in section 1128(h).” Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191, § 204(a)(7), 110 Stat. 1936, 2000 (1996) (codified at 42 U.S.C. § 1320f (2011)).

15. AM. HOSP. ASS’N, *Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program* (July 17, 2018), <https://www.aha.org/>

The Anti-Kickback Statute (“AKS”), the Physician Self-Referral Law, and the False Claims Act (“FCA”) are three of the main health care fraud and abuse laws that are used to deter fraudsters from abusing Medicare and Medicaid programs.¹⁶ The AKS statute prohibits the payment or receipt of remuneration in exchange for health care referrals.¹⁷ The Physician Self-Referral Law, also known as the “Stark law” (“Stark”), prohibits a physician from referring patients for a designated health service to an entity that has a financial relationship with the physician or one of the physician’s immediate family members.¹⁸ The FCA is used to bring a claim against a person who submits a false or fraudulent bill to the government for reimbursement.¹⁹ These three laws work in tandem to prevent fraud and abuse of the Medicare and Medicaid programs.²⁰ Alleged violations of the AKS and the Stark law are often litigated through the use of the FCA, which allows for *qui tam* actions.²¹ While these laws serve an essential role in protecting patients from unnecessary medical treatment, overutilization of services, unfair competition, and general abuse of the federal programs,²² these laws are also blocking innovation in health care required to address the need for alternative models for health care delivery and payment.²³

Additionally, compliance with these health care fraud and abuse laws is often difficult, even for the well-meaning who in good faith attempt to understand the requirements under the law.²⁴ Numerous regulations and interpretive laws have been created in an effort to clarify how to implement and interpret these fraud and abuse laws. Guidance from both the Centers for Medicare and Medicaid Services (“CMS”) and the Office of Inspector General (“OIG”) has been very limited due to the relatively small number of advisory opinions issued

system/files/2018-07/180718-aha-statement-house-ways-means-stark-law.pdf [https://perma.cc/P2E7-HEBM].

16. *A Road Map for New Physicians: Fraud & Abuse Laws*, U.S. DEP’T HEALTH & HUMAN SERVS., <https://oig.hhs.gov/compliance/physician-education/01laws.asp> (last visited Nov. 24, 2019) [https://perma.cc/56YV-S27G].

17. 42 U.S.C. § 1320a–7b(b) (2012).

18. 42 U.S.C. § 1395nn (2012).

19. 31 U.S.C. § 3729–33 (2012).

20. U.S. DEP’T HEALTH & HUMAN SERVS., *supra* note 16.

21. 31 U.S.C. § 3730(c) (2012); *see also* John W. Nisbett, *The Three-Headed Monster of Health Care Fraud Enforcement: The False Claims Act, Stark Law, and the Anti-Kickback Statute*, AM. BAR ASS’N (Aug. 1, 2015), https://www.americanbar.org/groups/young_lawyers/publications/tyl/topics/health-law/three-headed-monster-health-care-fraud-enforcement-false-claims-act-stark-law-anti-kickback-statute/ [https://perma.cc/RQY7-8YKX].

22. U.S. DEP’T HEALTH & HUMAN SERVS., *supra* note 16.

23. Anne B. Claiborne et al., *Legal Impediments to Implementing Value-Based Purchasing in Health Care*, 35 AM. J.L. & MED. 442, 455–57 (2009).

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

over the years.²⁵ Moreover, there is evidence that the guidance has been misused by the Department of Justice (“DOJ”).²⁶ There is scant case law on many of the possible health care arrangements because stakeholders either shy away from entering into these arrangements for fear of violating a vague and ambiguous rule, or they settle with the DOJ to avoid litigation for fear of ruinous financial consequences of fighting the government.²⁷ The law must be reformed to provide clarity and opportunity for innovation.

As health care has dramatically evolved over the last three decades,²⁸ so must the laws that were meant to prevent abuse in the health care system. Laws that were once relevant based on the traditional payment models are now largely irrelevant and an impediment to necessary change that will improve health care costs and outcomes.

Due to the incredibly complex and numerous business relationships that exist in any given health care system, initiating change will be difficult. However, one approach that will alleviate the stress on hospitals and providers is to reform the Stark law to create an exception for value-based payment models,²⁹ as well as to provide clarity for language currently included in the Stark law.³⁰ I contend that these regulatory changes would enable hospitals and providers to create new arrangements that would focus on patient care, unobstructed by the myriad regulations that have prevented this type of collaboration.

In Part II of this Article, I will examine the United States’ health care crisis and how it led to increased enforcement of the fraud and abuse laws that help deter the abuse in the system.³¹ Part III will center on the analysis of the fraud and abuse laws mentioned above and on how these laws work together to help prevent fraud in health care.³² In Part IV of this Article, I will discuss several necessary changes to the Stark law to help correct the direction of our health care spending and outcomes.³³ I propose that a value-based exception

25. See *Advisory Opinions (AOs)*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html (last updated Feb. 14, 2019, 6:48 AM) [<https://perma.cc/T377-SPSE>]; *Advisory Opinions*, OFF. INSPECTOR GEN., <https://oig.hhs.gov/compliance/advisory-opinions/index.asp> (last visited Aug. 12, 2019) [<https://perma.cc/8G23-H6NE>].

26. See Memorandum from the Associate Attorney General, U.S. Department of Justice, to the Heads of Civil Litigating Components and United States Attorneys, Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases (Jan. 25, 2018).

27. See *Tuomey*, 675 F.3d at 394; Pete Strom, *Tuomey Could File Bankruptcy for Medicare Fraud Payments*, STROM L. FIRM (May 7, 2014), <https://stromlaw.com/tuomey-file-bankruptcy-medicare-fraud-payments/> [<https://perma.cc/4XNH-4EEJ>].

28. Thomas P. Conklin, *Health Care in the United States: An Evolving System*, 7 MICH. FAM. REV. 5, 5 (2002).

29. Claiborne et al., *supra* note 23, at 486–87.

30. *Id.* at 488.

31. See discussion *infra* Part II.

32. See discussion *infra* Part III.

33. See discussion *infra* Part IV.

be added to the current exceptions, as well as discuss the need for clarity of several critical terms to understand how to comply with the Stark exceptions. Additionally, I propose that the rules regarding advisory opinions should be amended to provide more guidance to the health care industry on these complicated issues. These changes, I contend, will relieve the barriers that are blocking the health care industry from making transformative changes and meeting the goal of higher quality care and increased efficiency.

II. THE HEALTH CARE CRISIS MOVES LAWMAKERS TO INCREASE FRAUD AND ABUSE ENFORCEMENT

During the Democratic primary debate hosted on June 26, 2019, the first few minutes were dominated by debating the American health care system. Politicians jockeyed for an opportunity to share their policies regarding the future of health care while they debated ideas such as Medicare for All, universal coverage, and how private insurance coverage fits into the solution.³⁴ Senator Elizabeth Warren pointed out that insurance companies last year alone “sucked \$23 billion in profits out of the health care system, and that doesn’t count the money that was paid to executives, [and] the money that was spent on lobbying Washington.”³⁵ Former Congressman John Delaney stated that in campaigning at over 400 events, “the number-one issue the American people [want to know] about . . . [is] what [they are] going to do for health care.”³⁶ Each candidate that spoke agreed that there needed to be a change in our approach to providing health care because millions of Americans are not receiving care due to the high costs.³⁷

To clarify, this issue is not just a concern to the Democratic party. On June 24, 2019, President Trump issued an executive order requiring hospitals and insurers to disclose their prices in hopes that price transparency would create informed consumers, competition among providers, and ultimately, lower prices for the American people.³⁸

34. See Jeremia Kimelman, *Full Transcript: 2019 Democratic Debate Night One*, NBC NEWS (June 27, 2019, 2:13 AM CDT), <https://www.nbcnews.com/politics/2020-election/full-transcript-first-democratic-primary-debate-2019-n1022816> [https://perma.cc/5YYP-V6PF].

35. *Id.*

36. *Id.*

37. *Id.*

38. Exec. Order No. 13,877, 84 Fed. Reg. 30,849 (June 24, 2019); see also Susannah Luthi, *Trump’s Transparency Executive Order Leaves Details to HHS, CMS, MOD. HEALTH CARE* (June 24, 2019, 11:40 AM), <https://www.modernhealthcare.com/payment/trumps-transparency-executive-order-leaves-details-hhs-cms> [https://perma.cc/84RQ-K2KB]. There is debate, as in all things involving health care, as to whether this will in fact help lower prices. Some health care stakeholders have argued this approach of requiring price disclosure perpetuates the idea of paying for volume over value. CEO Matt Eyles of American Health Insurance Plans noted this could be a boost to the fee-for-service system that the government is trying to get away from. *Id.*

Likewise, in May of 2019, the Department of Health and Human Services (“HHS”) and CMS issued a final rule requiring pharmaceutical transparency pricing for television advertisements, expecting that the disclosure of this information would force down drug prices.³⁹ This topic is at the forefront of American policy as politicians on both sides of the aisle want to reduce costs so that Americans have access to health care.

Spending on health care is at an all-time high. In the words of Warren Buffet, “The ballooning costs of health care act as a hungry tapeworm on the American economy.”⁴⁰ American health care spending increased 3.9% in 2017 to reach \$3.5 trillion dollars.⁴¹ The United States ranks highest per capita on health care spending in the world.⁴² In 2017, health spending per person was \$10,224,⁴³ which was 28% higher than Switzerland, the second highest per capita spender.⁴⁴ The overall GDP related to health care spending was 17.9% in 2017.⁴⁵ These numbers have been on an upward trend for years.⁴⁶ In the well-known and often-cited article, “It’s the Prices, Stupid: Why the United States Is So Different From Other Countries,” lead author Gerard Anderson and his coauthors examined the data published by the Organization for Economic Cooperation and Development (“OECD”) to compare the United States spending on health care to that of the thirty member countries in 2000.⁴⁷ Their analysis of the data reflected that while the United States spent considerably more on health care

39. Medicare and Medicaid Programs; Regulation to Require Drug Pricing Transparency, 84 Fed. Reg. 20,732 (May 10, 2019) (to be codified at 42 C.F.R. pt. 403); see also John Commins, *Final Rule Requires Drug Price Disclosures in TV Ads*, HEALTH-LEADERS (May 8, 2019), <https://www.healthleadersmedia.com/final-rule-requires-drug-price-disclosures-tv-ads> [<https://perma.cc/R5D5-74RM>].

40. Nick Wingfield et al., *Amazon, Berkshire Hathaway and JPMorgan Team Up to Try to Disrupt Health Care*, N.Y. TIMES (Jan. 30, 2018), <https://www.nytimes.com/2018/01/30/technology/amazon-berkshire-hathaway-jpmorgan-health-care.html> [<https://perma.cc/MVF6-BPUE>].

41. CTRS. FOR MEDICARE & MEDICAID SERVS., *National Health Expenditures 2017 Highlights* (2017), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf> [<https://perma.cc/6KH4-CPQ2>] [hereinafter *National Health Expenditures 2017*].

42. *Id.*

43. Bradley Sawyer & Cynthia Cox, *How Does Health Spending in the U.S. Compare to Other Countries?*, PETERSON-KAISER HEALTH SYS. TRACKER (Dec. 7, 2018), <https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/> [<https://perma.cc/7UVN-XFKC>]. CMS lists this price per capita as \$10,739 in 2017, which would make the gap between the United States and Switzerland even greater. See *National Health Expenditures 2017*, *supra* note 41.

44. Sawyer & Cox, *supra* note 43.

45. *National Health Expenditures 2017*, *supra* note 41.

46. *Health Spending*, ORG. FOR ECON. CO-OPERATION AND DEV., <https://data.oecd.org/healthres/health-spending.htm> (last visited Jan. 13, 2020) [<https://perma.cc/4JLH-LVSQ>].

47. Gerard F. Anderson et al., *It’s the Prices, Stupid: Why the United States Is So Different From Other Countries*, HEALTH AFF., May/June 2003, at 89, 103, <https://doi.org/10.1377/hlthaff.22.3.89>.

than any country—both per capita and percentage of GDP—the measures of aggregate usage, such as physician visits per capita and hospital days per capita, were below the OECD median.⁴⁸ This implied that patients in the United States pay higher prices than patients in other countries.⁴⁹ The problem, however, is linked to many other factors in addition to the price.⁵⁰

Many health-law commentators argue that the health care delivery models are a key part of the problem. In the earliest phases of commercial health insurance plans, health insurance companies simply indemnified their insureds for the cost of care.⁵¹ Generally speaking, if the insured went to see a doctor and received a bill for \$80, the insurance company sent a check to the doctor for \$80. The insurance company was not involved in choosing the providers or determining what was medically necessary for the patient or insured.⁵² It simply wrote checks to cover the cost of care.⁵³ The physicians named their prices and the insurance companies paid them.⁵⁴ However, the advent of managed care plans in the 1980s dramatically changed the relationships between insurer, patient, and provider.⁵⁵

Managed care entered the health care scene as an attempt to control skyrocketing health care costs.⁵⁶ The insurance companies persuaded the public that they would be able to keep prices down by negotiating on behalf of patients and by providing another check in the system to ensure that physicians would not perform unnecessary services to increase their profit margins.⁵⁷ The insurance companies would intervene and stop the runaway prices being charged by physicians and hospitals. The managed-care companies still operated in a fee-for-service model,⁵⁸ in which each service had a separate fee. The

48. *Id.* at 103.

49. *Id.*

50. Corbin Santo, Note, *Walking a Tightrope: Regulating Medicare Fraud and Abuse and the Transition to Value-Based Payment*, 64 CASE W. RES. L. REV. 1377, 1385 (2014).

51. *Id.* at 1379. See Louis S. Reed, *Private Health Insurance in the United States: An Overview*, SOC. SECURITY BULL., Dec. 1965, at 3, 6, <https://www.ssa.gov/policy/docs/ssb/v28n12/v28n12p3.pdf>; see also D. ANDREW AUSTIN & THOMAS L. HUNGERFORD, *THE MARKET STRUCTURE OF THE HEALTH INSURANCE INDUSTRY 2-3* (Cong. Res. Serv. 2010), <https://www.ncsl.org/documents/health/MrktStrOfHlthIns.pdf>.

52. See AUSTIN & HUNGERFORD, *supra* note 51, at 3, 11.

53. See *id.*

54. Cf. INST. OF MED., *EMPLOYMENT AND HEALTH BENEFITS: A CONNECTION AT RISK* 68 (Marilyn J. Field & Harold T. Shapiro eds., 1993) (noting shift in Blue Cross Blue Shield Plan to providing services rather than cash payments).

55. Jon Gabel et al., *The Changing World of Group Health Insurance*, HEALTH AFF., Summer 1988, at 48, 49, 51-52, <https://doi.org/10.1377/hlthaff.7.3.48>.

56. Anderson et al., *supra* note 47, at 91; see also AUSTIN & HUNGERFORD, *supra* note 51, at 1, 31.

57. Elizabeth W. Hoy, *Change and Growth in Managed Care*, HEALTH AFF., Winter 1991, at 18, 19, <https://doi.org/10.1377/hlthaff.10.4.18>.

58. See THOMAS BODENHEIMER & KEVIN GRUMBACH, *UNDERSTANDING HEALTH POLICY: A CLINICAL APPROACH* § 6.4 (7th ed. 2016).

insurance company paid a negotiated rate with the “in-network” doctor for the service, and in addition, the patient would pay whatever cost-sharing obligation was required on her part.⁵⁹ This model rewards a higher volume of services with a higher profit rather than focusing on the quality of services provided.⁶⁰ In essence, a doctor is not paid more when she cures the patient, but rather she is paid more if the patient comes back to the office multiple times for additional services.⁶¹

Managed care did not promise what the public had hoped. Prices continue to rise, and new health insurance plans have emerged with the promise of keeping costs down. The high deductible health plan is one of these plans that provides low premiums and does not provide coverage for most services until the patient has met a high annual deductible amount.⁶² This plan keeps in check the idea of moral hazard.⁶³ Nevertheless, critics argue that it exposes the patient to high costs and discourages people from seeking necessary care.⁶⁴

59. *Managed Care: Summary*, MEDLINEPLUS, <https://medlineplus.gov/managed-care.html> (last updated May 22, 2019) [<https://perma.cc/ZX6Y-R4CW>]. There are numerous types of managed-care plans. Most plans involve a network of providers that have contracted with the managed-care company to provide discounted rates for services. Under some plans, the patient can go outside of the network of providers but will be exposed to a greater portion of the cost. Plans vary between whether you need to see a primary care physician before getting a referral for a specialist, or whether you can go directly to a specialist. Plans vary by the amount of deductible, co-insurance exposure, premium rates, and many other factors. *See id.* Cost sharing obligations refer to the amount of costs for which the patient is responsible. This can include co-pays, deductibles, or co-insurance percentages. Kevin Haney, *After Health Insurance Pays Medical Bills*, GROWING FAM. BENEFITS (Dec. 31, 2018), <https://www.growingfamilybenefits.com/after-insurance-pays-medical-bills/> [<https://perma.cc/GK6F-GD3J>].

60. *See generally* THE HEALTHCARE IMPERATIVE: LOWERING COSTS AND IMPROVING OUTCOMES: WORKSHOP SERIES SUMMARY 173 (Pierre L. Yong et al. eds., 2010).

61. Atul Gawande, *Overkill*, NEW YORKER (May 4, 2015), <https://www.newyorker.com/magazine/2015/05/11/overkill-atul-gawande> [<https://perma.cc/PX3J-824F>].

62. These plans are usually accompanied with a Health Saving Account (“HSA”). The IRS allows contributions to the HSA that will not be taxed, and the money can be used to go towards the high deductibles. DEP’T TREASURY, PUBLICATION 969: HEALTH SAVINGS ACCOUNTS AND OTHER TAX-FAVORED HEALTH PLANS (2018) <https://www.irs.gov/publications/p969> [<https://perma.cc/X2JY-74SM>].

63. Moral Hazard is the idea that patients will use more services, even if they are not needed, because they are not paying for it directly. Therefore, if the patient must pay for the services via a deductible payment, she will only use what is actually necessary. Mark Thoma, *Explainer: What Is “Moral Hazard”?*, CBS MONEYWATCH (Nov. 22, 2013, 8:00 AM), <https://www.cbsnews.com/news/explainer-moral-hazard/> [<https://perma.cc/6N5W-MGF2>].

64. Rachel Martin, *Employees Start to Feel the Squeeze of High-Deductible Health Plans*, NPR (May 3, 2019), <https://www.npr.org/sections/health-shots/2019/05/03/719519579/employees-start-to-feel-the-squeeze-of-high-deductible-health-plans> [<https://perma.cc/B5FS-2Q4E>].

Medicare,⁶⁵ with its numerous parts and options, as well as the many variations of Medicaid⁶⁶ across our country, employ various health plans to manage care and costs. In 2017, Medicare spending grew 4.2% to \$705.9 billion.⁶⁷ Total Medicaid spending decelerated in 2017, increasing just 2.9% to \$581.9 billion compared to a growth in 2016 to 4.2%.⁶⁸ Even with the United States' astronomical figures for health care spending, the data reveals that the United States is performing subpar for population health compared to similar OECD countries.⁶⁹ The United States ranked last among its peers in amenable mortality rates.⁷⁰ This data shows that health care is not delivered effectively in our nation.⁷¹ The problem is draining the vitality of our national economy and failing millions of Americans.

The Department of Health and Human Services and CMS are working to find solutions. CMS's Innovation Center is testing various payment and service-delivery models that aim to achieve better care for patients, smarter spending, and healthier communities.⁷² Value-based payment reform is one delivery model that has been gaining

65. *An Overview of Medicare*, KAISER FAM. FOUND. (Feb. 13, 2019), <https://www.kff.org/medicare/issue-brief/an-overview-of-medicare/> [<https://perma.cc/HBL7-6AGT>] (“Medicare is the federal health insurance program created in 1965 for people ages 65 and over, regardless of income, medical history, or health status. The program was expanded in 1972 to cover certain people under age 65 who have a long-term disability. Today, Medicare plays a key role in providing health and financial security to 60 million older people and younger people with disabilities. The program helps to pay for many medical care services, including hospitalizations, physician visits, prescription drugs, preventive services, skilled nursing facility and home health care, and hospice care. In 2017, Medicare spending accounted for 15% of total federal spending and 20% of total national health spending.”).

66. *CMS Program History*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/About-CMS/Agency-Information/History/index> (last updated Nov. 13, 2019) [<https://perma.cc/K7CM-V27H>] (“On July 30, 1965, President Lyndon B. Johnson signed into law the bill that led to the Medicare and Medicaid. . . . At first, Medicaid gave medical insurance to people getting cash assistance. Today, a much larger group is covered: low-income families, pregnant women, people of all ages with disabilities, and people who need long-term care. States can tailor their Medicaid programs to best serve the people in their state, so there’s a wide variation in the services across the country.”).

67. *National Health Expenditures 2017*, *supra* note 41.

68. *Id.* However, the deceleration in growth was tied to “slower growth in enrollment and a reduction in the Medicaid net cost of health insurance. State and local Medicaid expenditures grew to 6.4 percent, while federal Medicaid expenditures increased to 0.8 percent in 2017.” *Id.*

69. Sawyer & Cox, *supra* note 43.

70. Michael Winter, *Health Survey Ranks U.S. Last Among Rich Peers*, USA TODAY, <https://www.usatoday.com/story/news/nation/2014/06/16/health-survey-us-last/10638811/> (last updated June 17, 2014) [<https://perma.cc/92F9-CJ6B>]. “Mortality amenable to health care is a measure of the rates of death considered preventable by timely and effective care. While the health care system might not be expected to prevent death in all instances, differences in amendable [sic] mortality indicate how effectively health care is delivered.” Sawyer & McDermott, *supra* note 6.

71. Sawyer & Cox, *supra* note 43.

72. *Where Innovation Is Happening*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/> (last visited Jan. 13, 2020) [<https://perma.cc/NY42-LU5A>].

popularity as a possible solution to skyrocketing costs and poor patient outcomes.⁷³

Value-based reimbursement models were launched by the Patient Protection and Affordable Care Act (“ACA”).⁷⁴ When the ACA was enacted, it included incentives for value-based payment models such as the Medicare Shared Savings Program.⁷⁵ Additional value-based payment models were tested and used with limited adoption, such as bundled payments, variations on Accountable Care Organizations (“ACO”), medical home models, and special payments to physicians for care coordination.⁷⁶ The promise of these new models is that, by incentivizing providers to show data of improved quality of care instead of increasing volume, they will result in health care cost savings and a healthier population. However, there are regulatory barriers that exist and are impeding full adoption of value-based care.

III. ENFORCEMENT OF HEALTH CARE FRAUD AND ABUSE LAWS SAVE BILLIONS OF DOLLARS IN THE MEDICARE AND MEDICAID PROGRAMS

As mentioned in Part II above, \$3.5 trillion dollars was spent in 2017 on health care in the United States.⁷⁷ The government paid for approximately 37% of those costs through Medicare and Medicaid.⁷⁸ The sheer volume of claims that are processed by Medicare and Medicaid each year makes this a fertile area for fraud to go undetected. In an attempt to put an end to the fraud and abuse in the system, which adds to the problem of increased health care costs, the United States government began to allocate more resources to fraud enforcement.⁷⁹ For example, the Department of Health and Human Services Office of the Inspector General, along with state and federal law enforcement, initiated an unprecedented nationwide health care fraud takedown in June 2018 which resulted in over 600 defendants in fifty-eight districts and recovered over \$2 billion dollars for the government.⁸⁰

73. See Bruce Merlin Fried & Jeremy David Sherer, *Value Based Reimbursement: The Rock Thrown Into the Health Care Pond*, HEALTH AFF. (July 8, 2016), <https://www.healthaffairs.org/doi/10.1377/hblog20160708.055764/full/> [<https://perma.cc/DVC6-SQMR>].

74. See Karen Kane, *How Much Does Quality Cost? Analyzing the Patient Protection and Affordability Care Act's Value-Based Purchasing Provision and How it Could Affect the Delivery of Care by Hospitals*, 14 DUQUESNE BUS. L.J. 69, 71 (2011).

75. Fried & Sherer, *supra* note 73.

76. *Id.*

77. *National Health Expenditures 2017*, *supra* note 41.

78. *Id.*

79. DAVID E. MATYAS ET AL., LEGAL ISSUES IN HEALTHCARE FRAUD AND ABUSE: NAVIGATING THE UNCERTAINTIES 1–2 (4th ed. 2012).

80. 2018 *National Health Care Fraud Takedown*, U.S. DEP'T HEALTH & HUM. SERVS. (2018), https://oig.hhs.gov/newsroom/media-materials/2018/takedown/2018HealthCareTakedown_FactSheet.pdf [<https://perma.cc/DXX8-J6R7>].

The government has been successful in curtailing this illegal behavior.⁸¹ Multi-agency initiatives such as “strike teams” have been created to combat fraud in various regions across the United States that are high targets for health care fraud and abuse activities.⁸² Additionally, the Department of Justice and the Department of Health and Human Services, through the Health Care Fraud Prevention and Enforcement Action Team (“HEAT”) effort, use data analytics and surveillance to crack down on, prevent, and prosecute health care fraud.⁸³ As a result of these increased efforts and the coordination among the local, state, and federal government, the government has been able to recover \$4 for every \$1 spent on enforcement.⁸⁴

Historically, most health care fraud was enforced primarily through the use of the FCA.⁸⁵ This law prohibits false or fraudulent claims from being submitted to the government for reimbursement.⁸⁶ The law has been interpreted to include factually false claims, such as submitting a bill for a service that was never rendered,⁸⁷ and legally false claims, such as submitting a bill that is based on a physician’s inappropriate self-referral, thus violating the Stark law.⁸⁸ Nonetheless, over the last two decades, the DOJ has increased enforcement of Stark and AKS in their own right as well, in addition to the expansion of claims that may be brought under the FCA.

This Part will first give a brief overview of the AKS and the FCA in order to provide context for the discussion of the Stark law. Next, this Part will review the evolution of the Stark law. Moreover, the ambiguity and uncertainty of interpreting Stark law and its impact on the health care industry will be analyzed. This will be followed by a discussion of the role of guidance documents and their involvement in

81. U.S. DEP’T HEALTH & HUMAN SERVS., HEALTH CARE FRAUD & ABUSE CONTROL PROGRAM REPORT 1–2 (Feb. 2016), <https://oig.hhs.gov/publications/docs/hcfac/FY2015-hcfac.pdf> [<https://perma.cc/6KBV-NYDX>].

82. *Id.* at 8–11.

83. U.S. DEP’T JUSTICE, PRESS RELEASE 18-416, DEPARTMENT OF JUSTICE AND HEALTH AND HUMAN SERVICES RETURN \$2.6 BILLION IN TAXPAYER SAVINGS FROM EFFORTS TO FIGHT HEALTHCARE FRAUD (Apr. 6, 2018), <https://www.justice.gov/opa/pr/departments-justice-and-health-and-human-services-return-26-billion-taxpayer-savings-efforts> [<https://perma.cc/JM7G-8EEY>].

84. *Id.* (“Health and Human Services Secretary Alex Azar and Attorney General Jeff Sessions today released a fiscal year (FY) 2017 Health Care Fraud and Abuse Control Program report showing that for every dollar the federal government spent on health care related fraud and abuse investigations in the last three years, the government recovered \$4.”).

85. 31 U.S.C. §§ 3729–33 (2017).

86. U.S. DEP’T. HEALTH & HUMAN SERVS., OFFICE INSPECTOR GEN., A ROADMAP FOR NEW PHYSICIANS: AVOIDING MEDICARE FRAUD AND ABUSE 3 (2020), https://oig.hhs.gov/compliance/physician-education/roadmap_web_version_pdf [<https://perma.cc/5SRS-3VJV>].

87. *See id.* at 4 (noting inappropriate self-referral violates Stark); *see also* Nisbett, *supra* note 21.

88. DEP’T HEALTH & HUMAN SERVS., *supra* note 86, at 3.

adding to the confusion about what kind of behavior is allowed and what is prohibited.

A. *The AKS as a Tool to Combat Health Care Fraud*

The current federal AKS⁸⁹ is a criminal statute that makes it a felony for individuals or entities knowingly and willfully to offer, pay,⁹⁰ solicit, or receive⁹¹ any remuneration in order to induce business reimbursed under any federal health care program.⁹² Although laws prohibiting kickbacks have existed for almost a hundred years,⁹³ the first version of the health care anti-kickback provisions was passed as part of the Social Security Amendments of 1972 to bolster public confidence in the integrity of the Medicaid and Medicare programs.⁹⁴ This first iteration of AKS left many questions unanswered, including what level of intent, if any, was required under AKS, as well as other core questions, such as what constituted a kickback.⁹⁵ Since 1972, AKS has been amended several times, which has resulted in an expansion of the law. Nowadays, any type of remuneration triggers scrutiny,

89. 42 U.S.C. § 1320a-7b(b)(1)–(2) (2012).

90. *See id.* § 1320a-7b(b)(2).

91. *See id.* § 1320a-7b(b)(1).

92. The actual language of Subsection 1128B(b)(1) of the Social Security Act, amended in August 1996, provides as follows:

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return 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) in return for purchasing, leasing, ordering, or arranging for or 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

42 U.S.C. § 1320a-7b(b)(1)(A)–(B).

Subsection 1128B(b)(2) of the Social Security Act provides:

(2) whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer 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) to purchase, lease, order, or arrange for or recommend 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

42 U.S.C. § 1320a-7b(b)(2)(A)–(B).

93. Copeland Anti-Kickback Act of 1935, Pub. L. No. 73-324, 48 Stat. 948, 73d Cong., Sess. 2 (1934) (amending and further fortifying the Davis-Bacon Act of 1931).

94. ALICE G. GOSFIELD, MEDICARE AND MEDICAID FRAUD AND ABUSE § 2:4 & n.1 (2019).

95. *See id.* at § 2:4.

and specific intent is no longer necessary to violate AKS.⁹⁶ Penalties for violating AKS include both civil and criminal monetary penalties, imprisonment, and exclusion from participating in the federal programs.⁹⁷ Currently, enforcement of AKS is responsible for billions of dollars in recovery for the federal government each year.⁹⁸

AKS contains both exceptions and safe harbors that describe specific examples of when the exchange of referrals for remuneration may be deemed “safe” and not a violation of the AKS.⁹⁹ If an individual or entity complies with the exact language of a safe-harbor provision or exception, they will be safe from prosecution. If the arrangement does not fall within the exact language of a safe-harbor provision or exception, however, it still may be an acceptable relationship. In this sense, the arrangement should be evaluated on a case-by-case basis to determine if there is a risk of fraud or abuse, and the prosecution would have discretion on whether to proceed with a claim.¹⁰⁰

The AKS is important to ensure that patient services or treatments are only provided when medically necessary and not as a result of a hidden kickback or remuneration that a physician or service provider will receive in exchange for the patient referral.¹⁰¹ Overutilization of services and exposure of patients to unnecessary medical care for pecuniary gain creates potential danger to the patient, as well as constitutes fraud against the federal government.¹⁰² Additionally, when these types of illegal arrangements exist between parties, successful competition from new businesses will be hindered.¹⁰³ A robust competitive market in health care would provide better quality for a better value as businesses compete for clients.¹⁰⁴ Therefore, this lack of com-

96. Catherine A. Martin et al., *Federal Antikickback Statute*, in HEALTH LAW HANDBOOK § 4.3 (Alice G. Gosfield, ed. 2013); Catherine A. Martin et al., *CMPs: New Exceptions to What Constitutes “Remuneration,”* in HEALTH LAW HANDBOOK § 4.6 (Alice G. Gosfield, ed. 2013).

97. While criminal sanctions, civil money penalties, and exclusion are often available for the same conduct, the focus of the sanctions is different. ALICE G. GOSFIELD, *supra* note 94, at § 4:2.

98. *Justice Department Recovers Over \$2.8 Billion From False Claims Act Cases in Fiscal Year 2018*, DEP’T JUSTICE (Dec. 21, 2018), <https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018> [https://perma.cc/45WR-TZT5].

99. ALICE G. GOSFIELD, *supra* note 94, §§ 2:21 & 2:28.

100. *Id.* § 2:28.

101. *See* United States v. Greber, 760 F.2d 68, 71–72 (3d Cir. 1985).

102. *See, e.g.*, DEP’T HEALTH & HUMAN SERV., OFFICE INSPECTOR GEN., Advisory Op. No. 98-13 (1998) (“In assessing the potential risk of fraud or abuse under the AKS, our concerns are primarily fourfold: increased risk of overutilization, increased program costs, patient freedom of choice, and unfair competition.”).

103. *See id.*

104. *Id.*

petition ultimately hurts both the patients and the federal programs, resulting in less freedom of choice between providers for patients.¹⁰⁵

B. *The FCA as a Tool to Combat Health Care Fraud*

The false-claims statutes have both criminal and civil components. The purpose of these laws is to prevent the federal government from paying for a bill when the service was not provided, or it was not provided per the requirements of the law.¹⁰⁶ The FCA imposes civil liability on any person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval” to an officer or employee of the United States government.¹⁰⁷

The federal FCA permits the federal government to recover from a person who knowingly submits a false claim to the government a penalty ranging from \$11,181 to \$22,363 for each false claim submitted.¹⁰⁸ Additionally, the government may recover three times the amount of actual damages—known as “treble damages”—realized by the government.¹⁰⁹ There are additional administrative monetary penalties as well as provisions for exclusion from participating in the federal programs.¹¹⁰

The FCA is unique when compared against the other major health care federal fraud and abuse laws because it allows for *qui tam* actions.¹¹¹ The FCA *qui tam* provision is one of the strongest whistleblower protection laws in the United States.¹¹² This allows a private individual to bring a claim against a health care entity or individual if the relator or “whistleblower” has independent knowledge that the FCA is being violated.¹¹³ The *qui tam* relator is awarded a percentage of the damages won against the defendant.¹¹⁴ This incentivizes the public to come forward and sue individuals or entities who are defrauding the government.¹¹⁵ Historically, most health care fraud claims were initiated by *qui tam* actions until the government began

105. *Id.*

106. “[F]ederal law makes it a felony knowingly and willfully to make or cause to be made a false claim or statement under any health benefit program which receives federal funding . . . or a state health program, including Medicaid.” GOSFIELD, *supra* note 94, at § 5:1 (citing 42 U.S.C. § 1320a-7b(a) (2012)).

107. 31 U.S.C. § 3729(a)(1)(A) & (b)(2)(A)(i) (2012).

108. *Id.* § 3729(a). The most recent increases in penalties were published in 83 Fed. Reg. 3944, 3945 (Jan. 29, 2018) (to be codified at 28 C.F.R. pt. 85).

109. 31 U.S.C. § 3729(a) (2012).

110. 42 U.S.C. § 1320a-7(a)(1)–(3), (b)(1)–(15) (2012); *Id.* § 1320a-7(a)(1)–(3), (b)(1)–(15); *see also* GOSFIELD, *supra* note 94, at § 5:1.

111. 31 U.S.C. § 3730(b) (2012).

112. *False Claims Act/Qui Tam FAQ*, NAT’L WHISTLEBLOWER CTR., <https://www.whistleblowers.org/faq/false-claims-act-qui-tam/> (last visited Jan. 13, 2020) [<https://perma.cc/SPM7-JAG3>].

113. *Id.*

114. United States *ex rel.* Alderson v. Quorum Health Grp., Inc., 171 F. Supp. 2d 1323, 1340 (M.D. Fla. 2001) (whistleblower was awarded over \$20 million).

115. NAT’L WHISTLEBLOWER CTR., *supra* note 112.

allocating more resources to investigate and bring claims independently.¹¹⁶ The FCA is still an essential law used today to deter health care fraud and recover billions of dollars for the government.

The theory of a false claim allegation may rest on a factually false claim or a legally false claim. Traditionally, the FCA was used to penalize providers who sent a bill to Medicare for goods or services that were never provided.¹¹⁷ This would be an example of a factually false claim. In addition, behaviors such as upcoding, providing services that are not medically necessary, unbundling, and mischaracterizing a patient's Diagnosis Related Group to recoup a greater reimbursement are other examples of factually false claims.¹¹⁸

In addition to claims that are factually false, a person may be liable under the FCA for submitting a claim to the government that is a legally false claim.¹¹⁹ The person who submits the bill, or causes the bill to be submitted, must certify that she is aware of the rules and regulations pertaining to the Medicare or Medicaid program and that the organization is in compliance with those rules.¹²⁰ If the bill submitted to the government for payment was for services actually rendered (and necessary), but the provider received a kickback in connection with the service, then this would be a tainted bill. The person who

116. See, e.g., *United States v. Cathedral Rock Corp.*, No. 4:03CV1090 HEA, 2007 WL 4270784, at *1–3 (E.D. Mo. Nov. 30, 2007); see also Carolyn J. Paschke, *The Qui Tam Provision of the Federal False Claims Act: The Statute in Current Form, Its History and Its Unique Position to Influence the Health Care Industry*, 9 J.L. & HEALTH 163–65, 177 (1994). Cf. Office of Pub. Affairs, Dep't of Justice, Press Release 18-1690, Justice Department Recovers \$2.8 Billion from False Claim Act Cases in Fiscal Year 2018 (Dec. 21, 2018), <https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018> [<https://perma.cc/GF2E-DAWF>]; Marc. S. Raspanti & Sara R. Lavelle, *Who is Enforcing the Stark Law of the United States?*, AHLA CONNECTIONS, Sept. 2012, at 24, 26.

117. 31 U.S.C. § 3729(a) (2012); see also GOSFIELD, *supra* note 94, at § 5:1.

118. Christopher L. Martin, Jr., *Reining in Lincoln's Law: A Call to Limit the Implied Certification Theory of Liability Under the False Claims Act*, 101 CALIF. L. REV. 227, 239 (2013).

119. *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1993 (2016) (holding that “[t]he implied false certification theory can be a basis for FCA liability when a defendant submitting a claim makes specific representations about the goods or services provided, but fails to disclose noncompliance with material statutory, regulatory, or contractual requirements . . .”).

120. An example of this certification is found in *United States ex rel. Kester v. Novartis Pharmaceutical Corp.*:

I agree to abide by the Social Security Act and all applicable Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

United States ex rel. Kester v. Novartis Pharm. Corp., 23 F. Supp. 3d 242, 248 (S.D.N.Y. 2014).

submitted this tainted bill would be liable under the FCA, in addition to any liability under the AKS.¹²¹ The same argument can be made with a bill that is tainted because of an inappropriate physician referral under the Stark law.

C. *The Stark Law as a Tool to Combat Health Care Fraud*

Congress further strengthened the government's ability to combat fraud by creating the Physician Self-Referral law.¹²² Concerned with the fact that physicians who had an ownership interest in an entity would disproportionately refer their patients for procedures or diagnostics compared with physicians who did not have an ownership interest, Congress sought to curtail this problem of unnecessary provision of medical services.¹²³ In 1988, Congress put a provision of what would eventually become part of Stark law into the Medicare Catastrophic Coverage Act of 1988.¹²⁴ While repealed in 1989, this prevented a physician from referring a patient for infusion therapy if the physician had a financial relationship with the infusion facility.¹²⁵ Subsequently, Congressman Pete Stark became concerned with the growing problem that physicians were valuing their own financial interests over appropriate treatment for their patients.¹²⁶ With the help of his efforts, the present day Stark law came into existence through the Omnibus Reconciliation Act of 1989.¹²⁷

Today, this is referred to as Stark I, and it very narrowly regulates physician referrals.¹²⁸ Effective as of January 1, 1992, Stark I prohibits a physician from referring patients for clinical laboratory testing if the physician either invested in the laboratory or had a compensation arrangement with the entity.¹²⁹ The next year, the modern-day Stark law was born. As part of the Omnibus Budget Reconciliation Act of 1993, Stark II prohibits referrals not only to tainted clinical laboratory services but also to a detailed list of designated health services ("DHS").¹³⁰ It was not until August 14, 1995, eight months after Stark

121. 42 U.S.C. § 1320a-7b(g) (2012).

122. Lynn Gordon, *Payors Acquiring Physician Practices: Purchase Price Limitations and Other Stark & Anti-Kickback Rules of the Road*, HEALTH L., Apr. 2014, at 24, 25; see also Bailey Wendzel et al., *Healthcare Fraud*, 56 AM. CRIM. L. REV. 1033, 1068 (2019).

123. Gordon, *supra* note 122, at 25.

124. MATYAS ET AL., *supra* note 79, at 131.

125. *Id.*

126. Matt Frederiksen & Emily Egan Weaver, *Understanding the Federal Physician Self-Referral Statute: "Stark Law" Statute May Be Difficult to Understand, but Compliance Officers Must Have at Least a Basic Understanding*, J. HEALTH CARE COMPLIANCE, Mar.-Apr. 2015, at 47, 48.

127. MATYAS ET AL., *supra* note 79, at 131.

128. STARK LAW, http://starklaw.org/stark_law.htm (last visited Jan. 13, 2020) [<https://perma.cc/F5FF-VG3L>].

129. MATYAS ET AL., *supra* note 79, at 133.

130. *Id.* at 134.

II went into effect, that final regulations on interpreting Stark I were released.¹³¹ CMS did explain, however, that these regulations would guide how all DHS referrals would be viewed and thus provided limited guidance to physicians on how to adapt to the new changes.¹³² Stark II regulations were not finalized until September 2007.¹³³

In the early 2000s, Congress sought to crack down on physician ownership interests in specialty hospitals.¹³⁴ After a moratorium lapsed on prohibiting physicians from owning cardiac-care centers, orthopedic centers, and other surgical facilities, Congress was able to incorporate its failed objectives into the ACA.¹³⁵ Now, unless the hospital existed or was planned prior to December 31, 2010, physician equity in hospitals is restricted under Stark.¹³⁶ Notably, ACA and the subsequent Health Care and Education Reconciliation Act of 2010 also established a self-referral disclosure protocol (“SRDP”).¹³⁷ This allows an entity that finds itself in violation of Stark to self-report to CMS or OIG if other laws have been violated and to face lower penalties than had the violation been found externally by the government.¹³⁸

The Stark law can be essentially broken down as follows: a physician cannot make a referral for a DHS that is payable by Medicaid or Medicare to an entity in which the physician has a financial relationship, unless an exception applies.¹³⁹ A Stark violation only occurs if the entire definition is satisfied, and it is sometimes difficult to determine whether a violation occurred.¹⁴⁰ Thus, it is important to understand each element of the rule to assess as accurately as possible whether an arrangement is prohibited.

A physician includes a medical or osteopathic doctor, podiatrist, optometrist, or a doctor of dental surgery or medicine.¹⁴¹ A referral is a physician request for a service or item.¹⁴² If the physician personally performs the service, then Stark is not implicated.¹⁴³ DHSs include: clinical laboratory services; physical therapy services; occupational

131. *Id.*; BRADFORD E. ADATTO ET AL., REPRESENTING PHYSICIANS HANDBOOK 97 (4th ed. 2016).

132. MATYAS ET AL., *supra* note 79, at 135.

133. *Id.* at 137 & n.32 (citing 72 Fed. Reg. 51,012 (Sept. 5, 2007) (codified at 42 C.F.R. pts 411, 424)).

134. *Id.* at 134–36.

135. *Id.*

136. *Id.*

137. *Id.* at 206.

138. *Id.*; see also Daniel R. Levinson, Office Inspector Gen., An Open Letter to Healthcare Providers (Mar. 24, 2009), <https://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf> [<https://perma.cc/DGT7-W4FV>].

139. See 42 U.S.C. § 1395nn (2012); Frederiksen & Weaver *supra* note 126, at 47–48.

140. Frederiksen & Weaver *supra* note 126, at 48.

141. 42 C.F.R. § 411.351 (2017).

142. 42 U.S.C. § 1395nn(h)(5)(A) (2012).

143. *Id.* § 1395nn(b)(1).

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; inpatient and outpatient hospital services; and outpatient speech-language pathology services.¹⁴⁴ The entity is the business that performs the DHS or submits the claim to Medicare.¹⁴⁵

A financial relationship constitutes either a direct or indirect investment interest, or a direct or indirect compensation arrangement with the entity.¹⁴⁶ Further, the physician does not need to be the one with the financial relationship; instead, a physician's immediate family member, including spouses, children, step-family, in-laws, grandparents and grandchildren themselves and their spouses, could trigger a Stark violation.¹⁴⁷ Various exceptions to the law exist; however, unless the referral arrangement fits squarely within the statute, a violation occurs.

Stark law is a solely civil statute, but Stark II expanded the law's reach by making a physician strictly liable for a violation.¹⁴⁸ As such, the physician does not need to be aware of or intend to enter into an inappropriate referral arrangement for a violation to occur. Instead, even if a physician refers a patient for a service and the patient inadvertently goes to a facility which has a financial relationship with the prescribing physician, a violation may occur unless an exception applies.¹⁴⁹ A violation can result in any or a combination of the following consequences: denial of payment, mandated return of payments received, civil monetary penalties up to \$15,000 per service provided, and exclusion from Medicare and Medicaid.¹⁵⁰ Additionally, civil monetary penalties of up to \$100,000 can be imposed for each scheme in which the physician was involved. However, civil monetary penalties or exclusion would only be imposed if the physician knowingly committed a violation.¹⁵¹ Physicians act knowingly when they either knew or should have known that the claim was fraudulent.¹⁵²

As mentioned above, CMS primarily regulates Stark compliance; however, claims for violations are usually filed as *qui tam* suits under the FCA.¹⁵³ When providers submit a claim to Medicare for reim-

144. *Id.* § 1395nn(h)(6).

145. 42 C.F.R. § 411.351.

146. 42 U.S.C. § 1395nn(a)(2).

147. 42 C.F.R. § 411.351.

148. 42 U.S.C. § 1395nn(b)-(e); Jo-Ellyn Sakowitz Klein, *The Stark Laws: Conquering Physician Conflicts of Interest?*, 87 GEO. L.J. 499, 500 (1998).

149. See Klein, *supra* note 148, at 515.

150. 42 U.S.C. § 1395nn(g)(1)-(3).

151. *Id.* § 1395nn(g)(4).

152. *Id.* § 1320a-7a(a)(1)(B).

153. See 31 U.S.C. § 3730(c) (2012); Sean Hanssler, "Stark" Raving Mad: Making the Self-Referral Disclosure Protocol Better, Faster, Stronger, 45 HOFSTRA L. REV. 951, 951 (2017).

bursement, they are certifying that they are in compliance with federal law.¹⁵⁴ Thus, if a physician violates Stark, he or she also violates the FCA once the claim is submitted to Medicare or Medicaid. FCA violations can be penalized from \$5,000 to \$10,000 per claim in addition to treble damages.¹⁵⁵ Under the FCA, a relator brings a *qui tam* suit against the party that is allegedly in violation.¹⁵⁶ From there, the DOJ decides whether to intervene in the case or, if not, the relator continues with a private suit.¹⁵⁷ The number of *qui tam* suits is on the rise and the law's broad scope implicates even justified business arrangements.¹⁵⁸

D. MACRA Reform Highlights the Need for Value-Based Care

An important piece helpful in understanding the urgency to reform the Stark law is a newly implemented law that transformed the Medicare payment process for physicians. The Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”) is bipartisan legislation signed into law on April 16, 2015.¹⁵⁹ Implementation began in January of 2017, but the law was not fully implemented until 2019.¹⁶⁰ MACRA was passed with the support of more than 750 physician membership organizations—who supported the new payment models outlined in this law.¹⁶¹ The goal of this legislation is to change the way that Medicare rewards clinicians for volume over value. In order to accomplish the goal and transition to reward value over volume, CMS created the Merit Based Incentive Payments System (“MIPS”). Moreover, MACRA also provides economic incentives for participation in eligible Alternative Payment Models (“APM”) as part of the new Quality Payment Program (“QPP”).¹⁶² The bill passed overwhelmingly in

154. Hanssler, *supra* note 153, at 958.

155. 31 U.S.C. § 3729(a)(1) (2012).

156. Hanssler, *supra* note 153, at 951.

157. *Id.*

158. *Id.* at 976; Patrick A. Sutton, *The Stark Law in Retrospect*, 20 ANNALS HEALTH L. 15, 45 (2011).

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

160. Quality Payment Program, 82 Fed. Reg. 53,568, 53,568 (Nov. 16, 2017) (codified at 42 C.F.R. pt. 414).

161. Bob Doherty, *SGR Repeal and MACRA: Here's Why it is Remarkable*, KEVIN MD (Apr. 16, 2015), <http://www.kevinmd.com/blog/2015/04/sgr-repeal-and-macra-heres-why-its-remarkable.html> [https://perma.cc/ZP2X-CJJK].

162. Quality Payment Program, 82 Fed. Reg. 53,568, 53,569 (Nov. 16, 2017) (codified at 42 C.F.R. pt. 414).

In addition, the Medicare Sustainable Growth Rate formula was repealed. *See id.* Section 1848(f) of the [Social Security] Act, as amended by section 4503 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), enacted on August 5, 1997, replaced the Medicare Volume Performance Standard (MVPS) with a Sustainable Growth Rate (SGR) provision. Section 1848(f)(2) of the Act specifies the formula for establishing yearly SGR targets for physicians' services under Medicare. The use of SGR targets is intended to control the growth in aggregate Medicare expenditures for physicians' services.

Congress, with a 392–37 vote in the House of Representatives¹⁶³ and a 92–8 vote in the Senate.¹⁶⁴

Prior to the QPP, payment increases for Medicare services were set by the Sustainable Growth Rate (“SGR”) law.¹⁶⁵ This capped spending increases according to the growth in the Medicare population, with a modest allowance for inflation.¹⁶⁶ MACRA repealed the SGR. The new QPP is a paradigm shift in Medicare payment for services. The QPP requires physicians to participate in MIPS unless they are otherwise exempt.¹⁶⁷ Additionally, the physician may participate in an eligible APM.¹⁶⁸ Under the MIPS program, the eligible physician will be measured based on four criteria: quality of service provided, promoting interoperability, improvement activities, and cost of care.¹⁶⁹ Each performance category will be evaluated on an annual basis and reported to CMS. Based on the total score, the physician will receive a payment adjustment—either a bonus or reduction in reimbursement, depending on how they scored against these metrics.¹⁷⁰ MIPS ties payments to the improvement in the quality of care while reducing costs

M. KENT CLEMENS, CTRS. FOR MEDICARE & MEDICAID SERVS., ESTIMATED SUSTAINABLE GROWTH RATE AND CONVERSION FACTOR, FOR MEDICARE PAYMENTS TO PHYSICIANS IN 2015 1 (2014), <https://www.cms.gov/medicare/medicare-fee-for-service-payment/sustainablegratesconfact/downloads/sgr2015p.pdf> [https://perma.cc/42CA-YUKN].

163. 161 CONG. REC. H2045 (daily ed. Mar. 26, 2015) (regarding the consideration of H.R. 2, Medicare Access and CHIP Reauthorization Act of 2015).

164. 161 CONG. REC. S2161 (daily ed. Apr. 14, 2015).

165. *Quality Payment Program Overview*, QUALITY PAYMENT PROGRAM, <https://qpp.cms.gov/about/qpp-overview> (last visited Jan. 15, 2020) [https://perma.cc/JCY4-ACW8].

166. *Id.*; see also Lee Squitieri & Kevin C. Chung, *Value-Based Payment Reform and the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015: A Primer for Plastic Surgeons*, PLASTIC RECONSTRUCTIVE SURGERY (July 1, 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC548279/> [https://perma.cc/D3XJ-TRBN].

167. *How MIPS Eligibility is Determined*, QUALITY PAYMENT PROGRAM, <https://qpp.cms.gov/mips/how-eligibility-is-determined> (last visited Nov. 16, 2019) [https://perma.cc/8HST-UXEV]. Clinicians must exceed the low-volume threshold in order to be eligible for MIPS. In addition, “[clinicians] must participate in MIPS (unless otherwise exempt) if, in both twelve-month segments, [they]: bill more than \$90,000 for Part B covered professional services, see more than 200 Part B patients, and; provide 200 or more covered professional services to Part B patients.” *Id.* Additionally, only certain clinicians are eligible, if the clinician is not one of the enumerated types, then she is exempt:

Physicians (including doctors of medicine, osteopathy, dental surgery, dental medicine, podiatric medicine, and optometry), Osteopathic practitioners, Chiropractors, Physician assistants, Nurse practitioners, Clinical nurse specialists, Certified registered nurse anesthetists, Physical therapists, Occupational therapists, Clinical psychologists, Qualified speech-language pathologists, Qualified audiologists, Registered dietitians or nutrition professionals.

Id.

168. *Quality Payment Program Overview*, *supra* note 165.

169. *MIPS Overview*, QUALITY PAYMENT PROGRAM, <https://qpp.cms.gov/mips/overview> (last visited Jan. 15, 2020) [https://perma.cc/PD57-74Z5].

170. *Id.*

as well as increasing the electronic exchange of health information that will promote comprehensive care.¹⁷¹

Physicians may also choose to participate in an eligible APM for reimbursement. An APM is defined by CMS as “a payment approach that gives added incentive payments to provide high-quality and cost-efficient care.”¹⁷² Reimbursement under this approach can be applied to a specific clinical condition, a care episode, or a population.¹⁷³ Reimbursement requires a showing that the quality of care for the patient is improved and the costs for the payers and patients are reduced.¹⁷⁴ This is intended to move the clinician away from the fee-for-service reimbursement to a value-based payment mechanism.¹⁷⁵ Examples of approved APMs are the ACO¹⁷⁶ and the Medicare Shared Savings Program (“MSSP”).¹⁷⁷ CMS and HHS has permitted

171. *Id.* See also critique of MIPS and the possible effect on rural providers who are not equipped with infrastructure or resources to support transition to EHR. John Koncelik, MD, DO, MACRA: A Legal Conundrum for Solo, Rural & Small Practice Physicians 6–7 (2018) (unpublished manuscript) (on file with the author).

172. *APMs Overview*, QUALITY PAYMENT PROGRAM, <https://qpp.cms.gov/apms/overview> (last visited Nov. 16, 2019) [<https://perma.cc/M4FB-PF64>].

173. *Id.*

174. *Id.* Also, the Quality Payment Program created an Advanced APM model that raised the standards for participating clinicians to receive a lump sum annual bonus of up to 5% of the previous year’s reimbursement for Part B and possible exemption from MIPS for taking on additional risks for participating in the advanced APMs. CMS estimates less than 10% of clinicians will participate in the advanced APMs in the initial years of this program. See 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 - EBG ADVISORS CLIENT ALERT (June 21, 2016), <https://www.ebglaw.com/news/all-about-apms-what-will-it-take-for-physicians-to-earn-the-apm-bonus-under-macra/> [<https://perma.cc/X9D4-FCVV>].

175. See *Quality Payment Program Overview*, *supra* note 165.

176. An example of an approved APM is the ACO:

Accountable Care Organizations (ACOs) are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high-quality care to the Medicare patients they serve. Coordinated care helps ensure that patients, especially the chronically ill, get the right care at the right time, with the goal of avoiding unnecessary duplication of services and preventing medical errors. When an ACO succeeds in both delivering high-quality care and spending health care dollars more wisely, it will share in the savings it achieves for the Medicare program.

Accountable Care Organizations (ACOs): General Information, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/initiatives/aco/> (last updated Oct. 31, 2019) [<https://perma.cc/6XT9-VQD4>].

177. Another approved APM is the Medicare Shared Savings Program:

The Shared Savings Program offers providers and suppliers (e.g., physicians, hospitals, and others involved in patient care) an opportunity to create an Accountable Care Organization (ACO). . . . The Shared Savings Program has different tracks that allow ACOs to select an arrangement that makes the most sense for their organization.

The Shared Savings Program is an important innovation for moving CMS’ payment system away from volume and toward value and outcomes. It is an alternative payment model.

Id.

fairly broad waivers to be used to allow the MSSP and ACOs to form and operate.¹⁷⁸ Without these waivers, these payment models would violate the Stark law. This approach of allowing waivers has created uncertainty and fragmentation in relation to whether ACO arrangements implicate the Stark law and, if so, to what extent.¹⁷⁹ Health-law stakeholders have contended the need to eliminate this uncertainty with an amendment to the Stark law in order to create an exception for MSSPs, ACOs, and other models established by CMS and tested under the Innovation Center.¹⁸⁰ Undoubtedly, MACRA has added to the complexity of navigating Stark law as clinicians propose alternative payment models that are technically in violation of Stark absent a waiver from CMS. MACRA and the Stark law are in direct conflict, thus adding to the need to reform the Stark law.¹⁸¹

IV. PROPOSED CHANGES TO THE STARK LAW WILL ALLOW HOSPITALS AND PROVIDERS THE FREEDOM TO CREATE NEW ARRANGEMENTS AND INFRASTRUCTURE TO SUPPORT VALUE-BASED CARE

As mentioned above, the fee-for-service reimbursement models, which necessitated laws such as Stark, are quickly becoming obsolete as the push for value-based reimbursement takes over. Stark has evolved into an ambiguous and highly complex law that is impeding the full adoption of new models of care that seek to clinically and financially integrate providers.¹⁸² As Judge James A. Wynn of the United States Court of Appeals for the Fourth Circuit noted in 2015, “[E]ven for well-intentioned health care providers, the Stark law has become a booby trap rigged with strict liability and potentially ruinous

178. Letter from Clifton Gaus, CEO of the National Association of ACOs, to Senate Finance Committee (Feb. 5, 2016), <https://www.naacos.com/comments-on-effects-of-stark-law> [<https://perma.cc/3NS9-TH4Y>].

179. *Id.*

180. *Id.*; *Innovation Models*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/initiatives/#views=models> (last visited Nov. 22, 2019) [<https://perma.cc/DR3M-BHV3>] (“The CMS Innovation Center develops new payment and service delivery models in accordance with the requirements of section 1115A of the Social Security Act. . . . The Innovation Center also plays a critical role in implementing the Quality Payment Program, which Congress created as part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) to replace Medicare’s Sustainable Growth Rate formula to pay for physicians’ and other providers’ services . . .”).

181. Rebecca Olavarria, *MACRA and Stark: Strange Bedfellows at the Heart of Health Care Reform*, 62 WAYNE L. REV. 131, 179–80 (2017).

182. See Press Release, U.S. Senate Comm. on Fin., Hatch Statement at Finance Hearing on the Stark Law (July 12, 2016), <https://www.finance.senate.gov/chairmans-news/hatch-statement-at-finance-hearing-on-the-stark-law> [<https://perma.cc/9RWZ-L7A5>] [hereinafter *Senate Finance Committee Press Release*]; Jeff Overley, *Stark Law Overhaul Gains Traction on Capitol Hill*, LAW360 (July 12, 2016), <https://www.law360.com/articles/815929/stark-law-overhaul-gains-traction-on-capitol-hill> [<https://perma.cc/5MDZ-KNLA>].

exposure—especially when coupled with the FCA.”¹⁸³ The Senate Finance Committee noted that Stark’s “breadth, complexity, and impenetrability have created a minefield for the health care industry.”¹⁸⁴ In addition,

[t]he risk of overutilization, which drove the passage of the Stark law, is largely or entirely eliminated in alternative payment models. When physicians earn profit margins not by the volume of services but by the efficiency of services and treatment outcomes, their economic self-interest aligns with the interest to eliminate unnecessary services.¹⁸⁵

Most agree that Stark needs to be reformed in a way to allow these new coordinated care relationships to form.¹⁸⁶ Former Secretaries of HHS, Kathleen Sebelius and Tommy Thompson, described the Stark law, along with AKS, as a “remnant of the fee-for-service world [that] harm the very patients they are supposed to protect by deterring more comprehensive patient-centered care.”¹⁸⁷ Calls to reform Stark law are not new.¹⁸⁸ However, the enactment of MACRA has made the case for reforming Stark even stronger.¹⁸⁹ The Senate Finance Committee examined the Stark law in 2015, which resulted in the 2016 White Paper, “Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models.”¹⁹⁰ In the White Paper, the committee “observed that the Stark Law’s strict liability standard and significant penalties are viewed by health care companies as serious obstacles to implementing MACRA and other alternative payment reforms.”¹⁹¹

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

184. SEN. ORRIN HATCH, U.S. SENATE COMM. ON FIN., WHY STARK, WHY NOW? SUGGESTIONS TO IMPROVE THE STARK LAW TO ENCOURAGE INNOVATIVE PAYMENT MODELS 1 (2016), <https://www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff.pdf> [<https://perma.cc/72H5-USMT>].

185. See *Senate Finance Committee Press Release*, *supra* note 182; see also Overley, *supra* note 182.

186. See Medicare Program; Request for Information Regarding the Physician Self-Referral Law, 83 Fed. Reg. 29,524 (June 25, 2018).

187. Amy H. Kearbey & Amandeep S. Sidhu, *INSIGHT: Stark Law Reform Could Shift the Dynamics—And Maybe Even the Burden of Proof—in Future FCA Cases*, BLOOMBERG L. NEWS (Sept. 18, 2018, 9:07 AM), <https://news.bloomberglaw.com/health-law-and-business/insight-stark-law-reform-could-shift-the-dynamicsand-may-be-even-the-burden-of-proofin-future-fca-cases> [<https://perma.cc/6HLC-TTDZ>].

188. See, e.g., Kathy H. Butler, *Stark Law Reform: Is It Time?*, 18 J. HEALTH CARE COMPLIANCE 5 (2016); Nicholas J. Diamond, *Giving Disclosure Its Due: A Proposal for Reforming the Stark Law*, 16 DEPAUL J. HEALTH CARE L. 1, 1 (2014); Christian D. Humphreys, *Regulation of Physician Self-Referral Arrangements: Is Prohibition the Answer or Has Congress Operated on the Wrong Patient?*, 30 SAN DIEGO L. REV. 161 (1993).

189. HATCH, *supra* note 184, at 1.

190. *Id.*

191. *Id.* at 19; Kearbey & Sidhu, *supra* note 187.

Despite the call for change by the Senate Finance Committee, meaningful change has yet to be adopted. There is sharp disagreement about which way to move forward with reform. Some health-law commentators have argued for the complete repeal of Stark.¹⁹² Their position is that Stark and its numerous and detailed exceptions have made compliance nearly impossible.¹⁹³ Even Congressman Fortney “Pete” Stark, who is the namesake of the Stark law, lamented that the law is now filled with “complications . . . added by high-priced lawyers who tried to build loopholes for their clients.”¹⁹⁴ Congressman Stark said he would be in favor of repealing the law as it currently exists.¹⁹⁵ During the Senate Finance Committee meeting in July of 2016, Dr. Ronald Paulus, MD, CEO of Mission Health based in Asheville, North Carolina, remarked that problems with the Stark law cannot be fixed by tinkering around the edges, but a full repeal is necessary to allow for the appropriate business relationships to form and move forward with population health efforts.¹⁹⁶

As momentum was growing for Stark reform, Congress considered this law and the problems it was creating in achieving health care payment reform. During the 2017–2018 legislative session, a bill was introduced in both the House and the Senate, titled “Medicare Care Coordination Improvement Act of 2017.”¹⁹⁷ This bill was referred to committee for consideration to “amend Title XVIII of the Social Security Act to modernize the physician self-referral prohibitions[,] to promote care coordination in the merit-based incentive payment system[,] and to facilitate physician-practice participation in alternative payment models under the Medicare program”¹⁹⁸ However, no

192. Olavarria, *supra* note 181, at 179–81.

193. Susan O. Scheutzwow, *Challenges to Employed Physicians' Compensation: Direct, Indirect, or Unintelligible Compensation*, 7 J. HEALTH & LIFE SCI. L., Feb. 2014, at 1, 5 (applying this analysis to physicians hired by hospitals or hospital subsidiaries can be extremely technical and confusing); Claire Turcotte, *Keeping Clients Compliant with Stark and Other Health Care Laws*, HEALTH CARE L. ENFORCEMENT & COMPLIANCE, Sept. 2011, at *2, 2011 WL 4454656.

194. Joe Carlson, *Peter Stark: Repeal the Stark Law*, MOD. HEALTHCARE (Aug. 2, 2013, 1:00 AM), <https://www.modernhealthcare.com/article/20130802/BLOG/308029995/pete-stark-repeal-the-stark-law> [<https://perma.cc/V598-LJFN>].

195. *Id.*

196. *Id.*; *Examining the Stark Law: Current Issues and Opportunities: Hearing Before U.S. Senate Fin. Comm.*, 114th Cong. (July 12, 2016), <https://www.finance.senate.gov/imo/media/doc/26440.pdf> [<https://perma.cc/HM36-S3A5>].

197. Medicare Care Coordination Improvement Act of 2017, S. 2051, 115th Cong. (2017). The House of Representatives also introduced a coordinating bill. H.R. 4206, 115th Cong. (2017).

198. H.R. 4206, 115th Cong. (2017); *H.R. 4206 – Medicare Care Coordination Improvement Act of 2017*, CONGRESS.GOV, <https://www.congress.gov/bill/115th-congress/house-bill/4206> (last visited Jan. 15, 2020) [<https://perma.cc/B82U-HKW6>] (referred to the House Energy and Commerce Committee, House Energy and Commerce Subcommittee on Health, and House Ways and Means Committee).

further action was taken during this legislative session other than the referral to various committees.¹⁹⁹

A. *Finding a Path to Comprehensive Stark Reform*

Some health-law commentators have argued for the elimination of Stark altogether, proffering that the AKS and the FCA achieve the necessary protection for the integrity of the health care programs.²⁰⁰ However, others argue for removal of only the physician-compensation arm of Stark, while leaving the ownership and investment prohibitions intact.²⁰¹ One argument for removing the physician-compensation arm of Stark is that Stark was meant to provide a bright-line rule to prohibit a physician from referring a patient for a service in order to make a greater profit.²⁰² Nevertheless, due to the fact-intensive nature of proving terms such as “fair-market value,” “takes into account the volume or value of referrals,” and “commercially reasonable,” which are present in the physician compensation exceptions, the result is anything but a bright-line test.²⁰³ In this sense, some health-law commentators argue that, due to the courts’ varied interpretations of these terms and the fact-intensive nature of proving them in litigation, it is nearly impossible for a defendant to win on a motion to dismiss or summary judgment.²⁰⁴ As a result, defendants are exposed to costly litigation in order to dispose of a frivolous claim brought by a relator.²⁰⁵ Repealing the physician compensation arrangement arm of

199. *H.R. 4206 – Medicare Care Coordination Improvement Act of 2017*, *supra* note 198.

200. Letter from Philip Wheeler, Mercy Health, to Seema Verma, Adm’r, Ctrs. for Medicare & Medicaid Servs., Dep’t Health & Human Servs. (August 23, 2018) (on file in the regulations docket browser at <https://www.regulations.gov/document?D=CMS-2018-0082-0210> [<https://perma.cc/798S-M8NA>]).

201. Olavarria, *supra* note 181, at 179–80. As mentioned above, Stark has two arms. One arm prohibits relationships of ownership and investment in the DHS entity and exceptions exist for this arm. The second arm prohibits compensation received from the DHS entity and exceptions exist for this arm as well. Some exceptions apply to both ownership and compensation models. *See* 42 U.S.C. § 1395nn (2012); *see also* Olavarria, *supra* note 181, at 148–52.

202. *See* Olavarria, *supra* note 181, at 179–180 (citing Patrick A. Sutton, *The Stark Law in Retrospect*, 20 ANNALS HEALTH L. 15, 16–18 (2011)).

203. *See id.*

204. “Ultimately, fair market value is determined based on facts and circumstances. The appropriate method will depend on the nature of the transaction, its location, and other factors.” Medicare Program; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 Fed. Reg. 51,012, 51,015–16 (Sept. 5, 2007) (codified at 42 C.F.R. pts 411 & 424).

205. Kearbey & Sidhu, *supra* note 187 (“For example, in *United States ex rel. Bingham v. BayCare Health Systems* (M.D. Fla., No. 8:14-cv-73), the defendant hospital was unable to dispense with an FCA complaint based on a questionable Stark theory and very loose facts. While the hospital ultimately prevailed on summary judgment, it was forced to endure another year and a half of time-consuming and costly discovery and motion practice to defeat a relator who apparently had no evidence to support his claims.”).

Stark, along with these nebulous terms at the heart of each exception, could eliminate the need to debate the meaning of these terms that have varying interpretations depending on the jurisdiction.

Additionally, some commentators argue that the primary risk of overutilization of services is not an issue with the implementation of value-based payment models.²⁰⁶ The value-based payment models reward efficiency and improved patient care and do not financially reward an increase in volume of services.²⁰⁷ Therefore, there is lower risk that a physician will refer patients for unnecessary services.²⁰⁸

In light of the data supporting a transition to alternative payment models,²⁰⁹ and of the lessened risk of abuse with these new models, HHS sought public comment through a Request for Information (“RFI”) regarding the best way to reform Stark and allow new payment systems to be fully adopted in health care.

B. *CMS Issues a Request for Information on June 25, 2018*

On June 25, 2018, in response to the Trump Administration’s push to simplify administrative regulations that are impeding health care delivery,²¹⁰ HHS, through CMS, issued a RFI seeking comments from the public on how to reform the Stark law.²¹¹ In this request, CMS explained that HHS “is working to transform the health[]care system into one that pays for value.”²¹² CMS explained that removing unnecessary government obstacles to care coordination is a key priority for the agency.²¹³ To accelerate the process and realize this goal of moving to a value-based payment system, HHS launched a “Regulatory Sprint to Coordinated Care” focused on identifying requirements or obstacles that “act as a barrier to coordinated care.”²¹⁴

CMS explained that some aspects of the Stark law may present a barrier to coordinated care and to the transition to a value-based payment system. Therefore, one of CMS’s goals in the “Regulatory Sprint to Coordinated Care” was to address these barriers created by the

206. See Olavarria, *supra* note 181, at 180.

207. Douglas A. Conrad, *The Theory of Value-Based Payment Incentives and Their Application to Health Care*, 50 HEALTH SERVS. RES. 2057, 2057 (2015).

208. Olavarria, *supra* note 181, at 180.

209. *Id.* at 163–64.

210. Medicare Program; Request for Information Regarding the Physician Self-Referral Law, 83 Fed. Reg. 29,524, 29,524 (June 25, 2018).

211. *Id.* The OIG for HHS similarly published an RFI for input on how it might add or amend safe harbors to the AKS statute. Although relevant to the regulatory landscape for the healthcare industry, AKS potential for reform is outside the scope of this Article. Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, 83 Fed. Reg. 43,607 (Aug. 27, 2018).

212. Medicare Program; Request for Information Regarding the Physician Self-Referral Law, 83 Fed. Reg. 29,524, 29,524 (June 25, 2018).

213. *Id.*

214. *Id.*

Stark law. CMS posed twenty specific requests for information regarding the Stark law.²¹⁵ CMS asked for comment regarding concerns of the applicability of existing Stark exceptions, the ability to enter into commercial alternative payment models, and the ability to enter into novel financial relationships.²¹⁶ CMS sought comment on whether any additional exceptions would be necessary to protect entities and individuals participating in these alternative payment models.²¹⁷ The RFI also sought feedback regarding the specific language in the current law, including “fair-market value,” “commercial reasonableness,” and “takes into account the volume or value of referrals.”²¹⁸ Finally, CMS requested information as to the positive and negative effects the Stark law had on the health care industry.²¹⁹ The RFI was so far-ranging that CMS effectively invited comments on every aspect of Stark law that a stakeholder believed warranted revision or clarification.²²⁰

CMS received hundreds of replies in respect to the RFI.²²¹ Responses were received from major organizations such as the American Bar Association (“ABA”), the American Hospital Association (“AHA”), American Medical Association (“AMA”), universities, medical device manufacturers, and major health systems, as well as from individual providers and patients.²²²

215. *Id.* at 29,525–26 (Part III).

216. *Id.* at 29,525.

217. *Id.*

218. *Id.* at 29,526.

219. *Id.* Additional points for comment in the RFI included barriers to the “group practice” definition, the utility of the risk sharing and personal services arrangements exceptions, the cost of compliance with Stark, and whether CMS should measure the effectiveness of Stark Law in preventing unnecessary utilization and other forms of program abuse relative to the cost burden on the regulated industry. *Id.*

220. Eric B. Gordon, MD. et al., *CMS Seeks Comment on Stark Law Reforms Needed to Reduce Obstacles to Innovation*, MCDERMOTT WILL & EMERY (June 26, 2018), <https://www.mwe.com/insights/cms-seeks-comments-on-stark-law-reforms/> [<https://perma.cc/PA27-39DB>].

221. *See Medicare Program; Physician Self-Referral Rulemaking Documents*, REGULATIONS.GOV, <https://www.regulations.gov/docketBrowser?rpp=50&so=DESC&sb=postedDate&po=0&dct=PS&D=CMS-2018-0082> (last visited Nov. 22, 2019) [<https://perma.cc/M5C2-QDHP>].

222. *See, e.g.*, Letter from Simeon Carson, Director, ABA Health L. Sec., to Ctrs. for Medicare & Medicaid Servs., (Dec. 30 2019) (on file at <https://www.regulations.gov/document?D=CMS-2018-0082-0612>) [<https://perma.cc/5XBC-5YZK>]; Letter from James L. Madara, Exec. V.P. & CEO, Am. Med. Ass’n, to Seema Verma, Adm’r, Ctrs. for Medicare & Medicaid Servs., Dep’t Health & Human Servs. (Aug. 24, 2018) (on file in the regulations docket browser at <https://www.regulations.gov/document?D=CMS-2018-0082-0550>) [<https://perma.cc/XCL8-E7HB>].

C. *The Public Responds to CMS's Request for Information*

1. A Call to Amend the Definitions of Key Terms to Provide Clarity

Common themes emerged in the hundreds of responses to the RFI. One common response called for clarification with regard to the terms “fair market value,” “taking into account the volume or value of referrals,” and “commercial reasonableness.”²²³ Most of the self-referral compensation exceptions include these terms. However, due to the ambiguity as to the interpretation of these terms by different courts, health care entities spent many resources trying to establish compliance with these terms. The AMA, the AHA, and many other responses—which incorporate AMA’s and AHA’s responses into their own response—called for a return to the “fair market value” definition that was adopted in the original rulemaking in 1995.²²⁴ This shift

223. Letter from Alexandria Hien McCombs, ABA Health L. Sec. Chair, to Ctrs. for Medicare & Medicaid Servs., Dep’t Health & Human Servs. 4 (Sept. 26, 2018) (on file in the regulations docket browser at <https://www.regulations.gov/document?D=CMS-2018-0082-0393> [<https://perma.cc/C2JH-EZ7P>]); Letter from Thomas M. Priselac, Pres. & CEO Cedars-Sinai, to Ctrs. for Medicare & Medicaid Servs. (July 23, 2018) (on file in the regulations docket browser at <https://www.regulations.gov/document?D=CMS-2018-0082-0038> [<https://perma.cc/Y8MY-DNLD>]); Letter from Peter B. Mancino, Deputy Gen. Counsel Johns Hopkins, to The Honorable Seema Verma 3–4 (Aug. 20, 2018) (on file in the regulations docket browser at <https://www.regulations.gov/document?D=CMS-2018-0082-0380> [<https://perma.cc/FG2U-ABYB>]); Letter from The Health Care Transformation Task Force, to Ctrs. for Medicare & Medicaid Servs., Dep’t Health & Human Servs. 3 (Dec. 31, 2019) (on file in the regulations docket browser at <https://www.regulations.gov/document?D=CMS-2018-0082-0677> [<https://perma.cc/2NMM-QMNV>]); Letter from Philip Wheeler, *supra* note 200; Letter from Janis M. Orłowski, Ass’n of Am. Med. Colls., to The Honorable Seema Verma, Adm’r, Ctrs. for Medicare & Medicaid Servs. (Aug. 24, 2018) (on file at regulations docket browser at <https://www.regulations.gov/document?D=CMS-2018-0082-0292> [<https://perma.cc/A8MD-AAEJ>]).

224. Letter from Am. Hosp. Ass’n to Seema Verma, Adm’r, Ctrs. for Medicare & Medicaid Servs., Re: CMS-1720-NC, Request for Information Regarding the Physician Self-Referral Law, 10, 18–19 (Aug. 3, 2018) (on file in the regulations docket browser at <https://www.aha.org/system/files/2018-08/180803-letter-stark-rfi.pdf> [<https://perma.cc/J5SE-HV6J>]) [hereinafter *Am. Hosp. Ass’n RFI Letter*]. The codified revision to the definition of “Fair Market Value” reads:

Fair market value means the value in arm’s-length transactions, consistent with the general market value. “General market value” means the price that an asset would bring as the result of *bona fide* bargaining between well-informed buyers and sellers, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement, on the date of acquisition of the asset or at the time of the service agreement. Usually, the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement. With respect to rentals and leases described in § 411.357(a), (b), and (l) (as to equipment leases only), “fair market value” means the value of rental property for general commercial purposes (not taking into account its intended use). In the case of a lease

would eliminate the confusion caused by the 2001 change that conflated the determination of “fair market value” with whether the payment took into account the “volume or value of referrals.”²²⁵ These two terms were intended to be distinct determinations.²²⁶

A second change urged by the AHA and the AMA was to allow for a rebuttable presumption of “fair market value” if the hospital or health system has received a valuation from a qualified valuator prior to entering into the arrangement.²²⁷ This proposed modification would shift the burden of proof onto the person challenging the validity of the “fair market value” of compensation.²²⁸ It would also provide increased stability to business arrangements that have followed the process to receive an independent evaluation by a qualified evaluator.²²⁹

Furthermore, Johns Hopkins Health System advanced the argument that the “current lack of clarity” for these terms “introduces business uncertainty and has a chilling effect on legitimate arrangements.”²³⁰ Stakeholders argue that the “fair market value” test and the “takes into account the volume or value of referrals” test do not adequately protect “hospitals under arrangements to appropriately align physician behavior with hospital cost reduction and outcome improvement goals.”²³¹

of space, this value may not be adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee. For purposes of this definition, a rental payment does not take into account intended use if it takes into account costs incurred by the lessor in developing or upgrading the property or maintaining the property or its improvements.

42 C.F.R. § 411.351; *see also* Letter from James L. Madara, *supra* note 222, at 15.

225. Medicare Program; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16,054-01 (Mar. 26, 2004) (to be codified at 42 C.F.R. pts. 411, 424); Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 855, 856-01 (Jan. 4, 2001) (to be codified at 42 C.F.R. pts. 411, 424); *see also* Letter from James L. Madara, *supra* note 222.

226. *Am. Hosp. Ass’n RFI Letter*, *supra* note 224, at 10.

227. *Id.* at 10. The AHA’s proposed addition, 42 C.F.R. § 411.354(d)(5), reads:

Compensation will be presumed to be “fair market value” where the DHS entity has obtained a valuation of fair market value from a person or entity that has certified to the DHS entity their qualifications and training to provide such an opinion and their independence from the DHS entity. Where appropriate, the valuation may address and protect the methodology used to determine the compensation. The burden of proof in such circumstances will be on the person challenging such valuation.

Id. at 19.

228. *Id.*

229. ROBERT JOHN KRANE & LAWRENCE E. SINGER, *THE LAW OF MEDICAL PRACTICE IN ILLINOIS* § 26:35 (2019).

230. Letter from Peter B. Mancino, *supra* note 223, at 4.

231. Letter from R. Brent Rawlings, Senior Vice President & Gen. Counsel, Va. Hosp. & Health Care Ass’n, to Ctrs. for Medicare & Medicaid Servs., Dep’t Health &

The AHA also advocated for clarity and stated that the phrase “takes into account the volume or value of referrals” is a bright-line, objective test that does not look to the state of mind of the parties entering into the arrangement.²³² Additionally, they recommend the regulations confirm that a “fixed payment per service is deemed not to vary or take into account the volume or value of referrals as long as the amount is determined initially by a methodology that does not take into account referrals and is not subsequently adjusted during the term based on referrals.”²³³ AHA proposed that the regulations should “clarify and reaffirm that the volume/value prohibition is not implicated where the payment is based on a physician’s personally performed services notwithstanding a correlation with services being performed at a hospital.”²³⁴ AHA argues that this is especially important in light of the innovative payment arrangements and quality improvement and care redesign efforts related to clinical integration initiatives.²³⁵

As mentioned above, ambiguity also exists as to whether an arrangement is “commercially reasonable.”²³⁶ Once again, these key terms have been conflated during their interpretation by courts.²³⁷ “Commercial reasonableness” analysis has been conflated with “fair market value for compensation,” causing confusion. AHA requested clarity on the fact that “commercial reasonableness” does not relate to the compensation paid by the parties, but instead focuses solely on the “need for and the utility of the items or services purchased.”²³⁸ Pro-

Human Servs. 2 (Aug. 21, 2018) (on file in regulations docket browser at <https://www.regulations.gov/document?D=CMS-2018-0082-0166> [<https://perma.cc/8B24-4WFC>]).

232. *Am. Hosp. Ass'n RFI Letter*, *supra* note 224, at 10.

233. *Id.*

234. *Id.* at 11. For example, the AHA urged for the addition of a provision to the Code of Federal Regulations:

Definition of When Compensation Does Not Vary With or Otherwise Take Into Account the Volume or Value of Referrals [Proposed] New Language
42 C.F.R. § 411.354 (d)(5):

Except as provided in subparagraph (c)(2)(ii), compensation shall be deemed not to be “determined in a manner that takes into account the volume or value of referrals” if, by the plain terms of the arrangement, the amount of compensation does not increase or decrease according to increased or decreased value or volume of referrals, respectively during the term of the arrangement. Except as provided in subparagraph (c)(2)(ii), compensation based on personally performed relative value units shall be deemed not to take into account the volume or value of referrals solely because the physician’s professional service is related to or correlates with the physician’s DHS referrals, as in the case of surgeries performed in a hospital or evaluation and management services performed in a provider-based clinic.

Id.

235. *Id.* at 11.

236. *Id.*

237. *Id.* at 10–11.

238. *Id.* AHA’s proposed clarification read:

viding clarity on these three terms will allow entities and physicians additional freedom to enter into arrangements without fear of the uncertainty in interpreting these terms.

2. A Call to Reform the Guidance Process Under the Stark Law

Another common theme emerged from responses to the RFI was the need for effective guidance from CMS. One critique of Stark is that the current Advisory Opinion process is inadequate. There is scant information available to help provide guidance on Stark compliance in the ever-changing health care arena.²³⁹ Compared with the AKS that has over 200 Advisory Opinions issued, only fifteen Advisory Opinions have been issued in the last twenty years that are related to compensation issues under Stark.²⁴⁰ The AHA, in its response to the RFI, urged CMS to provide “clear, authoritative, and timely guidance.”²⁴¹

Another suggested change by the AHA was to accept questions of general interpretation and hypotheticals through the Advisory Opinion process.²⁴² Currently, these types of questions are not accepted. The admission of questions and hypotheticals of this kind would be very useful for providers and entities—that are in anticipation to enter into arrangements and in need of clarity—to help ensure they are in compliance.²⁴³ AHA argues that substantial resources are being diverted away from patient care because they are being spent on navigating the complexity of the Stark law, along with its legal and compliance requirements.²⁴⁴ This is particularly troublesome for rural or small providers who do not have the resources for high legal and compliance fees.²⁴⁵ Clear and timely guidance from CMS could help eliminate some of these fees.

In addition to reforming the Advisory Opinion process, others have called for a more developed “Frequently Asked Questions” guidance for commonly recurring provider circumstances.²⁴⁶ For example, the

Definition of Commercial Reasonableness [Proposed] New Language 42 C.F.R. § 411.351: Commercial reasonableness shall mean that the services or items purchased or contracted for are of use in the business of the purchasing or contracting party and are of the amount, kind and type of items or services purchased or contracted for by similarly situated entities.

Id. at 19; *see also* Letter from James L. Madara, *supra* note 222, at 1.

239. *Am. Hosp. Ass'n RFI Letter*, *supra* note 224, at 12.

240. *Id.*; *see Advisory Opinions (AOs)*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html (last updated Oct, 22, 2019 10:12 AM) [<https://perma.cc/H9G9-8VCE>].

241. *Am. Hosp. Ass'n RFI Letter*, *supra* note 224, at 2.

242. *Id.* at 12.

243. *Id.*

244. *Id.*

245. *Id.*

246. Letter from The Health Care Transformation Task Force to Seema Verma, Adm'r, Ctrs. for Medicare & Medicaid Servs. 2–3 (August 24, 2018) (on file in regula-

Health Care Transformation Task Force (“HCTTF”) noted that there is limited commentary on the waiver applicability for APM participants.²⁴⁷ HCTTF urged CMS and OIG to explore mechanisms for providers to ask questions for guidance about these waivers short of an Advisory Opinion. HCTTF argued that when “regulated entities have abundant sub-regulatory guidance on their legal compliance requirements under Stark, entities will have a better understanding of what activities are and are not permitted.”²⁴⁸

3. A Call to Amend Rules Regarding Technical Noncompliance with the Stark Law

Another common critique that emerged from the RFI was that Stark is riddled with numerous complex and technical requirements that could result in minor and inadvertent noncompliance accompanied with ruinous penalties.²⁴⁹ Mercy Health argued for the expanded ability to correct Stark law violations because of this issue. Specifically, Mercy Health argued that health systems spend a significant amount of time and financial resources to comply with Stark, but even a minor technical omission, that does not otherwise involve overutilization of services or harm to patients, is a violation of this strict liability statute.²⁵⁰

An example of this type of technical compliance can be found in the writing requirements at the inception of a business arrangement aiming to fall within a compensation exception.²⁵¹ The AHA argues that the documentation requirements do not add any additional substantive protection against overutilization of services, but instead, can result in “catastrophic payment denials for clerical errors even when an arrangement satisfies the substantive elements of an exception.”²⁵² The AHA advocates for a different approach instead of the signature and writing requirements currently found in many of the compensation exceptions.²⁵³ In this regard, the hospital “should be deemed to satisfy the writing requirement and signature requirements” if it can demonstrate “the existence of a binding, enforceable contract under state law.”²⁵⁴ The AHA states that this will not increase problematic arrangements, since the substantive elements of the exception will be

tions docket browser at <https://www.regulations.gov/document?D=CMS-2018-0082-0324> [<https://perma.cc/9WHR-WSBP>].

247. *Id.*

248. *Id.*

249. Letter from Philip Wheeler, *supra* note 200.

250. *Id.*

251. *See, e.g.*, 42 C.F.R. § 411.357(x).

252. *Am. Hosp. Ass'n RFI Letter, supra* note 224, at 12.

253. *Id.* at 13.

254. *Id.*

intact, and it will prevent the disallowance of payments based on paperwork mistakes.²⁵⁵

4. A Call to Add a New Value-Based Exception to the Stark Law

Although many suggestions emerged from the RFI, one key suggestion that was mirrored by countless stakeholders was the need for a new value-based payment exception.²⁵⁶ Supporters of this new exception argued that “the health care system will plateau in its progress towards value-based care models without the reform and modernization of the existing fraud and abuse laws.”²⁵⁷ The AHA advocated for an exception dedicated to value-based arrangements that could provide certainty and allow hospitals, physicians, and health systems to join forces in achieving a patient-centered approach.²⁵⁸ They argue that:

The new exception should cover only those arrangements with a declared objective of achieving one or more of the pillars of coordinated care: promoting accountability for the quality, cost, and overall care for patients; managing care for patients across and among other providers; and, encouraging investment in infrastructure and redesigned care processes for high quality and efficient care delivery for patients.²⁵⁹

Additionally, the AHA urges a broad definition of “remuneration” that includes “incentive payments, shared savings payments based on actual cost savings, and infrastructure payments or in-kind assistance (including, but not limited to, electronic health records (EHRs) technology, cybersecurity resources, data or clinical analysis tools, and start-up support).”²⁶⁰ The AHA accompanies this suggestion with the

255. *Id.*

256. *See id.* at 1–2; Letter from James L. Madara, *supra* note 222, at 2; Letter from Peter. B. Mancino, *supra* note 223, at 2; Letter from Jeffrey R. Balsler, Vanderbilt Univ. Med. Ctr., to Seema Verma, Adm’r, Ctrs. for Medicare & Medicaid Servs., Dep’t Health & Human Servs. 6, 10 (Aug. 24, 2018) (on file in regulations docket browser at <https://www.regulations.gov/document?D=CMS-2018-0082-0333> [<https://perma.cc/CG9P-JUK7>]); Letter from Betsy Van Hecke, Medtronic, to Seema Verma, Adm’r, Ctrs. for Medicare & Medicaid Servs. 4 (Aug. 24, 2018) (on file in regulations docket browser at <https://www.regulations.gov/document?D=CMS-2018-0082-0306> [<https://perma.cc/389M-4RJB>]); Letter from The Health Care Transformation Task Force to Seema Verma, *supra* note 246, at 3; Letter from Anne Adams, Emory Univ., to Seema Verma, Adm’r, Ctrs. for Medicare & Medicaid Servs., Dep’t Health & Human Servs. 2 (Aug. 24, 2018) (on file in regulations docket browser at <https://www.regulations.gov/document?D=CMS-2018-0082-0356> [<https://perma.cc/QBP3-JHUJ>]); Letter from R. Brent Rawlings, *supra* note 231, at 2; Letter from Philip Wheeler to Seema Verma, *supra* note 200; Letter from Janis M. Orlovski, Ass’n of Am. Med. Colls., to The Honorable Seema Verma, Adm’r, Ctrs. for Medicare & Medicaid Servs. 2, 7 (Aug. 24, 2018) (on file at regulations docket browser at <https://www.regulations.gov/document?D=CMS-2018-0082-0292> [<https://perma.cc/A8MD-AAEJ>]).

257. Letter from Betsy Van Hecke to Seema Verma, *supra* note 256, at 2.

258. *Am. Hosp. Ass’n RFI Letter*, *supra* note 224, at 1–4.

259. *Id.* at 4.

260. *Id.*

inclusion of basic accountabilities with the use of these types of incentives. Some suggestions for accountability include transparency in documentation, recognizable improvement processes that are consistent with medical standards and improving patient care, and internal monitoring of the performance under the new processes to guard against adverse effects.²⁶¹

From a policy perspective, health care stakeholders argue this value-based exception will promote interprofessional relationships because many different health care providers can work together as a team to care for the patient. For example, care for a patient in the community might include a physician, clinical staff, advance practice nurses, dietitians, and social workers.²⁶² The physician would be responsible for the overall goals for the patient, but the team would work together to ensure the success of the plan.²⁶³ A team approach would also provide patients and their families with more readily available information about their care. Creating a value-based exception would allow reimbursement for this type of team-based care to reflect the increased quality of care and improved value to the federal programs.²⁶⁴

The AHA and AMA, along with many others who replied, stated that the value-based arrangements would not carry the risk of overutilization that the Stark law was intended to prevent.²⁶⁵ The exception, they argue, would have protections in place to ensure payment corresponds with both an increase in quality of care to the patient and a cost-savings to the federal program, therefore removing any incentive to refer for services not needed by the patient.²⁶⁶ Additionally, the value-based arrangements would be part of the “existing quality oversight programs of the Medicare program, which will guard against underutilization.”²⁶⁷

261. *Id.* at 4–5; Letter from Betsy Van Hecke to Seema Verma, *supra* note 256, at 4.

262. U.S. DEP’T HEALTH & HUMAN SERVS., *Defining the PCMH*, PATIENT CENTERED MED. HOME RESOURCE CTR., <http://pcmh.ahrq.gov/page/defining-pcmh> (last visited Jan. 25, 2020) [<https://perma.cc/Y7GA-QT5X>]; *Am. Hosp. Ass’n RFI Letter*, *supra* note 224, at 6.

263. *Am. Hosp. Ass’n RFI Letter*, *supra* note 224, at 6–7.

264. *See id.* at 2; Letter from Betsy Van Hecke to Seema Verma, *supra* note 256, 1–4; *see also* Charles P. Vega & Amy Bernard, *Interprofessional Collaboration to Improve Health Care: An Introduction*, MEDSCAPE (Mar. 8, 2017), <https://www.medscape.org/viewarticle/857823> [<https://perma.cc/38TB-7GGF>].

265. *Am. Hosp. Ass’n RFI Letter*, *supra* note 224, at 7; Letter from James L. Madara, *supra* note 222, at 2.

266. *Am. Hosp. Ass’n RFI Letter*, *supra* note 224, at 7; Letter from James L. Madara, *supra* note 222, at 5–6.

267. *Am. Hosp. Ass’n RFI Letter*, *supra* note 224, at 7. The risk of underutilization is that the doctor will not refer for additional services to keep the costs down, but then the patient does not receive necessary care and is harmed by this decision. Mary Du-Bois Krohn, *The False Claims Act and Managed Care: Blowing the Whistle on Underutilization*, 28 CUMB. L. REV. 443, 446–47 (1998). Studies have shown this is a problem especially for minority communities. *See* Jocelyn T. Chi & Mark S.

Ultimately, they argue, this exception for value-based care models is needed to promote widespread adoption of this new delivery model that will help correct the skyrocketing health care costs while improving patient outcomes.²⁶⁸

5. Arguments Against Adding a New Value-Based Exception to the Stark Law

Despite the support from major health care organizations for a new value-based exception, many individual providers and smaller entities responded that relaxing the Stark law to allow more exceptions will lead to more problems for the federal programs. Many argue that a new value-based exception will keep the referrals within a system without focusing on what is best for patient care and convenience.²⁶⁹ It is possible to imagine that this type of behavior could lead to a lack of competition in the market. Moreover, these opponents contend that relaxing Stark to allow increased coordination of care will drive out smaller providers.²⁷⁰ A response from a physical-therapy provider noted that the “MDs have the money to pay lobbyists to influence these types of decisions . . . [and] benefit . . . by monopolizing the physical therapy market.”²⁷¹ Another physical-therapy provider with a small office commented that an orthopedic group in her region partnered with a hospital system that obligated the group to keep referrals to physical therapists within their system.²⁷² She added that the cost is higher in a hospital system than in private practice, and geo-

Handcock, *Identifying Sources of Health Care Underutilization Among California's Immigrants*, J. RACIAL & ETHNIC HEALTH DISPARITIES 207, 207 (2014); Daphne Chandler, *The Underutilization of Health Services in the Black Community: An Examination of Causes and Effects*, 40 J. BLACK STUD. 915, 915 (2010).

268. See *Am. Hosp. Ass'n RFI Letter*, *supra* note 224, at 4.

269. Letter from Francis J. Crosson, MD, Chairman of Medpac, to Seema Verma, Ctrs. for Medicare & Medicaid Servs. 6 (Dec. 20, 2019), http://www.medpac.gov/docs/default-source/comment-letters/12202019_selfreferral_medpac_comment_v2_sec.pdf?sfvrsn=0 [<https://perma.cc/UQV4-9GK8>].

270. See, e.g., Jodi Blacketer, Comment to *Centers for Medicare Medicaid Services (CMS) Proposed Rule: Medicare Programs: Request for Information Regarding Physician Self-Referral Law*, REGULATIONS.GOV (Aug. 14, 2018), <https://www.regulations.gov/document?D=CMS-2018-0082-0110> [<https://perma.cc/4BY7-HM5G>]; see also Pete Bartel, Comment to *Centers for Medicare Medicaid Services (CMS) Proposed Rule: Medicare Programs: Request for Information Regarding Physician Self-Referral Law*, REGULATIONS.GOV (Aug. 13, 2018), <https://www.regulations.gov/document?D=CMS-2018-0082-0059> [<https://perma.cc/SKJ2-GK97>]; Ana Sanchez, Comment to *Centers for Medicare Medicaid Services (CMS) Proposed Rule: Medicare Programs: Request for Information Regarding Physician Self-Referral Law*, REGULATIONS.GOV (Aug. 29, 2018), <https://www.regulations.gov/document?D=CMS-2018-0082-0216> [<https://perma.cc/VQU8-6456>].

271. Mary Kroth-Brunet, Comment to *Centers for Medicare Medicaid Services (CMS) Proposed Rule: Medicare Programs: Request for Information Regarding Physician Self-Referral Law*, REGULATIONS.GOV (July 12, 2018), <https://www.regulations.gov/document?D=CMS-2018-0082-0009> [<https://perma.cc/7PQT-ZF48>].

272. Blacketer, *supra* note 270.

graphical convenience to the patient was never considered.²⁷³ She argued that exceptions to Stark “promote monopolies, limit small business opportunities, and are not patient centered.”²⁷⁴

Furthermore, the Association of Independent Doctors (“AID”) opposes the removal of obstacles in Stark that will achieve coordinated care but allow more self-referral within health care systems.²⁷⁵ The AID represents over 1000 physician members from over thirty states.²⁷⁶ This group argues that the major stakeholders in health care have an ulterior motive and their suggestions to add a new value-based exception are driven by financial gain.²⁷⁷ Moreover, the AID argues that although “integrat[ing] care” and “manag[ing] risk” sound positive, these terms are actually merely a cover to gain more control of the marketplace by owning more physicians and clinics, thus creating monopolies.²⁷⁸ In its RFI response, AID stated that “the proposal to soften or roll back Stark law, and the ‘associated fraud and abuse laws,’ . . . is a thinly disguised effort for hospitals to gain permission to financially reward doctors for referrals”²⁷⁹

Instead of adding additional exceptions to Stark, AID advocates for transparency in pricing to keep health care costs down.²⁸⁰ AID contends that “full transparency, that is letting consumers know before they have a procedure what it will cost, and who would financially benefit from facility fees, for instance, would help drive quality up and costs down.”²⁸¹ According to AID, “[t]ransparency is a bipartisan issue all Americans want”; but special interests, “specifically hospital, insurance, and pharmaceutical lobbies, stand in the way.”²⁸²

Finally, the AID concludes that shifting to value-based payments is based on a faulty premise. The entire system is based on rewarding providers for improved patient outcomes “when practically speaking, no one knows how to measure value.”²⁸³ They argue that the attempts to measure outcomes are flawed:

[W]hen doctors’ outcomes are based on “value” they will tend to make patients look sicker on paper than they really are. This is no different from emergency room doctors coaching patients who come

273. *Id.*

274. *Id.*

275. Letter from Marni J. Carey, Exec. Director, Ass’n of Indep. Doctors Fl., to Ctrs. for Medicare & Medicaid Servs. (July 26, 2018) (on file in regulations browser at <https://www.regulations.gov/document?D=CMS-2018-0082-0034> [[https://per\]ma.cc/89QX-WKTT](https://per]ma.cc/89QX-WKTT)).

276. *Membership*, ASS’N. INDEP. DOCTORS, <http://www.aid-us.org/join> (last visited Nov. 11, 2019) [<https://perma.cc/4WZV-D9C5>].

277. Letter from Marni J. Carey, *supra* note 275.

278. *Id.*

279. *Id.*

280. *Id.*

281. *Id.*

282. *Id.*

283. *Id.*

in with, say, abdominal pain into thinking they are also having chest pain since a cardiac admission generates a higher reimbursement[.]²⁸⁴

AID asserts that a value-based payment will incentivize providers to manipulate outcomes in their own favor in order to receive greater reimbursements.²⁸⁵ With opposing arguments on either side of this debate, the public is awaiting the agency's next step in amending the Stark law.

D. CMS Confirms Stark Law Reform is Underway

As the public awaits CMS's decision on how Stark will be reformed, Seema Verma, Administrator for CMS, commented on this topic at the Federation of American Hospitals 2019 Public Policy Conference. On March 4, 2019, Ms. Verma specifically addressed upcoming changes to Stark.²⁸⁶ Ms. Verma acknowledged that the majority of the commenters believed that regulatory changes were needed to support the move to value-based payments.²⁸⁷ She also acknowledged the comments regarding the potential for program-integrity vulnerability or other abuses.²⁸⁸ Moreover, Ms. Verma said that CMS is currently working on changes to Stark based on the feedback, and she stated these changes will reflect "the most significant changes to Stark law since its inception."²⁸⁹

In her speech to the Federation of American Hospitals, Ms. Verma announced some of changes to expect. CMS will propose regulations to clarify the definitions for "volume or value, commercial reasonableness and fair market value."²⁹⁰ Additionally, CMS will address the areas of technical noncompliance, including the signature requirement.²⁹¹ These remarks reflected that CMS listened to the commenters and will be addressing issues that were brought up in many of the responses. Ms. Verma reiterated that CMS hopes that "these changes will help spur better care coordination and help support

284. *Id.*

285. *Id.*

286. *See generally* Seema Verma, Adm'r, CTRS. FOR MEDICARE & MEDICAID SERVS., Remarks at the Federation of American Hospitals 2019 Public Policy Conference (Mar. 4, 2019) (transcript available at <https://www.cms.gov/newsroom/press-releases/speech-remarks-administrator-seema-verma-federation-american-hospitals-2019-public-policy-conference> [<https://perma.cc/DLB5-XNRL>]) [hereinafter Verma Remarks at Federation of American Hospitals].

287. *Id.*

288. *Id.*

289. *Id.*

290. *Id.*

291. *Id.* In addition, she stated that CMS would be updating the regulation to address a world in which there are cybersecurity and electronic health records requirements. *Id.*

[CMS's] work to remove barriers to innovation while continuing to provide appropriate safeguards for [CMS's] programs."²⁹²

Equally important as to what Ms. Verma did address is what she did not address.²⁹³ Based on her remarks, the public has some certainty that CMS will clarify key definitions and ease some of the burdens of technical noncompliance.²⁹⁴ Nevertheless, adding a value-based exception to the list of Stark exceptions was not touched upon.²⁹⁵ As explained above, many stakeholders believe that a new value-based exception is critical to the widespread adoption of a value-based care model.²⁹⁶ However, a value-based exception was not addressed in Ms. Verma's comments.²⁹⁷

Without a new exception to allow value-based payment models on a broad scale, CMS will fail in its effort to transform the system. The Stark law is too complex. Likewise, there is insufficient guidance on Stark to help businesses and physicians enter into new business arrangements that are centered on integrated care and value-based payment. This problematic combination has a chilling effect on innovation in health care business arrangements. Stakeholders will be reluctant to attempt new models in light of the draconian penalties should they inadvertently fall out of compliance with Stark. In order to truly transform health care, hospitals, health systems, providers, and other members of the community need clear rules that allow them to enter into new business arrangements that can provide the value-based care that CMS is seeking.

As the CMS RFI stated, "HHS is working to *transform* the health care system into one that pays for value."²⁹⁸ The question remains as to whether the health care system can truly be transformed without a broad new value-based exception that allows reimbursement to be tied to value. As Dr. Ronald Paulus noted, the Stark law can[not] be fixed by "tinkering around the edges."²⁹⁹ CMS must balance the goal of transforming the health care system into one that pays for value

292. *Id.* Ms. Verma expanded on the safeguards by announcing that CMS is also revamping the Recovery Audit Contract, or RAC audits, to be more effective. *Id.*

293. Verma Remarks at Federation of American Hospitals, *supra* note 286.

294. *Id.*

295. *Id.*

296. *See e.g.*, Letter from AAMC to Seema Verma (Dec. 30, 2019), <https://www.aamc.org/system/files/2019-12/o-comm-ogr-AAMC%20Comment%20Letter%20CMS%20Stark%20Proposed%20Rule%2012.30.2019.pdf> [<https://perma.cc/66VP-3MUK>]; PHILIPS, VALUE-BASED CARE (Apr. 2012 Position Paper), https://www.philips.com/c-dam/b2bhc/de/innovation/vitalhealth/Value-based_care_position_paper.pdf. [<https://perma.cc/FGJ9-SELJ>].

297. Verma Remarks at Federation of American Hospitals, *supra* note 286.

298. Medicare Program; Request for Information Regarding the Physician Self-Referral Law, 83 Fed. Reg. 29,524, 29,524 (June 25, 2018) (emphasis added).

299. Ayla Ellison, *Stark Law: The 27-year-old Act Killing Health Care Reform Before It Can Begin?*, BECKER'S HOSP. REV. (Sept. 7, 2016), <https://www.beckershospitalreview.com/legal-regulatory-issues/stark-law-the-27-year-old-act-killing-health-care-reform-before-it-can-begin.html> [<https://perma.cc/J8FG-MVZD>].

while maintaining safeguards to ensure program integrity. Will CMS continue to tinker around the edges, or will this new set of proposed regulations significantly reform Stark and remove the longstanding barriers to coordination of care? The health care community is anxiously awaiting the proposed regulations and will be greatly impacted by the direction CMS chooses to take these reforms.

V. CONCLUSION

The health care crisis in our country demands attention on many levels. Skyrocketing health care costs and a population that is in comparatively poor health have made health care reform one of the most pressing topics in our government. Regulatory barriers exist, however, that are preventing the type of reform that is needed. CMS is working to transform our health care system into a system that pays for positive health outcomes as opposed to paying for individual services. Currently, the Stark law is a barrier to the widespread adoption of this type of value-based care model. The Stark law is ambiguous and complex. The unpredictable interpretation of key terms by the courts, coupled with the many complex technical requirements found in the exceptions, make this strict-liability law incredibly problematic for the health care industry. The Stark law should be reformed to clarify key terms, provide more access to guidance, as well as allow for a new value-based exception that will give providers the freedom to enter into innovative business arrangements that focus on patient-care pathways and clinically integrated care. These reforms are necessary to reshape health care delivery in the United States. The health care community anxiously awaits the proposed regulations that seek to reform Stark and transform our health care system.