

THE STARK LAW IN THE MODERN HEALTH-CARE WORLD

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I. INTRODUCTION

When does the cure become worse than the disease? One instance is when the circumstances creating the disease change, as evidenced by the U.S. health-care system's evolution over the past forty years into the complex, expensive maze it is today. In 2017, health-care spending in the United States reached \$3.5 trillion, or \$10,739 per person.¹ Hoping to rein in health-care spending and improve patient outcomes, payers—particularly the federal government—have increasingly pushed the industry away from fee-for-service (“FFS”) and toward a value-based payment system.² Many regulations once pertinent in the FFS regime now seem ill-suited and are described as unduly burdensome and unnecessary. One such set of statutes and regulations is known as the “Stark Law,” which originated in legislation first proposed in 1988 by former Representative Fortney (Pete) Stark in an effort to eliminate the practice of physicians referring patients to facilities in which they held a financial interest.³ The prohibition on such “self-referrals” then grew into a complex web of prohibitions and exemptions through regulations promulgated over the succeeding quarter-century.

To address whether this “cure” is now worse than the disease, this Note offers first a description of the U.S. health-care system and its ongoing shift toward value-based payment. Next, Part III introduces the Stark Law and examines its connection to the Anti-Kickback Statute and False Claims Act (“FCA”). Finally, Part IV analyzes three current proposals for Stark Law reform, ultimately advocating for the repeal and replacement of the Stark Law with a streamlined version that promotes value-based care while policing self-referrals for providers operating under the FFS system. Enforcement of intentional fraud against the federal government would not be affected, as it would continue to be enforced under the Anti-Kickback Statute through FCA actions.

¹*National Health Expenditures 2017 Highlights*, CTRS. MEDICARE & MEDICAID SERVS. (2017), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf>.

² *Value-Based Programs*, CTRS. MEDICARE & MEDICAID SERVS. (2020), <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs>.

³ 42 U.S.C. § 1395nn (1990).

II. THE U.S. HEALTH-CARE SYSTEM AND ITS SHIFT TOWARD VALUE-BASED PAYMENT

A. BACKGROUND

Health care in the United States accounts for roughly 18 percent of the country's gross domestic product ("GDP").⁴ As a percentage of GDP, the United States spends significantly more on health care than any other nation.⁵ Unfortunately, higher spending has not necessarily resulted in a higher quality of care. In 2000, the World Health Organization ranked the U.S. health-care system thirty-seventh in the world, and independent studies have estimated that 100,000 patients die every year from preventable medical errors.⁶ Following the enactment of the Affordable Care Act ("ACA"), growth in health-care spending has slowed and markets have begun to stabilize. While the stabilization in growth is encouraging, the continued political debate regarding health care means that any stabilization is subject to potential upheaval.

In December 2018, the ACA was effectively struck down by U.S. District Court Judge Reed O'Connor when he ruled the law unconstitutional following Congress's elimination of the financial penalty for failure to obtain health insurance.⁷ While the decision will be reviewed by the Supreme Court, it adds to the pressure on a divided Congress to come up with a bipartisan solution. The current political climate will assuredly make that task nearly impossible; the Left has called for a single-payer system and Medicare-for-All, while the Right has repeatedly attempted to accomplish what Judge O'Connor did in one decision.⁸ Whether or not health care is a "right or privilege" has never been more

⁴ *Id.*

⁵ Org. Econ. Coop. Dev. [OECD], *Spending on Health: Latest Trends*, at 2 (June 2018), <http://www.oecd.org/health/health-systems/Health-Spending-Latest-Trends-Brief.pdf>. Of the countries studied, the United States spends the most on health care at 17.2 percent of its GDP; the world average of health-care consumption in 2016 was 8.9 percent of GDP. *Id.*

⁶ Ajay Tandon, et. al., *Measuring Overall Health System Performance for 191 Countries*, GPE DISCUSSION PAPER SERIES: NO. 30, WORLD HEALTH ORGANIZATION [WHO] (2000), <https://www.who.int/healthinfo/paper30.pdf>.

⁷ *Texas v. United States*, 340 F. Supp. 3d 579, 601 (N.D. Tex. 2018), *cert. granted*, 140 S. Ct. 1262 (2020); see Kristina Peterson & Stephanie Armour, *Ruling Against Health Law Puts Political Divide in Stark Relief*, WALL ST. J. (Dec. 15, 2018), <https://www.wsj.com/articles/ruling-against-health-law-puts-political-divide-in-stark-relief-11544920199>.

⁸ *Id.*

important. As health-care delivery often begins and ends outside of hospitals, there is a widening divide between the haves and have-nots.⁹

In its current state, the health-care industry includes a wide array of private and public entities. These entities are spread across all corners of the economy and fall under many jurisdictions. Though not immediately associated with health care, surprisingly the Internal Revenue Service (“IRS”) holds jurisdiction over some vital aspects of the U.S. health-care system.¹⁰ The IRS became involved following the passage of the ACA in 2010 and the Medicare Access and CHIP Reauthorization Act in 2015;¹¹ it mandated that nonprofit hospitals conduct community health need assessments and provide more community health benefits.¹² The IRS is a great example of an agency that is not typically associated with health care but is now working to evaluate and improve health care outside of hospitals in hopes of decreasing the overall cost of health-care delivery.

B. THE TRANSITION TO VALUE-BASED PAYMENTS

The way in which Americans pay for their health-care services has slowly been changing for the better part of the last two decades. Americans have traditionally paid for their health care on a FFS basis in which patients only pay for the health-care services rendered.¹³ Around 2000, America began transitioning from FFS toward a value-based system.¹⁴ This shift meant that instead of paying for each service, payment would be for a “bundle” of services designed to maintain or improve one’s overall health.¹⁵ The purpose of bundling services is to shift financial risk to the providers in the hopes of lowering costs and increasing quality of care.¹⁶ In a review of value-based payment systems, one study found that quality measures improved across the board, though it was unclear what

⁹ James C. Leonard, *Reflections on Evolving Understandings of the Role of Healthcare Providers*, 46 J. L., MED., & ETHICS 680, 680 (2018).

¹⁰ See, e.g., Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 251 (2010) (authorizing the IRS to administer programs under the ACA).

¹¹ Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87 (2015).

¹² Lindsay F. Wiley & Gene W. Matthews, *Health Care System Transformation and Integration: A Call to Action for Public Health*, 45 J. L., MED., & ETHICS 94, 94 (2017).

¹³ Michael E. Porter & Robert S. Kaplan, *How to Pay for Health Care*, HAR. BUS. REV. (July–August 2016).

¹⁴ Eleanor D. Kinney, *The Affordable Care Act and the Medicare Program: Linking Medicare Payment to Quality Performance*, 68 N.Y.U. ANN. SURV. AM. L. 567, 568–69 (2013).

¹⁵ *Id.* at 568. 570-72.

¹⁶ *Id.* at 573-77.

role financial incentives played in those improvements.¹⁷ The ACA's passage in 2010 further accelerated the move toward value-based payments.¹⁸

The need to transition to value-based payment was brought mainstream in 2009 by Atul Gawande, who described the tale of two Texas cities, El Paso and McAllen, and their relative Medicare costs.¹⁹ In his comparison, Gawande detailed how Medicare's cost per enrollee was almost double in McAllen compared to El Paso, and how that cost discrepancy did not necessarily correlate with an increase in McAllen's quality of care.²⁰ Gawande's findings helped show the general public that increased cost does not necessarily equal increased quality.²¹

Additionally, prior to the value-based payment, many health-care providers struggled to increase their quality of care because of the financial limitations.²² For example, in 2007, Virginia Mason Medical Center (located in Seattle, Washington) worked with health insurer Aetna and other local large employers, such as Starbucks, Costco, and Nordstrom, to standardize care and realign payment incentives so that all groups could be rewarded for their efforts.²³ This novel approach was a highly complex way to realign incentives, and the providers' outreach to large employers was critical to its success.²⁴

Following the passage of the ACA, the Center for Medicare & Medicaid Services ("CMS") established the Center for Medicare & Medicaid Innovation ("CMMI") to test different methodologies in an attempt to increase the quality of care while decreasing costs.²⁵ Since its inception, CMMI has developed innovative programs to push the move to value-based payment.²⁶ To date, different types of value-based payments

¹⁷ Jon B. Christianson et al., *Lessons From Evaluations of Purchaser Pay-for-Performance Programs: A Review of the Evidence*, 65 MED. CARE RES. REV. (SUPP.) 5S, 5S (Dec. 2008).

¹⁸ Kinney, *supra* note 14, at 568.

¹⁹ Atul Gawande, *The Cost Conundrum*, THE NEW YORKER (June 1, 2009), <https://www.newyorker.com/magazine/2009/06/01/the-cost-conundrum>.

²⁰ *Id.*

²¹ *Id.*; see Raymond Gibbons, et. al., *Payment Changes Necessary to Catalyze Higher-Quality, Lower-Cost Care*, 25 NOTRE DAME J. L. ETHICS PUB. POL'Y 393, 395–96 (2011).

²² Gawande, *supra* note 19.

²³ Gibbons, *supra* note 21, at 397–98; Vanessa Fuhrmans, *A Novel Plan Helps Hospital Wean Itself Off Pricey Tests*, WALL ST. J. (Jan. 12, 2007), <https://www.wsj.com/articles/SB116857143155174786>.

²⁴ Fuhrmans, *supra* note 23.

²⁵ Lisa G. Han & Colin McDermott, *Understanding Alternative Payment Models and Related Regulatory Issues*, HEALTH LAW., Aug. 2018, at 1, 3.

²⁶ *Where Innovation is Happening*, CTRS. MEDICARE & MEDICAID SERVS. <https://innovation.cms.gov/initiatives/map/#model=> (last visited Oct. 20, 2020).

have been introduced, many of which have proven successful. Examples include fixed fee payments for preventative services and bundled payments for a set episode of care.²⁷ As technology continues to advance, value-based payments will continue to more accurately follow evidence of positive health outcomes, ensuring that the best services result in the highest profits.²⁸ Many of the industry's biggest names, such as Cigna, Aetna, and Novartis, have supported the transition to value-based contracting.²⁹

III. FEDERAL LEGISLATION IN THE HEALTH-CARE ARENA

A. THE STARK LAW

The Stark Law was passed in 1989 after studies demonstrated that physician referrals were higher when the referring physician had a financial incentive tied to the volume or value of those referrals.³⁰ At the time, many saw the Stark Law as a powerful tool to prevent physicians from enriching themselves at the expense of their patients.³¹ As passed, the statute presumed illegal all referrals made in which the physician had an ownership interest or compensation arrangement.³² The Stark Law's passage, therefore, was predicated on FFS payment methodology.³³ As the health-care industry has moved to value-based payments, the financial incentive to increase referrals—and with it, utilization—will likely dissipate over time, with payment instead tied to patients' overall welfare.³⁴ From this standpoint, physicians will be incentivized to decrease services so long as the quality of care is maintained. From its simple and good-natured beginnings to its current complex state, however, the Stark

²⁷ Han & McDermott, *supra* note 25, at 3.

²⁸ Barry H. Boise, et. al., *Value-Based Contracting for Prescription Drugs and Medical Devices: An Innovative Solution Impaired by Outdated Regulations*, HEALTH LAW., Oct. 2017, at 1, 3.

²⁹ *Id.*

³⁰ 42 U.S.C. § 1395nn (2018).

³¹ MAJORITY STAFF S. COMM. ON FIN., 114TH CONG., WHY STARK, WHY NOW? 4-5 (Rep. 2016),

<https://www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff.pdf>; see also PUB. INT. COMM., AM. HEALTH LAW. ASS'N, A PUBLIC POLICY DISCUSSION: TAKING MEASURE OF THE STARK LAW 12 (2009) [hereinafter AM. HEALTH LAW. ASS'N], <https://library.ahima.org/doc?oid=93447#.XuE84p5KjfY>.

³² Corbin Santo, *Walking a Tightrope—Regulating Medicare Fraud and Abuse and the Transition to Value-Based Payment*, 64 CASE W. RES. L. REV. 1377, 1380 (2014).

³³ MAJORITY STAFF OF S. COMM. ON FIN., *supra* note 31.

³⁴ Kathy H. Butler, *Stark Law Reform—Is it Time?*, J. HEALTH CARE COMPLIANCE, Dec. 2016, at 5, 7.

Law has made it increasingly difficult for providers to comply with the law while moving toward value-based payments.³⁵

The current health-care climate is not the first in which the Stark Law has been called into question. Representative William Thomas (R-CA) questioned the role of the Stark Law in a 1999 hearing before the Subcommittee on Health of the House of Representatives Committee on Ways and Means.³⁶ In the hearing, Rep. Thomas stated:

The guiding principle for the self-referral laws was to prevent physicians from inappropriately referring patients based on the potential for financial gain. These laws were meant to provide a bright-line test, and yet we are further from clarity in this area of the law than probably any other area of health policy.³⁷

More interestingly, former Representative Stark, after whom the legislation is named, stated in 2007 that when he sponsored the 1989 bill, he did not believe that physician self-referral was “such a big deal.”³⁸

Over time, CMS has attempted to modify the law to adapt to the changing industry; but lack of a complete understanding regarding providers’ relationships and changing payment models has hampered its efforts.³⁹ Through its rulemaking, CMS takes care to warn providers that it is not enough to conform to Stark regulations—they must also comply with federal anti-kickback and other fraud and abuse laws.⁴⁰ This cross-coverage of legal authority ensures that new regulations do not create loopholes in enforcement under different rules. As discussed *infra*, eliminating this cross-coverage is one proposed to streamline this area of health policy.⁴¹

This caution by CMS is also noteworthy because the Stark Law is typically not implicated alone but rather in conjunction with other federal and state regulations. The Stark Law, along with the federal Anti-

³⁵ Patrick A. Sutton, *The Stark Law in Retrospect*, 20 ANNALS OF HEALTH L. 15, 34 (2011).

³⁶ Travis G. Lloyd & Ogi C. Kwon, *Modernizing Stark*, J. HEALTH LIFE SCI. L., Feb. 2018, at 114, 114.

³⁷ *Medicare Self-Referral Laws: Hearing on P.L. 103-66 Before Subcomm. on Health H. Comm. on Ways and Means*, 106th Cong. 2 (1999) (statement of Rep. William Thomas, Chairman, Subcomm. on Health of H. Comm. on Ways and Means), <https://www.govinfo.gov/content/pkg/CHRG-106hhr65695/html/CHRG-106hhr65695.htm>.

³⁸ Sutton, *supra* note 35, at 17.

³⁹ Lloyd & Kwon, *supra* note 36, at 116.

⁴⁰ *Id.*

⁴¹ See *infra* Part III (B-D).

Kickback Statute and the FCA, are routinely implicated together.⁴² As a result, to comply with all relevant statutes, providers must be able to fit into the existing safe harbors for *each* statute. The safe harbors for each, however, are not the same, making it impossible to fit in to a safe harbor for one statute while violating another.⁴³ This is incredibly important because the FCA may subject violators to treble damages in addition to other penalties for prohibited referrals.⁴⁴ Additionally, the Anti-Kickback statute is a criminal statute, so violations may also result in *criminal* penalties.⁴⁵ Overall, the Stark Law, FCA, and Anti-Kickback statutes could subject violators to severe civil and criminal penalties.

Most Stark Law claims are brought under private FCA actions.⁴⁶ In 2016 alone, the Department of Justice (“DOJ”) recovered more than \$2.5 billion in civil FCA settlements from the health-care industry.⁴⁷ Penalties for violations can be incredibly severe; for example, in *United States ex rel. Drakeford v. Tuomey*, the U.S. Court of Appeals for the Fourth Circuit affirmed summary judgment and \$237 million in damages on FCA claims against a community hospital.⁴⁸ The sheer size of the judgment was best described by Judge James Wynn in his concurrence as “a likely death sentence for a community hospital in an already medically underserved area.”⁴⁹ This ruling further emphasized the need for reform, as it was a perfect example of the divide between richer, urban populations with ample providers and poorer, rural populations with potentially only one provider. In communities with few providers, the simple truth is that there may be no choice but to “self-refer.”

In examining whether Stark Law financial penalties are burdensome on the health-care industry, it is important to remember the sheer size of the industry itself. As health care accounts for 18 percent of U.S. GDP, many argue that the industry is well-equipped to shoulder Stark’s financial

⁴² Rachel V. Rose, *The Stark Law and Anti-Kickback Statute—What are they and Why do Health Care Industry Participants Need to Know?*, FED. LAW., July 2016, at 12, 12.

⁴³ *Id.*

⁴⁴ Kenya Woodruff & Neil Issar, *A Balancing Act: Alternative Payment Models and Physician Compensation*, HEALTH LAW., Oct. 2017, at 10, 13–14.

⁴⁵ 42 U.S.C. § 1320a-7b (2018).

⁴⁶ Sean Hanssler, “Stark” Raving Mad—Making the Self-Referral Disclosure Protocol Better, Faster, Stronger, 45 HOFSTRA L. REV. 951, 951 (2017).

⁴⁷ Woodruff & Issar, *supra* note 44, at 3–4.

⁴⁸ *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 389–90 (4th Cir. 2015); *see* Hanssler, *supra* note 46, at 952.

⁴⁹ *Tuomey*, 792 F.3d at 393 (Wynn, J., concurring); Hanssler, *supra* note 46, at 952.

burdens.⁵⁰ While former Rep. Pete Stark has supported its overhaul and possible repeal, he has also dismissed the notion that the penalties are too severe, countering that stiff penalties help control costs by discouraging self-referral.⁵¹

To remain in compliance with the Stark Law, physicians must only receive fair market value for services rendered.⁵² Any violation of this rule would require providers to repay the federal government—mostly in Medicare cases—all payments that were received through the illegal arrangement.⁵³ In addition to repaying the federal government, providers could also face placement on the Medicare Preclusion List and FCA liability.⁵⁴

Another avenue of compliance with Stark is falling within one of its three categorical exemptions, each of which requires substantial resources to ensure compliance.⁵⁵ The three categories are (1) all-purpose exemptions; (2) ownership and investment exemptions; and (3) direct and indirect compensation arrangement exemptions.⁵⁶ Because it is a strict liability statute, Stark can immediately be implicated if a provider does not fall within one of these three categories.⁵⁷ Beyond these categorical exemptions, physicians are liable for unintended Stark Law violations so long as they have any sort of financial relationship with a given referral recipient.⁵⁸ In addition to Stark's strict liability, the combination of severe penalties—including repayment to the federal government, Medicare exclusion, and FCA liability—has made many providers hesitant to

⁵⁰ 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/#item-start>.

⁵¹ Joe Carlson, *Pete Stark: Repeal the Stark Law*, MODERN HEALTHCARE (Aug. 2, 2013), <https://www.modernhealthcare.com/article/20130802/BLOG/308029995/pete-stark-repeal-the-stark-law>.

⁵² Ayla Ellison, *Stark Law: The 27-Year-Old Act Killing Healthcare 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-healthcare-reform-before-it-can-begin.html>.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ Hanssler, *supra* note 46, at 960.

⁵⁶ *Id.*

⁵⁷ Santo, *supra* note 32, at 1403.

⁵⁸ Theresamarie Montese & Gregory Nowakowski, *Land Mine: Hidden Stark Law Issues Can Explode*, MICH. BAR J., Oct. 2014, at 48, 48.

commit to value-based payment initiatives, as not all fall within one of Stark’s three exceptions.⁵⁹

The extent of the Stark Law’s reach has been questioned in recent years as it has caused immense confusion and delay in the movement from a FFS to a value-based payment system.⁶⁰ While the Stark Law is encoded in the Medicare chapter of the Social Security Act, the DOJ and at least three federal courts have ruled that it also applies to Medicaid claims.⁶¹

CMS’s recognition of unduly burdensome regulations is not new. In the years since the Stark Law’s inception, CMS has been waived Stark Law compliance in certain situations.⁶² CMS has the ability to grant Stark Law waivers to Accountable Care Organizations (“ACOs”), which are defined as “groups of doctors, hospitals, and other health-care providers who come together voluntarily to give coordinated, high-quality care to their Medicare patients.”⁶³ For example, in 2016, CMS enacted a timeshare arrangement exception for physicians in rural and underserved communities as a mechanism to promote access to quality care.⁶⁴ The exemption allowed independent physicians to share office space with hospitals.⁶⁵ As part of the 2016 Physician Fee Schedule, the exemption was part of the first major overhaul of the Stark Law since the passage of the ACA.⁶⁶ The overhaul was designed to reduce regulatory burdens to further incentivize innovation within the industry.⁶⁷ Following this overhaul, CMS revamped its rules regarding self-disclosure, recognizing that most disclosures were not violations of the Stark Law and did not

⁵⁹ Ellison, *supra* note 52.

⁶⁰ Jennifer Tharp, *Stark Law and the Affordable Care Act—Bridging the Disconnect*, 35 J. LEGAL MED. 433, 433 (2014).

⁶¹ United States *ex rel.* Schubert v. All Child.’s Health Sys., No. 8:11-cv-01687, 2013 U.S. Dist. LEXIS 163075, at *12–19 (M.D. Fla. Nov. 15, 2013); United States *ex rel.* Parikh v. Citizens Med. Ctr., 977 F. Supp. 2d 654, 665–66 (S.D. Tex. 2013); United States *ex rel.* Baklid-Kunz v. Halifax Hosp. Med. Ctr., No. 6:09-cv-1002, 2012 U.S. Dist. LEXIS 36304, at *9–11 (M.D. Fla. Mar. 19, 2012); Scott R. Grubman, *If the Shoe Doesn’t Fit—Stark’s Self-Referral Prohibition and Medicaid Claims*, 8 J. HEALTH LIFE SCI. L. 82, 84 (2015).

⁶² *Fraud and Abuse Waivers*, CTRS. MEDICARE & MEDICAID SERVS., <https://www.cms.gov/medicare/physician-self-referral/fraud-and-abuse-waivers>.

⁶³ Tharp, *supra* note 60, at 441–42; *see also Accountable Care Organizations (ACO)*, CTRS. MEDICARE & MEDICAID SERVS. (May 3, 2018), <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/>.

⁶⁴ 42 C.F.R. § 411.357(y) (2016).

⁶⁵ *Id.*

⁶⁶ *See* Adrienne Dresevic & Clinton Mikel, *Final CY 2016 Stark Law Changes—Welcomed Revisions to Stark*, HEALTH LAW., Dec. 2015, at 1, 1–3.

⁶⁷ Revisions to Payment Policies Under the Physician Fee Schedule, 80 Fed. Reg. 70,885, 70886 (Nov. 16, 2015) (to be codified at 42 C.F.R. pt. 405).

pose any of the risks that the Stark Law was designed to prevent.⁶⁸ Overall, CMS has enacted over thirty-five exemptions, each of which has its own set of complex rules and requirements with which providers must comply if they wish to be protected.⁶⁹

B. THE FEDERAL ANTI-KICKBACK STATUTE

The Anti-Kickback Statute states that any person who “willfully and knowingly solicits, receives, offers, or pays any remuneration . . . directly or indirectly” in return for the referral of an individual for any service reimbursable by Medicare or Medicaid shall be guilty of a felony.⁷⁰ Penalties for violations can include fines of up to \$100,000, imprisonment of up to ten years, and exclusion from participation in Medicare and Medicaid programs.⁷¹ Unlike the Stark Law, however, the Anti-Kickback Statute is an intent-based criminal statute, meaning those who unintentionally find themselves in the statute’s crosshairs will not be penalized.⁷² Additionally, the Anti-Kickback Statute’s jurisdiction is significantly broader than the Stark Law. First, the Anti-Kickback Statute applies to referrals from anyone and not just health-care providers.⁷³ Second, it applies to any items or services rendered and not just designated health-care services.⁷⁴ Third, it is applicable to all federal health-care programs and not just Medicare or Medicaid.⁷⁵

The key to compliance with the Anti-Kickback Statute is the establishment of fair market values for the services rendered, as failure to do so could lead to severe penalties.⁷⁶ The criminal penalties for the statute, however, are incredibly severe considering the few safe harbors available, raising questions with regard to how value-based payment systems can succeed. Additionally, with the passage of the Bipartisan Budget Act of 2018, penalties for violations of the Anti-Kickback Statute

⁶⁸ See Adrienne Dresevic & Clinton Mikel, *Final CY 2016 Stark Law Changes—Welcomed Revisions to Stark*, HEALTH LAW., Dec. 2015, at 1, 1–3.

⁶⁹ Carlson, *supra* note 51.

⁷⁰ Han & McDermott, *supra* note 25, at 6; see 42 U.S.C. § 1320a-7b(b) (2018).

⁷¹ Han & McDermott, *supra* note 25, at 6.

⁷² Santo, *supra* note 32, at 1401.

⁷³ 42 U.S.C. §1307 (2018).

⁷⁴ *Id.*

⁷⁵ *Comparison of the Anti-Kickback Statute and Stark Law*, OFF. INSPECTOR GEN., <https://oig.hhs.gov/compliance/provider-compliance-training/files/starkandakscharthandout508.pdf> (last visited Oct. 20, 2020).

⁷⁶ Lynn Gordon, *Payors Acquiring Physician Practices: Purchase Price Limitations and Other Stark & Anti-Kickback Rules of the Road*, HEALTH LAW. Apr. 2014, at 24, 27.

have become increasingly harsh, with some civil penalties doubled and some criminal penalties quadrupled.⁷⁷ In addition to the criminal penalties, violators of the Anti-Kickback Statute may also be subject to civil liability through the FCA like the Stark law.⁷⁸

C. THE FEDERAL FALSE CLAIMS ACT

The FCA allows a private individual with knowledge of past or present fraud on the U.S. government to bring a claim on behalf of the government to recover civil penalties and treble damages.⁷⁹ The purpose of the statute is to discourage fraud against the federal government.⁸⁰ Its broad reach covers any fraudulent claim for payment made by the United States.⁸¹

While the FCA is not a health-care statute, it has become the primary method of Stark Law enforcement and its most prominent cases and recoveries have involved health care.⁸² In 2011, nearly 75 percent of all FCA recoveries, as well as 18 of the 20 largest FCA recoveries, involved health-care cases.⁸³ Additionally, it is estimated that the federal government recovered \$15 for every \$1 spent on health-care investigations and prosecutions.⁸⁴

D. “THE THREE-HEADED MONSTER”

The combination of the Stark Law, the Anti-Kickback Statute, and the FCA has been coined the “three-headed monster of healthcare fraud enforcement.”⁸⁵ All three statutes carry significant penalties on their own but carry even heavier penalties when taken altogether. Alone, Stark Law

⁷⁷ *Civil and Criminal Fraud and Abuse Penalties Increase and Stark Law Changes*, MCGUIRE WOODS LLP (Mar. 5, 2018), <https://www.mcguirewoods.com/client-resources/Alerts/2018/3/Civil-Criminal-Fraud-Abuse-Penalties-Increase-Stark-Law-Changes>.

⁷⁸ *Comparison of the Anti-Kickback Statute and Stark Law*, *supra* note 75.

⁷⁹ 31 U.S.C. § 3729 (2018).

⁸⁰ 31 U.S.C. § 3729(a) (2018).

⁸¹ *Id.*

⁸² 31 U.S.C. § 3729 (2018).

⁸³ Marc S. Raspanti & Sarah R. Lavelle, *Who Is Enforcing the Stark Law of the United States?*, AHLA CONNECTIONS, Sept. 2012, at 24, 26.

⁸⁴ *Id.*

⁸⁵ John W. Nisbett, *The Three-Headed Monster of Healthcare Fraud Enforcement: The False Claims Act, Stark Law, and the Anti-Kickback Statute*, A.B.A. TYL HEALTH L., Aug. 2015, https://www.americanbar.org/groups/young_lawyers/publications/tyl/topics/health-law/three-headed-monster-healthcare-fraud-enforcement-false-claims-act-stark-law-anti-kickback-statute/.

enforcement has rarely been initiated by the federal government.⁸⁶ But in conjunction with the FCA, private citizens are incentivized to bring suit on behalf of the government with the potential reward of up to 30 percent of a successful recovery.⁸⁷ In effect, the government incentivizes private litigants to engage in complicated health-care enforcement, which could subject providers to Anti-Kickback civil penalties of hundreds of thousands of dollars and up to ten years' imprisonment, in return for a substantial civil recovery. In addition to civil and criminal penalties, a violation would likely result in a health-care provider landing on the CMS Preclusion List, effectively ending the provider's career.⁸⁸ The Preclusion List is a list of providers who are precluded from receiving payment for health services rendered to Medicare beneficiaries.⁸⁹ Not only are precluded providers themselves not allowed to bill Medicare or Medicaid for their services but also their employers are not allowed to bill Medicare or Medicaid for services rendered by precluded providers.⁹⁰ In turn, employers and group practices would have little incentive to hire a provider listed on the Preclusion List.

E. THE CURRENT STATE

To best meet the needs of the insured and ensure profitability, many insurers have increased their physician holdings to better facilitate care.⁹¹ Rapid consolidation in the market has occurred in recent years, with Kaiser Permanente ("Kaiser") emerging as a model for others. Kaiser is an integrated health-care model that provides insurance and care as a single entity.⁹² Kaiser's model, therefore, incentivizes provision of the highest quality of care at the lowest expense.⁹³ But rapid consolidation within the

⁸⁶ *The Intersection Between the False Claims Act and the Federal Stark Law—Part I*, BERGER MONTAGUE, <https://bergermontague.com/understanding-the-intersection-between-the-false-claims-act-and-the-federal-stark-law-part-one/> (last visited Oct. 20, 2020).

⁸⁷ Nisbett, *supra* note 85.

⁸⁸ CTRS. MEDICARE & MEDICAID SERVS., PRECLUSION LIST FREQUENTLY ASKED QUESTIONS (Nov. 20, 2019), https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/Preclusion_List_FAQs.pdf.

⁸⁹ *Id.*; see also CY 2019 Policy and Technical changes to the Changes to Medicare Plans and Programs, 83 Fed. Reg. 16,440 (Apr. 18, 2018) (to be codified at 42 C.F.R. pt. 405).

⁹⁰ *A Roadmap for New Physicians*, U.S. DEP'T HEALTH & HUM. SERVS., OFF. INSPECTOR GEN., <https://oig.hhs.gov/compliance/physician-education/01laws.asp> (last visited Oct. 20, 2020).

⁹¹ Gordon, *supra* note 76, at 24.

⁹² Shelby Livingston, *Kaiser CEO Tyson says value-based care is here to stay, may invest in new growth*, MODERN HEALTHCARE (January 18, 2017).

⁹³ Gordon, *supra* note 76, at 24.

industry has not occurred without controversy. As a result of this increased consolidation, for example, antitrust actions have significantly increased.⁹⁴

Recently, CMS issued Requests for Information (“RFIs”) with regard to both the Stark Law and the Anti-Kickback Statute.⁹⁵ The RFIs were to address any undue regulatory burdens that may act as barriers to coordinated- or value-based care.⁹⁶ In the RFIs, CMS acknowledges the regulatory barriers preventing physicians from moving to coordinated- and value-based care.⁹⁷ In response to the RFIs, the American Hospital Association (“AHA”) welcomed the opportunity to comment and made several suggestions. The AHA recommended (1) protections for value-based payment methodologies via a new exemption, (2) clear and timely guidance by CMS, and (3) refocusing regulations on reducing overutilization.⁹⁸

Moreover, the AHA explicitly denounced waivers as an insufficient remedy due to their limited scope and duration.⁹⁹ In addition to the AHA, many within the health-care industry, such as pharmaceutical company Eli Lilly and health insurance provider Anthem have published white papers detailing their opinions on the specific language that should be included in rulemaking and new proposals.¹⁰⁰ Trade associations, such as Advanced Medical Technology Association and Pharmaceutical Research and Manufacturers of America, have expressed concerns over the current state of inadequate protections and regulatory burdens in their respective fields.¹⁰¹ This area of health policy is one in which all stakeholders are aligned in their belief that these regulations are unduly burdensome and waiver protections are inadequate. The problem is that stakeholders have not agreed on a solution to relieve these burdens.

One method that CMS has attempted to utilize to reduce the regulatory burden on health-care providers is its waiver authority. CMS’s waiver authority, granted by Congress with the passage of ACA, has facilitated the development of innovative value-based payment pilot

⁹⁴ *Id.*

⁹⁵ Request for Information Regarding the Physician Self-Referral Law, 83 Fed. Reg. 29,524 (June 25, 2018) (to be codified at 42 C.F.R. Pt. 411).

⁹⁶ 42 C.F.R. §§ 411, 1001, 1003 (2018).

⁹⁷ *Id.*

⁹⁸ Letter from Melinda Reid Hatton, Gen. Couns., Am. Hosp. Ass’n, to Seema Verma, Adm’r, Ctr. Medicare & Medicaid Servs., Request for Information Regarding the Physician Self-referral Law (Aug. 3, 2018) [hereinafter AHA Letter], <https://www.aha.org/system/files/2018-08/180803-letter-stark-rfi.pdf>.

⁹⁹ *Id.*

¹⁰⁰ Boise, et al., *supra* note 28, at 3.

¹⁰¹ *Id.* at 4.

programs.¹⁰² The granted waivers provide broad protection for ACOs from potential compliance issues with both the Stark Law and Anti-Kickback Statute.¹⁰³ The limitation of these waivers, however, is their conditionality; CMS can revoke a waiver, exposing an ACO to legal complications.¹⁰⁴ Therefore, as these waivers are only temporary measures, health-care providers may be hesitant to fully commit to these programs.

IV. CURRENT PROPOSALS AND CRITIQUES

A. WAIVER EXPANSION

One proposal that has garnered support involves the expansion of the waiver system. This reform would extend waiver coverage indefinitely so that health-care providers are more certain about their futures.¹⁰⁵ This proposal would also expand waiver eligibility criteria so that more innovative programs could be covered.¹⁰⁶ Waivers would also protect health-care providers from retroactive penalties should they later lose their waiver. This protection would be critical, as it would allow providers to move forward without the fear of future administrations backtracking, which could otherwise expose providers to potential penalties.¹⁰⁷

Two major critiques of this proposal are (1) the need for providers to navigate a bureaucratic system to receive waivers and (2) the potential for a never-ending amount of waiver applications. First, while CMS has worked tirelessly to approve waivers and enable innovation, providers must nonetheless satisfy certain eligibility criteria, apply for waivers, and await approval.¹⁰⁸ To be successful, the waiver eligibility criteria and approval process must be streamlined so that providers are timely informed of the decision. When applications are denied, there must be an adequate explanation accompanying the denial, so that other providers do not fall within the same pitfalls and can make the necessary changes to increase the likelihood of future acceptance.

Second, and perhaps more significantly, a waiver system would become unmanageable for CMS. As each provider innovates, a new

¹⁰² Santo, *supra* note 32, at 1377.

¹⁰³ *Id.* at 1408.

¹⁰⁴ *Id.* at 1410.

¹⁰⁵ *Id.* at 1412-17.

¹⁰⁶ *Id.* at 1413.

¹⁰⁷ *Id.* at 1414.

¹⁰⁸ *Fraud and Abuse Waivers*, CTRS. MEDICARE & MEDICAID SERVS., <https://www.cms.gov/medicare/fraud-and-abuse/physiciansselfreferral/fraud-and-abuse-waivers.html> (last visited Oct. 20, 2020).

waiver becomes necessary; already there are waivers for specific states, medical specialties, and different innovation models.¹⁰⁹ The potentially massive influx of applications could overwhelm the system and delay implementation of innovative solutions. Overly broad waiver approval could be equally problematic as it could enable providers to take advantage of the system, using it to protect themselves from penalties associated with intentional self-referrals. This can lead to problematic proposals slipping through as CMS attempts to timely review applications.

Expanding the waiver system would allow CMS to individually review innovative proposals and determine their implementation. This, in turn, would give providers, whose waivers are approved, some certainty they will be rewarded and—importantly—that they will not be punished. However, the proposal's success relies on CMS having adequate resources to properly review each application and the existence of a clear, timely, non-arbitrary review process. As highlighted by the AHA, waivers are likely an insufficient remedy due to their limited scope.¹¹⁰ This proposal could be an adequate short-term solution within a transition to a regulatory structure more aligned with value-based payments.¹¹¹

B. ENHANCED SELF-DISCLOSURE

A second proposal would be to replace the Stark Law with a system of self-disclosure to the patient of any financial interests that the provider may have.¹¹² In effect, this system would allow providers to make self-referrals so long as the referred patient receives adequate disclosure about how the provider may benefit from the referral. Some industry leaders, such as the American Medical Association, have recommended that self-referrals in this proposal should only occur under specific conditions that ensure financial incentives are not predicated on the volume of referrals.¹¹³

One major critique of this proposal is the fact that the burden of adequate disclosure rests with the health-care providers; another is the danger of assuming patients are able to assess disclosures and make the best decision for themselves.¹¹⁴ First, providers must be adequately informed of their own financial interests. If the provider is an individual

¹⁰⁹ *Id.*

¹¹⁰ AHA Letter, *supra* note 98.

¹¹¹ Santo, *supra* note 32, at 1414.

¹¹² Nicholas J. Diamond, *Giving Disclosure its Due—A Proposal for Reforming the Stark Law*, 16 DEPAUL J. HEALTH CARE L. 1, 13 (2014).

¹¹³ *Id.* at 7.

¹¹⁴ *Id.* at 13.

practitioner, this may be simple as they need only disclose their own personal financial interests. However, in today's heavily consolidated health-care market where most providers are part of a larger provider network,¹¹⁵ the question arises of what constitutes adequate disclosure. The line distinguishing what must be disclosed, and with that what each provider must understand about his or her network's financial interests, must be clearly drawn in order for this proposal to function properly. In effect, this proposal will force all providers to not only provide the best care possible but also become fluent in the business of their care.

The second and equally troublesome assumption upon which this proposal relies is patients' ability to adequately assess providers' disclosures. Most patients expect doctors to look out for patients' best interests in terms of their health and well-being.¹¹⁶ Additionally, most patients do not have medical experience.¹¹⁷ They generally do not know what care is appropriate or best—they trust their doctor to make that decision. The relationship between the health-care provider and patient is one of unequal standing, in which the patient will almost assuredly defer to the provider's superior medical knowledge.

Furthermore, many may equate higher costs to better care and newer technology to better technology. Providers could take advantage of their patients' misguided beliefs by equating their higher margins to better care. In effect, providers could upsell their services.¹¹⁸ This may chip away at the trust between patient and provider, as patients could wonder whether providers' health-care decisions are made in the patients' best interests or in the providers' financial interest.

A modification of this proposal could involve the self-disclosure of financial ties both to the patient and to CMS.¹¹⁹ In effect, this proposal would be a system of self-policing. It is feasible because it could simply be added to the Department of Health & Human Services ("HHS") self-referral disclosure protocol ("SRDP") established by the ACA.¹²⁰ The SRDP is a mechanism by which providers can self-disclose potential or actual violations of the Stark Law and receive reduced penalties.¹²¹ However, there is currently a lack of clear guidance on self-disclosures,

¹¹⁵ Jane M. Zhu, et. al., *Networks in ACA Marketplaces Are Narrower For Mental Health Care Than For Primary Care*, HEALTH AFFAIRS, Sept. 2017.

¹¹⁶ Fatimah Lateef, *Patient expectations and the paradigm shift of care in emergency medicine*, 4 J. EMERG. TRAUMA SHOCK. 163 (2011).

¹¹⁷ *Id.*

¹¹⁸ Atul Gawande, *Overkill*, THE NEW YORKER (May 2015).

¹¹⁹ Diamond, *supra* note 112, at 16.

¹²⁰ *Id.* at 14.

¹²¹ Diamond, *supra* note 112, at 14.

and the self-disclosure process has been criticized for its slow pace.¹²² In 2015, for example, CMS resolved only forty-nine self-disclosures cases with a backlog of more than 400 cases.¹²³ Some cases have been dragging on for more than four years.¹²⁴

This proposal relies on many of the same assumptions as direct disclosure to the patient. Similarly, this proposal puts pressure on providers to know what to disclose and on the patient to understand what that disclosure entails. Additionally, there is an issue ensuring the provider's self-disclosure is readily accessible to the patient. This could make poor and technology-deficient populations particularly vulnerable.¹²⁵ Likewise, this proposal would put pressure on CMS to adequately oversee providers as patients may feel a false sense of security with the federal government enforcing disclosure. To ensure compliance, CMS would need to provide clear guidance as to what providers must disclose and what penalties they may face for non-compliance.¹²⁶ This pressure could be a logistical nightmare as it could lead to the same cumbersome regulations that currently afflict the Stark Law.

In summary, this second proposal's success would hinge on providers being adequately informed of their own business dealings and fully compliant in disclosing those business dealings. It also relies on patients being capable of understanding what those disclosures entail. From both perspectives, this proposal would likely fall flat as all parties would need to be highly educated and well-versed in the health-care industry to be able to fully navigate the complexities that self-disclosures would entail. Similar to the first proposal, this proposal may be an adequate stopgap while transitioning to a permanent regulatory regime but would be inadequate as a long-term solution.

C. REPEAL, REPLACE?

A third proposal is the outright repeal of the Stark Law to be replaced by a simplified, streamlined version. Former Rep. Stark himself said that when he proposed the legislation he did not believe physician self-referral

¹²² Hanssler, *supra* note 46, at 965.

¹²³ *Id.* at 954.

¹²⁴ *Id.* at 968, 972.

¹²⁵ *Internet/Broadband Fact Sheet*, PEW RESEARCH CENTER (June 2019) (illustrating that over 25 percent of those living below the poverty line do not have access to the Internet), <https://www.pewresearch.org/internet/fact-sheet/internet-broadband/>.

¹²⁶ Hanssler, *supra* note 46, at 974.

was a significant problem.¹²⁷ Consequently, former Rep. Stark has become a proponent of repealing the law in favor of a significantly simpler regime.¹²⁸ Legislators and those within the health-care community have questioned the complex and burdensome regulations that the Stark Law has created.¹²⁹ The Anti-Kickback Statute largely covers the same conduct that the Stark Law is intended to cover, can also be enforced via the FCA, and is already how most Stark Law claims are brought.¹³⁰ This concurrent coverage makes the Stark Law largely superfluous.

The relationship among the Stark Law, FCA, and Anti-Kickback Statute has evolved over time. Prior to the 2000s, the Stark Law was rarely invoked in tandem with the FCA, as the Stark Law was seen as a vague statute with no definitive scope or interpretation.¹³¹ Instead, the government relied primarily on the Anti-Kickback Statute to enforce the FCA.¹³² Starting in the 2000s, however, the Stark Law gradually became the preferred mechanism since it helped maximize recoveries while minimizing costs.¹³³ This move was likely made as the Stark Law was a civil statute, lowering the government's burden of proof and obviating its need to prove intent.¹³⁴ This dramatic shift in the government's tactics raised the stakes of FCA enforcement and solicited calls for FCA reform.¹³⁵

As the relationship among the Stark Law, Anti-Kickback Statute, and FCA has changed, calls to reform one or all of the statutes have intensified. In March 2017, the Stark Law was marked as an anti-competitive, regulatory headache that would be an early target for the new Trump administration.¹³⁶ The move to value-based payments is one that has wide support on both sides of the aisle.¹³⁷ Value-based payments largely include payment for "bundles" of services—to make these

¹²⁷ Sutton, *supra* note 35, at 17.

¹²⁸ Yulian Shtern, *Will Congress Repeal the Stark Law?*, PHYSICIANS PRACTICE, Aug. 2016.

¹²⁹ *Id.*

¹³⁰ Butler, *supra* note 34, at 10.

¹³¹ See Robert Salcido, *The Government Unleashes the Stark Law to Enforce the False Claims Act: The Implications of the Government's Theory for the Future of False Claims Act Enforcement*, HEALTH LAW., Aug. 2001, at 1, 2–3.

¹³² *Id.* at 6.

¹³³ *Id.*

¹³⁴ 42 U.S.C. § 1395nn (2018).

¹³⁵ Salcido, *supra* note 131, at 7.

¹³⁶ *Quick Hits: Top News Stories of the Month*, HEALTHCARE FIN. MGMT ASS'N, Mar. 2017, at 14, 14.

¹³⁷ Thomas Sullivan, *Bipartisan Legislation Drafted on New Payment Models*, POL'Y & MED. (Feb. 5, 2019), <https://www.policymed.com/2019/02/bipartisan-legislation-drafted-on-new-payment-models.html>.

“bundles” cost efficient, care coordination is crucial.¹³⁸ Care coordination, however, can easily run afoul of the Stark Law when providers work together and share information in order to avoid duplicative care.¹³⁹ In many of these instances, care coordination would involve financial collaboration so that providers’ financial and care interests are aligned.¹⁴⁰ The most recent proposed Physician Fee Schedule reflects CMS’s understanding that changes to these laws are necessary to promote care coordination.¹⁴¹

A collection of hospitals and health systems have highlighted the Stark Law as a regulatory burden and laid out suggested principles to accelerate the move to value-based payments for the new administration.¹⁴² Dr. Ronald Paulus, CEO of Mission Health, testified to the Senate Finance Committee in 2016 that Mission Health had not launched innovative proposals to improve care for its over 900,000 North Carolina patients for fear of a potential Stark Law violation.¹⁴³ Dr. Paulus testified that “a total Stark repeal would not only help health systems do what we need to do, but precisely what [lawmakers] have asked us to do, which is focus on what’s best for patients and transform our outdated fee-for-service system to a value-based care system.”¹⁴⁴

A full repeal of the Stark Law, however, is not without uncertainties. While the shift from FFS to value-based payments may change the financial incentives to “over-care,” it does not mean that all financial incentives are eliminated. Questions regarding physician ownership and compensation arrangements would still need to be addressed. For example, one study found that physician-to-physician referrals nearly doubled between 1999 and 2009 from 4.8 percent to 9.3 percent, and the

¹³⁸ Kathleen Sebelius & Tommy G. Thompson, *Overcoming Health-care Challenges by Moving from Volume to Value*, THE HILL (July 17, 2018), <https://thehill.com/opinion/healthcare/397433-overcoming-health-care-challenges-by-moving-from-volume-to-value>.

¹³⁹ *Id.*

¹⁴⁰ *Support Grows for Stark Law Modification or Repeal*, DAY PITNEY LLP (July 23, 2018), <https://www.mondaq.com/unitedstates/Food-Drugs-Healthcare-Life-Sciences/721528/Support-Grows-For-Stark-Law-Modification-Or-Repeal>.

¹⁴¹ See CY 2020 Revisions Medicare Physician Fee Schedule, 84 Fed. Reg. 62,568, 62,997 (Nov. 15, 2019) (to be codified at 42 C.F.R. pt. 403); see also RFI Regarding the Physician Self-Referral Law, 83 Fed. Reg. 29,524, 29,525–26 (June 25, 2018) (to be codified at 42 C.F.R. pt. 411).

¹⁴² Sebelius & Thompson, *supra* note 138.

¹⁴³ Virgil Dickinson, *Health Systems Urge Senate to Revamp or Repeal Stark Law*, MODERN HEALTHCARE (July 12, 2016), <https://www.modernhealthcare.com/article/20160712/NEWS/160719972/health-systems-urge-senate-to-revamp-or-repeal-stark-law>.

¹⁴⁴ *Id.*

increased referrals affected all physician subgroups except among physicians who held ownership stakes within their practice.¹⁴⁵ The lack of referral growth among physicians with ownership stakes can be explained by the financial incentives to keep services “in-house,” which has become increasingly popular.¹⁴⁶ Providers have increasingly invested in ancillary services, such as installing MRI machines and computed tomography scanners in their offices.¹⁴⁷ This trend is notable because the Stark Law prevents physicians from referring patients to outside entities with which a physician has a financial relationship; therefore, keeping all services “in-house” allows a provider to profit and avoid Stark liability.¹⁴⁸ But the increased use of “in-house” services has not been proven to increase the quality of care for patients; in fact, the increased availability of services and the resulting increase in utilization have been linked to worse care and an increased risk of excessive utilization.¹⁴⁹

In a time when increased and potentially wasteful utilization is a prominent problem, the full repeal of the Stark Law could result in even higher national health-care spending. The Stark Law was premised on numerous empirical studies that showed that financial arrangements tying physicians’ income to self-referrals led to increased utilization and higher cost of care.¹⁵⁰ Unfortunately, these studies were not entirely conclusive; the results could not determine whether the higher utilization was inappropriate or increased the quality of patient care.¹⁵¹ Nevertheless, researchers have continued to study the link between physicians’ self-interest and greater utilization without improved outcomes. For example, a 2008 study examined Oklahoma physician-owned specialty hospitals, which had recently grown in number, and their effects on health-care costs.¹⁵² Proponents argued these hospitals would result in economies of scale, thereby reducing patient costs and providing physicians with more

¹⁴⁵ Michael L. Barnett, et al., *Trends in Physician Referrals in the United States, 1999–2009*, 172 ARCH INTERN MED. 163, 165–67 (2012).

¹⁴⁶ *Id.*

¹⁴⁷ Jeffrey Clemens & Joshua D. Gottlieb, *Do Physicians’ Financial Incentives Affect Medical Treatment and Patient Health?*, 104 AM. ECON. REV. 1320, 1341 (2014).

¹⁴⁸ *Id.* at 1354.

¹⁴⁹ *Id.* at 1351.

¹⁵⁰ See CONFLICTS OF INTEREST IN CLINICAL PRACTICE AND RESEARCH, 299–317 (Roy G. Spece et al., eds., 1st ed., 1996).

¹⁵¹ *Id.*; MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO THE CONGRESS: PHYSICIAN-OWNED SPECIALTY HOSPITALS REVISITED 6–13 (2006).

¹⁵² Jean M. Mitchell, *Do Financial Incentives Linked to Ownership of Specialty Hospitals Affect Physicians’ Practice Patterns?*, 46 MED. CARE 732, 732–37 (2008).

direct control and accountability to their patients.¹⁵³ However, these benefits were not realized; instead, the study found that financial incentives linked to ownership altered the practice patterns of physicians.¹⁵⁴ The frequency of certain procedures increased and the cost of health care was substantially greater for patients at the physician-owned hospitals compared to care at hospitals not owned by physicians.¹⁵⁵

D. PROPOSED LONG-TERM SOLUTION

While each of the three main reform proposals has advantages and disadvantages, it seems clear that only one proposal provides a long-term solution. Both waiver expansion and the enhanced self-disclosure proposals fail to provide a permanent regulatory system that providers could confidently follow as the health-care system transitions to value-based payments. As a result, reforming the Stark Law is the best path forward and should be pursued in two steps. First, Congress should repeal the Stark Law and release providers from its burdensome regulations. Second, Congress should adopt a streamlined version of the Stark Law that is narrowly tailored to target self-referrals in areas where many health-care providers are compensated on a FFS basis.

It is important to note that the Stark Law has saved the U.S. government millions, if not billions, of dollars over its history.¹⁵⁶ Any change to this regime must be made carefully and involve all stakeholders within the health-care industry. For example, one past misstep involved a Stark Law exemption for physicians who provided advanced imaging services in their offices; this was estimated to have resulted in more than 400,000 additional cases of advanced imaging services and to have cost Medicare an additional \$109 million.¹⁵⁷ In 2017, health care alone cost the United States \$3.5 trillion, so every effort must be made to contain or reduce spending by reducing unnecessary utilization of services.¹⁵⁸

¹⁵³ *Id.*

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Making Sense of the Stark Law: Compliance for the Medical Practice*, MASS. MED. SOC. 22 (2005).

¹⁵⁷ U.S. GOV'T ACCOUNTABILITY OFF., GAO-12-966, HIGHER USE OF ADVANCED IMAGING SERVICES BY PROVIDERS WHO SELF-REFER COSTING MEDICARE MILLIONS 22 (2012).

¹⁵⁸ *National Health Expenditures 2017 Highlights*, *supra* note 1.

1. Repealing the Stark Law

While the Stark Law has been an integral part of the American health-care system since its adoption, its current burdensome state no longer fits the system. The Stark Law has become a regulatory behemoth filled with exemptions, loopholes, and addenda to close loopholes, leaving health-care providers in doubt about how to comply.¹⁵⁹ It has become a “complex web of duct tape and a door that only opens if you know exactly where to kick it.”¹⁶⁰

To keep up with the changing health-care industry and to promote the move to value-based care, the Stark Law should be fully repealed. While this move will assuredly disrupt the industry in the immediate aftermath, the long-term benefits of reforming the system will greatly outweigh the short-term pains. Repealing and replacing the Stark Law could help restore its relationship with the Anti-Kickback Statute and FCA to its pre-2000 status quo. Some health-care stakeholders have already called the Stark Law with an intent requirement duplicative of the Anti-Kickback Statute.¹⁶¹ The removal of the Stark Law would lessen the regulatory burden on providers, as unintended violations would no longer result in prohibitive penalties under the FCA.¹⁶² More importantly, it would allow providers to better coordinate care, likely reducing utilization. CMS’s own rulemaking further illustrates how the Stark Law duplicates the Anti-Kickback Statute. For example, CMS Stark regulations consistently have to caution providers that any provider arrangements may not violate anti-kickback statutes or other fraud and abuse laws.¹⁶³

Politically, initially repealing the Stark Law may face criticism and could be seen as capitulating to powerful players in health care. While the industry has increasingly moved to value-based payments, a significant

¹⁵⁹ Stephanie Zaremba, *A Healthcare Law Held Together by Duct Tape*, ATHENA INSIGHT, Aug. 2016, at 1, <https://www.athenahealth.com/insight/sites/insight/files/08.12%20A%20healthcare%20law%20held%20together%20by%20duct%20tape.pdf>.

¹⁶⁰ *Id.*

¹⁶¹ MAJORITY STAFF S. COMM. ON FIN., 114TH CONG., WHY STARK, WHY NOW? 17 (Rep. 2016), <https://www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff.pdf>; see also PUB. INT. COMM., AM. HEALTH LAW. ASS’N, A PUBLIC POLICY DISCUSSION: TAKING MEASURE OF THE STARK LAW 12 (2009) [hereinafter AM. HEALTH LAW. ASS’N], <https://library.ahima.org/doc?oid=93447#.XuE84p5KjfY>.

¹⁶² AM. HEALTH LAW. ASS’N, *supra* note 161, at 12.

¹⁶³ Lloyd & Kwon, *supra* note 36, at 117.

portion of the industry still operates on a FFS system.¹⁶⁴ While self-referrals that have harmed the federal government could still be prosecuted under the Anti-Kickback Statute and FCA, many argue that such prosecutions would be fewer in number because the intent requirement makes them more resource intensive for the prosecuting agencies.¹⁶⁵

With the repeal of the Stark Law and its strict liability, the diminished threat of legal action might embolden some providers to seek financial reward from illicit activities, such as self-referrals. Further, repealing the Stark Law would remove a major means of current enforcement because it would remove the financial incentives (i.e. 30 percent of the amount recovered) that private parties have had in enforcing the Stark Law through FCA claims.¹⁶⁶ These financial incentives may seem less attractive in light of the reduced chance of success and increased litigation costs. This could result in less prosecution of health-care fraud. In turn, this may push the federal government to more actively enforce these laws. Overall, however, it would likely decrease providers' fears of becoming litigation targets.

Additionally, the repeal of the Stark Law would not answer many of the same questions that afflict the Anti-Kickback Statute. As the health-care industry increasingly consolidates, more providers will bring services in-house in order to avoid potential violations. With many providers still working on a FFS basis, this could allow a large segment of the industry to overutilize services without fear of repercussion.¹⁶⁷ Moreover, this proposal would require an immediate legislative replacement. A repeal of the Stark Law without a replacement could leave the entire Medicare program and its beneficiaries vulnerable.¹⁶⁸ Beneficiaries could be targeted for more services, some of which may have harmful effects. General overutilization could lead to increased spending,¹⁶⁹ endangering the financial stability of the Medicare program.¹⁷⁰

¹⁶⁴ Naoki Ikegami, *Fee-for-service payment—an evil practice that must be stamped out?*, 6 INT. J. HEALTH POLICY MANAG. 57 (2015).

¹⁶⁵ 42 U.S.C. § 1320a-7b (2018); *see also* 31 U.S.C. § 3729 (2018).

¹⁶⁶ 42 U.S.C. § 1395nn (2018); *see also* 31 U.S.C. § 3729 (2018).

¹⁶⁷ OFF. INSPECTOR GEN., *A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse Laws*, U.S. DEP'T HEALTH AND HUM. SERVS., https://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf (last visited Oct. 20, 2020).

¹⁶⁸ Steven Porter, *Stark Law Reform Push Sees Movement on Multiple Fronts*, HEALTH LEADERS (Aug. 27, 2018), <https://www.healthleadersmedia.com/finance/stark-law-reform-push-sees-movement-multiple-fronts>.

¹⁶⁹ COMM. ON FIN., 114TH CONG., *EXAMINING THE STARK LAW: CURRENT ISSUES AND OPPORTUNITIES* (July 2016), <https://www.finance.senate.gov/imo/media/doc/26440.pdf>.

¹⁷⁰ *Id.*

Notably, the repeal of the Stark Law would likely draw political support from the Trump administration. In Executive Order (“EO”) 13771, President Trump signaled that his administration was in favor of deregulation as it implemented a “one-in, two-out” order.¹⁷¹ EO 13771 stated that “for every one new regulation issued, at least two prior regulations be identified for elimination.”¹⁷² Eliminating the Stark Law would be a significant deregulation that would excuse unintentional violators, while still allowing prosecutors to pursue intentional violators accused of defrauding the federal government.

With a full repeal of the Stark Law, CMS could expedite the move to value-based payments. Value-based payments eliminate the incentive to bring more services in-house simply for financial benefit.¹⁷³ The value-based compensation model rewards providers who focus on maximizing patients’ health outcomes in deciding which patient services to provide in-house and which to outsource to independent facilities.¹⁷⁴ This proposal would appease most major stakeholders in the industry as it assures providers that innovation will not be punished. At the same time, providers who intentionally defraud would still be subject to prosecution under the FCA via the Anti-Kickback Statute.

The key to successfully repealing the Stark Law unfortunately relies on a major overhaul of the U.S. health-care industry. The repeal must be the beginning of a chain reaction that would need to include increased transparency and increased competition. There would need to be increased transparency over not only the cost of health services but also the availability of such services and the availability of alternative providers. Additionally, in many communities, there are simply not enough providers nor resources outside of hospitals to prevent the need for their services in the first place. Reforming the Stark Law would allow providers to these poorer, rural communities to share hospital resources, improve their quality of care for their patients, and embrace more quickly value-based care.

¹⁷¹ Exec. Order No. 13,771, 82 Fed. Reg. 9,339 (Feb. 3, 2017).

¹⁷² *Id.*

¹⁷³ *Value-Based Programs*, CTRS. MEDICARE & MEDICAID SERVS. (last updated Jan. 6, 2020), <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs>.

¹⁷⁴ *Id.*

2. Replacing the Stark Law

As has become increasingly clear over the years, the Stark Law has benefitted patients and payers alike by reducing providers' incentives to profit from overutilizing expensive health-care services. But the current state of the law is simply untenable with the transition to value-based care. Alongside the repeal of the current Stark Law, Congress should enact a streamlined version of the current law. To resolve detractors' fears about the consequences of a Stark repeal, the new statute and future regulations would need to maintain the current regime's strict liability and core objective of prohibiting self-referral within health care. Imposing strict liability is crucial for the law to be an effective deterrent, as it would force providers to remain vigilant in their compliance.

One key difference in the new Stark Law should be its coverage. It should only apply to "urbanized areas," defined by the U.S. Census Bureau as areas of "50,000 or more people."¹⁷⁵ As such, "rural areas," those with less than 50,000 people,¹⁷⁶ would not fall under the purview of the new law. This key provision would remove the onus currently afflicting rural areas that may only have one or a few providers from running afoul with the law, given that they may have no choice but to self-refer in order to meet the needs of their community.

Additionally, the new Stark Law should apply differently to value-based payments. Arguably the most persuasive critique of the current law is its incompatibility with the transition from FFS to value-based payments, as it is focused on minimizing overutilization in FFS settings.¹⁷⁷ Thus, the coverage of the new statute and regulations should be limited to the FFS setting. Any providers participating in value-based payment programs would be exempt from the new law, regardless of whether they are practicing in a rural or urban setting. Exemption from strict liability would create another incentive for providers to more quickly shift from FFS to value-based payments. Providers participating in value-based payment programs would still need to abide by the Anti-Kickback Statute, however. Even though Stark's strict liability would not apply to value-based payment providers, the providers would not be entirely free from regulatory oversight of self-referrals.

A second crucial distinction would be the penalties imposed on providers for violations of the new law. One key criticism of the current

¹⁷⁵ Michael Ratcliffe, et. al., U.S. CENSUS BUREAU, ACSGEO-1, DEFINING RURAL AT THE U.S. CENSUS BUREAU 3 (Dec. 2016).

¹⁷⁶ *Id.*

¹⁷⁷ Butler, *supra* note 34, at 9.

the Stark Law, along with its enforcement via the FCA, is that providers can face severe penalties for unintentional violations.¹⁷⁸ While it is critical that we continue to hold providers accountable for their practices and encourage them to stay informed of their financial endeavors, it is equally important that any punishment be proportional to the crime. In this respect, punishment for new Stark Law violations should be limited to payments received from self-referrals—and should not allow recovery of FCA treble damages.

Limiting these harsh monetary penalties would address one of the fiercest criticisms of the current Stark Law—that its penalties are too severe as a strict liability statute. In effect, the purpose of this law is to ensure that providers do not financially benefit from self-referrals. This proposal eliminates the current possibility that unintentional violators can unfairly incur career-ending penalties. Meanwhile, intentional violators who attempt to defraud the federal government would not only be strictly liable under the new Stark Law but would also still face civil and criminal liability under the Anti-Kickback Statute and FCA. By enforcing the Anti-Kickback Statute via the FCA, the government could still use treble damages to punish those providers with fraudulent intent.

The third and final distinguishing feature of the new Stark Law would be its enforcement. While the current Stark Law is enforced through private actions brought under the FCA, the new law would be enforced through private actions brought under the Stark Law itself. This would not diminish the FCA's effectiveness in enforcing the Anti-Kickback Statute and other federal laws but rather would emphasize proportional punishment by eliminating the possibility of treble damages for violations of a strict liability civil statute.

In sum, the new Stark Law will remain true to the core mission that former Rep. Stark had in mind when he introduced the legislation in 1989 and would do so without the burdensome and often-times confusing regulatory hurdles. Providers will have clear guidance as to whether they fall within the confines of the new Stark Law. Penalties for non-compliance will be more aligned with the severity of the offense. As the health-care industry furthers its transition to value-based payments, the new Stark Law will effectively become less and less useful as its jurisdiction will become negligible. In effect, the new Stark Law would be a simple mechanism to police self-referrals and serve as a powerful incentive for providers to transition more quickly to value-based payments.

¹⁷⁸ *Id.* at 13.

E. CRITIQUES OF THE TWO-STEP PROPOSAL

Critics of the proposal to repeal and replace the Stark Law primarily rely on two arguments. First, the two-step process itself is inherently flawed because it is possible that once the Stark Law is repealed, it will not be replaced.¹⁷⁹ However, the health-care industry is a behemoth that takes time to shift, as evidenced by its gradual move toward value-based payments, warranting more radical change. Nevertheless, repealing the Stark Law would not leave providers completely free to self-refer since they would remain under the purview of the Anti-Kickback Statute. A repeal of the Stark Law would only remove one layer of regulation.¹⁸⁰ Moreover, the two-step process is ideal because it would give industry stakeholders and political leaders time to observe how the market unfolds. The two-step process also gives Congress and administrative agencies time to evaluate the appropriateness of any proposed replacement and best tailor the new law to the new environment.

Critics also argue that a newly proposed Stark Law's limited scope, coverage, and penalties may not be broad or severe enough to adequately deter self-referrals.¹⁸¹ However, this is misguided, as the new law would deter self-referrals by retaining Stark's strict liability. Moreover, intentional self-referrals will continue to face penalties and treble damages under the much stricter Anti-Kickback Statute. Overall, the Stark Law's original purpose will be restored, and the law will still deter providers, cautioning them to comply with Stark or otherwise risk liability under the more unforgiving Anti-Kickback Statute.

V. CONCLUSION

Health care in the United States is a complex industry affecting every single person. The current Stark Law unnecessarily adds to that complexity. Throughout its history, modifications and proposals for its reform have all fallen short of reducing providers' regulatory burden while still curtailing overutilization. For innovation to continue within the industry, the Stark Law should be repealed and replaced with a streamlined version that promotes value-based care while policing self-referrals for providers operating under the FFS system. Enforcement of intentional fraud against the federal government would not be affected, however, as it can continue to be enforced under the Anti-Kickback Statute

¹⁷⁹ MAJORITY STAFF S. COMM. ON FIN., *supra* note 31, at 8.

¹⁸⁰ *Id.* at 17-18.

¹⁸¹ *Id.*

through FCA actions. This two-step proposal is the best approach to help the industry further transition to value-based payments while deterring inappropriate physician self-referrals.