WHAT EXACTLY IS HEALTHCARE FRAUD AFTER THE AFFORDABLE CARE ACT?

Jeffrey B. Hammond*

I. INTRODUCTION

A. A Snapshot of Healthcare Fraud before the Affordable Care Act

Deceit pays. Just ask Medline Industries, a medical-device company headquartered in Mundelein, Illinois, a Chicago suburb.[1] In March of 2011, Medline entered into an agreement with the United States Attorney for the Northern District of Illinois and the United States Department of Justice to settle multiple allegations[2] that it had violated the federal False Claims Act[3] and the federal Anti-Kickback Statute.[4]

The government accused Medline of offering various healthcare providers bribes, which were thinly conceived as discounts and more covertly disguised as charitable donations and remuneration for employment, to incentivize the healthcare providers to order Medline-branded durable medical equipment and

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 Associate Professor of Law, Faulkner University, Thomas Goode Jones School of Law. J.D., Emory University School of Law, 2001; M.T.S., Emory University, Candler School of Theology, 2001; B.A., Harding University, 1998. I would like to thank Michael DeBoer for his thoughtful reading of a previous draft of this Article. I would also like to thank Ian Kennedy for his helpful research assistance.

1. Medline Indus., Inc., *Contact*, http://www.medline.com/cz/contact.php (accessed Jan. 6, 2013) (indicating that Medline's headquarters are in Mundelein, Illinois).

2. Settle. Agreement between the U.S. Dep't Just., U.S. Att'y for N. Dist. Ill., Medline Indus., Inc., Medline Found. & Sean Mason 2 (Mar. 10, 2010) (available at http://healthlawsidebar.com/wp-content/uploads/2011/03/Medline-Settlement-Agreement1.pdf) [hereinafter Medline Settle. Agreement]; Brian Zeeck, Illinois White Collar Crime Blog, *False Claims Act Case Settles in Northern District for $85 Million*, http://illinoiswhitecollar.blogspot.com/2011/05/false-claims-act-case-settles-in.html (May 17, 2011, 12:52 p.m.).

3. 31 U.S.C. §§ 3729–3733 (2006).

4. The federal Anti-Kickback Statute is a statute that prevents (among other things) medical providers from offering, paying, or receiving bribes, kickbacks, or other "remuneration" in exchange for referrals for goods and services reimbursed by federal healthcare programs. 42 U.S.C. § 1320a–7b (2006).

other supplies.[5] The healthcare providers reciprocated on Medline's inducements by ordering the Medline equipment and then submitting the bills for those goods to agents for Medicare and the Illinois Medicaid program.[6]

The government discovered Medline's fraud when a courageous, yet self-interested, employee provided a tip-off about Medline's deceptions.[7] As a qui tam relator, the tipster in Medline's case stood to recover up to thirty percent of the government's ultimate settlement with or judgment against the defendant.[8] Though public-spiritedness or a robust sense of right and wrong could have compelled the relator to turn on his employer, it is equally as likely that the informer's greed was the (rather large) margin that compelled him to report Medline's fraudulent activity.

Before President Obama signed the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act),[9] as modified by the Health Care Education and Reconciliation Act of 2010,[10] the "tattle-tale" method of fraud detection was the best weapon available to combat the largest silo of fraud in the American healthcare landscape.[11] The Affordable Care Act has changed fraud detection from a rather hopeless game of "pay and chase" into a system firmly supported by sophisticated information-technology platforms, comprehensive data mining, and increased financial and human resources devoted to fraud investigation and enforcement, which allows the government to be less dependent

5. Medline Settle. Agreement, *supra* n. 2, at 2, 3.

6. *Id.* at 2.

7. *Mason v. Medline Indus., Inc.*, 731 F. Supp. 2d. 730, 732 (N.D. Ill. 2010).

8. *See* 31 U.S.C. § 3730(d)(2) (stating that a qui tam plaintiff can receive no less than twenty-five percent and no more than thirty percent of the award from an action or settlement).

9. Pub. L. No. 111-148, 124 Stat. 119 (2010) (amending various sections of the United States Code including the Anti-Kickback Statute and the False Claims Act).

10. Pub. L. No. 111-152, 124 Stat. 1029 (2010).

11. *See* Press Release from U.S. Dep't Just., *Health Care Fraud Prevention and Enforcement Efforts Result in Record-Breaking Recoveries Totaling Nearly $4.1 Billion* (Feb. 14, 2012) (available at http://www.justice.gov/opa/pr/2012/February/12-ag-213.html) [hereinafter U.S. Dep't Just., *Record-Breaking Recoveries*] (stating that total healthcare fraud recoveries for the 2011 fiscal year amounted to approximately $4.1 billion while healthcare related civil False Claims Act recoveries totaled approximately $2.4 billion). Elsewhere, the DOJ attributed $2.8 billion in total recoveries to qui tam False Claims Act cases of all stripes. Press Release from U.S. Dep't Just., *Justice Department Recovers $3 Billion in False Claims Act Cases in Fiscal Year 2011* ¶ 6 (Dec. 19, 2011) (available at http://www.justice.gov/opa/pr/2011/December/11-civ-1665.html).

on the high-mindedness or avarice of disaffected acquaintances of dishonest parties in the healthcare system.[12]

Indeed, with Congress' passage of the Affordable Care Act and the Supreme Court's recent affirmance of its constitutionality,[13] the Act promises to usher American healthcare providers into a new era of fraud enforcement and detection.[14] One of the many factors leading to the new fraud-detection methodology was Congress and enforcement agencies' realization that old methods of detection, prosecution, and enforcement were no longer rooting out large swaths of fraud from federal programs.[15] The sheer size of federal healthcare programs incentivizes crooks to ply their fraudulent schemes, knowing it is very likely they will never be caught.[16] The Affordable Care Act begins to close the door to this incentive by making it much harder for new providers, especially those who present a high risk of committing fraud, to enroll in the first place.[17] In addition to the barriers to entry, Congress has made it much easier for a provider to commit healthcare fraud

12. *Infra* pt. III (providing an overview of the False Claims Act's approach to fraud detection).

13. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2601 (2012) (holding that the "individual mandate" is constitutional pursuant to Congress' taxing power, but the mandate would be unconstitutional pursuant to Congress' commerce power). The Court also held that the federal government could not remove the states' existing Medicaid funding if the states did not agree to expand their respective Medicaid programs. *Id.* at 2601–2607.

14. U.S. Dep't Health & Human Servs., *New Tools to Fight Fraud, Strengthen Federal and Private Health Programs, and Protect Consumer and Taxpayer Dollars*, http://www.healthcare.gov/news/factsheets/2011/03/fraud03152011a.html (posted Mar. 15, 2011) (providing detailed predictions of the ways the Act will detect and prevent healthcare fraud).

15. *See* T.R. Goldman, *Eliminating Fraud and Abuse*, Health Affairs, http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=72 (July 31, 2012) (maintaining that the Affordable Care Act represents a shift in focus in investigating and prosecuting health fraud away from the typical "pay and chase" method). Indeed, the DOJ seems to take the position that the fraud-enforcement and -prevention tools scattered throughout the Affordable Care Act accentuated the cooperative initiatives between the OIG and the DOJ in 2009. U.S. Dep't Just., *Record-Breaking Recoveries*, *supra* n. 11.

16. For example, the Trustees of the Medicare Program report that the program spent $549.1 billion in 2011. Bds. Trustees, Fed. Hosp. Ins. & Fed. Supp. Med. Ins. Trust Funds, *2012 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplemental Medical Insurance Trust Funds* 6 (Apr. 23, 2012) (available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2012.pdf). Compare the size of just the Medicare program with the size of all healthcare fraud recoveries, and even in its best year, the trickster could argue that the chances of being caught are exceedingly slim.

17. *Infra* pt. II.

and get caught, thus making it easier for the Department of Health and Human Services, Office of Inspector General (OIG), and Department of Justice (DOJ) to apply the draconian penalties attendant to most healthcare fraud crimes and civil violations.[18]

Regrettably, the other reasons for the reform of healthcare fraud prevention appear to be political and rhetorical. In the build-up to the passage of the Affordable Care Act in early 2010, the Obama Administration took great pains to claim that tougher enforcement of the nation's healthcare fraud laws would cover the Act's costs.[19] On several occasions, the President and his surrogates claimed that the fiscal path to greater insurance coverage for all Americans was to stop the cash flowing to fraudsters, whose only intentions were to lie, cheat, and steal from the federal fisc.[20] Ultimately, these promises were nothing more than rhetorical ruffles and flourishes meant to whip the President's political base into fevered anticipation of passing the bills now known as the Affordable Care Act.[21]

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18. *Infra* pts. III–V.

19. *See e.g.* U.S. Gov't, *White House*, *The Administration*, *Putting Americans in Control of Their Health Care*, *Overview of Health Reform*, http://www.whitehouse.gov/health-care-meeting/proposal/whatsnew/overview (accessed Jan. 6, 2013) (stating that "[healthcare reform] *puts our budget and economy on a more stable path* by reducing the deficit by more than $100 billion over the next ten years—and more than $1 trillion over the second decade—by cutting government overspending and reining in waste, fraud[,] and abuse").

20. *Id.*; U.S. Gov't, *The Affordable Care Act: Strengthening Medicare* (May 8, 2012) (available at http://www.whitehouse.gov/sites/default/files/medicarefraudchart_printready_0.pdf); U.S. Gov't, *Home*, *The Administration*, *Health Reform in Action*, *A More Secure Future*, "Seniors," http://www.whitehouse.gov/healthreform/relief-for-americans-and-businesses (accessed Jan. 6, 2013). The President and his Administration wildly differed on the amount of money that could be saved through the reduction of waste, fraud, and abuse. *Compare* Ctrs. for Medicare & Medicaid Servs., *Affordable Care Act: Implementing Medicare Cost Savings* 9 (available at http://www.cms.gov/apps/docs/ACA-Update-Implementing-Medicare-Costs-Savings.pdf) (placing savings occasioned by some of the Affordable Care Act's anti-fraud provisions at $5 billion over ten years) *with* U.S. Dep't Health & Human Servs., *Reducing Costs, Protecting Consumers: The Affordable Care Act on the One Year Anniversary of the Patient's Bill of Rights* 1, 10 (Sept. 23, 2011) (available at http://www.healthcare.gov/law/resources/reports/patients-bill-of-rights09232011a.pdf) (calculating potential fraud savings at $1.8 billion through 2015); Cheri Jacobus, *Waste, Fraud and Abuse*, http://thehill.com/opinion/columnists/cheri-jacobus/86321-waste-fraud-and-abuse (posted Mar. 11, 2010, 6:21 p.m. ET) (stating that "[t]he president has already schooled us in creative budgeting and claims the projected savings from eliminating waste, fraud[,] and abuse will pay for the bulk of his healthcare plan, providing roughly $900 billion in savings"). These differing figures can be confusing because they are set on different (and sometimes undisclosed) timelines.

21. So far, healthcare fraud recoveries have not met the optimistic predictions. *See* U.S. Dep't Just., *Record-Breaking Recoveries*, *supra* n. 11 (designating 2011 as the best

B. Does the Affordable Care Act Provide Revolutionary Change to Healthcare Fraud Laws?

To be sure, the numbers, as they say, don't lie. Fraud detection and elimination, however important, could never begin to pay for all the disparate programs, initiatives, and mandates in the Act.[22] One independent researcher anticipates that implementation of the Affordable Care Act will increase the federal deficit by at least $340 billion over ten years.[23] In 2011, the federal government had its best year ever in fraud detection and recovery, posting $4.1 billion in total judgments and settlements of fraud-related cases.[24] It is not hard to do the math. Fraud recoveries could never even begin to approach the overall cost of the Act, even though, at roughly $60 billion per year, fraud accounts for one of the largest "expenditures" of the federal Medicare program.[25]

What, then, explains the significant expansion and refinement of the fraud and abuse laws in the Affordable Care Act? Despite rhetorical excess, the yawning gulf between the fraud perpetrated on government programs and recoveries made by the government cried out for legislative reform by Congress. Plainly, the government needed to get more serious about fraud enforcement, and it needed more tools with sharp enough edges to make potential swindlers think twice about their potential schemes. But do the changes that come with the Affordable Care Act amount to revolutionary changes to the complement of healthcare fraud laws? The answer must be no if one is looking for a statute

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year in healthcare fraud recovery ever at $4.1 billion); *see also infra* nn. 22–25 and accompanying text (explaining that fraud recoveries could not possibly cover the costs of the Act).

22. *Compare* Laxmaiah Manchikanti et al., *Patient Protection and Affordable Care Act of 2010: Reforming the Health Care Reform for the New Decade*, 14 Pain Physician E35, E38, E49 (2011) (available at http://www.painphysicianjournal.com/2011/january/2011;14;E35-E67.pdf) (estimating that the Affordable Care Act will cost "far more than $2.7 trillion over [ten] years") *with* Jacobus, *supra* n. 20 (placing President Obama's projection for savings from eliminating waste, fraud, and abuse at roughly $900 billion).

23. Charles Blahous, *The Fiscal Consequences of the Affordable Care Act* 45 (1st ed., Mercatus Ctr. at George Mason U. 2012) (available at http://mercatus.org/sites/default/files/publication/The-Fiscal-Consequences-of-the-Affordable-Care-Act_1.pdf) (asserting that the Affordable Care Act could increase federal deficits by some measure between $340 billion and $530 billion, depending on the success of the cost-savings provisions).

24. U.S. Dep't Just., *Record-Breaking Recoveries*, *supra* n. 11.

25. CBSNews, *Medicare Fraud: A $60 Billion Crime*, http://www.cbsnews.com/2100-18560_162-6825948.html (posted Sept. 5, 2010, 8:35 p.m.).

that will fundamentally change the way that physicians and hospitals cooperate in the practice of and payment for medicine and its related services, like the physician self-referral law (the Stark Law) did.[26] On the other hand, the answer must be yes if one is looking for a statute that merely contributes to the big picture of fraud detection and enforcement, rather than a statute that provides comprehensive changes. Taken in its entirety, the statute represents the largest single, collective change to federal fraud and abuse law since the creation of the Medicare and Medicaid programs.[27] Practically every substantive fraud and abuse law has seen some change, whether minor or major. Rather than changing the purposes of the disparate fraud and abuse laws, however, the collective changes wrought by the Affordable Care Act make existing fraud and abuse laws tighter, stricter, and more exacting.[28]

The explanation for accretions to the palate of fraud and abuse laws lies in the system of reimbursement that predominates in federal programs—if not in the percentage of claims paid, certainly in the percentage of overall money spent.[29] By its nature, fee-for-service reimbursement incentivizes fraudulent

26. 42 U.S.C. § 1395nn (2006). The Stark Law prohibits physicians from referring federal healthcare program patients to entities with which they have a financial relationship, with limited exceptions. William H. Thompson, *Aligning Hospital and Physician Incentives in the Era of Pay-for-Performance*, 3 Ind. Health L. Rev. 327, 344 (2006).

27. It is customary to call the federal Anti-Kickback Statute, 42 U.S.C. § 1320a–7b, the "Fraud and Abuse Law." *E.g.* James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 Am. J.L. & Med. 205, 206–207, 206 n. 8. For the purposes of this Article, all fraud-related laws fall into the "fraud and abuse" category.

28. This Article focuses on the changes made by the Affordable Care Act to healthcare fraud law in four distinct (and rather large) sub-areas: provider enrollment, the Civil False Claims Act, the Stark (physician self-referral) law, and the federal Anti-Kickback Statute. The discussion in the Article does not exhaustively analyze the changes made to healthcare fraud law by the Act. For one of the many comprehensive analyses of the Affordable Care Act's changes to healthcare fraud law, see Thomas S. Crane et al., *Risky Business: Health Care Reform's Fraud-Fighting Provisions Increase the Potential for Liability for All in the Health Care Industry*, BNA's Health Care Fraud Report (Apr. 7, 2010) (available at http://www.mintz.com/newsletter/2010/Advisories/0270-0310-NAT-HCR/BNA_HealthCareFraudReport.pdf).

29. *See* Test. of Deborah Taylor, Acting Dir. & Chief Fin. Officer, Off. of Fin. Mgt., Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., before the Homeland Sec. & Gov't Affairs, *Preventing and Recovering Medicare Payment Errors*, http://www.hhs.gov/asl/testify/2010/07/t20100715a.html (July 15, 2010) (explaining that "Medicare and Medicaid alone account for [thirty-five] cents of each [healthcare] dollar spent in the United States").

behavior.[30] The more a person orders a good or service, the more the government pays the person making the order.[31] Thus, the federal reimbursement system is ripe for unprincipled people to abuse by ordering many procedures that are not necessarily required for sound patient care or bribing or soliciting kickbacks for transactions that require many claim submissions to the federal reimbursement programs.[32]

The Affordable Care Act does nothing to fundamentally change the fee-for-service reimbursement system. There are changes around the margins to reimbursement methodologies such as the creation of the Accountable Care Organization,[33] bundled payment,[34] and other innovations;[35] however, the Affordable Care Act itself does not make a wholesale substitution of fee-for-service payment with another reimbursement paradigm. Instead, after a brief adjustment period, the Act maintains fee-for-service reimbursement for many different types of providers but slashes the amount of payment made to those providers.[36] Left alone, it will be interesting to witness the effects these deep reimbursement cuts will have on providers and to determine whether providers seek to recoup the amounts cut in any possible way, even by resorting to lying, cheating, and stealing to make up the differences in their bottom lines.

This Article attempts to outline the major changes in fraud and abuse law made by the Affordable Care Act. Importantly, the Article seeks not merely to report on the Act's changes to fraud

30. Rachel Lynn Wilson, Paul G. Rogers Mem'l Scholars Program Blog, *Combating Fraud in Medicare and Medicaid*, http://nchc.org/node/1246 (July 31, 2012).

31. Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique on the Backlash against Fraud and Abuse Enforcement*, 51 Ala. L. Rev. 239, 251–256 (1999); *see also* Jeffrey Kluger, *Is There a Better Way to Pay Doctors?* Time, http://www.time.com/time/printout/0,8816,1930501,00.html (Oct. 26, 2009) (reporting that the fee-for-service system has incentivized doctors to adopt an itemized system of billing to receive more payments from the government).

32. Jost & Davies, *supra* n. 31, at 251–256.

33. 124 Stat. at 395–399 (amending 42 U.S.C. § 1395jjj).

34. *Id.* at 399–403 (amending 42 U.S.C. § 1395cc–4).

35. *Id.* at 941–942 (amending 42 U.S.C. §§ 1395cc–4, 1395cc–5).

36. *Id.* at 178 (to be codified at 42 U.S.C. § 18031). Eventual cuts to fee-for-service providers mainly affect facilities that render services under Part A of the Medicare program. *See id.* at 324–325, 390, 395–399 (to be codified at 42 U.S.C. §§ 1315(a), 1395jjj); 124 Stat. at 1047–1049 (amending 42 U.S.C. § 1395ww(b)(3)(B)). For a detailed summary of those payment changes, see Patricia A. Davis et al., *Medicare Provisions in PPACA (P.L. 111-148)* 4–9 (Cong. Research Serv. Apr. 21, 2010) (available at http://www.coburn.senate.gov/public/index.cfm?a=Files.Serve&File_id=55a563ed-0be1-4715-9fd3-ad0bf6e9b2bf).

law, but rather to set the changes in the context of their respective statutes' purposes and policy goals, particularly as those purposes and policy goals affect healthcare providers.[37] After all, it is providers who will have to bear the burdens of compliance and conforming their practice decisions and habits to the mandates of the new and amended laws.[38]

This Article proceeds in four substantive steps, covering some of the most important changes in the new and amended laws. Part II of the Article focuses on the changes the Affordable Care Act made to Medicare's provider-enrollment system, which make it considerably more difficult for new enrollees to access the Medicare billing system.[39] Provider-enrollment barriers to entry should be viewed as the firewall through which new and cunning schemers cannot pass in their bids to steal from federal and state programs. This new enrollment architecture has also erected significant hardships for existing providers to keep their billing privileges.[40] Providers must devote significant resources to monitoring, maintaining, and reapplying for their billing privileges.[41] These are not merely ministerial matters. Existing providers must engage in economically strategic and calculating behavior to

37. This Article liberally uses the word "provider" for convenience of use and will continue to do so although in the world of Medicare, "provider of services" and "supplier" have distinct meanings. 42 U.S.C. § 1395x(d), (u) (2006). The term "provider of services" refers to those who facilitate services paid for by Part A of the Program (generally hospitals and other healthcare facilities), and the term "supplier" refers to those who facilitate services paid for by Part B of the program (most notably physicians). *Id.* CMS regulations and the Medicare State Operations Manual provide more insight into the program's omnibus use of the term "provider" that includes both institutional and individual providers. 42 C.F.R. §§ 431.107(a), 433.37 (2011); Ctrs. for Medicare & Medicaid Servs., *State Operations Manual*, ch. 2, § 2002 (Mar. 20, 2009) (available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf).

38. Cynthia S. Marietta, *Small Group Physicians and Other Health Care Providers: Now Is the Time to Structure Your Mandatory Compliance Programs* in *Health Law Perspectives* 2 (U. of Houston L. Ctr. July 2011) (available at http://www.law.uh.edu/healthlaw/perspectives/2011/(CM)%20Compliance.pdf).

39. U.S. Dep't Health & Human Servs., *supra* n. 20, at 9.

40. *See* Leslie Dykman, *Understanding Changes to Medicare Provider Enrollment and CMS-855 Application*, The Edge (newsltr. of the Healthcare Fin. Mgt. Ass'n, N. Cal. Ch.) 1, 9 (July 2012) (explaining the Medicare provider-enrollment process).

41. *See* Ctrs. for Medicare & Medicaid Servs., *Supporting Statement*, *CMS-6028-P: Letter Requesting Waiver of Medicare/Medicaid Enrollment Application Fee; Submission of Fingerprints; Submission of Medicaid Identifying Information; Medicaid Site Visit and Rescreening* 4–7 (available at http://www.reginfo.gov/public/do/DownloadDocument?documentID=208342&version=1) (providing estimates for burdens that the Affordable Care Act places on providers).

maintain the right to bill a program that provides paltry, although vitally needed, reimbursement.[42]

Part III focuses on the changes to the False Claims Act, the heart of the government's fight against healthcare fraud. After the arrival of the Affordable Care Act, qui tam relators have a much firmer evidentiary base upon which to make their reports to the government.[43]

Part IV of the Article focuses on changes to the federal physician self-referral law (the Stark Law), which prevents physicians from referring patients to an entity in which the physicians have a financial interest unless the physician's situation falls into a statutory or regulatory exception.[44] Congress has tightened a welter of prohibitions and regulatory exceptions within the Stark regime to prevent physicians' easy access to the ancillary streams of business that supplement the relatively paltry amounts they receive for their professional services.[45]

Part V focuses on the federal Anti-Kickback Statute, which prevents parties from paying, soliciting, or offering bribes, kickbacks, or other "remuneration" in exchange for referrals that are reimbursed by a federal healthcare program.[46] Congress has made two small (in comparison to the size of the Affordable Care Act's complete text) changes to the Anti-Kickback Statute that will have profound consequences for its enforcement in the future. First, Congress stripped the guts of the scienter requirement from the statute.[47] This means that now all the government must prove at trial is that the defendant knowingly and willfully performed the actions proscribed by the statute, not that the defendant knowingly and willfully violated the Anti-Kickback Statute.[48]

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42. *Infra* nn. 108–110 and accompanying text (explaining that some medical providers may attempt to meet their financial goals through the provision of ancillary services).

43. Corrine Propas Parver & Allison Cohen, *The Affordable Care Act: Strengthening Compliance through Health Care Fraud Provisions*, 5 Health L. & Policy Br. 5, 6 (Spring 2011).

44. 42 U.S.C. § 1395nn.

45. *See* Jennifer Staman, *Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview* 6–8 (Cong. Research Serv. Aug. 10, 2010) (available at http://aging.senate.gov/crs/medicaid20.pdf) (explaining the Affordable Care Act amendments to the Stark Law exceptions).

46. 42 U.S.C. § 1320a–7b(b).

47. Staman, *supra* n. 45, at 4–5 (explaining the reduced evidentiary standard under the Affordable Care Act).

48. *Id.*

Second, Congress made violations of the Anti-Kickback Statute automatic violations of the False Claims Act, thereby dramatically increasing the financial penalties for defendants.[49]

Part VI provides a brief conclusion to this Article.

II. CLOSING THE FRONT DOOR: PROVIDER-ENROLLMENT LIMITATIONS AS THE FIRST LINE OF DEFENSE AGAINST FRAUD

At first glance, it is counterintuitive to think that the mechanical processes attendant to enrolling or reenrolling a provider in the Medicare program would be an effective means to prevent widespread programmatic fraud. One might determine that Congress, the DOJ, and the Inspector General should focus on the traditional loci of fraud: false claims, bribes, kickbacks, and tainted referral relationships. Yet, Congress has slowly come to the conclusion that if it has tighter controls on the front gate, where the wolves are scratching at the door, then it will have fewer problems with the wolves absconding through the back gate with federal loot.[50] That is, more exacting controls on who may receive billing privileges in the first place are likely to prevent providers who would engage in outright theft through patently false claims from abusing the program.[51] Therefore, Congress has authorized the Secretary of Health and Human Services to examine prospective providers with much more intense scrutiny to determine whether the provider's criminal history suggests untrustworthiness or deceitfulness.[52]

Provider enrollment is the long-ignored and decidedly unglamorous part of the Medicare universe. It is, more or less, a mechanical process driven by the proper completion of forms required by Medicare regulations and program manuals.[53]

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49. Madeleine Lovette, *Medicare Fraud and Abuse 101: An Introduction to the False Claims, Anti-Kickback, Stark, Exclusion, and Civil Monetary Penalty Laws*, AAOS Now, http://www.aaos.org/news/aaosnow/aug11/advocacy3.asp (Aug. 2011).

50. U.S. Dep't Health & Human Servs., *supra* n. 20, at 9.

51. *Id.*

52. Patricia A. Davis et al., *Medicare Provisions in the Patient Protection and Affordable Care Act (PPACA)* 74 (Cong. Research Serv. Apr. 23, 2010) (available at http://www.ncsl.org/documents/health/MCProv.pdf).

53. Novitas Solutions, *The Medicare Enrollment Process at a Glance*, "How to Enroll as a New Medicare Provider," https://www.novitas-solutions.com/enrollment/process.html (accessed Jan. 6, 2013).

Though provider-enrollment issues primarily exist in the background of providers' Medicare concerns, with billing, reimbursement, and general compliance issues occupying the forefront, enrollment issues become significant when a provider tries to start its business or engages in a transaction in which a "change of ownership" occurs.[54]

Provider-enrollment issues have historically gained little attention among those concerned about Medicare.[55] Politicians simply have more pressing concerns regarding the Medicare program (or so it is thought), such as significant underfunding for beneficiaries' services.[56] Thus, when policymakers contemplate how to streamline and improve the program, the mechanical parts of the program, like provider enrollment, get short shrift.

Medicare contractors (payment agents), which are dubbed "fiscal intermediaries" for Part A providers and "carriers" for Part B suppliers, have found it easy, and indeed necessary, to assign billing numbers to applicants without conducting a fulsome inves-

54. *See* James Gutman, *New HHS Fraud-Prevention Rules Could Cause New Barriers to Entry for Providers*, 2 AIS's Health Reform Week 1, 2 (Jan. 31, 2011) (available at http://www.ebglaw.com/files/43366_Valiant-AISs-Health-Reform-Week-New-HHS-Fraud-Prevention-Rule.PDF) (explaining that it can take a long time for providers to "jump through [the legal] hoops" when changing ownership or location). Medicare changes of ownership require a sophisticated understanding of Medicare rules, so experienced healthcare lawyers often conduct such transactions. *See e.g.* Sternstein, Rainer & Clarke, *About Us*, *Frank P. Rainer*, http://www.srclawfirm.com/about-us/frank-p-rainer/ (accessed Jan. 6, 2013) (providing the qualifications of an attorney with over twenty years of experience in healthcare law and change-of-ownership issues). At least one healthcare consultant recommends consulting with an experienced healthcare attorney before engaging in a transaction that could implicate Medicare's change-of-ownership rules. *See* Haydel Consulting Servs., LLC, *Three Ways to Buy a Medicare Facility*, http://haydelconsultingservices.com/2009/05/27/three-ways-to-buy-a-medicare-facility/ (May 27, 2009) (suggesting that, if possible, people should not make final decisions about transferring Medicare provider numbers until they have sought advice from an attorney who is experienced in Medicare changes of ownership).

55. H.R. Subcomm. on Oversight & Investigations of the Comm., H.R., *Medicaid Provider Enrollment: Assessing State Efforts to Prevent Fraud*, 106th Cong. 27 (July 18, 2000) (available at http://www.gpo.gov/fdsys/pkg/CHRG-106hhrg65912/pdf/CHRG-106hhrg65912.pdf) (providing the prepared statement of Leslie G. Aronovitz, associate director of the Health Financing and Public Health Issues; Health, Education, and Human Services Division; General Accounting Office).

56. For example, before the passage of the Affordable Care Act, the Medicare Trustees' 2009 report noted that the Hospital Insurance (Part A) Trust Fund was projected to be significantly underfunded over the following ten years. Bds. Trustees, Fed. Hosp. Ins. & Fed. Supp. Med. Ins. Trust Funds, *2009 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* 2 (May 12, 2009) (available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2009.pdf).

tigation into the applicants' backgrounds.[57] Thus, historically, it has been relatively easy for an applicant to receive a provider number.[58]

The bias for quick assignment of provider numbers has begun to change. The Affordable Care Act has already authorized the Secretary to make significant changes to the application process for providers who wish to participate in federal reimbursement programs.[59] Now providers may have to undergo significant background checks, including fingerprinting, licensure examinations, and criminal background checks through sophisticated databases, among other assessments.[60] Institutional providers will be subject to significant enrollment fees that will be used for program integrity efforts.[61] Providers may even have to submit to unannounced site visits before they can participate.[62]

This last innovation is particularly significant. There are considerable coordination and timing issues at play when a provider seeks initial certification, including waiting for the Centers for Medicare and Medicaid Services (CMS) to conduct a certification survey.[63] Now, if the payment agent can choose certain providers

57. *See* Mark Potter, *Criminals Find Medicare Easy to Defraud*, NBC News, http://www.msnbc.msn.com/id/22202073/ns/nbcnightlynews/t/criminals-find-medicare-easy-defraud/ (updated Dec. 12, 2007) (explaining that Medicare relies on regional contractors who use automated claim verification to process applications because of the large volume of claims Medicare receives).

58. *See e.g.* CBSNews, *supra* n. 25 (describing fly-by-night Medicare enrollees with unmanned offices in locations remote from any possible patient contact). The outlets described in the news story bill the Medicare program for thousands to millions of dollars for goods and services that are never provided to patients. *Id.*

59. *See* 124 Stat. at 747 (amending 42 U.S.C. § 1395cc(j)) (detailing the provider-enrollment changes to the Medicare program); *id.* at 751 (amending 42 U.S.C. § 1396a(a)) (detailing the provider-enrollment changes mandated upon state Medicaid programs).

60. *See id.* at 747–748 (describing various screening procedures for new Medicare enrollees).

61. *Id.* at 748–749.

62. *Id.* at 748.

63. *See* Ctrs. for Medicare & Medicaid Servs., *supra* n. 37, at §§ 2005, 2005A (explaining the process by which CMS receives application forms, processes those forms, and initiates the certification survey, and warning against unrealistic expectations regarding an application's turn-around time). It is unlikely that hospitals and certain other institutional providers could successfully use the Joint Commission accreditation process to receive "deemed status" and work around the time-consuming initial-certification process outlined in the State Operations Manual. *See* Jt. Comm'n, *Facts about the Joint Commission*, "Federal Deemed Status and State Recognition" (available at http://iom.edu/~/media/Files/Activity%20Files/Workforce/ResidentDutyHours/PaulSchyveTestimonyFactsabouttheJointCommission.ashx) (explaining that "federal

to receive site-based surveys, and if the program does not concomitantly increase the number of personnel devoted to those surveys (or does not delegate the application of its survey to the state licensure personnel or other surveyors who perform certification surveys for Medicare or Medicaid), then those providers chosen for survey will have to wait a long time before receiving their "clean bill of health" and provider number. Of course, these surveys have the potential to weed out nefarious applicants who do not have a legitimate business. Even still, these rules also have the potential to catch or simply hinder bona fide providers who desire to provide real, medically necessary services.

Another significant innovation that the Affordable Care Act authorizes is the prepayment review of all newly enrolled providers.[64] According to the statute, this review can range anywhere from thirty days to one year.[65] It can consist of prepayment-claims review or caps on payment during the review period.[66] While all new durable-medical-equipment providers are not automatically put on prepayment review, those providing equipment from certain suspect categories and located within particularly susceptible "geographic areas" can be put on prepayment review.[67] The reason for the delay in payments seems clear—durable-medical-equipment providers have been particularly prone to set up fly-by-night operations, complete with false addresses.[68] Once in possession of a provider number, many new "providers" have billed for services or goods that were never provided or are not medically necessary.[69]

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deemed status does not typically provide an exemption from current state requirements for state licensure" but that many states recognize and rely on such status).

64. 124 Stat. at 747–753 (amending 42 U.S.C. § 1395cc(j)).

65. *Id.* at 749.

66. *Id.*

67. *Id.* at 750.

68. *See* Kendrick B. Meek, *Repeal the Ineffective DMEPOS Competitive Bidding Program: Limiting Access to Important Medical Equipment Will Harm Our Patients*, The VGM Group (available at http://www.vgm.com/Files/manual/GovtRel/CB_Packet-4-2010.pdf) (criticizing the bidding program for Durable Medical Equipment, Prosthetics/Orthotics, and Supplies (DMEPOS) because it was flawed and awarded bids to fly-by-night providers).

69. *See* Test. of Daniel R. Levinson, Inspector Gen., Off. of Inspector Gen., U.S. Dep't of Health & Human Servs., before the Sen. Spec. Comm. on Aging, *Combating Fraud, Waste, and Abuse in Medicare and Medicaid* 2, 3–6 (May 6, 2009) (available at http://aging.senate.gov/events/hr208dl.pdf) (describing a fraudulent durable-medical-equipment scheme in South Florida that used illegitimate businesses and a common address); State.

The post-Affordable Care Act zeal for compliance enforcement through provider-enrollment issues is also manifesting itself in the area of required notices to the Medicare contractor. The Medicare world was thrown on its heels in August of 2011 when the United States District Court for the Middle District of Tennessee announced a civil False Claims Act summary judgment against a provider of imaging services.[70] A front-line provider affiliate of MedQuest Associates, the large parent corporation, underwent a transaction involving the transfer of corporate stock from a prior physician owner to MedQuest that eventually resulted in the issuance of a new tax identification number.[71] Even though the stock

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of Lewis Morris, Chief Counsel, Off. of Inspector Gen., Dep't of Health & Human Servs., before the Sen. Subcomm. on Fed. Fin. Mgt., Gov't Info., Fed. Servs. & Int'l Sec., *The Framework for Combating Fraud, Waste, and Abuse in Federal Health Care Programs* 4 (Apr. 22, 2009) (available at http://oig.hhs.gov/testimony/docs/2009/4-22 -09HomelandSecurity.pdf) (noting that "in 2008, OIG inspected 905 suppliers in Los Angeles County and found that [thirteen] percent did not have physical facilities or were not open during repeated unannounced site visits"). The government has also had trouble monitoring durable-medical-equipment suppliers. Judith Waltz, *Turning up the HEAT: Health Care Compliance and Enforcement in the Climate of Health Care Reform*, in *Health Care Law Enforcement and Compliance: Leading Lawyers on Understanding Recent Trends in Health Care Enforcement, Updating Compliance Programs, and Developing Client Strategies* 99, 109 (Thomson Reuters/Aspatore 2011).

> The government's enforcement efforts have also consistently focused on [durable-medical-equipment] suppliers (known as DMEPOS by Medicare), which remain a huge area of risk because the sector includes many small-time operators that are widely dispersed geographically, including some who distribute products primarily by mail. There are multiple players in the DMEPOS business, with suppliers able to open a location with relatively low capitalization and little set-up time. Typically, they operate from an office/storeroom (rather than a facility) with the covered medical items picked up or delivered to patient homes. Because of the nature of their operations, DMEPOS operators were often able to move on to new locales by the time the government started looking at them, although recent claims by the government indicate that they now have access to virtually contemporaneous claims data that will enhance the ability to respond quickly to identified claims abnormalities.

Id.

70. *United States v. MedQuest Assocs., Inc.*, 812 F. Supp. 2d 821, 862–868, 870 (M.D. Tenn. 2011); *see* Jennifer L. Weaver & Patsy Powers, *Federal Court Issues FCA Summary Judgment against Imaging Company for Failure to Follow Medicare Rules*, BNA Health Care Fraud Rpt. (Oct. 19, 2011) (reporting that the United States Attorney's Office for the Middle District of Tennessee was "taking on [healthcare] providers and winning" and that the court had assessed "tens of millions of dollars in damages and penalties under the federal False Claims Act" for flagrant violations of Medicare rules).

71. *See MedQuest Assocs.*, 812 F. Supp. 2d at 825–826, 835, 842–845 (describing the procedural history of the case and the factual premises of the False Claims allegations, namely that Nashville-area MedQuest imaging centers did not have proper physician supervision for certain types of contrast-based radiological studies and that a Nashville-

transfer itself was not a classic indicator of a change of ownership, a change in tax identification number was such a classical indicator.[72] It was also important for the court that the provider affiliate did not timely change its status from a "physician office" to an "independent diagnostic testing facility" (IDTF), as it was required to do once the facility's control changed from physician to lay hands.[73]

The *United States v. MedQuest Associates, Inc.*[74] case indicates a serious turn by the government toward non-traditional approaches to False Claims Act liability. The government's "false-certification" approach to False Claims liability is not novel at all. The government has used this approach to bootstrap False Claims Act liability onto alleged violations of the federal Anti-Kickback

based MedQuest center did not register as an independent diagnostic testing facility in a timely manner).

72. *Id.* at 866–867 (describing the stock sale of the physician's practice and subsequent tax identification number change without timely filing the appropriate paperwork to the CMS payment agent as "reckless disregard" of CMS regulations regarding changes of ownership and thereby appending one theory of False Claims liability onto MedQuest). The *MedQuest Associates* case follows traditional thinking within the Medicare world that a change in tax identification number results in a change of ownership. *See* Ctrs. for Medicare & Medicaid Servs., *Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers* 3 (July 2011) (available at http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855b.pdf) (grouping providers that have new tax identification numbers with new enrollees for Medicare-application purposes and explaining that entities undergoing changes in ownership must submit applications for "new ownership"); Palmetto GBA, *Tips to Facilitate the Change of Ownership (CHOW) Process* (available at http://www.palmettogba.com/Palmetto/Providers.Nsf/files/Change_of_Ownership_(CHOW)_Process_Job_Aid_rev10262010.pdf/$File/Change_of_Ownership_(CHOW)_Process_Job_Aid_rev10262010.pdf) (explaining that providers that change their tax identification numbers should typically apply for a change of ownership). While the Medicare change-of-ownership regulations do not explicitly say that a change in tax identification number constitutes a change in ownership, 42 C.F.R. § 489.18, the Medicare Program Integrity Manual states the following:

> If a supplier is changing its tax identification number, the transaction shall be treated as a brand new enrollment as opposed to a change of information. Consequently, the supplier must complete a full CMS-855 application and a new enrollment record must be created in [the Provider Enrollment, Chain, and Ownership System].

U.S. Dep't Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., *Medicare Program Integrity Manual* § 5.4(B) (Dec. 14, 2007) (available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R230PI.pdf) (emphasis removed). This likely follows the guidance provided in the regulations that a "consolidation" of two or more corporate entities results in a change of ownership. 42 C.F.R. § 489.18(a)(3).

73. *MedQuest Assocs.*, 812 F. Supp. 2d at 865–868.

74. 812 F. Supp. 2d 821.

Statute and Stark Law for several years.[75] What is new, however, is that in the new era of fraud enforcement, the courts are willing to wade through remote minutiae to make a case.[76] For example, in *MedQuest Associates*, the company was not seated with False Claims Act liability because it perpetrated blatant fraud and theft, such as "upcoding."[77] Unlike other fraudulent providers who have been caught,[78] MedQuest actually provided services to patients.[79] The court subjected MedQuest to False Claims Act liability because it did not follow the correct reporting and registration requirements at the times specified in the detailed regulations.[80] One possible interpretation of this lawsuit is that if the government cannot recover one hundred percent of the money lost to fraud (and it would be virtually impossible to do so), it will try to make up for it by seeking every possible margin of "fraud" in the system, even if the supposed margin is, in reality, a technical oversight of minute regulations, rather than intentional theft of the government's property.

III. FALSE CLAIMS AS THE GOVERNMENT'S FRAUD-COMBATING WEAPON OF CHOICE: EXPANDING THE FALSE CLAIMS ACT CASE

It is natural and completely intuitive that the False Claims Act should be the weapon of choice in the federal government's battle against healthcare fraud. Medicare and Medicaid (and other federal healthcare programs) are, at their foundations, all

75. *See e.g. United States v. Rogan*, 459 F. Supp. 2d 692, 721–724 (N.D. Ill. 2006) (describing false-certification theory based on underlying violations of the Anti-Kickback Statute and Stark Law); *MedQuest Assocs.*, 812 F. Supp. 2d at 863–864 (describing "express" and "implied" certification theories of false claims).

76. *See e.g. MedQuest Assocs.*, 812 F. Supp. 2d at 828–845 (devoting almost seventeen pages of the opinion to detailed findings of fact).

77. Upcoding is a process whereby a provider claims that it rendered more expensive services than it actually provided to patients. Staman, *supra* n. 45, at 9.

78. *See e.g.* Jack Cloherty & Pierre Thomas, *Biggest Medicare Fraud in History Busted, Says Feds*, ABC News, http://abcnews.go.com/Blotter/biggest-medicare-fraud-history-busted-feds/story?id=15809129#.UGyXJE3yqD8 (Feb. 28, 2012) (reporting on a healthcare scam that certified hundreds of fraudulent Medicare claims for services that were not needed or not even delivered to patients).

79. *MedQuest Assocs.*, 812 F. Supp. 2d at 828, 836–838 (finding that MedQuest billed Medicare "for diagnostic testing of Medicare beneficiaries at its IDTFs" and describing patient interactions at MedQuest's Nashville location).

80. *Id.* at 864–868.

about the submission of and payment for claims for goods and services related to the provision of healthcare.[81] Stated differently, Medicare and Medicaid are social insurance programs whose main purpose is to provide for the healthcare of ordinary Americans through physicians', facilities', and other healthcare providers' payment claims.[82] It is a happy coincidence for the government that the civil False Claims Act exacts fearsome penalties from those who violate it. The possibility of being hit with a penalty of between $5,500 and $11,000 per "false" claim, plus three times the total loss to the government, should channel providers' behavior safely away from the theft to which false claims are rightly compared.[83]

The primary tool the government has used to expose defendants to False Claims liability has been the qui tam suit.[84] With the qui tam suit, the government lets private citizens do the dirty work of developing the initial factual premises of the alleged fraud and reporting those to the government.[85] Only after first seeing the facts as presented by the relator and then conducting its own investigation does the government decide whether to intervene in the False Claims Act case.[86] It is practically, nay, actually impossible for the government to monitor every claim for every possible permutation of fraud, even with the new data-mining and filter-screen tools that CMS has instituted over the past few years. There are too many claims, too many ways to commit fraud, and not enough human interactions with claim

81. For a broader commentary on the purpose of Medicare, see Dean M. Harris, *Beyond Beneficiaries: Using the Medicare Program to Accomplish Broader Public Goals*, 60 Wash. & Lee L. Rev. 1251, 1252–1253 (2003) (explaining that Medicare's purpose is to provide for the cost of treating its beneficiaries).

82. *See e.g.* Jonathan Oberlander, *The Political Life of Medicare* 8–10 (U. of Chi. Press 2003) (describing "benefits, regulation, and financing" as the three large touchstones upon which the political story of Medicare is built).

83. *See* 31 U.S.C. § 3729(a)(1)(G) (providing the penalties for False Claims liability).

84. *See* Gretchen L. Forney, Student Author, *Qui Tam Suits: Defining the Rights and Roles of the Government and the Relator under the False Claims Act*, 82 Minn. L. Rev. 1357, 1365–1369 (1998) (discussing the increased False Claims Act litigation after the 1986 amendments to the False Claims Act gave qui tam plaintiffs more power to initiate claims); *e.g. Ex rel. Gublo v. NovaCare, Inc.*, 62 F. Supp. 2d 347 (D. Mass. 1999).

85. *See* Forney, *supra* n. 84, at 1361–1362 (explaining how qui tam plaintiffs file the initial complaint containing the allegations against the provider).

86. *See* U.S. Dep't Just., *False Claims Act Cases: Government Intervention in Qui Tam (Whistleblower) Suits* (available at http://www.justice.gov/usao/pae/Documents/fcaprocess2.pdf) (describing the government's process for intervention in a False Claims qui tam case).

forms to catch every possible iteration of fraud.[87] Therefore, the government must depend upon civic-minded citizens close to the alleged fraud to alert the government to its existence.[88] After making initial contact with the prospective relator, the United States Attorney decides whether to take the file, in which case he or she takes over the investigation and prosecution of the case in exchange for sharing a portion of any recovery made with the qui tam relator.[89] Because potential liability can be massive,[90] so can potential recoveries by relators, who can gain fifteen to thirty percent of the total recovery.[91]

Before the Affordable Care Act, if information regarding a potential fraudfeasor had already been publicly disclosed, qui tam relators had to provide uninterrupted, originally sourced information about the fraud that they reported to the government.[92] If the information was gleaned from some other source, even another governmental source, then such public disclosure of the allegedly fraudulent claims submarined the relator's prospects of

87. For a list of possible Medicare fraud claims, see U.S. Dep't Health & Human Servs. & U.S. Dep't Just., *About Fraud*, *What is Medicare Fraud?* http://www.stopmedicarefraud.gov/aboutfraud/index.html (accessed Jan. 6, 2013).

88. Though some defendants and opponents of the statute argue that the relators are often disgruntled employees who seek revenge by turning their employers in to the government for activities that may turn out to be non-fraudulent. *See* Jonathan H. Gold, *Legal Duties That Qui Tam Relators and Their Counsel Owe to the Government*, 20 Geo. J. Leg. Ethics 629, 631–632, 634 (2007) (explaining that relators' private interests, such as their interests in retaliation, can cause tensions in False Claims Act suits); John T. Boese & Michael J. Anstett, *Dramatic Changes to the False Claims Act Are No Laughing Matter*, 17 Metro. Corp. Counsel (newsltr. of Metro. Corp. Counsel, Inc.) (Feb. 2009) (explaining that qui tam relators are often "disgruntled employee[s]" or "jealous competitor[s]").

89. *Supra* nn. 84–86 and accompanying text (describing the relator's and the government's responsibilities in a qui tam suit).

90. *See* Medline Settle. Agreement, *supra* n. 2, at 4 (agreeing to an $85 million settlement for Medline's False Claims Act case, roughly $23 million of which was designated as the "Relator's Share").

91. *See* 31 U.S.C. §§ 3730(d)(1)–(2) (limiting the relator's award to between fifteen and twenty-five percent of the proceeds from the action, costs, and attorney's fees if the government intervenes and wins, and between twenty-five and thirty percent of the award, costs, and attorney's fees if the government chooses not to intervene).

92. *See* Anonymous, Fraud Fighters: A Blog about the False Claims Act and Whistleblowing, *Health Care Overhaul Bill Amends "Public Disclosure Bar" to Qui Tam Lawsuits Brought under the False Claims Act*, http://fraudfighters.wordpress.com/2010/04/13/health-care-overhaul-bill-amends-%E2%80%9Cpublic-disclosure-bar%E2%80%9D-to-qui-tam-lawsuits-brought-under-the-false-claims-act/ (posted Apr. 13, 2010, 9:15 a.m.) [hereinafter Fraud Fighters] (discussing the changes to the public-disclosure bar as a result of the Act).

recovery.[93] Without a direct, unmediated pipeline of information, many feared that relators would cash in upon facts that they had gleaned secondhand without the necessary personal investment to see the False Claims Act case all the way to its arduous completion.[94] This so-called public-disclosure bar prevented relators from using facts disclosed in other forums, like state administrative proceedings, in their own qui tam suits.[95] In the Affordable Care Act, though, Congress has shifted some of the discretion away from the federal district courts that hear motions about the public disclosure of foundational information into the hands of the government.[96] The public-disclosure bar part of the statute now mandates dismissal of the qui tam case, but the government has a tacit right of first refusal to maintain the case.[97] Previously, the law disincentivized company insiders from telling the government of similar—but not "on all fours" the same—facts as those disclosed through the prior proceeding.[98] Now, Congress has modified the rule so that only facts that are "substantially the same" as the facts disclosed in the prior proceeding would lead to application of the bar.[99]

Further, the bar now only applies if the information on which the claim is based has been disclosed in a federal proceeding at which the government is a participant.[100] Thus, the bar does not intercept information disclosed in state court or other non-federal governmental proceedings. In addition, the bar does not apply when the relator is an "original source" of the information's provenance and veracity.[101] If the relator disclosed the information to

93. *See e.g. Graham Co. Soil & Water Conserv. Dist. v. United States ex rel. Wilson*, 130 S. Ct. 1396, 1411 (2010) (ruling that public disclosures, including those made by a state or local source, may trigger the public-disclosure bar).

94. *Id.* at 1408 n. 16 (quoting *United States ex rel. Doe v. John Doe Corp.*, 960 F.2d 318, 319 (2d Cir. 1992)) (referring to the Court's desire to prevent individuals from bringing lawsuits when they "contributed nothing" to exposing the fraud).

95. *E.g. id.* at 1411.

96. Fraud Fighters, *supra* n. 92 (discussing the increased discretion for the government to determine if a case can go forward, even if the case is barred by public disclosure).

97. 124 Stat. at 901 (amending 31 U.S.C. § 3730(e)(4)).

98. *See* Fraud Fighters, *supra* n. 92 (noting that the previous law "problematically discouraged insiders or other persons who may have had similar, but substantively different knowledge" from coming forward).

99. 124 Stat. at 901 (amending 31 U.S.C. § 3730(e)(4)).

100. *Id.* It is important to note that the public-disclosure bar only applies if the government does not voice its opposition to the bar. *Id.*

101. *Id.*

the government before it was publicly disclosed, then the relator's suit may proceed.[102] Additionally, if a person has information that is "independent of and materially adds to" the government's case and that person discloses his or her information to the government before the suit is filed, the person may remain as a relator.[103] This is a significant change because it mollifies the harshness of the public-disclosure bar. Before the Affordable Care Act, the public-disclosure bar acted as a hook to remove from the outset all claims that were tainted by public information. This new modification, like the Affordable Care Act's other amendments to the False Claims Act, serves to broaden the scope of possible claims that can be prosecuted by qui tam relators, thereby broadening the scope of the government's possible recovery.[104]

IV. STARK LAW CHANGES: ATTENUATING PHYSICIAN RELATIONSHIPS

A. Disclosure As a Roadblock?

It is surprising that Congress desired to change the Stark Law. Stark is already a comprehensive strict-liability regime that prevents a physician from referring a patient to an entity with which the physician has a financial relationship, absent a statutory or regulatory exception.[105] The changes to Stark suggest Congress' desire to monitor physicians' ancillary income and their relationships with entities to which they make referrals more closely.[106]

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102. *Id.*

103. *Id.*

104. By contrast, another positive jurisprudential element of the Affordable Care Act's fraud provisions is that the provisions give providers much more certainty with respect to their obligations and duties under the various fraud laws. One change to the False Claims Act provides an instance of this newfound certainty. The Act now requires providers to return overpayments within sixty days of identifying the overpayment. *Id.* at 755 (amending 42 U.S.C. § 1320a–7k). Further, an overpayment is now an "obligation" under the False Claims Act that must be conveyed to the government, or else the provider will be subject to the penalties found in the False Claims Act. *Id.*

105. 42 U.S.C. § 1395nn(a)(1); *see* StarkLaw.org, *Stark Law*, http://starklaw.org/stark_law.htm (accessed Jan. 6, 2013) (describing the Stark Law).

106. *See* 124 Stat. at 697 (amending 43 U.S.C. § 1395nn to require more disclosure, reporting, and transparency); Staman, *supra* n. 45, at 7–8 (describing how Congress

Congress' most important change is the change to the rules governing in-office ancillary services. In short, the statutory and regulatory exceptions for in-office ancillary services allow a physician to refer patients for services ancillary to the main office visit as long as those services are performed in the physician's office or a building closely related to the physician's main office.[107] Physicians make a significant amount of revenue from laboratory tests, imaging studies, and other technical tests that happen in the physician's office, yet outside the physician's physical presence.[108]

The current system incentivizes physicians, whether overtly or covertly, to order ancillary tests for their patients because the direct patient-care revenue that physicians earn from Medicare does not adequately compensate them for the services they render to patients.[109] Physicians can try to make up the difference between what they think they should make and what they actually make during office visits and other direct-care encounters through ancillary revenue, which provides pure profit for the physician after he or she pays applicable overhead.[110] The nagging fraud-related question presented by the in-office-ancillary-services exception boils down to a determination of medical necessity: is a physician's motivation to order ancillary services solely driven by the patient's medical needs?[111] If so, the physician's purposes are pure, and he or she should not worry about fraud

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increased regulation under the Stark Law through its Affordable Care Act amendments by requiring more physician-patient disclosure).

107. 42 U.S.C. § 1395nn(b)(2); 42 C.F.R. § 411.355(b).

108. *See* Joan Szabo, *Ancillary Services Can Increase Revenues*, Dr.'s Dig. 82 (Mar./Apr. 2005) (available at http://www.doctorsdigest.net/pdf/0102_04.pdf) (explaining that charging for ancillary services can help supplement physicians' profitability).

> Physicians are finding that adding ancillary services can help maximize practice profitability and better serve patients. . . . "As professional reimbursement goes down, the way to try to enhance practice revenues and profitability is by maximizing the utilization of the practice resources. This often means delivering ancillary services that are legal, appropriate, within quality-of-care standards and . . . needed by patients . . . ."

Id. (quoting Denver attorney Bruce A. Johnson).

109. *See id.* (describing how some doctors deliver ancillary services to enhance profitability); Medicare Payment Advisory Comm'n, *Report to the Congress: Aligning Incentives in Medicare* 213, 214 (June 2010) (available at http://www.medpac.gov/documents/jun10_entirereport.pdf) (noting that self-referral "creates incentives to increase volume").

110. *See* Szabo, *supra* n. 108, at 82–84 (discussing various opportunities for physicians to increase profits using ancillary services).

111. *See* Medicare Payment Advisory Comm'n, *supra* n. 109, at 219, 221 (explaining that it is unclear if growth in certain practices is related to need or increase in supply).

liability. It would be glib and overreaching, though, to presume that every physician's intentions are wholly focused on patient well-being when he or she orders ancillary tests or procedures. Rather, it may be closer to reality to claim that some physicians will have mixed motives when ordering side tests and therapies.[112] They may fashion plausible reasons for the necessity of the test yet not be one hundred percent convinced that the test is the optimal modality to diagnose or treat the patient's condition.[113]

The Affordable Care Act has raised merely a minor roadblock to the continued ordering of in-office ancillary services. Before the Affordable Care Act, a physician would order a laboratory test, an x-ray, or a magnetic resonance imaging (MRI) scan, and most patients would meekly comply and shuffle off to the laboratory or imaging suite within the doctor's office for their test or scan.[114] Neither physicians nor patients needed to give much thought to the ordering or performance of office-based tests. Now, with the Affordable Care Act's changes, physicians must alert their patients to alternative service providers when ordering imaging services for their patients, although physicians can often easily perform the services with in-office equipment in which they have an ownership interest.[115] Theoretically, when presented with genuine choices, patients will dispassionately exercise their powers of discernment and choice, and they will choose a service provider that offers tests that are more convenient or cheaper than the

112. For popular treatment of this issue, see Shankar Vedantam, *Doctor Self-Referrals Part of Health-Care Cost Trend*, Wash. Post, http://www.washingtonpost.com/wp-dyn/content/article/2009/07/30/AR2009073004285.html (July 31, 2009) (reporting that "physicians who own scanners order many more scans than those who do not"). For a scholarly treatment of self-referral arrangements across payers, see Jean M. Mitchell, *The Prevalence of Physician Self-Referral Arrangements after Stark II: Evidence from Advanced Diagnostic Imaging*, 26 Health Affairs w415 (May 2007) (available at http://content.healthaffairs.org/content/26/3/w415.full).

113. *See generally* CJ Wolf, *Putting the Medical in Medical Necessity* (available at http://www.healthlawyers.org/Events/Programs/Materials/Documents/Fraud10/wolf.pdf) (providing an interesting and accessible overview of medical necessity from a clinical perspective).

114. *See* George Loewenstein, Sunita Sah & Daylian M. Cain, *The Unintended Consequences of Conflict of Interest Disclosure*, 307 J. Am. Med. Assoc. 669, 669–670 (2012) (discussing patients' willingness to comply with physicians' recommendations, which could be due to patients' fear of showing distrust).

115. 124 Stat. at 697 (amending 42 U.S.C. § 1395nn(b)(2)).

doctor's tests. But this is a perilous assumption.[116] Patients have a hard time making rational choices with respect to their healthcare.[117] Whether patients are driven by the convenience of having the test available in the doctor's office suite, the fear of angering the physician, or some other motivation, it is unlikely that merely presenting patients with a list of alternative ancillary-service providers will cause patients to coolly weigh their options and then choose the one that *might* give them—or better stated, their insurer—a better price or more convenience. It is more likely that when doctors give patients a list of alternative service providers for the ancillary tests, the patients will quickly dismiss and crumple the piece of paper.

B. Tightening the Grip on Physician-Owned Hospitals

Because of the Stark Law's broad prescriptive authority, it is implicated in situations in which a physician has an ownership interest in a hospital.[118] Formerly, an exception to the statute for ownership interests in whole hospitals shielded those ownership arrangements from liability.[119] The government has put many machinations in place over the past decade to curb physicians' ownership interest in and referrals to specialty hospitals, which are hospitals that have received the benefit of the whole-hospital exception and the largesse of generous, hospital-based reimbursement, but at the same time, have siphoned off significantly lucrative cases from general hospitals.[120] The Affordable Care Act is simply the latest (and arguably the harshest) iteration of these tight controls. Though the Affordable Care Act placed many significant controls on physician-owned hospitals, including limits on

116. Disclosure of a physician's conflict of interest may not necessarily lead to a patient's dispassionate understanding of the conflict or to clear patient decision-making. It may, in fact, lead to physicians compensating patients so that the patients will consent to the conflict. *See* Loewenstein et al., *supra* n. 114, at 669–670 (analyzing the current trend of patients complying with disclosure and how this in turn may be hurting, rather than helping, them).

117. *See* Faith Lagay, *Physicians' Responsibilities in the Face of Patients' Irrational Decisions*, 5 Virtual Mentor 4, ¶¶ 1–3 (Apr. 2003), http://virtualmentor.ama-assn.org/2003/04/jdsc1-0304.html (discussing the dilemma that doctors face in dealing with patients who make irrational healthcare decisions).

118. 42 U.S.C. § 1395nn(d)(3)(C).

119. *Id.*

120. *Id.* at § 1395nn(a).

hospital expansion and contours on the nature of physician investment in the hospital,[121] the most important of those controls requires the hospital to have its Medicare provider agreement by December 31, 2010, to qualify for the exception.[122] With this change, Congress has effectively foreclosed the whole-hospital exception and has made it retrospective rather than prospective.

Further, with this amendment to the Stark Law, Congress has made it extremely hard on physician-owned specialty hospitals to continue as a viable business model for physicians.[123] These hospitals' abilities to expand their current physical plants are closely circumscribed.[124] Because of the temporal limitation on the whole-hospital exception, the CMS is not enrolling any more hospitals into the Medicare program under the exception.[125] At any time, Congress or the CMS could change the reimbursement methodology so that it is not attractive to perform expensive surgeries or procedures within the specialty hospital. These amendments likely will shift the focus of doctors' respective practices back to the general hospitals that need the benefit of the doctors' profitable referrals.

C. Disclosure of Possible Stark Violations

Despite the strict-liability Stark Law's hard edges, Congress has forged a path so that violators of the law (or those who think that they might have violated the law) can now disclose their "tainted" business relationship and seek pardon from the government.[126] The Stark Self-Disclosure Protocol, which is administered by the CMS, is similar to the Anti-Kickback Self-

121. 124 Stat. at 684–689 (amending 42 U.S.C. § 1395nn).

122. 124 Stat. at 1037 (amending 124 Stat. at 685).

123. *See e.g. Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 653, 659 (5th Cir. 2012) (disallowing judicial review of allegations regarding the whole-hospital exception without first submitting the review for evaluation by the Secretary of Health and Human Services).

124. 124 Stat. at 685 (amending 42 U.S.C. § 1395nn).

125. Craig Conway, *Physician Ownership of Hospitals Significantly Impacted by Health Care Reform Legislation*, Health L. Perspectives 2 (Apr. 2010) (available at http://www.law.uh.edu/healthlaw/perspectives/2010/%28CC%29%20Stark.pdf).

126. 124 Stat. at 772 (amending 42 U.S.C. § 1395nn).

Disclosure Protocol, which is administered by the Department of Health and Human Services' Office of Inspector General (OIG).[127]

The Stark Self-Disclosure Protocol is a true innovation, in a way that the Anti-Kickback protocol is not, because the Stark protocol allows the CMS to evaluate and compromise on any possible claims that the government might have against the applicant.[128] This ability to compromise under the Stark protocol is the same as the Anti-Kickback protocol in that the OIG is authorized to compromise potential claims.[129] But what makes the Stark protocol unique is the civil statute's strict-liability nature.[130] The Stark Law is written in such a way that if a physician triggers the trip wire by engaging in a tainted financial relationship and that physician does not enjoy the benefit of a statutory or regulatory exception, then liability should be automatic. Theoretically, there should be no compromise in a true Stark Law violation, for the statute as originally written mandates the certainty of the violation. The Anti-Kickback protocol is different. Because the Anti-Kickback Statute is an intent-based criminal statute, it is natural for the government to evaluate fact scenarios that could lead to criminal complaints and then decide whether to further pursue

127. *See* Dep't Health & Human Servs., Ctrs. for Medicare & Medicaid Servs., *Avoiding Medicare Fraud and Abuse: A Roadmap for Physicians* 12 (Mar. 2012) (available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Avoiding_Medicare_FandA_Physicians_FactSheet_905645.pdf) (advising providers who suspect that they have engaged in an improper relationship to consider using either the OIG's or CMS' self-disclosure protocol).

128. 124 Stat. at 772 (amending 42 U.S.C. § 1395nn).

129. 63 Fed. Reg. 58399, 58400 (Oct. 30, 1998). In the publication of the OIG's Provider Self-Disclosure Protocol, the OIG stated the following:

> Because a provider's disclosure can involve anything from a simple error to outright fraud, the OIG cannot reasonably make firm commitments as to how a particular disclosure will be resolved or the specific benefit that will enure to the disclosing entity. In our experience, however, opening lines of communication with, and making full disclosure to, the investigative agency at an early stage generally benefits the individual or company. In short, the Protocol can help a [healthcare] provider initiate with the OIG a dialogue directed at resolving its potential liabilities.

Id.; *see also* Ltr. from Daniel R. Levinson, Inspector Gen., Off. of Inspector Gen., *An Open Letter to Health Care Providers* (Mar. 24, 2009) (available at https://oig.hhs.gov/fraud/docs/openletters/OpenLetter3-24-09.pdf) (stating that the OIG would not agree to settle an Anti-Kickback claim for less than $50,000); 77 Fed. Reg. 36281, 36281 (June 18, 2012) (highlighting the OIG's successful resolution of many Self-Disclosure Protocol matters).

130. Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 L. & Psychol. Rev. 20, 26 (2003); Michael Pretzer, *Stark Reality: The Latest Self-Referral Regs*, http://medicaleconomics.modernmedicine.com/memag/article/articleDetail.jsp?id=119462 (Sept. 3, 2001).

those fact scenarios.[131] It is also natural for the government to engage in the gamesmanship that is endemic to the securing of convictions. Thus, the government will try to assert its leverage over a defendant (or potential defendant) in the form of a possible conviction, and the (potential) defendant will react to that leverage by insisting on a trial or trying to compromise on the charges.[132] The Stark protocol is different because it places the government in the same position it would be in when evaluating criminal charges. This could bespeak a desire for more enforcement for Stark Law claims, even if not "full" enforcement.

V. ANTI-KICKBACK STATUTE CHANGES: CHANGING THE INTENT STANDARD FOR EASIER CONVICTIONS

A. The Intent Transformation

The federal Anti-Kickback Statute is one of the more confounding statutes in the fraud arsenal. Because it is a criminal statute, the government must prove, beyond a reasonable doubt, both the defendant's guilty mind (*mens rea*) and that he or she did the acts proscribed by the statute (*actus reus*).[133] Similarly, a conviction under any criminal statute requires the proof of *mens rea* and *actus reus*.[134] Between the Anti-Kickback Statute's first iteration in 1972 and the passage of the Affordable Care Act in 2010, however, federal prosecutors were left with the unenviable task of trying to prove that the party offering, paying, or accepting "remuneration" intended to incentivize referrals for claims paid for by a federal healthcare program.[135]

131. 42 U.S.C. § 1320a–7b (2006) (applying the "knowingly" and "willfully" intent standards).

132. *See* H. Mitchell Caldwell, *Coercive Plea Bargaining: The Unrecognized Scourge of the Justice System*, 61 Cath. U. L. Rev. 63, 67–75 (2011) (applying game theory to the plea-bargaining process, which would be similar to seeking a settlement in the Stark Law protocol process).

133. The Anti-Kickback Statute proscribes providers from "knowingly and willfully solicit[ing] or receiv[ing] any remuneration (including any kickback, bribe, or rebate)" in exchange 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." 42 U.S.C. § 1320a–7b(b)(1).

134. *See United States v. Cornelio–Pena*, 435 F.3d 1279, 1286 (10th Cir. 2006) (explaining that "[a]s with most crimes, solicitation requires both *mens rea* and *actus reus*").

135. *See* Terri Sabella, *American Health Lawyers Association*, *Health Law Resources*, *Anti-Kickback Statute*, "Authority," http://www.healthlawyers.org/hlresources/Health

This prosecutorial task should be relatively easy now because Congress dramatically changed the prohibited act. No longer are the prohibited acts only to offer or pay a bribe or kickback in exchange for the prohibited referral.[136] Those obviously evil acts were left in the statute.[137] In addition, Congress added the catch-all "remuneration" to the prohibited acts.[138] The problem with expanding the statute to include "remuneration" is that Congress ignored the basic reality of healthcare business—indeed all business that is premised on a capitalistic profit motive. For any transaction to occur, parties must exchange remuneration.[139] Indeed, remuneration is the *raison d'être* of all capitalistic encounters between enlightened, self-interested parties.[140]

Yet, the Act proscribes remuneration if one of its motivating factors is to encourage a referral paid for by a federal healthcare program. Further, not only must "one purpose"[141] of the healthcare actor's motivation be to incentivize referrals that lead to claims paid by Medicare or Medicaid, but now with the Affordable Care Act, the criminal intent required for a successful prosecution is dramatically lower. This intent evaluation leads to the unreasoned result that the actor will be prosecuted by fulfilling the "one purpose." The Statute's text requires the actor to "knowingly and willfully" offer, pay, or accept the remuneration in exchange for the prohibited referral.[142] As one might imagine, "knowing" and "willful" action has a plethora of meanings as established by federal criminal jurisprudence.[143] These range from actual, precise knowledge that the defendant's actions triggered and violated a

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%20Law%20Wiki/Anti-Kickback%20Statute.aspx (last modified May 26, 2011, 5:37 p.m.) (explaining that in most courts, the government had to prove that at least one purpose of a payment was to induce future referrals to establish a Medicare statute violation).

136. 42 U.S.C. § 1320a–7b.

137. *Id.*

138. *Id.* at § 1320a–7b(b) (2006 & Supp. 2010).

139. David M. Frankford, *Creating and Dividing the Fruits of Collective Economic Activity: Referrals among Health Care Providers*, 89 Colum. L. Rev. 1861, 1870–1871 (1989).

140. *See* Antony Flew, *The Profit Motive*, 86 Ethics 312, 312 (1976) (recognizing the common notion that profit is a defining feature of capitalist markets).

141. Though several United States Circuit Courts of Appeal have approved the one-purpose test, the court in *United States v. Greber*, 760 F.2d 68, 71–72 (3d Cir. 1985), popularized the test.

142. 42 U.S.C. § 1320a–7b(b).

143. *Bryan v. United States*, 524 U.S. 184, 191 (1998) (defining "willful" as "a word of many meanings," which are dependent on context).

particular statute to something much looser: knowledge that the defendant's actions were against the law or otherwise "wrongful."[144]

The Anti-Kickback Statute has given rise to caselaw that has tracked the general caselaw about criminal intent. The Ninth Circuit's signature Anti-Kickback case, *Hanlester Network v. Shalala*,[145] adopted the most exacting intent standard found in the federal criminal jurisprudence. In *Hanlester Network*, the court determined that a partnership had violated the Anti-Kickback Statute when it knowingly and willfully offered and paid physician limited partners as an inducement for the physicians to refer federally reimbursable lab tests to the partnership's laboratories.[146] The court held that the defendant must actually know that the Anti-Kickback Statute's text prohibits the payment of remuneration for referrals and perform the acts proscribed by the Anti-Kickback Statute "with the specific intent to disobey the law."[147] The rule is "exacting," of course, because it is very hard for the government to meet this standard and obtain a conviction. The Eighth Circuit tempered this rule in *United States v. Jain*[148] by holding that the defendant must have known that he or she did something "wrong" or "unethical" to meet the intent standard for conviction.[149] In short, there is a significant split among the circuits regarding the degree of intent required for a defendant to violate the Anti-Kickback Statute. Theoretically, a California businessperson could engage in a transaction that eventually results in referrals to Medicare, and as long as he or she did not know about the Anti-Kickback Statute's existence and the specific

144. *Compare id.* at 191–192 *with United States v. McInnis*, 976 F.2d 1226, 1234 (9th Cir. 1992) (citing *United States v. Loera*, 923 F.2d 725, 730 (9th Cir. 1991)) (stating that "[t]he general intent requirement is satisfied by proof that a defendant committed a volitional act that he or she knew or reasonably should have known was wrongful").

145. 51 F.3d 1390 (9th Cir. 1995).

146. *Id.* at 1394–1396.

147. *Id.* at 1400.

148. 93 F.3d 436 (8th Cir. 1996).

149. *Id.* at 441. *United States v. Neufeld*, 908 F. Supp. 491 (S.D. Ohio 1995), also provides an interesting take on willfulness. In *Neufeld*, the Court declined to pin an exact definition of "willfulness" that would comport with the *mens rea* necessary for a conviction; however, it did say that "[a] formulation of 'willful' which takes into account the purpose to commit a wrongful act is sufficient to eliminate the vagueness challenge." *Id.* at 497; s*ee also United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (providing another approach to "willfulness," under which the defendant must know that his or her conduct is unlawful).

prohibitions found therein, he or she could offer, pay, or accept remuneration with the resulting referrals leading to claims paid by Medicare.[150] If that businessperson engaged in the same transaction in Iowa, however, he or she would commit a felony leading to significant jail time, fines, and the possibility of debarment from the Medicare program if he or she had an inkling of a thought that his or her conduct was *unethical* (and not necessarily *unlawful*).[151]

Decisions in a significant number of the circuits exacerbate this problem because they have adopted close variations of the Third Circuit's classic test of an actor's *motivation* (as distinguished from his or her criminal intent, or lack thereof): the "one-purpose" test.[152] Under the one-purpose test, a defendant may be convicted of violating the Anti-Kickback Statute if one of his or her purposes (motives) is for the offer or payment of remuneration to lead to referrals paid for by a federal healthcare program.[153] Importantly, the defendant may have had other motives for engaging in the transaction that eventually led to prohibited referrals (like increasing access to or bolstering the quality of healthcare in a particular area), but if just one of the purposes in a defendant's mind was to engage in the prohibited referral, then the transaction is fatally tainted.[154] This, of course, works at cross-purposes with the general principle that an actor's motive is immaterial to the resolution of the criminal case.[155] Like Jean Valjean, I may take a loaf of bread from the market because I am

150. *See Hanlester Network*, 51 F.3d at 1400 (applying the exacting "specific intent to disobey the law" rule).

151. *See Jain*, 93 F.3d at 441 (applying the standard of knowledge of "wrong" or "unethical" behavior).

152. *E.g. United States v. Bay St. Ambul. & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 30 (1st Cir. 1989); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States v. Borrasi*, 639 F.3d 774, 781 (7th Cir. 2011); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *United States v. McClatchey*, 217 F.3d 823, 829 (10th Cir. 2000).

153. *Greber*, 760 F.2d at 72.

154. *Id.* The Third Circuit went far beyond discussing motive, explaining that "[e]ven if the physician performs some service for the money received, the potential for unnecessary drain on the Medicare system remains." *Id.* at 71.

155. *See e.g. United States v. Boardman*, 419 F.2d 110, 113–114 (1st Cir. 1969) (upholding the trial court's jury instruction explaining that "[w]here a person has a specific intent to bring about a result which the law seeks to prevent, what induces him [or her] to act, his [or her] motive, is immaterial").

hungry.[156] The reason I stole the bread, however, is not significant in criminal law—what matters is my *intent*: did I intend to take the bread without paying for it first?[157]

In the context of Anti-Kickback enforcement, motive has served as a useful proxy for intent for the past several years. If a transaction is not otherwise shielded by a statutory or regulatory safe harbor, then one "bad" purpose by transaction participants can bring significant criminal liability on one or more of those participants.[158] Nevertheless, prosecutors have not been completely uninhibited in leveraging settlements or winning verdicts against defendants: at least one court has made government prosecutors prove, beyond a reasonable doubt, the evil nature of the defendant's mind.[159]

This is where Congress' change to the Anti-Kickback Statute comes into play. In the Affordable Care Act, Congress resolved the circuit split concerning the degree of intent required for a conviction under the Anti-Kickback Statute.[160] Now, one simply has to commit the acts forbidden by the statute (offering, paying, or accepting bribes, kickbacks, or remuneration in exchange for referrals paid by a federal healthcare program), but one does not have to possess a malignant mind coupled with the prohibited acts.[161] Although the actor has to intend to do the prohibited acts, it no longer matters whether the actor thinks his or her actions

156. *See* Victor Hugo, *Les Misérables* vol. 1, bk. 2, ch. VI–VII, at 73, 76–77 (Charles E. Wilbour trans., Random House Inc. 1992) (describing the protagonist, Jean Valjean, and his struggle to come to terms with a nineteen-year sentence to prison he received for stealing a loaf of bread and repeatedly attempting to escape prison after he was arrested).

157. *See Boardman*, 419 F.2d at 113–114 (providing a jury instruction explaining that the intent to commit the act, not the motive, is material in a criminal case).

158. The federal Anti-Kickback Statute provides for fines of up to $25,000 per violation and felony conviction punished by imprisonment up to five years, or both, as well as possible exclusion from federal healthcare programs. Joan H. Krause, Skilling *and the Pursuit of Healthcare Fraud*, 66 U. Miami L. Rev. 363, 372 (2012); Staman, *supra* n. 45, at 1–2.

159. *See e.g. McClatchey*, 217 F.3d at 829 (requiring the government to show a "specific intent to violate the [Anti-Kickback Statute]" to convict the defendant).

160. See Kirk Ogrosky & Daniel A. Kracov, *The Impact of the Patient Protection and Affordable Care Act on Fraud Prevention and Enforcement* C-3 (ABA 10th Annual Nat'l Inst. on Health Care Fraud 2010) (available at http://www.arnoldporter.com/resources/documents/Arnold%26PorterLLP_ABA_Ogrosky_Kracov_2010.pdf) (explaining that the Affordable Care Act "settles a [f]ederal circuit split about the definition of 'willfully' as applied to the [Anti-Kickback Statute's] intent requirement").

161. 124 Stat. at 759 (amending 42 U.S.C. § 1320a–7b to state that "a person need not have actual knowledge of this section or specific intent to commit a violation of this section").

are unethical or even unlawful.[162] Congress has drastically changed the intent of the Anti-Kickback Statute. Thus, this resolution makes a conviction pursuant to the Anti-Kickback Statute quick, neat, and utterly tilted in favor of the government winning every time it brings a legitimate, colorable case.

This small change eviscerates not only the criminal-intent standard in the Anti-Kickback Statute, but also the beleaguered one-purpose test. Now, it does not even matter if the accused intended the remuneration to lead to claims reimbursed by a federal healthcare program. All that matters is that the offer, payment, or acceptance does lead to such federally reimbursed claims.

This should be chilling for anyone involved in transactions in the healthcare industry. Presently, an unsuspecting hospital administrator or physician-practice executive can make an offer or receive an offer from a doctor or someone else in the position to influence federally reimbursable referrals, and if the offer leads to claims reimbursed by a federal healthcare program, the administrator has violated the Anti-Kickback Statute through the mere act of making or receiving the offer. Further, because business people are now even more apparent on the government's radar, it is very likely that business people and their lawyers will shy away from cutting-edge transactions. This is significant because previously, both the Department of Health and Human Services' Office of Inspector General and well-known health law practices accentuated the fact that transactions that do not meet a statutory or regulatory safe harbor do not themselves *necessarily* violate the Anti-Kickback Statute.[163] The theory behind this protective statement was that criminal intent to violate the Statute

162. *Id.* The Congressional Research Service questions whether this section applies to the entirety of Section 1320a–7b or to only the Anti-Kickback Statute at Section 1320a–7b(b). Staman, *supra* n. 45, at 4 n. 24.

163. *See e.g.* 64 Fed. Reg. 63518, 63536 (Nov. 19, 1999) (recognizing that "some legitimate [ambulatory surgical centers'] arrangements may not fit precisely" in the safe harbor); Steve Goldstein, *Safe Harbors for Ambulatory Surgery Centers: DHHS Brings Clarity to Complying with Anti-kickback Statutes*, http://sackstierney.com/articles/safeharbors.htm (July 2003) (explaining that business "[a]rrangements [that] fall outside of the safe harbors do not necessarily violate the statute, but do not have the immunity from prosecution [that] the safe harbors provide"); s*ee also* CoxHealth, *Home*, *About Us*, *Compliance & Ethics*, *Complying with Referral Laws*, http://www.coxhealth.com/body.cfm?id=3449 (accessed Jan. 6, 2013) (providing that a "[f]ailure to meet all criteria in a safe harbor does not necessarily mean that a violation of the statute has occurred").

was required in addition to the mechanical actions of the proposed transaction.[164] The Affordable Care Act has taken away this thin veneer—criminal intent in the sense of a malignant mind is no longer required to violate the Statute.

With this statutory amendment, Congress has collapsed the division of labor that existed between the Anti-Kickback Statute and the Stark Law. Previously, Stark was the strict-liability regime from which a business deal could only find refuge if the boundaries of the transaction fit squarely within the four corners of a statutory or regulatory exception.[165]

In fact, the nomenclature of "exception" is important to distinguish from the "safe harbor" carve-outs of the Anti-Kickback Statute. Congress and the Department of Health and Human Services were truly excepting physicians from the hard, steely, otherwise exceptionless norms of the Statute. A "safe harbor" connotes something qualitatively different—that the business actor could be violating the Anti-Kickback Statute, but certain factors would have to come into play, including the actor's state of mind (intent) and prosecutorial desire to develop and prosecute the case.[166] Nevertheless, if a person's conduct fit completely within the contours of the safe harbor, then he or she was immune from prosecution.[167] If it did not, the prosecutor would have to determine whether the actor had the requisite intent to violate the Statute, which often left an actor's plans undisturbed.[168]

Furthermore, Congress was oblivious to the realities of the healthcare marketplace and, indeed, the broader American marketplace. It is axiomatic that money, or remuneration, must be discussed, offered, paid, and accepted in order for any commerce to be transacted in the United States, else the thing exchanged between the parties cannot rightly be called "commerce." This is

164. 64 Fed. Reg. at 63519.

165. 72 Fed. Reg. 51012, 51026 (Sept. 5, 2007); CoxHealth, *supra* n. 163.

166. *See* Sabella, *supra* n. 135, at "Overview of Issue" (explaining that the Anti-Kickback Statute's safe harbors protect businesses from prosecution if their otherwise suspect practices fall within certain "parameters" that minimize the risk of corrupt business practices).

167. *Id.*

168. *See id.* (explaining that business practices not included within the safe harbors are not "per se violations of the Anti-Kickback Statute" and that the OIG evaluates those practices on an independent basis).

the most basic, yet most incisive, insight of David M. Frankford's standard-bearing article about the Anti-Kickback Statute, *Creating and Dividing the Fruits of Collective Economic Activity: Referrals among Health Care Providers*.[169] Frankford argues that remuneration must be shared between any number of parties committed to forming and launching an enterprise for profit, including a healthcare enterprise.[170] Without the possibility of sharing remuneration, people do not want to go through the painful steps to start and maintain a business. Now, with the amendments to the Anti-Kickback Statute, the government has taken away any incentive to give voice to—much less actively discuss and pursue—actions that would lead to remunerated, federally reimbursable claims because under the new language, the mere discussion of such business plans, which many businesses require, violates the Statute if it leads to federally reimbursed claims.

B. Codification of False-Certification Theory

If it is not enough that Congress has hamstrung the generation of innovative business ideas in the healthcare industry through its tightening of the Anti-Kickback Statute's intent standard, it has also codified and given its approval to a practice used by government prosecutors to leverage the quickest possible settlement or highest possible judgment against Anti-Kickback defendants.[171] Another amendment to the Anti-Kickback Statute spells out that any violation of the Anti-Kickback Statute is automatically a violation of the civil False Claims Act.[172] For years, prosecutors have pressed a "false-certification" theory of False Claims Act violations, arguing that when providers certify by their electronic signatures on the Medicare claim forms that they have complied with all applicable laws and then the certification

169. *See* Frankford, *supra* n. 139, at 1869–1876.

170. *Id.* at 1870–1871.

171. This, of course, is a hyperbolic overstatement made for effect. The proposed business transaction discussed would be sheltered from prosecution if it fits within a statutory or regulatory safe harbor.

172. 124 Stat. at 759 (amending 42 U.S.C. § 1320a–7b). The Act also bootstrapped violations of the Anti-Kickback Statute as "healthcare fraud" crime. 124 Stat. at 1008 (amending 18 U.S.C. § 24(a) (2006)).

turns out to be false, they have violated the Anti-Kickback Statute, thereby tainting all of the claims requisitioned on the form.[173]

The government's false-certification theory, now codified by Congress, represents bootstrapping in its rawest and most aggressive form. It is relatively easy to see that a provider has not necessarily made claims that are fraudulent or untrue simply because he or she might have violated the Anti-Kickback Statute. The services the provider billed for might have been legitimately performed according to all applicable standards in Medicare or Medicaid billing manuals. There may be no issue whatsoever with a service because it was actually provided to a patient, and there may be no problem with the way the service is marked on the claim form because the coding is consonant with the level or intensity of service provided to the patient. Yet the government may weigh False Claims liability upon the provider just because he or she signed the bottom of the claim form.

Historically, whenever the government could make a colorable prosecution under the Anti-Kickback Statute, it has also sought civil sanction pursuant to the Civil Money Penalties law, and the OIG has pursued administrative debarment remedies.[174] That the government combines the criminal Anti-Kickback Statute with the civil money penalties and debarment should not pose a problem for any defendant. All three statutory regimes are conceptually related; indeed, all three work together to severely punish people who participate in bribes and kickbacks that lead to the draining of federal healthcare programs. Fraudsters should expect to be hit hard by tough criminal sanctions and debilitating civil fines. They should be outcast and forbidden for a significant amount of time from participating in the same programs that they defrauded, but the government should not hold them liable

173. *See e.g. United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F. Supp. 2d 153, 159 (D.D.C. 2008) (explaining that violations of the Anti-Kickback Statute and Stark Law could be pursued under the False Claims Act because "they would influence the Government's decision of whether to reimburse Medicare claims"); *United States ex rel. Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 54 (D. Mass. 2011) (holding that "liability under the False Claims Act can be predicated on a violation of the Anti[-]Kickback Statute" where "compliance with the Anti[-]Kickback Statute is a precondition of Medicare payment").

174. U.S. Dep't Health & Human Servs., *Medicare Fraud & Abuse: Prevention, Detection, and Reporting* 2–4 (Medicare Learning Network Oct. 2011) (available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Fraud_and_Abuse.pdf).

in a statutory scheme that was intended to capture and punish the concept of theft and not the concepts of bribes and kickbacks. Like the diminished intent standard, with this jurisprudential anomaly, Congress has disincentivized providers from engaging in innovative transactions that will result in referrals eventually paid for by a federal healthcare program. Providers know that if they mess up in the slightest, they could be in line for a triple remedy: the criminal fine and imprisonment found in the Anti-Kickback Statute itself, the Civil Money Penalties and program debarment, and the False Claims Act liability.

VI. CONCLUSION

The Affordable Care Act does not fundamentally revolutionize healthcare fraud law. There is not a set of provisions that regulates providers in original ways, as did the Stark Law back in 1989. Nevertheless, Congress is showing the seriousness with which it combats fraud and the massive drain that it wreaks on the federal fisc by adroitly focusing its attention on enforcement. Couple a newfound focus on the money leaving through the front door with a much easier path to a favorable conviction or judgment (especially in False Claims and Anti-Kickback cases), and the government stands a much better chance to narrow the gap between the dozens of billions of dollars lost to fraud in any one year with the relatively paltry single billions recovered through existing legal tools. It remains to be seen, though, how long it will take for the gap to narrow and for provider behavior to change.