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## Doctoring Fraud & (and) Abuse: Enforcement of Stark and the Antikickback Law in Physician Recruitment May Be Bad for Your Health

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# DOCTORING FRAUD & ABUSE: ENFORCEMENT OF STARK AND THE ANTI- KICKBACK LAW IN PHYSICIAN RECRUITMENT MAY BE BAD FOR YOUR HEALTH

## I. INTRODUCTION

In 1998, Mina Nazaryan, associate administrator at Alvarado Hospital Medical Center in San Diego, California, successfully recruited an eye surgeon from a competing hospital. The recruitment agreement guaranteed the eye surgeon a \$435,000 yearly income.<sup>1</sup> Nazaryan boasted that this enabled the hospital to handle an additional 104 retinal cases.<sup>2</sup> Federal prosecutors were not impressed. They allege that Nazaryan received kickbacks from some of the physicians she recruited for Alvarado.<sup>3</sup>

The federal government claims Alvarado Hospital and Tenet Health Systems Hospitals, Inc. (“Tenet”) paid more than ten million dollars to recruit doctors to the San Diego area, and that much of the money was used to bribe doctors to send patients to Alvarado.<sup>4</sup> Although offering incentives to recruit physicians is not a practice unique to Tenet, the indictment does not define why Tenet’s arrangements differ from the common legal practices of other hospitals.<sup>5</sup> This indictment has sent a shock wave through the health care industry and many attorneys are “recommending that hospitals . . . suspend using the [recruitment] agreement until [they] see what happens with the [Tenet] case.”<sup>6</sup>

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1. *Feds: Administrator Made Desperate Moves Before Arrest in Alvarado Case*, REP. ON MEDICARE COMPLIANCE, Oct. 2, 2003, at 1.

2. *Id.*

3. *Id.*

4. *Id.* at 1, 6.

5. Leigh Page, *Hospitals Review Recruitment Strategy*, MOD. PHYSICIAN, Sept. 1, 2003, 2003 WL 2,248,365, at \*1.

6. Brad Cain, *Investigation into Tenet’s Physician Recruitment Practices*

Tenet's president criticized the indictment as "very broad" and claimed it "mistakenly attacks a well-established, lawful and common means by which U.S. hospitals attract needed physicians to their communities."<sup>7</sup> While this argument may seem insincere in light of a host of other federal government investigations into Tenet's practices,<sup>8</sup> it cannot be ignored because "[financial] incentives are a part of most, if not all, health care relationships and do not necessarily increase health care costs or threaten patient welfare."<sup>9</sup> This Note will demonstrate, in fact, that prohibiting these incentives may result in the very detriment to our health care system that fraud and abuse laws are supposed to remedy.<sup>10</sup>

The government fears that physician recruiting incentives either explicitly or implicitly invite improper referrals to the hospital providing the incentive.<sup>11</sup> As the Tenet case suggests, some hospitals view physician recruitment as central to growing their businesses since new physicians bring new patients to the hospital. This Note analyzes the propriety of the hospital-physician relationship and whether that relationship has been overly restricted.

Part II of this Note defines the current state of hospital-physician relationships and discusses the growing shortage of physicians that

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*Expands to Seven L.A. Facilities: U.S. Attorney Subpoenas Documents on Tenet's Relocation Agreements*, CAL. HEALTHFAX, July 21, 2003, at 1, 1-2. After four months of testimony, the case ended in a mistrial. The jury could not reach a verdict on any count. Sarah Skidmore, *Mistrial Declared for Tenet, Hospital; Court Case Involved Kickback Allegations*, SAN DIEGO UNION-TRIB., Feb. 18, 2005, at C1.

7. Debora Vrana & Ronald D. White, *Tenet Hospital Indicted Over Doctor Payments: Grand Jury Alleges the Facility and a Company Unit Bribed Physicians to Refer Patients*, L.A. TIMES, July 18, 2003, at C1.

8. See Vince Galloro, *Under Scrutiny: Tenet Legal Woes Multiply with Kickback Probe*, MOD. HEALTHCARE, July 21, 2003, 2003 WL 9,136,105, at \*1 (detailing investigations into Tenet's Medicare outlier payments, allegations that two physicians at another of its hospitals performed medically unnecessary procedures and then falsely billed the government for them, and a trial in a "whistleblower" lawsuit alleging violations related to its purchases of physician practices in the mid-1990s). The confluence of these investigations into Tenet's practices has overshadowed the legitimate goals of physician recruitment arrangements in general. *Id.*

9. Robert Fabrikant, *The Need for Repeal or Decriminalization of the Health Care Antikickback Statute*, HEALTH CARE FRAUD & ABUSE NEWSL., Oct. 2002, WL 3 No. 9 HTHCFAN 7, at \*1.

10. See *infra* Part V.

11. See *infra* Part IV.

hospitals face today. Part III examines the tremendous arsenal of laws used to combat fraud and abuse, chief among them Medicare and Medicaid's Anti-Kickback law (the "Anti-Kickback law")<sup>12</sup> and the Stark statute ("Stark").<sup>13</sup> Part IV discusses the application of these laws and demonstrates their relation to efforts by hospitals to recruit physicians.

Part V argues that while the government's enforcement tactics may be necessary to combat a real and critical problem, their future cost to our health system will negate any benefit reaped from these efforts. The current approach taxes already stressed and struggling institutions that are in dire need of doctors. The financial success of any hospital is vital to its ability to provide continued access to health care for its community. Because of overzealous enforcement of fraud and abuse laws, however, hospitals must jump through multiple rings of fire to avoid an investigation. Yet many still get burned. As an alternative, this Note advocates adoption of the Internal Revenue Service model for assessing the tax-exempt status of nonprofit hospitals.

## II. THE NEED FOR PHYSICIAN RECRUITMENT

The government's attack on hospital-physician relationships has exacerbated the decline in the number of physicians practicing and entering the field of medicine. A December 2002 survey of more than 1,200 physicians in San Diego County alone found that:

[o]ne in three physicians (35 percent) report[ed] they will leave the practice of medicine within three to five years. Of those who are staying, one-third plan to reduce patient care hours. Sixty-four percent state[d] the region is undergoing a physician shortage. In addition, 71 percent report[ed] problems recruiting physicians to the county, which is the nation's fifth largest in population.<sup>14</sup>

Because San Diego is considered a bellwether city due to its early adoption and high penetration of managed care, some experts say that the city is on the "bleeding edge" of a medical crisis that is

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12. 42 U.S.C. § 1320a-7b(b) (2000).

13. *Id.* § 1395nn.

14. *Report Reveals Looming Physician Shortage*, PR NEWSWIRE, Dec. 4, 2002, <http://www.prnewswire.com>.

bound to spread across the country.<sup>15</sup>

A shortage of physicians makes recruitment incentives more critical to the quality of care. The threat of a health care crisis which some say is well underway should cause the government to reconsider the aggressive tactics of its campaign against practices it claims constitute fraud and abuse. The Tenet indictment is emblematic of that enforcement campaign.

While this Note focuses on the growing shortage of physicians in California and the critical problems facing its hospitals, ample evidence suggests the crisis is nationwide. For example, in the past ten years, U.S. hospitals lost 103,000 staffed beds and 7,800 medical/surgical beds, and 370 emergency departments closed between 1994 and 1999.<sup>16</sup> California presents a practical study of this problem since it has been the vanguard with respect to health care trends in this country.<sup>17</sup>

According to a recent study conducted by Shattuck Hammond Partners, high managed care penetration, competitive pricing, and

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15. *Id.*

16. Stephanie Mencimer, *Rich Man, Spore Man: If the Elite Want to Survive Bioterrorism, They'll Have to Make Sure the Poor Do, Too*, WASH. MONTHLY, Dec. 1, 2001, at 30, 34, available at <http://www.washingtonmonthly.com/features/2001/0112.mencimer.html>.

In the last five years, California has closed more than 23 hospitals and 50 emergency rooms . . . . Massachusetts lost 24 percent of its hospital beds between 1988 and 1998. In a recent one-week period in Boston, the city's 17 major hospitals were operating at an unheard of 96.2 percent occupancy rate, and emergency rooms have closed to ambulances on a regular basis. In Cleveland, four of the region's leading hospitals last year were in bankruptcy; the high-level trauma center at Mt. Sinai was closed . . . . In the month of May, metro Cleveland's 22 emergency rooms were simultaneously closed to ambulances for almost 10 percent of the month due to the lack of space.

*Id.*; see also Mary Chris Jaklevic, *Trouble in the City: Mergers, Medicare and Managed Care Combine to Force Closing of 38 Urban Hospitals*, MOD. HEALTHCARE, Jan. 8, 2001, 2001 WL 9,418,069, at \*1 (describing the fiscal pressures that have forced urban hospitals to shut their doors); Julie Piotrowski, *How Secure is the Safety Net? Public Hospitals Learn to Survive in an Increasingly Tight Market by Closing, Building, Replacing and Sometimes Converting*, MOD. HEALTHCARE, Feb. 25, 2002, 2002 WL 9,524,662, at \*1 (detailing the "precarious financial position" of public hospitals and local efforts to preserve the safety net).

17. See *supra* notes 14–15 and accompanying text.

low utilization threaten the viability of many California hospitals.<sup>18</sup> More than half the state's hospitals are losing money from operations,<sup>19</sup> and some may even face closure.<sup>20</sup> The study identified staffing as one "trigger point[]" that could contribute to the financial weakening of California's hospitals.<sup>21</sup> Meanwhile, "the state has a legitimate interest in ensuring that hospital services are available in communities where needed."<sup>22</sup>

Across the United States, the communities most in need of these services are located in rural and poor urban areas.<sup>23</sup> Reports of physician and provider shortages in these areas date back to as early as 1933.<sup>24</sup> The government has targeted areas lacking medical resources by designating them as Health Professional Shortage Areas ("HPSAs").<sup>25</sup> In 1997, 855 urban areas qualified as HPSAs.<sup>26</sup> Today, over 47 million people, one in every six Americans, live in a designated shortage area.<sup>27</sup> Not all communities suffering shortages qualify as HPSAs, however.<sup>28</sup>

The lack of practicing physicians leaves rural and poor inner-city patients to rely on hospital emergency rooms and outpatient clinics for care.<sup>29</sup> Hospitals with emergency departments are required by state and federal law to maintain physician call panels,<sup>30</sup>

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18. *California Hospitals Face Financial Crisis that Threatens Viability of Weaker Institutions*, HEALTH CARE STRATEGIC MGMT., Nov. 1, 2001, at 6.

19. *Id.*

20. *Id.*

21. *Id.*

22. *Id.*

23. COUNCIL ON GRADUATE MED. EDUC., U.S. DEP'T OF HEALTH & HUMAN SERVS. TENTH REPORT: PHYSICIAN DISTRIBUTION AND HEALTH CARE CHALLENGES IN RURAL & INNER-CITY AREAS 1 (1998) [hereinafter COGME REP.].

24. *Id.*

25. See Health Professionals Educational Assistance Act of 1976, Pub. L. No. 94-484, § 332, 90 Stat. 2270 (1976); see also *id.* § 752 (describing obligated service in health manpower shortage areas under the National Health Service Corps Scholarship Program).

26. COGME REP., *supra* note 23, at 29.

27. *Id.* at 6.

28. See *infra* note 175 and accompanying text.

29. See COGME REP., *supra* note 23, at 35-36.

30. See Emergency Medical Treatment and Labor Act ("EMTALA"), 42 U.S.C. § 1395dd (2000). The EMTALA

requires that an individual be evaluated and provided with medical support services and/or transfer arrangements that are consistent with

but most hospitals are suffering from insufficient call panel participation.<sup>31</sup> Inadequate physician reimbursement for services provided through call panel participation is a significant obstacle to maintaining physician participation.<sup>32</sup> Physicians generally do not receive adequate reimbursement for care provided to uninsured and indigent patients.<sup>33</sup> As a result, they are reluctant to join hospital staffs that require panel participation.<sup>34</sup>

Physician lifestyles and lack of financial incentives also inhibit participation on call panels.<sup>35</sup> “With [the] rise of managed care, call panel participation is not a good way to build [a] private practice.”<sup>36</sup> Furthermore, “professional liability concerns and increased cost of malpractice coverage steer physicians toward more lucrative opportunities.”<sup>37</sup> As well, “[m]any physicians believe that malpractice lawsuits are more likely to arise” from patients seen in the emergency department.<sup>38</sup>

The government’s recent attempt to alleviate these pressures may be misguided. For example, the Bush Administration relaxed the rules requiring hospitals to have specialists on call around the clock.<sup>39</sup> As a result, patients will likely find it more difficult to obtain some types of emergency care.<sup>40</sup> This remedy skirts the issue

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the capability of the institution and the well-being of the patient. The Social Security Act at § 1866(a)(1)(I)(iii) requires that hospitals have a list of physicians who are on-call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition.

Memorandum from Centers for Medicaid & Medicare Services, Department of Health & Human Services, to the Associate Regional Administrators (June 13, 2002) (on file with the Loyola of Los Angeles Law Review). California law requires the same. See CAL. HEALTH & SAFETY CODE §§ 1317, 1317.1, 1317.2, 1317.2a, 1317.6, 1371.4 (2002).

31. Healthcare Law Section, L.A. County Bar Assoc., Healthcare Prof. Shortage: Cal. in Crisis; Physician On-Call Coverage Issues (2003) (on file with the Loyola of Los Angeles Law Review).

32. *Id.*

33. *Id.*

34. *Id.* at 3.

35. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

39. Robert Pear, *Emergency Rooms Get Eased Rules on Patient Care*, N.Y. TIMES, Sept. 3, 2003, <http://www.nytimes.com/2003/09/03/politics>.

40. *Id.*

of physician compensation that has plagued on-call panels and implicated the fraud and abuse laws.

Private hospitals that remain in urban areas respond to these problems by limiting service to Medicaid patients or closing their emergency rooms altogether in order to discourage use of their facilities by low income patients.<sup>41</sup> The increasing closures and the relocation of private hospitals from poor, urban communities to other areas requires residents of those communities to rely on teaching hospitals, which are "public" institutions that accept all Medicare and Medicaid patients regardless of their ability to pay. Not only are these hospitals overcrowded and understaffed,<sup>42</sup> but because of the large number of Medicare and Medicaid patients they serve, providers in these areas are more likely to be targeted in the government's vigil for fraud and abuse.

### III. THE ARSENAL OF FRAUD AND ABUSE LAWS

To appreciate how fraud and abuse enforcement has complicated the ability of hospitals to recruit physicians, one must have a basic understanding of the laws, their origins and the way they have been applied. The multiplicity and diversity of federal health care fraud and abuse enforcement provisions is truly remarkable.<sup>43</sup>

A range of criminal authorities address fraud and abuse,<sup>44</sup> including the Anti-Kickback law.<sup>45</sup> Criminal prosecutions may also be brought under more general federal statutes that prohibit the knowing presentation of false or fraudulent claims to the United States,<sup>46</sup> the making of false or fraudulent statements or representations to the United States,<sup>47</sup> and the use of the mail or electronic communications to commit frauds.<sup>48</sup> Generic charges of

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41. Marianne L. Engelman Lado, *Breaking the Barriers of Access to Health Care: A Discussion of the Role of Civil Rights Litigation and the Relationship Between Burdens of Proof and the Experience of Denial*, 60 BROOK. L. REV. 239, 248 (1994).

42. *Id.* at 247.

43. See Aaron M. Altschuler et al., *Health Care Fraud*, 35 AM. CRIM. L. REV. 841, 842-44 (1998).

44. See Pamela H. Bucy, *Crimes by Health Care Providers*, 1996 U. ILL. L. REV. 589, 591-647.

45. 42 U.S.C. § 1320a-7b(b) (2000).

46. 18 U.S.C. § 287 (1994).

47. *Id.* § 1001 (1994 & Supp. III 1997).

48. *Id.* §§ 1341, 1343 (1994).



aiding and abetting, conspiracy, Racketeer Influenced and Corrupt Organizations Act (“RICO”) violations, money laundering, obstruction of justice, or tax evasion may supplement health care criminal charges.<sup>49</sup>

An equally potent range of civil authorities address health care fraud. These include Stark, the federal civil False Claims Act (“FCA”),<sup>50</sup> and an array of administrative sanctions. The most serious administrative penalty from the perspective of most providers is exclusion from participation in federal and state health care programs.<sup>51</sup> Four situations warrant mandatory exclusion from federal and state programs for at least five years.<sup>52</sup> Most notably, these include conviction of a felony criminal offense related to the delivery of an item or service paid for by a federal or state health care program.<sup>53</sup> For many providers who are dependent on Medicare, the five year mandatory exclusion can be the most devastating consequence of a criminal fraud and abuse conviction, which may otherwise result in little or no prison time.<sup>54</sup> Finally, the Medicare and Medicaid statutes specify numerous situations in

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49. See TIMOTHY S. JOST & SHARON L. DAVIES, *MEDICARE AND MEDICAID FRAUD AND ABUSE* §§ 2:2, 2:3, 2:5 (2003).

50. 31 U.S.C. § 3729 (1994). The civil FCA provides that one who knowingly presents a false or fraudulent claim or makes a false statement to the United States to get a false or fraudulent claim paid is liable for treble damages, plus civil penalties of \$5,000 to \$10,000 per claim. *Id.* It also authorizes qui tam, “whistleblower” enforcement, affording persons with inside knowledge of fraud and abuse the opportunity to sue a provider in hopes of recovering a bounty of between 15% and 30% of the total civil FCA judgment or settlement, thereby encouraging private enforcement to supplement and stimulate public prosecutions. *See id.*

51. See Julie Johnsson, *Are You Guilty Until Proven Innocent? Tougher Rules on Fraud Enforcement Put Providers on the Defensive*, AM. MED. NEWS, June 9, 1997, (noting that Medicare fraud cases are often settled because providers cannot risk being excluded from Medicare participation), [http://www.ama-assn.org/amednews/1997/pick\\_97/pick0609.htm](http://www.ama-assn.org/amednews/1997/pick_97/pick0609.htm).

52. 42 U.S.C. § 1320a-7 (2000).

53. *Id.* § 1320a-7(a); see JOST & DAVIES, *supra* note 49, § 5:3.

54. JOST & DAVIES, *supra* note 49, § 5:5 (delineating consequences of exclusion from federal programs, including “professional license revocation in many states, possible loss of hospital staff privileges, loss of access to government financing programs, required disclosure under the securities laws, and difficulties in accessing government programs supporting marketing abroad”).

which civil money penalties can be administratively imposed.<sup>55</sup> Although these authorities provide one more vehicle for pursuing fraudulent or abusive conduct, most of them are rarely, if ever, used.<sup>56</sup>

#### A. Anti-Kickback Law

The Office of Inspector General (“OIG”), established at the Department of Health and Human Services (“HHS”) by Congress in 1976, conducts a nationwide program of audits, investigations, and inspections aimed at identifying and eliminating fraud, abuse, and waste in HHS programs.<sup>57</sup> The OIG actively investigates violations of the Medicare and Medicaid Anti-Kickback statute to reduce fraud in the Medicare and Medicaid programs.<sup>58</sup>

Provisions of the Anti-Kickback statute penalize anyone who knowingly and willfully solicits, receives, offers, or pays remuneration in cash or in kind to induce a person:

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care [Medicare or Medicaid] program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under [the Medicare or Medicaid] program.<sup>59</sup>

Violators are subject to criminal penalties<sup>60</sup> and/or exclusion from participation in the Medicare and Medicaid programs.<sup>61</sup> Because the

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55. *Id.* §§ 2:5, 5:4.

56. Amendments to the Medicare and Medicaid administrative penalty provisions, for example, provided penalties for upcoding, 42 U.S.C. § 1320a-7(a)(a)(1)(A) (2000), and for billing medically unnecessary care, *id.* § 1320a-7(a)(a)(1)(E). Upcoding and billing for unnecessary services are also, of course, already covered by the criminal statutes, *see id.* § 1320a-7(a), (b), and civil statutes, *see False Claims Acts*, 31 U.S.C. § 3729 (1994).

57. Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994), <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html> [hereinafter OIG Special Fraud Alerts].

58. *Id.*

59. 42 U.S.C. § 1320a-7b(b)(2)(A)-(B) (2000).

60. *Id.* § 1320a-7b(b)(2).

61. *Id.* § 1320a-7; *see also* JOST & DAVIES, *supra* note 49, § 5:3–5:4 (discussing mandatory and permissive exclusions).

Anti-Kickback provisions are so broad that virtually every health care arrangement or transaction falls within its reach, the OIG has chosen to allow twenty-one payment practices that might otherwise come under the auspices of the Anti-Kickback law.<sup>62</sup>

### B. The Stark Statute

The Stark statute provides a civil means for protecting patients and federal Medicare dollars from fraud and abuse.<sup>63</sup> The Act prohibits any entity or individual from furnishing a service reimbursable under Medicare to a patient if the patient's referring physician or an immediate family member of the referring physician has a financial relationship with the entity.<sup>64</sup>

This self-referral ban covers both Medicare and Medicaid and extends to nearly all types of health services: (1) clinical laboratory services; (2) physical therapy services; (3) occupational therapy services; (4) radiology services; (5) radiation therapy services and supplies; (6) durable medical equipment and supplies; (7) parental and enteral nutrients, equipment, and supplies; (8) prosthetics, orthotics, and prosthetic devices and supplies; (9) home health services; (10) outpatient prescription drugs; and (11) inpatient and outpatient hospital services.<sup>65</sup> Like the Anti-Kickback law, Stark has several exceptions to its self-referral prohibition.<sup>66</sup> Indeed, while the basic prohibition is narrowly defined, it still encompasses a wide

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62. 42 C.F.R. § 1001.952 (2001) (codifying most updated version of safe harbor regulations). Nevertheless, compliance with one of the safe harbors does render a party immune from investigation, prosecution, or exclusion under the Anti-Kickback provisions if the party entered the relationship with the requisite illegal intent to induce referrals. See JOST & DAVIES, *supra* note 49, § 3:24.

63. In 1989, Representative Fortney H. Stark introduced the Ethics in Patient Referrals Act to provide a civil means for protecting patients and federal Medicare dollars. The Ethics in Patient Referrals Act was enacted into law in 1992 and was codified as section 1877 to the Social Security Act, 42 U.S.C. § 1395nn (2000). The Act became known as "Stark I." See Jo-Ellyn Sakowitz Klein, *The Stark Laws: Conquering Physician Conflicts of Interest?*, 87 GEO. L.J. 499, 499-500 (1998). By the time Stark took effect, Congress had already expanded the scope of the law. The result became known as Stark II. Maria A. Morrison, *An Analysis of the Stark II Proposed Rule*, 67 U. MO. KAN. CITY L. REV. 613, 614 (1999).

64. 42 U.S.C. § 1395nn(a) (2002).

65. *Id.* § 1395nn(h)(6)(A)-(K).

66. *Id.* § 1395nn.

range of common and legitimate business relationships in health care.

### C. Differences Between the Anti-Kickback Law & Stark

To complicate matters, the Stark statute and the Anti-Kickback provisions are not entirely consistent with one another.<sup>67</sup> As a result, arrangements that comply with one may still violate the other.<sup>68</sup> There are three major differences between the Anti-Kickback provisions and the Stark statute. First, because the Anti-Kickback law is a criminal law, improper intent is necessary to violate its provisions.<sup>69</sup> The same is not true of the Stark law, which is a civil statute.<sup>70</sup> Second, arrangements must fall entirely within an exception to the Stark statute to be legal, but arrangements that fall outside the scope of the Anti-Kickback law's safe harbor protections are not necessarily unlawful.<sup>71</sup> Finally, due to variations in the requirements of the prohibition and its exceptions, compliance with one law's safe harbor provisions does not necessarily mean that the arrangement or transaction is also protected under the other.<sup>72</sup>

## IV. THE PROBLEM WITH PHYSICIAN RECRUITMENT

Physician recruitment programs have become effective tools in the highly competitive market for skilled doctors. In rural or poor urban areas, they are critical for luring any doctor at all.<sup>73</sup> Some physicians actively solicit such incentives.<sup>74</sup> As a consequence, there

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67. See Linda A. Baumann, *Navigating the New Safe Harbors to the Anti-Kickback Statute*, HEALTH LAW., Feb. 2000, at 1, 3 (comparing Stark statute and Anti-Kickback regulations).

68. See *id.*; 64 Fed. Reg. 63,518, 63,519 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt. 1001).

69. Baumann, *supra* note 67, at 4 (explaining different intent requirements).

70. *Id.*

71. *Id.* (comparing scope of Stark exceptions to scope of anti-kickback safe harbors); 64 Fed. Reg. at 63,519.

72. Bauman, *supra* note 67, at 4. Likewise, a valid relationship under Stark still may violate the Anti-Kickback law.

73. Cf. OIG Special Fraud Alerts, *supra* note 57, at 65,375 (discussing that "hospitals have become more aggressive in their attempts to recruit and retain physicians").

74. *Id.* The OIG identifies several incentives that may result in the reduction of physician's professional expenses or the increase of his or her revenues, including discounted office rental, income guarantees, low-interest or interest-free loans, and travel expenses. *Id.* at 65,375-65,376.

may be an explicit or implicit expectation that the physician refer some or all of her patients to the hospital providing the incentives.<sup>75</sup>

The OIG has increasingly considered these arrangements suspect under the Anti-Kickback law “because they can constitute remuneration offered to induce, or in return for, the referral of business paid for by Medicare or Medicaid.”<sup>76</sup> As effective as they may be in attracting doctors, these incentive programs may inflate costs to the Medicare program and result in compromised care to patients.<sup>77</sup> For instance, a doctor who has an interest in referring patients to the hospital providing the incentives, particularly in the form of salaries or medical office overhead, may inappropriately overuse the services of that hospital.<sup>78</sup> Such incentive programs may give rise to a doctor’s implicit obligation to refer a patient to that hospital, instead of a hospital offering the best or the most appropriate care for that patient.<sup>79</sup>

Similarly, under Stark, a recruitment contract between a hospital and a physician constitutes a suspect financial relationship since the remuneration flowing from the hospital to the physician takes the form of an incentive.<sup>80</sup> Once that financial relationship is established, any referral by the physician to the hospital for certain kinds of services triggers a violation of the statute.<sup>81</sup> The catch here is that almost all inpatient and outpatient services fall under the scope of Stark, and thereby prohibit any form of referral. As will be shown below, while Stark has a broad exception for physician recruitment, it is ambiguous, rendering compliance something of a guessing game.

#### *A. Complexity of Enforcement and Uncertainty of Compliance*

The Centers for Medicare and Medicaid Services expect health care expenditures in the United States to climb to 2.8 trillion dollars by the year 2011.<sup>82</sup> Health care fraud accounts for up to ten percent

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75. *Id.*

76. *Id.* at 65,375.

77. *Id.*

78. *Id.*

79. *Id.* While there is an express safe harbor for physician recruitment, discussed below, it is very narrow and cannot be relied upon for most cases.

80. *See infra* Part IV.A.3.

81. *See infra* Part IV.A.3.

82. Jonathan Cone et al., *Health Care Fraud*, 40 AM. CRIM. L. REV. 713,

of those costs.<sup>83</sup> In 2001, the government prosecutions of health care fraud resulted in over 1.7 billion dollars in penalties.<sup>84</sup> Because of the severity of the penalties and the government's penchant for imposing them, most providers are as concerned about compliance as the government is about enforcement. The statistics belie the difficulties of both provider compliance and government enforcement of the fraud protection laws.

### 1. Compliance with the Anti-Kickback Law: A Narrow Exception

The OIG insists that its "experience over the past few years has shown that practitioner recruitment is an area frequently subject to abusive practices."<sup>85</sup> Nonetheless, the OIG recognizes that such practices may be necessary in geographic areas that have difficulty attracting physicians.<sup>86</sup>

The safe harbor provision will protect payments that an entity makes to a practitioner to induce her to relocate<sup>87</sup> to an HHS-defined HPSA for the practitioner's specialty area if nine conditions are met.<sup>88</sup> Outside of this exception, practitioner recruitment practices

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715 (2003).

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

84. *Id.* (citing HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM, DEP'T OF HEALTH & HUMAN SERVS. & DEP'T OF JUSTICE, ANNUAL REPORT FOR FY 2001, at <http://www.usdoj.gov/dag/pubdoc/hipaa01fe19.htm>).

85. 64 Fed. Reg. 63,518, 63,543 (Nov. 19, 1999).

86. While the proposed rules applied only to rural areas, the 1999 Regulations base the qualification for this safe harbor on the HPSA standards and thus include some urban centers as well as rural areas. Some rural areas are not HPSAs, however, and thus would not qualify under this safe harbor even if they did qualify under the proposed rules. Baumann, *supra* note 67, at 13.

87. The safe harbor regulation for practitioner recruitment does not apply to retention agreements. It protects only the recruitment of a genuinely relocating practitioner or a new practitioner (a physician who has been practicing in his or her current specialty for less than one year). See 64 Fed. Reg. at 63,542; JOST & DAVIES, *supra* note 49, § 3:48.

88. 42 C.F.R. § 1001.952(n)(2), 8) (2001). The other conditions include: (1) the arrangement is recorded in a written contract that specifies the benefits that the entity is to provide, the terms under which they are provided, and the obligations of each party; (2) the benefits paid by the entity to the practitioner must not be provided for longer than three years and the contract cannot be

are generally not protected.

## 2. Compliance with the Anti-Kickback Law: The Intent Requirement

The Anti-Kickback law's safe harbor provision constitutes a narrow exception. Failure to fit squarely into it does not necessarily constitute a violation of the law. The government must first prove that the defendant: (1) knowingly and willfully; (2) solicited or received remuneration; (3) in return for, or to induce, referral of program-related business.<sup>89</sup> In other words, even if a hospital provides financial incentives to recruit a doctor to its area, and that doctor refers patients to the recruiting hospital, there is no violation of the statute in the absence of evidence that the hospital intended to induce those referrals.

Some argue that the intent requirement eliminates the concerns over the complexity of the statutory construction by presenting a "formidable hurdle for prosecutors."<sup>90</sup> Indeed, a prosecutor will have to prove that the charged offender acted with some form of scienter, but varying interpretations of this requirement have led to conflicting decisions.

Anti-kickback cases have presented two *mens rea* issues. The first issue concerns whether a physician or hospital must know that a particular financial relationship is unlawful in order to constitute prohibited "willful" conduct under the statute.<sup>91</sup> The second issue concerns the level of proof required to show that remuneration was

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renegotiated during this term; (3) the practitioner cannot be required to generate business for the entity as a condition for receiving benefits, but the practitioner may be required to maintain staff privileges at the entity; (4) the practitioner cannot be prevented from establishing staff privileges at or referring business to any other entity; (5) the amount of the benefits that the entity pays a practitioner may not be tied to the amount of business that the practitioner generates for the entity if that business is to be reimbursed in whole or in part by Medicare or a State health program; (6) the practitioner must treat any patient receiving medical benefits or assistance under any Federal health care program in a non-discriminatory manner; and (7) the agreement between the entity and the practitioner may not benefit anyone other than the practitioner with the power to generate business for the entity. *Id.*

89. See 42 U.S.C. § 1320a-7b(b).

90. Timothy S. Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 ALA. L. REV. 239, 302 (1999).

91. *Id.*

given to induce referrals.<sup>92</sup> Circuit courts have struggled to distinguish illegal intent from a lawful desire to recruit physicians for a legitimate need when the entity is aware that the physician will probably increase its revenues. Consequently, the courts are inconsistent with respect to their treatment of these *mens rea* issues.<sup>93</sup>

The first issue facing courts is the lack of a statutory definition for the terms “knowingly and willfully.”<sup>94</sup> A number of circuits have construed the terms to require that “the Government . . . prove that defendants knew their conduct was unlawful.”<sup>95</sup> For example, in *Hanlester Network v. Shalala*, the Ninth Circuit interpreted “knowingly and willfully” to require that defendants know the law prohibits offering or paying remuneration to induce referrals and, nevertheless, engage in prohibited conduct with the specific intent to disobey the law.<sup>96</sup> Other circuits have applied a lower standard of intent, requiring the government to prove only that the defendant knew her conduct was wrong, rather than to prove she violated “a known legal duty.”<sup>97</sup>

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92. See JOST & DAVIES, *supra* note 49, § 3:58.

93. See Timothy J. Aspinwall, *The Anti-Kickback Statute Standard(s) of Intent: The Case for a Rule of Reason Analysis*, 9 ANNALS HEALTH L. 155, 165–66 (2000); see generally Douglas A. Blair, *The “Knowingly and Willfully” Continuum of the Anti-Kickback Statute’s Scierter Requirement: Its Origins, Complexities, and Most Recent Judicial Developments*, 8 ANNALS HEALTH L. 1 (1999) (discussing the intent requirement).

94. See 42 U.S.C. § 1320a-7b(b) (2000); see also Blair, *supra* note 93, at 6–7 (searching for the true meaning of the terms “knowingly and willfully” in the Anti-Kickback law).

95. *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995); see also *United States v. McClatchey*, 217 F.3d 823 (10th Cir. 2000) (requiring specific intent to violate the law); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) (upholding jury instruction that defined “willfully” as acting “with the specific intent to do something the law forbids; that is to say, with [a] bad purpose either to disobey or disregard the law”); *United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) (holding Anti-Kickback statute only requires knowledge that one’s conduct is unlawful, as opposed to knowledge that one violated the statute).

96. *Hanlester Network*, 51 F.3d at 1400 (requiring defendant to engage in prohibited conduct with knowledge that conduct is unlawful and with “specific intent” to disobey law).

97. *United States v. Jain*, 93 F.3d 436, 440–41 (8th Cir. 1996); see also *United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20 (1st Cir. 1989) (requiring proof that primary purpose of payment was to induce



Under *Hanlester*, ignorance of the law is a defense. This would appear to protect providers who *incorrectly* believe they are engaging in legitimate practices, and to ensure that government enforcement only targets real fraud. This, however, would generally require the defendant to “successfully persuade[] the finder of fact that he was somehow unaware that Congress had passed a statute that outlawed such an arrangement.”<sup>98</sup>

The second issue facing courts has been whether a defendant should be convicted “when his offer or payment of remuneration was motivated merely *in part* to induce referrals,” or whether conviction requires that “motivation to induce referrals [be] the defendant’s *primary purpose*.”<sup>99</sup> The OIG and the only three circuits to have decided this issue have applied the “one purpose” test.<sup>100</sup>

For example, in *United States v. Greber*,<sup>101</sup> a doctor who owned a diagnostic laboratory was convicted for violating the Anti-Kickback law because he paid “interpretation fees” to other physicians to induce them to refer patients to his laboratory services.<sup>102</sup> The defense argued that these fees compensated physicians both for providing initial consultation services and for explaining the test results to the patients.<sup>103</sup> The district judge instructed the jury that as long as *one purpose* of the interpretation fee was to induce referrals, the legitimacy of other actual purposes was immaterial.<sup>104</sup>

Greber appealed, insisting that the government must show that the inducement was the *only* purpose.<sup>105</sup> The Third Circuit rejected his argument.<sup>106</sup> The court analyzed the legislative intent of the statute and held that “if one purpose of the payment was to induce

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referrals); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985) (stating if at least one purpose was to induce referrals, requirement is met).

98. JOST & DAVIES, *supra* note 49, § 3:60.

99. *McClatchey*, 217 F.3d at 834.

100. *See Davis*, 132 F.3d at 1094; *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); *Greber*, 760 F.2d at 71–72; *see also Aspinwall*, *supra* note 93, at 165 (explaining that the OIG and the Third Circuit favor the broadest interpretation of the anti-kickback prohibitions “one purpose test”).

101. 760 F.2d 68 (3d Cir. 1985).

102. *Id.* at 69–70.

103. *Id.* at 70.

104. *Id.* at 71.

105. *Id.*

106. *Id.*

future referrals, the [Act was] violated.”<sup>107</sup> In particular, the court noted that the addition of the words “[any] remuneration” to the statute suggested that Congress intended that “even if the transaction was not considered to be a ‘kickback’ for which no service had been rendered, payment nevertheless violated the Act.”<sup>108</sup>

Consequently, Greber’s “one purpose” test minimized the impact that the intent requirement would have on the government’s burden of proof. The case of *United States v. McClatchey*<sup>109</sup> provides a recent illustration of how this test is now applied.

In *McClatchey*, Baptist Medical Center entered into a series of agreements with doctors Robert and Ronald LaHue, the owners of a medical practice that provided care to nursing home patients.<sup>110</sup> The contract guaranteed the LaHues annual salaries of \$75,000 each in exchange for their services as co-directors of gerontology at Baptist.<sup>111</sup> Subsequently, the LaHues transferred their patients from the hospital they had previously used to Baptist.<sup>112</sup> Despite the LaHues’ failure to perform substantial services, the hospital renewed their contract.<sup>113</sup>

The court concluded that McClatchey, the hospital’s chief operating officer who renewed the contracts, “knowingly and willfully” violated the Anti-Kickback law because he knew the LaHues had not performed their duties under the prior contract, because he knew hospital staff did not want the LaHues to perform those tasks, and because he understood the critical value of the LaHues’ patient referrals.<sup>114</sup> From these facts, the court reasoned that a jury “could infer that McClatchey’s very reason for negotiating a new contract with the LaHues . . . was to induce them to continue their profitable referrals.”<sup>115</sup>

The court recognized that “[e]very business relationship between a hospital and a physician is based ‘at least in part’ on the hospital’s expectation that the physician will choose to refer

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107. *Id.* at 69.

108. *Id.* at 72.

109. 217 F.3d 823 (10th Cir. 2000).

110. *Id.* at 826–27.

111. *Id.* at 827.

112. *Id.*

113. *Id.* at 828.

114. *Id.* at 830, 835.

115. *Id.* at 830.

patients.”<sup>116</sup> Nevertheless, it held that a hospital “may lawfully enter into a business relationship with a doctor and even hope for or expect referrals from that doctor, so long as the hospital is motivated to enter into the relationship for legal reasons entirely distinct from its collateral hope for referrals.”<sup>117</sup>

How is a trier of fact to know when that “hope for referrals” is a motivating factor and when it is “entirely distinct”?<sup>118</sup> Granted, the “one purpose” test eliminates an easy defense for wrongdoers who attempt to mask prohibited kickbacks as “interpretive fees,”<sup>119</sup> “handling fees,”<sup>120</sup> or “management fees.”<sup>121</sup> However, the *McClatchey* decision underscores the fundamental unworkability of compliance with the Anti-Kickback statute for “[t]here is no point in debating how much purpose is too much when there is no objective way of measuring a person’s or organization’s purpose, and when the purportedly prohibited purpose necessarily accompanies every transaction.”<sup>122</sup> It is this hairsplitting that decimates the hurdle of the intent requirement and, in effect, shifts the burden from the prosecution to the defendant provider.<sup>123</sup>

### 3. Compliance with Stark: The Perils of Ambiguity

Complying with Stark’s civil ban on self-referrals has been equally difficult. The scope of the law has increased with the addition of ten designated health services. The law’s numerous exceptions, the issuance of various subsequent proposed rules, the comment periods that followed, and the changes in the final rules that resulted from the comments have produced a law that makes compliance a dubious task.<sup>124</sup>

116. *Id.* at 834.

117. *Id.*

118. In a footnote, the Tenth Circuit ineffectually dismisses this conundrum by asserting that the making of such distinctions is the role we assign to juries while at the same time acknowledging that it is unlikely a jury will be able to accomplish the task. *Id.* at 834 n.7.

119. *See* United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

120. *See* United States v. Hancock, 604 F.2d 999 (7th Cir. 1979).

121. *See* United States v. Lipkis, 770 F.2d 1447 (9th Cir. 1985).

122. Fabrikant, *supra* note 9, at \*4.

123. This burden is exacerbated by the threat to the defendant’s reputation and finances in having to defend against the action.

124. Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, 27 LAW & PSYCHOL. REV. 1, 21

For a compensation relationship to fall under one of Stark's safe harbor provisions, the parties must meet any number of loosely defined requirements. Payment by an employer to a physician is excepted, provided it is for "identifiable services," is consistent with the "fair market value" of the services, does not take into account the "volume or value" of referrals, is based on an agreement that would be "commercially reasonable" even if no referrals were made to the employer, and meets other requirements imposed by the Secretary of Health and Human Services.<sup>125</sup>

In particular, payment to induce a physician to relocate to the hospital's geographic area and to join its medical staff is acceptable, provided the physician is not required to refer patients to the hospital,<sup>126</sup> the amount of remuneration is not determined by the volume or value of patient referrals,<sup>127</sup> and the arrangement meets all other regulations designed "to protect against program or patient abuse."<sup>128</sup> There is no "fair market value" requirement under the physician recruitment exception; however, once the physician becomes a member of the hospital staff, that compensation arrangement must be consistent with the "fair market value" of the services rendered.<sup>129</sup>

Unlike the Anti-Kickback law, there is no *mens rea* requirement under Stark, "yet the penalties may *feel* criminal to those upon whom they are being imposed."<sup>130</sup> This raises a fundamental question of fairness. Under a regulatory scheme, damages are augmented "to account for harms that remain unpunished and to provide added deterrence" because it is understood that "only one in three violators of a law will be caught."<sup>131</sup> Thus, the ease with which innocent offenders might be subject to stiff penalties is troubling since lack of intent is no defense.

Some attempts at enforcing Stark have been successful,<sup>132</sup>

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(2003).

125. 42 U.S.C. § 1395nn(e)(2) (2000).

126. *Id.* § 1395nn(e)(5)(A).

127. *Id.* § 1395nn(e)(5)(B).

128. *Id.* § 1395nn(e)(5)(C).

129. *Id.*

130. Klein, *supra* note 63, at 524.

131. *Id.*

132. See *Gublo v. Novacare, Inc.*, 62 F. Supp. 2d 347 (D. Mass. 1999) (qui tam suit involving Stark law violations); United States *ex rel.* Thompson v.

however, enforcing Stark has proved to be as challenging as compliance. In several instances, Stark “enforcers” have experienced difficulty in defining and identifying inappropriate acts.<sup>133</sup> The complicated exceptions to the rules can make spotting infractions as cumbersome for the enforcers as it is for the providers and physicians. The difference is that the latter must walk that perilous line between compliance and illegality in their attempt to provide health care in an ever tightening market.<sup>134</sup>

#### 4. The Impact of Uncertain Compliance Issues

Critics cite overzealous enforcement and confusion over intricate and complicated compliance as chief among the flaws in fraud and abuse legislation.<sup>135</sup> As case law demonstrates, even well-meaning judges are unable to interpret and apply the Anti-Kickback statute in a principled and foreseeable manner.<sup>136</sup>

A lack of clear compliance guidelines chills the efforts of hospitals and physicians to alleviate the looming health care crisis<sup>137</sup> in their regions. Compliance is not optional, and in the case of Stark neither ignorance, naiveté, nor lack of intent are defenses.<sup>138</sup> Failure to comply can be catastrophic, even if all parties never intended to break any law. Because of the uncertainty and risk of fighting these claims, many defendants are forced to settle.<sup>139</sup>

This chilling effect may have extreme consequences for the future of health care in the United States. Compliance with fraud and abuse laws has proved unworkable, particularly in the area of

Columbia/HCA Healthcare Corp., 20 F. Supp. 2d 1017 (S.D. Tex. 1998) (healthcare provider and affiliates accused of Stark and anti-kickback violations).

133. Anne W. Morrison, *An Analysis of Anti-Kickback and Self-Referral Law in Modern Health Care*, 21 J. LEGAL MED. 351, 378 (2000) (commenting that the ambiguity of the language of the Stark laws is an obstacle to understanding whether a particular arrangement is in violation of the statute).

134. See Kellye M. Gordon, Note, *Friend or Foe: The Role of Multidisciplinary Practices in a Changing Legal Profession*, 36 IND. L. REV. 1363, 1375 (2003).

135. See Fabrikant, *supra* note 9, at \*5.

136. *Id.*

137. See *supra* Part II.

138. Michael Pretzer, *Stark Reality: The Latest Self-Referral Regs.*, MED. ECON., Sept. 3, 2001, 2001 WL 25,619,733, at \*3.

139. See *infra* note 149 and accompanying text.

criminal enforcement.<sup>140</sup> As described above, it is impossible for health care professionals and their legal advisers to be confident that their business conduct does not violate a criminal statute.<sup>141</sup> As a result, “a significant amount of procompetitive, legitimate business conduct is needlessly discouraged.”<sup>142</sup> Furthermore, the benefits of prohibited practices outweigh the costs of potential abuse that would go unchecked, and, ironically, achieve the same goals of cost-effectiveness and quality of care advocated by proponents of fraud and abuse legislation.<sup>143</sup>

#### V. THE PROBLEM WITH THE CURRENT SYSTEM AND WHAT CAN BE DONE

At some point, the policy arguments from which fraud and abuse laws arose will be eclipsed by the burden they impose on our health care system. As discussed above, stemming overutilization, controlling costs, and maintaining quality of care were the driving concerns behind the government’s initiation of Stark and the Anti-Kickback law.<sup>144</sup> In its fervent attempt to punish and deter inappropriate financial relationships, however, the government’s actions have produced many of the results its efforts were designed to eliminate.

First, the conduct prohibited by fraud and abuse laws can just as easily produce the positive results the government claimed were the purpose behind the prohibition. For example, in a letter from the Federal Trade Commission’s (FTC) Bureaus of Competition, Consumer Protection and Economics, the FTC argued that self-referral arrangements can improve quality of care “because an investment interest may lead to a stronger, more permanent working relationship between the referring practitioner and the entity in which [the practitioner] has a financial interest.”<sup>145</sup> Moreover, a physician’s interest in a facility is directly linked to the facility’s

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140. Fabrikant, *supra* note 9, at \*1.

141. *Id.*

142. *Id.* at \*2.

143. *See infra* Part V.

144. *See supra* notes 49–51 and accompanying text.

145. Theodore N. McDowell, Jr., *Physician Self-Referral Arrangements: Legitimate Business or Unethical “Entrepreneurialism,”* 15 AM. J.L. & MED. 61, 71 (1989).

reputation for quality.<sup>146</sup> Other physicians will not refer patients to a facility if it becomes known for providing poor quality services.<sup>147</sup>

Second, the law itself has paralyzed the industry to the extent that it threatens to undermine the provision of quality care. The amount of money the government collects from penalties and settlements has its costs as well. Because of the uncertainty regarding compliance, particularly the conflicting standards for anti-kickback liability, health care payers and providers are forced to expend substantial legal fees simply trying to follow the law, let alone the costs of fighting or settling actual claims.<sup>148</sup> Moreover, health care providers often abandon potentially beneficial arrangements because of the ease with which anti-kickback liability can be established.<sup>149</sup> Certainly, the administrative burden requires physicians and hospitals alike to devote an increasing amount of attention to compliance instead of care. Finally, patients who require multiple services may be inconvenienced by limits requiring physicians to refer patients to a single provider, which may result in compromised care.<sup>150</sup>

As the law stands, the government has complete authority over any fraud and abuse investigation. Consequently, the impact of the government's efforts has been great. Nearly 3,000 providers were excluded from Medicare in fiscal year 1999.<sup>151</sup> 550 of those exclusions resulted from criminal convictions for program-related crimes, 323 from patient abuse and neglect, and 1,416 were based on license revocations.<sup>152</sup>

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146. *See id.*

147. *Id.*

148. *See* Aspinwall, *supra* note 93, at 157 (citing the "statutory ambiguities surrounding the issue of intent" under the anti-kickback statute as a cause of substantial and unnecessary legal fees); Klein, *supra* note 63, at 522–23 (describing the "chartsmanship" a pulmonologist would have to conduct to protect herself from penalties under the Stark Laws).

149. *See* James F. Blumstein, *Rationalizing the Fraud and Abuse Statute*, HEALTH AFF., Winter 1996 (suggesting that current fraud and abuse laws discourage forms of integration that enhance both quality and efficiency), <http://contenthelthaffairs.org/content/vol15/issue4> (last visited Oct. 2, 2004).

150. *See* Klein *supra* note 63, at 522.

151. HEALTH CARE FRAUD & ABUSE CONTROL PROGRAM, U.S. DEP'T OF HEALTH & HUMAN SERVS. & U.S. DEP'T OF JUSTICE, ANNUAL REPORT FOR FY 1999, at <http://www.usdoj.gov/dag/pubdoc/hipaa99ar21.htm>.

152. *Id.*

While health care abuse is rampant and the cost is real, many providers criticize the fraud enforcement community for turning its mission into a crusade.<sup>153</sup> In light of the flexibility courts have given the government to prove intent under the Anti-Kickback law<sup>154</sup> and the virtual strict liability of Stark,<sup>155</sup> it is not surprising that few fraud and abuse cases involving large-scale providers are ever tried; virtually all are settled.<sup>156</sup> In addition to the potential treble penalties and criminal prosecution one risks in litigation, there is also the cost of personal defense, negative publicity, and exclusion from the Medicare program—a virtual economic death sentence.<sup>157</sup>

Whether a provider who innocently misconstrues a complex regulation would ever be found guilty in a court of law is in some ways a moot issue if the provider cannot risk putting the issue of its culpability to a trier of fact. When a law creates the risk of victimizing innocents more than punishing wrongdoers, its enforcement mechanism must be reevaluated. Because of physician shortages and the stringent limits on recruitment incentives, innocents are no longer limited to those health care providers who are struggling through the complex and ambiguous maze of anti-kickback legislation. The list of victims has grown to include residents of communities no longer served by those providers directly targeted by the legislation.

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153. Johnsson, *supra* note 51.

154. *See supra* Part IV.A.2.

155. *See supra* notes 1458–1580 and accompanying text.

156. There are no publicly available statistics on the proportion of fraud and abuse cases that are settled or that go to judgment. For one indication of the prevalence of settlements, see U.S. DEP'T. OF JUSTICE, HEALTH CARE FRAUD REPORT: FY 1997 (describing a sampling of cases brought or settled under criminal or civil false claims authorities), <http://www.usdoj.gov/dag/pubdoc/health97.htm>. The Report describes 307 individual conviction cases under the FCA plus the settlement of 102 more hospitals in the Diagnosis Related Group (DRG) project, but it mentions only two FCA judgments. *Id.* *See also* U.S. DEP'T OF HEALTH & HUMAN SERVS. & U.S. DEP'T OF JUSTICE, HEALTH CARE FRAUD & ABUSE CONTROL PROGRAM, ANNUAL REPORT FOR FY 2002 (specifying more than 1.8 billion dollars in judgments, settlements, and administrative impositions won or negotiated by the Federal government in health care fraud cases, of which well over a billion was the result of settlements), <http://www.usdoj.gov/dag/pubdoc/hcfacreport2002.htm>.

157. Johnsson *supra* note 51.



### *A. Recent Attempts to Address the Problem*

The chilling effect on physician recruitment might be palatable if viable alternatives existed to alleviate the problem. California has experimented with several different pilot programs to counter the flow of physicians from shortage areas. These programs have had little success, a result that can be traced to the threat of fraud and abuse enforcement.

An example of an ineffective pilot program is the Mexico Physician Pilot Program. This program proposed an accelerated issuance of three-year licenses to up to thirty Mexican primary care physicians working in non-profit community health centers.<sup>158</sup> However, the California Medical Association (“CMA”) rejected the proposal, arguing that “Californians need and deserve adequate numbers of properly trained, culturally sensitive physicians . . . .”<sup>159</sup> Instead, the CMA sponsored student loan repayment programs and other incentives for doctors to join the California Physician Corps in serving medically underserved communities.<sup>160</sup>

Physician recruitment and retention efforts such as the Mexico Physician Pilot Program are evidence of the problem, not the solution. The CMA advocates a role that has become too risky for providers to undertake. Hospitals fear using incentives to lure physicians to their call panels precisely because of their vulnerability to allegations of fraud and abuse.<sup>161</sup> Yet, it should be the responsibility of hospitals, not the CMA, to determine their incentives. The CMA is not equipped to offer the incentives necessary to draw the requisite number of physicians and specialists to any given area.<sup>162</sup>

### *B. An Alternative Approach: IRS Tax-Exempt Model*

Tax-exempt status is as critical to non-profit hospitals as

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158. Live Symposium, Anmol S. Mahal, M.D., California Medical Association, Health Care Professionals Shortage: California in Crisis (2003) (describing the Mexico Physician Pilot Program under California Business & Professions Code section 853).

159. *Id.*

160. *Id.*

161. *See supra* notes 31–35 & 123–31 and accompanying text.

162. *See supra* notes 31–35 & 123–31 and accompanying text (explaining how hospitals attract physicians by offering incentives that CMA cannot).

Medicare and Medicaid participation is to health care providers.<sup>163</sup> In policing tax-exempt health care organizations, the Internal Revenue Service (“IRS”), like the OIG, must ensure that “public” monies are not inappropriately funneled to private parties.<sup>164</sup> Nevertheless, the IRS and the OIG have made clear that what may constitute a lawful exemption under the Internal Revenue Code may still violate the Medicare and Medicaid Anti-Kickback statute.<sup>165</sup>

In light of the troubles of fraud and abuse enforcement discussed above, the OIG could benefit from an acute examination of the IRS model. The IRS uses a more efficient method to determine whether a hospital violates the requirements for federal tax exemption when it provides recruitment incentives to private practitioners to join its medical staff or to provide medical services in its community.<sup>166</sup> The IRS model is as effective as the OIG’s current approach in its respective area of law, but the IRS model has fewer debilitating effects on actual health care services.<sup>167</sup>

Section 501(c)(3) of the Internal Revenue Code provides, in part, for the exemption from federal income tax of corporations organized and operated exclusively for charitable or educational purposes, provided “no part of the [organization’s] net earnings . . . inures to the benefit of any private shareholder or individual . . . .”<sup>168</sup> Furthermore, a compensation arrangement used to induce a doctor to locate a practice in a particular area must “bear a reasonable relationship to promotion and protection of the health of the community.”<sup>169</sup> Moreover, any private benefit to the physician must be incidental to the public purpose achieved.<sup>170</sup>

When a 501(c)(3) hospital recruits a physician, the hospital must show that it is paying reasonable compensation for the physician’s services.<sup>171</sup> When a 501(c)(3) hospital recruits a physician to

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163. BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 886 (4th ed. 2001).

164. *See id.*

165. *See Rev. Rul. 97-21, 1997-1 C.B. 121; 4 Op. Off. Inspector Gen. 2 n.1 (2001).*

166. *See Rev. Rul. 97-21, 1997-1 C.B. 121.*

167. *Id.*

168. 26 U.S.C.A. § 501(c)(3) (West Supp. 2002).

169. *Rev. Rul. 73-313, 1973-2 C.B. 176.*

170. *See Rev. Rul. 97-21, 1997-1 C.B. 123.*

171. *See id.*

provide services to the surrounding community, but not necessarily for the hospital, it must comply with the following four requirements: (i) the hospital may not engage in substantial activities that do not further its exempt purposes; (ii) the hospital must not engage in activities that result in inurement of the hospital's net earnings to a private shareholder or individual; (iii) it may not engage in substantial activities that cause the hospital to be operated for the benefit of a private interest rather than the public interest so that it has a substantial non-exempt purpose; and (iv) it may not engage in substantial unlawful activities.<sup>172</sup>

In contrast to the test applied in anti-kickback cases, the factors described above suggest that, instead of determining whether "one purpose" of a financial arrangement between a hospital and physician is to benefit that physician, the IRS simply asks whether "the community benefit provided by the activity outweighs the private benefit provided to [the physician]. . . ."<sup>173</sup> The IRS's balancing test must take into account the hospital and the community's real circumstances, regardless of any illegal intent. Conversely, Anti-Kickback law enforcers must only consider these facts if the financial arrangement fits squarely within the narrow language of a safe harbor regulation.

For example, under the Anti-Kickback law, if a physician is recruited to a designated health professional shortage area for that physician's particular specialty, recruitment alone may be evidence of an objective need for the practitioner's services.<sup>174</sup> However, an area can only be designated as a HPSA for one or more of seven health professional types: primary medical care, dental, mental health, vision care, podiatric, pharmacy, and veterinary.<sup>175</sup> Moreover, the definition of primary medical care is limited to doctors of medicine or osteopathy who practice primarily in one of four primary care specialties—general or family practice, general

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172. *Id.* at 123–24 (noting a "substantial unlawful activity" includes a violation of the Medicare and Medicaid Anti-Kickback statute).

173. *See id.* at 124 (finding that the determination of the Board of Directors of the hospital that it needs additional diagnostic radiologists to provide adequate coverage and to ensure high quality of medical care was a "significant fact").

174. 4 Op. Off. Inspector Gen. 8 (2001).

175. *See* 42 C.F.R. pt. 5 (2001).

internal medicine, pediatrics, and obstetrics and gynecology.<sup>176</sup>

The arrangement proposed in the OIG's Advisory Opinion No. 01-4 exemplifies the dilemma hospitals face when they do not fit squarely within the definitions of the statute.<sup>177</sup> In the opinion, a recruiting hospital's service area was not designated a HPSA for any medical specialty.<sup>178</sup> The service area was designated as a medically underserved area ("MUA"),<sup>179</sup> however, and, based on a *bona fide* objective-needs analysis, the hospital argued that a shortage of otolaryngologists existed within its service area.<sup>180</sup> The hospital wanted to recruit a recent medical school graduate to relocate to the area by offering the physician a loan to cover the expenses of his five-year residency training in otolaryngology.<sup>181</sup> The loan would be forgiven on the condition that the physician maintain a full-time practice for three years in the hospital's area upon completion of the residency program.<sup>182</sup>

The OIG noted that when arrangements like this implicate the Anti-Kickback statute and do not qualify for the practitioner recruitment safe harbor, the OIG evaluates them on a case-by-case basis.<sup>183</sup> Like the IRS, the OIG looks to "documented evidence of an objective need for the practitioner's services."<sup>184</sup> However, while evidence of this kind may be sufficient for an IRS ruling, it is only one of a number of factors the OIG considers.<sup>185</sup> Additional factors the OIG uses to assess the level of risk presented by a physician recruitment arrangement include whether the practitioner has "an existing stream of referrals within the recruiting entity's service area," whether the benefit is "narrowly tailored so that it does *not* exceed that which is reasonably necessary to recruit a practitioner," and whether "remuneration directly or indirectly benefits other

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176. *See id.* app. A.

177. 4 Op. Off. Inspector Gen. 2 (2001).

178. *Id.*

179. The OIG does not protect MUAs because, unlike HPSAs, which target practitioner shortages, MUAs only measure shortages of health care services generally. *See* 64 Fed. Reg. 63,518, 63,542 (Nov. 19, 1999).

180. 4 Op. Off. Inspector Gen. 2 (2001).

181. *Id.*

182. *Id.* at 3.

183. *Id.* at 8.

184. *Id.*

185. *Id.* at 8-9.

referral sources.”<sup>186</sup>

Such a case-by-case approach is both a safeguard and a bull whip. The OIG recognizes that “even when an area is *not* designated as a HPSA, the area may be deficient with respect to a particular specialty.”<sup>187</sup> As demonstrated by Advisory Opinion No. 01-4, the OIG’s approach may protect the hospital from administrative sanctions.<sup>188</sup> The opinion suggests, however, that the OIG could just as easily wield the heavy hand of the law because, under the “one purpose” test, “[w]hen a hospital provides remuneration to a physician in exchange for relocating or establishing his or her medical practice within the hospital’s service area, an inference may be drawn that one purpose of the remuneration is to generate referrals for the hospital . . . .”<sup>189</sup>

This comparative analysis with the test for tax-exempt status reveals the troubling uncertainty a provider faces even after the delivery of an opinion from the OIG. While an OIG advisory opinion may provide some guidance to a provider before entering into an arrangement, the OIG does not give a binding determination on the critical question of intent.<sup>190</sup> By adopting the tax-exempt model, the OIG would, in effect, abandon the “one purpose” test, and perhaps, the intent requirement entirely. As demonstrated by the IRS, the government can still be effective in combating fraud and abuse without creating more victims along the way.

## VI. CONCLUSION

Notwithstanding these recommendations, one cannot ignore the important deterrent function of fraud and abuse laws. The severity of sanctions has served that purpose well.<sup>191</sup> At the same time,

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186. *Id.*

187. *Id.* at 8.

188. *Id.* at 9.

189. *Id.* at 7.

190. Most, if not all, advisory opinions on proposed arrangements under the Anti-Kickback statute include this or similar language: “Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties’ intent, which determination is beyond the scope of the advisory opinion process.” 13 Op. Off. Inspector Gen. 6 (2002).

191. Johnson, *supra* note 51 (noting that most entities cannot afford to operate without formal compliance plans and “[t]he feds have promised lighter fines and penalties for entities that diligently uncover errant employees or inaccurately coded claims . . .”).

government enforcement must not ignore the devastating price our society will pay for its “success.”

The IRS model described in this Note is an attractive alternative approach largely because of its similarities to the method currently used in health care fraud and abuse enforcement. Both methods encourage compliance by dangling a large carrot in front of starving hospitals—tax exemption under the IRS laws and Medicare or Medicaid reimbursement under the Anti-Kickback law. Both have been very successful. While Stark and the Anti-Kickback law leave little room for error, however, the IRS model comfortably accommodates a common sense analysis.

By focusing its analysis on the benefit of a particular physician recruitment plan, the IRS model never loses sight of the central purpose of this legislation: to provide and promote a fair and equitable health care system. The difference between the two approaches is critical, but the similarities make the change from one to the other feasible.

As fewer doctors choose to practice medicine, and as competition for those remaining doctors increases, the crisis will only escalate. The opportunity to commit fraud and abuse will persist even under the strictest form of enforcement, but we must not forget that virtually every transaction in health care is, at least in part, designed to generate referrals.<sup>192</sup> As the saying goes, even with the best intentions, “there is no mission without money.”<sup>193</sup>

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192. United States v. McClatchey, 217 F.3d 823, 834 (10th Cir. 2000).

193. Keith Berndtson, *Improving Health or Making Money?*, PHYSICIAN EXECUTIVE, May–June 1999, at 6.

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