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Toward a Fair and Practical Definition of "Willfully" in the Medicare/Medicaid Anti-Kickback Statute

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I. INTRODUCTION

Health care fraud takes on a variety of forms—from billing insurance companies for services not provided, to falsifying injuries for tort plaintiffs, to practicing medicine without a license.[1] All these types of fraud contribute to the astronomical cost of health care in the United States.[2] As federal policymakers have focused on ways to contain these costs,[3] health care fraud has become an increasing object of scrutiny.[4] At the same time, the health care industry is experiencing significant institutional change, particularly with the emergence of health maintenance organizations ("HMOs") and other managed care systems.[5] The Medicare/Medicaid anti-kickback statute,[6] which prohibits payments from one provider to another in exchange for future referrals, is caught in the crossfire. On the one hand, it addresses a costly form of fraudulent activity that may be pursued more vigorously in the overall attempt to control health care fraud and abuse.[7] On the other hand, the statute is broadly worded, and technically it prohibits certain provider arrangements that are inevitable and desirable consequences of health care reform in the United States.[8] Courts interpreting the statute will face the challenge of balancing concerns about the costs of fraud with the need to

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1. See Pamela H. Bucy, *Fraud by Fright: White Collar Crime By Health Care Providers*, 67 N.C. L. Rev. 855 (1989) (outlining types of health care fraud based on an extensive survey of prosecuted cases).

2. It is commonly estimated that at least 10% of Medicare's tetal spending, or $17 billion annually, is lost to fraud and abuse. See, for example, Thomas A. Schatz, *Medicare Fraud: Tales from the Gypped*, Wall St. J. A8 (Aug. 25, 1995) (quoting June Gibbs Brown, Inspector General of the Department of Health and Human Services). Some disagree with this estimate. See, for example, Jerry L. Mashaw and Theodore R. Marmor, *Conceptualizing, Estimating, and Reforming Fraud, Waste, and Abuse in Healthcare Spending*, 11 Yale J. Reg. 455, 459 (1994) ("There is no empirical evidence to support the popular notion that fraud and abuse add about 10% to U.S. medical costs.").

3. Controlling health care costs became a major policy issue in the 1970s. Paul Starr, *The Social Transformation of American Medicine* 380-88 (Basic Books, 1982).

4. See David S. Nalven, *Medicare and Medicaid Fraud: An Enforcement Priority for the 1990s*, 38 Boston Bar J. 9 (Oct. 1994) ("The federal government is aggressively prosecuting fraud and abuse by health care providers for the same reason that Willie Sutton robbed banks: it's where the money is.").

5. See James P. Freiburg, *The ABCs of MCOs: An Overview of Managed Care Organizations*, 81 Ill. Bar J. 584 (1993) (giving a brief introduction to the concept of managed care). Managed care is a broad term used to describe health care arrangements that use prearranged fee structures rather than paying for whatever the provider bills under traditional fee-for-service reimbursement plans. Id. HMOs, a subset of managed care, agree to provide medical services for groups of people at prearranged rates. Id. at 585.

6. 42 U.S.C. § 1320a-7b(b) (1994 ed.).

7. See Part III.C.

8. See Part III.A.

encourage health care reform in a fair, practical and consistent manner.

The anti-kickback statute prohibits offering, paying, soliciting or receiving any remuneration in exchange for future referrals or future use of a particular good, service, or facility.[9] A common example of prohibited conduct involves a medical laboratory paying handling fees or referral fees to doctors who send specimens to the laboratory.[10] The statute prohibits not only cash payments, but also remuneration in kind.[11] Thus, for example, a hospital violates the statute by providing amenities to staff physicians in order to influence them to refer their patients to that hospital.[12] A wide variety of business

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9. The statute provides as follows:

(b) Illegal remunerations

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

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under subchapter XVIII of this chapter or a State health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under subchapter XVIII of this chapter or a State health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

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

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under subchapter XVIII of this chapter or a State health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under subchapter XVIII of this chapter or a State health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b). For exceptions to the statute, see note 69.

As of the 1996 amendments, the words "title XVIII or a State health care program" will be replaced by "a Federal health care program" wherever they appear. Thus the statute is now applicable to all federal health care programs, not just to Medicare and Medicaid. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 204(a)(5), 110 Stat. 1936, 1999.

10. See, for example, *United States v. Porter*, 591 F.2d 1048, 1051 (5th Cir. 1979) (laboratory paid defendant doctors $35 for each blood specimen sent to it for analysis).

11. For the full text of the statute see note 9.

12. Examples of physician incentive plans include providing discounted billing and staff services, paying for continuing education courses, financing travel to conferences, and granting

conduct potentially falls within the statute, because technically a violation occurs any time one health care entity gives something to another as part of an effort to increase its own business.

The broad reach of the statute, confirmed by current caselaw,[13] has caused considerable anxiety in the health care industry.[14] Furthermore, the criminalization of this type of conduct is implicated in a larger debate about the appropriateness of creating criminal penalties for conduct that is not inherently or obviously criminal.[15] Such overcriminalization may compromise due process rights by failing to give adequate notice of what behavior will result in criminal prosecution.[16]

Recently, in *Ratzlaf v. United States*,[17] the Supreme Court responded to similar concerns regarding a provision of the Bank Secrecy Act that makes it illegal to knowingly and willfully structure financial transactions in order to evade reporting requirements.[18] The Court held that the statutory term "willfully" requires the government to prove that a defendant specifically knew that such structuring is illegal.[19] In 1995, the Ninth Circuit applied this holding to the anti-kickback statute in *Hanlester Network v. Shalala*,[20] requiring the government to show that defendants who had engaged in prohibited conduct did so with the specific intent to violate the law.[21] Although several courts, including the Eighth Circuit, have specifically rejected the *Hanlester* holding,[22] it remains good law in the Ninth Circuit, and

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coverage on the hospital's group health insurance plan. Carol Colborn, *Fraud and Abuse: Anti-Kickback Developments and Practical Considerations*, 669 PLI/Comm 355, 360-61 (1993).

13. See *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985) (holding that intent to induce referrals need not be the sole motivation for making a payment). See Part II.D.

14. See Part III.A.

15. See John C. Coffee, Jr., *Does "Unlawful" Mean "Criminal"?: Reflections on the Disappearing Tort/Crime Distinction in American Law*, 71 B.U. L. Rev. 193 (1991) (arguing that overcriminalization blurs the line between tort and crime and will ultimately weaken criminal law's social control objective); Susan L. Pilcher, *Ignorance, Discretion and the Fairness of Notice: Confronting "Apparent Innocence" in the Criminal Law*, 33 Am. Crim. L. Rev. 1 (1995) (arguing that the use of criminal law should track public expectations of what constitutes criminal conduct).

16. See *Connally v. General Construction Co.*, 269 U.S. 385, 391 (1926) ("[A] statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application, violates the first essential of due process of law.").

17. 510 U.S. 135 (1994).

18. See Part IV.A.

19. *Ratzlaf*, 510 U.S. at 138.

20. 51 F.3d 1390 (9th Cir. 1995).

21. Id. at 1400.

22. *United States v. Jain*, 93 F.3d 436, 441 (8th Cir. 1996); *United States v. Neufeld*, 908 F. Supp. 491, 497 (S.D. Ohio 1995). See also *Medical Development Network, Inc. v. Professional Respiratory Care*, 673 So.2d 565, 566 (Fla. Ct. App. 1996) (holding a contract between a

it could potentially be adopted by other courts faced with the task of construing the anti-kickback statute.[23]

This Note argues that the *Hanlester* court was right to look to intent principles in trying to rationalize the broad reach of the statute, but that requiring a specific intent to violate the law is excessive. The *Ratzlaf* definition of "willfully" should be limited to the anti-structuring statute.[24] In interpreting the anti-kickback statute, courts should instead define "willfully" in the more traditional sense of requiring a defendant to act deliberately and voluntarily—in short, with a corrupt intent.[25] This definition of "willfully" has been routinely used by courts both before and since the *Ratzlaf* holding.[26] Moreover, unlike specific intent to violate the law, corrupt intent can be readily inferred from the circumstances of a given case, using the same types of evidence that traditionally have been offered in other health care fraud cases.[27] Requiring a corrupt intent will ensure, however, that criminal penalties are only imposed on those acting with a genuine mens rea, or guilty mind.

Part II of this paper provides background, including the legislative history of the anti-kickback statute and case law interpreting it. Part III explores some of the issues raised by the breadth of the statute and by the general notion of criminalizing this type of behavior. Part IV concludes that defining "willfully" as requiring a corrupt intent, but not necessarily a specific intent to violate the law, is a rational and practical response to the difficulties posed by the breadth of the anti-kickback statute.

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marketing company and a durable medical equipment supplier invalid on the grounds that it violated the anti-kickback statute).

23. The fact that *Ratzlaf* is still good law means that courts must distinguish the anti-kickback statute from the anti-structuring statute in order to reject the *Hanlester* approach. This may be a factor in influencing some courts te adopt the *Hanlester* approach.

24. Nothing in the *Ratzlaf* opinion indicates that its definition of "willfully" applies te every statute in which the word appears. On the contrary, the Court recognized that "willful" can have different meanings depending on the context in which it is used. *Ratzlaf*, 510 U.S. at 141.

25. See notes 228-29 and accompanying text.

26. See note 227 and accompanying text.

27. See notes 231-32 and accompanying text.

II. BACKGROUND ON THE ANTI-KICKBACK STATUTE

Congress created the Medicare/Medicaid system in 1965,[28] after several decades of political debate over access to medical care and the distribution of health care costs in American society.[29] The support of the medical profession was considered crucial to both the passage and the ultimate success of the legislation.[30] To secure this support, Congress structured the system to replicate the reimbursement mechanisms of traditional third-party insurance.[31] Like third-party payment systems, Medicare/Medicaid reimbursement structures are extremely generous to providers.[32] If a third-party insurance company absorbs the costs of treatment, neither the patient nor the provider has any reason to limit consumption of medical resources.[33] The provider, in fact, has an incentive to maximize the volume of services, even if costs outweigh any benefit to the patient.[34]

The Medicare/Medicaid system therefore involves the "fee-for-service" system of third-party payment that is the primary cause of America's problem with rising health care costs.[35] In a fee-for-service environment, kickbacks and other forms of illegal remuneration can be highly profitable. For example, in the case of a laboratory that makes payments to a doctor for referring a patient, neither the doctor nor the patient has any incentive to limit the amount of blood work ordered.[36] Presumably, doctors will order as much blood work as possible, regardless of patient need. In other words, the extra payment the provider receives from the laboratory magnifies the incentives for overutilization inherent in the fee-for-service system.

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28. For an overview of the history and original structure of the Medicare and Medicaid legislation, see Margaret Greenfield, *Medicare and Medicaid: The 1965 and 1967 Social Security Amendments* (U. of California, 1968).

29. Id. at 76-77.

30. Starr, *Social Transformation of American Medicine* at 375 (cited in note 3).

31. Id. Rather than controlling the program directly, the federal government authorizes private insurance companies to serve as "fiscal intermediaries." Id. The federal government then pays the bills submitted by these intermediaries. Id.

32. Id.

33. Id.

34. Id.

35. Id. at 385.

36. See notes 115-17 and accompanying text.

A. The Original Legislation (1972-1977): Identifying Bribes and Kickbacks in Health Care Arrangements

Initially, Medicare and Medicaid were regulated by the general antifraud section of the Social Security Act.[37] This section, however, contained no specific prohibition of kickback-type activity.[38] In 1972, as part of the first comprehensive revisions of the Medicare/Medicaid legislation,[39] Congress explicitly outlawed soliciting or offering "kickbacks, bribes or rebates" to induce patient referrals.[40] There was no intent requirement, but violation of the statute was only a misdemeanor.[41] In passing the legislation, Congress was primarily motivated by a desire to contain costs.[42] A more general concern for regulating the ethical standards of the program, however, was also a motivating factor.[43]

A circuit split soon arose over what constituted a kickback, bribe or rebate.[44] Although Congress subsequently amended the statute to resolve this issue,[45] the courts' struggle to define the boundary between legal and illegal conduct in this context previews some of the difficulties courts today face in construing the current statute.[46] The courts agreed that Congress intended to use the terms according to their established and ordinary meanings,[47] but they conld not agree on

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37. 42 U.S.C. § 408 (1994 ed.).

38. Arguably, the general antifraud statute could have been applied to kickbacks and other forms of illegal remuneration. David M. Frankford, *Creating and Dividing the Fruits of Collective Economic Activity: Referrals Among Health Care Providers*, 89 Colum. L. Rev. 1861, 1877 n.46 (1989).

39. Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1329, 1419, codified as amended at 42 U.S.C. §§ 1720a-1776.

40. Id. §§ 242(b), 242(c), 86 Stat. at 1419-20, codified at 42 U.S.C. §§ 1395nn(b), 1396(b) (prior to 1977 amendments).

41. Id. The penalties were a fine of up te $10,000, imprisonment for a maximum of one year, or both. Id.

42. See Frankford, 89 Colum. L. Rev. at 1877-89 (cited in note 38) ("These amendments were spurred, in large part, by Congress's concern that the Medicare and Medicaid programs . . . created substantial incentives for inefficient behavior [and] inflated prices.").

43. David A. Hyman and Joel V. Williamson, *Fraud and Abuse: Regulatory Alternatives in a "Competitive" Health Care Era*, 19 Loyola U. Chi. L. J. 1133, 1166 (1988).

44. Compare *United States v. Porter*, 591 F.2d 1048 (5th Cir. 1979) (defining bribe or kickback restrictively, and *United States v. Zacher*, 586 F.2d 912 (2d Cir. 1978) (same), with *United States v. Tapert*, 625 F.2d 111 (6th Cir. 1980) (defining bribe or kickback expansively) and *United States v. Hancock*, 604 F.2d 999 (7th Cir. 1979) (same). These cases were decided at the appellate level after the 1977 amendments, but they were construing the original statute.

45. See notes 65-67 and accompanying text.

46. See Part II.D. (discussing *Greber*).

47. See, for example, *Zacher*, 586 F.2d at 914 ("[W]here Congress borrows terms of art in which are accumulated the legal tradition and meaning of centuries of practice, it presumably

what those meanings encompassed.[48] In *United States v. Zacher*,[49] the Second Circuit held that a nursing home operator who had charged the families of Medicaid patients four dollars a day to supplement Medicaid payments was not guilty of receiving bribes.[50] The court reasoned that because it would not be treated as a bribe for Zacher to require extra payments from the families of people who had private insurance, such payments would not be considered bribes in the Medicaid context.[51] The court held that the term "bribe" connoted an "element of corruption, breach of trust, or violation of duty" that was not present in the *Zacher* facts.[52]

Similarly, the Fifth Circuit, in *United States v. Porter*,[53] held that physicians who had accepted payments for referring patients to certain laboratories had not received kickbacks within the meaning of the statute.[54] The laboratories in that case used a manual method to perform a battery of blood tests at a cost of $214 to Medicare.[55] A laboratory using an automated system would have charged approximately thirty-five dollars for the same blood work.[56] To the extent that there was any difference in quality between the two types of laboratories, automated systems were probably superior.[57] The defendant doctors, however, sent blood samples to the more expensive manual laboratories in order to receive the referral payments.[58] Medicare therefore paid more than six times as much as necessary for each procedure, and the doctors directly benefited. Nonetheless, the court reversed the doctors' convictions because the payments were authorized by Medicare, the services were legitimately performed,

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knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken and the meaning its use will convey to the judicial mind unless otherwise instructed." (citing *Morissette v. United States*, 342 U.S. 246, 263 (1952))).

48. Generally, a bribe is "[a]ny money, goods, right in action, property, thing of value, or any preferment, advantage, privilege or emolument, or any promise or undertaking to give any, asked, given, or accepted, with a corrupt intent to induce or influence action, vote, or opinion of person in any public or official capacity." *Black's Law Dictionary* 191 (West, 6th ed. 1990). A kickback is "[p]ayment back by seller of a portion of the purchase price to buyer or public official to induce purchase or to improperly influence future purchases or leases." Id. at 869.

49. 586 F.2d 912 (2d Cir. 1978).

50. Id. at 916.

51. Id.

52. Id. at 915.

53. 591 F.2d 1048 (5th Cir. 1979).

54. Id. at 1054.

55. Id. at 1051.

56. Id.

57. Id. at 1050.

58. Id.

and the statute had not specifically defined "kickback" to include the conduct in question.[59]

The Sixth Circuit, however, when faced with a substantially similar fact pattern in *United States v. Tapert*,[60] held that such conduct did violate the statute.[61] The defendants in *Tapert* were osteopathic physicians who accepted payments in return for sending urine and blood work to Titan Laboratories.[62] After a couple of years, the doctors started to deposit the payments into an escrow account, and eventually purchased a forty percent interest in the laboratories.[63] The court held that the payments to the doctors were kickbacks, citing the District Court judge's detailed discussion in support of a broad legal definition of the term.[64]

B. Amendments to the Statute (1977-1980): Expanding the Range of Prohibited Conduct and Increasing Criminal Penalties

In 1977, Congress amended the statute to prohibit receiving or paying "any remuneration" to induce referrals.[65] In so doing, Congress indicated that the statute was to be interpreted broadly.[66] Congress also expressed concern that existing penalties had not adequately deterred illegal practices.[67] The 1977 amendment therefore upgraded the offense to a felony and increased the maximum fine.

Several years later, however, Congress became concerned that the statute's lack of a mens rea requirement could result in unfairly imposing criminal sanctions on individuals who had only inadvertently violated the statute.[68] Because the offense had been upgraded

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59. Id. at 1052-54.
60. 625 F.2d 111 (6th Cir. 1980).
61. Id. at 121.
62. Id. at 113.
63. Id. at 114.
64. Id. at 121. See *United States v. Weingarden*, 468 F. Supp. 410, 414 (E.D. Mich. 1979) (offering a "large body of legal and lexicographical authority confirming a broad[] meaning for 'kickback' ").
65. Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, §§ 4(a), 4(b), 91 Stat. 1175, 1180, 1182 (1977).
66. See Medicare-Medicaid Antifraud and Abuse Amendments, H.R. Rep. No. 95-393(II), 95th Cong., 1st Sess. 46 1977, reprinted in 1977 U.S.C.C.A.N. 3039, 3049 (emphasizing that "[k]ickbacks take a number of forms").
67. Id. at 48.
68. Omnibus Reconciliation Act of 1980, H.R. Rep. No. 96-1167, 96th Cong., 2nd Sess. 59, reprinted in 1980 U.S.C.C.A.N. 5526, 5572 ("The Committee is concerned that criminal penalties may be imposed under current law to an individual whose conduct, while improper, was inadvertent. Accordingly, the section clarifies current law to assure that only persons who

to a felony, this was a serious issue. Amendments in 1980 therefore added a requirement that the illegal conduct be engaged in "knowingly and willfully."

After these amendments, the statute appeared in substantially the same form as it does today. There have, however, been additions to the third paragraph, which specifically exempts certain practices from prosecution under the statute.[69] One significant exception authorizes the Secretary of Health and Human Services to issue regulations specifying arrangements that will not be subject to prosecution

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knowingly and willfully engage in the prescribed conduct could be subject to criminal sanctions."). This is the extent of the legislative history on the 1980 amendments.

69. Paragraph (3) reads as follows:

(3) Paragraphs (1) and (2) shall not apply to—

(A) a discount or other reduction in price obtained by a provider of services or other entity under subchapter XVIII of this chapter or a State health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under subchapter XVIII of this chapter or a State health care program;

(B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;

(C) any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under subchapter XVIII of this chapter or a Stato health care program if—

(i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and

(ii) in the case of an entity that is a provider of services (as defined in section 1395x(u) of this title), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity;

(D) a waiver of any coinsurance under part B of subchapter XVIII of this chapter by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act [42 U.S.C. §§ 201 et seq.]; and

(E) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987.

42 U.S.C. § 1320a-7b(b)(3).

The 1996 amendments added new subsection (F):

(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant te a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1876 or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combimation thereof, which the individual or entity is obligated to provide.

Health Insurance Portability and Accountability Act, 110 Stat. at 2007. See Part II.C.

under the statute.[70] The Secretary has created eleven such "safe harbor" provisions.[71]

C. *1996 Amendments: Health Care Reform in an Era of Managed Care*

As part of a comprehensive health care reform effort,[72] Congress in 1996 stiffened penalties associated with health care fraud generally,[73] increased funding for health care fraud enforcement[74] and extended the anti-kickback statute to all federal health programs.[75] These amendments reveal Congress's resolve to fight fraud and abuse in health care with increased vigor. At the same time, however, Congress recognized the potentially unfair breadth of the anti-kickback statute. It thus authorized the issuance of advisory opinions on whether certain conduct violates the anti-kickback statute,[76] and it added a new exception to the statute for certain "risk sharing" provider arrangements.[77]

At one time, the Health Care Financing Administration's Office of Program Integrity issued advisory opinions in individual cases.[78] In 1981 it ceased this practice on the basis that it is

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70. 42 U.S.C. 1320a-7b(b)(3)(E).

71. 42 C.F.R. § 1001.952 (1996). The eleven safe harbors are for investment interests, space rental, equipment rental, personal services and management contracts, sale of practice, referral services, warranties, discounts, employees, group purchasing organizations, and waiver of beneficiary coinsurance and deductible amounts. All the safe harbors specify certain standards that must be met before the conduct is immunized from prosecution.

72. In 1995, a comprehensive health care reform bill was passed by both the House and Senate, then vetoed by President Clinton. See *Historic House Medicare Vote Affirms GOP Determination*, 53 Cong. Q. 3206 (Oct. 21, 1995); *Conferees Work Furiously to Overhaul Medicare*, 53 Cong. Q. 3456 (Nov. 11, 1995); *GOP Scores on Medicare, But Foes Aren't Done*, 53 Cong. Q. 3535 (Nov. 18, 1995). In 1996, another comprehensive health care reform bill passed Congress and was signed by the President. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936, to be codified at scattered sections of 42 U.S.C. The main focus of the bill is to ensure that individuals who are already sick can keep insurance even if they lose or leave jobs. *Kennedy, Kassebaum Steer Insurance Bill to Safety*, 54 Cong. Q. 2197 (Aug. 3, 1996). The bill was co-sponsored by Republican Senator Nancy Landon Kassebaum of Kansas and Democratic Senator Edward Kennedy of Massachusetts. President Clinton was a strong supporter of the bill. Id.

73. Health Insurance Portability and Accountability Act §§ 211-218, 110 Stat. at 2003-2009.

74. Id. § 201, 110 Stat. at 1994. The bill allocates $104 million for fiscal year 1997, to be increased by 15% each fiscal year until 2003. Id.

75. Id. § 204, 110 Stat. at 1999.

76. Id. § 205(b), 110 Stat. at 2001-02. See notes 78-83 and accompanying text.

77. Id. § 216, 110 Stat. at 2007-08. See notes 84-87 and accompanying text.

78. Eugene Tillman, *Scope of the Conference*, in Jeanie M. Johnson, ed., *Medicare Fraud and Abuse: Understanding the Law* 9-10 (National Health Lawyers Assoc., 1986).

inappropriate for an administrative agency to issue advisory opinions on criminal conduct.[79] In the 1996 amendments, however, Congress specifically authorized the Inspector General of the Department of Health and Human Services ("HHS") to begin issuing advisory opinions.[80] These opinions will be available to the public, but will be binding only on the HHS Secretary and the party requesting the opinion.[81] HHS is currently soliciting public comments on how the advisory opinion process should work.[82] President Clinton, however, who was a strong supporter of the health care reform bill generally, is calling for the repeal of the advisory opinion authorization on the grounds that providers might obtain an opinion under false pretenses and then use it as a shield against prosecution.[83]

Congress also added an exception to the statute for "risk sharing" provider arrangements.[84] This exception applies to remuneration between an individual or organization and a health care provider if a written contract between the parties puts the provider at "substantial financial risk" for the cost or utilization of services.[85] The exception is intended to protect certain efficient and cost-reducing forms of health care delivery that have emerged since the statute was originally enacted.[86] The standards governing this exception are currently being developed through a negotiated rulemaking process involving the HHS and various interest groups.[87]

D. United States v. Greber*: Judicial Endorsement of the Current Anti-Kickback Statute's Broad Reach*

Although the semantic issue of what constitutes a bribe or kickback is no longer a concern, courts still face substantially similar issues in defining the boundaries of permissible and impermissible

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79. Id.

80. Health Insurance Portability and Accountability Act § 205(b)(1), 110 Stat. at 2001.

81. Id. § 205(b)(4)(A), 110 Stat. at 2002.

82. *HHS IG to Seek Public Comments on New Advisory Opinion Process*, 5 Health L. Rptr. (BNA) 1279 (Aug. 29, 1996).

83. *Clinton Proposes to Repeal Three Recently Enacted Provisions*, 5 Health L. Rptr. (BNA) 1341 (Sept. 12, 1996).

84. Health Insurance Portability and Accountability Act § 216, 110 Stat. at 2007-08. See note 69.

85. Id.

86. *HR 3103 Creates Kickback Exception, Intermediate Sanctions for Risk HMOs*, 5 Health L. Rptr. (BNA) 1281 (Aug. 29, 1996).

87. *Managed Care Safe Harbor Rulemaking Underway, But Deadlines Unrealistic*, 5 Health L. Rptr. (BNA) 1523 (Oct. 17, 1996). The legislation originally set a target date of January 1, 1997 for an interim final rule, but an official from the Inspector General's Office has said that the negotiated rulemaking process typically takes from nine months to a year. Id.

conduct under the statute. The line between legitimate business arrangements and illegitimate profit schemes can be difficult to draw. The most prominent appellate decision pursuing this issue is the Third Circuit's decision in *United States v. Greber*,[88] which interprets the statute extremely broadly. Congress has not contradicted this decision in subsequent amendments.[89]

Dr. Greber was a osteopath specializing in cardiology.[90] He was also president of a company called Cardio-Med, Inc., which supplied other physicians with diagnostic services, including a cardiac device known as a "Holter-monitor."[91] Cardio-Med billed Medicare for the device and forwarded a portion of the payment received to the referring physician.[92] The government indicted Dr. Greber for paying remuneration to the physicians in exchange for referrals.[93]

Dr. Greber's main defense was that the payments were for services rendered by the referring physicians in interpreting the results of the Holter-monitor test.[94] He argued that legitimate payments for services rendered did not violate the statute unless the *only* purpose behind them was to induce future referrals improperly.[95] That is, Dr. Greber argued that because he was paying the physicians for legitimate services as well as for making referrals, he was not violating the statue. The court rejected this claim, holding that the statutory term "remuneration" implies a service rendered.[96] Thus, by adding the term "remuneration" to the statute in 1977, Congress intended to prohibit improper payments even if some service is rendered.[97] The court noted a "potential for unnecessary drain on the Medicare system" exists even if the physician does provide service in exchange for the remuneration.[98]

A substantial body of caselaw defining the limits of the anti-kickback statute has not emerged. *Greber*'s broad interpretation of

88. 760 F.2d 68 (3d Cir. 1985).
89. See *United States v. Bay State Ambulance*, 874 F.2d 20, 31 (1st Cir. 1989) ("[T]he fact that Congress, in reenacting the substantive sections of the Medicare Fraud statute did not change them, implies that Congress approved prior interpretations such as *Greber*.").
90. *Greber*, 760 F.2d at 69.
91. Id. at 70.
92. Id.
93. Id.
94. Id.
95. Id. at 71.
96. Id.
97. Id. at 72.
98. Id. at 71.

the statute thus effectively states the current law in this area.[99] Recently, however, courts have begun to look to mens rea as a way of limiting this broad interpretation. In 1995, the Ninth Circuit placed a formidable limit on the statute by requiring a specific intent to violate the law in order to exclude providers from Medicare and Medicaid.[100] In 1996, the Eighth Circuit rejected this approach, but did require a heightened intent standard.[101] Thus intent is beginning to function as the locus for resolution of the issues surrounding the anti-kickback statute. The next section explores these issues.

III. ISSUES RAISED BY THE ANTI-KICKBACK STATUTE

A. The Over-Inclusiveness of the Anti-Kickback Statute

In broadening the statute to prohibit any remuneration intended to induce future referrals,[102] Congress achieved its goal of extending the statute's reach beyond payments that fall neatly within the ordinary definitions of "bribe" and "kickback."[103] This is a rational move in that it makes the law more flexible and therefore better able to deal with emerging types of fraudulent or abusive behaviors. Now, however, the statute is arguably too broad, in that it potentially can be applied to a variety of perfectly legitimate and even desirable arrangements.[104] Some accepted business practices and certain cost-containment innovations are at least technical violations of the statute.[105]

For example, a hospital might pay for its staff physicians to attend conferences in their areas of specialty.[106] Technically, this

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99. See notes 96-98 and accompanying text.

100. *Hanlester*, 51 F.3d at 1400. See Part IV.B.

101. *Jain*, 93 F.3d at 439-41.

102. See notes 65-67 and accompanying text.

103. See note 48 and accompanying text.

104. See Gregory Miller, *The* Greber *Case*, in Jeanie M. Johnson, ed., *Medicare Fraud and Abuse: Understanding the Law* 15 (National Health Lawyers Assoc., 1986) (addressing the argument that after the *Greber* case, the accepted interpretation of the statute is so broad that it should be amended).

105. See James F. Blumstein, *Rationalizing the Fraud and Abuse Statute*, 15 Health Affairs 118, 118 (Winter 1996) (stating that "the extremely broad interpretation of the law serves as a major potential obstacle to the continued evolution and rationalization of the health care marketplace in response to competitive market forces and pressures to contain costs").

106. In May 1992, one of the fraud alerts issued by the Office of the Inspector General specifically listed this as a suspect activity. Colborn, 669 PLI/Comm at 361 (cited in note 12).

practice is paying remuneration to induce the physicians to refer their patients to the hospital. It is also arguably harmless. Moreover, giving incentives to physicians might be the only way for rural or other hospitals to attract competent physicians.[107] Another example might be a pacemaker company's providing educational resources to doctors who use its product—again a seemingly harmless activity. Although these arrangements are unlikely to be prosecuted,[108] the fact remains that the statute technically proscribes them.[109] One commentator has described the situation as a legal "speakeasy," where sipping sherry is winked at and only loud and obnoxious drunks are prosecuted.[110] This situation, with its widespread tolerance for technical violations, its excessive dependence on prosecutorial discretion, and the general uncertainty it provokes, could promote a fundamental disrespect for the law.

Lack of clarity about what is *really* illegal under the anti-kickback statute generates corresponding uncertainty about whether the statute can accomplish its goals of containing unnecessary costs and promoting ethical behavior in the health care industry. For one thing, the current statute may deter behavior that is a desirable part of the reform movement.[111] The current congressional agenda aims to reduce costs and raise efficiency in health care.[112] The anti-kickback statute, however, even with the new "risk sharing" exception, may prohibit some of the joint ventures and other collective activity necessary to fulfill this mandate.[113] In fact, the anti-kickback statute is overtly hostile to the concept of medicine as a for-profit enterprise.[114] The statute's goals are therefore fundamentally out of sync with reform efforts that focus on creating competitive pressures to lower the costs of health care.

In 1977, when Congress amended the anti-kickback statute to bring it to its present form, fee-for-service reimbursement was very

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107. Hyman and Williamson, 19 Loyola U. Chi. L. J. at 1144 (cited in note 43).

108. See Richard Kusserow, *The Medicare & Medicaid Anti-Kickback Statute and the Safe Harbor Regulations—What's Next?*, 2 Healthmatrix 49 (1992) (former Inspector General of the Department of Health and Human Services describing the process by which United States attorneys decide whether or not to prosecuto a particular violation).

109. Physician incentive plans and sales incentives do not fall within any of the safe harbors. See note 71 and accompanying toxt.

110. James F. Blumstoin, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 Am. J. L. & Med. 205, 218 (1996).

111. Blumstoin, 15 Health Affairs at 119 (cited in note 105).

112. Hyman and Williamson, 19 Loyola U. Chi. L. J. at 1188 (cited in note 43).

113. Blumstoin, 15 Health Affairs at 121 (cited in note 105).

114. Id. at 119.

much the norm.[115] Health care providers thus had great incentives to overutilize the system and generate unnecessary costs.[116] In this environment, it made sense to target financial arrangements that could lead to wasteful or improper patient referrals and unnecessary care. Some emerging methods of care, however, have essentially reversed these traditional incentives.[117] For example, in 1983, Medicare and Medicaid switched to a prospective payment system, under which hospitals are reimbursed at a rate set in advance according to diagnosis-related groups ("DRGs").[118] If the hospital can treat the patient for less than the fixed reimbursement, it makes money.[119]

Collective activity is necessary to any economic venture, and it is particularly important in the health care industry; a single patient might encounter several physicians, laboratories, radiologists, home health care nurses, hospitals, and equipment suppliers in the course of a single illness.[120] Allowing these entities to work together might result in lower health care costs, but patient flow might also necessitate payments from some group to another that could be construed as illegal remuneration.

Before the 1996 amendments, the statute technically prohibited transactions that are essential to managed care.[121] For example, if a provider negotiated discounted fees or provided other remuneration to a covered group in exchange for assurances about patient vol-

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115. See notes 35-36 and accompanying text (discussing the traditional fee for service system). See also Hyman and Williamson, 19 Loyola U. Chi. L. J. at 1156-66 (cited in note 43) (discussing whether the rationales for the fraud and abuse statute apply in an increasingly market-oriented health care industry).

116. See note 34 and accompanying text.

117. See Hyman and Williamson, 19 Loyola U. Chi. L. J. at 1133 (cited in note 43) ("Efforts to maintain or increase market share have led health care providers to . . . develop incentive programs that reward efficiency and cost-effective care.").

118. Social Security Amendments of 1983, Pub. L. No. 98-21, § 601, 97 Stat. 65, 149-72, codified as amended at 42 U.S.C. § 1395ww. See generally Judith R. Lave, *The Impact of the Medicare Prospective Payment System and Recommendations for Change*, 7 Yale J. Reg. 499 (1990).

119. Hyman and Williamson, 19 Loyola U. Chi. L. J. at 1138-39 (cited in note 43).

120. See Frankford, 89 Colum L. Rev. at 1869-76 (cited in note 38) (giving a detailed economic analysis of collective activity among health care providers).

121. See discussion of the 1996 amendments in Part II.C. Even before these amendments, there was a safe harbor provision for price reductions offered to health plans. 42 C.F.R. § 1001. The provision requires contracts between providers and health plans te be longer than one year, and to set in advance the covered items and services and the methodology for computing payments. Id. It is difficult to set payments in advance, however, because the number of people who will be enrolled is not known. *Legislation Has Not Kept Pace with Managed Care, Attorney Says*, 1 Managed Care Rptr. (BNA) 8 (July 5, 1995). The safe harbor provisions thus did not adequately address HMOs and capitation systems. *Final Managed Care Safe Harbors Still Do Not Protect Many Arrangements*, 2 Managed Care Rptr. (BNA) 197 (Feb. 28, 1996).

ume, technically it ran afoul of the law.[122] Many other collective transactions that are fundamental to the emergence of managed care were potentially prohibited by the statute.[123] Indeed, some commentators have suggested that the anti-kickback statute has significantly inhibited the development of efficient, cost-reducing forms of health care delivery in America.[124]

In 1996, Congress addressed this issue by amending the statute to exempt certain "risk sharing" arrangements.[125] This new exception applies to remuneration between individuals or organizations and providers if there is a written agreement between the parties that places the provider "at a substantial financial risk for the cost or utilization of the items or services . . . which [the provider] is obligated to provide."[126] The boundaries governing this exception are currently being drawn.[127] Hopefully, the fully drawn exception will provide much needed reassurance to the managed care industry.[128]

Nevertheless, the statute's broad reach is likely to remain a source of anxiety. For one thing, the scope of the risk-sharing exception has not yet been defined.[129] It may be that the exception will be construed narrowly. Moreover, the statute's reach is not necessarily limited to arrangements between providers and other health care entities. There are a number of other relationships in the health care industry that potentially could be subject to prosecution under the statute.

For example, a Florida Appeals Court recently held that a contract between a durable medical equipment supplier and a marketing company was void because it violated the anti-kickback law.[130] Under the contract, the durable medical equipment supplier agreed to pay a marketing company a percentage of all business developed by the company's marketing strategy.[131] No doctor, hospital or other provider was a party to the contract. The decision impacts

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122. Blumstein, 22 Am. J. L. & Med. at 213 (cited in note 110).

123. Id. at 213-19.

124. See Hyman and Williamson, 19 Loyola U. Chi. L. J. at 1133-35 (cited in note 43).

125. See notes 84-87 and accompanying text.

126. Health Insurance Portability and Accountability Act, 110 Stat. at 2007.

127. See note 110 and accompanying text.

128. See Blumstein, 22 Am. J. L. & Med. at 230 (cited in note 110) ("If ultimately enacted . . . the Kassebaum-Kennedy legislation . . . would be significant and would change the impact of the antikickback provisions.").

129. See note 87 and accompanying text.

130. *Medical Development Network, Inc. v. Professional Respiratory Care/Home Medical Equipment Services, Inc.*, 673 So.2d 565 (Fla. Ct. App. 1996).

131. Id.

the health care industry in two ways. First, it emphasizes the fact that the anti-kickback statute can be applied to any type of business that involves services or goods that are reimbursable under a federal health care program. Second, and more fundamentally, it means that the health care industry has to be very careful about consulting with marketing or public relations specialists.[132]

This second point illustrates one of the main tensions between the anti-kickback law and the health care reform effort in America: the anti-kickback law is fundamentally opposed to the idea of medicine as a for-profit industry.[133] It simply does not recognize the possibility that health care providers can be financially motivated and still provide quality care. Much of the health care reform effort, however, involves creating financial incentives for physicians to provide cost-effective treatment. The anti-kickback statute is thus somewhat inconsistent with the comprehensive effort to control health care costs. Although it may have effectively targeted the kinds of abuses that occur in a traditional fee-for-service environment, it may do more harm than good in the contemporary reform context.[134]

It is also possible that the anti-kickback statute could be applied to renumeration between a provider and the *patient*. In a fee-for-service environment, referrals and remuneration typically flow from one provider to another. For example, to induce referrals a laboratory might pay a doctor, or a durable medical equipment dealer might recompense a hospital.[135] In an HMO, however, certain incentives that flow from provider to consumer could be considered illegal.[136] For example, an HMO might reward high-risk expectant mothers with child car seats for making appropriate prenatal visits.[137] This could be construed as a violation of the anti-kickback statute.[138] Similarly, HMOs naturally want to enroll as many members as possible, and they want any enrollees to be as healthy as possible.[139] An HMO, then, might offer certain incentives to get healthier groups

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132. See *Anti-Kickback Law Covers Non-Providers, Florida State Appeals Court Affirms*, 5 Health L. Rptr. (BNA) 860 (June 6, 1996).

133. Blumstein, 15 Health Affairs at 119 (cited in note 105).

134. See Blumstein, 22 Am. J. L. & Med. at 207-10 (cited in note 110) (discussing the incentives for overutilization existing in the health care field at the time the anti-kickback statute was enacted).

135. Pamela H. Bucy, *Health Care Reform and Fraud By Health Care Providers*, 38 Vill. L. Rev. 1003, 1033 (1993).

136. Id.

137. *Legislation Has Not Kept Pace with Managed Care*, 1 Managed Care Rptr. at 9 (cited in note 121).

138. Id.

139. Bucy, 38 Vill. L. Rev. at 1033 (cited in note 135).

of people to enroll.[140] If characterized as "remuneration" paid to selected consumers to get their business, these incentives might be illegal under the anti-kickback statute.[141]

B. Civil Remedies as an Alternative to Overcriminalization

In addition to concerns about inclusiveness, the statute raises general issues about the proper scope of criminal conduct and the legitimacy of using criminal penalties to deter and punish this sort of behavior. Criminal penalties are by no means the only way to deter, redress, or punish undesirable conduct on the part of Medicare/Medicaid providers. Civil and administrative penalties, including fines[142] and program exclusion[143] can have a devastating impact on providers.[144] The availability of these sorts of civil penalties suggests that criminal sanctions should be reserved for conduct that is immediately recognizable as corrupt.

As Professor John Coffee has noted, statutes like the anti-kickback statute have the undesirable effect of blurring the line between tort law and criminal law.[145] Criminal law, he argues, seeks to punish behavior that society recognizes as fundamentally wrong.[146] Tort law, in contrast, strives to "price" behavior by weighing its social value against the harm it produces.[147] Criminalizing conduct that should be priced, he concludes, will ultimately dilute the power of the criminal law to effect social control.[148]

Professor Coffee's observations suggest that as a criminal provision, the anti-kickback statute should be applied only to behavior that society recognizes as fundamentally wrong. Undesirable behavior that is not fundamentally corrupt, on the other hand, should be handled through civil and administrative "pricing" remedies. This

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140. Id.
141. Id.
142. Under the False Claims Act, 31 U.S.C. § 3729, the government can recover fines of $5,000 to $10,000 per claim plus treble damages and costs.
143. HHS has the power the bring actions to exclude from Medicare/Medicaid participation any health care provider it deems to be in violation of the anti-kickback statute. 42 U.S.C. § 1320a-7(b).
144. Prosecutors have incentives to bring civil, instead of criminal, actions because civil penalties are potentially much greater than criminal ones, and because intent need not be proven in the civil arena. Nalven, 33 Boston Bar J. at 17 (cited in note 4).
145. See Coffee, 71 B.U. L. Rev. at 193 (cited in note 15).
146. Id. at 193-94.
147. Id. at 194.
148. Id. at 201.

distinction should be borne in mind by courts aiming to formulate a workable intent standard under the anti-kickback statute.

C. *The Anti-Kickback Statute and the Health Care Reform Effort in America*

For several reasons, the issues raised by the anti-kickback statute are likely to become even more pressing in coming years. First, the health care industry in America is changing rapidly, but in a piecemeal fashion.[149] This transition period will provoke new opportunities for fraud, particularly in areas not yet regulated.[150] Moreover, health care reform will likely mean that doctors and hospitals will make less money,[151] which may increase the temptation to resort to fraudulent practices.[152]

At the same time, enforcing health care fraud laws has become a top government priority.[153] The end of the Cold War has freed a number of FBI agents for assignment to health care fraud task units.[154] The Department of Justice recently formed a special unit devoted to prosecuting instances of health care fraud.[155] President Clinton has launched "Operation Restore Trust," which aims to regulate health care providers, particularly home health care, nursing homes, and durable equipment suppliers.[156] The government has even established a special hotline for Americans to report instances of fraud and abuse.[157] In addition to increased enforcement in the health care area, government agencies are increasingly making use of standard criminal investigatory techniques like search warrants, asset forfeiture, and undercover sting operations.[158] Indeed, one

149. Bucy, 38 Vill. L. Rev. at 1008 (cited in note 135).

150. Id.

151. Glenn Ruffenach, *Scams on the Rise in Health Insurance*, Wall St. J. at 27 (June 22, 1988).

152. Id.

153. Nalven, 38 Boston Bar J. at 9 (cited in note 4). In 1996 Congress allocated significantly more money to health care fraud enforcement. See note 74 and accompanying text.

154. Charles H. Roistacher and Jack Y. Chorowsky, *End of Cold War Frees FBI to Target Health Care Fraud and Abuse*, 10 HealthSpan 3, 3 (1993).

155. Nalven, 38 Boston Bar J. at 10 (cited in note 4).

156. *HHS Fact Sheet Concerning HHS' Operation Restore Trust*, Medicare and Medicaid Guide (BNA) ¶ 43,213. The program will use funds generated from enforcement activities for expanded enforcement efforts. Id.

157. Id.

158. Roistacher and Chorowsky, 10 HealthSpan at 4-5 (cited in note 154).

commentator has described health care as a "growth area" for prosecutors.[159]

Increased enforcement efforts may lead to more prosecutions in gray areas. Moreover, courts are beginning to allow private plaintiffs to sue violators of the anti-kickback statute under the qui tam provisions of the False Claims Act.[160] Thus the difficult questions surrounding the anti-kickback statute may require answers in the near future. Currently, prosecutors must be relied on to exercise discretion concerning what conduct to prosecute under the broad statute.[161] Prosecutors may also decline cases where it would be difficult to prove intent.[162] Grand juries may perform a weeding-out function as well.[163] Despite these safeguards, however, the uncertainty surrounding potential application of the statute remains a pressing problem. With the government taking the offensive on health care fraud, this uncertainty will only increase.

IV. DEFINING "WILLFULLY" TO FURTHER THE STATUTE'S GOALS WITHOUT VIOLATING DUE PROCESS RIGHTS

A. Ratzlaf v. United States

In 1994, the Supreme Court decided *Ratzlaf v. United States*, an important case construing the term "willfully" in a regulatory statute.[164] Waldemar Ratzlaf tried to give a Las Vegas casino $100,000 cash towards a gambling debt.[165] A casino official told him that cash transactions over $10,000 had to be reported to the

159. Miller, *The* Greber *Case*, in Johnson, ed., *Medicare Fraud and Abuse* at 17 (cited in note 104).

160. See, for example, *United States ex. rel. Pogue v. American Healthcorp, Inc.*, 914 F. Supp. 1507 (M.D. Tenn. 1996). See also Michael J. Astrue, *Attacking the Kickback Violations of Competitors*, 10 HealthSpan 3 (1993); Robert Fahrikant, *Health Care Reform: The Use of Anti-Kickback Statutes in Private Litigation, and the Need for an Antitrust-Type Approach*, 700 PLI/Comm 453 (1994).

161. See Blumstein, 15 Health Affairs at 123 (cited in note 105) (attributing a lack of tough law enforcement partly to a belief that "much technically illegal activity is either harmless or downright essential in a market-driven health care environment").

162. Kusserow, 2 Healthmatrix at 68 (cited in note 108).

163. Bucy, 67 N.C. L. Rev. at 878 (cited in note 1).

164. 510 U.S. 135 (1994).

165. Id. at 137.

government.[166] To avoid the reporting requirement, Ratzlaf obtained cashier's checks for less than $10,000 each to pay the casino.[167] In doing so, he violated a law making it illegal to knowingly and willfully "structure" transactions in order to evade the reporting requirements.[168] Ratzlaf admitted that he was purposely evading the requirements.[169] He argued on appeal, however, that in order to be convicted for "willful" conduct, he first had to know that structuring was illegal.[170]

In a five-to-four decision, the Supreme Court held that in order to give full effect to the statutory term "willfully," a defendant must know his conduct is unlawful.[171] A variety of due process concerns motivated the Court,[172] including the rule of lenity in criminal statutory construction[173] and the need to give adequate notice of the anti-structuring law.[174] Most importantly, the Court expressed concern that structuring is not inherently or obviously evil.[175] To demonstrate that structuring is not "inevitably nefarious," [176] the Court cited the example of a small business operator who wishes to avoid reporting requirements in order to reduce the risk of an IRS audit.[177]

The Court acknowledged that ignorance of the law is generally no defense to a criminal charge.[178] It reasoned, however, that Congress had decreed otherwise in this instance by including the

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166. Id. Banks and other financial institutions must report cash transactions over $10,000 pursuant to 31 U.S.C. § 5313. The statute is part of the Currency and Foreign Transactions Reporting Act, Pub. L. No. 91-508, Tit. II, 84 Stat. 1118 (1970), which was designed to prevent the use of banks as intermediaries for criminal activity.

167. *Ratzlaf*, 510 U.S. at 137. The casino gave Ratzlaf the use of a limousine and assigned a casino employee to help him go to various banks around town. Id.

168. 31 U.S.C. § 5324. Ratzlaf was prosecuted under 31 U.S.C. § 5322, which imposed criminal penalties on those who "willfully" violated § 5324. *Ratzlaf*, 510 U.S. at 137. After the *Ratzlaf* decision, Congress added a criminal penalty to § 5324 which does not require a "willful" violation. Reigle Community Development and Regulatory Improvement Act of 1994, Pub. L. No. 103-325, § 411, 108 Stat. 2160, 2253.

169. *Ratzlaf*, 510 U.S. at 140.

170. Id. at 138.

171. Id.

172. See Rachael Simonoff, Ratzlaf v. United States*: The Meaning of "Willful" and the Demands of Due Process*, 28 Colum. J. L. & Soc. Probs. 397 (1995) (discussing the due process issues *Ratzlaf* raised).

173. *Ratzlaf*, 510 U.S. at 148 ("[W]ere we to find [the] 'willfuhess' requirement ambiguous . . . we would resolve any doubt in favor of the defendant.").

174. Id.

175. Id. at 146 ("[W]e are unpersuaded by the argument that structuring is so obviously 'evil' or inherently 'bad' that the 'willfulness' requirement is satisfied irrespective of the defendant's knowledge of the illegality of structuring.").

176. Id. at 144.

177. Id.

178. Id. at 149.

word "willfully" in the structuring statute.[179] Interestingly, the Court admitted that the legislative history of the statute suggested otherwise,[180] but it declined to use legislative history to "cloud a statutory text that is clear."[181] In any event, the Court in effect established an "ignorance of the law" defense to a structuring charge.

B. Hanlester Network v. Shalala

To date, there have been few appellate decisions construing the reach of the current anti-kickback statute. In 1995, however, the Ninth Circuit, in *Hanlester Network v. Shalala*,[182] issued an opinion that may have a significant impact on future jurisprudence in this area. At the very least, the decision represents one jurisdiction's sensitivity to the issues raised by the statute's expansiveness. Specifically, the Ninth Circuit found that the statute's requirement that the defendant engage in the prohibited conduct "knowingly and willfully" meant that the defendant had to have a specific intent to violate the law.[183]

Hanlester Network was a corporation that owned medical laboratories.[184] It sold limited partnership shares in the enterprise to physicians.[185] It also entered into a "master laboratory service agreement" with Smithkline laboratories, through which Smithkline would perform management services and Hanlester would send eighty to ninety percent of its testing to Smithkline facilities.[186] The Inspector General of the HHS determined that Hanlester had violated the anti-kickback statute by offering and paying remuneration to physicians in exchange for referrals, and by soliciting and receiving remuneration from Smithkline in exchange for referrals.[187] The Inspector General proposed excluding the physicians from Medicare for varying periods of time.[188]

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179. Id.
180. Id. at 147-48.
181. Id. at 148.
182. 51 F.3d 1390 (9th Cir. 1995).
183. Id. at 1400.
184. Id. at 1394-95.
185. Id.
186. Id.
187. Id. at 1395.
188. Id.

The Ninth Circuit held that the statutory term "willful" requires proof of a specific intent to do something the law forbids.[189] Applying this requirement to the facts of the *Hanlester* case, the court held that in order to be excluded, the defendants had to have known that there was a statute prohibiting paying or receiving remuneration in exchange for referrals, and they had to have engaged in the illegal conduct with the specific intent to violate that statute.[190] While a heightened intent requirement is appropriate given the broad sweep of the anti-kickback statute, this paper argues that the specific intent requirement the *Hanlester* court imposed is excessive and impractical.

The *Hanlester* case illuminates a larger problem with the criminalization of regulatory and economic crimes.[191] Unlike murder, arson, rape and other traditional crimes, regulatory and economic crimes are not things people presumptively know are prohibited by law. Congress can transform previously legitimate conduct into criminal activity with the passage of appropriate legislation. The newly criminalized conduct may not be obviously or inherently wrong.[192] In this context, it is often difficult to apply traditional principles of criminal intent. The fact that a defendant intends to do a certain act, in other words, may not be enough to establish criminal intent, if the conduct is not inherently or clearly immoral.

C. United States v. Jain: *The Eighth Circuit's Heightened Intent Approach*

In 1996, the Eighth Circuit specifically rejected the *Ratzlaf/Hanlester* approach to the anti-kickback statute in *United States v. Jain*.[193] It recognized, however, that the statute's breadth calls for a heightened intent standard.[194] In *Jain*, a psychologist was accused of receiving payments for referring patients to a psychiatric hospital.[195] Dr. Jain claimed that the payments were made for marketing services.[196] His defense was thus based on the factual claim that he had not received payments in exchange for referring

189. Id. at 1400 (citing *United States v. Dahlstrom*, 713 F.2d 1423, 1427 (9th Cir. 1983)).
190. Id.
191. Environmental law is another example of a regulatory area that has seen increasing criminalization. See generally Susan F. Mandiberg, *The Dilemma of Mental State in Federal Regulatory Crimes: The Environmental Example*, 25 Envir. L. 1165 (1995).
192. See generally Michael L. Travers, Comment, *Mistake of Law in Mala Prohibita Crimes*, 62 U. Chi. L. Rev. 1301 (1995).
193. 93 F.3d 436 (8th Cir. 1996).
194. Id. at 440.
195. Id. at 438.
196. Id. at 438-39.

patients. Nevertheless, on appeal, the court analyzed his claim that the district court had erred by failing to instruct the jury that the defendant had to have a specific intent to violate the law in order to be convicted.[197]

Dr. Jain argued that the *Ratzlaf* specific intent standard should be applied to the anti-kickback statute.[198] The government argued that the "willfully" requirement should be satisfied by "consciousness of the act."[199] The court, however, affirmed the district court's approach, which it described as a "middle ground."[200] The district court had instructed the jury that "the word 'willfully' means unjustifiably and wrongfully, known to be such by the defendant. . . ."[201]

The court reasoned that the statute at issue in *Ratzlaf* was different from the anti-kickback statute because it made it a crime to violate willfully another statute.[202] The anti-kickback statute, on the other hand, makes it a crime to willfully engage in certain conduct.[203] The court, however, noted that the anti-kickback statute is like the statute in *Ratzlaf* in that both statutes potentially apply to conduct that is not "inevitably nefarious."[204] This breadth justified the heightened intent requirement imposed by the district court.[205]

At least one other district court has also declined to follow the *Hanlester* holding. In *United States v. Neufeld*,[206] the Southern District of Ohio faced the issue of whether the anti-kickback statute is unconstitutionally vague. The court recognized the need to impose a rigid scienter requirement to balance the statute's breadth.[207] The court, however, did not go as far as the *Hanlester* court did in requiring that doctors actually intend to violate the anti-kickback

197. Id. at 440. The court noted, however, that because mens rea was not at issue, even if the district court had erred in its instruction, it was harmless error. Id. at 441.

198. Id. at 440.

199. Id. (citing *Cheek v. United States*, 498 U.S. 192, 209 (1991) (Scalia, J., concurring)).

200. Id.

201. Id. The district court derived this language from Edward J. Devitt, Charles B. Blackmar, and Kevin F. O'Malley, 2 *Federal Jury Practice and Instructions* ¶ 30.05 (West, 4th ed. 1990).

202. *Jain*, 93 F.3d at 441.

203. Id.

204. Id. at 440 (quoting *Ratzlaf*, 510 U.S. at 144).

205. Id.

206. 908 F. Supp. at 497. Caremark, a home infusion company, paid Dr. Neufeld to develop treatment and educational programs for its staff in connection with a new home health program for AIDS patients. Id. at 493. Dr. Neufeld was indicted for violating the anti-kickback statuto and brought a motion to dismiss on vagueness grounds, which the court denied. Id. at 497.

207. Id. at 497.

statute.[208] The court stated that a definition of "willful" that encompasses an intent to do a wrongful act would better serve the goals of the statute.[209] It refrained, however, from formulating a more precise standard.[210]

D. The Inapplicability of Ratzlaf *to the Anti-Kickback Statute*

Leaving aside the issue of whether *Ratzlaf* itself was correctly decided,[211] there are strong arguments against extending its application to the anti-kickback statute. First, the structuring law at issue in *Ratzlaf* prohibits trying to evade another law.[212] Actual knowledge of both laws thus seems to be more germane to the intent issue than knowledge of the law would be in the case of the illegal remunerations law, which targets core behavior. Second, any kind of criminal intent is difficult to prove in the context of health care, where regulations are complex[213] and where courts usually give a great deal of deference to physician judgment.[214] While a jury might be able to infer specific intent to violate a money laundering law, such an inference will be very difficult to draw in the context of health care provider arrangements.[215] Third, although the *Ratzlaf* court felt that the general public could not be presumed to know that structuring is illegal, health care providers, as professionals, arguably can be presumed to know the regulations affecting the health care industry.[216] In this sense, it may be appropriate to hold health care providers to a higher standard. Congress certainly did not intend to give health care providers an incentive to fail to get legal advice

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208. Id.

209. Id.

210. Id. ("The Court hesitates from embarking on an exact definition of the scienter requirement at this time.").

211. Justice Blackmun, writing for the four *Ratzlaf* dissenters, argued that the majority's holding lacked support in the statutory text and in the legislative history. 510 U.S. at 150-51 (Blackmun, J., dissenting). Moreover, Justice Blackmun stressed that structuring is not potentially innocent conduct. Id. at 155-56 (Blacknun, J., dissenting).

212. See note 202 and accompanying text.

213. Bucy, 67 N.C. L. Rev. at 877 (cited in note 1).

214. Id. at 876.

215. See Wayne R. LaFave and Austin W. Scott, Jr., *Criminal Law* § 3.5(f) at 226 (West, 2d ed. 1986) ("[A defendant's] thoughts must be gathered from his words . . . and actions in the light of all the surrounding circumstances.").

216. The anti-kickback statute targets behavior that is grounds for professional discipline in some statos. See, for example, Ariz. Rev. Stat. Ann. § 13-3713 (West, 1989); Cal. Labor Code § 3215 (1996); Col. Rev. Stat. § 12-36-125; Ill. Ann. Stat. ch. 225, § 60/22.A(14) (Smith-Hurd, 1993); N.Y. Educ. Law § 6530.18; Ohio Rev. Code Ann. § 4731.22(B) (Baldwin, 1995); Wash. Rev. Code § 19.68.010 (1989).

before engaging in business ventures, or otherwise to avoid learning the law of the industry.

Moreover, it is fundamentally absurd to impose a requirement of specific intent to violate the law in order to mitigate the effects of a statute so broad that no one knows what the law really is. The level of scienter a statute requires is an important factor in a vagueness inquiry.[217] Indeed, the *Hanlester* court specifically relied on its interpretation of the anti-kickback statute's "knowing and willful" requirement in holding that the statute was not unconstitutionally vague.[218] Yet the ultimate holding of the case is that the defendants cannot be convicted unless they "engage in prohibited conduct with the specific intent to disobey the law."[219] This creates a significant gap in liability: the law is not too vague because it requires defendants te act willfully, but the defendants cannot act willfully unless the law is sufficiently clear for them to form a specific intent to violate it.

The word "willfully," though often used in criminal statutes, does not have one precise and authoritative definition.[220] Indeed, the Supreme Court has acknowledged that it is susceptible to different meanings, depending on the context in which it is used.[221] Nothing in the *Ratzlaf* opinion indicates that the court meant its definition of "willfully" to apply in any other context than that of structuring financial transactions. In the specific context of the anti-kickback statute, an alternative definition of "willfully" can and should be formulated.

E. Toward a Fair and Practical Definition of "Willfully"

The anti-kickback statute should require an intent beyond the mere intent to give or receive remuneration in exchange for receiving or providing patient referrals. Neither of these exchanges is in itself evidence of a "guilty mind." A more meaningful intent standard would speak to the main issue: did the health care provider act with a corrupt purpose?

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217. *Hoffman Estates v. Flipside*, 455 U.S. 489, 498-500 (1982).

218. *Hanlester*, 51 F.3d at 1397-98.

219. Id. at 1400.

220. See *Ratzlaf*, 510 U.S. at 141 (" 'Willful,' this Court has recognized, is a 'word of many meanings,' and 'its construction [is] often . . . influenced by its context.") (quoting *Spies v. United States*, 317 U.S. 492, 497 (1943)).

221. Id.

The statute requires that the prohibited conduct be engaged in "knowingly" and "willfully."[222] The rules of statutory construction require these two words to have different meanings so that neither is superfluous.[223] Moreover, knowingly engaging in behavior that violates the anti-kickback statute is not by itself sufficient to warrant criminal liability, since the statute prohibits such a broad range of conduct.[224] Courts therefore should define "willfully" so as to identify clearly the conduct as criminal. A "willful" act in violation of the statute, in other words, should involve a criminal choice.

That criminal choice does not necessarily have to be the choice to violate a specific law. Before the *Ratzlaf* decision, the lower courts that dealt with ignorance-of-the-law defenses to structuring crimes recognized this. For example, in *United States v. Scanio*,[225] the Second Circuit sustained the conviction of a defendant who had acted with a "bad purpose" in structuring financial transactions, even though the defendant claimed not to know that structuring was illegal.[226] The overwhelming majority of circuits also followed this approach.[227]

Such an approach is consistent with traditional understandings of the word "willful." The word ordinarily has three basic connotations: desire, voluntariness, and obstinacy.[228] In a more general sense, "willfulness" implies placing oneself and one's own wishes above the demands of society. It implies, in other words, that a person acting willfully knows not only that she is doing something wrong, but also that she desires it, sets out with a purpose to do it, and acts not according to reason, but instead according to her own self-interest. In a legal context, "willfully" may be defined as "proceeding from a conscious motion of the will," "deliberate," "designed," "purposeful," or in other ways that track the ordinary definition of the term.[229] All of

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222. For the full text of the statute see note 9.

223. *Ratzlaf*, 510 U.S. at 140-41.

224. See Part III.A.

225. 900 F.2d 485 (2d Cir. 1990).

226. Id. at 491.

227. *United States v. Baydoun*, 984 F.2d 175, 180 (6th Cir. 1993); *United States v. Jackson*, 983 F.2d 757, 767 (7th Cir. 1993); *United States v. Shirk*, 981 F.2d 1382, 1389-92 (3d Cir. 1992), vacated, 114 S. Ct. 873 (1994); *United States v. Rogers*, 962 F.2d 342, 344-45 (4th Cir. 1992); *United States v. Beaumont*, 972 F.2d 91, 93-95 (5th Cir. 1992); *United States v. Gibbons*, 968 F.2d 639, 643-44 (8th Cir. 1992); *United States v. Brown*, 954 F.2d 1563, 1568-69 (11th Cir. 1992); *United States v. Dashney*, 937 F.2d 532, 538-40 (10th Cir. 1991).

228. Wehster's defines "willful" as "governed by will without yielding te reason or without regard to reason: obstinately or perversely self-willed; ready or disposed to comply: willing; done of one's own free will: not compulsory."
Webster's Third New International Dictionary 2617 (Merriam-Webster, 1993).

229. *Black's Law Dictionary* at 1599 (cited in note 48).

these definitions are very different from "knowingly," and yet none goes so far as to require a specific intent to violate the law.

The word "willfully" in the anti-kickback statute should therefore be construed as requiring that a defendant have acted with a fundamentally corrupt intent. This intent requirement, though perhaps not overly precise, certainly renders the statute no more vague and open-ended than the current version of the statute.[230] Moreover, unlike the *Hanlester/Ratzlaf* version of intent,[231] this type of intent would be possible to infer from the circumstances of a given case. For example, under the facts in *United States v. Porter*,[232] in which the defendants received payments to send blood work to laboratories that charged the government six times as much as other available laboratories, a jury could easily reach the conclusion that the defendants willfully acted with a corrupt purpose.

In fact, it already may be that some decisions turn largely on generalized feelings about the level of corrupt intent a defendant has displayed. For instance, in the *Greber* case,[233] which provoked much anxiety about the broad reach of the statute,[234] there was a great deal of evidence as to Dr. Greber's fundamentally corrupt intent.[235] For example, in his private practice alone, Dr. Greber ordered as many Holter-monitors as the entire Hershey Medical Center.[236] There was thus significant evidence of overutilization.[237] Additionally, at least one physician had refused to sign the interpretation form, apparently because he did not believe he was qualified to interpret the test.[238] Most damningly, Dr. Greber had admitted in a prior civil proceeding that "if the doctor didn't get his consulting fee, he wouldn't be using our service. So the doctor got a consulting fee."[239]

The *Greber* court articulated a legal intent standard in holding that requisite intent was present if one of the reasons a defendant made payments to another provider was to induce future referrals. An argument can be made, however, that the court's opinion was

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230. For the full text of the statute, see note 9.
231. See Parts IV.A and IV.B.
232. 591 F.2d 1048 (5th Cir. 1979).
233. 760 F.2d 68 (3d Cir. 1985). See Part II.D.
234. See Part II.D.
235. Miller, *The* Greber *Case*, in Johnson, ed., *Medicare Fraud and Abuse* at 14 (cited in note 104).
236. Id.
237. Id.
238. Id.
239. *Greber*, 760 F.2d at 70.

partly driven by a factual intent inquiry. This Note argues that such an approach is legitimate and workable. Courts should look not merely to whether defendants intend to provide remuneration to induce future referrals, which encompasses a great deal of harmless and even desirable conduct, nor to whether they intend to violate the law. Rather, courts should refocus the intent issue as a straightforward mens rea or "guilty mind" standard. That is, courts should look to whether a defendant acted with a corrupt intent.

Moreover, courts should construe the intent requirements that Congress puts into statutes in ways that will further the goals of these statutes within the bounds of due process, not in ways that will eviscerate them entirely. Congress responded to the *Ratzlaf* decision by simply taking the word "willfully" out of the statute.[240] Thus, in trying to address due process concerns, the *Ratzlaf* court succeeded in encouraging Congress to significantly reduce the intent requirement. With all the current attention to health care reform and to controlling fraud and abuse, it is unlikely that Congress would be any more willing to allow an ignorance of the law defense for the anti-kickback statute than it was for the anti-structuring statute.

A heightened intent standard is a better approach. It is legitimate because it fulfills Congress's goals in making remunerations for referrals criminal conduct, but it does not unfairly penalize innocent parties. It is workable because courts are institutionally capable of inferring corrupt intent from the kinds of evidence that can be offered in health care fraud cases, including insider testimony, expert testimony, documents, and extrinsic act evidence.[241] It is therefore consistent with both the goals of due process and the need to have an effective statute to target criminal behavior in the health care industry.

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240. The current version of the statute: Whoever violates this section shall he fined in accordance with Title 18, United States Code, imprisoned for not more than 5 years, or both." 31 U.S.C. § 5324(c)(1). The House Conference Report stated:

> [This provision] was adopted in order te correct the recent Supreme Court holding in *Ratzlaf v. United States*.... This [provision] restores the clear Congressional intent that a defendant need only have the intent to evade the reporting requirement as the sufficient mens rea for the offense.

Riegle Community Development Act, H. Conf. Rep. No. 103-652, 103d Cong., 2d Sess. 194 (1994), reprinted in 1994 U.S.C.C.A.N. 1977, 2024.

241. See generally Pamela Bucy, *Litigating Health Care Fraud*, 10 Crim. Just. 20, 21 (Spring 1995).

V. CONCLUSION

The anti-kickback statute walks a fine line between being broad enough to encompass creative and unforeseen business arrangements and being clear enough to give adequate notice of what conduct will be considered criminal. The statute achieves the first objective by broadly prohibiting all illegal remunerations, rather than only those things that fall within the specific definitions of "bribe" or "kickback." The statute attempts to achieve the second by containing a "knowingly and willfully" requirement. "Knowingly" engaging in conduct that is harmless, or even socially desirable, however, does not establish a true mens rea for purposes of imposing criminal punishment. The *Hanlester* court therefore properly looked to the word "willfully" to supply an overt element of criminality. The court, however, unnecessarily construed this element of criminality as requiring a specific intent to violate the statute. Criminality can instead be established by acting in a corrupt manner, whether or not one knows that a specific law or regulation exists which makes such action a crime.

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