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The Medicare Anti-Kickback Statute: In Need of Reconstructive Surgery for the Digital Age

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The Medicare Anti-Kickback Statute: In Need of Reconstructive Surgery for the Digital Age

Michael E. Paulhus*

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> Perspicuity, therefore, requires not only that the ideas should be distinctly formed, but that they should be expressed by words distinctly and exclusively appropriate to them. But no language is so copious as to supply words and phrases for every complex idea, or so correct as not to include many equivocally denoting different ideas.[1]

> The best laws should be constructed as to leave as little as possible to the decision of the judge.[2]

I. Introduction

Every day millions of Americans log on to Web sites and click on hyperlinks[3] that direct them to related Web pages.[4] Consider the following hypothetical: a physician creates a convenient service for her patients, whereby the patient accesses a Web site and types in a password. After entering the password, the patient may access a list of all the medications he or she is taking, including descriptions of potential side effects and negative interactions with other drugs.[5] The page also may contain a section permitting the patient to self-schedule appointments, a discussion group for others suffering from similar

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1. THE FEDERALIST NO. 37, at 269-70 (James Madison) (Benjamin Fletcher Wright ed., Belknap 1966).

2. THE QUOTABLE LAWYER 165 (David Shrager & Elizabeth Frost eds., 1986) (quoting ARISTOTLE, RHETORIC (322 B.C.)).

3. *See* http://www.dictionary.com/cgi-bin/dict.pl?term=hyperlink (defining "hyperlink" as "[a] reference (link) from some point in one hypertext document to (some point in) another document or another place in the same document") (last visited Feb. 10, 2002).

4. *See* THOMAS E. MILLER, CYBER DIALOGUE, MAJOR CYBER TRENDS FOR 2000: TAKING THE "E" OUT OF E-COMMERCE 1 (2000) (finding that U.S. Internet users spend approximately 17,500 hours online during lifetime, equal to 4% of entire lives); *As Health Systems Step Into the Web World, They Stumble on Unexpected Legal Pitfalls*, MED. & HEALTH NEWSL. (Faulkner & Gray, Inc., Washington, D.C.), May 15, 2000, at 2S1 (noting that at least 17,000 Web sites address health and estimating that 43% of Web surfers retrieve health care information).

5. *See* Press Release, Cyber Dialogue, Cyber Dialogue Reports that Doctors Are Missing Internet Health Opportunity (Oct. 12, 1999) (proposing Internet as interactive source for patients to find answers regarding treatment regimens or drug side-effects without office visit), *at* www.cyberdialogue.com/news /releases/1999/10-12-cch-doctors.html.

ailments, or a link allowing the patient to e-mail the physician with questions.[6] This concept has the potential to enhance patient control of health care decisions and reduce Medicare expenditures.[7] However, under a strict reading of the anti-kickback statute, this service could expose the physician to a fine of $25,000, exclusion from participation in Medicare and Medicaid programs, and five years in prison.[8] The anti-kickback statute prohibits referrals, which are the very core of the Internet commerce business model.[9] Consequently, courts may impose potentially draconian punishments if, for example, the site contains advertising or a link to a drug manufacturer.[10] Consumers eventually bear the weight of this potential liability, either by denial of access to innovations such as the Web site described or by increased costs of medical care due to foregone cost-reducing transactions.[11]

In 2000, health care expenditures in the United States exceeded one trillion dollars.[12] The General Accounting Office (GAO) estimates that health care

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6. *See* Gunther Eysenbach, *Consumer Health Informatics: Recent Advances*, 320 BRIT. MED. J. 1713, 1715 (2000) (highlighting MedicaLogic's testing of Internet-based health records that allow users to search for information on health conditions, order prescription refills, and communicate with their physician's office); Frances H. Miller, *Health Care Information Technology and Informed Consent: Computers and the Doctor-Patient Relationship*, 31 IND. L. REV. 1019, 1022 (1998) (noting that increasing number of physicians are using e-mail to communicate test results and answer patient questions (citing Esther B. Fein, *For Many Physicians, E-mail Is the High-Tech House Call*, N.Y. TIMES, Nov. 21, 1997, at 1)). *See generally* http://www.aboutmyhealth.net (permitting personalized interactive health management by consumers) (last visited Feb. 10, 2002).

7. *See* Kathleen M. Vyborny, *Legal and Political Issues Facing Telemedicine*, 5 ANNALS HEALTH L. 61, 763-64 (1996) (discussing potential of telemedicine to reduce costs and increase quality of care); Paul Starr, *Health Care Reform and the New Economy*, HEALTH AFF., Nov.-Dec. 2000, at 23, 27 (suggesting e-health will introduce competition into health care resulting in consumer benefits).

8. Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (1994); *see infra* Part III (discussing elements of statute and legislative history).

9. *See* Bruce Fried, *Limits Can Advance E-Health*, MODERN HEALTHCARE (Supp. Eye on Info), May 29, 2000, at 36 (noting that online pharmacies may compensate physicians for placement of ads on physicians' Web sites in several ways, such as flat fees or total number of hits on advertising banner); *see also infra* Part II.B (describing e-health business models).

10. *See As Health Systems Step into the Web World, They Stumble on Unexpected Legal Pitfalls*, MED. & HEALTH NEWSL. (Faulkner & Gray, Inc., Washington, D.C.), May 15, 2000, at 2S1 (commenting on potential liability for hyperlinks from provider Web pages to pharmaceutical company Web pages); *infra* Part II.C.2 (same).

11. *See* RICHARD A. POSNER, ECONOMIC ANALYSIS OF LAW 259 (5th ed. 1998) (discussing notion that criminal laws should be clear to avoid creating substantial avoidance costs that result in forgone socially beneficial transactions); *infra* Part V (developing economic consequences of anti-kickback statute).

12. *See* Amy Schofield & Linda D. Weaver, *Health Care Fraud*, 37 AM. CRIM. L. REV. 617, 618 n.1 (2000) (discussing projections of health care expenditures in excess of 1.4 trillion

fraud and abuse costs more than $100 billion annually.[13] There is a clear consensus that policymakers must reduce the cost of health care;[14] consequently, the legal community lately has focused much attention on the anti-kickback statute.[15] In response to the problem of health care fraud, the Clinton Justice Department chose to enforce the Medicare anti-fraud statutes aggressively, labeling a number of potentially cost-efficient transactions "fraudulent."[16] Moreover, Congress joined the crusade against Medicare and Medicaid fraud and abuse by significantly increasing statutory and administrative penalties.[17]

This Note argues that Congress has failed to recognize that health care functions in a capitalist market and that regulations based on sound economic principles are capable of limiting fraud and promoting efficient business relationships.[18] The current regulatory framework is exceptionally confusing and unstable.[19] Even attorneys well versed in issues of corporate and commercial

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dollars in 2000 (citing PROSPECTIVE PAYMENT ASSESSMENT COMM'N, REPORT AND RECOMMENDATIONS TO THE CONGRESS 12 (June 1996))).

13. *See Health Law Symposium*, 7 U. MIAMI BUS. L. REV. 401, 439 (1999) (noting GAO's estimate of fraud and abuse costs).

14. *See* Stuart M. Gerson & Jennifer E. Gladieux, *Advice of Counsel: Eroding Confidentiality in Federal Health Care Law*, 51 ALA. L. REV. 163, 165-66 (1999) (noting "clear public mandate" for aggressive enforcement of health care anti-fraud laws and suggesting that in absence of Congressional agreement on health policy, politicians have chosen to wage visible war on fraud to retain institutional credibility).

15. *See* Laura Keidan Martin, *Not So Fast, It's Regulated: Some Warnings for the E-Health Biz*, BUS. L. TODAY, Sept.-Oct. 2000, at 10-14 (discussing anti-kickback prosecution prominently); Stanley A. Twardy & Michael P. Shea, *Anti-kickback Anxiety: How a Criminal Statute Is Shaping the Health-Care Business*, BUS. L. TODAY, May-June 2000, at 18-22 (same).

16. *See Health Law Symposium*, *supra* note 13, at 439 (describing Attorney General Janet Reno's elevation of health care fraud to number two priority behind violent crime). The symposium panelists commented that some prohibited practices actually increase the quality of care. *Id.* at 447; *see also* Charles J. Williams, *Toward a Comprehensive Health Care Anti-Kickback Statute*, 64 U.M.K.C. L. REV. 291, 307-08 (1995) (discussing Clinton administration's failed Health Security Act plan to broaden anti-kickback liability through codification of judicial "one purpose test"). See *infra* Part III.C.1 for further explication of the "one purpose" test.

17. *See* Health Insurance Portability and Accountability Act of 1996 (HIPPA), Pub. L. No. 104-191, 110 Stat. 1936 (1996) (allocating substantial funding to health care fraud enforcement and raising level of civil monetary penalties); Balanced Budget Act of 1997 (BBA), Pub. L. No. 105-33, 111 Stat. 251 (1997) (expanding Office of Inspector General's (OIG) authority to exclude providers from participation in all federal health care programs).

18. *See Health Law Symposium*, *supra* note 13, at 444 (asserting that "in the real world" businesspeople in health care industry seek profitable, efficient relationships based on referrals); Michael J. Myers, *"Elder-Comp, L.L.C.,"* 45 S.D. L. REV. 540, 549 (2000) ("[M]edicine . . . [is] past the mid-point of [its] migration from professionalism to commercialism; a journey not initiated by the [profession], but rather undertaken in a para-sympathetic response to market forces."); *infra* Part V (analyzing efficiency of statute's deterrent effect).

19. *See* Joan Burgess Killgore, Comment, *Surgery with a Meat Cleaver: The Criminal Indictment of Health Care Attorneys in* United States v. Anderson, 43 ST. LOUIS L.J. 1215, 1216

law frequently are surprised to learn that the anti-kickback statute prohibits many health care transactions, the equivalents of which are legal in most industries.[20] In addition to the many problems that plague the anti-kickback statute generally, the current federal fraud prevention structure is woefully inadequate for the regulation of emerging technology in the health care field.[21] The burgeoning Internet health industry requires the swift revision of the anti-fraud and abuse laws because "heavy-handed regulation will constrain the evolution of the [technology-driven] health system, limiting its ability to deliver extraordinary clinical achievements, economic efficiencies, and consumer empowerment."[22]

Part II of this Note describes the significance of technology for the future of health care. Part III examines the legislative history of the anti-kickback statute and the subsequent judicial expansion of liability. Part IV confronts the problem of inadequate guidance from Congress and regulatory agencies regarding the convergence of health care and the Internet. The economic analysis of Part V suggests that the application of the anti-kickback statute is theoretically flawed because it hinders innovation and stymies efficient relationships between medical providers. Finally, Part VI contains suggestions for the revision of the current anti-kickback statute, and, in the alternative, for the promulgation of new rules for the field of e-health. The foremost recommendation calls for a shift from the present intent-based scheme to a clear objective framework similar to that of the Stark self-referral provisions.

II. Importance of Technology in the Delivery of Health Care

"[T]he 'new economy' rooted in information technology (IT) is not a transitory phenomenon. Fundamental changes in communications and society

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(1999) (commenting that health care regulations are confusing even for experienced health care professionals (citing BARRY R. FURROW ET AL., HEALTH LAW CASES, MATERIALS AND PROBLEMS 574 (3d ed. 1997))).

20. *See* Killgore, *supra* note 19, 1216-17 n.12 (noting that "'the state and federal laws [governing many healthcare financial relationships] prohibit many contractual relationships, investments, marketing, and recruitment practices that are perfectly legal in other businesses'" (quoting FURROW ET AL., *supra* note 19, at 574)).

21. *See As Health Systems Step into the Web World, They Stumble on Unexpected Legal Pitfalls*, MED. & HEALTH NEWSL. (Faulkner & Gray, Inc., Washington, D.C.), May 15, 2000, at 2S1 ("Because the OIG has not published any guidelines addressing Internet health care relationships, nobody can predict exactly how it may determine whether a particular relationship violated the anti-kickback statutes. . . ." (quoting Eric Tower, of law firm Mintz, Levin, Cohen, Ferris, Glovsky & Popeo)); *see also infra* Part IV (discussing inadequacy of guidance from advisory opinions and fraud alerts, as well as minimal value of health care attorney opinion letters).

22. Bruce Merlin Fried et al., *E-Health: Technologic Revolution Meets Regulatory Constraint*, HEALTH AFF., Nov.-Dec. 2000, at 124, 124.

are in the making, and entire new industries are taking shape."[23] In response to this shifting economy, many investors have embraced the e-health sector.[24] Investment bankers predict that by the year 2003 the health care electronic commerce market will be valued at $205 billion, a figure slightly less than current annual Medicare expenses.[25] If regulatory agencies respond appropriately to this changing environment, Internet technologies can help repair some of the problems plaguing the health care system in the United States.[26] Before proceeding further, explication of technical definitions and discussion of e-health business models may be helpful to the reader.

A. Medical Community's Need for Subsidized Technology

Telemedicine involves the transmission of medical data from one location to a distant site.[27] Telemedicine's current applications are numerous and include providing medical care to underserved populations[28] and fostering

23. Starr, *supra* note 7, at 23, 23. Starr's work concludes that the emerging digital economy will have significant impact on health care. *Id.* at 31-32.

24. *See* James C. Robinson, *Financing the Health Care Internet*, HEALTH AFF., Nov.-Dec. 2000, at 72, 72 (noting unprecedented flood of capital into Internet health sector in 1999 and 2000).

25. Stephen T. Parente, *Beyond the Hype: A Taxonomy of E-Health Business Models*, HEALTH AFF., Nov.-Dec. 2000, at 89, 89 (citing C. TAYLOR, THE E*VOLUTION OF HEALTHCARE, E*OFFERING WORKING PAPER (E*TRADE GROUP, 1999)).

26. *See* Fried et al., *supra* note 22, at 124 (concluding that excessive regulation will limit extraordinary potential of e-health to increase efficiency and quality of patient care); J.D. Kleinke, *Vaporware.com: The Failed Promise of the Health Care Internet*, HEALTH AFF., Nov.-Dec. 2000, at 57, 69 (suggesting that Internet technologies may serve as partial solution to health care problems, but calling for tempered optimism).

27. *See* Barry B. Cepelewicz et al., *Recent Developments in Medicine and Law*, 33 TORT & INS. L.J. 583, 591-92 (1998) (defining "telemedicine" and discussing potential applications); *see also* Ranney V. Wiesemann, *On-Line or on-Call? Legal and Ethical Challenges Emerging in Cybermedicine*, 43 ST. LOUIS U. L. J. 1119, 1119-20 (1999) (defining cybermedicine as "Internet driven practice of medicine" frequently entailing diagnoses through e-mail). Cybermedicine and health e-commerce are similar to telemedicine in that they transmit medical data over a distance by computers. *Id.* at 1122. However, while telemedicine is the communication between two known providers, cybermedicine frequently consists of a provider communicating with an unknown patient. *Id.* at 1119-20. In some cases, the distinction between telemedicine, cybermedicine, and e-health commerce is valuable; however, this Note employs the terms interchangeably because the anti-kickback statute's language affects these subsets of medical communication equally. *See infra* Part III (discussing how anti-kickback statute expansively prohibits any exchange of remuneration for referrals).

28. *See* Jeff Tieman, *Dialing Up High Tech Medicine: LA University Opens Doors to Its Third Telemedicine Center to Serve Urban Patients*, MODERN HEALTHCARE, JAN. 1, 2001, at 36 (noting that pediatric clinic opened in downtown Los Angeles, in addition to two ophthalmology telemedicine clinics, already serving housing projects). Traditionally, telemedicine projects have focused on providing services to rural communities, but physicians are utilizing the technology

global medical conferences and exchanges of technical expertise.[29] Further beneficial uses of technology include patient record devices that reduce the administrative overhead resulting from paper filing and handheld wireless technology that could prevent errors at pharmacies.[30] Moreover, a wealth of possibilities exists for the future of medicine as it merges with information technology.[31] For example, "internal biological sensors [may soon] continuously monitor body function, reporting highly accurate data to disease management technologies."[32] These technologies have the potential to reduce health care costs, but they require an initial outlay for the hardware.[33] Although the preceding technologies are promising, the anti-kickback statute stands as a barrier to their implementation because many business arrangements that enable advances in health care technology violate the statute by contemplating the exchange of discounted technology for patient referrals.[34]

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with increasing regularity to reach underserved inner city populations. *Id.* One should note that these outreach projects require significant capital. *Id.* In the Los Angeles project, donors contributed over $3 million dollars to start the project, which served 2,000 patients in the year 2000. *Id.* While a $2 million dollar grant from the county funded a significant portion of the Los Angeles project, *id.*, many areas that could benefit from such high-tech programs do not have the tax base or the political support to fund these initiatives. *See* Teresa G. Norris, *Telemedicine and Teleradiology*, RADIOLOGIC TECH., Nov. 1, 1999, at 139 (rural telemedicine networks frequently require financial support from network providers). In such cases, the statute should permit profit motivated private sector actors to intervene and help provide a technological infrastructure without having such "free technology provision" characterized as impermissible and felonious remuneration. *Id.*

29. *See* Tieman, *supra* note 28, at 36 (commenting on potential of telemedicine to improve future of health care for underserved populations); Edward H. Shortliffe, *Health Care and the Next Generation Internet*, ANNALS INTERNAL MED., July 15, 1998, at 138, 138-39 (suggesting that with proper investment in technology by academia, industry, and government health care providers can streamline patient record keeping). Shortliffe suggests the following:

> [In the future] citizens will no longer have several medical records scattered in the offices of various physicians and in the medical record rooms of numerous hospitals. Instead, their records will be linked electronically over the Internet so that each person has a single "virtual health record," the distributed but unified summary of all the health care they have received in their lives.

Id.

30. *See* Fried, *supra* note 9, at 36 (commenting on computer chips allowing physicians to use wireless handheld patient record retrieval devices).

31. *See id.* (predicting that biological sensors implanted in humans will monitor health).

32. *See* Shortliffe, *supra* note 29, at 139 (describing patients' remarkable enthusiasm when familiar physicians provide Internet-based interactions for disease management).

33. *See* Norris, *supra* note 28, at 139 (discussing significant cost of telemedicine networks); Tieman, *supra* note 28, at 36 (same); *supra* note 7 (noting benefits of telemedicine).

34. *See generally* Fried et al., *supra* note 22 (discussing restraints imposed upon growth of e-health by anti-kickback and other regulatory schemes).

Telemedicine may entail the use of normal analog phone lines to link two computer modems or it may transmit data over the Internet.[35] Advanced telemedicine applications frequently require high bandwidth lines that can support the exchange of data-intense radiology images from labs or patient test results from home monitors to physician offices.[36] The prohibitive costs of these high bandwidth connections and sophisticated computers impede the development of Internet-based health care exchanges.[37] In many cases, unless an interested party provides the lines and hardware free of charge or with a subsidy, health care providers will not participate in technology exchanges because they will not be able to justify the cost.[38] A typical technology company's proposal to provide physicians with equipment, such as high-speed computers, Digital Subscriber Lines (DSL), and special monitors, may violate the anti-kickback statute.[39] For example, physicians could supervise a patient's treatment through monitoring chips connected to a central processing database.[40] Applying a reasonable business model, the chip manufacturer would provide the technology to the physicians free of charge.[41] The physicians then would refer their patients to the chip manufacturer, which would

35. *See* Kristen R. Jakobsen, Note, *Space-Age Medicine, Stone-Age Government: How Medicare Reimbursement of Telemedicine Services Is Depriving the Elderly of Quality Medical Treatment*, 8 ELDER L. J. 151, 157 (2000) (describing methods of telemedical data transmission (citing Daniel McCarthy, Note & Comment, *The Virtual Health Economy: Telemedicine and the Supply of Primary Care Physicians in Rural America*, 21 AM. J.L. & MED. 111, 113 (1995); William J. Crump et al., *Is Telemedicine Ready for Prime Time?*, PATIENT CARE, Feb. 15, 1997, at 64)).

36. *See* Jim Grigsby & Jay H. Sanders, *Telemedicine: Where It Is and Where It's Going*, ANNALS INTERNAL MED., July 15, 1998, at 123, 124 (defining bandwidth as "amount of information sent per unit of time"); Tieman, *supra* note 28, at 36 (noting that telemedicine employs high-speed data connections and videoconferencing technology to reach isolated individuals).

37. *See* Fried, *supra* note 9, at 36 ("The expense of designing, developing and deploying Web-based health care systems will be immense. [However, t]he commerce that results from this deployment will generate huge flows of revenue.").

38. *See* Norris, *supra* note 28, at 139 (discussing cost prohibitive nature of telemedicine equipment and need for sponsorship by network providers).

39. *See* Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (1994) (prohibiting offer, solicitation, receipt, and inducement of "remuneration" in return for referral of patients). In this case, the provision of the technology serves as remuneration and the use of the technology to diagnose patients constitutes referrals. *See* H.R. REP. NO. 95-393, at 53 (1977), *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056 (asserting congressional intent to define "remuneration" broadly).

40. *See* Martin, *supra* note 15, at 12 (describing portable diagnostic device that transmits patient test results via Internet to physician).

41. *See* Norris, *supra* note 28, at 139 ("When providers design telemedicine programs, it is often the burden of the larger provider (or network) to absorb the highest costs, particularly when dealing with rural providers on the transmitting end.").

recoup the cost of the system and make a profit.[42] This business relationship likely would violate the anti-kickback statute because, under the act's broad "remuneration" language, the physicians refer patients to the chip company in return for remuneration in the form of the interpretation technology located in the physician's offices.[43] This analysis of the anti-kickback statute is applicable to any proposed subsidization by the private sector of care-enhancing medical technology.[44] To focus the discussion of the statute's far-reaching provisions, it is helpful to turn to a consideration of the effect on business arrangements based on Web sites.[45]

B. E-Health Business Models

E-health business models generally take the following four forms: portals, business-to-business applications, business-to-consumer applications, and connectivity sites, each with its own revenue model and potential to benefit consumers.[46] E-health sites have business plans based upon consumer demand.[47] By 1999, twenty-five million Americans were online, and by May of 2000, thirty-seven million people in the United States had Internet access.[48] One survey found that about half of Internet users were interested in benefiting from a Web site operated by their doctor's office, but only four to six percent were actually doing so.[49] Interestingly, one-third of online health

42. *See id.* (noting that physicians "refer" their patients through technology-providing company's network, which receives fee per patient).

43. *See id.* ("[T]he fact that these providers are connected via some sort of technological network or system could mean that the incentive to refer to one another is high."). This quotation understates the implicit understanding in the relationship. The network providing the technology to the individual physician does not do so through purely beneficent motives; there is clearly an intent to induce referrals, which violates the statute. *Cf.* Martin, *supra* note 15, at 12 (commenting upon probable violation in analogous situation that encourages referrals by paying finder's fee).

44. *See generally* Part IV (discussing HHS's negative stance toward provision of free or discounted technology to physicians).

45. *See infra* Parts II.B & C (discussing e-health business models and hypothetical patient-oriented physician site).

46. *See* Parente, *supra* note 25, at 90 (introducing four types of e-commerce health sites). These business models may have a substantial overlap, but are characterized in this manner for simplicity of explanation. *Id.*

47. *See* Jerome P. Kassirer, *Patients, Physicians, and the Internet*, HEALTH AFF., Nov.-Dec. 2000, at 115, 118 (discussing Web-based healthcare industry business model (citing Cyber Dialogue, *supra* note 5; Press Release, Cyber Dialogue, Online Health Information Seekers Growing Twice as Fast as Online Population (May 23, 2000), *at* www.cyberdialogue.com/news/releases/2000/05-23-cch-future.html)).

48. Kassirer, *supra* note 47, at 118.

49. *Id.* (citing SCOTT REENTS, IMPACTS OF THE INTERNET ON THE DOCTOR-PATIENT RELATIONSHIP: THE RISE OF THE INTERNET HEALTH CONSUMER (1999), *at* www.cyberdialogue.com/pdfs/wp/wp-cch-1999-doctors.pdf (last visited Feb. 10, 2002)).

seekers interviewed said they probably would switch physicians if they could communicate with them by e-mail.[50] The Internet has great potential to increase the quality of patient care due to the declining significance of proximity and geography.[51] Additionally, the concept of "click loyalty" will force health providers to adapt to and respond to patient demand because the Internet always will allow the consumer to turn to a competitor with the click of a mouse.[52]

1. Portals

Portals provide a gateway to the vast wealth of information found on the Internet and are the sites that consumers most commonly access.[53] A portal aggregates in one location many of the services that consumers seek on the Web, such as e-mail, stock tickers, and search engines.[54] Examples of popular portals include Yahoo!, AltaVista, AOL.com, and various newspaper Web sites.[55] Portals advertise heavily to create a name that consumers will remember and turn to as their first source of information when logging on.[56] Advertising is the primary source of revenue for portals.[57] To generate revenue, a Web site must attract a large number of people because advertisers reimburse the Web page owners either per person visiting the site or by the number of users following a hyperlinked banner to the advertiser's site.[58] With huge

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50. Kassirer, *supra* note 47, at 119 (citing Cyber Dialogue Reports, *supra* note 5).

51. *See* Nicholas P. Terry, *Structural and Legal Implications of E-Health*, 33 J. HEALTH L. 605, 607 (concluding that declining influence of proximity and geography will accelerate decline of traditional hierarchal health care delivery, giving patients more choice).

52. *See id.* at 607 n.10 (quoting Ray Lane, President, Oracle, Keynote Address at the Internet & Electronic Commerce Conference & Exposition (Apr. 28, 1999), *at* http://www.pcworld.com/cgi-bin/pcwtoday?ID=10740) (commenting that Internet customers have "click loyalty" and will revisit site as long as they like prices and content); *see also* Starr, *supra* note 7, at 27 (asserting that Internet creates ability for consumers to compare levels of care, which will require health plans and providers to be sensitive to cost and quality issues).

53. *See* Parente, *supra* note 25, at 90 (describing concept of portal site).

54. *See* Rob Fixmer, *From Search Engines to Portal Sites*, N.Y. TIMES, July 27, 1998, at D4 (describing concept of aggregating free services to entice consumers to make specific portal their home page); http://www.drkoop.com (last visited Feb. 10, 2002) (providing health care portal with health encyclopedia, program alerting patient to dangerous drug reactions, and search engine).

55. *See* Parente, *supra* note 25, at 90 (listing popular portal sites).

56. *See id.* at 90-91 (describing prominence of advertising as portal revenue source); *see also* MILLER, *supra* note 4, at 5 (discussing aggressive advertising known as "cyber branding"). The drive to secure name recognition is the reasoning behind the incredible number of high-priced "Dot com" Super Bowl commercials seen in 2000. *Id.*

57. Parente, *supra* note 25, at 91.

58. *See* Maureen A. O'Rourke, *Fencing Cyberspace: Drawing Borders in a Virtual World*, 82 MINN. L. REV. 609, 626 (1998) ("[T]he effectiveness of [an] ad is usually measured

coffers dedicated to generating publicity, pharmaceutical companies invest significantly in e-health advertising.[59]

2. Business-to-Business and Business-to-Consumer E-Commerce

The business-to-business (b-to-b) model entails the sale of goods by firms to each other and to government agencies.[60] Web-savvy physicians may use the b-to-b model to increase their practice volume by directly contracting their services through online auctions.[61] An example of a health care b-to-b site is Neoforma.com, which provides an online marketplace for the sale of goods among medical suppliers, equipment vendors, and health care providers.[62] Business-to-consumer (b-to-c) sites focus on direct marketing and decreasing overhead.[63] B-to-c models are able to undercut traditional retailers because technology reduces transaction costs by eliminating many players such as wholesalers, financiers, and warehousers.[64] Examples of the b-to-c model include Drugstore.com, an online pharmacy, and Bluecross.com, a site that gives consumers the capability to design their own health plans on the Internet.[65] In addition to the benefits of individual business sites, the Internet also presents the potential for choreographing the relationships of numerous parties in the delivery of healthcare through connectivity sites.

3. Connectivity Sites

One of the primary innovations of the Internet is its potential to facilitate seamless links between information systems.[66] Health care Internet companies

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by how many viewer's [sic] 'click-through' (or link) from the Web site displaying the ad to the web [sic] site of the advertiser itself.").

59. *See* REENTS, *supra* note 49, at 5 (indicating that Web marketing by pharmaceutical companies has significant effect on increased consumer requests for brand name drugs from physicians).

60. Parente, *supra* note 25, at 94.

61. *Id.*

62. *Id.*; *see* http://www.neoforma.com (last visited Mar. 5, 2002) (providing online marketplace for health care community).

63. *See* Parente, *supra* note 25, at 95 (noting that b-to-c e-commerce involves sale of goods directly to consumers).

64. *See* LARRY DOWNES & CHUNKA MUI, UNLEASHING THE KILLER APP: DIGITAL STRATEGIES FOR MARKET DOMINANCE, 45-46 (1998) (asserting that technology reduces role of "middleman" in business).

65. *See* http://www.drugstore.com (last visited Mar. 4, 2002) (providing online ordering and renewal of prescriptions, vitamins and non-prescription drugs, and information about drug interactions); http://www.bluecross.com (last visited Mar. 4, 2002) (allowing consumers to design health care plan coverage).

66. Parente, *supra* note 25, at 92.

commonly promote Internet connectivity as the solution to fragmentation among physicians, physician groups, hospitals, and ancillary services.[67] The object of connectivity sites is to streamline transactions by linking health plans, physicians, hospitals, clinical laboratories, pharmacies, consumers, and other participants involved in health care financing, marketing, and delivery.[68] Connectivity sites produce revenue by charging transaction fees for the service.[69] Web-based connectivity sites such as Healtheon/WebMD are appealing because the provider needs no complex proprietary software or hardware package – one only requires a connection to the Internet.[70] A similar connectivity site, Abaton.com, allows providers to access clinical data such as laboratory and imaging results, to prescribe drugs, and to refer patients, all in real time.[71] Although the potential variations of e-health business relationships are innumerable, it is possible to highlight many benefits of e-health through the description of a consumer-oriented Web site, such as the hypothetical physician's site from the Introduction.[72]

C. Practical Example: Physician Web Site

1. Potential Benefits to Consumers

The most significant potential for an individual physician's site is the ability to customize the offerings to the individual patient.[73] Physicians could use the model of commercial portals as the basis for their sites and include a wide array of services and tools to allow a patient to manage his health online.[74] A significant problem with retrieving health information from the Internet is assuring the quality of what one accesses.[75] Physicians could

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67. *See* Kleinke, *supra* note 26, at 62 (describing Internet connectivity purveyors' claims that technology can solve communication failures in health care delivery).

68. Parente, *supra* note 25, at 92.

69. *See id.* (discussing connectivity sites' revenue model).

70. *See id.* at 93 (noting versatility of Healtheon/WebMD's Web interface); http://www.webmd.com (last visited Mar. 5, 2002) (providing consumer with personalized format, search engine, health news, and marketing potential for swifter reimbursement through electronic claims submission).

71. *See id.* (describing capabilities of Abaton.com); http://www.abaton.com (last visited Mar. 5, 2002) (allowing physicians to manage patient diagnostic results online).

72. *See supra* notes 5-11 and accompanying text (discussing hypothetical physician's patient-directed Web site).

73. *See generally* Parente, *supra* note 25, at 91 (noting personalized trackers that identify specialized content to meet patient's needs).

74. *See supra* notes 53-54 and accompanying text (discussing concept of aggregating diverse products in one location for consumer's convenience).

75. *See* Gunther Eysenbach & Thomas L. Diepgen, *Consumer Health Informatics: Recent Advances*, 317 BRIT. MED. J. 1496, 1496 (1998) (finding quality and completeness of health information on Internet variable).

address this concern by creating a page of suggested, reputable links sending patients to in-depth information about specific ailments or any health information.[76] A similar use of the portal concept would be to link patients to online support groups to help patients and family cope with illnesses.[77]

Providers could employ the business-to-consumer model on the site by handling prescription requests and renewals online.[78] This would remove some of the problems involved with mistakes that are made when deciphering written prescriptions, would allow patients to manage their prescriptions more easily, and would reduce the administrative costs involved with contacting physicians directly to request prescription renewals.[79] The physician could provide a section of the page that would allow patients to manage their insurance information and use the connectivity concept to link this information with their business office to expedite the chain of payment after patients have received the physician's services.[80] Of course, the site would have a link permitting patients to contact their physician by e-mail.[81]

2. *Financing Issues*

The potential value of a personalized Web site to a physician's patients may be great; however, financial constraints generally make it impractical for individual physicians or small physician groups to undertake these projects alone.[82] Consequently, health care providers must secure an alternate source

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76. *See* REENTS, *supra* note 49, at 6 (suggesting physicians could have tremendous impact on patient education by recommending sites with credible information).

77. *See* Kleinke, *supra* note 26, at 65 (discussing educational, clinical, and psychological value derived from patients with similar ailments communicating with each other). The Web and the existence of real time chat and news groups make communication possible between similarly situated patients, connecting both individuals suffering rare ailments and those with more common maladies living thousands of miles apart. *Id.*

78. See *Cybermedicine: The Benefits and Risks of Purchasing Drugs Over the Internet*, 5 J. TECH. L. & POL'Y 1, 1-2 (2000) (discussing benefits and drawbacks of marketing and selling prescriptions online). The article notes the potential benefits that could accrue to elderly people who may have mobility concerns and those living in rural locations. *Id.*

79. *Id.* at 20-21; *see supra* note 5 and accompanying text (discussing potential for interactive prescription management on Web).

80. *See supra* notes 66-72 and accompanying text (describing connectivity concept and application to medicine).

81. *See* Helen Burstin, *Traversing the Digital Divide*, HEALTH AFF., Nov.-Dec. 2000, at 245, 246-47 (physician describing her effective use of e-mail with patients). Dr. Burstin described how she used e-mail to make sure her patients were complying with their treatment regimens and to help foster a caring doctor-patient relationship that has been lost in the complex paper shuffle of modern health care. *Id.*

82. *See* REENTS, *supra* note 49, at 5 (asserting that time and capital investments required by physicians to engage patients through a Web site are considerable).

of financing to create such sites[83] and, as discussed above, advertising drives the Internet revenue model.[84] Sheer lack of capital and patient demand may force physicians to include commercial advertising on their sites or to allow sponsorship of parts of a site.[85] A physician might choose to sell ads and links on the Web site to a health spa or to an online pharmacy.[86] The advertiser may compensate the physician in several ways, "including flat fees, a percentage of online sales or rewards based on Web traffic volume–for example, 'hits' on the pharmacy's linked site."[87] Although consumers appear to accept this model of banner advertising in exchange for "free" services in other business sectors,[88] according to the anti-kickback statute, this arrangement may constitute an impermissible practice of payment in exchange for patient referrals.[89] Furthermore, regulatory agencies may find that a physician has referred patients to a pharmacy by virtue of an ad's size and placement on the physician's Web site simply because there are no other advertisers listed on the site.[90] An alternative to a physician creating a potentially suspect relationship with well-financed drug manufacturers is for a hospital to establish and maintain Web sites for its affiliated physicians.[91] To recoup the costs incurred in maintaining the site, the hospital might place its logo on the physician's home page with a link to its own Web site.[92] However, as discussed above, the current regulatory climate probably would prohibit this arrangement.[93]

83. *See* Kassirer, *supra* note 47, at 122 (noting that Web site hosting is expensive and time-consuming for individual physicians and describing solution of partnering with commercial enterprises for funding).

84. *See* MILLER, *supra* note 4 (discussing concept of "cyber branding" as revenue model); O'Rourke, *supra* note 58, at 626 (noting that hyperlinked advertising is becoming Web publishers' primary revenue source).

85. *See* Kassirer, *supra* note 47, at 122 (discussing potential reimbursement arrangements between physicians and advertisers); REENTS, *supra* note 49, at 5 (noting significant time and capital expenditures required to operate Web site).

86. *See* Fried, *supra* note 9, at 37 (commenting on liability under anti-kickback statute for inclusion of links to pharmacy).

87. *Id.*

88. *See generally* http://www.yahoo.com (last visited Mar. 6, 2002) (providing users with search engine, maps, news, and e-mail but dedicating significant portion of page to direct sales links); http://www.altavista.com (last visited Mar. 6, 2002) (same).

89. *See* Fried, *supra* note 9, at 37 (commenting that advertiser to physician payment plans may constitute kickback schemes); *infra* Part IV (discussing regulatory agencies' position against technology exchanges).

90. Fried, *supra* note 9, at 37.

91. *Id.*

92. *Id.*

93. Fried, *supra* note 9, at 37 (discussing prohibition of Web site in exchange for advertising referrals); Kleinke, *supra* note 26, at 63 ("The easiest and most obvious application of a

The advance of technology alone will not produce the desired integration and reduction in health care delivery cost.[94] A number of obstacles stand in the path of an electronic revolution in health care delivery, the most prominent being antiquated and cynical federal laws and regulations, such as the anti-kickback statute.[95] Having described health care on the Web and its potential for increasing the quality of care to patients, it is appropriate to turn to a brief consideration of the anti-kickback statute.

III. Anti-Kickback Statute

A. Current Provisions

The primary policy underlying the anti-kickback statute is a concern that health care providers motivated by their own financial interests will over-utilize medical services by referring patients for unnecessary procedures, resulting in a drain of Medicare funds.[96] To combat this perceived risk, the anti-kickback statute[97] criminalizes the "knowing and willful offer, payment, solicitation, or receipt of any remuneration (directly or indirectly, overtly or covertly, in cash or in kind) in return for or to induce a referral of services or goods payable by Medicare or Medicaid . . . ."[98] Congress has established severe penalties for violating the anti-kickback provisions, including fines of up to $25,000, imprisonment of up to five years, and exclusion from participation in Medicare and Medicaid.[99] Recognizing that some situations are

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shared hospital/physician group Web site–marketing and coordinated scheduling–flies directly in the face of these [anti-kickback] laws because the effort would be designed specifically to direct patient referrals.").

94. Kleinke, *supra* note 26, at 62-63.

95. *Id.*

96. *See* TIMOTHY STOLTZFUS JOST & SHARON L. DAVIES, THE LAW OF MEDICARE AND MEDICAID FRAUD AND ABUSE 100 (2001-02 ed. 2000) (listing concerns that "patients will suffer, program funds will be unnecessarily depleted, and taxpayer dollars will be wasted" if kickbacks are permitted). The anti-kickback statute affects both Medicare and Medicaid, but this note focuses on Medicare alone for the sake of brevity. *Cf. id.* at 206-07 (discussing state anti-kickback prohibitions designed to target Medicaid fraud).

97. 42 U.S.C. § 1320a-7b(b) (1994). *See generally* JOST & DAVIES, *supra* note 96 (comprehensively treating prosecution of health care fraud); Schofield & Weaver, *supra* note 12 (same).

98. James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 AM. J.L. & MED. 205, 206 (1996).

99. Anti-Kickback Statute, 42 U.S.C. 1320a-7b(b) (1994 & Supp. V 1999). The statute provides, in pertinent part, 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 –

unlikely to give rise to fraud and abuse, legislators carved out six statutory exemptions.[100] In addition to promulgating the statutory exceptions, Congress vested the Department of Health and Human Services (HHS) with the power to create safe harbors to further protect arrangements that the agency deems unlikely to result in program abuse.[101] The combination of the anti-kickback statute's broad reach and the congressional delegation of interpretive powers has made investigators and attorneys at the Office of Inspector General (OIG), a subdivision of HHS, and the Department of Justice (DOJ) arbiters of the legality of health care transactions.[102]

> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony 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 a Federal health care program, or
> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

Id.

100. *See* 42 U.S.C. § 1320a-7b(b)(3) (1994) (providing exceptions for discounts, payments within bona fide employment relationship, protection for group purchasing organizations, waivers of Medicare Part B coinsurance obligations, and certain risk-sharing arrangements of managed care organizations). The ramifications of these provisions are complex and beyond the scope of this Note because they generally do not affect the e-health transactions under consideration. *But see infra* Part IV (discussing OIG position that typical telemedicine arrangements are not covered under discounts exemption).

101. *See* Medicare and Medicaid Patient and Program Protection Act of 1987 (MMPPPA), Pub L. No. 100-93, § 2, 101 Stat. 680, 682 (codified at 42 U.S.C. § 1320a-7(b)(7) (1994)) (providing that Secretary of HHS shall promulgate safe harbor regulations describing practices not subject to prosecution).

102. *See* S. REP. NO. 94-1324, at 3 (1976), *reprinted in* 1976 U.S.C.C.A.N. 5420, 5422 (describing one of OIG's responsibilities as investigation of health care fraud "to increase [Medicare and Medicaid's] economy and efficiency and to reduce the likelihood of fraud and abuse"); *Health Law Symposium*, *supra* note 13, at 444 (noting OIG's aggressive prosecution of anti-kickback violations).

B. Legislative History

The anti-kickback statute originally prohibited only "bribes and kick-backs"[103] until Congress amended the statute in 1977 to extend its reach by substituting "any remuneration" for the "bribes and kickbacks" language.[104] The amendment simultaneously elevated violations from misdemeanor to felony status.[105] It is clear from the legislative history that Congress intended for regulators and courts to interpret the phrase "remuneration" broadly.[106] However, the expansive language has raised opposition from many practitioners and scholars who argue that the broad construction of the provisions not only punishes unscrupulous providers, but also inhibits innocuous and socially beneficial arrangements.[107] The dynamics of e-health exacerbate the problem of overbroad language because Internet business models rely heavily on the use of referrals.[108]

In response to concerns about the breadth of the statute, Congress created a requirement of specific intent to preclude the conviction of an individual acting improperly but inadvertently.[109] The Omnibus Reconciliation Act of 1980 added the requirement that a violation must result from "knowing" and "willful" action.[110] Although the core of the statute amounts to no more than a page in the United States Code, the anti-kickback statute is both perplexing

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103. Social Security Amendments of 1972, Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972) (codified as amended at 42 U.S.C. § 1320a-7b (1994)).

104. *See* JOST & DAVIES, *supra* note 96, at 112 n.4 (discussing substitution of "remuneration" for "bribes and kickbacks" (citing Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. No. 95-142, 91 Stat. 1175 (1977) (codified as amended at 42 U.S.C.A. §§ 1320a-7b(b)(1)(A) and (B) (1994)))).

105. *Id.* at 113.

106. *See* H.R. REP. NO. 95-393, *supra* note 39, at 53 (asserting congressional intent to define "remuneration" broadly).

107. *See, e.g.*, Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,952 (July 29, 1991) (codified at 42 C.F.R. pt. 1001); JOST & DAVIES, *supra* note 96, at 114 n.14 (noting criticism of statute's broad scope (citing David M. Frankford, *Creating and Dividing the Fruits of Collective Economic Activity: Referrals Among Health Care Providers*, 89 COLUM. L. REV. 1861, 1875-76 (1989))); Killgore, *supra* note 19, at 1222 (noting concern that broad application would ensnare socially beneficial transactions (citing TIMOTHY STOLTZFUS JOST & SHARON L. DAVIES, THE LAW OF MEDICARE AND MEDICAID FRAUD AND ABUSE 95 (1998 ed. 1997)).

108. *See supra* notes 53-59, 82-93 and accompanying text (discussing reliance on referrals by e-commerce enterprises).

109. *See* JOST & DAVIES, *supra* note 96, at 114-15 n.1 (discussing addition of scienter requirement (citing Omnibus Reconciliation Act of 1980, Pub L. No. 96-499, 94 Stat. 2599 (1980) (codified at 42 U.S.C. § 1320a-7b(b)(1) & (2) (1994)))).

110. *See* The Omnibus Reconciliation Act of 1980, *supra* note 109 (creating liability for anyone who "knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate)").

and controversial because of the controversy surrounding the scienter element.[111] Courts currently are adjudicating two interrelated and controversial elements of the anti-kickback statute: first, whether an impermissible referral must be a "substantial purpose" of a transaction,[112] and second, the meaning of the "knowing and willful" scienter standard.[113]

C. Judicial Expansion of Liability

1. United States v. Greber *and the "One Purpose" Test*

The most significant judicial development in health care fraud is the Third Circuit's promulgation of the "one purpose" test in *United States v. Greber*,[114] wherein the court greatly expanded liability under the anti-kickback statute.[115] In *Greber*, the Third Circuit considered whether payments made to a physician as "interpretation fees" in connection with clinical tests could serve as a basis for Medicare fraud.[116] The defendant, a cardiologist named Dr. Alvin Greber, ran his own business that provided physicians with diagnostic services, including heart monitors.[117] Dr. Greber's payment practices entailed billing Medicare for heart monitors and subsequently forwarding forty percent of any Medicare reimbursement to the referring physician as an "interpretation fee."[118] At issue on appeal was the trial court's jury instruction, stating that even though the referring physician might interpret the results as a consultant, this consulting was immaterial when "a purpose" of the fee was to induce a referral.[119] In opposition to this reading, Dr. Greber claimed that the jury could find a violation only if he rendered a fee *solely* to induce a referral.[120] Evaluating Congress's intent, the Third Circuit agreed with the trial court's instruction and reasoned that "remuneration" covers not only

111. *See* JOST & DAVIES, *supra* note 96, at 82 (noting that while statute's goal of stopping overutilization appears uncontroversial, in practice statute creates enormous controversy); Killgore, *supra* note 19, at 1244-45 (asserting that anti-kickback statute has been controversial since its creation, and that even seasoned health care attorneys find the statute and its subsequent "clarifications" very confusing).

112. *See infra* Part III.C.1 (discussing "one purpose" test).

113. *See infra* Part III.C.2 (discussing scienter element).

114. 760 F.2d 68 (3d Cir. 1985).

115. *See* United States v. Greber, 760 F.2d 68, 69 (3d Cir. 1985) (establishing violation of anti-kickback statute if one purpose of payment is to induce referrals); *see also* United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998) (adopting "one purpose test"); United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989) (same).

116. *Greber*, 760 F.2d at 70.

117. *See id.* at 69-70 (describing nature of Dr. Greber's diagnostic services business).

118. *Id.* at 70.

119. *Id.* at 71.

120. *Id.*

sums for which a physician performs no actual service, but also amounts for which a physician expends some professional effort.[121] Consequently, the court held that "[I]f *one purpose* of the payment was to induce future referrals, the medicare [sic] statute has been violated."[122]

In *United States v. McClatchey*,[123] the Tenth Circuit reaffirmed the viability of *Greber*'s "one purpose" test.[124] The *McClatchey* court recognized the reality of the defendant's argument 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 patients."[125] However, the court validated the district court's instruction, finding that a "hospital or individual 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."[126] Failing to elaborate on the distinction between "hoping" and "intending," the court created a game of semantics for attorneys to contest.[127]

Although the "one purpose" test is the prevailing standard, in *United States v. Bay State Ambulance and Hospital Rental Service, Inc.*,[128] the First Circuit questioned the doctrine.[129] In *Bay State*, the court of appeals approved

121. *Id.*

122. *Id.* at 69 (emphasis added).

123. 217 F.3d 823 (10th Cir. 2000).

124. *See* United States v. McClatchey, 217 F.3d 823, 835 (10th Cir. 2000) (following "sound reasoning" of *Greber* and holding that one purpose of offer or payment for referral sufficient for conviction). In *McClatchey*, the Tenth Circuit considered the validity of a trial court's jury instruction resulting in conviction of a hospital executive. *Id.* at 826. The defendant took exception to the trial court's instruction that the jury could convict "if remuneration was paid 'at least in part' to induce patient referrals." *Id.* McClatchey, the Chief Operating Officer of Baptist Medical Center, was integral in completing and renewing contracts with physicians who owned a specialized practice that treated nursing home patients. *Id.* at 827. The arrangement gave the two physicians $75,000 each per year and titles as Co-Directors of Gerontology in return for the referral of patients requiring hospitalization. *Id.* The court reasoned that the trial court's distinction between a collateral hope for referrals and an intent to induce referrals was sufficient to protect McClatchey's rights. *Id.* at 834-35. Consequently, the court upheld McClatchey's conviction, finding that an individual violates the anti-kickback statute "so long as one purpose of the offer or payment is to induce Medicare or Medicaid patient referrals." *Id.* at 835.

125. *Id.* at 834.

126. *Id.* The court addressed the problematic issues of proof that the "one purpose" standard creates and concluded simply that this is the "role which our system of justice assigns to the finder of fact." *Id.* at 834 n.7.

127. *See id.* at 834 n.7 (recognizing problematic issues of proof that "one purpose" standard creates but leaving resolution to finder of fact).

128. 874 F.2d 20 (1st Cir. 1989).

129. *See* United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 29-30 (1st Cir. 1989) (approving jury instruction allowing conviction only if improper motiva-

a jury instruction that required that the improper purpose motivating a transaction be the "primary purpose" for making payments.[130] Although *Bay State* supports the "primary purpose" test, the opinion is disjointed.[131] After accepting the primary purpose test, the court referred to the reasoning of *Greber* as "impressive," leaving the vitality of the "primary purpose" jury instruction in question.[132] In addition to disagreeing about the validity of the one purpose test, courts and scholars continue to debate the meaning of the statute's "willful" and "knowing" requirement.[133]

2. *Scienter Standard*

Critics of the anti-kickback statute continually have argued that despite administrative attempts to clarify the bounds of liability,[134] regulators cannot reasonably expect health care providers to know when the industry's complex transactions will violate the statute's provisions.[135] This concern about the statute's ambiguity forms the basis for the argument over whether the scienter element requires specific knowledge of an arrangement's illegality.[136] In *Hanlester Network v. Shalala*,[137] the Ninth Circuit Court of Appeals considered the level of intent required for a conviction under the "knowingly and

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tion was primary purpose of transaction). In *Bay State*, the First Circuit considered the validity of a jury instruction creating a "primary purpose" test for violation of the anti-kickback statute. *Id.* The facts indicated that Bay State Ambulance Company gave a hospital official two cars and seven checks in order to secure a city ambulance service contract. *Id.* at 26. In reviewing the jury instruction, the court of appeals concluded that it was not prejudicial error to provide the higher "primary purpose" standard for the government to convict the defendants. *Id.* at 30. However, the court did not "decide the exact reach of the statute," and stated that it was "impressed" by the reasoning of *Greber*. *Id.* at 29-30. The court ultimately held that the "primary purpose" jury instruction comported with congressional intent and affirmed the defendant's conviction. *Id.* at 30, 36.

130. *Id.* at 30.

131. *See supra* note 129 (noting court's juxtaposition of "primary purpose" test and approval of *Greber*'s reasoning).

132. *Id.* at 29-30.

133. *See infra* Part III.C.2 (addressing judicial interpretation of anti-kickback statute's scienter element).

134. *See infra* Part IV.A-B (discussing Office of Inspector General's attempts to clarify statute through fraud alerts and advisory opinions).

135. JOST & DAVIES, *supra* note 96, at 163; *see, e.g.*, *As Health Systems Step into the Web World, They Stumble on Unexpected Legal Pitfalls*, *supra* note 4, at 2S1 (criticizing absence of guidance by OIG regarding Internet health care transactions); James F. Blumstein, *Rationalizing the Fraud and Abuse Statute*, HEALTH AFF., Winter 1996, at 118, 122 (lambasting present regulatory scheme's ambiguity); David S. Krakoff & Matthew C. Holloran, *The Accidental Kickback*, LEGAL TIMES, Sept. 15, 1997, at S50 (discussing danger of accidental violation).

136. *See* JOST & DAVIES, *supra* note 96, at 163-64 (explaining that due to statute's ambiguity critics seek increased level of intent to avoid accidental violation).

137. 51 F.3d 1390 (9th Cir. 1995).

willfully" scienter standard.[138] The defendant, Hanlester Network (Hanlester), was a general partnership of physician joint venture laboratories.[139] Hanlester and its affiliated labs entered into agreements with Smithkline Bioscience Laboratories (SKBL), whereby SKBL agreed to provide management services in return for a percentage of each lab's profits.[140] In accordance with the agreements, SKBL performed eighty-five to ninety percent of the tests ordered by physicians at the Hanlester labs.[141] The defendants, general partners of the Hanlester network, argued that they could not possess the appropriate level of intent because the interpretation of the statute was "highly debatable."[142] The Ninth Circuit rejected the defendant's approach but concluded that the "knowingly and willfully" language required the defendants to "(1) know that [the anti-kickback statute] prohibits offering or paying remuneration to induce referrals, and (2) engage in prohibited conduct with the specific intent to disobey the law."[143] Ultimately, the court found that the individual defendants did not posses the requisite intent, and it reversed the trial court's grant of summary judgment for the government.[144] This decision marked a significant victory for the health care industry.[145] Under the *Hanlester* framework, a defendant who has a good faith but mistaken belief that a business arrangement is proper, or who is ignorant of the law, is not guilty of an anti-kickback violation.[146] Having considered the prominent role of the OIG in interpreting the anti-kickback statute[147] and the importance of telemedicine technology

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138. *See* Hanlester Network v. Shalala, 51 F.3d 1390, 1399-1401 (9th Cir. 1995) (evaluating meaning of "knowing and willful" action).

139. *See id.* at 1394-95 (describing composition and structure of partnership).

140. *See id.* at 1395 (discussing elements of management services arrangement).

141. *Id.*

142. *See id.* at 1399 (arguing that liability cannot flow from statutes with highly debatable interpretations (citing United States v. Dahlstrom, 713 F.2d 1423, 1427 (9th Cir. 1983))). In *Dahlstrom*, the Ninth Circuit found that the defendant could not willingly violate a complex Internal Revenue Service regulation, the interpretation of which was open to debate. *Dahlstrom*, 713 F.2d at 1427-28. The *Hanlester* court rejected the defendants' reliance on *Dahlstrom*, finding the complicated tax regulations of *Dahlstrom* distinguishable from the complexity presented by the anti-kickback statute. *Hanlester*, 51 F.3d at 1399.

143. *Id.* at 1400.

144. *See id.* at 1402 (finding no personal liability and reversing HHS's imposition of sanctions).

145. *See* JOST & DAVIES, *supra* note 96, at 164 (noting significance of ruling in *Hanlester*). *But see* United States v. Davis, 132 F.3d 1092, 1094 (5th Cir. 1998) (construing *Hanlester* closely). In *Davis*, the Fifth Circuit read *Hanlester* narrowly to conclude that the prosecution need not prove the defendant knew of the particular statute that criminalized his action; it need only prove that the defendant knew the conduct was generally unlawful.

146. *See* Krakoff & Holloran, *supra* note 135, at S50, S53 (commenting on absence of liability for mistaken belief or ignorance under *Hanlester*).

147. *See supra* note 101-02 and accompanying text (describing breadth of OIG's discretion in interpreting anti-kickback statute).

grants,[148] it is appropriate to consider their convergence in the OIG's pronouncements regarding the provision of discounted technology.[149]

IV. Anti-Kickback Statute's Obsolescence

A. Special Fraud Alerts and Correspondence

The anti-kickback statute is an antiquated law that is not suited for regulation of the digital economy.[150] Consequently, health care regulators generally have taken a dim view of transactions proposing the transfer of subsidized technology to physicians in return for patient referrals.[151] The final rule adopting the anti-kickback safe harbor provisions of 1991 comments on the practice of providing free computers to physicians.[152] The preamble to the regulations draws a distinction between machines that physicians can use only for a specific purpose and those that physicians may use to perform numerous tasks, such as personal computers.[153] The preamble suggests that the latter "may well constitute an illegal inducement."[154] Accordingly, to avoid liability under the anti-kickback statute, technology providers must develop a method for limiting the equipment so that physicians may use it in a circumscribed manner relating to the relationship.[155]

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148. *See supra* Part II (describing value of telemedicine and need for subsidized technology).

149. *See infra* Part IV (discussing OIG's stance towards technology grants).

150. *See* John Bentivoglio, *Unleash the Internet: Outdated Laws and Regulations Are Holding Back Advances in E-Health Ventures*, MODERN HEALTHCARE, Nov. 6, 2000, at 76 (arguing that current anti-kickback statute is outdated and criminalizes many e-health ventures that pose little risk of abuse); Fried et al., *supra* note 22, at 129 (discussing need for modernization of anti-kickback statute to meet challenges of e-health).

151. *See infra* notes 152-75 and accompanying text (discussing HHS's stance against telemedicine relationships involving discounted technology).

152. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,978 (July 29, 1991) (codified at 42 C.F.R. pt. 1001 (1999)). The preamble states:

> In some cases the computer can only be used as part of a particular service that is being provided, for example, printing out the results of laboratory tests. In this situation, it appears that the computer has no independent value apart from the service being provided and that the purpose of the free computer is not to induce an act prohibited by the statute. . . . In contrast, sometimes the computer that is given away is a regular personal computer, which the physician is free to use for a variety of purposes in addition to receiving test results. In that situation the computer has a definite value to the physician, and, depending on the circumstances, may well constitute an illegal inducement.

Id.

153. *See id.* (distinguishing legality of providing free computers by level of versatility).

154. *Id.*

155. *See* 42 C.F.R. § 1001.952 (h)(1999) (including discounts within safe harbor).

In its 1994 publication, *Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services*, HHS commented that "whenever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business."[156] Additionally, the alert describes situations leading to impermissible arrangements between labs and physicians that implicate the anti-kickback statute.[157] Prohibited arrangements include the provision of computers or fax machines, unless the physician uses such equipment exclusively for the performance of the outside laboratory's work.[158] The OIG also has addressed the issue of discounted technology through two letters, dated July 1, 1997[159] and July 3, 1997.[160] The correspondence comments that parties may be able to craft free technology transfers in a way that avoids sanction under the anti-kickback statute, but that such arrangements frequently are "shams" and are "generally disfavored."[161] Fraud alerts and published correspondence may serve to afford health care providers insight into HHS's priorities and interpretations; however, parties must request a formal advisory opinion from the OIG to secure overt approval of a contemplated transaction.[162]

B. Advisory Opinions

1. Substantive Treatment of Telemedicine

Congress recognized the need for clarification of the anti-kickback statute. Consequently, as part of the Health Insurance Portability and Accountability Act of 1996 (HIPPA), it required HHS to issue prospective advisory opinions to individuals contemplating transactions that might violate the

156. Special Fraud Alert: Arrangements for the Provision of Clinical Lab Services, 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994).

157. *See id.* (discussing provision of free computers).

158. *Id.*

159. *See* Op. Letter, Off. Inspector Gen., HHS (July 1, 1997) (stating that provision of free fax machines could potentially violate statute unless use is restricted), *at* http://oig.hhs.gov/ak/provision070197.htm.

160. *See* Op. Letter, Off. Inspector Gen., HHS (July 3, 1997) (warning that OIG will examine substance of arrangement over form and that it will hold technology provider liable for any "reasonably foreseeable 'misuse' of loaner computer and dedicated fax line), *at* http://oig.hhs.gov/ak/freecomputers.htm. The letter also notes that agreements providing that the user will not employ the technology for an improper purpose are not sufficient to preclude liability. *Id.*

161. *See id.* (commenting that OIG will view all free technology arrangements "with skepticism").

162. *See* JOST & DAVIES, *supra* note 96, at 178 (discussing special fraud alerts); *id.* at 200-205 (describing advisory opinion process).

statute.[163] Two OIG advisory opinions deal specifically with telemedicine.[164] Advisory Opinion 98-18 discusses the exchange of equipment that allows an optometrist to consult with an ophthalmologist at a distant location.[165] In the opinion, the OIG allowed the proposed arrangement after considering the parties' intent to pay fair market value for the equipment rental and the physician's agreement not to advertise the availability of the technology.[166] Under the circumstances, the OIG concluded that the arrangement limited the potential for abuse.[167] However, one should read the language carefully. The opinion does not state that these arrangements are permissible.[168] Rather, it concludes that the OIG will not impose liability in the instant case, even though the arrangement may technically violate the statute.[169] Advisory Opinion 99-14 concerns technology that permits rural physicians to consult with specialists in a metropolitan area.[170] The opinion comments that there is a presumption against the distribution of free technology, but states that in the case at hand the OIG will not impose sanctions.[171] The opinion provides a number of reasons for the decision, including a clear congressional intent to favor the program, an enforcement mechanism in place to regulate the relationship, and the significant potential public benefit from the technol-

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163. Health Insurance Portability and Accountability Act of 1996 (HIPPA), Pub. L. No. 104-191, § 205, 110 Stat. 1936, 2000-03 (1996) (codified as amended at 42 U.S.C. § 1320a-7d (Supp. V 1999)).

164. *See* Advisory Op., Off. Inspector Gen., HHS No. 98-18 (Nov. 25, 1998) [hereinafter Advisory Op. 98-18] (discussing arrangement in which ophthalmologist rented equipment to optometrist to facilitate telemedicine consultation), *at* http://oig.hhs.gov/advopn/1998/ao98_18.htm; Advisory Op., Off. Inspector Gen., HHS No. 99-14 (Dec. 28, 1999) [hereinafter Advisory Op. 99-14] (evaluating propriety of proposed telemedicine grant to rural community), *at* http://oig.hhs.gov/advopn/1999/ao99_14.htm.

165. *See* Advisory Op. 98-18, *supra* note 164 (evaluating likelihood that proposed arrangement would result in improper referrals in exchange for remuneration).

166. *See id.* (finding that agreement not to advertise technology reduced likelihood of abuse and concluding that payment of fair market value for lease negated fraudulent intent). This is an example of a case in which the regulatory scheme rejects common sense. If hypothetical optometrist *A*'s arrangement were publicized, presumably patients from competitors, optometrists *B* and *C*, would seek the services of optometrist *A*, who has the telemedicine arrangement. Optometrist *A*'s arrangement would force optometrists *B* and *C* to seek similar arrangements, increasing the quality of eye care for all of the community's citizens.

167. *See id.* (concluding that safeguards lowered potential for abuse to acceptable level).

168. *See id.* (stating that "arrangement may constitute prohibited remuneration").

169. *See id.* (concluding that "although the telemedicine consultation arrangement may constitute prohibited remuneration under the anti-kickback statute if the requisite intent is present, the OIG will not subject it to sanctions arising under the anti-kickback statute").

170. *See* Advisory Op. 99-14, *supra* note 164 (considering whether hospital's provision of technology grants to rural hospitals constitutes anti-kickback violation).

171. *See id.* (concluding "the Arrangement . . . could potentially involve prohibited remuneration . . . however, the Office of Inspector General ('OIG') will not impose sanctions").

ogy.[172] Advisory Opinion 99-14 is particularly concerned with the benefit to the community at large.[173] Policymakers should codify this position so that individuals may rely on it when structuring their transactions.[174] One positive feature of the advisory opinion process is the OIG's willingness to consider the relevance of whether the contemplated transaction will increase costs to federal health care programs.[175]

2. *Structural Shortcomings*

As noted in Part III, the scienter standard and purpose required to violate the anti-kickback statute are murky.[176] Nevertheless, representatives of the OIG have argued that in light of the advisory opinion process, "[i]ndividual providers need not guess anymore whether their business arrangements will be subject to applicable sanctions [and that] . . . the industry as a whole benefits from the reasoning contained in the opinions."[177] Notwithstanding the OIG's confidence in the efficacy of the advisory opinion process, the experiences of many transactional attorneys in the health care field do not support these broad claims.[178] It is an infrequent occurrence when an OIG advisory

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172. *See id.* (listing congressional intent to foster arrangements, enforcement mechanisms, limited remuneration, and significant potential community benefit as factors mitigating against imposing liability).

173. *See id.* (favoring potential health benefits to rural community accruing from proposed arrangement).

174. *See infra* Part VI.A (proposing requirement that government prove increase in cost to federal health care program for conviction under anti-kickback statute).

175. *See* Twardy & Shea, *supra* note 15, at 21 ("[T]he agency has said in many cases that although the statute applies, it should not be enforced because the proposed arrangement would not increase costs to federal health-care programs.").

176. *See supra* notes 114-49 and accompanying text (discussing debate over appropriate level of intent); *see also* JOST & DAVIES, *supra* note 96, at 101 (describing mens rea element as murky).

177. Lewis Morris & Gary W. Thompson, *Reflections on the Government's Stick and Carrot Approach to Fighting Health Care Fraud*, 51 ALA. L. REV. 319, 351 (1999). The authors of the preceding article, Lewis Morris and Gary W. Thompson, play important roles for the OIG. *Id.* at 319. Morris serves as the Assistant Inspector General for Legal Affairs within the OIG. *Id.* His responsibilities include coordinating the OIG's role in investigation and resolution of health care fraud cases. *Id.* Thompson is the Associate Counsel in the Civil Recoveries Branch, Office of Counsel to the Inspector General, HHS. *Id.* Thompson's duties include representing the OIG in resolution of civil health care fraud matters. *Id.* Given the authors' stake in the discussion, one should examine critically their blanket statement concerning the value of the advisory opinion process.

178. *See As Health Systems Step into the Web World, They Stumble on Unexpected Legal Pitfalls*, *supra* note 4, at 2S1 (criticizing lack of guidance from OIG concerning Internet transactions); Blumstein, *supra* note 135, at 127-28 (asserting that HHS guidance is of limited value because it does not constitute legal precedent); Retta M. Riordan, *Will New Guidance Mechanisms Provide Needed Clarifications to Industry Under Medicare/Medicaid Anti-Kickback*

opinion actually states that a given arrangement does not violate the statute.[179] The typical language states that an arrangement "potentially implicates" the statute, but under the facts of the case at hand, sanctions will not follow.[180] In fact, the OIG issues on average sixteen opinions per year, making the likelihood of securing a response to a specific question low.[181] These opinions bind only the parties that request them.[182] Consequently, an individual who is not a party to an opinion should rely on a previous opinion only as possible guidance.[183]

In addition to the failure to resolve the statute's ambiguity, concerns regarding the severity of punishment and significant costs further limit the value of the advisory opinion process.[184] Considering the requirement that the requesting party disclose "all relevant facts" to the OIG and the existence of severe criminal penalties, many health care entities are likely to decline to present candid information to the agency, fearing that the OIG will use the information against them in a later proceeding.[185] Even if the Fifth Amendment would bar this evidence from a criminal prosecution, no shield exists to protect individuals and entities from the potentially devastating administrative remedies available to the OIG.[186] In light of the aggressive regulatory environ-

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Statute?, 1 Health Care Fraud Rep. (BNA) 133, 133 (Feb. 26, 1997) (questioning ability of advisory opinions to clarify statute).

179. *See supra* note 169 and accompanying text (providing example of OIG's noncommittal language).

180. *Id.*

181. *See* http://oig.hhs.gov/fraud/advisoryopinions/opinions.html (last visited Mar. 25, 2002) (listing advisory opinions). The OIG issued nineteen advisory opinions in 1998, fourteen in 1999, eleven in 2000, and twenty-one in 2001 resulting in an average of 16.25 advisory opinions for all years in which the statute was in effect for the entire year. *Id.*

182. *See* JOST & DAVIES, *supra* note 96, at 205 (explaining that advisory opinions are instructive but not binding upon nonparties).

183. *Id.*

184. *See infra* note 193 and accompanying text (discussing potential use of request by prosecution and prohibitive cost).

185. *See* Morris & Thompson, *supra* note 177, at 351 ("To receive substantive guidance, parties are required to submit detailed descriptions of their arrangements, including operating and financial documents." (citing 42 C.F.R. § 1008.31 (1998), *as amended in* 63 Fed. Reg. 38,311, 38,312 (1998))); *see also* Killgore, *supra* note 19, at 1229 (noting that many health care providers are reluctant to give OIG candid disclosure due to agency's ability to use reported information in later civil, criminal, or administrative action (citing Robert S. Ryland, *HHS OIG Advisory Opinion Process: Better Than Voluntary Disclosure*, 4 BUS. CRIM. BULL.: COMPL. & LITIG. 1, 3-4 (1997))). One should note that DOJ actually prosecutes criminal cases, whereas the OIG pursues administrative and civil remedies. *See* JOST & DAVIES, *supra* note 96, at 3-4 (describing division of enforcement responsibilities). For convenience, this Note refers to the OIG as "prosecuting" because it typically conducts investigations and makes initial determinations of legality before transmitting findings to the DOJ. *Id.*

186. *See* JOST & DAVIES, *supra* note 96, at 103-04 (describing administrative exclusion power); *see also* U.S. CONST. amend. V (extending privilege from self-incrimination only to criminal prosecution).

ment, clients are now more likely to request opinion letters from legal counsel.[187] The theory motivating clients to seek opinion letters is that at trial, an individual under indictment could use the letters in an "advice of counsel" defense to counter the government's proof of intent.[188] Ironically, health care attorneys are now less likely to render the unequivocal advice clients seek because of the heightened enforcement of the anti-kickback statute.[189] Consequently, attorneys bill clients to compose thirty-page vacillating opinion letters advising, "This transaction should be fine, but it might come under the ambit of the statute, although I don't think it does - but it might."[190] Moreover, should clients seek to use an opinion letter to defend themselves at trial, the prosecution likely would turn the document around and use the advice about the potential for violation as evidence of "knowledge."[191] An additional problem with the advisory opinion process is the cost a client incurs to collect all of the relevant documents and to compose a request.[192] Consequently, small health care providers such as individual physicians may be unable to pay the costs and attorneys fees for such a request.[193] Thus, the OIG opinions are of questionable value to the e-health community. The complexity of the statute, its overbroad language, and its low general intent standard deter a number of socially beneficial transactions that are foregone due to confusion about the bounds of legal action.[194] Thus, the anti-kickback statute creates

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187. *See* JOST & DAVIES, *supra* note 96, at 178 (stating that increased governmental scrutiny of transactions makes clients likely to seek more definite advice).

188. *See id.* at 174-78 (discussing advice of counsel defense).

189. *See* United States v. Anderson, 85 F. Supp. 2d 1047, 1052 (D. Kan. 1999), *rev'd sub nom. on other grounds*, United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000) (prosecuting health care attorneys for structuring transactions violating anti-kickback violation); JOST & DAVIES, *supra* note 96, at 178 n.21 (advising, in aftermath of *Anderson*, that "health care lawyers examine the bounds of their own potential liability like they never have done before" (citing W. Bradley Tully, *Attorney Liability Under the Fraud and Abuse Laws: Managing Risk by Managing the Client Relationship*, HEALTH LAW, July 1999, at 17)).

190. *See Health Law Symposium*, *supra* note 13, at 444 (noting that given transaction "might or might not" come within statute and concluding that statute's scope is often difficult to predict due to its vagueness).

191. *See* Twardy & Shea, *supra* note 15, at 22 (concluding that if client consults attorney about statute, he or she already knows of its existence, thereby foreclosing defense that client did not act "knowingly and willfully").

192. *See* Killgore, *supra* note 19, at 1229 (noting that requesting an advisory opinion is structured, time consuming, and expensive (citing JOST & DAVIES, *supra* note 96, at 159-61)).

193. *See* Norris, *supra* note 28, at 139 (discussing limited budgets of small health care providers).

194. *See* Killgore, *supra* note 19, at 1216 n.12, 1223 n.54 (stating that laws governing health care relationships prohibit many relationships, investments, and marketing practices that are legal in other businesses (quoting BARRY R. FURROW ET AL., *supra* note 19, at 574) and raising critics' claims that statute is incomprehensible and harmful to innovative alliances beneficial to care health consumers).

problems of economic inefficiency.[195]

V. Economic Analysis

The concept of optimal criminal sanctions suggests that policymakers should construct criminal laws to impose a sanction severe enough to make the punishment more costly than the benefit derived by committing the crime.[196] However, if the level of punishment is set too high for the offense and if there is the chance of accidental conviction, the statute will deter risk-adverse individuals from engaging in socially beneficial transactions.[197] The problem becomes acute as the offense proceeds toward the possibility of accidental conviction.[198] This lack of clarity is a problem for even the most sophisticated health care attorneys who attempt to advise their clients about arrangements implicating the anti-kickback statute.[199] Moreover, federal circuit courts have not agreed upon whether there is a "one purpose" test or what the standard of intent is for anti-kickback violations.[200] Therefore, many scholars and practitioners agree that much ambiguity and confusion surrounds the question of legality of health care transactions.[201] The scienter requirements of the statute, which require knowing and willful action to commit a violation, supposedly overcome this problem, but really have only muddied the waters.[202] The combination of the statute's ambiguity and threat of harsh

195. *See* Blumstein, *supra* note 135, at 120 (commenting that anti-kickback statute criminalizes "practices that encourage cost-effective care . . . and the development of efficient relationships among providers").

196. POSNER, *supra* note 11, at 242.

197. *Id.* at 243-44; *see* Morris & Thompson, *supra* note 177, at 350-51 (asserting that in complex regulatory environment, ambiguity harms the honest, risk-adverse businessperson and encourages reckless and unscrupulous individuals).

198. POSNER, *supra* note 11, 259 ("[B]ecause criminal sanctions are severe, to attach them to accidental conduct (and *a fortiori* to unavoidable conduct) creates incentives to steer clear of what may be a very broad zone of perfectly lawful activity in order to avoid the risk of criminal punishment."); *see* Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 ALA. L. REV. 239, 295 n.287 (1999) (applying Posner's analysis to health care context).

199. *See supra* note 189 and accompanying text (discussing inability of experienced health care attorneys to predict legality of transactions).

200. *See supra* Part III.C (discussing competing interpretations of scienter).

201. *See supra* note 107 and accompanying text (discussing a number of sources finding that anti-kickback statute inhibits beneficial transactions); Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the OIG Safe Harbor Anti-Kickback Provisions 59 Fed. Reg. 37,202, 37,203 (July 21, 1994) (codified at 42 C.F.R. pt. 1001) (recording OIG's admission that statute and regulations can be ambiguous and confusing).

202. *See* JOST & DAVIES, *supra* note 96, at 101 (characterizing state of scienter element as "murky").

criminal penalties proves that the anti-kickback statute deters activity at the margins of legality, such as e-health ventures based on referral models.

The regulatory framework prohibits common economic arrangements and inhibits e-health innovation disproportionately.[203] As developed in the case of the hypothetical physician's Web site, a hospital's provision to physicians of free Web sites with the hospital's logo on the home page may be an impermissible kickback.[204] The hospital's liability for engaging in the transaction rests upon whether the hospital had the requisite intent to induce referrals.[205] Without the intent to induce referrals, the logo on the Web page is merely marketing.[206] Unfortunately, the distinction between inducing referrals and merely marketing is, at best, very fine.[207] This uncertainty leads to the perceived necessity of securing extensive opinion letters from counsel and of requesting advisory opinions from the OIG, wasting hundreds of millions of dollars wasted each year in pursuit of elusive certainty about the legality of health care transactions.[208] Moreover, it results in a significant loss of revenue from foregone transactions.[209]

VI. Proposed Solutions

Although courts have relied upon numerous policy arguments to support convictions under the anti-kickback statute,[210] two primary justifications for

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203. *See* Fried et al., *supra* note 22, at 128-29 ("Business arrangements and transactions that are structurally sound from a business perspective frequently implicate (and occasionally violate) the principal federal laws designed to prevent and deter fraud and abuse within Medicare, Medicaid, and other federally funded health care programs.").

204. *See supra* notes 82-93 and accompanying text (discussing potential liability for physician Web page partnered with hospital or pharmaceutical company).

205. *See supra* Part III.C (discussing unsettled scienter requirement).

206. *See* Fried, *supra* note 9, at 36 (commenting on fine distinction between intent to induce referrals and intent to market hospital).

207. *Id.*

208. *See* Twardy & Shea, *supra* note 15, at 21 (commenting on statute's imposition of expensive monitoring and transaction costs on health-care clients).

209. *See supra* note 194 (discussing result of lost revenue through rejection of strategic business relationships implicating statute).

210. *See* United States v. Ruttenberg, 625 F.2d 173, 177 (7th Cir. 1980) (concluding that increased cost to federal health care program is irrelevant in light of alternative policies served by statute). The *Ruttenberg* Court stated the following:

> Though we are concerned with the law, not the ethics of the medical profession, United States v. Porter, 591 F.2d [1048, 1058 (5th Cir. 1979)], it should be noted that the law does not make increased cost to the government the sole criterion of corruption. In prohibiting "kickbacks," Congress need not have spelled out the obvious truisms that, while unnecessary expenditure of money earned and contributed by taxpaying fellow citizens may exacerbate the result of the crime, kickback

the government's enforcement of the statute are reduction of health care cost[211] and prevention of harm to patients.[212] If a proposed transaction violates neither of the above policies, it seems logical that the imposition of liability for kickback arrangements is inappropriate.[213]

A. Legislative Preemption of "One Purpose" Test

As unworkable as the anti-kickback statute may be in practice, the judicially created "one purpose" doctrine of *Greber* is particularly problematic.[214] Either Congress or HHS should eliminate this illogical doctrine from the law. The reality of capitalism is that businesspeople react to the dynamics of the free market, including competition.[215] If consumers demand electronic interaction with their physicians, market participants will create surreptitious referral arrangements.[216] The concept of goodwill is fundamental to capitalism and the anti-kickback statute is wrong to ignore it.[217] It would be more

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> schemes can freeze competing suppliers from the system, can mask the possibility of government price reductions, can misdirect program funds, and, when proportional, can erect strong temptations to order more drugs and supplies than needed. Nor need Congress have spelled out duties, beyond the duty of avoiding receipt and payment of kickbacks.

Id. at 177 n.9.

211. *See* Williams, *supra* note 16, at 295 (stating that kickbacks may impede physicians' judgment, leading to increased cost and harm to patients). Williams points to increased cost as the primary motivation for government prosecution of health care fraud. *Id.* at 296. However, he notes a number of anti-kickback convictions in which the government introduced no evidence of increased cost to Medicare. *Id.* at 296 n.41 (citing Bay State Ambulance & Hosp. Rental Serv., 874 F.2d 20, 25-27 (1st Cir. 1989); United States v. Ruttenberg, 625 F.2d 173, 177 (7th Cir. 1980); United States v. Denton, No. 90-55-Cr-T-17 (M.D. Fla. May 30, 1990); Andrew Grosso, *Medical Necessity and the Medicare and Medicaid Anti-Kickback Statute*, 40 FED. B. NEWS & J. 301, 303 (June 1993)).

212. *See* Williams, *supra* note 16, at 295 (suggesting that kickbacks may harm patients by diminishing quality of medical services).

213. *See* Jakobsen, *supra* note 35, at 169 (suggesting that telemedicine cuts costs by allowing providers to diagnose and treat illness earlier, rather than in later stages when treatment is more expensive (citing Vybomy, *supra* note 7, at 63)).

214. *See infra* notes 217-21 and accompanying text (discussing nature of "goodwill" and free market's impact on medical community).

215. *See supra* note 18 (asserting that regulatory prohibitions notwithstanding, as a practical matter, health care industry creates referral arrangements (citing *Health Law Symposium*, *supra* note 13, at 444)). For example: A hospital might provide a Web site and support to "cultivate the goodwill of the physician." What may in fact be occurring is an unstated understanding that the hospital will maintain the Web site as long as the flow of inpatient referrals continues.

216. *See supra* note 18 (discussing realities of medical practice).

217. *See* STANLEY SIEGEL & DAVID A. SIEGEL, ACCOUNTING AND FINANCIAL DISCLOSURE: A GUIDE TO BASIC CONCEPTS 70-71 (1983) (describing concept of "goodwill" in business valuation). From a business perspective, goodwill is the additional value of a venture in excess

realistic for Congress to implement a balancing test requiring the government to prove either increased cost or actual harm to a patient.[218] If the social utility – that is, efficiency increase – from *any purpose* of the transaction outweighs the cost of potential over-utilization of Medicare by referrals, the possible formula could provide that the transaction should not give rise to liability.[219] Should a physician and hospital create a system that reduces Medicare costs while both the physician and hospital increase their revenues, they would have achieved a positive result.[220] Eliminating one hundred percent of an actor's motivations in making referrals is impossible, and it rejects fundamental concepts of capitalism.[221]

B. Discounted Technology Safe Harbor

Congress has vested the HHS with the responsibility to regulate the application of the anti-kickback statute and granted it the authority to protect

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of its total individual assets reflecting its extra earning power. *Id.* at 70. Name recognition resulting from past advertising, customer loyalty, quality of service, efficient management, and established relationships with vendors or suppliers may all contribute to an entity's goodwill. *Id.* at 70-71. A hypothetical example of the value of goodwill in the medical community helps to illuminate the anti-kickback statute's fallacious assumption that goodwill does not exist in medicine. Suppose cardiologists *A* and *B* both hold staff privileges at hospital *X* in a city with competing hospitals. Over a ten-year period, *A* refers a large stream of patients to hospital *X*, generating significant profits for the hospital. During the same period, *B* refers some of his patients to hospital *X* but also refers a number to the hospital's competitors *Y* and *Z*. In year ten, the lucrative and prestigious position of Chief of Cardiology becomes vacant. Assuming that physicians *A* and *B* have identical credentials, given the goodwill that *A* has created from the previous referrals, it is logical that *A* will receive the nod for the position, even though the action technically violates the anti-kickback statute. Of course, well-counseled hospital administrators will not record this motive in the corporate minutes, and it will be almost impossible to prosecute. One scholar has analogized the current regulatory climate to that of a speakeasy, "where sipping sherry is winked at and only loud and obnoxious drunks are prosecuted." Tamsen Douglass Love, Note, *Toward a Fair and Practical Definition of "Willfully" in the Medicare/Medicaid Anti-Kickback Statute*, 50 VAND. L. REV. 1029, 1043 (1997) (citing Blumstein, *supra* note 135, at 218).

218. *See* Williams, *supra* note 16, at 308 (labeling prosecution of health care provider when he has caused no harm as inequitable and proposing requirement of harm).

219. *See id.* (proposing economic balancing test).

220. *See supra* notes 211-12 and accompanying text (noting statute's goal of improving patient care and reducing costs).

221. *See* Krakoff & Holloran, *supra* note 135, at S50. Krakoff and Holloran assert the following:

> In many contexts, the government will have little difficulty proving directly or circumstantially that a business arrangement had, at least one purpose, the intention to induce future business. Individuals and companies enter into business arrangements for a multitude of reasons. Rarely are these arrangements made where the parties do not have some thought of doing future business or where they do not expect to obtain a benefit from the arrangement.

Id.

certain arrangements through the promulgation of safe harbors.[222] HHS's charge includes updating the statute periodically to reflect changing business practices and technologies in the health care industry.[223] The promulgation of new safe harbors does not solve the overbroad and imprecise nature of the anti-kickback statute. However, industry groups should lobby HHS for regulations favorable to developing technology as a temporary solution until policymakers revise the statute itself.[224]

The health care industry should urge HHS to recognize that the provision of free or substantially discounted hardware presents little threat of abuse under the statute.[225] By considering a cost-benefit approach, policymakers will save many more Medicare dollars by the efficient use of electronic patient records, transmission of data images from laboratories, and development of new technologies, with the cost of the innovation borne wholly by the private sector.[226] Industry trade groups should lobby HHS to seek comments in the Federal Register about potential transactions that present little chance of abuse because under the current rules, "[m]any entities are offering providers 'free' Web sites .... While the initial development of [ ] Web site[s] may require only a minimal capital outlay on the part of the entity, the government would still likely view the provision and maintenance of [ ] Web site[s] as 'in kind' remuneration ...."[227]

C. Shift from Intent-Based Framework to Objective Standard

This Note identifies the flaws in the anti-kickback statute's design.[228] Congress drafted the statute broadly, and it has become a weapon of intimidation that forces individuals away from the gray areas of the law into only "safe transactions."[229] This result is hardly efficient. Policymakers should jettison

222. *See* JOST & DAVIES, *supra* note 96, at 124-25 (describing OIG's role in promulgating safe harbors).

223. *See* Medicare and Medicaid Patient and Program Protection Act of 1987 (MMPPPA), Pub. L. No. 100-93, § 2, 101 Stat. 680, 682 (codified at 42 U.S.C. § 1320a-7(b)(7) (1994)) (discussing OIG's responsibilities in promulgating safe harbors).

224. *See* Bentivoglio, *supra* note 150, at 76 (imploring health care and technology industries to lobby Congress for updated regulations).

225. *See supra* note 166 (presenting hypothetical arrangement illustrating positive results accruing from telemedicine).

226. *See supra* Part II.C (describing benefits of physician Web site with costs subsidized by advertisers).

227. Fried et al., *supra* note 22, at 129 (discussing government's probable negative response to provision of free Web site).

228. *See supra* notes 196-97 and accompanying text (discussing economic concept of optimal deterrence and attempt to encourage greatest number of socially beneficial transactions).

229. *See Health Law Symposium*, *supra* note 13, at 447 (suggesting that OIG employs intimidation tactics by prosecuting huge entities such as Columbia/HCA for activities that are

the intent-based muddle in favor of a clear law similar to the Stark self-referral statute[230] based on objective criteria for violation.[231] The value of an objective framework under the Stark regulations is that all players know clearly what is permissible, and although they may not agree with the regulations, it is clear which transactions they must avoid.[232] Of course, in contemplating this strict liability regime, lawmakers must draw lines.[233] It would do more harm than good merely to retain the current sweeping remuneration language and shift the proof standard for violation to strict liability.[234] Lawmakers should accompany the shift to an objective standard with a change back to the original language prohibiting "bribes and kickbacks."[235] The restricted nature of a reconstructed anti-kickback statute will not open wide the door to abuse because the government still will be able to target these abuses under a myriad of additional federal laws, including generic criminal, mail, and wire fraud[236] statutes and the False Claims Act.[237] The OIG also would retain the administrative authority to exclude providers from further participation in Medicare and Medicaid programs.[238]

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common in industry to "hold[ ] someone out as an example and beat[ ] them up in public to kind of scare everyone else off").

230. 42 U.S.C. § 1395nn (1994). *See generally* Albert Shay & Gary Francesconi, *Proposed Stark II Rules: Clarification or More Confusion?*, 31 J. HEALTH & HOSP. L. 95 (1998) (providing extensive discussion of Stark I and Stark II legislative history).

231. *See* JOST & DAVIES, *supra* note 96, at 219 (describing Stark's lack of intent required for violation, but accompanied by voluminous regulations describing exempt relationships).

232. *See* JOST & DAVIES, *supra* note 96, at 209 (describing clear-cut nature of whether violation exists).

233. *Id.* at 221-25 (discussing contours of Stark limits).

234. *See supra* Part III.C (discussing overbroad nature of current scienter elements).

235. *See supra* Part III.B (discussing anti-kickback statute's legislative history).

236. *See* Schofield & Weaver, *supra* note 12, at 620-22 (listing alternative bases for prosecution, including False Claims Act, False Statements Act, mail fraud, wire fraud, and generic fraud statutes). "The generic criminal fraud statutes include: 18 U.S.C. § 371 (1994) (conspiracy to defraud government), 18 U.S.C. § 1341 (1994) (mail fraud), 18 U.S.C. § 1343 (1994) (wire fraud), . . . , and 18 U.S.C. §§ 1961-1968 (1996) (RICO)." *Id.* at 621 n.20.

237. 18 U.S.C. § 287 (1994); *see* Schofield & Weaver, *supra* note 12, at 622-26 (discussing prosecution of health care fraud under False Claims Act).

238. *See* Schofield & Weaver, *supra* note 12, at 621 & n.23 ("Exclusion from participation in Medicare and Medicaid programs is the equivalent of 'capital punishment' for health care entities." (citing David S. Nalven, *Medicare and Medicaid Fraud: An Enforcement Priority for the 1990s*, BOSTON B.J., SEPT.-OCT. 1994, at 9, 16)). Administrative exclusion from Medicare and Medicaid is so severe because the federal government is the payer of about 40% of health care expenditures each year and no significant provider can afford to lose this revenue. *See* Gerson & Gladieux, *supra* note 14, at 171 (describing significance of exclusion penalty).

VII. Conclusion

There is great potential for Web sites linking hospitals, physicians, pharmaceutical manufacturers, and consumers to streamline the delivery of health care services.[239] However, advancing technology alone will not reduce the cost of health care or provide consumers with direct physical improvements in health care unless the government rethinks regulation of the industry for the digital age.[240] Congress drafted the anti-kickback statute with noble intentions of safeguarding public dollars and protecting patients from unscrupulous individuals.[241] The statute has not been successful in practice.[242] The anti-kickback statute particularly is unsuited for the digital age of medical delivery, in which private financing must play a prominent role and policymakers must clarify the legality of action.[243] It is time for health care regulators to recognize that medicine is a business operating in a capitalist economy.[244] The reformation of the health care fraud and abuse statutes is not the responsibility solely of policymakers at the Department of Health and Human Services and the Department of Justice; industry trade groups must vocalize support in driving these changes.[245] The future of e-health is bright, but the timetable and track of its development rest in large part upon the successful modernization of the anti-kickback statute.[246] Until the health care community persuades Congress to reconstruct the anti-kickback statute for the Digital Age, physicians will have to continue steering a delicate course between the Scylla of aggressive fraud prosecutors and the Charybdis of consumers demanding interactive health care on the Web.[247]

239. *See supra* notes 66-72 and accompanying text (describing elements and potential of connectivity sites).

240. *See supra* note 22 and accompanying text (describing revolutionary potential of e-health, but calling for appropriate revisions of regulations).

241. *See supra* notes 211-12 and accompanying text (discussing statute's dual purpose).

242. *See supra* note 20 and accompanying text (noting that statute prohibits efficient relationships allowed in other industries).

243. *See supra* note 28 (discussing need for private financing of telemedical endeavors); *supra* note 203 and accompanying text (suggesting that statutory ambiguity could lead to overdeterrence).

244. *See supra* notes 217-21 and accompanying text (discussing nature of referral "goodwill" and impact of market dynamics on health care industry).

245. *See* Bentivoglio, *supra* note 150, at 76 (calling upon health care and technology industries to place e-health promotion on national agenda).

246. *See supra* note 150 (concluding that inadequacy of antiquated government regulation will significantly affect future of e-health).

247. *See supra* note 229 (discussing aggressive prosecution tactics OIG employs); *supra* notes 47-48 and accompanying text (noting consumer demand for Web interaction).

ARTICLES