

11-1-1994

The Physician as Entrepreneur: State and Federal Restrictions on Physician Joint Ventures

Jennifer Herndon Puryear

Follow this and additional works at: <http://scholarship.law.unc.edu/nclr>Part of the [Law Commons](#)

Recommended Citation

Jennifer H. Puryear, *The Physician as Entrepreneur: State and Federal Restrictions on Physician Joint Ventures*, 73 N.C. L. REV. 293 (1994).
Available at: <http://scholarship.law.unc.edu/nclr/vol73/iss1/9>

This Comments is brought to you for free and open access by Carolina Law Scholarship Repository. It has been accepted for inclusion in North Carolina Law Review by an authorized administrator of Carolina Law Scholarship Repository. For more information, please contact law_repository@unc.edu.

COMMENT

The Physician as Entrepreneur: State and Federal Restrictions on Physician Joint Ventures

I. INTRODUCTION

Doctors in private practice had good reason to feel threatened by changes in the American health care market in the 1980s. They saw the growing popularity of health maintenance organizations, preferred provider organizations, and other alternative delivery systems.¹ They felt the pinch of a more cost-conscious federal government that changed the basis of Medicare payments for inpatient procedures to a Prospective Payment System.² At the same time, new technologies emerged that could be used effectively in non-hospital settings.³ This confluence of trends provided the setting for investors who sought to attract physicians to invest in freestanding facilities providing services such as magnetic resonance imaging (MRI) and clinical laboratory tests.⁴ Physicians were attractive to investors as sources of future re-

1. Jean M. Mitchell & Elton Scott, *Evidence on Complex Structures of Physician Joint Ventures*, 9 YALE J. ON REG. 489, 489 (1992); John K. Iglehart, *The Debate Over Physician Ownership of Health Care Facilities*, 321 NEW ENG. J. MED. 198, 203-04 (1989).

2. Office of the Inspector General, Department of Health and Human Services, *Financial Arrangements Between Physicians and Health Care Businesses* (1989), reprinted in [1989-2 Transfer Binder] MEDICARE AND MEDICAID GUIDE (CCH) ¶ 37,838, at 19,925-26 [hereinafter *OIG Report*]. Under the Prospective Payment System (PPS), a physician is reimbursed according to a predetermined "average" cost per patient, based on the patient's condition. Since this limitation only applies to in-hospital services, PPS encouraged the use of outpatient facilities. Christian D. Humphreys, Comment, *Regulation of Physician Self-Referral: Is Prohibition the Answer or Has Congress Operated on the Wrong Patient?*, 30 SAN DIEGO L. REV. 161, 162 (1993) (citing David A. Hyman & Joel V. Williamson, *Fraud and Abuse: Regulatory Alternatives in a "Competitive" Health Care Era*, 19 LOY. U. CHI. L.J. 1133, 1138-39 (1988)). See generally Judith R. Lave, *The Impact of the Medicare Prospective Payment System and Recommendations for Change*, 7 YALE J. ON REG. 499, 505-12 (1990) (explaining effects of PPS on provision of health care services).

3. *OIG Report*, *supra* note 2, at 19,926.

4. Freestanding joint venture facilities funded by outside investors and physicians have attracted the most attention from critics, and the problems associated with these facilities will be the focus of this Comment. See *infra* notes 15-30 and accompanying text. See generally MARC A. RODWIN, MEDICINE, MONEY, AND MORALS: PHYSICIANS' CONFLICTS OF INTEREST 73-79 (1993) (describing other kinds of joint ventures in which physicians have invested); Robert A. Metry, *Physician Ventures*, A.L.I.-A.B.A. COURSE OF STUDY (Qualified Plans, PCS and Welfare Benefits), March 1, 1990, at 509, 511, available in WESTLAW, TP-ALL database, C472 ALI-ABA *509, *511 (1990) ("A joint venture can be virtually any relationship between a physician (or group of physicians) and any other party, such as a hospital clinic, equipment lessor, or independent sponsor, whose purpose is to derive a profit from a joint business endeavor.").

referrals. Orthopedic surgeons, for instance, frequently refer patients to outside facilities for x-rays and imaging services. Investors would seek these surgeons to become limited partners in MRI centers because of the stream of referrals that would likely result from their personal interests in the facility.⁵ A physician's channeling of patients to a facility in which he owns an interest, known as "physician self-referral," has become highly controversial.⁶

Some physicians defend self-referral because their medical expertise and awareness of patients' needs arguably place physicians in the best position to evaluate the demand for new medical technologies.⁷ More frequently, supporters of self-referral argue that physicians ought to be able to provide the capital for needed facilities, especially when other investors will not.⁸ One doctor in Texas, for example, be-

5. See Mitchell & Scott, *supra* note 1, at 492-93.

6. Self-referral has been a particularly contentious subject within the medical profession. Dana Priest, *AMA Decrees "Self-Referral" is Unethical*, WASH. POST, Dec. 9, 1992, at A1 (quoting American Medical Association Chairman Raymond Scalettar, who described the debate over self-referral as "lacerating and divisive"). The American Medical Association (AMA) opposed legislation in 1989 regulating self-referral, but in 1991 its Council on Ethical and Judicial Affairs recommended some restrictions. In June 1992 the organization's House of Delegates rejected those recommendations, but six months later it reversed itself and adopted them. For a more detailed discussion of the AMA's response to the problem, see RODWIN, *supra* note 4, at 44-45, and Council on Ethical and Judicial Affairs, Am. Med. Ass'n, *Conflicts of Interest: Physician Ownership of Medical Facilities*, 267 JAMA 2366, 2366 (1992) [hereinafter *Council Report*].

On state medical societies' responses to self-referral, see Brian McCormick, *AMA, State Society on Opposite Sides*, AM. MED. NEWS, June 1, 1992, at 1 (discussing the rift between New Jersey's medical society and the AMA); Brian McCormick, *Self-Referral Tug of War: Ethical Policy vs. State Politics*, AM. MED. NEWS, Apr. 27, 1992, at 3 (comparing AMA's position with that of Florida Medical Association).

7. *Council Report*, *supra* note 6, at 2368; see also *Physician Ownership and Referral Arrangements: Hearings on H.R. 345 Before the Subcomm. On Health of the House Comm. on Ways and Means*, 103d Cong., 1st Sess. 252 (1993) [hereinafter *1993 Hearings*] (statement of Dr. Nancy W. Dickey, Member, Board of Trustees, AMA) (suggesting that physicians first recognized the value of MRI technology); Bernhard Heersink, *Letter to the Editor*, 321 NEW ENG. J. MED. 1192, 1193 (1989) (arguing that doctors can best determine patients' needs for services).

8. *E.g.*, 1993 *Hearings*, *supra* note 7, at 201 (testimony of Dr. Nancy W. Dickey, Member, Board of Trustees, AMA) ("Many facilities would not be available in some communities but for physician ownership. Patient benefit and patient access to health care facilities must be of primary concern in enacting self-referral legislation."). A representative of the American College of Radiology testified to the contrary that physician-investors often do not contribute the capital that allows a facility to be built; rather, "[m]ost often referring physicians' participation in these joint ventures involves only signing a note for debt We do not believe that these joint ventures are created because there is no money in town." 1993 *Hearings*, *supra* note 7, at 293 (statement of Dr. Karl K. Wallace, Jr., Chairman, Board of Chancellors, American College of Radiology). For a discussion of federal treatment of facilities in which physician-investors have contributed little capital, see *infra* notes 65-69 and accompanying text.

came a limited partner in an MRI center near his practice because he felt that local hospitals were not providing adequate imaging and radiology services to outpatients. These patients "were forced to wait extended periods of time, frequently over-night, pay extra for call-back technologists, or . . . make return visits of 50-200 miles to get the services"⁹ The doctor asserted that the imaging center in which he invested eliminated these significant delays.¹⁰

Critics of self-referral fear that physicians who self-refer put themselves in a dangerous position. Having an interest in a facility may lead them consciously or unconsciously, to recommend more tests than are necessary.¹¹ In this way, self-referral may present a conflict of interest for physicians, as their own pecuniary interests compete with the financial interests of their patients.¹² Furthermore, self-referral may adversely affect the health care market. Excessive testing clearly wastes health care dollars. Self-referral may also have the effect of squeezing competing facilities out of the market.¹³ A facility

9. *Issues Related to Physician "Self-Referrals": Hearings on H.R. 939 Before the Subcomm. on Health and Subcomm. on Oversight of the House Comm. on Ways and Means*, 101st Cong., 1st Sess. 98 (1989) (statement of AMA) [hereinafter 1989 Hearings].

10. *Id.*

11. As one critic put it,

it is often difficult if not impossible to distinguish cases in which financial gain does have improper influence from those in which it does not. It is difficult even in one's own case, and all the more so in the case of people one does not know personally, to determine what motives have influenced a professional decision.

Dennis F. Thompson, *Understanding Financial Conflicts of Interest*, 329 NEW ENG. J. MED. 573, 574-75 (1993). Most critics of self-referral are far more suspicious of the motives of physicians who self-refer. In the 1980s, one doctor concluded that "greed became the dominant motive [for these investments]. There were many unscrupulous dollar jockeys and wheeler-dealers to broker deals. . . . There was squabbling. One doctor would say, 'I referred X patients and Harry only referred half that many. Shouldn't I get more money?'" Charles R. Babcock, *Defending Physician Self-Referrals*, WASH. POST, July 7, 1993, at A19 (quoting Dr. Stanley L. Malkin).

12. Scholar Marc Rodwin argues that doctors should be held to the same high standards as other professionals:

The law holds financial advisers, brokers, dealers and others accountable as fiduciaries. Because of their position of trust, such persons are required to act in their clients' interests rather than their own. The conflicts of interest among these groups are dealt with by numerous rules against the abuse of that trust. Physicians, who now have nearly free rein, should be held to the same high standards in the market for their services.

Marc A. Rodwin, *Letter to the Editor*, 321 NEW ENG. J. MED. 1192, 1193 (1989).

13. For example, in Charlotte, North Carolina, investors and physicians opened a new radiation care center, provoking the owners of the other radiation care center in the city to complain, "[h]ow can we hope to compete on the basis of cost, quality or convenience of care when a large subset of our referring physicians stand to financially benefit from a referral to their own facility?" Karen Garloch, *Doctor Investments in Medical Centers Prompt Ethics Debate*, CHARLOTTE OBSERVER, Jan. 21, 1992, at 1A (quoting Dr. Robert Fraser).

that gets a "lock" on referrals stands a good chance of driving others out of the market, regardless of the price or quality of services provided.¹⁴

This Comment first describes some of the types of joint ventures in which physicians invested during the 1980s, showing how they have been structured to reward physicians for making referrals.¹⁵ It then describes the major studies that provide evidence of the extent and effects of physician self-referral.¹⁶ After discussing the federal responses to the proliferation of physician joint ventures,¹⁷ this Comment focuses on the highly varied state responses to the issue, because state legislation has received relatively scant attention in the academic literature.¹⁸ The Comment discusses the strengths and weaknesses of state legislation, the interaction of state and federal law, and finally the continuing need for state legislation.

II. PHYSICIAN OWNERSHIP AND REFERRAL PATTERNS

A. Structures of Joint Ventures

To appreciate the controversy surrounding physician self-referral, it is necessary to understand the business structures of physician joint ventures.¹⁹ The simplest may be a limited partnership in which physi-

14. The executive director of Quality Imaging Association (QIA) testified regarding the validity of these concerns: "Centers operated by QIA members have been told that the quality of services they offered was irrelevant because the physician would refer only to the facility in which he had an ownership interest." 1993 *Hearings, supra* note 7, at 283-84 (statement of Richard E. Geier, Executive Director, QIA). QIA commissioned a report which concluded that overutilization of imaging tests by physicians who owned interests in imaging centers cost the health care system \$258 million in 1992 alone. *Id.* at 284.

15. See *infra* notes 19-31 and accompanying text.

16. See *infra* notes 32-53 and accompanying text.

17. See *infra* notes 54-121 and accompanying text. Federal legislation has been given significant attention in the scholarly literature. See, e.g., Pamela L. Gorski, *The Big Chill: Safe Harbors in the Medicare and Medicaid Fraud and Abuse Statutes*, 5 J.L. & HEALTH 237 (1990-91); Mitchell & Scott, *supra* note 1, at 494-499; John J. Farley, Note, *The Medicare Antifraud Statute and Safe Harbor Regulations: Suggestions for Change*, 81 GEO. L.J. 167 (1992); Humphreys, *supra* note 2, at 167-79; Kimberly A. King, Comment, *Regulating Physician Investment and Referral Behavior in the Competitive Health Care Marketplace of the '90s—An Argument for Decentralization*, 65 WASH. L. REV. 657, 657-62 (1990); Carolyn M. Pengidore, Note, *Dubious Practice? The Storm Over Physician Self-Referral*, 31 DUQ. L. REV. 167, 168-87 (1992). This Comment will not consider antitrust issues related to physician joint ventures. For an overview of potential antitrust problems, see Susan Tedrick, *Legal Issues in Physician Self-Referral and Other Health Care Business Relationships*, 13 J. LEGAL MED. 521, 542-48 (1992).

18. See *infra* notes 122-97 and accompanying text. E.g., Mitchell & Scott, *supra* note 1, at 500-01; Tedrick, *supra* note 17, at 552-53; Humphreys, *supra* note 2, at 179-81; Pengidore, *supra* note 17, at 187-89.

19. Physician joint ventures have three defining characteristics, according to Marc Rodwin: "(1) the physician earns money only if the facility is profitable; (2) the physician

cians are limited partners and outside investors are general partners who manage the business.²⁰ Outside investors may join with physicians who specialize in internal medicine, for instance, to form a limited partnership clinical laboratory. According to the partnership agreement, the physicians would be required to contribute only capital, but it would be understood that they would refer patients to the facility. As limited partners, physicians would not be involved in the management of the lab in any significant way, and thus would not be in a position to affect the quality or cost of the lab's services.

Researchers Jean Mitchell and Ellen Scott observed a more complex partnership that owned an ambulatory service center, a clinical laboratory, and a durable medical equipment business.²¹ The partners were two corporations, one of which was owned by outside investors and the other by 200 separate corporations.²² Each of the 200 corporations was owned by just one stockholder—a physician.²³ This kind of arrangement disguises the identity of the investors and, in some states, evades self-referral legislation.²⁴

Apart from their varying degrees of complexity, joint ventures can be divided into two important categories: those that require significant capital investment from investing physicians and those that do

can enhance the venture's profitability by referring patients, ordering equipment, or using the facility's services; and (3) the physician, acting as a clinician, either chooses or recommends the services that the facility provides." RODWIN, *supra* note 4, at 67; *see also* ROSS E. STROMBERG & CAROL R. BOMAN, JOINT VENTURES FOR HOSPITALS AND PHYSICIANS: LEGAL CONSIDERATIONS 15-35, 193-241 (1986) (detailing possible structures for joint ventures involving hospitals and physicians).

20. *See* RODWIN, *supra* note 4, at 67-68. A study conducted by the Office of the Inspector General found that 25% of health care joint ventures with physician owners were set up as partnerships, as compared to 4% of health care joint ventures without physician-investors. 1989 *Hearings*, *supra* note 9, at 129 (statement of Richard P. Kusserow, Inspector General of the Department of Health and Human Services).

21. Jean M. Mitchell & Elton Scott, *New Evidence of the Prevalence and Scope of Physician Joint Ventures*, 268 J. AM. MED. ASS'N 80, 81 (1992).

22. *Id.*

23. *Id.*

24. Researchers Mitchell and Scott found that complex ownership arrangements were significantly more common in joint ventures with physician-investors than in companies without them. Mitchell & Scott, *supra* note 1, at 513. Complex ownership structures generally serve to isolate risk for independent operating units of a larger corporation. Complex ownership structures generally do not serve that purpose for joint venture medical service facilities, because the facilities are usually independent businesses. Mitchell & Scott, *supra* note 1, at 512. This evidence suggests that investors are attempting to avoid self-referral legislation through indirect ownership arrangements. *See id.*

Some state self-referral statutes still do not explicitly deal with indirect investment interests. *See infra* note 122 and accompanying text. The most recent federal self-referral legislation, commonly known as Stark II, brings indirect ownership arrangements within the purview of the statute. *See infra* note 114 and accompanying text.

not.²⁵ The ventures that have drawn the most criticism fall into the latter category, promising high rates of return on very small investments.²⁶ An Ohio corporation, for instance, sought physician-investors for a facility providing intravenous services. Interested physicians would be required to invest \$15,000, but only \$100 in cash. The remainder could be funded by a bank loan at one percent above prime. The prospectus clearly documented the organizers' goal:

The organizers believe that physicians will be more likely to refer patients to the corporation if the physician owns an interest in the corporation . . . [T]he ability of the corporation to compete successfully with other entities will depend upon the corporation's ability to secure a large number of referrals from physician-investors.²⁷

The profit distributions to referring physicians look very much like payments for referrals, or "kickbacks," in these circumstances.²⁸

The other kind of joint venture arrangement, in contrast, requires investing physicians to contribute significant amounts of capital. In Gainesville, Florida, for instance, a group of urologists invested \$20,000 each to raise \$1 million in equity and borrowed \$3 million to set up a center providing lithotripsy services.²⁹ The doctors asserted that the facility made the technology more accessible and less expensive for many patients in the area, but that other investors had not been interested in funding the facility.³⁰ Critics find these arrangements troubling because financial incentives to overutilize the facility

25. See RODWIN, *supra* note 4, at 68.

26. *Id.* at 71. One letter seeking physician investors began: "Dear Doctor, Would you pass up the opportunity to increase your office revenue by an amount of anywhere from \$35,000 to \$200,000/year after a relatively minimal investment?" RODWIN, *supra* note 4, at 71.

27. 1993 *Hearings*, *supra* note 7, at 194 (testimony of Marc Rodwin). Other evidence that investors primarily seek referrals can be found in some of the prospectuses submitted to the Office of the Inspector General as part of its 1989 study of physician self-referral. Of the 30 offerings and prospectuses, for instance, 12 stated that the stock or units of partnerships were only being offered to physicians, 5 required divestiture of a physician's interest upon his retirement from active practice, and 5 required divestiture if the physician left the immediate area. 1989 *Hearings*, *supra* note 9, at 129. Another offering made to physicians located close to the proposed facility sought a \$4000 initial investment and promised annual returns of 300 percent. *Id.* at 130.

28. The Medicare Anti-Fraud and Abuse statute prohibits kickbacks for referrals of Medicare patients. See *infra* notes 54-64 and accompanying text.

29. Mitchell & Scott, *supra* note 1, at 493. Lithotripsy, also known as lithotrity, is the crushing of a stone in the bladder or urethra. STEDMAN'S MEDICAL DICTIONARY 888 (25th ed. 1990).

30. Mitchell & Scott, *supra* note 1, at 493.

remain and because the investing physicians so frequently lack control over the quality or cost of care provided.³¹

B. *Extent of Physician Ownership*

Before 1989, few studies had examined physician ownership and referral patterns.³² That year the Office of the Inspector General (OIG) published the first major study to document the prevalence of physician self-referral.³³ The OIG estimated that about twelve percent of physicians billing Medicare owned a direct investment interest in a facility to which they referred patients.³⁴ Three years later, an AMA survey found that only eight percent of physicians owned an interest in private health care facilities.³⁵ Those figures hide the concentration of physician ownership in certain kinds of facilities. The OIG found, for example, that twenty-five percent of all independent clinical laboratories and twenty-seven percent of all independent physiological labs were owned by referring physicians.³⁶

Researchers in Florida who conducted one of the largest studies of self-referral to date found ownership to be far more widespread in that state in 1990.³⁷ The study showed that forty to forty-six percent of physicians in Florida owned an interest in a joint venture, and that ownership was highly concentrated in a few medical specialties. Referring physicians owned, in whole or in part, over ninety percent of all diagnostic imaging centers, over seventy-five percent of all ambula-

31. See *supra* notes 9-11 and accompanying text.

32. Several studies of self-referral had been conducted in Michigan during the 1980s. *OIG Report, supra* note 2, at 19,927. A 1981 study found that Medicaid recipients referred by physician-investors received 41% more tests than those referred by non-investors. *Id.* A 1984 study found that clinical laboratories with physician-investors provided 40% more services than laboratories without physician-investors. *Id.*

33. *Id.* at 19,925, 19,929.

34. *Id.* at 19,931-32. The OIG's estimate was conservative because it did not take into account ownership interests held through family members or through parent companies. *1989 Hearings, supra* note 9, at 129. The study concluded that 15% of physicians billing Medicare had some sort of compensation arrangement with an entity to which they referred patients. *Id.*

35. The AMA collected data between 1988 and 1992. It found that physician ownership in private facilities to which they referred patients declined from 9.3% in 1988 to about 8% in 1992. The surveys also showed that three-fourths of physicians who owned an interest in a facility referred patients to the facility in 1988, while less than two-thirds did so in 1992. *1993 Hearings, supra* note 7, at 218-20 (submitting report with testimony of AMA).

36. *OIG Report, supra* note 2, at 19,932.

37. Mitchell & Scott, *supra* note 21, at 83 (describing STATE OF FLORIDA HEALTH CARE COST CONTAINMENT BOARD, JOINT VENTURES AMONG HEALTH CARE PROVIDERS IN FLORIDA (1991)).

tory surgical facilities, and about half of the radiation therapy centers and clinical laboratories in the state.³⁸

Other populous states have similar ownership patterns. In California, for instance, more than eighty-five percent of freestanding imaging centers are wholly or partly owned by referring physicians.³⁹ In New Jersey, at least seventy-five percent of the freestanding imaging centers have ownership arrangements involving referring physicians.⁴⁰

C. *Effects of Self-Referral*

The fact that significant numbers of physicians own facilities to which they refer patients means little without an inquiry into the effects of self-referral on the quantity, quality, and cost of care provided to patients. The clearest finding of the studies is that physician-investors refer patients for services provided at facilities in which they own interests more frequently than noninvesting physicians refer patients for similar services. The OIG's 1989 study, for instance, showed that Medicare patients treated by doctors who owned interests in clinical laboratories received forty-five percent more clinical laboratory services than Medicare patients in general.⁴¹ Researchers in California found that physician owners of physical therapy centers referred patients for physical therapy more than twice as often as other physicians.⁴² A study of radiation therapy showed that patients with similar symptoms were at least four times more likely to have diagnostic imaging performed if a physician self-referred.⁴³ The most recent study by the Health Care Finance Administration reveals an additional link between the cost of a test and the likelihood that a physician owner will refer for the test. Physicians with interests in imaging

38. *Id.* at 83-84. The Florida study also found that 91% of physicians who invested in facilities were in areas of practice that were likely to refer for ancillary services, such as internal medicine, general practice, surgery, and orthopedics. *Id.* at 82.

39. *Id.* at 84. These percentages may have decreased since 1992, when researchers Mitchell and Scott reported them.

40. *Id.*

41. *OIG Report, supra* note 2, at 19,933. The study found great variation among the states. *1989 Hearings, supra* note 9, at 130. In West Virginia and New York, for instance, patients referred by physician-owners were not likely to have more tests performed, while in California, they were likely to have 30% more tests, and in Michigan, 87% more. *Id.*

42. Alex Swedlow et al., *Increased Costs and Rates of Use in the California Workers' Compensation System as a Result of Self-Referral by Physicians*, 327 NEW ENG. J. MED. 1502, 1503-04 (1992). Physical therapy is big business in California, accounting for 56% of all outpatient procedures for the treatment of injured workers in 1990. *Id.* at 1504.

43. Bruce J. Hillman et al., *Frequency and Costs of Diagnostic Imaging in Office Practice, A Comparison of Self-Referring and Radiologist-Referring Physicians*, 323 NEW ENG. J. MED. 1604, 1606 (1990).

centers, the study shows, referred for costly MRIs fifty percent more frequently than other physicians, yet referred for simple X-rays only two percent more often.⁴⁴ The inference one is tempted to draw from the studies is that physicians with ownership interests in facilities overutilize those facilities, particularly when it provides more expensive services.

The studies do not, however, necessarily prove that conclusion.⁴⁵ They do not take into account, for instance, physicians' different levels of knowledge of tests and services. Doctors who own an interest in a particular facility may be more informed about the services performed there and for that reason refer patients there more frequently.⁴⁶ Furthermore, these studies do not investigate whether the greater number of tests and services provided at joint venture facilities reduce overall health care costs per patient. Early diagnostic tests, for instance, may allow physicians to treat patients most effectively and economically in the long term.⁴⁷ The authors of several studies admit that they do not know whether investing or non-investing physicians use services more appropriately.⁴⁸

At least two studies strongly suggest that self-referring physicians are overutilizing their facilities. In one, researchers compared radiation therapy referrals in Florida to radiation therapy referrals in the rest of the country. Forty-four percent of radiation therapy centers in Florida are physician joint ventures, as compared to seven percent in the rest of the nation.⁴⁹ After controlling for age and other variables, researchers found that the number of radiation-therapy procedures in Florida was fifty-eight percent higher per 1000 Medicare patients than

44. 1993 *Hearings*, *supra* note 7, at 151 (statement of Janet L. Shikles, Director, Health Financing and Policy Issues, Human Resources Division, U.S. General Accounting Office). These figures suggest that self-referral is particularly likely when expensive technology is involved.

45. Jean Mitchell, one of the authors of the Florida study, admitted that "[w]e couldn't determine whether use was inappropriate. We can only say it was higher than non-joint venture facilities." Laurie Jones, *Stark Wants to Expand Ban on Self-Referral Beyond Labs*, AM. MED. NEWS, Nov. 4, 1991, at 1, 32.

46. See 1993 *Hearings*, *supra* note 7, at 157 (statement of Rep. Bill Thomas) (suggesting that "people who have investigated and decided to spend money in it would probably have a higher knowledge of its uses and potentials . . . and that therefore as a diagnostic tool they might see it as more useful").

47. See *id.* at 157-58.

48. Hillman, *supra* note 43, at 1608; Jones, *supra* note 45, at 32.

49. Jean M. Mitchell & Jonathan H. Sunshine, *Consequences of Physicians' Ownership of Health Care Facilities—Joint Ventures in Radiation Therapy*, 327 NEW ENG. J. MED. 1497, 1498-99 (1992). Radiation therapy for cancer is somewhat standardized, so treatment does not vary tremendously across the country as the result of different approaches. *Id.* at 1498.

in the rest of the nation, but that fifty-four percent of the patients with cancer died in Florida, as opposed to fifty-three percent nationwide.⁵⁰ The extensive use of radiation therapy in Florida thus appears to have produced few health benefits for state residents.⁵¹ A recent study in California focused on MRI referrals covered by workers' compensation. Researchers found that self-referring physicians recommended medically inappropriate scans in thirty-eight percent of the cases examined, while other physicians did so in only twenty-eight percent of the cases.⁵² These studies bolster the others that reveal such a striking correlation between ownership and a high level of referrals.

While definitive evidence about overuse is limited, evidence about quality of care at joint venture facilities is even more scarce. In one study, researchers compared the care given at joint venture physical therapy centers to that provided at non-joint venture centers. They found that facilities with physician owners provided fewer minutes of care per patient and less overall care by licensed therapists.⁵³ The implication of this study is that facilities with physician owners provided lower quality care. The researchers did not, however, compare the results achieved at physician joint venture facilities with those achieved at non-joint venture facilities, and thus a meaningful comparison of the relative quality of care cannot be made. Few studies examine the issue of quality of care, and none have yet proven that facilities with physician investors get a "lock" on referrals and subsequently provide substandard care.

The studies, taken as a whole, do not definitively prove that physician joint ventures lead to a distortion of the market or to lower quality care. Instead, most prove only a strong correlation between a physician's ownership interest in a facility and the likelihood that she will refer patients for the type of services provided at the facility more frequently than other physicians. The fundamental question posed by the studies is whether we should take the chance that the clear link between ownership and referral does *not* imply overutilization of tests and services. The federal government has been increasingly unwilling to take that gamble.

50. *Id.* at 1499.

51. *See id.* at 1500. The researchers concluded that "joint ventures must be regarded as a likely explanation for the high levels of use and costs characteristic of Florida." *Id.*

52. Swedlow et al., *supra* note 42, at 1504.

53. Jean M. Mitchell & Elton Scott, *Physician Ownership of Physical Therapy Services: Effects on Charges, Utilization, Profits, and Service Characteristics*, 268 JAMA 2055, 2058 (1992).

III. THE FEDERAL RESPONSE

A. Medicare Anti-Fraud and Abuse Statute

To regulate self-referral, the federal government first used old legislation in a new way. The Medicare Anti-Fraud and Abuse Statute (the "Anti-Fraud Statute"), enacted in 1972,⁵⁴ was designed to deal with abuses of the Medicare reimbursement system.⁵⁵ In part, the statute made it illegal for medical testing facilities to make payments to physicians who referred patients to the facilities.⁵⁶ These payments for referrals, or "kickbacks," encouraged physicians to order more tests and services than were necessary.⁵⁷ Specifically, the statute prohibited a person or entity from knowingly and willfully offering or paying any remuneration directly or indirectly, in cash or in kind, to any person, to "induce" that person to refer patients for the furnishing of medical services.⁵⁸

In its 1985 case against physician and entrepreneur Alvin Greber, the Justice Department advanced a broad interpretation of that language.⁵⁹ Greber had formed a corporation called Cardio-Med to perform diagnostic tests on patients referred to the facility.⁶⁰ Cardio-Med billed Medicare for the services it performed, and forwarded part of the payment fee it received to the referring physician.⁶¹ Greber claimed that the money paid to referring physicians was not intended to induce them to refer future patients, but to compensate them for interpreting the tests and explaining test results to patients.⁶² The government argued that the payments to the referring physicians constituted kickbacks within the meaning of the Anti-Fraud Statute—

54. Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b),(c), 278(b)(8)-(a), 86 Stat. 1329, 1419-20 (1972) (codified as amended at 42 U.S.C. § 1320a-7b (1988 & Supp. IV 1992)).

55. See generally Farley, *supra* note 17, at 168-71 (discussing the impetus behind the original legislation and the amendments to the statute).

56. 42 U.S.C. § 1320a-7b(b)(2) (1988 & Supp. IV 1992); see also Theodore N. McDowell, Comment, *The Medicare-Medicaid Anti-Fraud and Abuse Amendments: Their Impact on the Present Health Care System*, 36 EMORY L.J. 691, 715-20 (1987) (discussing the negative impact of federal legislation on the Medicare-Medicaid health care system).

57. *United States v. Greber*, 760 F.2d 68, 71 (3d Cir.), cert. denied, 474 U.S. 988 (1985) ("Congress intended to combat financial incentives to physicians for ordering particular services patients did not require."). Criminal penalties alone could be levied against both providers and doctors and included up to five years in prison and fines up to \$25,000. See 42 U.S.C. § 1320a-7b(b) (1988 & Supp. IV 1992). Accordingly, enforcement of the statute fell squarely within the province of the Department of Justice.

58. 42 U.S.C. § 1320a-7b(b) (1988 & Supp. IV 1992).

59. *Greber*, 760 F.2d at 71-72.

60. *Id.* at 70.

61. *Id.*

62. *Id.*

even if they were paid for purposes other than inducing referrals—so long as one purpose of the payments was to encourage future referrals. The Third Circuit Court of Appeals agreed, reading the statute expansively.⁶³

Congress followed the lead of the Justice Department several years later when it first suggested that illegal remuneration under the Anti-Fraud Statute could also take place through physician joint ventures. Based on the presumption that referrals could be induced by profit distributions from a joint venture in the same way they were induced by more direct kickbacks, Congress required the Office of the Inspector General (OIG) to publish a list of "safe harbors" describing the kinds of joint venture arrangements that would not violate the Anti-Fraud Statute.⁶⁴

1. The Fraud Alert

The OIG first responded to the Congressional mandate by releasing a Fraud Alert in 1989 outlining joint venture financing arrangements that are "suspect" under the Anti-Fraud laws.⁶⁵ The OIG indicated that two types of initial investments from physician-investors will provoke further scrutiny of the venture; nominal capital contribution's and those consisting of a loan from the entity. Suspicious profit distribution arrangements require disproportionately small investments from physicians and promise them extremely large returns, or pay physicians extraordinary returns on their investment compared to the associated risks.⁶⁶

63. See *id.* at 69. The First and Ninth Circuit Courts of Appeals and a district court in Texas have followed the *Greber* interpretation of the Anti-Fraud Statute. See *United States v. Bay State Ambulance & Hosp. Rental Serv.*, 874 F.2d 20, 29 (1st Cir. 1989) ("The gravamen of Medicare Fraud is inducement. . . . We are impressed by the Third Circuit's reasoning. . . ."); *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (quoting *Greber*, 760 F.2d at 71) ("*Greber's* interpretation is consistent with the legislative history. . . . '[E]ven if the physician performs some service for the money received, the potential for unnecessary drain on the Medicare system remains.'"); *Polk County v. Peters*, 800 F. Supp. 1451, 1454-55 (E.D. Tex. 1992) (Mem.) (citing *Greber*, *Kats*, and *Bay State*).

64. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat. 680, 697 (1987) (codified at 42 U.S.C. § 1320a-7b note (Supp. IV 1992)). The 1987 Act also added civil penalties to the statute, giving the Department of Health and Human Services the power to fine violators and to exclude them from reimbursement from Medicare and Medicaid. 42 U.S.C. §§ 1320a-7, 1320a-7a (1988 & Supp. IV 1992). In 1988, the Medicare Catastrophic Coverage Act mandated an OIG study of physician self-referral, and the resulting report was submitted to Congress in May of 1989. *Metry, supra* note 4, at *516.

65. *Metry, supra* note 4, at *667 (providing text of Fraud Alert).

66. *Id.* at *668.

The Fraud Alert also identifies suspect methods of selecting and retaining physician-investors.⁶⁷ If outside investors choose physicians because they are in a position to make referrals, or if they offer particularly lucrative arrangements to those physicians expected to make a high volume of referrals, investors may be violating the Anti-Fraud Statute.⁶⁸ Similarly, if outside investors actively encourage physicians to refer patients to the facility, limit their ability to transfer their interest, require divestment of their interest upon relocation, or track and distribute the numbers of referrals per physician-investor, the investment may be subject to scrutiny.⁶⁹

2. The Hanlester Network Case

Several years before the issuance of the Fraud Alert, the Hanlester Network investors in California unabashedly sought physician-investors to provide a consistently large stream of referrals to clinical laboratories the Network was establishing.⁷⁰ They deliberately targeted as potential investors physicians who regularly ordered outpatient tests.⁷¹ The investors required physicians to make a minimal investment—only \$1500—and promised extremely high returns in private placement memoranda.⁷² One investor told physicians that their returns could be as high as 300 to 400 percent annually and that physicians who failed to refer a high volume of patients would be pressured to increase their numbers or withdraw their investment.⁷³ The OIG commenced a high-profile suit against the investors in 1991, arguing that they unlawfully induced referrals by giving physicians “the opportunity to own shares in the laboratories and to share in the

67. *Id.*

68. *Id.*

69. *Id.* The Alert also explains how certain business structures may violate the Anti-Fraud Statute. *Id.* The use of a “shell” laboratory, for instance, is illegal under the statute. *Id.* A shell lab is set up in order to bill Medicare for work done at another lab in which a physician owns an interest. *Id.* A physician would employ a shell lab to bill Medicare because other federal legislation prevents a physician from billing Medicare for services performed at a lab when he owns an interest in the lab. *See infra* notes 98-108 and accompanying text.

70. For a good summary of the strategies of these investors and the subsequent litigation, see David Azevedo, *Joint Ventures Become Even Riskier*, MED. ECON., July 26, 1993, at 36. The facts of the case are set out more comprehensively in *Inspector General v. Hanlester Network*, [1991 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,034 (Mar. 1, 1991).

71. *Inspector General v. Hanlester Network*, [1992-2 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 40,406B, at 31,783 (July 24, 1992).

72. *Inspector General v. Hanlester Network*, [1992-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,566, at 27,742 (Sept. 18, 1991).

73. *Id.*

laboratories' profits where . . . the partners were 'virtually guaranteed' a high rate of return on their investments, so long as they referred laboratory tests to the joint ventures."⁷⁴ The administrative law judge initially held for the investors,⁷⁵ but the Appellate Board agreed with the OIG that referrals had been unlawfully induced.⁷⁶ A federal district court in California ruled in favor of the OIG in February of 1993.⁷⁷ This case is significant because it was the first to test the OIG's interpretation of the Anti-Fraud Statute as set forth in the Fraud Alert. The Hanlester Network investors engaged in most of the conduct identified in the Fraud Alert as problematic. This case should give physicians and investors particularly strong incentives to attend to the Fraud Alert.⁷⁸

3. Safe Harbors

In addition to its commencement of the *Hanlester Network* suit, the OIG issued "safe harbors," as required by Congress, describing joint venture arrangements that will not be subject to Anti-Fraud scrutiny.⁷⁹ The "large entity" safe harbor allows a physician to refer Medicare patients to a facility that is part of a large corporation in which he owns an interest.⁸⁰ The "small entity" safe harbor protects physicians who self-refer when no more than forty percent of the facility is owned by persons in a position to make referrals and no more than forty percent of its revenues come from referrals from investors.⁸¹ Other requirements also must be met for protection under

74. *Inspector General v. Hanlester Network*, [1991 Transfer Binder] Medicare & Medicaid Guide (CCH), ¶ 39,094, at 25,523 (Mar. 1, 1991).

75. *Id.* at 25,510-11.

76. *Inspector General v. Hanlester Network*, [1992-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,566 at 27,740 (Sept. 18, 1991).

77. *Hanlester Network v. Sullivan*, [1993-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 41,076, at 34,723 (C.D. Cal. Feb. 10, 1993).

78. If the decision stands, "the Inspector General will have won a broad new definition of his power to prosecute doctors and their non-physician business partners" for offenses involving Medicare referrals. Azevedo, *supra* note 70, at 36.

79. See Howard Larkin, *Most Joint Ventures Unlikely to be in a 'Safe Harbor'*, AM. MED. NEWS, Aug. 26, 1991, at 11; Sharon McIlrath, *New Safe Harbor Rules Narrow*, AM. MED. NEWS, Aug. 12, 1991, at 1. However, Deputy Inspector General Larry Morey argued that "even though the safe harbors are narrow, they have a chilling effect on prosecutors, who may be reluctant to take a case which may involve a colorable claim that a safe harbor applies." 1993 Hearings, *supra* note 7, at 169.

80. 42 C.F.R. § 1001.952(a)(1) (1993). The net assets of the corporation must have exceeded \$50 million in the previous year and its securities must be registered on a national exchange. *Id.*

81. *Id.* § 1001.952(a)(2)(i), (vi). Also, there must not be any requirement that a passive investor make referrals to the entity in order to remain an investor. *Id.* § 1001.952(a)(2)(iv).

either safe harbor: a physician's return on his investment cannot be based on the volume of his referrals, only the amount of his capital contribution;⁸² investment opportunities must be offered to non-referring investors and referring investors on equal terms;⁸³ the joint venture entity cannot make a loan or guarantee a loan that enables the physician to acquire an interest in the corporation;⁸⁴ and the entity cannot market its services or products to physician-investors differently than to non-investors.⁸⁵

In September of 1993, the OIG proposed three new safe harbor provisions that expand protection for joint ventures involving Medicare referrals.⁸⁶ If the regulations are promulgated, a physician will be protected when he refers Medicare patients to a facility in a rural area in which he owns an interest.⁸⁷ This exemption will only be granted if eighty-five percent of the entity's business is derived from services to rural residents⁸⁸ and the opportunity to invest is offered "in a good faith, nondiscriminatory manner to any individuals or entities who are potential sources of capital."⁸⁹ This provision recognizes the fact that physicians are frequently the only willing investors in a rural community.⁹⁰ The second proposed safe harbor would allow physicians to refer their Medicare patients to ambulatory surgical care centers in which they own an interest when all investors in the center are surgeons who perform services there.⁹¹ This provision is based on the presumption that profit distributions from certain kinds of joint ventures are not likely to affect referrals. At an ambulatory care center, in particular, a surgeon's professional fee is so much greater than the profit she would receive as an investor in the facility that the profit distribution probably would not influence her volume of referrals.⁹² The third proposed safe harbor would allow physicians active in a group practice to refer Medicare patients to a facility when all inves-

82. *Id.* § 1001.952(a)(1)(v), (a)(2)(iii), (viii).

83. *Id.* § 1001.952(a)(1)(ii), (a)(2)(ii).

84. *Id.* § 1001.952(a)(1)(iv), (a)(2)(vii).

85. *Id.* § 1001.952(a)(1)(iii), (a)(2)(v).

86. 58 Fed. Reg. 49,008 (1993) (to be codified at 42 C.F.R. § 1001); the other four safe harbors would protect, under certain circumstances, practitioner recruitment, payment by hospitals of obstetrical malpractice insurance, referral agreements for specialty services, and cooperative hospital service organizations. *Id.*

87. 58 Fed. Reg. 49,008-09 (1993).

88. *Id.* "Rural area" would be defined according to Office of Management and Budget regulations and thus would encompass about 22.5 percent of the population as of 1990. *Id.*

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.*

tors in the facility are active in a group practice that refers patients to the entity.⁹³ As of August 1994, the OIG is still receiving comments and has not promulgated final regulations.

Joint ventures that accept referrals of Medicare patients from physician-investors are clearly subject to some scrutiny under the Anti-Fraud Statute, but there is not yet an entirely predictable legal environment for such ventures. The OIG clearly indicated its intention to apply the Anti-Fraud Statute to physician joint ventures when it brought the *Hanlester Network* suit, but it is difficult to know whether the OIG will investigate borderline violators or limit its inquiries to egregious offenders. Safe harbors provide some guidance to investors, but they are not the equivalent of statutory provisions. That is, a joint venture with sixty-five percent of its physician-investors in a position to refer to the facility, instead of the forty percent recommended in the safe harbor provisions, will not necessarily violate the Anti-Fraud Statute.⁹⁴ The venture simply will not be protected in a safe harbor. The most important document in this area is the Fraud Alert, which indicates the arrangements the OIG finds most offensive.⁹⁵

B. *Stark I*

Congress responded more directly and clearly to physician joint ventures in 1989 through the passage of the Ethics in Patient Referrals

93. *Id.* at 49,010. Recognizing that there are other kinds of joint ventures consisting only of active investors, such as partnerships with general partner investors, the OIG has solicited comments on whether these should be included in the new safe harbor. *Id.*

94. One attorney recommends a "pure heart" test to help investors and physicians determine whether the statute has been violated. Brian McCormick, *Feds Claim Victory in Limiting 'Self-Referral'*, AM. MED. NEWS, June 29, 1992, at 1, 39 (quoting San Francisco attorney Gerald Peters). He suggests that physicians should ask, "Was the venture an existing service spun off solely to provide profit for physicians, or was it a new service created to improve patient care?" *Id.* (quoting San Francisco attorney Gerald Peters). If the former, "you are not going to look like you have a pure heart." *Id.* (quoting San Francisco attorney Gerald Peters).

95. Attorney Sanford Teplitzky, clearly drawing on the Fraud Alert, recommends that a joint venture have the following in order to avoid violating the statute:

- (1) A well-documented, legitimate business purpose for the venture. There should be employees, customers, accounts payable, etc.
- (2) Legitimate sources of ownership investment, with investor capital at risk.
- (3) Neither entry into the venture nor continued participation tied to referrals.
- (4) Profits and losses tied to percentage of ownership, with volume-sensitive payments avoided.
- (5) Quality assurance and utilization review programs.
- (6) Disclosure of ownership to patients.

McCormick, *supra* note 94, at 39.

Act (Stark I).⁹⁶ Stark I became effective in January of 1992 and will be supplemented in January of 1995.⁹⁷ Stark I prohibits a physician from referring Medicare patients to a clinical laboratory in which the physician or his immediate family member owns an interest.⁹⁸ There are three major exceptions. The "personal services" exception allows a physician to make an otherwise prohibited referral when he or a member of his group practice⁹⁹ personally provides or supervises the services.¹⁰⁰ The "rural area" exception allows a physician to self-refer to a clinical lab located in a rural area.¹⁰¹ The "large corporation" provision allows self-referral when the lab is part of a publicly-held corporation with assets of \$100 million or more at the end of its last fiscal year.¹⁰²

96. 42 U.S.C. 1395nn(a) (Supp. IV 1992) [hereinafter Stark I]. The Act is known as "Stark I" because of the bill's sponsor, Representative Pete Stark. See Thomas Crane & John Steiner, Jr., *Congress Expands Self-Referral Prohibitions*, 3 Health L. Rep. (BNA) 159, 159 (Feb. 3, 1994). Representative Stark, chairman of the House Ways and Means Subcommittee on Health has been called, among other epithets, a "one-man legislative band" on the issue of self-referral. John K. Iglehart, *Congress Moves to Regulate Self-Referral and Physicians' Ownership of Clinical Laboratories*, 322 NEW ENG. J. MED. 1682, 1683 (1990). For a detailed discussion of the fashioning of the bill, see *id.* at 1684-85.

97. See *infra* notes 109-19 and accompanying text.

98. 42 U.S.C. § 1395nn(a) (Supp. IV 1992).

99. "Group practice" is defined as a group of two or more physicians legally organized as a partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association

(A) in which each physician who is a member of the group provides substantially the full range of services which the physician routinely provides (including medical care, consultation, diagnosis, or treatment) through the joint use of shared office space, facilities, equipment, and personnel;

(B) for which substantially all of the services of the physicians who are members of the group are provided through the group and are billed in the name of the group and amounts so received are treated as receipts of the group;

(C) in which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined by members of the group; and

(D) which meets such other standards as the Secretary may impose by regulation.

Id. § 1395nn(h)(4). This definition has provoked much controversy. The AMA wanted to allow doctors who were not part of a formal group practice to be able to refer to facilities in which they shared an interest. Diane M. Gianelli, *Budget Package Tightens Up Self-Referral*, AM. MED. NEWS, Aug. 23, 1993, at 8.

100. 42 U.S.C. § 1395nn(b)(1) (Supp. IV 1992). Further, a physician or a member of his group practice can provide in-office services ancillary to his practice. They must be provided or supervised by the referring physician or a member of his group practice. They must also be provided in a building in which the physician or group practice member practices medicine or in a central location set up by the group to perform the services. Certain billing requirements must be met as well. *Id.* § 1395nn(b)(2).

101. *Id.* § 1395nn(d)(2).

102. *Id.* § 1395nn(c). To be eligible for this exception, the physician must have purchased the security on terms generally available to the public and the security must have been listed for trading on the New York Stock Exchange or on the American Stock

The statute requires that each clinical lab affected by the statute provide the government with the names of physician-investors.¹⁰³ Further, Medicare reimbursement claims must identify the name and Medicare identification number of the referring physician.¹⁰⁴

Penalties for illegal referrals are stiff. A clinical lab providing services prohibited by the statute will not receive reimbursement for those services.¹⁰⁵ When a lab submits a Medicare claim for services provided to a patient as a result of a prohibited referral, the lab could be fined up to \$15,000 per test and lose its right to participate in the Medicare program.¹⁰⁶ A physician or entity that enters into an arrangement that has the purpose of circumventing the statute can be fined up to \$100,000.¹⁰⁷

Stark I is a rather limited measure, because it only affects referrals of Medicare patients to clinical¹⁰⁸ Representative Pete Stark successfully pushed for an expansion of the statute in 1993.

C. *The Comprehensive Physician Ownership and Referral Act of 1993*

The most important piece of self-referral legislation to date is the Comprehensive Physician Ownership and Referral Act of 1993 (Stark II).¹⁰⁹ Stark II, effective January 1, 1995, provides that a physician cannot self-refer for the following "designated health services": physi-

Exchange or must have been a national market system security traded under an automated interdealer quotation system operated by the National Association of Securities Dealers. *Id.* Other exceptions are provided for physician investment in prepaid plan organizations, *id.* § 1395nn(b)(3); hospitals, if the financial relationship does not relate to the provision of clinical laboratory services, *id.* § 1395nn(b)(4); hospitals in Puerto Rico, *id.* § 1395nn(d)(1); and hospitals themselves, not merely subdivisions thereof, when the referring physician is authorized to perform services at the hospital, *id.* § 1395nn(d)(3). The following are not prohibited by the statute when certain conditions are met: rental of office space, employment and service arrangements with hospitals, physician recruitment, and isolated transactions. *Id.* § 1395nn(e).

103. *Id.* § 1395nn(f).

104. *Id.*

105. *Id.* § 1395nn(g)(1).

106. *Id.* § 1395nn(g)(3).

107. *Id.* § 1395nn(g)(4).

108. At the time Stark I was passed, the best evidence relating to self-referral was the 1989 OIG study focusing on clinical laboratories and durable medical equipment. Since then, more studies have shown that self-referral may be a problem in a variety of contexts. See *supra* notes 39-40 and accompanying text.

109. The Comprehensive Physician Ownership and Referral Act of 1993, Pub. L. No. 103-66, 107 Stat. 312 (codified at 42 U.S.C. § 1395nn (Supp. VI 1994)). The Act is generally known as Stark II. See Crane & Steiner, *supra* note 96, at 159. For legislative history and a description of differences between Stark I and Stark II, see H.R. CONF. REP. NO. 103-213, 103d Cong., 1st Sess. (1993).

cal therapy; occupational therapy; radiology or other diagnostic services;¹¹⁰ radiation therapy; durable medical equipment;¹¹¹ parenteral and enteral nutrients, equipment, and supplies;¹¹² prosthetics, orthotics, and prosthetic devices; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.¹¹³ The statute further provides that indirect ownership will be treated the same as direct ownership of a facility.¹¹⁴

Stark II retains the same exceptions as Stark I, with a few modifications. As in Stark I, a physician may refer for services when he or a member of his group practice provides the services personally at the facility.¹¹⁵ The "rural area" exception in Stark I has been narrowed:

110. 42 U.S.C. § 1395nn(h)(5)(c) (Supp. VI 1994). However, a referral by a radiologist for diagnostic radiology services and by a radiation oncologist for radiation therapy are allowed if the service is performed by the referring provider pursuant to a consultation requested by another physician. *Id.*

111. An exception is made for the in-office provision of durable medical goods. *Id.*

112. An exception is made for the in-office provision of parenteral and enteral nutrients, equipment, and supplies. *Id.*

113. *Id.* § 1395nn(h)(6). This provision may or may not prohibit physicians from owning an interest in an ambulatory surgical care center. The provision could be interpreted as prohibiting physicians from referring patients to any facility that provides care that could be characterized as "outpatient hospital services," such as an ambulatory surgical care center. If the provision is interpreted this way, then Stark II effectively prevents physicians from investing in almost any kind of facility; almost every facility provides services that could be provided in a hospital. Alternatively, the provision could be interpreted to prohibit a physician from referring patients to a hospital in which the physician has an interest, whether the hospital provides the services on an inpatient basis or contracts with another entity to provide the services on an outpatient basis.

114. An ownership interest, for the purposes of Stark II, "may be through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service." *Id.* § 1395nn(a)(2). This provision addresses the concerns of critics that physicians and investors evaded Stark I through complex ownership arrangements. See Mitchell & Scott, *supra* note 1, at 498 ("Since the Stark legislation [of 1989] and the reporting requirements do not explicitly prohibit referrals by indirect owners, it may be possible to circumvent these laws through complex indirect ownership arrangements."). Mitchell and Scott argue that

[i]f regulation is meant to restrict referrals to for-profit health care facilities, then the legislation must clearly define investment interests, ownership structures, and compensation relationships to include both direct and indirect ownership arrangements. Failure to recognize indirect ownership and compensation arrangements will limit the impact of any regulation that attempts to prohibit the practice of self-referral.

Id. at 518.

115. 42 U.S.C. § 1395nn(b)(1) (Supp. VI 1994). A new requirement is added for physicians who seek to characterize themselves as members of a group practice under the statute: Members of the group must conduct personally no less than 75% of the physician-patient encounters of the group practice. *Id.* § 1395nn(h)(4)(A)(V). Stark II also specifies that a physician in group practice may not receive compensation based on the volume or value of her referrals, but she can be paid both a share of overall profits of the group, and a productivity bonus based on services personally performed or supervised. *Id.* Neither a

Stark II requires that "substantially all" of the health services furnished by the entity be provided to individuals living in a rural area.¹¹⁶ The "large corporation" exception requirements have been eased.¹¹⁷ The AMA argued that an exemption should be provided when community need for a facility and lack of available alternative financing could be shown,¹¹⁸ but no such provision was included. The greatest weakness of Stark II is the same as that of Stark I: it only covers referrals of Medicare patients.¹¹⁹

D. *The Federal Response: Conclusion*

Before Stark II, most physician-investors were affected only by the Anti-Fraud Statute. A doctor who learned of an opportunity to invest in an MRI center near her practice,¹²⁰ for instance, would not have needed to consider Stark I, since it only applies to investments in clinical labs. If she heeded the Fraud Alert, she would have made a reasonable capital investment in the enterprise. The safest investment would have been one in which no more than forty percent of her co-investors were physicians and the physicians provided no more than forty percent of referrals to the facility, because safe-harbor provi-

profit distribution nor a productivity bonus can be related to the volume or value of referrals by a physician. *Id.* § 1395nn(h)(4)(B)(i).

Attorneys Thomas Crane and John Steiner, Jr. assert that "Congress . . . toughened the requirements to qualify in an effort to restrict group practices without walls," but they note that Congress's failure to limit the numbers of physicians allowed to participate in a "group practice" encourages small physician groups to form combinations. Crane & Steiner, *supra* note 96, at 160.

116. *Id.* § 1395nn(d)(2). The statute also allows a new type of investment: ownership of shares in a regulated investment company as defined in § 851(a) of the Internal Revenue Code of 1986, if such company has assets of \$75 million. *Id.* § 1395nn(c)(2).

117. *Id.* § 1395nn(c). "Large corporation" is defined as a corporation having assets of \$75 million at the end of its last fiscal year, or on average during the previous three fiscal years, rather than \$100 million at the end of its last fiscal year. *Id.*

118. 1993 *Hearings*, *supra* note 7, at 205 (statement of Dr. Nancy W. Dickey, Member, Board of Trustees, American Medical Association). See generally Diane M. Gianelli, *Budget Package Tightens Up Self-Referral*, AM. MED. NEWS, Aug. 23, 1993, at 1 (describing response of AMA to new legislation).

119. 42 U.S.C. § 1395nn(a). Some argue that Stark II significantly strengthens the federal response to self-referral because of the way in which it acts as a supplement to the Anti-Fraud Statute:

[Stark II] will likely have the effect of decriminalizing conduct covered by both pieces of legislation because unless clear criminal intent is present it is likely that the first line enforcement authority will be Stark II, which provides for only civil sanctions. Thus, Stark II should have the effect of leaving criminal prosecutors more free time to prosecute clear criminal conduct and financial inducements not covered under Stark II.

Crane & Steiner, *supra* note 96, at 160.

120. A 1990 AMA survey showed that physicians were most likely to invest in MRI, radiology, or clinical laboratory facilities. Mitchell & Scott, *supra* note 1, at 506.

sions protect that structure. The Anti-Fraud statute would not have posed insurmountable hurdles to self-referrals.

After Stark II goes into effect in January of 1995, a doctor who made such an investment will likely have to divest herself of it. Stark II unequivocally prohibits self-referral of Medicare patients to MRI centers in most instances. Only if the doctor's investment falls within a statutory exception will she be able to retain the investment. Many physicians will find themselves in a similar position—required to divest—in early 1995. For those doctors who invested in facilities in rural areas or those in which they provide services personally (both of which may be retained), the Fraud Alert will continue to be the most important guideline.

Stark II will unquestionably have a significant effect on existing joint ventures and will deter the formation of others, but its great limitation is that it only affects referrals of Medicare patients. Since forty percent of the nation's health care bills are paid by public programs, many physicians do treat Medicare patients.¹²¹ Still, the majority of bills are not covered by Medicare—and state law alone deals with self-referral in this context.

IV. THE STATE RESPONSES

By September of 1994, thirty-two states had enacted self-referral legislation. Statutes in eighteen states restrict the practice,¹²² while statutes in fourteen require physicians only to disclose investment interests to patients.¹²³ Briefly described, the fourteen "disclosure" stat-

121. U.S. GENERAL ACCOUNTING OFFICE, *HEALTH INSURANCE: VULNERABLE PAYERS LOSE BILLIONS TO FRAUD AND ABUSE* 21 (1992).

122. FLA. STAT. ANN. §§ 455.241 (West 1981), 455.236-237 (West Supp. 1994); GA. CODE ANN. § 43-1B-3 to -24 (Michie Supp. 1993); ILL. ANN. STAT. ch. 225, P 47/15-/25 (Smith-Hurd Supp. 1994); ME. REV. STAT. ANN. tit. 22, § 2081-2087 (West Supp. 1993); MD. CODE ANN., HEALTH OCC. § 1-301 to -306 (West Supp. 1993); MICH. STAT. ANN. § 14.15(16221) (Callaghan 1988); MO. ANN. STAT. § 334.252-.253 (Vernon Supp. 1994); MONT. CODE ANN. § 37-2-101 to -102 (1993); NEV. REV. STAT. ANN. §§ 439B.420-425, 630.305, 652.235 (Michie Supp. 1993); N.J. STAT. ANN. § 45:9-22.4 to .5 (West 1991); N.Y. PUB. HEALTH LAW § 238-a to -e (McKinney Supp. 1994); N.C. GEN. STAT. § 90-405 to -408 (1993); OHIO REV. CODE ANN. § 4731.65-.68 (Anderson Supp. 1992); R.I. GEN. LAWS § 5-48.1-1 to -5 (Supp. 1993); S.C. CODE ANN. § 44-113-10 to -80 (Law. Co-op. Supp. 1993); TENN. CODE ANN. § 63-6-601 to -608 (Supp. 1993); VA. CODE ANN. § 54.1-2410 to -2414 (Michie Supp. 1994).

In addition, at least 36 states prohibit physicians from receiving or paying kickbacks for referrals. U.S. DEP'T OF HEALTH & HUMAN SERVICES: *FINANCIAL ARRANGEMENTS BETWEEN REFERRING PHYSICIANS AND HEALTH CARE BUSINESSES: STATE LAWS AND REGULATIONS* 6 (1989).

123. ARIZ. REV. STAT. ANN. § 32-1401(24)(ff) (Supp. 1993); CAL. BUS. & PROF. CODE §§ 650, 654.1-2 (West 1990); CONN. GEN. STAT. ANN. § 20-7a to -7b (West Supp. 1993); KAN. STAT. ANN. § 65-2837(29) (Supp. 1993); LA. REV. STAT. ANN. § 37: 1744 (West Supp.

utes do not require physicians to divest their interest in a facility to which they refer patients, but only to reveal the interest to those patients.¹²⁴ Most of the other state legislation can be characterized as taking a "community need" or "federal model" approach, though some statutes combine elements in unique ways. The seven community-need statutes impose significant limits on a physician's discretion, generally allowing self-referral only when there is a demonstrated community need for the service and no alternative financing available.¹²⁵ More restrictive are the six federal-model statutes, which mainly allow self-referral to facilities when the referring physician personally provides services there or when the facility is located in a rural area.¹²⁶ Anomaly statutes are broader and narrower in unique ways. The remainder of this Comment distinguishes the various patterns of legislation, explains how each type supplements federal law, and examines the strengths and weaknesses of the statutes.

A. Disclosure States

States allowing self-referral when it is accompanied by disclosure are Arizona, California, Connecticut, Kansas, Louisiana, Massachusetts, Minnesota, New Hampshire, Oklahoma, Pennsylvania, South Dakota, Utah, Washington, and West Virginia.¹²⁷ Typically, these states do not have extensive or detailed legislation on the subject. Failure to disclose often results in the sanctions associated with other violations of the state's code of professional conduct.¹²⁸

West Virginia's statute, perhaps the most ambiguous of the disclosure laws, provides that it is unprofessional conduct for a physician to refer a patient to any clinical laboratory or pharmacy in which she

1993); MASS. GEN. LAWS ANN. ch. 112, § 12AA (West Supp. 1994); MINN. STAT. § 147.091(p)(3)-(4) (Supp. 1994); N.H. REV. STAT. ANN. § 125:25-a to -c (Supp. 1993); OKLA. STAT. tit. 59, § 725.4 (Supp. 1994); PA. STAT. ANN. tit. 35, § 449.21-22 (1993); S.D. CODIFIED LAWS ANN. § 36-2-19 (Supp. 1994); UTAH CODE ANN. § 58-12-44 (Supp. 1994); WASH. REV. CODE ANN. § 18.130.180 (West 1989); W. VA. CODE § 30-3-14(c)(7) (1993).

124. See statutes cited *supra* note 123. For further discussion, see *infra* notes 127-51 and accompanying text.

125. Georgia, Illinois, Maine, Maryland, North Carolina, Tennessee, and Virginia have community-need statutes. See statutes cited *supra* note 122. For further discussion, see *infra* notes 152-74 and accompanying text.

126. Florida, Nevada, New York, Ohio, Rhode Island, and South Carolina have federal model statutes. See statutes cited *supra* note 122. For further discussion, see *infra* notes 175-86 and accompanying text.

127. See statutes cited *supra* note 123.

128. See, e.g., MINN. STAT. §§ 147.091, 147.141 (Supp. 1994). Oklahoma provides that violations of the disclosure requirements are punishable by disciplinary action by the relevant state agency and by a fine of between \$100 and \$1000. OKLA. STAT. ANN. tit. 59, § 725.4(B) (West Supp. 1993).

has a proprietary interest unless she discloses the interest in writing.¹²⁹ The writing must indicate that the patient may have any clinical laboratory perform the requisite tests or any pharmacy provide the drugs prescribed.¹³⁰ This statute provokes many questions. Must a physician disclose an indirect financial interest, such as her ownership interest in a corporation that is a partner in a facility to which she refers?¹³¹ Should she reveal an investment interest held by her spouse or another member of her immediate family? Must the disclosure form reveal the amount or nature of the interest? Should the form identify specific alternative entities where the patient may also receive the drug or service? Must the written disclosure be provided to the patient directly, or may it be posted on a wall? If provided to the patient directly, must it be given in advance of the patient's receipt of the treatment? In West Virginia, physicians must provide their own answers until these questions are answered by the courts.

Other states' statutes are somewhat more detailed. Kansas, for instance, only requires disclosure of an interest in a facility when the interest is greater than ten percent.¹³² Louisiana does not require disclosure when referral is made within a group practice,¹³³ and Minnesota does not when the referring physician performs services at the facility.¹³⁴ Other states have more specific requirements for the disclosure forms themselves. Arizonad, for instance, requires that patients sign the disclosure form.¹³⁵

129. W. VA. CODE § 30-3-14(c)(7) (1993). The statute applies to podiatrists as well as physicians. *Id.*

130. *Id.*

131. West Virginia only specifically excludes lease arrangements from the purview of the statute. *Id.* § 30-3-14(c)(7).

132. KAN. STAT. ANN. § 65-2837(29)(h) (Supp. 1993). California requires disclosure when a provider or member of his immediate family owns an investment interest greater than five percent of the entity or \$5,000, whichever is lower, CAL. BUS. & PROF. CODE § 654.2(d) (West 1990), and South Dakota requires disclosure when the investment interest is greater than twenty-five percent, S.D. CODIFIED LAWS ANN. § 36-2-19 (Supp. 1994).

133. LA. REV. STAT. ANN. § 37:1744(A)-(B) (West Supp. 1994).

134. MINN. STAT. § 147.091(p)(4) (1992). Oklahoma has a similar provision, exempting disclosure when the testing center or laboratory is an extension of or ancillary to the provider's practice and the health provider "provides for and supervises the services at the facility." OKLA. STAT. ANN. tit. 59, § 725.4(A) (Supp. 1994).

135. See ARIZ. REV. STAT. ANN. § 32-1401(24)(ff) (Supp. 1993). The statute requires that a patient or his guardian sign a form by which he acknowledges his understanding that "the doctor has a direct financial interest" in the goods or services prescribed and, if such is the case, that "the prescribed treatment, goods or services are available on a competitive basis." *Id.* Massachusetts's statute provides that a physician who refers a patient for physical therapy services to an entity in which the physician owns an interest must disclose that interest in the following language: "The referring registered or licensed person maintains an ownership interest in the facility to which you are being referred for physical therapy

New Hampshire's statute is the most comprehensive of the disclosure statutes.¹³⁶ It applies to referrals made by any health care provider for diagnostic services, physical therapy, radiation therapy, intravenous therapy, rehabilitation services, or services provided in a hospital when the service is not exclusively owned by the hospital.¹³⁷ In-office diagnostic tests are not within the scope of the statute.¹³⁸ Investment interests of a provider or his spouse or child trigger the statute, but not when the ownership interest is comprised of publicly-traded securities purchased on terms available to the general public.¹³⁹

New Hampshire's law details the disclosure process itself. A written disclosure form must be given to each patient at the time of referral or, if referred by phone, verbal disclosure must be followed by a prompt written statement.¹⁴⁰ The form must "conspicuously" contain the following language:

The referring health care practitioner maintains an ownership interest in the facility to which you are being referred. You are not required to utilize the facility to which you are being referred for these services. These services may be available elsewhere in the community. This office will provide an alternative referral upon your request.¹⁴¹

Failure to provide a disclosure form can result in suspension of a professional's license.¹⁴²

New Hampshire has also set up a mechanism for monitoring physician self-referral. The statute requires practitioners who self-refer to report on a quarterly basis their financial interest in the facility and the total number of their referrals to that facility.¹⁴³ The division of public health services will transmit the information to the state legislature by April 1, 1995, and will make a recommendation regarding the need for further self-referral legislation.¹⁴⁴

service. Physical therapy services may be available elsewhere in the community." MASS. GEN. LAWS ANN. ch. 112, § 12AA (West Supp. 1994).

136. N.H. REV. STAT. ANN. § 125:25-a to -c (Supp. 1993). Massachusetts's law, in contrast, is the most limited. It covers only referrals to physical therapy centers. See *supra* note 135.

137. *Id.* §§ 125:25-a(I), -a(V), -b(I), -b(IV), -b(V). Rehabilitation services include physical therapy, occupational therapy, and speech pathology. *Id.* § 125:25-a(IV).

138. *Id.* § 125:25-b(IV), (V).

139. Investment interests are defined as "including, but not limited to, any membership, proprietary interest, stock interest, partnership interest, co-ownership in any form, or any profit-sharing arrangement." *Id.* § 125:25-a(IV).

140. *Id.* § 125:25-b(II).

141. *Id.* § 125:25-b(III).

142. *Id.* § 125:25-b(VI).

143. *Id.* § 125:25-c.

144. Act of June 29, 1993, ch. 334, 1993 N.H. Laws 334:3.

State disclosure laws affect physicians in two ways. First, the statutes supplement federal law when federal law permits self-referral. Stark II will allow a physician to self-refer to an occupational therapy center in a rural area, for example, but New Hampshire law further requires the physician to disclose his interest to patients he refers.¹⁴⁵ Disclosure statutes also affect referrals of private patients not covered by federal law. Though a physician who refers only private patients to a lab in which he has invested is not affected by Stark II, New Hampshire's statute requires him to disclose that interest to such patients.

The wisdom of disclosure statutes is questionable.¹⁴⁶ The impetus behind self-referral legislation has been the need to reduce unnecessary utilization of tests and services and thus lower health care costs generally.¹⁴⁷ By simply requiring a physician to disclose his interest to a patient, however, it is not clear that any wasteful practices will be stopped. Most statutes do not require specific language, creating the possibility that the disclosure form is actually being used as an advertisement. The Deputy Inspector General testified in 1993 that "such a 'disclosure' by the physician is often turned into a positive testimonial about the entity where the patient is being sent."¹⁴⁸ Also, most states do not monitor how and when disclosure takes place. Studies in a related area, informed consent, have shown that full disclosure "still occurs relatively infrequently and not as envisioned by the law."¹⁴⁹

Even if a physician's financial interest is adequately and disinterestedly disclosed, patients may not have the incentive to seek a different facility or to question the necessity of the recommended test or service. Most patients trust their doctors and would not be inclined to question their physician's recommendation.¹⁵⁰ Further, many health insurance plans and Medicare and Medicaid do not give patients a

145. For a discussion of Stark II, see *supra* notes 109-19 and accompanying text.

146. The OIG Report describes disclosure laws as "perhaps the least onerous" of restrictions on self-referral, but also "the least likely to influence actual patterns of use of services." *OIG Report*, *supra* note 2, at 19,937. For a contrary viewpoint, see Carol Michna, *Note, The Patient Has Not Been Informed: A Proposal for a Physician Conflict of Interest Disclosure Law*, 27 VAL. U. L. REV. 495, 523-528 (1993).

147. See *supra* notes 11-13 and accompanying text.

148. See 1993 *Hearings*, *supra* note 7, at 170 (statement of Larry Morey, Deputy Inspector General for Investigations, Office of Inspector General).

149. Marc Rodwin, *Physicians' Conflicts of Interest: The Limitations of Disclosure*, 321 NEW ENG. J. MED. 1405, 1405 (1989).

150. As Rodwin states, patients are particularly vulnerable. Frequently, they are involuntary consumers who cannot plan their purchases and assess alternatives carefully. They often have little opportunity to learn from personal experience, or the cost of doing so may be high. These constraints distort their choices as consumers and increase their reliance on the recommendations of their physicians.

strong incentive to seek health care bargains. Even though some patients do have such an incentive in the form of a lower co-payment, it is often difficult for patients to evaluate their options in the health care market. In a 1989 survey, over fifty percent of those interviewed reported that they found it "somewhat or very hard to shop for doctors and hospitals," and nearly three-fourths found it similarly difficult to shop for ancillary services.¹⁵¹ In our present health care system, disclosure of a physician's investment will probably not significantly affect the choices patients make, and it is thus unlikely that disclosure will help limit overutilization of tests and services. In our present health care system, disclosure may do little more than increase awareness of physician investment.

B. Community-Need Statutes

Georgia, Illinois, Maine, Maryland, North Carolina, Tennessee, and Virginia have passed legislation that regulates self-referral far more effectively than disclosure alone.¹⁵² Statutes in these states generally prohibit physician self-referral, but the exceptions they provide are notable. Like Stark II, the statutes allow self-referral when the referring physician personally provides services at the facility or when the facility is part of a large corporation in which a physician has an interest.¹⁵³ Unlike Stark II, however, the statutes also allow self-referral when community need for the services and a lack of alternative financing can be shown, so long as referral to such a facility is accompanied by disclosure.

Statutes in North Carolina and Virginia illustrate some of the common characteristics, as well as some of the variations, in the community-need legislation.¹⁵⁴ Both states' laws prohibit any health care practitioner¹⁵⁵ from referring patients to an entity in which he or an

Id. at 1406. Rodwin suggests that disclosure statements might be more effective if they required "physicians who recommend expensive tests or procedures in facilities in which they have a financial interest . . . [to] advise their patients to seek a second opinion from a physician without a conflict of interest." *Id.*

151. *Id.* The OIG Report noted that "[p]atients have little basis with which to judge the efficiency, quality, or even pricing of one facility versus another." *OIG Report, supra* note 2, at 19,937.

152. See statutes cited *supra* note 122.

153. For discussion of Stark II exceptions, see *supra* notes 109-21 and accompanying text.

154. N.C. GEN. STAT. § 90-405 to -408 (1993); VA. CODE ANN. § 54.1-2410-2414 (Michie Supp. 1994).

155. Virginia's statute, like those of most of the other community-need states, encompasses referrals made by most health care professionals licensed by the state—Virginia excludes only embalmers and veterinarians. VA. CODE ANN. § 54.1-2410 (Michie Supp. 1994). In North Carolina, the statute specifically applies to those licensed or certified to

immediate family member has an investment interest,¹⁵⁶ but the statutes define "immediate family" very differently. In Virginia, "immediate family" encompasses a physician's spouse, child, child's spouse, stepchild, stepchild's spouse, grandchild, grandchild's spouse, parent, stepparent, parent-in-law, or sibling, while in North Carolina it includes only his spouse or dependent minor child.¹⁵⁷ Both statutes make exceptions for investments in large corporations,¹⁵⁸ but only Virginia makes the typical exception for facilities where the physician personally provides care.¹⁵⁹ Most importantly, both permit investment and referral if there is a "demonstrated need" in the community for the facility and alternative financing is not available.¹⁶⁰ North Carolina's requirements are probably easier to satisfy, since the statute does not define "demonstrated need" and only requires that alternative financing not be available "on reasonable terms from other sources."¹⁶¹ Virginia, in contrast, finds demonstrated need only when there is no facility in the community providing similar services and alternative financing is not available for the facility.¹⁶²

practice medicine, dentistry, optometry, osteopathy, chiropractic, nursing, podiatry, psychology, physical therapy, occupational therapy, speech and language pathology, and audiology. N.C. GEN. STAT. § 90-406(7) (1993). Tennessee's statute is unusual in this regard, as its statute regulates only physicians. TENN. CODE ANN. § 63-6-602 (Supp. 1993).

156. North Carolina also prohibits referral to a facility in which a member of a physician's group practice has an investment interest in the facility. N.C. GEN. STAT. § 90-406(2) (1993).

157. VA. CODE ANN. § 54.1-241 (Michie Supp. 1994); N.C. GEN. STAT. § 90-405(8) (1993). Definitions of "immediate family" vary significantly in community-need statutes. *E.g.*, MD. CODE ANN., HEALTH OCC. § 1-301 (Supp. 1993) (defining "immediate family" as spouse, child, child's spouse, parent, spouse's parent, sibling, and sibling's spouse); ILL. ANN. STAT. ch. 225, P 47/15(f) (Smith-Hurd Supp. 1994) (defining "immediate family" as spouse, child, child's spouse, and a parent).

158. N.C. GEN. STAT. § 90-405(9)(d) (1993); VA. CODE ANN. § 54.1-2411(D) (Michie Supp. 1994).

159. VA. CODE ANN. § 54.1-2411(A). North Carolina's is the only community-need statute that does not allow physicians to self-refer to facilities where they personally provide services. *See* N.C. GEN. STAT. § 90-405(9)(9).

160. N.C. GEN. STAT. § 90-408(a)(1) (1993); VA. CODE ANN. § 54.1-2411(B) (Michie Supp. 1994). The criteria for both statutes are the following: individuals other than practitioners must be offered an opportunity to invest in the entity on the same terms as those offered to referring practitioners; no investor-practitioner can be required or encouraged to refer patients to the entity or otherwise generate business as a condition of becoming or remaining an investor; the services of the entity must be marketed to practitioner-investors and other investors on the same terms; the entity cannot issue or guarantee loans for practitioners who are in a position to refer patients to the entity; the income on the practitioners' investment must be based on his equity in the entity, not his referral volumes; and the investment contract between the entity and the practitioner cannot include any covenant or clause limiting or preventing the practitioner's investment in other entities. *Id.*

161. N.C. GEN. STAT. § 90-408(a)(2) (1993).

162. VA. CODE ANN. § 54.1-2410 (Michie Supp. 1994). The AMA's Council on Ethical and Judicial Affairs recommended that demonstrated need for a facility could be shown

When the community-need exemption is granted in either state, a physician must disclose his interest in the facility to the patient. In both states, disclosure must be made at the time of referral, include a list of reasonably available alternative facilities, if any, and assure the patient that choosing another entity will not affect his treatment or care.¹⁶³ In Virginia, the entity must establish an internal-use review to ensure that investors are making appropriate referrals.¹⁶⁴ Penalties for prohibited self-referral are harsh in both states: referrals in contravention of the statute may subject a provider to \$20,000 in civil penalties for each referral and may be punished with disciplinary action by the appropriate regulatory board.¹⁶⁵ In North Carolina, an arrangement designed to circumvent the statute can be penalized by a \$75,000 fine, and an entity that performs services pursuant to a prohibited referral may not make a claim for payment for those services.¹⁶⁶

Statutes in Georgia, Maryland, Maine, Illinois, and Tennessee are generally similar to the North Carolina and Virginia legislation but vary in a few important ways. Illinois and Maine provide a more generous definition of the circumstances under which a state agency can find that a community need exists.¹⁶⁷ Georgia requires a community-

"when there is no facility of reasonable quality in the community or when use of existing facilities is onerous for patients." 1993 *Hearings*, *supra* note 7, at 211. Maine and Illinois follow these recommendations more closely. See *infra* note 167.

163. N.C. GEN. STAT. § 90-408(c) (1993); VA. CODE ANN. § 54.1-2411(C) (Michie Supp. 1994). North Carolina and Virginia thus do not require disclosure when a physician is allowed to self-refer under another statutory exception, such as the large corporation exception. In contrast, Illinois and Maine explicitly require all practitioners who are allowed to self-refer to disclose their interest to patients. ILL. ANN. STAT. ch. 225, ¶ 47/20(b)(7) (Smith-Hurd Supp. 1994); ME. REV. STAT. ANN. tit. 22 § 2085(2)(D)(7) (West Supp. 1993).

164. VA. CODE ANN. § 54.1-2411(C)(3) (Michie Supp. 1994).

165. N.C. GEN. STAT. § 90-407 (1993); VA. CODE ANN. § 54.1-2412(C)-(D) (Michie Supp. 1994).

166. N.C. GEN. STAT. §§ 90-407(c), 90-406(b) (1993).

167. In Illinois, demonstrated need exists when:

- (1) there is no facility of reasonable quality that provides appropriate service,
- (2) use of existing facilities is onerous or creates too great a hardship for patients,
- (3) the entity is formed to own or lease medical equipment which replaces obsolete or otherwise inadequate equipment in or under the control of a hospital located in a federally designated health manpower shortage area, or
- (4) such other standards as established, by rule, by the [Health Care Facilities Planning] Board.

ILL. ANN. STAT. ch. 225, P 42/20(b) (Smith-Hurd Supp. 1994). In Maine, the language is identical except in the last section, which requires that a facility meet other standards established by the Bureau of Insurance, "including a standard allowing the Bureau to determine whether the fees charged for the health services are competitive with fees charged for those services outside the community." ME. REV. STAT. ANN. tit. 22, § 2085(2)(D)(7) (West Supp. 1993).

need facility to provide uncompensated health services for indigent or charity patients at a rate at or above three percent of the gross revenues of the facility.¹⁶⁸ Tennessee's statute contains a grandfather clause allowing physicians who made investments before passage of the statute to retain their investments:

If physicians have invested in entities prior to the effective date of this act, the physicians shall reevaluate their activity in accordance with the provisions of this act and comply with its provisions. If compliance with the need and alternative investor criteria is not practical, it is essential that the identification of reasonably available alternative entities be provided.¹⁶⁹

Illinois and Maine have similar provisions, but they both require that a state agency designate, by rule, when compliance is "not practical."¹⁷⁰

The greatest strength of community-need legislation is its flexibility. The community-need provision takes the place of the Stark II exemption that allows physicians in rural areas to self-refer when the facility provides most of its services to rural residents. The purpose of the Stark II rural area exemption and the community-need exemption is the same: to allow physicians to invest where a facility is needed but capital is lacking. Federal law is willing to presume that these conditions are generally present in rural areas, while the state statutes allow physicians to show that it might be true in urban areas as well. Community-need legislation more fully acknowledges that physicians in any area may be motivated by a desire to meet their patients' needs and may be willing to provide capital for facilities when outside investors are not.¹⁷¹ It recognizes that a societal interest—the provision of medical services to those in underserved communities—sometimes outweighs the hazards associated with self-referral.¹⁷²

Illinois and Maine also allow providers to request advisory opinions as to the legality of a particular referral. ILL. COMP. STAT. ANN. ch. 225, § 47/20(g) (Michie Supp. 1994); ME. REV. STAT. ANN. tit. 22, § 2085(7) (West Supp. 1993).

168. GA. CODE ANN. § 43-1B-6(a)(4) (Supp. 1993). Georgia also provides that investment interests in facilities in rural areas are not covered by its statute. *Id.* § 43-1B-3(8)(A).

169. TENN. CODE ANN. § 63-6-605 (Supp. 1993).

170. ILL. ANN. STAT. ch. 225, para. 47/20(f) (Smith-Hurd Supp. 1994); ME. REV. STAT. ANN. tit. 22, § 2085(6) (West Supp. 1993).

171. See 1993 *Hearings*, *supra* note 7, at 206-17 (Report of the Council on Ethical and Judicial Affairs and Self-Referral Clarifications).

172. As the Council on Ethical and Judicial Affairs of the American Medical Association argued,

patients may be deprived of the best health care if physicians cannot invest and self-refer. Physicians have often been exclusively motivated by the important

At the same time, community need legislation does not allow self-referral when the need for a facility is questionable or other investors are available. In some instances raises higher hurdles to investment than Stark II does. Stark II requires a physician in a rural area who wants to invest in an occupational therapy center, for instance, to show that substantially all of the therapy services will be provided to people living in a rural area.¹⁷³ Community-need legislation requires an additional showing of demonstrated need and a lack of alternative financing. Community-need legislation also requires more than federal law in relatively affluent urban areas where physicians are likely

needs of their patients in becoming involved in such arrangements. Blanket bans on self-referral are inappropriate. Investing and referring when it is a direct extension of a physician's commitment to serve patients' needs is both ethical and desirable.

1993 Hearings, *supra* note 7, at 210 (Report by the Council on Ethical and Judicial Affairs). The Council has further noted that physicians may be willing to accept a lower rate of return on an investment in a rural or poor area, since they will be concerned not only with profits, the main concern of a non-physician-investor, but also with providing needed care for their patients. *Council Report, supra* note 6, at 2368.

On the other hand, arguments can be made that a genuine community need for a facility would attract outside investors, and that allowing this much flexibility in legislation leaves too much room for the unscrupulous to abuse the provision. As Rep. Pete Stark put it, "every time we start making exemptions from [a general ban on self-referral], six law firms and three accountants dream up new ways to get around it, and the fact is that it is very profitable" 1993 Hearings, *supra* note 7, at 189.

In an attempt to address such concerns, the Council on Ethical and Judicial Affairs has recently clarified its recommendations for community-need legislation. The Council recommends that self-referral be allowed only when there is no facility of reasonable quality in the area, the use of existing facilities is onerous to patients, and there is a lack of alternative financing, defining those terms as follows:

No facility of reasonable quality. Self-referral cannot be justified simply if the facility would offer some marginal improvement over the quality of services in the community. The potential benefits of the facility should be substantial to justify assuming the risks of self-referral. The question is whether the community has facilities that can provide medically appropriate services. . . .

Use of existing facilities is onerous This might occur, for example, if existing facilities are so heavily used that patients face undue delays in receiving services. A delay is undue if putting off the service could compromise the patient's care, i.e., it would affect the curability or reversibility of the patient's condition. There would also be a hardship if patients had long travel times that made it difficult for them to receive services. . . . Longer travel times would be acceptable if patients tended to use the facility rarely, while longer travel times would be unacceptable if patients tended to use the facility more regularly.

Alternative financing The burden on the builder of the facility is to show that adequate capital could not be raised without turning to self-referring physicians. As to the kind of efforts that must be made to secure alternative financing, the builder would have to undertake the usual steps that entrepreneurs undertake, including efforts to secure funding from banks, other financial institutions, and venture capitalists.

1993 Hearings, *supra* note 7, at 216.

173. See *supra* note 116 and accompanying text.

to have many privately insured patients.¹⁷⁴ A physician who treats many non-Medicare patients may decide that an investment in an MRI center, for instance, would be profitable since she could guarantee a flow of privately-insured patients to the facility. Stark II would only prevent the physician from referring Medicare patients to the center. Community-need legislation, however, prohibits self-referral unless she can show that the local population needs the center and there is no other means to finance it. In affluent urban areas and rural areas, community-need legislation probably supplements federal law effectively, serving as an additional barrier to joint ventures of questionable necessity.

Community need legislation cannot serve as an equally beneficial supplement in poor urban areas, but that shortcoming is due to Stark II. Community-need legislation would give physicians in poorer urban areas the opportunity to show that a particular facility was needed and yet did not interest an adequate number of non-physician-investors. Stark II, however, absolutely bars physicians from investing in such a center unless the physician performs services there personally or his investment meets the requirements of one of the other statutory exceptions. Despite this limitation, community need legislation generally fills the gaps in federal law in a cautious but not rigid manner.

C. Federal Model Statutes

"Federal model" statutes are fairly strict, allowing self-referral only in a few clearly defined situations. Florida, Nevada, New York, Ohio, Rhode Island, and South Carolina can be categorized as federal model states because their legislation in various ways extends federal law restrictions on referrals of Medicare patients to referrals of all patients. This type of legislation either parallels Stark I¹⁷⁵ or incorporates important elements of the Medicare Anti-Fraud and Abuse Statute.¹⁷⁶

174. There is some evidence suggesting that physicians with more privately insured patients are most likely to self-refer. In one Florida study, researchers found that joint ventures treated "relatively more patients with good insurance coverage." Mitchell & Scott, *supra* note 53, at 2058. Joint venture comprehensive rehabilitation centers received 44% of their payments from Blue Cross and commercial insurers and only 20.5% from Medicare, while non-joint venture centers received only 24.8% of their payments from Blue Cross and commercial insurers and 40% from Medicare. *Id.*

175. See *supra* notes 96-108 and accompanying text (discussing Stark I).

176. See *supra* notes 54-95 and accompanying text (discussing Anti-Fraud Statute); see also statutes cited *supra* note 122.

1. Stark I Model

New York and Ohio have enacted statutes that resemble the first federal self-referral legislation, Stark I.¹⁷⁷ Stark I prohibits referral of Medicare patients to clinical laboratories in which the referring physician has an interest. Both New York and Ohio have extended that prohibition to referrals of all patients to clinical laboratories in which the referring physician owns an interest, but New York has also broadened it to cover referrals for pharmacy services and x-ray or imaging services. Like Stark I, New York and Ohio allow self-referral when the physician personally provides services at the facility, when his investment is in a larger corporation of which the facility is but a part, or where the facility is located in a rural area.¹⁷⁸ New York also requires disclosure of the interest when self-referral is allowed.¹⁷⁹

While Stark I is in effect, the New York and Ohio statutes serve as fairly straightforward extensions of federal law: Stark I generally prevents a physician in New York or Ohio from self-referring Medicare patients, and New York and Ohio law prevent the same physician from referring his privately-insured patients to the lab. Once Stark II takes effect, however, New York and Ohio law will serve as a far more limited, and arguably less sensible, supplement to federal law. While Stark II will affect Medicare referrals to many kinds of facilities, Ohio law will prohibit other referrals only to clinical laboratories. In New York, the combination of Stark II and current state law will produce very different disclosure requirements for physician-investors depending on the type of facility in which they invest. For instance, a physician who is allowed under Stark II to self-refer to a clinical lab in a rural area must disclose that interest under New York law, but a physician who is allowed under Stark II to self-refer to a physical therapy center in a rural area does not need to disclose that interest. In Ohio, consistency with federal law has been lost. In New York, Stark II will wreak havoc on its initially rational extension of federal law.

177. N.Y. PUBLIC HEALTH LAW § 238 (McKinney Supp. 1994); OHIO REV. CODE ANN. § 4731.65 to .71 (Anderson 1994). See *supra* notes 96-108 (discussing Stark I).

178. See *supra* notes 99-102 and accompanying text.

179. N.Y. PUBLIC HEALTH LAW § 238-a(4)(D) (McKinney Supp. 1994). Ohio law provides a unique disclosure requirement: referrals for in-office ancillary services will only be considered an exception under the statute "if the third-party payer is aware of and has agreed in writing to reimburse the services notwithstanding the financial arrangement between the physician and the provider of such ancillary services." OHIO REV. CODE ANN. § 4731.67(D) (Anderson 1994).

2. Safe Harbor Models

Florida and South Carolina's statutes have never been generally consistent with federal law.¹⁸⁰ Each broadly prohibits self-referral, but also creates a patchwork of exceptions.¹⁸¹ The most important exception, allowing self-referral when less than fifty percent of investors are in a position to make referrals to an entity, is similar to a safe harbor as defined by the Office of the Inspector General.¹⁸²

The states' fifty percent provision is different from the OIG safe harbor, however, in a crucial way: the OIG mandates that no more than forty percent of an entity's revenues come from referrals of physician-investors, while there is no such requirement in Florida or South Carolina.¹⁸³ Because Florida and South Carolina do not limit the number of referrals from physician-investors, there is a danger that those physicians could have been pressured by outside investors into making excessive referrals. The fifty percent provision is a blunt instrument for limiting self-referral, the primary virtue of which is clarity.

180. FLA. STAT. ANN. § 455.25 (West 1991); *id.* § 455.236 (West Supp. 1993); S.C. CODE ANN. § 44-113-10 to -80 (Law. Co-op. Supp. 1993).

181. Both Florida and South Carolina allow self-referral when the provider's investment interest is in a large corporation, when the provider will perform services directly at the facility in which he owns an interest, or when the facility is located in a rural area. Like New York, both Florida and South Carolina require a provider to disclose his investment interest upon referral. FLA. STAT. ANN. § 455.25 (West 1991); *id.* § 455.236 (West Supp. 1993); S.C. CODE ANN. § 44-113-10 to -40 (Law. Co-op. Supp. 1993).

Florida's extensive list of additional exceptions makes its legislation unique. The statute does not cover, for instance, referrals made by a radiologist for diagnostic imaging services or by a physician specializing in the provision of radiation therapy services for such services. These specific exceptions replace the more typical provision allowing physicians to refer for services provided in their office. Other exceptions include referrals made by a cardiologist for cardiac catheterization services, a urologist for lithotripsy services, and a health care provider for diagnostic clinical laboratory services where such services are directly related to renal dialysis. The reasoning behind these exceptions may be that there are well-established norms for the provision of certain tests and services, so a physician's ownership in a facility therefore will have a negligible effect on the number of referrals he makes for the services.

182. FLA. STAT. ANN. § 455.236(4)(b)(2)(a) (West Supp. 1993); S.C. CODE ANN. § 44-113-30(A)(3)(a) (Law. Co-op. Supp. 1993). Certain investment criteria must be met: investment opportunities must be offered on equal terms to physicians and others; a physician who is expected to make a large number of referrals may not be offered a better investment opportunity; and a physician cannot be pressured to make referrals in order to become or remain an investor. FLA. STAT. ANN. § 455.236(4)(b)(2)(a); S.C. CODE ANN. § 44-113-30(A)(3)(a).

As noted previously, the OIG "small entity" safe harbor protects investments from Medicare Anti-Fraud scrutiny when no more than 40% of an entity is owned by persons in a position to make referrals and no more than 40% of its revenues come from investor referrals. See *supra* text accompanying note 81.

183. See *supra* note 81 and accompanying text.

3. Anti-Fraud Statute Model

Rhode Island's legislation can also be characterized as a federal model state, but one that creates a particularly ambiguous legal environment for physicians. Without prohibiting any specific kinds of self-referral, Rhode Island has explicitly applied the standards of the Medicare Anti-Fraud and Abuse Statute to the delivery of all health care services and items in the state.¹⁸⁴ The Medicare Anti-Fraud Statute prohibits remuneration for referrals in any form, and the OIG has used the statute to monitor physician self-referral in recent years, as is shown by the Fraud Alert, the promulgation of safe harbors, and the *Hanlester Network* suit.¹⁸⁵ The Rhode Island statute's statement of purpose suggests that the legislature intended the statute to be interpreted similarly, but the statute nonetheless leaves much to the imagination.¹⁸⁶ The Medicare Anti-Fraud statute was not designed to deal with physician self-referral, and has only recently been used for that purpose.

D. Anomaly States

The narrow statutes in some states are far from ambiguous. Missouri penalizes self-referral for the provision of physical therapy services.¹⁸⁷ Montana does not allow medical practitioners to own an

184. R.I. GEN. LAWS § 5-48.1-1 to -5 (Supp. 1993). For an explanation of the Medicare Anti-Fraud and Abuse Statute, see *supra* notes 54-95 and accompanying text.

185. See *supra* notes 65-95 and accompanying text.

186. Rhode Island's statute reads:

(1) Individuals and corporations sometimes establish joint ventures and other business arrangements to offer various diagnostic and therapeutic health care services and items to patients. While some of these arrangements assist in providing appropriate, but otherwise unavailable, services and items to patients or help finance nearby facilities as a convenience to patients, others appear to constitute opportunities for investment. Such arrangements can give rise to abuse by creating an environment in which health care providers could order unnecessary services from those facilities in which they own an interest. To limit such conduct, Congress of the United States amended the Social Security Act to prohibit certain financial arrangements. . . .

(2) The provisions of [these] amendments . . . apply only to Medicare/Medicaid reimbursed services and a void exists with respect to services rendered at the state level which are reimbursed by private payers.

(3) Accordingly, in order to protect the health, safety and welfare of all residents of this state, it is deemed appropriate to adopt the standards set forth in the federal statute as applicable to the delivery of all health care services and items in this state.

R.I. GEN. LAWS § 5-48.1-1 (Supp. 1993).

187. MO. ANN. STAT. § 334.253 (Vernon Supp. 1994). Exemptions are made: when the facility in which the physician owns an interest is the sole provider of the service within a rural area; when the physician owns registered securities in a large publicly held corporation; and in several other circumstances. *Id.* § 334.253(2).

interest in a drug company unless the interest is acquired through means available to the general public.¹⁸⁸ Massachusetts requires disclosure of an interest in a physical therapy center.¹⁸⁹ These statutes serve as a minimal supplement to federal law.

A number of other states, in contrast, have enacted sweeping provisions prohibiting self-referral. Michigan enacted a law in 1977 that made it illegal to direct or require a person to "purchase or secure a drug, device, treatment, procedure, or service from another person, place, facility, or business in which the licensee has a financial interest."¹⁹⁰ This statute, enacted before much attention was given to the problem of self-referral, could be interpreted to prohibit every instance of self-referral. Apparently, it has not been used to do so.¹⁹¹ Nevada's legislation is also quite comprehensive. It generally prohibits self-referral,¹⁹² the only significant exception being for circumstances in which the service or goods required by the patient are not otherwise available within a thirty-mile radius of the office of the practitioner.¹⁹³

New Jersey's statute is an odd combination of the strongest and the weakest elements of self-referral statutes.¹⁹⁴ It has one of the broadest prohibitions on the books, stating that "[a] practitioner shall not refer a patient or direct an employee of the practitioner to refer a patient to a health care service in which the practitioner, or the practitioner's immediate family, has a significant beneficial interest."¹⁹⁵ The New Jersey statute provides only two exceptions: for personal services provided at the practitioner's office and for radiation therapy pursuant to an oncological protocol, lithotripsy, and renal dialysis. However, the statute also exempts all financial interests acquired before July 31, 1991.¹⁹⁶ Practitioners who acquired their interest before that date need only disclose their interest to patients, not divest themselves of it.¹⁹⁷ New Jersey's statute is ironically very generous in its treatment of the investment interests that caused the concern about

188. MONT. CODE ANN. § 37-2-102 (1993).

189. MASS. GEN. LAWS ANN. ch. 112, § 12AA (West Supp. 1994).

190. MICH. STAT. ANN. § 14.15(16221)(d)(iv) (Callaghan 1988).

191. Iglehart, *supra* note 1, at 200.

192. NEV. REV. STAT. ANN. § 439B.425 (Michie Supp. 1993).

193. *Id.* § 439B.425(1)(a).

194. N.J. STAT. ANN. §§ 45:9-22.4 to -22.5 (West 1991).

195. *Id.* § 45:9-22.5(a).

196. *Id.* § 45:9-22.5. For further discussion of New Jersey's statute, see Brian McCormick, *AMA, State Society on Opposite Sides*, AM. MED. NEWS, June 1, 1992, at 1.

197. N.J. STAT. ANN. §§ 45:9-22.5 to 22.6 (West Supp. 1993). The disclosure form must contain the following language:

physician self-referral in the first place. Only federal legislation will limit referrals to those facilities.

V. CONCLUSION

Physician investment can certainly benefit communities in which an insufficient number of outside investors can be found for needed facilities. Where there is little need for a facility, however, the dangers associated with self-referral are serious. Studies of physician joint ventures do not conclusively prove that physicians who own an interest in health care facilities overutilize the services provided there, but they do reveal a striking correlation between ownership and referral patterns. The evidence is sufficient to warrant restrictions on self-referral, particularly when the structure of a joint venture reveals a clear design to ensure a stream of referrals from physician-investors.

Referrals of Medicare patients will be significantly curtailed by the advent of Stark II. The Anti-Fraud Statute will continue to be relevant for joint ventures that Stark I permits. Though the Fraud Alert lays out a number of guidelines for physician-investors, it is not yet clear how vigorously the OIG will seek compliance with them.

Because of the remaining gaps and uncertainties in federal law, state legislation remains important. States would be wise to consider community-need legislation that both safeguards against physician self-referral and allows physicians to demonstrate a need for their investment on a case-by-case basis.

JENNIFER HERNDON PURYEAR

Public law of the State of New Jersey mandates that a physician, chiropractor or podiatrist inform his patients of any significant financial interest he may have in a health care service.

Accordingly, I wish to inform you that I do have a financial interest in the following health care service(s) to which I refer my patients:

(list applicable health care services)

You may, of course, seek treatment at a health care service provider of your own choice. A listing of alternative health care service providers can be found in the classified section of your telephone directory under the appropriate heading.

Id. § 45:9-22.6.