

Comments

Regulation of Physician Self-Referral Arrangements: Is Prohibition the Answer or Has Congress Operated on the Wrong Patient?

Rapidly increasing health care costs have created a national crisis. Perceiving physician referral behavior as the principal cause, Congress and several state legislatures have prohibited certain referrals. This Comment analyzes the data that spawned such legislation and critiques prohibition as a solution to the crisis. The article asserts that the prohibition remedy is overly broad and largely ineffective. A more farsighted solution, such as the creation of a prepaid physician compensation system, is necessary. This system would minimize the incentive to make unnecessary referrals while simultaneously reducing the level of health care costs borne by the government.

I. INTRODUCTION

Health care costs in the United States are increasing at a staggering rate. Americans spent over \$600 billion on health care in 1989.¹ Only three years later, in 1992, costs were projected to exceed \$800 billion (roughly fourteen percent of the Gross National Product), of which twenty-five percent may be waste.² At the present rate of

1. James B. Couch, *The Potential Role of Corporate America in Ameliorating the Medical Liability Problem*, 15 J. MED. & PHIL. 243 (1990).

2. *Wasted Health Care Dollars*, 57 CONSUMER REP. 435 (July 1992). This article contends that waste, in the form of unnecessary care and bureaucratic inefficiency, adds

growth, health care costs are predicted to exceed \$1.2 trillion by 1995 and \$2.5 trillion by 2001.³

The increasing cost of health care has not gone unnoticed by the federal government, insurers, and third-party payors. The most significant pressure has been applied by the federal government. In an effort to control spiraling Medicare costs, Congress, in 1983, enacted legislation that changed the form of Medicare reimbursement.⁴ Prior to the 1983 amendments, hospitals were reimbursed by the federal government for the actual dollar amount incurred in the treatment of a Medicare patient.⁵ The 1983 amendments created the Medicare Prospective Payment System, under which reimbursement is a fixed, predetermined amount. The predetermined amount is calculated by reference to the average cost of treating a patient in a particular Diagnostic-Related Group, regardless of the actual cost of treating the patient.⁶

As a result, the practice of medicine has undergone dramatic changes. Many services previously resigned to hospitals are now commonly performed in outpatient settings.⁷ The increasing use of outpatient facilities, along with cost containment measures directed toward physician salaries and the introduction of expensive new technology, has created incentives for physicians to invest in facilities that provide services once delivered only in hospitals.⁸

Because physicians have the ability to refer patients to health care facilities in which they have an ownership interest,⁹ thereby potentially increasing their own financial well being, physician ownership of these facilities has sparked considerable debate. Critics argue that

\$200 billion to health care costs each year. *Id.* at 436-37. *Consumer Reports* estimates that unnecessary care and administrative inefficiency result in extra health care costs of \$130 billion and \$70 billion, respectively. *Id.*

3. Couch, *supra* note 1, at 243.

4. Social Security Amendments of 1983, Pub. L. No. 98-21 § 601, 97 Stat. 65, 149 (codified as amended at 42 U.S.C. § 1395 (1983)).

5. 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).

6. *Id.*

7. Because the Medicare Prospective Payment System (PPS) applies only to inpatient hospital services and the costs of these services often exceed the reimbursed amount, treatment in outpatient settings has greatly increased. OFFICE OF THE INSPECTOR GENERAL, DEP'T OF HEALTH & HUMAN SERV., FINANCIAL ARRANGEMENTS BETWEEN PHYSICIANS AND HEALTH CARE BUSINESSES 1 (May 1989) [hereinafter OIG REPORT]. For a general discussion of the effects of PPS on the practice of medicine, see Hyman & Williamson, *supra* note 5.

8. OIG REPORT, *supra* note 7, at 1-2.

9. One commentator estimates that physicians control up to 80% of health care spending. E. Haavi Morreim, *Conflicts of Interest: Profits and Problems in Physician Referrals*, 262 *JAMA* 390, 392 (1989). See also *Wasted Health Care Dollars*, *supra* note 2, at 438 (referring to a physician's ability to control both the supply and demand of health care services as the "law of induced demand").

these arrangements result in the overutilization of services and create an unethical conflict of interest for the referring physicians.¹⁰ Those who support physician ownership contend that it stimulates competition, resulting in superior and less costly care, and often provides much needed services.¹¹

In December 1989, federal legislation, sponsored by California Congressman Fortney "Pete" Stark (and generally referred to as the Stark Law), was passed making referrals of Medicare patients by physicians to clinical laboratories in which they have an ownership interest or compensation arrangement illegal.¹² The patient referral

10. See COMMITTEE ON IMPLICATIONS OF FOR-PROFIT ENTERPRISE IN HEALTH CARE, INSTITUTE OF MEDICINE, PHYSICIANS AND ENTREPRENEURISM IN HEALTH CARE 151, 158-59 (B. Gray ed. 1986) [hereinafter INSTITUTE OF MEDICINE]; Arnold S. Relman, *Dealing with Conflicts of Interest*, 313 NEW ENG. J. MED. 749 (1985); Arnold S. Relman, *Practicing Medicine in the New Business Climate*, 316 NEW ENG. J. MED. 1150 (1987). Overutilization (the provision of unnecessary or inappropriate care) increases the cost of health care. Although the conflict of interest issue is also important, the focus of this Comment is on the economic, rather than the ethical, effects of physician self-referrals.

11. See *The Ethics in Patient Referrals Act of 1989; Hearings Before the Subcomm. on Health and the Subcomm. on Oversight of the House Comm. on Ways and Means*, 101st Cong. 1st Sess. 90, 92 (1989) [hereinafter *Hearings*] (statement of the American Medical Association); *Hearings, supra*, at 111 (statement of the American Imaging Association).

12. Ethics in Patient Referrals Act of 1989, Pub. L. No. 101-239, Title VI, § 6204(a), 103 Stat. 2236 (codified as 42 U.S.C. § 1395nn (1989)) [hereinafter STARK LAW].

Section 1395nn provides, in pertinent part:

Limitation on certain physician referrals

(a) Prohibition of certain referrals

(1) In general. Except as provided in subsection (b) of this section, if a physician (or immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then-

(A) the physician may not make a referral to the entity for the furnishing of clinical laboratory services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to an individual, third party payor, or other entity for clinical laboratory services furnished pursuant to a referral prohibited under subparagraph (A).

(2) Financial relationship specified. For purposes of this section, a financial relationship of a physician (or immediate family member) with an entity specified in this paragraph is-

(A) except as provided in subsections (c) and (d) of this section, an ownership or investment interest in the entity; or

(B) except as provided in subsection (e) of this section, a compensation arrangement (as defined in subsection (h)(1)(A) between the physician (or immediate family member) and the entity. An ownership or investment interest described in subparagraph (A) may be through equity, debt, or other means.

prohibitions contained in the Stark Law became effective on January 1, 1992.¹³ This Comment will analyze: (1) the perceived need for regulation of physician self-referral arrangements,¹⁴ (2) the appropriateness of the Stark Law as a response to the perceived need,¹⁵ (3) subsequent legislation directed at physician self-referral arrangements,¹⁶ and (4) whether there may be a more effective means of containing health care costs.¹⁷ Finally, this Comment will conclude that the Stark Law is overly broad and is unlikely to result in a significant reduction of the federal government's health care costs.

II. BACKGROUND

To fully understand the current self-referral controversy, a basic knowledge of the previous regulatory attempts to prohibit payments made in return for patient referrals is necessary. Accordingly, a brief chronology of legislative and regulatory attempts, as well as the corresponding judicial interpretations, follows.

A. Legislative Guidelines

Legislative efforts to prevent financial incentives from influencing a physician's referral decisions is not a recent phenomenon. In 1972, Congress made its first legislative attempt to combat Medicare¹⁸-Medicaid¹⁹ fraud and abuse by making it a misdemeanor to solicit, offer, pay, or receive a kickback or bribe in connection with the furnishing of items or services paid for by Medicare or Medicaid.²⁰

Dissatisfied with the ability of the 1972 provisions to prevent fraud and abuse,²¹ Congress enacted the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977.²² The Amendments strengthened

13. *Id.*

14. For the purposes of this Comment the terms "physician self-referral arrangements" and "self-referrals" have been used to describe arrangements involving referrals to an entity in which the referring physician has an ownership interest. For analysis of the perceived need for regulation of physician self-referral arrangements, see *infra* notes 63-85 and accompanying text.

15. See *infra* notes 86-98 and accompanying text.

16. See *infra* notes 99-130 and accompanying text.

17. See *infra* notes 131-51 and accompanying text.

18. Medicare is a federal program that reimburses health care providers for providing various health services to qualifying patients (generally the aged and disabled). Social Security Act, 42 U.S.C. §§ 1395-1395ccc (1988 & Supp. 1990).

19. Medicaid provides federal funds to eligible state programs. Social Security Act, 42 U.S.C. §§ 1396-1396u (1988 & Supp. 1990).

20. Social Security Amendments of 1972, Pub. L. No. 92-603, § 242, 86 Stat. 1419 (1972).

21. For a detailed discussion of the congressional intent behind the amendments, see Hyman & Williamson, *supra* note 5, at 1151-85.

22. Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, 91 Stat. 1175 (1977) (codified as amended in scattered sections of 42 U.S.C.).

the 1972 provisions by broadening and clarifying the prohibited conduct, as well as increasing the penalties for violation.²³

The Medicare-Medicaid Anti-Fraud and Abuse Statute was again amended in 1980 and 1987. The 1980 Amendments added a specific intent requirement that the violation be done "knowingly and willfully."²⁴ In 1987, Congress enacted the Medicare and Medicaid Patient and Program Protection Act (MMPPPA).²⁵ The MMPPPA was significant for several reasons. First, the Secretary of Health and Human Services was authorized to exclude a person found to have violated the statute from participation in the Medicare or Medicaid program.²⁶ Because Medicare covers as much as forty percent of health care expenditures in the United States,²⁷ exclusion of a physician from participation in the program could be the financial equivalent of the death penalty. Second, the statute mandated the promulgation of regulations under the statute.²⁸

This mandate resulted in the Safe Harbor Regulations. The Safe Harbor Regulations were intended to specify "various payment practices which, although potentially capable of inducing referrals of business under Medicare or a State health care program, will be protected from criminal prosecution or civil sanctions under the anti-kickback provisions of the [Medicare-Medicaid Anti-Fraud and Abuse] statute."²⁹ The Safe Harbor Regulations are narrowly drawn and provide sanctuary for physician investment in entities to which they make referrals in only one instance: investment in an entity with assets of more than \$50,000,000 whose stock is available to the

23. The 1977 Amendments replaced the words "kickback" or "bribe" with the more inclusive term, "remuneration" (defined to include kickbacks, bribes, and rebates made either directly or indirectly, overtly or covertly, in cash or in kind). *Id.* § 4, 91 Stat. 1180. In addition, the 1977 Amendments made violation a felony punishable by a fine of up to \$25,000 and imprisonment for up to five years per claim. *Id.*

24. Medicare and Medicaid Amendments of 1980, Pub. L. No. 96-499, § 917, 94 Stat. 2599, 2625 (1980).

25. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat. 680 (1987).

26. Pub. L. No. 100-93, § 2, 101 Stat. 680, 680-86 (1987).

27. Morreim, *supra* note 9, at 393.

28. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93 § 14, 101 Stat. 680, 697 (1987).

29. Safe Harbor Regulations, 56 Fed. Reg. 35952 (1991) (to be codified at 42 C.F.R. pt. 1001). The breadth of the Medicare-Medicaid Anti-Fraud and Abuse Statute has caused considerable concern among health care providers that "many relatively innocuous, or even beneficial, commercial arrangements are technically covered by the statute and are, therefore, subject to criminal prosecution." *Id.* Apparently, the Safe Harbor Regulations were intended to allay these concerns.

general public through trading on a registered national securities exchange such as the New York Stock Exchange, the American Stock Exchange, or the National Association of Securities Dealers Automated Quotation System.³⁰

If a physician is involved in an arrangement that fully complies with a Safe Harbor provision, then he or she can be assured that the arrangement will not be prosecuted either criminally or civilly.³¹ When an arrangement fails to fully comply, one of three things can happen. First, the Medicare-Medicaid Fraud and Abuse Statute may not apply because the arrangement is not intended to induce a referral of business that is reimbursable by Medicare or Medicaid.³² In this case, there is no reason to comply with the Safe Harbor Regulations.³³ Second, the arrangement could be a clear statutory violation making prosecution very likely.³⁴ Third, the arrangement could be a less clear violation. Here, the provider is not exempt from prosecution, which may or may not occur.³⁵ Thus, except in a very limited number of circumstances, the Safe Harbor Regulations have done nothing to alleviate the uncertainty which prompted their promulgation.

Although the Medicare-Medicaid Anti-Fraud and Abuse Statute sought to prevent financial incentives from influencing a physician's referral decisions, it did not completely prohibit self-referral arrangements. Prior to the enactment of the Stark Law, federal legislation employed the complete prohibition alternative only in the context of home intravenous (IV) therapy. The prohibition was part of the Medicare Catastrophic Coverage Act of 1988 (MCCA).³⁶ The MCCA generally prohibited a home IV therapy provider from rendering services to a Medicare patient if the patient was referred by a physician who had a financial relationship with the provider.³⁷ In addition, the MCCA also mandated that the Office of the Inspector General, Department of Health and Human Services, study the potential of physician ownership of entities to influence the decision of

30. *Id.* at 35984.

31. *Id.* at 35954.

32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.* The General Comments to the Safe Harbor Regulations acknowledge that the risk of prosecution in this situation is impossible to predict. *Id.*

36. Pub. L. No. 100-360, § 203(d), 102 Stat. 683, 722-23 (1988) (codified as 42 U.S.C. § 1395m), *repealed by* Medicare Catastrophic Coverage Repeal Act of 1988, Pub. L. No. 101-234, 103 Stat. 1979 (1989).

37. *Id.* For further discussion of the Medicare Catastrophic Coverage Act, see Theodore N. McDowell, Jr., *Physician Self Referral Arrangements: Legitimate Business or Unethical "Entrepreneurialism,"* 15 AM. J.L. & MED. 61, 76-77 (1989).

a physician regarding referrals leading to the inappropriate utilization of these items and services.³⁸

On February 9, 1989, Congressman Stark introduced the Ethics in Patient Referrals Act of 1989.³⁹ Originally, the bill was very broad, prohibiting a physician from referring a Medicare patient to any health care entity with which the physician or an immediate family member has a financial arrangement.⁴⁰ However, the Stark Law, as enacted on December 19, 1989, prohibits self-referrals only to clinical laboratories.⁴¹

B. Judicial Application

Efforts by the courts to apply the Medicare Fraud and Abuse Statute has led to considerable confusion. In early cases, the statute was interpreted narrowly.⁴² Recent cases, however, indicate a judicial willingness to give the Medicare Fraud and Abuse Statute a broader interpretation.⁴³ A summary of these recent cases follows.

In *United States v. Greber*,⁴⁴ Cardio-Med, Inc., which provided

38. § 203, 102 Stat. at 724 (1988). More specifically, the Office of the Inspector General (OIG) was required to conduct a study and report to Congress on:

(A) physician ownership of, or compensation from, an entity providing items or services to which the physician makes referrals and for which payment may be made under the Medicare program;

(B) the range of such arrangements and the means by which they are marketed to physicians;

(C) the potential of such ownership or compensation to influence the decision of a physician regarding referrals and to lead to inappropriate utilization of such items and services; and

(D) the practical difficulties involved in enforcement actions against such ownership and compensation arrangements that violate current anti-kickback provisions.

Id. For a discussion of the OIG's findings, see *infra* notes 65-71 and accompanying text.

39. INTRODUCTION OF THE ETHICS IN PATIENT REFERRALS ACT, 135 CONG. REC. H240 (daily ed. Feb. 9, 1989).

40. *Id.* at H241.

41. See STARK LAW, *supra* note 12. The reduction in scope was the result of a last minute compromise between Representatives Stark, Bentsen, Rostenkowski, and Dingell. See John K. Inglehart, *Congress Moves to Regulate Self-Referral and Physicians' Ownership of Clinical Laboratories*, 322 NEW ENG. J. MED. 1682, 1684-85 (1990).

42. See *United States v. Zacher*, 586 F.2d 912 (2nd Cir. 1978) (holding that charging Medicaid patients four dollars per day more than the Medicaid allotment did not increase the cost to the government of patient care, decrease the quality of patient care purchased by the government, or involve the misapplication of government funds); *United States v. Porter*, 591 F.2d 1048 (5th Cir. 1979) (holding that payment of a handling fee to physicians for blood samples sent to a laboratory did not constitute a kickback, bribe, or rebate).

43. See *infra* notes 44-62 and accompanying text.

44. 760 F.2d 68 (3d Cir.), *cert. denied*, 474 U.S. 988 (1985).

cardiac monitoring devices and services, paid a portion of its Medicare reimbursement to the referring physicians.⁴⁶ The payment to the referring physician, classified by the defendant as an “interpretation fee,” allegedly represented compensation for the physician’s initial consultation services, as well as for explaining the test results to the patient.⁴⁸ At trial, evidence was presented showing that physicians received the interpretation fee even though some of them did not evaluate the test data.⁴⁷

Dr. Greber, Cardio-Med’s owner, was indicted for violating the statute, making false statements to Medicare, and committing mail fraud.⁴⁸ In his defense, Dr. Greber argued that the payments made to the referring physicians were for services actually rendered and, as such, could not be a violation of the statute.⁴⁹ The court was not persuaded by this argument and held that “if one purpose of the payment was to induce future referrals, the [M]edicare statute has been violated.”⁵⁰ Further, the court held that the Medicare statute would be violated “even if the payments were also intended to compensate for professional services.”⁵¹

In *United States v. Kats*,⁵² the defendant owned a twenty-five percent interest in a community medical clinic.⁵³ The clinic sent laboratory samples to a diagnostic laboratory, which agreed to forward to the owners of the clinic fifty percent of all Medicare payments received for work performed on the clinic samples.⁵⁴ At trial, Kats was convicted of receiving kickbacks in exchange for referrals.⁵⁵ On appeal, the court adopted the interpretation of *Greber* and held that the Medicare Anti-Fraud Statute is violated if “one purpose of the payment was to induce future referrals . . . even if the payments were also intended to compensate for professional services.”⁵⁶

Although the holdings in *Greber* and *Kats* were very broad, the facts indicated that the Medicare Fraud and Abuse Statute had clearly been violated. In *Greber*, the referring physicians were paid an interpretation fee even though Dr. Greber, and not the referring physicians, interpreted the test data. Similarly, the defendants in *Kats* received fifty percent of the Medicare reimbursement paid to

45. *Id.* at 70.

46. *Id.*

47. *Id.*

48. *Id.*

49. *Id.* at 71.

50. *Id.* at 69.

51. *Id.* at 72.

52. 871 F.2d 105 (9th Cir. 1989).

53. *Id.* at 107.

54. *Id.* at 106-07.

55. *Id.* at 106.

56. *Id.* at 108 (quoting *United States v. Greber*, 760 F.2d 68, 69, 72 (3rd cir. 1985)).

the laboratory to which the defendants referred their samples.

However, in a subsequent case the First Circuit of the United States Court of Appeals was faced with a less compelling set of facts. In *United States v. Bay State Ambulance and Hospital Rental Service, Inc.*,⁵⁷ no referral was made and no direct connection was established between referral and compensation. Here, a hospital employee was retained as a consultant by an ambulance company.⁵⁸ The ambulance company paid the hospital employee for "consulting services" and for developing a computer program (these services were in fact rendered).⁵⁹ Using his influence as a member of various hospital committees, the defendant helped the ambulance company secure a contract with the hospital.⁶⁰ The defendant and an ambulance company official were convicted of conspiring to commit Medicare fraud under the Fraud and Abuse Statute.⁶¹ Although the *Greber* court held that any inducement intended to influence referrals is illegal even if it is also intended to compensate for professional services, the *Bay State* court found it unnecessary to stretch the reach of the Medicare Anti-Fraud and Abuse statute that far. "We need not decide the exact reach of the [Medicare Anti-Fraud and Abuse] statute since, in this case, the district court instructed that the defendants could only be found guilty if the payments were made primarily as inducements."⁶² Despite the use of qualifying language to the contrary, the court did stretch the reach of the statute. In *Bay State*, the hospital employee was in no position to refer Medicare patients because he was an administrator, not a physician. Yet, because the employee could improperly use his influence to help secure a contract under which payments would ultimately be made by Medicare, the court affirmed the trial court's finding that the statute had been violated.

57. 874 F.2d. 20 (1st Cir. 1989).

58. *Id.* at 23-24.

59. *Id.* at 25-26.

60. *Id.* at 23-27.

61. *Id.* at 27.

62. *Id.* at 30. "The gravamen of Medicare Fraud is inducement. Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient." *Id.* at 29. Thus, it can be inferred that the inducement in *Bay State* was the ambulance company's payment of compensation to a person in a position to use his influence to secure a contract for the company where the ambulance company may ultimately be paid by Medicare under the contract.

III. THE PERCEIVED NEED FOR THE STARK LAW

The main criticism of physician self-referral arrangements is that they result in the overutilization of services. Overutilization involves the provision of unnecessary or inappropriate care. The potential problem has been aptly summarized as follows:

The danger of overutilization is created by the fact that the investing physician's investment return and profits depend, in part, on referral of patients to the facility in which he has an [ownership] interest. Consequently, the investing physician is encouraged to make excessive and unnecessary referrals to the venture in order to increase his investment return.⁶³

Some evidence that physician self-referral arrangements result in overutilization has been provided by various studies.⁶⁴ But does the evidence of abuse by physician-owners support a measure as drastic as complete prohibition? An analysis of the two most comprehensive studies to date, the OIG Report and the Florida Study, should have answered this question. Unfortunately, the studies were inconclusive.

A. The OIG Report

The Office of the Inspector General (OIG) studied physician investment in clinical and physiological⁶⁵ laboratories and durable medical equipment suppliers.⁶⁶ Study results varied by the type of entity. Patients of physician-owned clinical laboratories received forty-five percent more clinical laboratory services than all Medicare

63. McDowell, *supra* note 37, at 65.

64. Several studies were conducted prior to the enactment of the Stark Law (Dec. 19, 1989). The OIG Report cited and summarized these studies as follows: MEDICAL SERVICES ADMINISTRATION, MICHIGAN DEPARTMENT OF SOCIAL SERVICES, UTILIZATION OF MEDICAID LABORATORY SERVICES BY PHYSICIANS WITH/WITHOUT OWNERSHIP INTEREST IN CLINICAL LABORATORIES: A COMPARATIVE ANALYSIS OF SIX LABORATORIES (July 9, 1981) (studying Medicaid utilization of clinical laboratories in Michigan and finding that Medicaid recipients referred by physician owners had an average of 41% more tests than those referred by nonowners); HEALTH CARE FINANCING ADMINISTRATION, REGION V OPERATIONAL REVIEW BRANCH, DIVISION OF HEALTH STANDARDS & QUALITY, DIAGNOSTIC CLINICAL SERVICES IN REGION V (May 1983) (finding that laboratories owned by physicians are reimbursed more than those owned by non-physicians and attributing this result to higher prices and higher incidence of service per patient at the physician-owned laboratories); BLUE CROSS & BLUE SHIELD OF MICHIGAN, MEDICAL AFFAIRS DIVISION, A COMPARISON OF LABORATORY UTILIZATION AND PAYOUT TO OWNERSHIP (May 9, 1984) (finding that the physician owned clinical laboratories provided approximately 20% more services per patient than all other laboratories and approximately 40% more services than non-physician-owned laboratories). OIG REPORT, *supra* note 7, at 3-4. The OIG Report itself was released prior to the Stark Law's enactment. In addition, a comprehensive study has been completed and released subsequent to the Stark Law's enactment. See STATE OF FLORIDA HEALTH CARE COST CONTAINMENT BOARD, JOINT VENTURES AMONG HEALTH CARE PROVIDERS IN FLORIDA (1991) [hereinafter FLORIDA REPORT].

65. Physiological laboratories perform non-invasive tests such as magnetic resonance imaging (more commonly known as an MRI) and computerized axial tomography (more commonly known as a CAT scan).

66. OIG REPORT, *supra* note 7, at ii.

patients in general.⁶⁷ The OIG estimated that this increased utilization of clinical laboratory services cost the Medicare program \$28 million in 1987.⁶⁸ Patients of physician-owners of physiological laboratories received thirteen percent more physiological services than patients in general.⁶⁹ In contrast, patients of physicians who own or invest in durable medical equipment suppliers were found not to use any more equipment than all medicare patients in general.⁷⁰ According to the OIG, the above estimates are considered to be conservative because no true control group was used in the study.⁷¹

B. The Florida Report

In 1989, the Florida Legislature mandated that the Florida Health Care Cost Containment Board (HCCB) conduct a special study of "joint ventures"⁷² between persons providing health care.⁷³ The study concluded that joint ventures involving clinical laboratories, diagnostic imaging centers (physiological laboratories), and physical therapy centers have higher utilization rates per patient than their non-joint venture counterparts.⁷⁴ Utilization rates in clinical laboratories were found to be almost double (3.3 tests per patient versus 1.7).⁷⁵ Use of magnetic resonance imaging (more commonly known as an MRI), which is a type of diagnostic imaging,

67. *Id.* at 18.

68. *Id.* at 21.

69. *Id.* at 18.

70. *Id.* at 21.

71. *Id.* at 18. The results of patients who were referred by physician-owners were compared to the results of all patients. If a comparison had been made of the results of patients of physician-owners to those of non-physician-owners, a much greater difference in utilization would have been expected. See *Hearings, supra* note 11 (statement of the Inspector General of the Department of Health and Human Services). An example of such a result is provided by the 1984 Michigan Study. See *supra* note 64.

72. The term "joint venture" as used in the Florida Report is defined as "any ownership, investment interest or compensation arrangement between physicians (or any health care professional who makes referrals) and an entity providing health care goods or services." 2 FLORIDA REPORT, *supra* note 64, at iii (Sept. 1991). The results of the study were released in three volumes. Volume I, released in January of 1991, outlined preliminary results on the prevalence, scope, and nature of joint ventures among Florida health care providers. Volume II, released in September of 1991, evaluated the impact of joint ventures on access, utilization, costs, charges, and quality of health care services in Florida. In addition, this volume contained the final results released in Volume I. Volume III, released in October 1991, provided recommendations for the regulation of joint ventures with the objective of protecting the citizens of Florida from unnecessary and costly health care expenditures.

73. Study Enabling Legislation, 1989 Fla. Laws ch. 354, § 6 (1989).

74. 2 FLORIDA REPORT, *supra* note 64, at v.

75. *Id.* at III-10 to III-11.

was found to be fourteen to seventy percent higher.⁷⁶ Additionally, physical therapy centers averaged forty-three percent more visits per patient.⁷⁷

For other types of health care facilities, the study did not indicate that physician ownership resulted in higher utilization. Regarding ambulatory surgical centers, the study found that "there is no evidence that physicians with ownership interest [sic] in ambulatory surgical facilities tend to perform surgery more frequently."⁷⁸ Similarly, physician ownership of acute care hospitals appeared to have little impact on access, costs, or charges.⁷⁹ With respect to radiation therapy centers, physician-owned facilities rendered less services per patient than their non-physician-owned counterparts.⁸⁰ The Florida Report concluded that the average number of radiation treatments per patient was 45 for non-joint venture facilities but only 36.8 for physician-owned centers.⁸¹

Finally, the study was unable to reach a conclusion about the effects of physician ownership on the utilization of durable medical equipment suppliers.⁸² Researchers found that the diversity of services provided by durable medical equipment suppliers precluded a meaningful comparison of utilization.⁸³

The results of the above studies indicate that abuse, in the form of overutilization, may exist in certain types of physician-owned facilities. The question is how pervasive is this abuse?

Unfortunately, a weakness in the design of these studies makes this a very difficult question to answer. Neither the OIG nor the HCCB attempted to assess the medical necessity of the services provided as a result of the referrals.⁸⁴ Joint ventures have higher utilization rates than non-joint ventures, but the reason is unclear. As Uwe

76. *Id.* at IV-7 to IV-8. Since 93% of Florida's MRI centers are physician-owned, a meaningful comparison to non-joint venture centers located in Florida was impossible. 3 FLORIDA REPORT, *supra* note 64, at IV-1 (Oct. 1991). Therefore, the utilization rates of Florida joint ventures were compared with utilization rates of Baltimore, Md. *Id.* at IV-5. Study researchers believed that Baltimore provided a reasonable basis for comparison for two reasons. First, only one MRI center in Baltimore is owned by referring physicians. Second, the two areas have similar proportions of elderly and similar per-capita incomes. Former Inspector General chief counsel, Harvey Yampolsky, has criticized this comparison stating that the Florida population studied may be older, sicker, and wealthier than the population in Baltimore. See *Doctor Ownership Draws Fire*, Medicare Compliance Alert (United Communications Group, Rockville, Md), Oct. 14, 1991, at 2.

77. 2 FLORIDA REPORT, *supra* note 64, at IX-10.

78. *Id.* at II-2. This finding was attributed to the fact that third-party payors often require patients to seek a second opinion on recommended elective surgery procedures. *Id.*

79. *Id.* at VII-7.

80. *Id.* at X-2.

81. *Id.*

82. *Id.* at vii.

83. *Id.*

84. See Council on Ethical and Judicial Affairs, American Medical Association,

Reinhardt, Ph.D., James Madison Professor of Political Economy at Princeton, and member of the Physician Payment Review Commission for the United States Congress, explains:

A problem in conducting studies regarding the effects of joint ventures is that at least two conclusions are possible. The first is that the doctor needs to break even on the machine and therefore uses it more intensively. The second is that the doctor may be a test-intensive doctor and may therefore want a machine on the premises. It is difficult to tease out statistically the separate effects on each of these scenarios Ultimately, we need a study by clinicians who can judge the appropriateness of care—a clinical outcome type of study. Another type study could look at a physician's utilization before ownership and compare utilization after ownership.⁸⁵

The studies, however, presume that the higher utilization rates are due to the former conclusion without explaining why this conclusion is more likely.

IV. THE APPROPRIATENESS OF THE REGULATORY RESPONSE TO THE PERCEIVED PROBLEM

Clearly, the legislature should not disregard abusive practices. If the abuse is widespread, then complete prohibition of the practices responsible may be appropriate. Alternatively, if the evidence does not support a conclusion that physician self-referrals result in widespread abuse, then prohibition may do more harm than good. An analysis of the potential harm is therefore appropriate.

One major criticism of the Stark Law is that "shared laboratories"⁸⁶ are not exempt from the self-referral prohibition. Under the Stark Law, only group practice and in-office laboratories are exempt.⁸⁷

Conflicts of Interest: Physician Ownership of Medical Facilities, 267 JAMA 2366, 2367 (1992).

85. 1 FLORIDA REPORT, *supra* note 64, at D-7 (Jan. 1991).

86. "Shared laboratories" (or simply "shared labs") is a term used in the medical trade to describe an arrangement where physicians, who share office space but are not members of the same medical group (or otherwise affiliated), pool their resources to set up a laboratory for collective use.

87. STARK LAW, *supra* note 12. The Stark Law provides, in pertinent part:

(b) General exceptions to both ownership and compensation arrangement prohibitions. Subsection (a)(1) of this section shall not apply in the following cases:

(1) Physicians' services. In the case of physicians' services (as defined in section 1395x(q) of this title) provided personally by (or under the personal supervision of) another physician in the same group practice (as defined in subsection (h)(4) of this section) as the referring physician.

(2) In-office ancillary services. In the case of services-

(A) that are furnished-

Lack of an exception for shared laboratories is problematic for several reasons. First, the complete prohibition of these arrangements ignores their potential convenience and efficiency. As one commentator writes, to deny patients access to a laboratory shared by several independent physicians "simply adds burdens, delays and hassles to our [physicians'] attempts to provide adequate, timely, cost-efficient medical care."⁸⁸ Requiring physicians to send patients elsewhere for laboratory testing that otherwise could be performed in a shared lab (which is typically located in the referring physician's office, or at least in the same building) hampers both the convenience and the timeliness of the testing. Such a requirement might even force a physician to give up practicing entirely.⁸⁹ In addition, the cost of the tests may be less if performed in a shared lab. One physician has indicated that a urine test analyzed by her shared lab costs eight dollars while the other test site in town charges thirty dollars for the same test.⁹⁰

Second, prohibiting shared laboratories may result in an unnecessary duplication of resources. Instead of sharing the cost of equipment and technicians, each physician would have to bear these costs individually. The Stark Law encourages such inefficiency because it

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- (i) personally by the referring physician, personally by a physician who is a member of the same group practice as the referring physician, or personally by individuals who are employed by such physician or group practice and who are personally supervised by the physician or by another physician in the group practice, and
 - (ii) (I) in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians' services unrelated to the furnishing of clinical laboratory services, or
(II) in the case of a referring physician who is a member of a group practice, in another building which is used by the group practice for the centralized provision of the group's clinical laboratory services, and
 - (B) that are billed by the physician performing or supervising the services, by a group practice of which such physician is a member, or by an entity that is wholly owned by such physician or group practice, if the ownership or investment interest in such services meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

42 U.S.C. § 1395nn (1989).

88. MEDICARE COMPLIANCE ALERT (United Communications Group, Rockville, Md.), May 25, 1992, at 1 (citing Letter from James Scott, Jr. M.D. to Health Care Financing Administration (HCFA), Department of Health and Human Services (DHHS)).

89. This concern has been expressed to the HCFA by a California hematologist-oncologist. To provide leukemia patients with chemotherapy treatments, the physician must run blood counts and other tests. The lack of an exemption for shared laboratories would prohibit him from performing this necessary service and would effectively prevent him from practicing. *Id.* (citing Letter from Herbert Wohl, M.D. to HCFA, DHHS).

90. *Id.* (citing Letter from Anne MacGuire, M.D. to HCFA, DHHS).

exempts referrals made by an independent physician to a laboratory that he or she wholly owns if the laboratory is located within the office.⁹¹ Alternatively, the independent physician can forgo investment in his or her own laboratory and refer patients elsewhere. However, this alternative is often more costly and less convenient for the patient.⁹²

Finally, the Stark Law unfairly places independent physicians at a competitive disadvantage relative to their colleagues who have in-office laboratories or who are engaged in group practice. As one commentator explains:

If several physicians pooled their money in order to purchase superior lab equipment and hire better technicians than any of them could afford individually, they would be forbidden to refer their patients to this free-standing facility. At the same time, their colleagues with in-office services could use these freely for their own patients, with the very same dangers of poor quality, unnecessary or excessively priced services.⁹³

This discrepancy in treatment between in-office or group practice laboratories and shared laboratories is difficult to justify. The exception for referrals to in-office or group practice laboratories is based on the presumption that any potential abuse will be mitigated by the referring physician's direct supervision of the services provided.⁹⁴ Assuming that this presumption is correct,⁹⁵ how is the physician who makes referrals to a shared laboratory different from the physician who makes referrals to an in-office or group laboratory? He or she

91. The prohibition does not apply to referrals for certain "in-house ancillary services." To qualify for exemption, the services must (1) be furnished by the referring physician (or an individual who is an employee of the physician and who is personally supervised by the physician), and (2) be furnished in a building in which the referring physician provides physicians' services unrelated to the furnishing of clinical laboratory services: STARK LAW, *supra* note 12.

92. See *supra* notes 88-90 and accompanying text.

93. E. Haavi Morreim, *Physician Investment and Self-Referral: Philosophical Analysis of a Contentious Debate*, 15 J. MED. & PHIL. 425, 437 (1990).

94. This can be inferred from a reading of the requirements for the exception of referrals made for "in-office ancillary services." See *supra* note 91. In addition, a similar argument has often been advanced by commentators to explain why the conflict of interest created by referrals to physician-owned laboratories is more insidious than that inherent in the traditional fee-for-service arrangement. See *Hearings, supra* note 11 (statement of Arnold S. Relman, M.D.).

95. The presumption may in fact be incorrect. One study comparing the frequency and costs of imaging examinations performed by doctors who used their own in-office equipment (self-referring) against those of doctors who always referred to radiologists (non-self-referring) found that the self-referring doctors ordered 4 to 4.5 more examinations than the non-self-referring doctors. 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 (1990).

arguably has as much ability to supervise the provision of laboratory services as a physician who is a member of a group practice. Thus, if referrals for "in-office ancillary services" are exempt, then referrals to shared laboratories should also be exempt.

Another problem with the Stark Law concerns the exemption for self-referrals made to rural providers. Self-referrals are exempt if the clinical laboratory to which the referral is made is located in a rural area.⁹⁶ This exemption is subject to potential abuse by unscrupulous non-physician-owned laboratory companies because the physician owners would have to sell their laboratory once they were no longer the "sole rural providers." As one commentator explains:

[A] group of physicians in a remote area could purchase a magnetic resonance imager as 'sole rural providers.' If some for-profit corporation then saw the success of that operation and decided to set up a competing facility in the same area, the original physicians would be forced to close down their service - no longer the 'sole' rural providers - and virtually hand over a monopoly to the new competitors, regardless of their quality of services or their prices. One could actually envision a scam of sorts, wherein such a company could systematically target successful sole rural providers for easy - and legally protected - take-overs.⁹⁷

Although Congress had good intentions in creating the rural provider exemption, its potential for abuse illustrates the difficulty of designing a statute that prohibits only the undesirable conduct.⁹⁸

V. EFFECT OF THE STARK LAW ON SUBSEQUENT LEGISLATION

As stated previously, the Stark Law's applicability is limited to physician self-referrals to clinical laboratories.⁹⁹ However, Congress is currently considering a bill that would broaden the prohibition on self-referrals to additional types of physician-owned entities. In addition, several states have passed, or are considering passing, "Stark-Type" legislation. Following is a review of this current legislation.

96. 42 U.S.C. § 1395nn provides, in pertinent part:

(d) Additional exceptions related only to ownership or investment prohibition. The following, if not otherwise excepted under subsection (b) of this section, shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A) of this section:

(1) Hospitals in Puerto Rico. In the case of clinical laboratory services provided by a hospital located in Puerto Rico.

(2) Rural provider. In the case of clinical laboratory services if the laboratory furnishing the services is in a rural area (as defined in section 1395ww(d)(2)(D) of this title).

STARK LAW, *supra* note 12.

97. *See* Morreim, *supra* note 93, at 437-38.

98. *Id.* at 438.

99. STARK LAW, *supra* note 12.

A. Federal Legislation

1. Broad Anti-Referral Bill

Although an eleventh-hour compromise between Representative Stark and others reduced the scope of the Stark Law to clinical laboratories,¹⁰⁰ the potential for expanding its application remained intact. The language of the statute can easily be expanded by striking out "clinical laboratory services" and inserting additional health care services.¹⁰¹

This is precisely what a current congressional bill, sponsored by Fortney Stark and House Majority Leader Richard Gephardt, proposes to do.¹⁰² The bill, H.R. 5502, deletes all references to "clinical laboratory services" and inserts "designated health services."¹⁰³ This amendment would expand the application of the Stark Law to include virtually all ancillary health services by defining "designated health care services" to mean (1) clinical laboratory services, (2)

100. See *supra* note 41.

101. STARK LAW, *supra* note 12, §§ 1395nn(a)(1), (b)(2)(A)(ii), (b)(4), (d)(1), (d)(2), (d)(3).

102. See H.R. 5502, 102nd Cong., 2d Sess. (1992).

103. *Id.* § 252. H.R. 5502 expands the Stark Law as follows:

SEC. 252. EXTENSION OF SELF-REFERRAL BAN TO ADDITIONAL SPECIFIED SERVICES.

(A) IN GENERAL.-Section 1877 of the Social Security Act is further amended-(1) by striking "clinical laboratory services" and "CLINICAL LABORATORY SERVICES" AND INSERTING "DESIGNATED HEALTH SERVICES" RESPECTIVELY, [IN] EACH PLACE EITHER APPEARS IN SUBSECTIONS (A)(1), (B)(2)(A)(II)(I), (B)(4), (D)(1), (D)(2), AND (D)(3), AND (2) BY ADDING AT THE END THE FOLLOWING NEW SUBSECTION: "(1) DESIGNATED HEALTH SERVICES DEFINED.-IN THIS SECTION, THE TERM 'DESIGNATED HEALTH SERVICES' MEANS-"(1) CLINICAL LABORATORY SERVICES, "(2) PHYSICAL THERAPY SERVICES, "(3) RADIOLOGY SERVICES, INCLUDING MAGNETIC RESONANCE IMAGING, COMPUTERIZED AXIAL TOMOGRAPHY SCANS, AND ULTRASOUND SERVICES, "(4) RADIATION THERAPY SERVICES, "(5) THE FURNISHING OF DURABLE MEDICAL EQUIPMENT, "(6) THE FURNISHING OF PARENTERAL AND ENTERAL NUTRITION EQUIPMENT AND SUPPLIES, "(7) AMBULANCE SERVICES, "(8) HOME INFUSION THERAPY SERVICES, "(9) OCCUPATIONAL THERAPY SERVICES, AND "(10) INPATIENT AND OUTPATIENT HOSPITAL SERVICES."

(B) CONFORMING AMENDMENTS.-Section 1877 of such Act is further amended- (1) in subsection (d)(2), by striking "laboratory" and inserting "entity", (2) in subsection (g)(1), by striking "clinical laboratory service" and inserting "designated health service", . . .

physical therapy services, (3) radiology services, (4) radiation therapy services, (5) the furnishing of durable medical equipment, (6) the furnishing of parenteral and enteral nutrition equipment and supplies, (7) ambulance services, (8) home infusion therapy services, (9) occupational therapy services, and (10) inpatient and outpatient hospital services.¹⁰⁴

H.R. 5502, at least as to the provisions expanding the ban on physician self-referrals, is overly broad and should not be enacted. Many of the designated health care services for which self-referrals would be banned either have not been found to lead to overutilization or have never been studied.¹⁰⁵ For example, the Florida Report (which is considered to be the most comprehensive study of the effects of physician ownership on utilization conducted to date) found that patients of physician-owned radiation therapy centers received less treatments per patient than did patients of non-physician-owned centers.¹⁰⁶ Similarly, physician ownership of ambulatory surgical centers and acute care hospitals was not found to lead to overutilization.¹⁰⁷ With regard to the effects of physician ownership of durable medical equipment suppliers on utilization, the Florida Report was unable to reach a conclusion.¹⁰⁸

2. Prohibition of Self-Referral to DME Suppliers

Another Stark-Type bill has been introduced in the House which purports to prohibit referrals made by physicians to durable medical equipment (DME) suppliers in which they have a financial interest.¹⁰⁹ H.R. 3837, which was passed by the House on August 3, 1992, appears to have been directly influenced by the Stark Law. Other than the difference in application (H.R. 3837 prohibits self-referrals to DME suppliers instead of clinical laboratories), the language of H.R. 3837 is nearly identical to that of the Stark Law.¹¹⁰

104. *Id.*

105. All of the studies prior to the Stark Law's enactment focused on either clinical or physiological laboratories. For a listing of these studies, see *supra* note 64. The Florida Report, released after the Stark Law's enactment, studied the effects of joint ventures on (1) ambulatory surgical services, (2) clinical laboratory services, (3) diagnostic imaging services, (4) the furnishing of durable medical equipment, (5) home health services, (6) acute care hospital services, (7) nursing home services, (8) physical therapy services, and (9) radiation therapy services. FLORIDA REPORT, *supra* note 64. For a discussion of the findings of this report, see *supra* notes 72-83 and accompanying text. The effects of physician ownership on utilization for several of the designated health services addressed by H.R. 5502 have never been studied. These services include the furnishing of nutritional equipment and supplies, ambulance services, and occupational therapy services.

106. See *supra* notes 80-81 and accompanying text.

107. See *supra* notes 78-79 and accompanying text.

108. See *supra* notes 82-83 and accompanying text.

109. See H.R. 3837, 102nd Cong., 2d Sess. (1992).

110. Both H.R. 3837 and the Stark Law generally prohibit self-referrals and then

H.R. 3837 should not be adopted by Congress. The bill has even less of a justification than the Stark Law. While clinical laboratories owned by physicians have been found to have higher utilization rates than their non-physician-owned counterparts,¹¹¹ DME suppliers owned by physicians have not.¹¹² Therefore, no empirical support for the prohibition of self-referrals to DME suppliers exists.

B. State Legislation

Physician self-referrals have also been the subject of much debate in various state legislatures. "Driven by the need to contain costs, state governments continue to look at bills that would regulate joint ventures and health care providers' ability to refer to an entity they partly [or wholly] own."¹¹³ As discussed below, these bills are largely the result of the attention focused on physician joint ventures by the Stark Law.

1. Florida

The OIG report, which was reported to the United States Congress during the Stark Hearings,¹¹⁴ prompted the Florida legislature to order the Florida HCCB to study physician joint ventures.¹¹⁵ In its report, the OIG concluded that "[o]f the eight states covered by the study, Florida had the highest percentage of physicians involved in joint ventures."¹¹⁶ More importantly, the OIG concluded that "Medicare patients of physician owners in Florida received 40 percent more lab tests, 12 percent more diagnostic imaging tests, and utilized 16 percent more durable medical equipment than the general population of Florida Medicare beneficiaries."¹¹⁷

The HCCB's findings, which were issued in the Florida Report, led to the Florida legislature's enactment of the most comprehensive

proceed to make exceptions for (1) in-office ancillary services, (2) ownership of publically traded securities, and (3) rural providers.

111. See *supra* notes 67, 74-75 and accompanying text.

112. See *supra* notes 70, 82-83 and accompanying text.

113. See Terese Hudson, *States Extend Message of Stark Referral Bill*, HOSP., May 20, 1992, at 62.

114. See *Hearings, supra* note 11 (statement of the Inspector General, DHHS).

115. This can be inferred from a reading of the Executive Summary contained in Volume I of the Florida Report, which restated the OIG's conclusions as to the effect of physician ownership of health care facilities in Florida. See 1 FLORIDA REPORT, *supra* note 64, at v (Jan. 1991).

116. *Id.*

117. *Id.*

self-referral ban to date.¹¹⁸ The Florida Bill prohibits self-referrals to diagnostic imaging centers, rehabilitation services, radiation therapy services, and clinical laboratories. These four service areas are the same ones that the HCCB found to lead to higher utilization of services.¹¹⁹

2. California

A very broad Stark-Type bill was introduced in the California Legislature by Assemblywoman Jacqueline Spier on February 27, 1991.¹²⁰ Originally, A.B. 819 proposed to make it unlawful for a health care professional to refer a person to any laboratory, pharmacy, clinic, or health care facility which is owned, in whole or in part, by the professional.¹²¹

A similar version of A.B. 819 was easily passed by the California Assembly in a fifty-two to twenty-two vote on the Assembly floor.¹²² The Assembly, relying heavily on the conclusions of the Florida Report, ignored opposition by the American Imaging Association (AIA) and the California Medical Association (CMA).¹²³ However, A.B. 819's broad anti-referral provisions did not fare as well in the

118. The bill was enacted April 8, 1992. See Patient Self-Referral Act of 1992, 1992 Fla. Laws ch. 178 (1992) [hereinafter FLORIDA BILL].

119. See *supra* notes 74-77 and accompanying text.

120. See A.B. 819, 1991-1992 Reg. Sess. (1991).

121. *Id.* The bill also sought to prohibit these referrals if the professional had a proprietary interest in the facility to which the referral was made. *Id.*

122. See CALIFORNIA LEGISLATURE, 264 ASSEMBLY WEEKLY HISTORY 213 (July 10, 1992). The January 29, 1992 version of A.B. 819 (passed by the Assembly on the same date) is similar to the original version of February 27, 1991, except that the former more specifically enumerates the entities to which referrals would be prohibited. The January 29, 1992 version states:

[i]t shall be unlawful for any person licensed under this division to refer a person to any diagnostic imaging center, clinical laboratory, physical therapy or rehabilitation facility, or psychometric testing facility which is owned in whole or in part by the licensee or in which the licensee has a proprietary interest.

A.B. 819 (as Amended in Assembly January 29, 1992). For a description of the less precise language of the February 27, 1991 version, see *supra* note 121 and accompanying text.

123. See CALIFORNIA LEGISLATURE 1991-1992, ASSEMBLY FLOOR 2-3 (Jan. 30, 1992) (available in LEGI-TECH, Committee Analysis Function). The American Imaging Association (AIA), which represented outpatient diagnostic imaging centers, contended that physician joint ventures result in increased competition, improved access, and lower health care costs. Moreover, the AIA stated that it found no evidence to support a ban of referrals to physician-owned facilities other than with respect to clinical laboratories. The Assembly dismissed these contentions by pointing to the results of the Florida Report. The California Medical Association (CMA) argued that the existing California law on kickbacks and disclosure is sufficient to prevent the potential abuse of physician-owned facilities. The Assembly, referring to the findings of the OIG Report, responded that physician-owned facilities located in states with disclosure requirements have not been found to have lower utilization rates than those in states without such requirements. *Id.*

California Senate, where it ran into strong opposition from the CMA.¹²⁴ On June 15, 1992, the California Senate drastically amended A.B. 819, limiting the bill's application to the prohibition of physician self-referrals in workers' compensation cases.¹²⁵ Assemblywoman Spier apparently underestimated the CMA's lobby power, describing the confrontation with the CMA as "an encounter with an 800-pound gorilla."¹²⁶

3. Other States

Some other states are currently grappling with the self-referral issue. In the Illinois General Assembly, a broad anti-referral bill (seeking to prohibit self-referrals for clinical laboratory, physical therapy, comprehensive rehabilitative, diagnostic imaging, and radiation therapy services) was introduced by Assemblyman Matijevich.¹²⁷ The New York legislature has recently enacted a bill banning self-referrals to clinical laboratories and diagnostic imaging centers.¹²⁸ A.B. 7406 applies even in cases where the services are not paid for with state funds.¹²⁹ The bill was signed into law by Governor Mario Cuomo in August of 1992.¹³⁰

VI. A BETTER MEANS OF CONTAINING HEALTH CARE COSTS

In passing a law banning physician self-referrals, Congress has failed to see the "big picture." Assuming for the moment that the Stark Law can be justified, a significant reduction in health care costs is unlikely because the referral ban applies only to a small segment of the physician population.¹³¹ Meanwhile, the same financial

124. Paul Jacobs, *Doctors' Lobby Waters Down Bill on Self-Referrals*, L.A. TIMES, June 24, 1992, at A3. The CMA, reputedly the most free-spending special interest group in Sacramento, has poured \$500,000 into lobbying efforts in the first three months of 1992. *Id.*

125. See A.B. 819 (as Amended in Senate June 15, 1992). This limitation is significant because workers' compensation cases are estimated to account for only four percent of California's annual health care costs. See Mike McKee, *Medical Group Does Surgery on Referral Bill; but Lawmaker's Changes Still Don't Appease CMA*, THE RECORDER, June 23, 1992, at 1.

126. Jacobs, *supra* note 124. Spier felt that A.B. 819 easily passed the Assembly because the opposition (presumably the CMA) was caught off-guard and admitted that she made a tactical mistake by not moving the bill quickly through the Senate. *Id.*

127. See H.B. 4044, Ill. 87th Gen. Assembly, 1991-1992 Reg. Sess. (1991).

128. See A.B. 7406, N.Y. 214th Gen. Assembly, Reg. Sess. 2d, (1992).

129. *Medicare Compliance Alert News Briefs*, MEDICARE COMPLIANCE ALERT (United Communications Group, Rockville, Md.), Aug. 17, 1992, at 5.

130. *Id.*

131. The OIG Report concluded that 12% of physicians who bill Medicare have

incentives to overutilize services allegedly present in physician joint ventures remain unchecked for the rest of the population.¹³² What is needed is a means of removing the undesirable incentives from the *entire* medical practice population.

One policy alternative is to change to a health care system where providers are prepaid. For example, physicians providing services to Medicare beneficiaries could be paid under a capitated plan.¹³³ Under that policy, Congress could make enrollment in an Health Management Organization (HMO) or other capitated payment plan mandatory for all Medicare and Medicaid beneficiaries. To qualify for participation in the program, an HMO would have to agree to accept all Medicare and Medicaid applicants for a set payment.

A. Can Prepaid Plans Control Costs?

Prepaid plans have been found to have lower total costs per patient than fee-for-service plans.¹³⁴ However, the ability of prepaid plans to control long term health care costs is debatable. One experiment, which compared the cost experience of a prepaid plan to that of a fee-for-service plan, found that the costs of the former were twenty-five percent lower.¹³⁵ In contrast, other commentators have concluded that prepaid plans are not significantly less costly than their fee-for-service counterparts.¹³⁶

ownership interests in entities to which they make patient referrals. See *OIG REPORT*, *supra* note 7, at 11. Thus, the Stark Law applies, at most, to 12% of the physician population. However, this percentage is likely to be less than 12% because laboratory tests performed by group practices are exempt from the referral ban. See *supra* note 87 and accompanying text.

132. Medical treatment in the United States has traditionally been provided on a "fee-for-service" basis. *Wasted Health Care Dollars*, *supra* note 2, at 438. Thus, the more treatments a physician provides, the more he or she is paid.

133. A capitated plan is one in which providers are paid a fixed amount to cover all care required by each patient during a set period, regardless of the actual treatment cost. See Alan L. Hillman et al., *How Do Financial Incentives Affect Physicians' Clinical Decisions and the Financial Performance of Health Maintenance Organizations?*, 321 *NEW ENG. J. MED.* 86, 86 (1989).

134. Mark C. Hornbrook & Sylvester E. Berki, *Practice Mode and Payment Method: Effects on Use, Costs, Quality, and Access*, 23 *MED. CARE* 484, 493 (1985).

135. Willard G. Manning et al., *A Controlled Trial of the Effect of a Prepaid Group Practice on Use of Services*, 310 *NEW ENG. J. MED.* 1505 (1984). The cost savings were attributed to reduced hospitalization rates of nearly 40% for the prepaid group (as compared to a fee-for-service group). *Id.* at 1508-09. Study researchers concluded that the prepaid group practiced a less "hospital-intensive" brand of medicine than the fee-for-service group. *Id.* at 1505.

136. See Harold S. Luft, *Trends in Medical Care Costs: Do HMO's Lower the Rate of Growth?*, 18 *MED. CARE* 1 (1980) (examining the trends in total health care costs for Health Management Organization (HMO) members relative to non-HMO members and finding that HMOs are subject to the same inflationary pressures as fee-for-service providers); *Health Care in Crisis: Are HMOs the Answer?*, *CONSUMER REP.* 519, 526 (Aug. 1992). *Consumer Reports* rated 46 of the country's HMOs. *Id.* at 519. This survey concluded that, while many HMOs reduce out-of-pocket costs for individual

Regardless of whether prepaid plans are more cost effective than fee-for-service arrangements, the government will benefit from adopting a prepaid system for two reasons. First, because the providers receive the same amount per patient whether or not services are rendered, at least some of the incentive to overutilize services would be neutralized.¹³⁷ *Consumer Reports* has estimated that unnecessary care results in approximately \$130 billion of the annual amount spent on health care.¹³⁸ Assuming that this estimate is correct and that all unnecessary care results from the profit incentive to overutilize services, changing to a prepaid system would save the government \$52 billion per year (forty percent¹³⁹ times \$130 billion).

Second, and more importantly, the government's concern over increasing health care costs would be alleviated because the risk of increase would be shifted to the providers.¹⁴⁰ Although this shifting of costs cannot solve the nation's health care crisis, Congress may have no other choice because the time for bringing the Medicare system's costs under control is running critically short. "Bush administration health and financial policy leaders have predicted that at current expenditure growth rates, the Medicare program's budget will be running a deficit by 1994, and will exceed in size that of either Social Security or Defense by the turn of the century."¹⁴¹ Additionally, commentators predict that the program will likely be bankrupt by the year 2011.¹⁴²

members, HMOs' ability to hold down national health care costs is less clear. *Id.* at 526. *Consumer Reports* attributed this deficiency to several factors. First, HMO members appeared to use as many services as non-members. Second, HMOs often reduce costs by negotiating discounts with hospitals, which may merely increase costs for other users of hospital services. Third, the fastest growing HMOs are those in which doctors practice in their own offices and are paid on a fee-for-service basis. This keeps costs up because "[i]n fee-for-service HMOs, there's pressure to pay physicians fees that are close to those charged by doctors in traditional practices outside the HMO." Fourth, HMOs have little ability to control the costs of specialists, which are the most expensive physicians in their networks. Lastly, HMOs are under the same pressure as traditional providers to invest in costly new technology. *Id.*

137. Although profit is the most likely cause of overutilization, other factors such as individual practice styles and the uncertain nature of medicine also contribute to the problem.

138. *See supra* note 2.

139. Medicare and Medicaid accounts for approximately 40% of health care spending in the United States. Morreim, *supra* note 9, at 393.

140. Of course, the per-capita payment would need to be adjusted to keep up with inflation. However, the government would finally be assured of controlling the budget allocated to health care expenses because the cost per Medicare beneficiary would be a fixed, determinable amount.

141. Couch, *supra* note 1, at 243.

142. *Id.*

B. Do Prepaid Plans Provide Incentives to Underutilize?

Designing a health care policy that removes all improper incentives, while maintaining a high standard of patient care, is difficult. "All compensation systems—from fee-for-service to capitation or salary—present some undesirable incentives for providing too many services, or too few."¹⁴³ The most common criticism of prepaid compensation systems is that they provide incentives for providers to under-treat patients.¹⁴⁴ While this Comment has thus far focused on the potential to overutilize services and the corresponding effect on costs, the quality of patient care is extremely important and should be considered by the legislature before enacting a given health care policy. Accordingly, a brief analysis of this criticism follows.

Prepaid plans, such as HMOs, guarantee a comprehensive range of services for a fixed price.¹⁴⁵ The financial survival of an HMO, therefore, hinges on its ability to control costs.¹⁴⁶ Since physicians' decisions control the use of resources, HMOs often use financial incentives directed at the physicians to restrain costs.¹⁴⁷ Therefore, in theory, the incentives facing physicians who contract to provide services to HMOs are the reverse of those present in the traditional fee-for-service arrangement.

The pertinent question then becomes whether these "reverse incentives" adversely affect the quality of patient care. One commentator, Alan Hillman, concludes that the financial incentives commonly used by HMOs to control costs may create a conflict of interest which might result in a lower standard of care.¹⁴⁸ However, the weight of empirical evidence does not support Mr. Hillman's

143. INSTITUTE OF MEDICINE, *supra* note 10, at 153.

144. "The financial constraints found in health maintenance organizations (HMOs) encourage the parsimonious use of health care resources." Hillman, *supra* note 133, at 86.

145. Alan L. Hillman, *Financial Incentives for Physicians in HMO's: Is There a Conflict of Interest?*, 317 NEW ENG. J. MED. 1743, 1743 (1987).

146. *Id.*

147. *Id.*

In a typical HMO, after an administrative percentage is deducted, the premium is divided into various special-purpose funds . . . to pay for the services of primary care physicians, specialists, and hospitals and for outpatient laboratory tests. The primary care fund is used to pay the primary care physicians, although a percentage of their payment is often withheld until the status of the other funds is determined at the end of the year. If there is a surplus, the HMO may return the withheld amount to the primary care physicians; if there is a deficit, the withheld funds may be retained by the HMO. HMOs may share part or all of any surpluses in these funds with the primary care physicians as bonuses. Similarly, HMOs may penalize physicians beyond the withheld amount.

Id. at 1744.

148. *Id.* at 1743.

conclusion. A 1985 article, which summarized the available literature on the effects of the method of payment on use, costs, quality, and access to health care, concluded that, except for the California Medicaid experience, the quality of care has *not* been found to be lower in HMOs.¹⁴⁹ Similarly, two recent studies did not find a decreased quality of care in prepaid plans, as compared with fee-for-service arrangements.¹⁵⁰ Neither of these studies offered an explanation for the absence of a decrease in the quality of care. Two explanations are possible. First, prepaid providers are subject to the same malpractice standards as fee-for-service physicians and, thus, must adhere to applicable community standards.¹⁵¹ Second, one might speculate that the amount of waste in fee-for-service practice is so great as to allow prepaid plans to provide comparable care at less cost.

VII. CONCLUSION

Health care costs have risen rapidly over the last decade and were expected to exceed \$800 billion in 1992. Congress has made various attempts to contain these costs. One such attempt, the enactment of the Prospective Payment System, has been largely responsible for the proliferation of outpatient treatment centers. This trend toward treatment in outpatient settings, in turn, has created incentives for physicians to invest in facilities to which they refer patients. Because physicians profit by making referrals to facilities in which they have an ownership interest, self-referral arrangements have come under Congressional scrutiny. In the belief that self-referral arrangements result in the overutilization of services and thereby increase the amount spent on health care by the federal government, Congress

149. Hornbrook & Berki, *supra* note 134, at 501. The authors suggest that one possible explanation for this conclusion is that "HMOs must provide the prevailing community standard of practice to control their malpractice liability exposure." *Id.* Further, the authors speculate that HMOs may invest more in quality assurance than fee-for-service providers because their corporate form makes for a more attractive litigation target. *Id.* at 501-02.

150. See Timothy S. Carey et al., *Prepaid Versus Traditional Medicaid Plans: Lack of Effect on Pregnancy Outcomes and Prenatal Care*, 26 HEALTH SERVICES RES. 165 (1991) (comparing prenatal care and birth outcomes for women and children enrolled in capitated programs to those treated under fee-for-service arrangements and finding no demonstrated decrease in the quality of care given to the prepaid group); Timothy S. Carey et al., *Prepaid Versus Traditional Medicaid Plans: Effects on Preventative Health Care*, 43 J. CLIN. EPIDEMIOLOGY 1213 (1990) (testing the hypothesis that preventative care would be less in prepaid systems and finding that the use of capitated payments resulted in no apparent diminution of preventative services).

151. See *supra* note 149.

enacted the Stark Law in 1989.

The Stark Law, which makes it illegal for a physician to refer patients to clinical laboratories in which he or she has an ownership interest, is overly broad for two reasons. First, the studies supporting a ban of physician self-referral arrangements, such as the OIG and Florida Reports, are inconclusive. While these studies have amassed statistics which suggest that physician-owned facilities perform more services per patient than their non-physician-owned counterparts, the studies failed to analyze whether the prescribed services were medically necessary. Second, the Stark Law makes an unjustified distinction between physicians who are members of a group practice and those who practice independently. Referrals made to a clinical laboratory owned by physicians who practice as a group are exempt from the ban, while those made by sole practitioners to a shared laboratory are not.

More importantly, the Stark Law is unlikely to have the desired result of significant savings to the government because the referral ban effects only about twelve percent of the nation's physicians. Therefore, a more farsighted solution to the government's inability to control its health care costs is needed. One possible solution is to require all Medicare and Medicaid recipients to enroll in prepaid medical plans. The adoption of this policy would finally assure the federal government of cost containment because the amount spent per Medicare beneficiary is fixed.

The time has come for Congress to re-examine the nation's health care policy. Patchwork reforms, such as the Prospective Payment System and the Stark Law, have failed to adequately contain health care costs. Unfortunately, while federal and state legislatures continue to waste precious time and money on these patchwork reforms, the Medicare-Medicaid system is rapidly becoming insolvent.

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