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# THE PATIENT HAS NOT BEEN INFORMED: A PROPOSAL FOR A PHYSICIAN CONFLICT OF INTEREST DISCLOSURE LAW

## I. INTRODUCTION

Physicians are in a unique position to create demand for health care services and products.<sup>1</sup> The physicians' ability to create demand is attributable to two factors—the intimacy of the patient-physician relationship and the technical complexity of medical knowledge.<sup>2</sup> These two factors create an informational imbalance between the patient and the physician that fosters the patient's reliance on the physician's purchasing decisions, which are necessary for treatment.<sup>3</sup> The physician, as a learned intermediary, acts as a purchasing agent for the patient when selecting the health care service and product mix that is needed for the patient's treatment.<sup>4</sup> Physicians select ancillary services such

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1. Seventy to 90% of the health care expenditures are within the control of physicians. Mark A. Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PA. L. REV. 431, 434 (1988). Insurance companies could control the amount and type of medical services provided based on how the insurance companies reimbursed health insurance claims. But, whenever insurance companies endeavor to determine what medicine and how much, physicians allege that the insurance companies are practicing medicine in the corporate form, *id.* at 508-11, and tortiously interfering with the patient-physician relationship, *id.* at 467-71. The physician's ability to create demand is more pronounced if the service is elastic or consumable, such as laboratory services where an unlimited number of tests may be ordered for any given patient. OFFICE OF THE INSPECTOR GEN., DEP'T OF HEALTH AND HUMAN SERVS., FINANCIAL ARRANGEMENTS BETWEEN PHYSICIANS AND HEALTH CARE BUSINESSES, REPORT TO CONGRESS (Doc. No. OA-12-88-01410) (May 1989), *reprinted in* [1989-2 Transfer Binder] Medicare and Medicaid Guide (CCH) ¶ 37,838, at 19,936 (May 1989) [hereinafter OIG REPORT].

2. Patients commonly lack the knowledge to ascertain whether a particular health care service is necessary or is administered in an appropriate manner. Also, illnesses often produce anxiety, dependence, and loss of self-confidence that deprive patients of the self-protective bargaining power found in other consumer decisions. Daniel W. Brock, *Commentary: Implications of New Physician Payment Methods for Access to Health Care and Physician Fidelity to Patients' Interests*, 36 CASE W. RES. L. REV. 760, 765 (1986); *see also* Alexander M. Capron, *Containing Health Care Costs: Ethical and Legal Implications of Changes in the Methods of Paying Physicians*, 36 CASE W. RES. L. REV. 708, 734 (1986).

3. Arnold S. Relman, *The New Medical-Industrial Complex*, 303 NEW ENG. J. MED. 963, 966 (1980). The American Medical Association (AMA) has suppressed the standardization of medicine based on science. The AMA has often unduly mystified medicine as a judgmental art that increases the informational gap between the physician and the patient. Hall, *supra* note 1, at 475-78. Physicians, in spite of the legal requirements of informed consent, resist sharing information with their patients. Capron, *supra* note 2, at 734.

4. Generally, the consumer selects the goods and services that are desired from the available alternatives. However, in medical care, the patient usually selects a physician who then makes choices for the patient. Capron, *supra* note 2, at 734. The physician is often referred to as the

as hospitals, home health care companies,<sup>5</sup> durable medical equipment companies,<sup>6</sup> laboratories, radiologic imaging centers,<sup>7</sup> ambulatory care centers,<sup>8</sup> dialysis units for kidney failure,<sup>9</sup> nursing homes,<sup>10</sup> and other health care entities for their patients.

In return, the various health care entities compensate physicians for their ability to supply patients.<sup>11</sup> Eight percent of physicians have a compensation arrangement with health care entities to which they refer patients.<sup>12</sup> The financial incentives that these entities offer to physicians are often based on the volume of patients referred or the economic value of services provided.<sup>13</sup> Frequently, the compensation for referrals is in the form of gifts, long-term

"gatekeeper" for the health care system. *Id.* at 728. Three out of four people pick a hospital based on their physician's recommendation. Fred Bayles & Daniel Q. Haney, *Dealing for Doctors: Not a Healthy Situation*, THE INDIANAPOLIS STAR, Oct. 14, 1990.

5. Home health care companies provide home drug therapy, such as chemotherapy, postoperative pain management therapy, AIDS drug therapy, nutrition for dialysis patients, and intravenous antibiotics. Sandy Lutz, *Safe Harbor Rules Create Infusion Confusion: Physician Ties May Put Business in a Bind*, MOD. HEALTHCARE, Nov. 4, 1991, at 29. In addition, some home health care companies provide visiting nurses and even housekeeping. Relman, *supra* note 3, at 964.

6. Durable medical equipment companies provide wheelchairs, hospital beds, and other medical equipment.

7. Radiologic imaging centers feature CAT scanners and magnetic resonance imaging units, which are the new technology that essentially performs the X-ray function. Arnold S. Relman, *Dealing with Conflicts of Interest*, 313 NEW ENG. J. MED. 749, 749 (1985).

8. The word 'ambulatory' can be interchanged with the word 'outpatient' to indicate that the patient is not required to spend the night in the health care facility in order to obtain health care. Examples of ambulatory care services are outpatient drug and alcohol facilities, ambulatory surgical centers, and outpatient physical therapy centers. Theodore N. McDowell, *The Medicare-Medicaid Anti-Fraud and Abuse Amendments: Their Impact on the Present Health Care System*, 36 EMORY L.J. 691, 708 (1987).

9. PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 442-43 (1982). In 1972, the Medicare program was amended to provide funds for the victims of end-stage renal disease (kidney failure). A congressional study found that most dialysis was done in the home at a cost of \$4000 to \$6000 a year. Shortly after the 1972 amendment, a rapid growth in physician-owned dialysis centers increased the dialysis cost to between \$14,000 to \$20,000 a year. *Id.*

10. Most nursing homes are owned by small investors, many of them physicians. Relman, *supra* note 3, at 964.

11. See *infra* notes 12-14 and accompanying text.

12. OIG REPORT, *supra* note 1, at 19,932.

13. *United States v. Tapert*, 625 F.2d 111 (6th Cir.), *cert. denied*, 449 U.S. 1034 (1980). Hospital Corporation of America told a group physician practice of gynecologists which admissions and procedures were the most profitable for the hospital. Bayles & Haney, *supra* note 4. Psychiatric Institutes of America (PIA) paid 90% of Recovery Line's expenses in return for 20 to 60 patient referrals a month. Recovery Line workers infiltrated Alcoholics Anonymous and other groups to find patients for PIA. PIA then billed Texas' Crime Victims' Compensation Fund the maximum charge of \$25,000 for each patient. *PIA Suit Charges Kickbacks, Fraudulent Bills*, MOD. HEALTHCARE, Sept. 23, 1991, at 3.

credit arrangements, business equipment, medical equipment, office space, or personnel services.<sup>14</sup>

Physicians are also acquiring equity interests in various health care companies.<sup>15</sup> Physicians then refer their patients to the physician-owned facilities, thus getting paid for referrals through dividends.<sup>16</sup> Twelve percent of physicians have an ownership interest in entities to which they make patient referrals.<sup>17</sup> Nationally, referring physicians own in whole or in part at least twenty-five percent of independent clinical laboratories, twenty-seven percent of independent physiological laboratories, and eight percent of durable medical equipment companies<sup>18</sup> In essence, health care entities have vertically integrated by developing business relationships with physicians.<sup>19</sup>

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14. The results of a 1987 survey of 114 hospitals showed that 95 % of the hospitals used income guarantees to encourage physicians to refer patients to their facility, 88 % of the hospitals gave physicians unspecified assistance to start a practice, 52 % provided free office space, and 36 % gave interest free loans. Bayles & Haney, *supra* note 4. Ophthalmologists accepted free vacations and expensive office equipment from manufacturers of intraocular lens implants that are needed for cataract surgery. Relman, *supra* note 7, at 750; see also OIG REPORT, *supra* note 1, at 19,932.

15. Relman, *supra* note 7, at 749. An equity interest is an ownership interest as distinguished from a compensation arrangement.

16. The physician benefits twice, once by providing medical advice and again as an investor in the recommended facility. *Id.* at 750.

17. The Office of the Inspector General (OIG) found it difficult to obtain physician ownership information because many states do not keep or update adequately a full listing of owners, partners, or investors of registered entities in the state. Also, owners did not have to qualify their name with M.D., making it difficult for the OIG to discern physician owners. OIG REPORT, *supra* note 1, at 19,931. Now, a Unique Physician Identification Number (UPINs) must be placed on all medicare reimbursement forms to facilitate the OIG's future efforts to identify self-referral arrangements and their impact. Medicare and Medicaid Guide (CCH), Report No. 669 (Sept. 6, 1991) (Pursuant to Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508)). But 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. (1989). The AMA's survey, in contrast to the OIG Report, found that seven percent of physicians refer patients to a facility where the physician has an ownership interest. *Id.*

18. These were the only health care entities studied by the OIG. OIG REPORT, *supra* note 1, at 19,932.

19. Vertical integration, in the health care context, consists of developing a "feeder system" of patients by owning entities that provide different aspects of patient care. For instance, a hospital that owns an outpatient physical therapy center can generate a referral stream by recommending its physical therapy center to continue monitoring the patient's care after hospital care is no longer needed. McDowell, *supra* note 8, at 709-11. A hospital or group of physicians using their dominant market position to steer patients to a particular ancillary service, such as a physical therapy center, may be monopolizing or capturing the ancillary service. Physicians and other health care providers are preventing patients' free choice among competitors. David Burda, *FTC Looking at Provider Self-Referrals*, MOD. HEALTHCARE, Feb. 3, 1992, at 14. The Federal Trade Commission (FTC) is examining the antitrust implications of provider self-referral arrangements. Two physician-owned home medical equipment companies in California and a physician-owned lithotripsy service in Tennessee are being investigated by the FTC. David Burda, *Outlook Ominous after Probes into*

Business relationships between physicians and for-profit health care entities can weaken the fiduciary duty that the physician owes the patient. A physician cannot easily serve the patient's best interests when the physician has an economic arrangement with a profit-seeking business that regards those patients as consumers.<sup>20</sup> Physicians have aligned themselves with health care entities that compete in the market for consumers. Health care businesses employ marketing to encourage utilization, which enhances profits.<sup>21</sup> The greater the volume of health care that is sold, the greater the profits that physicians and other health care providers reap.<sup>22</sup>

Traditionally, physicians have been compensated by the fee-for-service payment mechanism.<sup>23</sup> Under this arrangement, the physician is paid a fee for each service performed; thus the physician who performs more procedures increases his or her personal income.<sup>24</sup> The conflict of interest between the physician's personal financial gain and doing what is in the patient's best interest is not new, and in many instances it is readily apparent to the patient.<sup>25</sup> However, referral payments create a more subtle conflict of interest.<sup>26</sup> The patient is unaware of the physician's financial or ownership interest in the entities referred and cannot assess how this conflict of interest may prejudice the physician's judgment as to the quality or medical necessity of treatment.<sup>27</sup>

In addition, while a patient respects a physician's medical judgment on purchasing decisions, the patient implicitly trusts the physician's business judgment on these same purchasing decisions. The patient trusts that the

*Provider Ownership*, MOD. HEALTHCARE, Jan. 6, 1992, at 56.

20. The patient's medical needs and the corporation's financial objectives are not always identical. Arnold S. Relman, *Practicing Medicine in the New Business Climate*, 316 NEW ENG. J. MED. 1150, 1150 (1987). See generally Letters to the Editor, *Conflicts of Interest and the Physician Entrepreneur*, 314 NEW ENG. J. MED. 250 (1986) [hereinafter Letters to the Editor].

21. The president of Humana, one of the largest for-profit hospital chains, commented that the company markets its hospitals coast to coast like the McDonald's hamburger. STARR, *supra* note 9, at 431.

22. Relman, *supra* note 3, at 965-66.

23. Fifty percent of the physicians are compensated by the fee-for-service payment mechanism. Twenty percent of the physicians receive a salary and the remaining 30% receive a mixed compensation form of salary and fee-for-service. Capron, *supra* note 2, at 712.

24. Most physicians' income is affected by the quantity of service provided. Capron, *supra* note 2, at 712. See generally Letters to the Editor, *supra* note 20. All compensation systems present some incentive to provide too much service or not enough service. *Id.*

25. Relman, *supra* note 7, at 750.

26. *Id.* The "health care as business" creed is changing the behavior of physicians. Physicians feel compelled to associate themselves with health care companies as employees or limited partners, thus weakening the fiduciary relationship between physician and patient. Relman, *supra* note 20, at 1150.

27. Theodore N. McDowell Jr., *Physician Self Referral Arrangements: Legitimate Business or Unethical "Entrepreneurialism,"* 15 AM. J.L. & MED. 61, 69-70 (1989).

physician has referred the patient to a good quality service at the appropriate cost, but the patient rarely audits the physician's business judgment.<sup>28</sup> Third party payors mask the physician's business judgment from the patient.<sup>29</sup> The patient is insulated from directly paying the bulk of health care costs which are borne by third party payors such as Medicare.<sup>30</sup> Thus, the patient who receives health care services has little cost incentive to become informed and to make wise consumer decisions.<sup>31</sup> Instead, the patient allows the physician to make many health care purchases regardless of the cost.<sup>32</sup>

This Note proposes a Physician Conflict of Interest Disclosure Law that is to be used by the federal government in the Medicare and Medicaid programs. The Medicare and Medicaid programs' structure and payment mechanisms have influenced the entire health care system. These programs have, perhaps inadvertently, created the incentives for physicians to align with for-profit health care entities. Therefore, the Medicare and Medicaid programs are the appropriate place to begin reform. This disclosure law can best be implemented as a requirement to receiving governmental Medicare and Medicaid funds. This Note will not discuss constitutional concerns that may exist if a federal disclosure law is mandated for physicians not serving Medicare and Medicaid patients.<sup>33</sup>

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28. *United States v. Porter*, 591 F.2d 1048 (5th Cir. 1979). Physicians sent their patients' blood samples to a manual laboratory that charged \$100 for an SMA-12 battery of blood tests. An automatic laboratory, located in the area, charged seven dollars for the same battery of blood tests. The automatic laboratory's quality of work was deemed as good if not better than the manual laboratory by the medical profession. The physicians who sent their patients' blood samples to the manual laboratory owned 60% of the manual laboratory's stock. *Id.*

29. The insured patient is no longer a consumer, but a claimant of health care regardless of the cost. Relman, *supra* note 3, at 966.

30. The consumption decision is separated from the payment responsibility. McDowell, *supra* note 8, at 700. The government pays nearly half of the nation's health care bill. RICHARD SORIAN, *THE BITTER PILL: TOUGH CHOICES IN AMERICA'S HEALTH POLICY* 105 (1988).

31. McDowell, *supra* note 8, at 700-02. Commentators often attribute overtreatment to the availability of health insurance. Insurance distorts the patient's attitude about the relative benefit of medical interventions because the patient does not directly pay for the treatment. Insurance encourages the patient's demand for medical care because the patient receives all of the benefits, yet bears little of the costs of treatment. Capron, *supra* note 2, at 747.

32. Health care is perceived as a public good because much of the cost of medical research, medical care, and physicians' medical education is subsidized by public funds. Thus, most citizens demand health care as a basic right. Relman, *supra* note 3, at 966. The patient expects the best health care regardless of the cost. The patient's "spare no expense" expectations coincide with the physician's ethical duty to do everything possible for the patient no matter what the cost. Hall, *supra* note 1, at 516. Interestingly, the physician's ethical duty to do everything that is of medical benefit for the patient, regardless of cost, happens also to be in the physician's best economic interest. Brock, *supra* note 2, at 766.

33. A federal physician conflict of interest disclosure law raises the constitutional issues of forced speech and interference with the state's power to license and regulate physicians.

This Note concludes that while physician ownership and compensation arrangements create innovative health care entities that may provide less costly health care, the patient should be informed of these financial arrangements. Section II of this Note discusses how the structure and payment mechanisms of the Medicare and Medicaid programs encourage the proliferation of business arrangements between physicians and other health care entities. Section II also explains that abuse of Medicare and Medicaid funds is essentially a manifestation of the physician's conflict of interest. Section III examines the regulation of physician self-referral arrangements. Finally, Section IV analyzes various state disclosure laws and proposes a necessary federal Physician Conflict of Interest Disclosure Law.

## II. THE MEDICARE AND MEDICAID PROGRAMS AND THEIR IMPACT ON THE HEALTH CARE SYSTEM

In 1965, Lyndon B. Johnson established the Medicare and Medicaid programs as part of "The Great Society" effort to eliminate poverty.<sup>34</sup> Poor health was deemed an integral component in the cycle of poverty.<sup>35</sup> The emphasis of the Medicare and Medicaid programs was to include the elderly and the poor in the health care system.<sup>36</sup>

Physicians immediately denounced these programs as socialism.<sup>37</sup> The AMA lobbied strongly against the programs, arguing that they would destroy the physicians' ability to make medical decisions in the best interest of their patients

34. President Kennedy initiated the "unconditional war on poverty in America" to rally Americans to a positive cause. Shortly after President Kennedy's assassination, President Johnson implemented President Kennedy's cause. STARR, *supra* note 9, at 366-67.

35. *Id.* Although many elderly Americans now lead vibrant and healthy lives, it was not too long ago that the elderly were among the nation's poorest and least cared for groups. When he signed the Medicare law, President Johnson said:

No longer will illness crush and destroy the savings that they have so carefully put away over a lifetime so that they might enjoy dignity in their later years. No longer will young families see their own incomes, and their own hopes, eaten away simply because they are carrying out their deep moral obligations to their parents, and to their uncles and to their aunts.

SORIAN, *supra* note 30, at 90.

36. There was extensive grassroots support for the Medicare program among the aged, who exerted strong pressure on Congress. In addition, the civil rights movement was asserting the need for equality in the access to medical care. STARR, *supra* note 9, at 368.

37. Since 1930, the federal government had made various attempts to have some form of public health insurance, but was unsuccessful due to the strong, cohesive, AMA lobby. McDowell, *supra* note 8, at 694; *see also* STARR, *supra* note 9, at 280-89.

because the government would be regulating those decisions.<sup>38</sup> To gain physician and hospital participation in the program, the Medicare Act guaranteed freedom from "any supervision or control over the practice of medicine or the manner in which medical services are provided."<sup>39</sup> The federal government allowed physicians to decide what health care was needed and the amount of health care that should be provided.<sup>40</sup>

#### A. *The Structure and Payment Mechanisms of the Medicare and Medicaid Programs*

The Medicare and Medicaid programs are structured to preserve physicians' autonomy from governmental control.<sup>41</sup> Medicare Part A generally pays for an elderly patient's institutional care, such as inpatient hospital care.<sup>42</sup> Medicare Part B largely covers physicians' services for the elderly.<sup>43</sup> To administer the Medicare program, the federal government contracted with private insurance companies.<sup>44</sup> Typically, the federal government chose Blue Cross & Blue Shield as the fiscal intermediary in each state.<sup>45</sup>

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38. The AMA's argument, that a national insurance plan threatened the patient-physician relationship, could no longer defeat the public's growing demand to be included in the health care system. STARR, *supra* note 9, at 368-69. Interestingly, the patient-physician relationship is fast becoming controlled by financial objectives, as opposed to government regulation. Relman, *supra* note 20, at 1150. The "health care as business" creed has interfered with the patient-physician relationship. Hall, *supra* note 1, at 514.

39. 42 U.S.C. § 1395 (1988).

40. The physicians and the hospitals threatened to boycott the program. In order to get the program underway, the Medicare Act accommodated the physicians and the hospitals in both structure and payment mechanisms. STARR, *supra* note 9, at 375-76.

41. Hall, *supra* note 1, at 446.

42. Medicare Part A also covers extended care services (nursing homes), home health services, and hospice care for individuals who are age 65 or over and are eligible for retirement benefits. Medicare Part A also covers all persons who have end-stage renal disease (kidney failure). 42 U.S.C. § 1395c (1988).

43. Medicare Part B also covers durable medical equipment, ambulatory surgical center services, hospital outpatient services, and outpatient physical therapy services. Medicare Part B is a voluntary insurance program that provides medical insurance benefits for aged and disabled individuals who elect to enroll in the program. The program is financed from enrollees' premium payments and funds appropriated by the Federal Government. 42 U.S.C. §§ 1395j-w (1988).

44. The payment scheme mirrored that of private insurance companies, reimbursing for the reasonable cost or reasonable charge of the health care provided. McDowell, *supra* note 8, at 698.

45. This was a structural accommodation to the physicians and hospitals. Blue Cross & Blue Shield, a private insurance company, was established by the AMA and the American Hospital Association (AHA) during the 1940's in response to the federal government's endeavor to create public health insurance. McDowell, *supra* note 8, at 694. The structure of the Medicare program even coincides with the structure of the AMA's and the AHA's private insurance company. Blue Cross administers Medicare Part A, whereas Blue Shield administers Medicare Part B. STARR, *supra* note 9, at 375.



Medicaid is administered by the states for the benefit of the poor.<sup>46</sup> The states determine who is eligible for their Medicaid programs and what services the program will provide.<sup>47</sup> The states have great discretion in deciding how to administer the Medicaid programs.<sup>48</sup> Indeed, some states have a Medicaid program that is based on the Health Maintenance Organization (HMO) format.<sup>49</sup> The federal government provides funds in the form of matching grants to help subsidize these state programs.<sup>50</sup>

By delegating the administration of the Medicare program to the private insurance companies and delegating the administration of the Medicaid program to the states, the federal government lost direct control of the programs at the outset.<sup>51</sup> By delegating the administration of the programs, the federal government also lost control of the cost of the programs.<sup>52</sup> Additionally, the federal government paid for the Medicare Part A program on a cost or cost-plus basis.<sup>53</sup> In contrast, the federal government paid for the Medicare Part B program using a customary charge basis, which is essentially a fee-for-service payment mechanism.<sup>54</sup> The reimbursement mechanisms provided an incentive to overuse and overcharge for health care services.<sup>55</sup>

46. The federal government gives grants to the states for the purpose of enabling each state, as far as is practical under the conditions in the state, to furnish medical assistance to those whose income is insufficient to meet the costs of necessary medical services. 42 U.S.C. § 1396 (1988).

47. The federal government must approve the states' Medicaid plans before grants are given. *Id.*

48. Unlike the Medicare program, the Medicaid program does not have uniform national standards for eligibility and benefits and is not bolstered by the Social Security Tax. STARR, *supra* note 9, at 370.

49. Health Maintenance Organization Act of 1973, 42 U.S.C. § 300e-17 (1988). A health maintenance organization (HMO) is a health care organization that effectively uses a pool of patients to contract for needed health care services for the patient members at a fixed lump sum payment. See FLA. STAT. ANN. § 409.266(c) (West 1986) for a state that uses a HMO format for its Medicaid program.

50. 42 U.S.C. § 1396 (1988).

51. McDowell, *supra* note 8, at 698.

52. *Id.*

53. Prior to the Medicare and Medicaid programs, Congress attempted to improve public access to health care by funding many hospital capital improvements (Hill-Burton assets). The hospitals insisted that the Medicare and Medicaid programs pay depreciation on the hospital's assets, including the Hill-Burton assets. As an accommodation to the hospitals, Congress paid the cost of many hospital assets plus the depreciation of those same assets, which is a cost-plus-payment mechanism. STARR, *supra* note 9, at 375.

54. Physicians were paid according to what the individual physician customarily charged for the service, not the cost of the physician's service. The customary charge was controlled by the area's prevailing charge to determine whether the individual physician's charge was reasonable. Capron, *supra* note 2, at 713-15.

55. Hospitals, under the cost-based reimbursement mechanism, spent lavishly to provide the latest technology, justifying the higher cost as necessary for the care of the patient. Harvey E. Pies, *Control of Fraud and Abuse in Medicare and Medicaid*, 3 AM. J.L. & MED. 323, 326 (1977).

In 1965, when the programs were initiated, national health care expenditures accounted for nearly six percent of the Gross National Product (GNP), or forty-seven billion dollars.<sup>56</sup> Currently, national health care expenditures account for fourteen percent of the GNP, or 838 billion dollars.<sup>57</sup> Furthermore, health care costs have consistently risen more rapidly than the general rate of inflation.<sup>58</sup> One study conducted to determine why health care costs rise quicker than the inflation rate found that three to ten percent of total health care expenditures are caused by fraud and abuse.<sup>59</sup>

As health care costs increase, so does the pressure from taxpayers, labor leaders, and employers to contain the costs.<sup>60</sup> However, no one wants the quality or accessibility of health care services to be diminished.<sup>61</sup> The premise of cost containment is that costs can be reduced without sacrificing service, because many of the procedures done could be foregone without harming the patient.<sup>62</sup> In an effort to contain health care costs, the federal government replaced the cost based reimbursement system in the Medicare Part A program with the Prospective Payment System (PPS) in 1982.<sup>63</sup>

The PPS reimburses hospitals based on a Diagnosis-Related Group (DRG) concept.<sup>64</sup> The DRG provides a predetermined rate for each patient depending

Physicians inflated the "customary charge" rate for a procedure by raising the amount the physician charged for the procedure. This increased the charge for their particular patient and the higher customary charge for all combined patients also inflated the prevailing charge in that locality. Capron, *supra* note 2, at 714.

56. Eli Ginzberg, *Sounding Board—A Hard Look at Cost Containment*, 316 NEW ENG. J. MED. 1151 (1987).

57. Eric Weissenstein, *Health Spending Hits \$838 Billion in 1992*, MOD. HEALTHCARE, Jan. 11, 1993, at 2.

58. SORIAN, *supra* note 30, at 105. In 1982, when overall inflation was five percent, hospital costs rose 15.5%. *Id.* at 112.

59. The 21 page study was done by a task force consisting of the Justice Department, the Health and Human Services Department, and the White House Office of Management and Budget. David Burda, *3 Agencies Wish for More Fraud, Abuse Laws*, MOD. HEALTHCARE, Jan. 18, 1993, at 3.

60. Changes in the health care system are affected by the financial concerns of the third parties who pay most health care bills, the government and employers. Relman, *supra* note 20, at 1150.

61. *Id.*

62. Hall, *supra* note 1, at 444. For example, gynecologists often recommend annual pap smear tests even though testing every three years produces nearly the same increase in life expectancy. *Id.* at 444 n.43.

63. 42 U.S.C. § 1395ww(d) (1988).

64. DRGs are essentially a coding system developed at Yale University from a data base of 1.4 million patient records to determine the consumption of hospital resources by individual patients depending on their illness. From this data base, a predetermined payment rate was established for each illness (diagnosis). *Prospective Payment Systems Hospital DRG Rates*, 1 Medicare & Medicaid Guide (CCH) ¶ 4204 (Sept. 1986).

on the patient's illness.<sup>65</sup> The actual cost that the hospital incurred to treat the patient is no longer factored into the reimbursement equation.<sup>66</sup> Therefore, the PPS forces the hospital to find the most economical way to treat the patient.<sup>67</sup> Inpatient payment constraints have led to increased levels of outpatient care, which can be provided in a less costly manner than inpatient care.<sup>68</sup> The health care cost containment measures actually encourage new outpatient health care businesses in an effort to provide economical health care.<sup>69</sup>

In addition, Resource Based Relative Value Scales (RBRVSs)<sup>70</sup> were put into effect on January 1, 1992.<sup>71</sup> The DRG experiment in Medicare Part A is being applied to Medicare Part B payments to physicians.<sup>72</sup> It is predicted that RBRVSs may provide a further impetus for physicians to protect or supplement their incomes by investing in other health care facilities.<sup>73</sup> Thus, the physician will continue to develop business relationships with other health care entities.

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65. *Id.*

66. Hospitals are allowed to retain the amount paid per diagnosis that is in excess of their costs, but they have to absorb the costs that exceed the amount paid. *Id.* at ¶ 4203.

67. The fixed set of rates places hospitals at risk in the use of their resources. The Prospective Payment System (PPS) establishes competitive market-like forces in the health care system. *Id.*

68. *Id.*

69. The strong link between payment and diagnosis encourages physician participation in the financial affairs and operating routines of hospitals. *Id.*

70. The Diagnosis-Related Group (DRG) concept was applied to physicians. A predetermined schedule of uniform physician fees, the Relative Value Units (RVUs), determines the amount of reimbursement, as opposed to the retrospective reimbursement system of customary charge. The physician, prior to treating the Medicare or Medicaid patient, will know the reimbursement amount. *Physicians' Medicare Fee Schedule, Medicare & Medicaid Guide (CCH), Report No. 678 (Dec. 4, 1991).*

71. The payment is the lesser of the physician's actual charge or the predetermined amount from the fee schedule. The first phase, of five annual phases, began January 1, 1992. 42 U.S.C.A. § 1395w-4 (West 1992).

72. *Id.*

73. Medicare now reimburses the physician a set amount and not whatever the physician decides to charge. Thus, physicians may attempt to provide other health care services along with their professional advice to receive Medicare reimbursements for both services. For example, physicians may establish laboratories or pharmacies in their offices. Also, physicians may invest in other health care entities, then refer their patients there. OIG REPORT, *supra* note 1, at 19,926. Currently, there is a doctor surplus in this country. The growing supply of doctors encourages either physician investment in other health care entities or furnishing the ancillary service directly as a means to maintain or supplement their incomes. STARR, *supra* note 9, at 421-24, 436. In response to RBRVSs, physicians may either try to make up for lost income by increasing patient volume unnecessarily or pressure other health care entities into business arrangements that violate the Anti-Fraud and Abuse Statute. David Burda, *Physician Reaction to Rules Could Affect Final Outcome*, MOD. HEALTHCARE, Jan. 6, 1992, at 46.

## B. Program Abuse

Program abuse in the Medicare and Medicaid programs is essentially the result of the physician's conflict of interest.<sup>74</sup> Program abuse manifests itself in three different ways: reimbursement for unacceptable medical judgment,<sup>75</sup> reimbursement for unacceptable business judgment,<sup>76</sup> or both. For example, physicians do not operate according to accepted medical judgment when they refer patients for unnecessary health care services to increase the physicians' financial gain.<sup>77</sup> Medicare and Medicaid attempt to protect federal funds from this type of abuse by requiring that health care services rendered be justified by "medical necessity."<sup>78</sup> However, the medical necessity standard is elusive because the determination of each patient's medical needs can be highly judgmental.<sup>79</sup>

In addition, a physician does not operate according to accepted business judgment when referring patients for necessary care in an especially costly setting.<sup>80</sup> Referrals are unnecessarily costly because the referral payment is commingled with the legitimate cost of necessary health care, which is submitted to Medicare for reimbursement.<sup>81</sup> Referral payments drive up Medicare costs without achieving any public benefit. Program abuse is difficult to detect for a single transaction because of the elusive medical necessity standard and the commingled payment.<sup>82</sup>

74. See *supra* notes 25-32 and accompanying text.

75. See *supra* notes 25-27 and accompanying text.

76. See *supra* notes 28-32 and accompanying text.

77. H.R. REP. NO. 393, 95th Cong., 1st Sess., reprinted in 1977 U.S.C.C.A.N. 3039, 3050. This is sometimes called "ping-ponging," which is referring a patient to another physician or another health care entity without a medical reason for doing so. *Id.* at 3048.

78. The AMA's guidelines also suggest a "medical necessity" criteria for patient care. McDowell, Jr., *supra* note 27, at 102.

79. Medical services are individualized because no two patients are exactly alike. Hall, *supra* note 1, at 476 n.155. Also, the medical community has not attempted to discern which medical procedures are preferable among the vast range of alternatives. *Id.* at 481.

80. H.R. REP. NO. 393, *supra* note 77, at 3050. This is sometimes called "steering," which is directing a patient to a particular health care entity, such as a pharmacy, in violation of the patient's freedom of choice. *Id.* at 3048.

81. The misapplication of federal funds is apparent when payment for the one-minute referral suggestion is added to the legitimate cost of the health care transaction. *United States v. Hancock*, 604 F.2d 999, 1001 (7th Cir. 1979). But see David M. Frankford, *Creating and Dividing the Fruits of Collective Economic Activity: Referrals Among Health Care Providers*, 89 COLUM. L. REV. 1861, 1873 (1989). Referrals are based on information shared by health care providers. Since information is not free, it is natural that payment would be made in exchange for referrals. *Id.*

82. See *supra* notes 78-81 and accompanying text. A kickback can be disguised as extra payment; the kickback is commingled with a legitimate business payment, such as a salary. See *infra* notes 149-52 and accompanying text for an example of a disguised payment.

Although program abuse may be difficult to ascertain for a single patient transaction, it is evident on a macroeconomic level. The Office of the Inspector General (OIG) found that patients of referring physicians with an ownership interest in clinical laboratories received an average of forty-five percent more clinical laboratory services than all Medicare patients in general.<sup>83</sup> Patients of referring physicians who have a compensation arrangement with a clinical laboratory received an average of thirty-two percent more laboratory services than all Medicare patients in general.<sup>84</sup> Patients of referring physicians known to have ownership interests in physiological laboratories use thirteen percent more physiological services than patients in general.<sup>85</sup> States and universities have conducted their own studies and have found similar results.<sup>86</sup>

### III. THE REGULATION OF PHYSICIAN SELF-REFERRAL ARRANGEMENTS

The structure and payment mechanisms used by the Medicare and Medicaid programs have led to documented abuse.<sup>87</sup> On one level, the federal and various state governments are trying to minimize the cost of program abuse by

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83. The OIG estimated the cost of excess referrals by physician-owners of clinical laboratories to be \$28 million. The OIG did not estimate the cost of other physician-owner referrals. OIG REPORT, *supra* note 1, at 19,933-34.

84. *Id.* at 19,934.

85. *Id.*

86. Blue Cross & Blue Shield's study of 148 laboratories revealed that the average number of services and the average payment per patient was 40% higher for patients whose physicians had an ownership interest in the laboratory referred. MEDICAL AFFAIRS DIVISION, BLUE CROSS & BLUE SHIELD OF MICHIGAN, A COMPARISON OF LABORATORY UTILIZATION AND PAYOUT TO OWNERSHIP, (May 9, 1984). One study, of six selected laboratories, found that Medicaid recipients referred for clinical laboratory services by physician-owners had an average of 41% more tests than those referred by non-owners. MEDICAL SERVICES ADMINISTRATION, STATE OF MICHIGAN DEPARTMENT OF SOCIAL SERVICES, UTILIZATION OF MEDICAID LABORATORY SERVICES BY PHYSICIANS WITH/WITHOUT OWNERSHIP INTEREST IN CLINICAL LABORATORIES: A COMPARATIVE ANALYSIS OF SIX SELECTED LABORATORIES, (July 9, 1981). The New York City Department of Consumer Affairs found markups of 400% on home infusion services. The federal government does not reimburse for most home infusion therapies, so the companies readily admit that they pay or share profits with physicians to induce referrals. As long as Medicare does not reimburse the referrals, the payments do not violate the law. Lutz, *supra* note 5, at 32. The Florida Health Care Cost Containment Board found that the profusion of physician-owned Magnetic Resonance Imaging (MRI) centers in Florida caused 65% more scans per resident than in Baltimore, where MRIs are usually hospital-owned. In 1991, the cost of the "extra" scans in Florida was \$185 million. Michael L. Millenson, *A Conflict of Image in Health Care*, CHI. TRIB., Feb. 23, 1992, at C1, C2. A joint study, done by the University of Virginia's School of Medicine and the American College of Radiology, found that 40% of the physicians who own MRI facilities ordered imaging tests for patients with knee pain, compared with only five percent of the physicians who do not own MRI facilities. Also, self-referring physicians tended to have higher imaging charges than physicians without such arrangements. David Burda, *Study: Physician-Investors Refer More Patients*, MOD. HEALTHCARE, Oct. 26, 1992, at 17.

87. See *supra* notes 83-86 and accompanying text.

enacting laws banning certain types of physician self-referral arrangements.<sup>88</sup> On another level, both the federal and many state governments have enacted Anti-Fraud and Abuse Statutes.<sup>89</sup> The Anti-Fraud and Abuse Statutes are aimed at individual physicians that fraudulently abuse Medicare and Medicaid funds, as opposed to a macroeconomic ban on all physician self-referral arrangements. Also, the AMA has issued guidelines addressing the conflict of interest present in physician self-referral arrangements.<sup>90</sup>

#### A. The Laws Banning Physician Self-Referral Arrangements

In 1989, the federal government enacted a statute that prohibits, with specified exceptions, Medicare payments to a physician who refers patients to a clinical laboratory in which the physician has a financial interest.<sup>91</sup> The statute, however, deals only with clinical laboratories and not with the many other types of ancillary services to which physicians may refer patients. Also, the statute contains numerous exceptions that seem to swallow the rule that prohibits referrals to even clinical laboratories.<sup>92</sup> The law protects only a small number of patients.

To date, five states have banned certain types of physician self-referral arrangements.<sup>93</sup> These state laws also illustrate where the exceptions swallow the rule prohibiting physician self-referral practices. For instance, the New York law exempts referring physicians who live in rural areas. This seems like a benign exception; however, a rural area is defined, in the New York law, as a county with a population of 200,000 or less. The New York law exempts forty-five of the state's sixty-two counties from its law.<sup>94</sup>

These state laws also present constitutional issues. For example, equal protection issues exist with respect to Florida's law because the law exempts

88. See *infra* notes 91-99 and accompanying text.

89. See *infra* notes 100-188 and accompanying text.

90. See *infra* notes 189-96 and accompanying text.

91. Medicare & Medicaid Guide (CCH), Report No. 706 (July 30, 1992). Congressman Fortney "Pete" Stark sponsored the self-referral bill that became law in the Omnibus Budget Reconciliation Act of 1989 (P.L. 101-239). The statute's effective date was January 1, 1992. James M. Gaynor Jr., *The Stark Reality*, CHI. HEALTHCARE, Feb. 1992, at 28.

92. For example, the statute exempts many hospital-physician financial arrangements, health maintenance organizations, and rural or medically under-served areas. Medicare & Medicaid Guide (CCH), Report No. 706 (July 30, 1992); James M. Gaynor Jr., *The Stark Reality*, CHI. HEALTHCARE, Feb. 1992, at 28.

93. Florida, Illinois, Michigan, New Jersey, and New York have banned certain types of physician self-referral arrangements. David Burda, *Study: Physician-Investors Refer More Patients*, MOD. HEALTHCARE, Oct. 26, 1992, at 17.

94. David Burda & Karen Pallarito, *New Illinois, New York Laws Address Self-Referrals*, MOD. HEALTHCARE, Oct. 5, 1992, at 14.

hospitals and physician-owned outpatient surgery centers, but includes physician-owned physical therapy centers. Therefore, the law targets certain physicians while exempting other physicians and other health care providers such as hospitals.<sup>95</sup> Takings issues also exist. In 1995, the Florida law will bar physicians from referring patients to health care entities in which the physician has an ownership interest. Prior to 1995, the Florida law places caps on fees charged by physician-owned health care centers. Physicians will have to sell their interests in these facilities or stop referring patients to them. The law may prevent physicians from earning reasonable returns on their investments, which may have the effect of taking property without the due process of law.<sup>96</sup>

The laws banning physician self-referral arrangements are limited and riddled with exceptions and thus do not sufficiently protect patients.<sup>97</sup> The laws also may not survive constitutional analysis.<sup>98</sup> Finally, banning physician self-referral arrangements may adversely impact the development of innovative health care entities.<sup>99</sup> Physicians have directed the course of medicine in deciding what ancillary services to provide, but who is better qualified to direct this function? Laws banning physician self-referral arrangements may have dire consequences on the medical infrastructure established by physicians. Education, instead of banning physician self-referral arrangements, is necessary. This education should take the form of the proposed Physician Conflict of Interest Disclosure Law.

### B. *The Anti-Fraud and Abuse Statutes*

The federal government has been monitoring and regularly strengthening the penalty for fraud and abuse of the Medicare and Medicaid programs.<sup>100</sup> Currently, involvement in a referral scheme is a felony.<sup>101</sup> Also, a physician or health care entity found to be involved in a referral scheme may be excluded from participating in the Medicare and Medicaid programs.<sup>102</sup> In spite of the

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95. David Burda, *Providers Challenge Florida's Ban on Referrals to Facilities They Own*, MOD. HEALTHCARE, June 15, 1992, at 6. The standard of review, however, for economic or social welfare legislation is mere rationality. The Court strongly presumes that economic legislation is constitutional. *Lindsley v. Natural Carbonic Gas Co.*, 220 U.S. 61 (1911).

96. Burda, *supra* note 95, at 6. The Taking Clause protects, to some extent, investment-backed expectations. JOHN E. NOWAK & RONALD D. ROTUNDA, CONSTITUTIONAL LAW 428 (West Publishing Co. 1991). But the state may regulate property in a manner consistent with the state's police power, even if the regulation substantially diminishes the property's value. *Penn Cent. Transp. Co. v. New York City*, 438 U.S. 104 (1978).

97. See *supra* notes 91-94 and accompanying text.

98. See *supra* notes 95-96 and accompanying text.

99. See *infra* notes 191-92 and accompanying text.

100. See *infra* notes 104-21 and accompanying text.

101. See *infra* notes 104-18 and accompanying text.

102. See *infra* notes 119-21 and accompanying text.

broad statutory language and judicial interpretation, however, it is still difficult to prosecute referral practices due to the inherent nature of referrals and the health care business climate.<sup>103</sup>

1. The 1972, 1977, and 1980 Medicare and Medicaid Anti-Fraud and Abuse Statutes

In 1972, only seven years after instituting the Medicare and Medicaid programs, Congress attempted to directly respond to fraud and abuse in the Medicare and Medicaid programs by adding sections 1877(b) and 1909(b) to the Social Security Act.<sup>104</sup> Sections 1877(b) and 1909(b) prohibited the soliciting, offering, paying, or accepting of kickbacks or bribes in connection with the furnishing of services or items that are paid by Medicare or Medicaid to an individual, including the rebate of any fee or charge for referrals.<sup>105</sup> The crime was a misdemeanor and the punishment was not to exceed \$10,000, or imprisonment for more than one year, or both.<sup>106</sup> When approving the specific strict liability provision, Congress noted that referral practices were regarded by professional organizations as unethical and were thought to contribute substantially to the cost of the Medicare and Medicaid programs.<sup>107</sup>

In 1977, Congressional hearings and investigations revealed "a disturbing degree [of] fraudulent and abusive practices associated with the provision of

103. See *infra* notes 176-88 and accompanying text.

104. Previously, the government had relied on conspiracy to defraud the government, false claims provisions, and other general statutes to prosecute physicians. Martha J. Yoakum, Comment, *Physician Fraud in the Medicare-Medicaid Programs—Kickbacks, Bribes, and Remunerations*, 10 MEM. ST. U. L. REV. 684, 685 (1980). The 1972 provisions were in addition to other penalty provisions in state and federal law. H.R. REP. NO. 231, 92d Cong., 2d Sess., reprinted in 1972 U.S.C.C.A.N. 4989, 5094. The Government still uses conspiracy and false claims provisions to prosecute. See also *United States v. Bay State Ambulance and Hosp. Rental Serv. Inc.*, 874 F.2d 20 (1st Cir. 1989); *United States v. Lipkis*, 770 F.2d 1447 (9th Cir. 1985).

105. Social Security Act, § 1877(b), 1909(b) as amended 42 U.S.C. §§ 1395nn(b), 1396h(b) (1976). The substantive language in § 1395nn(b)—the Medicare program—and § 1396h(b)—the Medicaid program—is identical. The full text of 42 U.S.C. § 1396h(b) is provided below:

(b) Kickbacks, bribes, or rebates of fees or charges

Whoever furnishes items or services to an individual for which payment is or may be made in whole or in part out of Federal funds under a State plan approved under this subchapter and who solicits, offers, or receives any—

(1) kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment, or

(2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services

shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than \$10,000 or imprisoned for not more than one year, or both.

106. *Id.*

107. H.R. REP. NO. 231, *supra* note 104, at 5093.



health services financed by the Medicare and Medicaid programs."<sup>108</sup> Fraudulent practices are disturbing because they cheat the taxpayers who pay for program costs, divert program dollars from the elderly and the poor who were the intended recipients of quality health service, erode the financial stability of state and local governments that must fulfill their obligations to the medical assistance program, and unfairly denigrate the majority of honest physicians and health care institutions.<sup>109</sup>

In response to the 1977 Congressional hearings, Congress enacted the Medicare-Medicaid Anti-Fraud and Abuse Amendments.<sup>110</sup> To strengthen the penalties, Congress upgraded the offense to a felony, punishable by a fine not

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108. H.R. REP. NO. 393, *supra* note 77, at 3047. The report discusses the pervasiveness of fraud in the Medicaid facilities, laboratories, nursing homes, and among physicians. *Id.* at 3047-50; *see also* Pies, *supra* note 55, at 326 (commenting that fraud and abuse in the Medicare and Medicaid programs had reached crisis proportions that cost \$1 billion a year).

109. H.R. REP. NO. 393, *supra* note 77, at 3047.

110. Act of Oct. 25, 1977, Pub. L. No. 95-142, § 1877(b), 91 Stat. 1175, 1180 (codified as amended at 42 U.S.C. § 1320a-7b(b) (1988)) provides:

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

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this title, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this title, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

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

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this title, or

(B) to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under this title, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

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

(A) a discount or other reduction in price obtained by a provider of services or other entity under this title if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under this title; and

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

to exceed \$25,000, or imprisonment for more than five years, or both.<sup>111</sup> Also, the term 'kickback' was changed to 'any remuneration'.<sup>112</sup> The term 'any remuneration' broadened the reach of the statute to include more business transactions.<sup>113</sup> It encompassed kickbacks, bribes, and rebates, but specifically excluded legitimate business payments, such as salaries to physicians for work performed.<sup>114</sup>

In 1980, Congress amended the Anti-Fraud and Abuse Statute by changing the strict liability standard to require that the abusive conduct be performed "knowingly" and "willfully,"<sup>115</sup> thus restricting the expansive reach that the 1977 "any remuneration" language had when coupled with the 1972 strict liability standard.<sup>116</sup> In enacting the initial Anti-Fraud and Abuse Statute, Congress intended to prosecute Medicare and Medicaid abuse. Yet, Congress later hampered enforcement of that same statute.

## 2. The Medicare and Medicaid Patient and Program Protection Act

In 1987, Congress repealed sections 1395nn(b) and 1396h(b), and re-

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111. *Id.* The 1972 penalties were inadequate deterrents and were inconsistent with existing federal criminal code sanctions, which made similar actions punishable as a felony. H.R. REP. NO. 393, *supra* note 77, at 3055-56.

112. The 'any remuneration' term was used to resolve the conflict among the courts in favor of a broad meaning of the terms 'bribe' and 'kickback'. *United States v. Zacher*, 586 F.2d 912, 916 (2d Cir. 1978) (narrowly construing the term 'bribe' as "acts that are *malum in se* because they entail either a breach of trust or duty or the corrupt selling of what our society deems not to be legitimately for sale. . . . It is this element of corruption that distinguishes a bribe from a legitimate payment for services"); *United States v. Porter*, 591 F.2d 1048, 1054 (5th Cir. 1979) (narrowly construing the term 'kickback' as "involv[ing] a corrupt payment or receipt of payment in violation of the duty imposed by Congress on providers of services to use federal funds only for intended purposes and only in the approved manner"); *United States v. Hancock*, 604 F.2d 999, 1002 (7th Cir. 1979) (broadly defining the term 'kickback' to be "a percentage payment for granting assistance by one in a position to open up or control a source of income"), *cert. denied*, 444 U.S. 991 (1979); *United States v. Tapert*, 625 F.2d 111, 121 (6th Cir. 1980) (affirming the *Hancock* court's definition of kickback), *cert. denied*, 449 U.S. 1034 (1980).

113. The term 'remuneration' is not specifically defined in the statute but is understood to include any compensation or payment for a service, loss, or expense. The term is used in various other federal statutes where considerable flexibility is needed to define payment arrangements. For example, the Internal Revenue Code defines wages as remuneration in order to compute unemployment and withholding taxes. *Yoakum*, *supra* note 104, at 693-94.

114. H.R. REP. NO. 393, *supra* note 77, at 3050; *see also* McDowell Jr., *supra* note 27, at 92.

115. Act of Dec. 5, 1980, Pub. L. No. 96-499, 1980 U.S.C.A.N. 5526, 5572.

116. *See* Stephen C. Pierce, *United States v. Greber and its Effect on the Medicare and Medicaid Programs*, 75 KY. L.J. 677, 691 (1986-87), for the view that Congress thought the strict liability statute was "unjust" because criminal prosecution was possible for individuals whose conduct, while improper, was inadvertent.

enacted the provisions in altered form at section 1320a-7b.<sup>117</sup> The substantive provisions for criminal sanctions were not materially changed.<sup>118</sup> However, in addition to the criminal sanctions, the 1987 Act added a civil remedy to

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117. 42 U.S.C. § 1320a-7b(b)(1) (1988). The text of § 1320a-7b(b)(1) provides:

(b) Illegal remunerations

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

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

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under subchapter XVIII of this chapter or a State health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

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

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

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under subchapter XVIII of this chapter or a State health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

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

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

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

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

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

118. The offense continues to be a felony, with fines not to exceed \$25,000, or imprisonment for not more than five years, or both. *Id.*

exclude an individual or entity from participation in the Medicare and Medicaid programs if the physician or health care entity engaged in a prohibited remuneration scheme.<sup>119</sup> The Department of Health and Human Services (HHS) has found it difficult to prove beyond a reasonable doubt that referral arrangements are done knowingly and willfully.<sup>120</sup> An additional advantage of the civil action is that it can be brought more expediently before an administrative law judge than before the crowded criminal courts.<sup>121</sup> The criminal sanction can ruin careers, whereas the civil sanction can financially devastate physicians who receive much of their income from Medicare and Medicaid.

Spawned by the 1982 Prospective Payment System (PPS) for hospitals, many new business arrangements between physicians, hospitals, and other health care entities were developed that may violate the any remuneration language in the Act.<sup>122</sup> The "any remuneration" language created uncertainty in the health care industry as to which business arrangements are legitimate and which are

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119. 42 U.S.C. § 1320a-7(b)(7) (1988). The OIG, which promulgated the civil remedy, anticipates this will increase prosecutions in the future. The proof burden of the civil remedy is a preponderance of the evidence. Fred Bayles, *Illegal Doctor—Hospital Relationship Hard To Prove*, THE INDIANAPOLIS STAR, Oct. 22, 1990.

120. Mr. Thomas Crane, an attorney with Health & Human Services (HHS), remarked, "Proving the intent of the parties is sometimes very complicated. . . . There are well-paid lawyers who help hide the intent of the parties." Fred Bayles, *Illegal Doctor—Hospital Relationship Hard To Prove*, THE INDIANAPOLIS STAR, Oct. 22, 1990. After criminal prosecution, HHS excluded only 335 physicians between 1977 and 1982. S. REP. NO. 109, 100th Cong., 1st Sess., reprinted in 1987 U.S.C.C.A.N. 682, 684.

121. The Justice Department lacked sufficient resources to train anti-fraud auditors, investigators, and attorneys. Pies, *supra* note 55, at 327. Appeals are heard within the Department of Health and Human Services by the Departmental Grant Appeals Board. Judicial review is available in federal district courts but is subject to the Administrative Procedure Act, 5 U.S.C. § 706 (1988).

122. Many hospitals and physicians formed joint ventures to provide outpatient health care facilities in the community, which may be a more economical form of health care. *Joint Ventures in Health Care: More than a Sideline Business*, HEALTHCARE FIN. MGMT., May 1986, at 68. Some hospitals carved out a profitable hospital department, such as cardiac nuclear medicine, to form a joint venture with physicians. The hospitals argued that the increased use of the department's services, now owned by physicians, reduced the unit cost of the service for each patient, and thus was a more economical form of health care. David Burda, *IRS to Joint Ventures: The Party's Over—Hospital/Physician Link Likely to put Tax Status in Jeopardy*, MOD. HEALTHCARE, Dec. 9, 1991, at 2, 14. The hospital, in an attempt to provide a more economical service, seems to have violated the Anti-Fraud and Abuse Statutes. It is hard to argue that the increase in use of these services after physician ownership is attributable to medical necessity upon which Medicare and Medicaid bills are filed. *Joint Ventures Imperil Hospitals' Tax Status*, 75 Federal Tax Guide Reports (CCH), Report No. 13 (Dec. 27, 1991).

illegal.<sup>123</sup> In response, the Act also directed the Secretary of Health and Human Services (HHS) to promulgate regulations specifying payment practices that shall not be treated as a basis for exclusion or criminal prosecution.<sup>124</sup>

### 3. The Safe Harbors

On July 29, 1991,<sup>125</sup> HHS issued eleven safe harbors. These rules protect various payment practices and business arrangements from criminal prosecution and civil sanctions under the Medicare and Medicaid Patient and Program Protection Act.<sup>126</sup> The safe harbor rules applicable to physician self-referral arrangements include investment interest,<sup>127</sup> space rental,<sup>128</sup>

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123. S. REP. NO. 109, *supra* note 120, at 707. The report reiterated the position taken when passing the 1977 Statute that the term 'any remuneration' was not to include legitimate business payments, such as employment salaries. McDowell Jr., *supra* note 27, at 92. However, the 1977 Statute does not address investments and contractual arrangements.

124. 42 U.S.C. § 1320a-7(b)(3)(D) (1988).

125. HHS initially proposed regulations on December 23, 1988. 53 Fed. Reg. 51,856 (1988). Five days later, the HHS withdrew the regulations due to pressure from the Department of Justice and the Office of Management and Budget. 53 Fed. Reg. 52,448 (1988). New proposed regulations were published for comment on January 23, 1989. 54 Fed. Reg. 3088 (1989). Final safe harbor rules were published two years after the statutory due date on July 29, 1991. 56 Fed. Reg. 35,952 (1991).

126. Gary W. Eiland, *Final Safe Harbors Narrow and Rarely Navigable*, HEALTHCARE FIN. MGMT., Oct. 1991, at 15; *Final Safe Harbor Rules Published*, HEALTHCARE FIN. MGMT., Sept. 1991, at 5.

127. 42 C.F.R. § 1001.952(a) (1992).

128. 42 C.F.R. § 1001.952(b) (1992). The regulation provides:

(b) *Space Rental*. As used in section 1128B of the Act, "remuneration" does not include any payment made by a lessee to a lessor for the use of premises, as long as all of the following five standards are met—

- (1) The lease agreement is set out in writing and signed by the parties.
- (2) The lease specifies the premises covered by the lease.
- (3) If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.
- (4) The term of the lease is for not less than one year.
- (5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

For purposes of paragraph (b) of this section, the term *fair market value* means the value of the rental property for general commercial purposes, but shall not be adjusted to reflect the additional value that one party (either the prospective lessee or lessor) would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare or a State health care program.

equipment rental,<sup>129</sup> personal services, and management contracts.<sup>130</sup> The safe harbors allow physician investments and financial interests in the listed entities, but the safe harbors do not provide for disclosure of a physician's investment and financial interest to the patient.<sup>131</sup>

The safe harbor protects physician investments in large health care entities—such as those registered with the Securities and Exchange Commission—or entities that have at least \$50 million in undepreciated net tangible health care assets from the Anti-Fraud and Abuse Statute.<sup>132</sup> The Office of the Inspector General (OIG) notes that payments from large entities to physicians could only be remotely attributable to referrals.<sup>133</sup> Therefore, the connection between the payments and the referrals is weak.<sup>134</sup>

The safe harbor also protects physicians who invest in a small health care entity, such as a limited partnership,<sup>135</sup> if no more than forty percent of the entity is controlled by physicians or other investors who are in a position to control the flow of business to the entity.<sup>136</sup> The OIG is of the opinion that physicians who control more than forty percent of an entity will not have to compete for business in the open market on the basis of cost, quality, and convenience.<sup>137</sup> The health care entity supported by a physician investor base

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129. The equipment rental safe harbor is substantively similar to the space rental safe harbor. 42 C.F.R. § 1001.952(c) (1992).

130. The personal services and management contracts safe harbor is substantively similar to the space rental safe harbor. 42 C.F.R. § 1001.952(d) (1992).

131. 56 Fed. Reg. 35,969 (1991).

132. 42 C.F.R. § 1001.952(a) (1992).

133. 56 Fed. Reg. 35,964-66 (1991). The more referrals the facility receives, the greater the facility's total profit, which increases the physician's return on investment. However, in a large health care facility, the referrals of any one physician will have less effect on that physician's return on investment. Therefore, the physician's incentive to make unnecessary referrals is diminished. Kimberly A. King, Note, *Regulating Physician Investment and Referral Behavior in the Competitive Health Care Marketplace of the '90s—An Argument for Decentralization*, 65 WASH. L. REV. 657, 672 (1990).

134. King, *supra* note 133, at 672.

135. 42 C.F.R. § 1001.952(a) (1992). Physician equity interests in limited partnerships are the most controversial. *The Ethics in Patient Referrals Act of 1989*, *supra* note 17.

136. 42 C.F.R. § 1001.952(a) (1992). *But see* Eiland, *supra* note 126, at 16 (stating that the 60/40 Rule will not include the typical physician joint venture. Most physician joint ventures have a much higher ratio of physician ownership.); Millenson, *supra* note 86, at C2 (citing Representative Stark, the chairman of the House subcommittee that oversees Medicare, who commented that the 60/40 Rule was nothing more than a loophole.).

137. 56 Fed. Reg. 35,966 (1991) (stating that the 60/40 Rule minimizes the corrupting influence the investment interest has on the physician's referral behavior.). *But see* 56 Fed. Reg. 35,969 (1991). Many commentators believe that physician joint ventures have no real business purpose and that the 60/40 Rule will not prevent abuse. *See also* King, *supra* note 133, at 672 (the more referrals the facility receives, the greater the facility's total profit, which increases the physicians's return on investment).

in excess of forty percent will have captive referrals.<sup>138</sup> The guidelines also specifically provide that payments—such as dividends—must be commensurate with the physician's investment and risk, to assure that payments do not fluctuate according to the amount of referrals.<sup>139</sup> The safe harbor rules allow physicians the freedom to invest in ventures within their expertise, which often benefit the public by providing access to medical services that would otherwise be unavailable.<sup>140</sup>

Space rental, equipment rental, and personal services and management contracts<sup>141</sup> are safe harbors, provided that there is a written contract for a term of at least one year that is based on the fair market value of the services.<sup>142</sup> These safe harbor provisions require that payments be consistent with fair market value. The regulations explicitly provide that safe harbor protection is not available where any part of the payments take into account the volume or value of referrals generated by the physician.<sup>143</sup> Frequently, payment for referrals is made by offering such items as medical equipment, business equipment, office space, and personnel services such as accountants, secretaries, and nurses either at a substantial savings or completely free of charge.<sup>144</sup>

138. See *supra* note 137.

139. Investments that base the rate of return on the volume of referrals provide a strong financial incentive for physicians to abuse their referral privilege. King, *supra* note 133, at 672. The physician's business decision to invest should be separated from the physician's referral decision, which is to be based on medical necessity. McDowell Jr., *supra* note 27, at 104.

140. David Burda, *States Lag in Regulating Self Referrals*, MOD. HEALTHCARE, Dec. 23/30, 1991, at 40 (noting that Jennifer Christian, M.D., president of the Alaska State Medical Association, commented that in frontier areas the physician's entrepreneurial activity established the medical infrastructure); King, *supra* note 133, at 669 (noting that local physicians pool their funds to provide the needed health care service, such as dialysis, in rural communities that do not attract corporate investors); McDowell Jr., *supra* note 27, at 71 (noting that the physician's investment interest creates an economic interest in the facility to provide a quality service). *But see* Letters to the Editor, *supra* note 20, at 252 (There is plenty of venture capital to start new health care entities. Hospitals and private corporations do not need physicians' capital. Physicians are given a financial stake in the enterprise to ensure their referrals.).

141. These three safe harbors are to protect legitimate compensation arrangements. The requirements for all three are the same. 56 Fed. Reg. 35,953 (1991).

142. The fair market value criteria was preceded by the *Lipkis* case. In *Lipkis*, the court emphasized the importance of determining the fair market value when assessing the legitimacy of payments made to physicians in a position to make referrals. The fair market value of the services was substantially less than the payment, therefore the excess payment amount must be for referrals. *United States v. Lipkis*, 770 F.2d 1447 (9th Cir. 1985).

143. 42 C.F.R. § 1001.952(b-d) (1992).

144. *E.g.*, *Tanquilut v. Illinois Dep't of Public Aid*, 396 N.E.2d 1126 (Ill. 1979). A pharmacist leased pharmacy space from a physician where the lease provided an incentive rent in addition to a base rent. The incentive rent was based on the pharmacist's sales; therefore the greater the amount of physician referrals to the pharmacist, the greater the incentive rent the pharmacist paid to the physician. *Id.*; see also *United States v. Universal Trade and Indus. Inc.*, 695 F.2d 1151 (9th

The safe harbors allow physician investment and compensation arrangements, which may create entities that provide less costly health care by attempting to distinguish the legitimate business payment from the illegal referral payment.<sup>145</sup> But, even the preamble of the rules notes that a safe harbor may not be all that safe. The OIG states that it "intend[s] to monitor business arrangements that comply with the terms of these safe harbor provisions, particularly investment interests, to determine whether abusive arrangements exist within the parameter of a particular safe harbor."<sup>146</sup> The preamble indicates how difficult it is to separate legitimate business arrangements from program abuse.<sup>147</sup> Indeed, it may be impossible to statutorily define a legitimate business arrangement from a fraudulent practice.<sup>148</sup> Clever lawyers can almost always structure business arrangements so that the arrangement complies with any set of rules, no matter how strictly they are written.

#### 4. Judicial Interpretation of the Anti-Fraud and Abuse Statutes

In *United States v. Greber*,<sup>149</sup> the defendant physician formed the company Cardio-Med to provide physicians with diagnostic services, such as analysis of readings from a Holter-monitor. Cardio-Med billed Medicare for the Holter-monitor service and, when payment was received, advanced a portion to the referring physician.<sup>150</sup> Cardio-Med characterized the payment as an "interpretation fee," and, indeed, many of the referring physicians did perform interpretive work.<sup>151</sup> The fee was more than the Medicare allowance for such services and was paid even when the defendant interpreted the data.<sup>152</sup>

The *Greber* court stated that the 1977 statute was aimed at the inducement factor, regardless of whether payments were also intended to compensate for professional services in connection with the tests.<sup>153</sup> The court held "that if one purpose of the payment was to induce future referrals, the Medicare statute

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Cir. 1983).

145. Physician ownership does not per se violate the Anti-Fraud and Abuse Statute. McDowell Jr., *supra* note 27, at 96.

146. 56 Fed. Reg. 35,958 (1991).

147. *Id.*

148. The health care system is in a transitional phase—no set of guidelines could keep up with the new business entities that are developing. McDowell, *supra* note 8, at 753. A major difficulty in statutorily defining fraud and abuse stems from the ambiguities inherent in these terms. These terms are vague and, to the extent they are vague, they do not sufficiently protect the patient. Pies, *supra* note 55, at 325.

149. *United States v. Greber*, 760 F.2d 68, 70 (3d Cir.), *cert. denied*, 474 U.S. 988 (1985).

150. *Id.*

151. *Id.*

152. *Id.*

153. *Id.* at 71.



has been violated."<sup>154</sup> Other courts as well have interpreted the 'any remuneration' term of the 1977 statute broadly.<sup>155</sup>

In *Inspector General v. Hanlester Network*,<sup>156</sup> the defendant promoters established three joint venture limited partnership laboratories, which sought approximately thirty-five licensed physicians—the number capable of supporting the laboratories by referrals—as investors for each laboratory.<sup>157</sup> The defendant promoters made it clear to the physicians that failure to refer laboratory tests would lead to investment failure.<sup>158</sup> A sales representative for the promoters further told potential physician investors that the percent of investment offered depended upon expected referrals and that the ownership interest was contingent upon the continuation of referrals.<sup>159</sup>

The Administrative Law Judge (ALJ), in a lengthy opinion, held that to violate the "to induce" language of the Act, there must be an agreement to refer business.<sup>160</sup> The Act does not prohibit offers or payments that are calculated to encourage physicians to refer business but do not require referrals as a condition for payment.<sup>161</sup> The ALJ further reasoned that the physicians did

154. *Id.* at 69. The phrase is most often quoted by the HHS as an accurate interpretation of the term 'any remuneration'. OIG REPORT, *supra* note 1, at 19,928.

155. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989). The owner of Tech-Lab agreed to kick back 50% of the Medicare payments received by Tech-Lab as a result of referrals from Total Health Care. The Ninth Circuit quoted approvingly from *United States v. Greber* in upholding the trial judge's charge to the jury. See also *United States v. Bay State Ambulance and Hosp. Rental Serv. Inc.*, 874 F.2d 20 (1st Cir. 1989). Bay State paid Mr. Felici, an official at Quincy City Hospital, \$9610 and gave him two cars to recommend that the hospital enter into an exclusive contract with Bay State for ambulance services. Bay State received payments from Medicare. The First Circuit upheld the convictions of Bay State and Mr. Felici, even though Mr. Felici did some computer programming for Bay State, based on the *Greber* court's definition of remuneration.

156. *The Inspector Gen. v. Hanlester Network*, HHS Departmental Appeals Bd. Civil Remedies Div., Docket Nos. C-186 through C-192, C-208 & C-213, reprinted in [1991 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,094, at 25,509 (Mar. 1, 1991). The *Hanlester* case is the first time the Inspector General attempted to exclude a provider from the Medicare and Medicaid programs. David Burda, *HHS Adopts Tough Kickback Definition*, MOD. HEALTHCARE, Sept. 23, 1991, at 2.

157. *The Inspector Gen. v. Hanlester Network*, HHS Departmental Appeals Bd. Civil Remedies Div., Docket Nos. C-186 through C-192, C-208 & C-213, reprinted in [1991 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,094, at 25,513 (Mar. 1, 1991).

158. *Id.* at 25,513-14. Prospectuses on limited partnership offerings to physicians generally do not state that referrals are required, which would violate the law, but indicate the expectation that the physician will refer to the entity. Nonphysicians are discriminated against in the formation of these limited partnerships. OIG REPORT, *supra* note 1, at 19,933.

159. *The Inspector Gen. v. Hanlester Network*, HHS Departmental Appeals Bd. Civil Remedies Div., Docket Nos. C-186 through C-192, C-208 & C-213, reprinted in [1991 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,094, at 25,516 (Mar. 1, 1991).

160. *Id.* at 25,544.

161. *Id.* at 25,540-42.

not receive "remuneration" because the physicians' investments entailed risk, and the distributions from the laboratory to the physicians were based on the physicians' equitable ownership interest—not on the basis of referrals.<sup>162</sup> The ALJ concluded that "the law does not attach liability to parties simply because they benefit from contracts."<sup>163</sup>

On appeal, the Departmental Appeals Board<sup>164</sup> held that the Act contemplates payments made with the intent of exercising influence over a physician's reason or judgment, in an effort to cause the referral of Medicare and Medicaid business.<sup>165</sup> The Departmental Appeals Board reasoned that nothing in the statutory language, legislative history, or case law explicitly or implicitly requires an agreement.<sup>166</sup> The statute focuses on the substance rather than the form of any transaction or relationship in analyzing the flow of cash between entities and physicians.<sup>167</sup> Therefore, the absence of any explicit agreement guaranteeing referrals does not mean that referrals are any less in return for remuneration if there is an intentional connection between the referral and the payment.<sup>168</sup> The Board remanded the case to the ALJ for further action.<sup>169</sup> The ALJ found all the defendants guilty, but curiously excluded only the laboratories—which had not been in operation for two years—from the Medicare program. No physicians were punished.<sup>170</sup>

The *Hanlester* decision arguably expands the *Greber* definition of illegal referrals.<sup>171</sup> The tenor of the *Hanlester* decision is reminiscent of Nathaniel R. Jones' concurring opinion in *United States v. Tapert*.<sup>172</sup> In *Tapert*, Judge Jones stated,

162. *Id.* at 25,545.

163. *Id.* at 25,510.

164. *The Inspector Gen. v. Hanlester Network*, HHS Departmental Appeals Bd. Appellate Div., Docket No. 1275, *reprinted in* [1992-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,566, at 27,739 (Sept. 18, 1991).

165. *Id.* at 27,762.

166. *Id.* at 27,748-56.

167. *Id.* at 27,749. Representative Rostenkowski, the sponsor of the 1977 Anti-Fraud and Abuse Statute, remarked that the Statute's remuneration term was needed because "[w]e are in a complex area where right and wrong are often clouded with shades of grey. In such situations, the committee stresses the need to recognize that the substance rather than simply the form of a transaction should be controlling." Yoakum, *supra* note 104, at 695.

168. *The Inspector Gen. v. Hanlester Network*, HHS Departmental Appeals Bd. Appellate Div., Docket No. 1275, *reprinted in* [1992-1 Transfer Binder] Medicare & Medicaid Guide (CCH) ¶ 39,566, at 27,748 (Sept. 18, 1991).

169. *Id.* at 27,740.

170. David Burda, *Three Physician-Owned Labs, Officers Found Guilty in Medicare Kickback Case*, MOD. HEALTHCARE, March 16, 1992, at 2.

171. David Burda, *supra* note 122.

172. *United States v. Tapert*, 625 F.2d 111 (6th Cir.) (Jones, J., concurring), *cert. denied*, 449 U.S. 1034 (1980).

The statute is satisfied if there is a logical relationship between the kickbacks and the services for which federal funds were paid. . . . The relationship between the physicians and the laboratory was formed around their payment of the kickbacks. The physicians chose to refer patients to a specific laboratory because of the negotiated kickback payments.<sup>173</sup>

The *Hanlester* court seems merely to require a connection between the payments and referrals,<sup>174</sup> whereas the *Greber* court placed emphasis on whether the business arrangement was calculated to induce referrals.<sup>175</sup> The difference may be due to semantics; nonetheless, the Act is expansively interpreted to encompass a wide variety of health care business arrangements.

However, the expansive interpretation of the 'any remuneration' term of the Act has not chilled new business arrangements.<sup>176</sup> New business arrangements are part of the changing industry's effort to find more cost efficient ways of providing health care.<sup>177</sup> The momentum of the Prospective Payment System (PPS) has naturally encouraged competitive business associations in spite of the fact that the arrangements may violate the Anti-Fraud and Abuse Statute. Indeed, the momentum of the PPS led to the safe harbors that allow certain physician financial and investment interests.<sup>178</sup>

The *Hanlester* and the *Greber* cases also exemplify the difficulty in prosecuting these activities. Physicians can contract and enter into business arrangements like all other citizens.<sup>179</sup> It is difficult for juries—as it was for the Administrative Law Judge in *Hanlester*—to distinguish legitimate business practices from program abuse.<sup>180</sup> Referral payments are often commingled with other payments to the physician for legitimate purposes.<sup>181</sup> Moreover,

173. *Id.* at 122-23.

174. *See supra* note 168 and accompanying text.

175. *See supra* note 153 and accompanying text.

176. The number of physician-owned Magnetic Resonance Imaging (MRI) centers in Illinois has increased dramatically in recent months according to state records. Illinois granted 22 MRI permits within the last 12 months, compared with 50 permits in the previous five years. Within the last six months, three MRI centers opened within a mile of each other in downtown Chicago. The MRI centers cost at least \$2 million each. Millenson, *supra* note 86, at C2.

177. *See supra* notes 64-73 and accompanying text.

178. *See supra* notes 123-48 and accompanying text.

179. U.S. CONST. amend. V; U.S. CONST. amend. XIV, § 1.

180. *See supra* notes 156-70 and accompanying text.

181. *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985) (characterizing payment as "interpretation fees"); *United States v. Universal Trade and Indus. Inc.*, 695 F.2d 1151 (9th Cir. 1983) (characterizing payment as "administrative fees"); *United States v. Hancock*, 604 F.2d 999 (7th Cir. 1979) (characterizing payment as "handling fees").

each business arrangement is structured differently.<sup>182</sup> Although the safe harbors provide some guidelines, they also admit their defeat in the preamble as to statutorily created criteria.<sup>183</sup> Few physicians have been prosecuted and little case law exists.<sup>184</sup>

In sum, the statutory language is broad, the judicial interpretation is expansive, and the penalties for violating the statute are strong.<sup>185</sup> Yet, the cost containment measures that encourage physician ownership in new health care entities seem to be stronger.<sup>186</sup> The physician's ownership and financial interests in other health care entities seem to be increasing.<sup>187</sup> Further, definitional problems inherent in the fraud and abuse terms hamper enforcement of the statutes.<sup>188</sup> Thus, a Physician Conflict of Interest Disclosure Law is necessary to protect the patient from abusive practices by facilitating patient autonomy.

*C. The Antitrust Laws Applied to the American Medical Association's Guidelines On Physician Self-Referral Arrangements*

The American Medical Association (AMA) has continually addressed the issue of physician self-referral arrangements throughout the 1980s and 1990s.<sup>189</sup> Succinctly stated, the dilemma facing the AMA is whether the physicians' fiduciary commitment to patients should be strengthened by banning

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182. Because many of these arrangements are structured differently, investigations are complex, labor-intensive, and difficult to explain to a fact-finder. OIG REPORT, *supra* note 1, at 19,935.

183. See *supra* notes 145-48 and accompanying text.

184. McDowell, *supra* note 8, at 753 (noting that the fraud provisions have been used sparingly); Letters to the Editor, *supra* note 20, at 251 (noting that the statutes are relatively new in terms of building a body of case law); Yoakum, *supra* note 104, at 685 (noting that few cases have been prosecuted).

185. See *supra* notes 111-21, 149-75 and accompanying text.

186. See *supra* notes 176-78 and accompanying text.

187. See *supra* notes 176-78 and accompanying text.

188. See *supra* notes 179-84 and accompanying text.

189. The AMA reminded physicians that medicine is a profession, a calling, and not a business. HOUSE OF DELEGATES OF THE AMA, COMMERCIALISM IN THE PRACTICE OF MEDICINE: REPORT OF THE BOARD OF TRUSTEES OF THE AMA, June 1983. In December 1991, at its interim annual meeting, the AMA approved new self-referral guidelines, which provide that physicians should not refer patients to entities in which the physician has an investment or financial interest unless there is a need in the community for the medical facility and there is no alternative financing available. David Burda, *AMA Toughens Guidelines on Physician Self-Referrals*, MOD. HEALTHCARE, Dec. 16, 1991, at 4. In May 1992, the AMA requested physicians to divest themselves of self-referral arrangements by January 1995. The guidelines apparently were not endorsed by many physicians. In June 1992, the AMA retracted the six-month-old guidelines. Currently, the AMA provides that referrals by a physician to a facility in which the physician has a financial interest are ethical as long as patients are informed of the ownership arrangement and of alternative sources of care. David Burda, *Self-Referral Issue Targeted on Two Fronts*, MOD. HEALTHCARE, June 29, 1992, at 3.

or limiting physician ownership in other health care entities, or whether entrepreneurialism and commercial competition should be encouraged.<sup>190</sup> The Federal Trade Commission (FTC) resolved the dilemma when it stated that the AMA cannot prevent physicians from investing and forming contractual relationships with other health care entities to which they refer patients. The antitrust laws do not permit professional organizations to restrain trade by preventing their members from investing and contracting, even when their purposes are noble.<sup>191</sup>

Prior to 1975, physicians doubted that economic competition had any role in the delivery of health care. At that time, physicians felt no pressure to offer patients services that the patients might want. For example, physicians rarely offered Saturday and evening office hours. In fact, health care was generally either provided in a hospital or a physician's office. Now, health care can be obtained in a variety of settings dealing with specialized problems. For instance, outpatient physical therapy centers and outpatient surgical centers serve as alternatives to hospitals. By preserving competition, the antitrust laws have fostered innovative health care entities that more readily meet the needs of patients.<sup>192</sup>

Although the AMA cannot devise an ethical rule that prohibits physicians from having an ownership interest in a facility to which they refer patients,<sup>193</sup> an ethical rule that merely requires physicians to disclose their equity interests in health care facilities when they refer patients would probably not raise antitrust questions. The FTC does not prohibit the AMA from adopting an ethics standard designed to protect the public, as long as the ethics standard is not anticompetitive.<sup>194</sup> Thus, the AMA allows physicians to refer their

190. Arnold S. Relman, *Antitrust Law and the Physician Entrepreneur*, 313 NEW ENG. J. MED. 884, 885 (1985).

191. *In re American Medical Ass'n*, 94 F.T.C. 701, 1016, 1037-38 (1979), *aff'd as modified*, 638 F.2d 443 (2d Cir. 1980), *aff'd by an equally divided Court*, FTC v. AMA, 455 U.S. 676 (1982). The AMA engaged in unfair trade practices by directing its members not to enter into a contract with terms that are inconsistent with the AMA's medical ethics. The AMA's preservation of fee-for-service compensation, as opposed to income sharing arrangements between physicians and nonphysicians, was found by the Court to impede the development of innovative forms of health care delivery. *Id.*; but see *Nat'l Soc. of Professional Engineers v. United States*, 435 U.S. 679 (1978). The "limited professional exemption" may entitle the AMA to application of the "rule of reason," which may allow the AMA to restrain trade if the professional justifications are sufficiently compelling.

192. L. Barry Costilo, *Antitrust Enforcement in Health Care: Ten Years After the AMA Suit*, 313 NEW ENG. J. MED. 901, 901 (1985).

193. A rule prohibiting physicians from having an ownership interest in a facility to which they refer patients is too broad a restriction on competition. *Id.* at 904.

194. Arnold S. Relman, *Antitrust Law and the Physician Entrepreneur*, 313 NEW ENG. J. MED. 884, 884 (1985).

patients to entities in which they have ownership or financial interests, as long as the interests are disclosed to the patient.<sup>195</sup> The AMA disclosure guideline, however, is only a guideline and does not have any legal force.<sup>196</sup>

#### IV. A PROPOSAL FOR A PHYSICIAN CONFLICT OF INTEREST DISCLOSURE LAW

In sum, the laws banning physician self-referrals contain multiple exceptions, present constitutional concerns, and—most importantly—may adversely affect innovative health care entities. The Anti-Fraud and Abuse Statutes are difficult to enforce because of the definitional problems inherent in the fraud and abuse terms and the current health care business climate. Finally, the AMA has a disclosure guideline but cannot legally enforce it. This Note's purpose is to provide a model disclosure law that the federal government should enact in light of the proliferation of business arrangements between physicians and other health care entities.

##### A. *The States' Regulation of Physician Self-Referral Arrangements*

States have chosen different regulatory responses to physician self-referral arrangements. For instance, many states have laws substantively similar to the federal government's Anti-Fraud and Abuse Statute.<sup>197</sup> These laws enable the

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195. One AMA opinion provides:

A physician may own or have a financial interest in a for-profit hospital, nursing home or other health facility, such as a freestanding surgical center or emergency clinic. However, the physician has an affirmative ethical obligation to disclose his ownership of a health facility to his patient, prior to admission or utilization.

Under no circumstances may the physician place his own financial interest above the welfare of his patients. The prime objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. For a physician to unnecessarily hospitalize a patient or prolong a patient's stay in the health facility for the physician's financial benefit would be unethical.

If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit.

AMA, *Current Opinion of the Council on Ethical and Judicial Affairs*, Section 8.07 (1989).

196. The AMA is an educational and political lobbying organization that represents less than half of the physicians in the United States. David Burda, *Self-Referral Issue Targeted on Two Fronts*, MOD. HEALTHCARE, June 29, 1992, at 3. The AMA's membership is dwindling and its power decreasing. STARR, *supra* note 9, at 427. Physicians that refer patients to entities they own have not rushed to divest their holdings or to disclose the potential conflict to patients. Millenson, *supra* note 86, at C2.

197. ALA. CODE § 22-1-11 (1990); ARK. CODE ANN. § 5-55-103 (Michie 1987); CAL. WELF. & INST. CODE § 14107.2 (West 1991); COLO. REV. STAT. § 26-1-127 (1989); CONN. GEN. STAT. ANN. 17-134a (West 1992); FLA. STAT. ANN. § 409.2664 (West 1986); HAW. REV. STAT. § 346.43.5 (1985); KY. REV. STAT. ANN. § 194.505 (Baldwin 1991); LA. REV. STAT. ANN. § 14:70:1 (West Supp. 1991); MASS. GEN. LAWS ANN. ch. 118E, § 21A-E (West Supp. 1992); MICH.

respective state's attorney general to prosecute on behalf of Medicaid and other state health care programs.<sup>198</sup> Another minority of states require physicians to disclose ownership interests to the referred patients.<sup>199</sup>

States differ greatly regarding disclosure requirements. For example, Pennsylvania requires any financial interest in the health care entity to be disclosed, whereas Florida requires disclosure if the equity interest is ten percent or more.<sup>200</sup> Many states require written disclosure, but some states deem a conspicuously located sign as adequate disclosure.<sup>201</sup> Generally, the states leave it to the state medical board to promulgate the form of disclosure; however, New Jersey statutorily prescribes the form.<sup>202</sup> Typically, most states

COMP. LAWS ANN. § 400.60 (West 1988); MISS. CODE ANN. § 43-13-207 (Supp. 1992); N.C. GEN. STAT. § 108A-63 (1992); OHIO REV. CODE ANN. § 2913.40 (Baldwin 1990); R.I. GEN. LAWS § 40-8.2-3 (1990); UTAH CODE ANN. § 26-20-4 (1989); VA. CODE ANN. § 32.1-315 (Michie 1992); WASH. REV. CODE ANN. § 74.09.210 (West Supp. 1992); W. VA. CODE § 9-7-5 (1990); WIS. STAT. ANN. § 49.49(2) (West 1987).

198. The Department of Justice in a criminal case or the OIG in a civil case are the only ones who can prosecute under the Medicare and Medicaid Program and Protection Act. OIG REPORT, *supra* note 1, at 19,937. Congress did not provide a private remedy to health care providers who may be injured as a result of a competitor's noncompliance with the Anti-Fraud and Abuse Statute. The plaintiff, West Allis Memorial Hospital, did not have standing. *West Allis Memorial Hosp. Inc. v. Bowen*, 852 F.2d 251, 255 (7th Cir. 1988).

199. ARIZ. REV. STAT. ANN. § 32-1401(21)(ff) (Supp. 1992); CAL. BUS. & PROF. CODE §§ 654.1, 654.2 (West 1990); FLA. STAT. ANN. § 458.331(gg) (West 1991); MD. HEALTH OCC. CODE ANN. § 1-206 (Supp. 1992); MASS. GEN. LAWS ANN. ch. 112 § 1 (West 1989); MASS. GEN. LAWS ANN. ch. 440, § 2 (West 1989); MINN. STAT. ANN. § 147.091(p)(3),(4) (West 1989); NEV. REV. STAT. ANN. § 630-305 (Michie 1992); N.J. STAT. ANN. §§ 45:9-22.4—45:9-22.8 (West 1991); PA. STAT. ANN. tit. 35 § 449.22 (Supp. 1992); R.I. GEN. LAWS § 5-37-22(e) (Supp. 1992); TENN. CODE ANN. §§ 63-6-501—63-6-503 (Supp. 1992); VA. CODE ANN. § 54.1-2964 (Michie 1991); WASH. REV. CODE ANN. § 19.68.010 (West 1989); W. VA. CODE § 30-3-14(c)(6),(7) (Supp. 1992). Some states, such as Arizona, Maryland, Minnesota, Pennsylvania, and Tennessee, rely solely upon their disclosure statutes and have no Anti-Fraud and Abuse Statute equivalents.

200. PA. STAT. ANN. tit. 35 § 449.22 (Supp. 1992); FLA. STAT. ANN. § 458.331(gg) (West 1991). *But see* CAL. BUS. & PROF. CODE §§ 654.1, 654.2 (West 1990). The California statute requires disclosure to be made if the physician's equity interest is five percent. *Id.*

201. The disclosure requirements may be met by posting a conspicuous disclosure statement at a single location, such as a common area or registration area, or by providing those patients with a written disclosure statement. CAL. BUS. & PROF. CODE §§ 654.1, 654.2 (West 1990).

202. N.J. STAT. ANN. § 45:9-22.6 (West 1991). The written disclosure form required pursuant to section 2 of this act shall be in the following form:

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.

deem a violation of the disclosure statute as grounds for disciplinary action, but Washington considers the offense a misdemeanor.<sup>203</sup>

As an example of state requirements, the Rhode Island disclosure statute provides:

Every physician who has an ownership interest in health facilities, or laboratories or any equipment not on the physician's premises shall, in writing, make full patient disclosure of his or her ownership interest in the facility or therapy prior to utilization. The written notice shall state that the patient has free choice either to use the physician's proprietary facility or therapy or may seek the needed medical services elsewhere.<sup>204</sup>

Similarly, Pennsylvania's disclosure of interest in referral facilities statute provides:

Any practitioner of the healing arts shall, prior to referral of a patient to any facility or entity engaged in providing health-related services, tests, pharmaceuticals, appliances or devices, disclose to the patient any financial interest of the practitioner or ownership by the practitioner in the facility or entity. In making any referral, the practitioner of the healing arts may render any recommendations he considers appropriate, but shall advise the patient of his freedom of choice in the selection of a facility or entity. A person who violates this section shall be liable to the Commonwealth for a civil penalty not to exceed \$1,000. The licensing boards in the bureau shall enforce this section.<sup>205</sup>

Most states do not require disclosure.<sup>206</sup> The states that do have disclosure laws often use vague language unnecessarily leaving much to be interpreted by the courts.<sup>207</sup> Thus, no one state has a disclosure law that the federal government could adopt. This Note proposes the following Model Physician Conflict of Interest Disclosure Law, which uses the best attributes of the current state disclosure laws.

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203. WASH. REV. CODE ANN. § 19.68.010 (West 1989). However, see PA. STAT. ANN. tit. 35 § 449.22 (Supp. 1992) for a State that makes violators liable to the Commonwealth for a civil penalty not to exceed \$1,000.

204. R.I. GEN. LAWS § 5-37-22(e) (Supp. 1992).

205. PA. STAT. ANN. tit. 35 § 449.22 (Supp. 1992).

206. Thirty-six states do not require disclosure.

207. *E.g.*, R.I. GEN. LAWS § 5-37-22(e) (Supp. 1992); PA. STAT. ANN. tit. 35 § 44.22 (Supp. 1992).



*B. Model Physician Conflict of Interest Disclosure Law*

(A) It is unlawful for any physician who receives payment from Medicare or Medicaid on behalf of the patient to refer the patient to a health care entity that the physician, the physician's employer,<sup>208</sup> or the physician's immediate family has a significant beneficial interest in, unless the physician first discloses the interest to the patient.

(B) The disclosure should be in writing, in bold print,<sup>209</sup> advising the patient of the physicians' interest, and that the patient may choose another health care entity to obtain the services and items requested by the physician.<sup>210</sup> The disclosure should be dated and signed by the patient, acknowledging that the patient has read and understands that the physician has a financial interest in the entity to which the patient is referred.<sup>211</sup>

(C) For the purposes of this law the following terms apply:

(1) "Significant beneficial interest"<sup>212</sup> means any financial interest that is greater than the lesser of the following:

(a) Two percent of the whole

(b) Five thousand dollars (\$5,000)

(2) "Immediate family"<sup>213</sup> includes the physician's spouse, children, parents, siblings, childrens' spouses, parents' spouses, and siblings' spouses.

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208. Florida was the only state that required disclosure if the patient was referred by a physician employee whose employer has a significant financial interest in the health care entity referred. FLA. STAT. ANN. § 458.331(gg) (West 1991).

209. The state of Virginia is the only state that requires the written disclosure to be conspicuous for the purpose of catching the patient's attention. VA. CODE ANN. § 54.1-2964 (Michie 1991).

210. The provision of notifying the patient of their choice is common to all the states' disclosure laws.

211. Arizona is the only state that requires the patient to acknowledge that the patient has read the disclosure. ARIZ. REV. STAT. ANN. § 32-1401(21)(ff) (Supp. 1992).

212. This section was essentially derived from the Maryland disclosure law. MD. HEALTH OCC. CODE ANN. § 1-206(a)(6) (Supp. 1991).

213. This section is essentially derived from the California disclosure law. CAL. BUS. & PROF. CODE § 654.2(d)(1) (West 1990). Some physicians hold ownership interests indirectly. OIG REPORT, *supra* note 1, at 19,932.

(D) This law does not apply to the following types of equity interest:

(1) The ownership of securities registered with the Securities and Exchange Commission, or securities of an entity that has at least \$50 million in undepreciated net tangible health care assets;<sup>214</sup> or

(2) An interest in real property resulting in a landlord-tenant relationship between the physician and the entity in which the equity interest is held, unless the rent is determined, in whole or in part, by the business volume or profitability of the tenant, or is otherwise unrelated to fair market value;<sup>215</sup> or

(3) A physician's own practice, whether he is a sole practitioner or part of a group, when the health care good or service is prescribed or provided solely for the physician's own patients and is provided or performed by the physician or under his supervision.<sup>216</sup>

(E) Any physician violating the provisions of this section will be fined \$2,500 and may be excluded from the Medicare or Medicaid programs.<sup>217</sup>

(F) This law should not be construed as permitting relationships or interests that are prohibited "referrals" as defined by the Medicare and Medicaid Patient and Program Protection Act.<sup>218</sup>

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214. This provision is substantively the same as the safe harbor. 42 C.F.R. § 1001.952(a) (1992). The connection between payments from large entities to physicians could only remotely be attributable to referrals. Therefore, payments from large entities do not have to be disclosed.

215. This provision is substantively similar to the federal safe harbor. 42 C.F.R. § 1001.952(b-d) (1992).

216. Here, there is no need to disclose because this epitomizes the fee-for-service payment mechanism. The conflict of interest is apparent to the patient. This provision would not encourage the formation of many small organizations because the equipment costs are too expensive and thus require pooled physicians' capital.

217. The Medicare and Medicaid Patient and Program Protection Act provides for physician exclusion. It is important to note that the operative word in this section is 'may'. The Secretary of the Health and Human Services Department has been given the discretion to exclude a physician who violates the disclosure law. 42 U.S.C. § 1320a-7(b) (1988).

218. The law's purpose is to provide patients with information to facilitate patient choice among health care providers.

*C. Comments*

Congress should enact the model disclosure law for all Medicare patients and should mandate its use by the state Medicaid programs as a condition for receiving Medicaid matching grant funds.<sup>219</sup> Further, Congress should give the Office of the Inspector General the power to enforce this law, because it already has developed expertise in this area through its enforcement of the Anti-Fraud and Abuse Statutes. A possible means of enforcement is to use a negative audit confirmation request. A random, computer-generated list of Medicare and Medicaid recipients would be sent a letter asking if their physician had disclosed to them any financial interests the physician had in entities to which they were referred. The recipient would only be requested to reply if the physician had not disclosed financial interests in entities referred. The negative audit confirmation request is a standard audit technique.

One attribute of the disclosure law is that patients who are armed with knowledge may better be able to protect themselves from unnecessary and possibly harmful medical procedures. Also, the Medicare and Medicaid programs may experience cost savings because patients may forego some services or find physicians who do not have financial arrangements with ancillary services. Finally, the model disclosure law has clearly defined terms, unlike the majority of existing state disclosure laws, so that it can be applied with ease. The law will be uniform throughout the Medicare and Medicaid programs.

#### V. CONCLUSION

Physicians often refer patients to health care entities in which physicians have a financial or ownership interest. Physicians have aligned themselves with for-profit health care entities that compete in the market for patients. Currently, a referred patient is unaware of the conflict of interest that may influence the physician's judgment as to the quality or medical necessity of treatment. The proposed Model Physician Conflict of Interest Disclosure Law will add legal force to the AMA's guidelines and fully apprise the patient of the financial incentives that may be affecting physicians' decisions. The disclosure law will facilitate patient autonomy without hindering innovative health care entities.

Carol Michna

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219. The federal government has the power to approve the states' Medicaid programs. 42 U.S.C. § 1396 (1988).