

1988

## Fraud and Abuse: Regulatory Alternatives in a "Competitive" Health Care Era

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### Recommended Citation

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

Available at: <http://lawcommons.luc.edu/lucj/vol19/iss4/2>

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# Fraud and Abuse: Regulatory Alternatives in a "Competitive" Health Care Era

David A. Hyman\*  
and Joel V. Williamson\*\*

## I. INTRODUCTION

The health care environment has changed dramatically in recent years.<sup>1</sup> In an effort to control the skyrocketing cost of health care,<sup>2</sup> cost containment through competition has become the guiding principle.<sup>3</sup> Efforts to maintain or increase market share have led health care providers to forge new relationships and joint ventures, to market themselves, and to develop incentive programs that reward efficiency and cost-effective care.<sup>4</sup> These developments are consistent with federal initiatives to control costs by instituting competition and market-like forces in the health care industry.<sup>5</sup>

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1. For an overview of the current state of affairs, see Califano, *The Health-Care Chaos*, New York Times Mar. 20, 1988 (Magazine) at 44; Kinzer, *The Decline and Fall of Deregulation*, 318 NEW ENG. J. MED. 112 (1988); Dickman, Ford, Liebman, Milligan, & Schorr, *An End to Patchwork Reform of Health Care*, 317 NEW ENG. J. MED. 1086 (1987). See also *infra* notes 27-103 and accompanying text.

2. Between 1965 and 1983, the cost of health care in the United States increased from \$43 billion to \$355 billion. Gibson, Levit, Lazenby & Waldo, *National Health Expenditures 1983*, 6 HEALTH CARE FINANCING REVIEW 1 (Winter, 1984). By 1986, the cost had increased to \$458 billion or \$1,837 for every person in the United States. Anderson & Erickson, *Data Watch: National Medical Care Spending* 6 HEALTH AFFAIRS 96 (Fall 1987). In 1980, health care expenditures consumed 9.1% of the gross national product. *Id.* By 1985, the proportion had risen to 10.6%. By 1986, the proportion was 10.9%. *Id.* In 1983, Medicare and Medicaid financed 29 cents of every dollar spent on health care. Gibson, Levit, Lazenby & Waldo, *supra*, at 1.

3. The development of competition has been encouraged by an oversupply of inpatient beds, a trend toward outpatient and home health care, an increased number of physicians, and marked changes in federal reimbursement policy. Telephone interview with E. Frederic Bockstahler, Senior Vice President, Voluntary Hospitals of America, Inc. (August 11, 1988). On the new competitive environment in health care that is fostered by federal reimbursement policy, see *infra* notes 27-48 and accompanying text.

4. See *infra* notes 49-103 and accompanying text.

5. The prospective payment system was touted as having the benefit of "restructuring the economic incentives facing the health care system to establish market like forces." 48 Fed. Reg. 39752, 39807 (1983). Strictly speaking, despite a great deal of rhetoric about

Paradigmatic of this initiative is the imposition of the prospective payment system ("PPS") by the Medicare program.<sup>6</sup>

Unfortunately, the development of new arrangements and incentive programs to respond to this new era of competition has been sharply constrained by the Fraud and Abuse statute.<sup>7</sup> This statute forbids payments that are in return for, or are intended to induce the referral of Medicare/Medicaid "business."<sup>8</sup> This statute was enacted when Medicare and Medicaid utilized retrospective fee-for-service reimbursement,<sup>9</sup> where all providers were paid a reasonable charge<sup>10</sup> for the treatment of program beneficiaries.<sup>11</sup> Minimal review meant that false claims were filed easily and

competition, the federal initiatives have not made the health care environment truly price competitive. Kalison & Averill, *The Challenge of 'Real' Competition in Medicare*, 6 HEALTH AFFAIRS 47 (Fall 1986). In fact, the prospective payment system is actually a form of price-fixing rather than a free-marketplace initiative. Kinzer, *The Decline and Fall of Deregulation*, 318 NEW ENG. J. MED. 112, 113 (1988). The DRG system is actually an effort to fix a "just price" — an ironic result when accompanied by rhetoric about competition, especially as just price theory was originally understood by guild members and medieval theologians as the means to salvation rather than cost-efficiency. Halper, *DRGs and the Idea of a Just Price*, 12 J. MED. PHILOS. 155, 157 (1987). However, the system is at least more competitive than it once was. Kalison & Averill, *supra* at 47.

Unfortunately, "[t]he big push to make the marketplace our primary mechanism for distributing health services and for imposing economic discipline on the health care system is running aground on some realities that just won't go away." Kinzer, *supra* at 112, 113. These include: (1) the idea that essential medical services are a right; (2) strong public feeling that a community hospital is as necessary as a fire or police department; (3) limitations on government expenditures; and (4) the "destabilizing" influence of that amount of competition presently allowed. *Id.* See also Fuchs, *The Counterrevolution in Health Care Financing*, 316 NEW ENG. J. MED. 1154 (1987).

6. Social Security Amendments of 1983, Pub. L. No. 98-21 §§ 601-07, 97 Stat. 65, 149-72 (1983).

7. 42 U.S.C. § 1395nn(b). For text of statute, see *infra* note 52.

8. This Article deals with both Medicare and Medicaid, as the underlying criminal statute applies to both programs. For simplicity, the Article usually refers to only Medicare. Obviously, there are differences between the programs in eligibility, benefits, and payment arrangements. See *infra* note 11 and generally Medicare & Medicaid Guide (CCH).

9. The adverse consequences of this arrangement are concisely noted in the interim final rule that sets forth the conditions and procedures for prospective payment. 48 Fed. Reg. 39752, 39804 (1983).

10. A reasonable charge is "the customary charge for similar services generally made by the physician or other person or organization furnishing the covered services, and also the prevailing charges for the locality for similar services." Pub. L. No. 89-97, *reprinted in* 1965 U.S. CODE CONG. & ADMIN. NEWS 1943, 1949.

11. Medicare, Title 18 of the Social Security Act, provides health care payment for the elderly over sixty-five who are eligible for Social Security and for certain disabled persons. Medicaid, Title 19 of the Social Security Act, created a program and provided grants to the states to provide for medical care to the indigent. Health Insurance for the Aged Act, Pub. L. No. 98-97, 79 Stat. 291 (1965).

overutilization was unchecked.<sup>12</sup>

Although the statute was an effective and logical response to fraud and abuse under a cost-based system,<sup>13</sup> it may be inappropriate to apply the same rules to the newly competitive health care environment. The statute is broadly worded and appears to prohibit many arrangements that pose little risk to the integrity of the program or the quality of medical care. Efforts to ensure a referral base or to reward efficiently rendered care are foreclosed unless one wishes to run the risk of criminal prosecution.<sup>14</sup> One court has gone so far as to hold that "if *one* purpose of the payment was to induce future referrals, the Medicare statute has been violated."<sup>15</sup> Providers are thus constrained in their responses to the new competitive environment.<sup>16</sup> Congress has recognized that hospitals and other health care providers are uncertain "as to which commercial arrangements are legitimate and which are prescribed."<sup>17</sup>

In response to this uncertainty, Congress enacted the Medicare and Medicaid Patient and Program Protection Act of 1987 ("MMPPPA")<sup>18</sup>. The statute requires the Secretary of Health and

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12. It has been estimated that the taxpayers were cheated out of between 725 and 975 million dollars in 1977 as a result of fraud and abuse of the sort prohibited by the statute. Statement of Thomas Morris, Inspector General of HHS, *Hearings before the Subcommittee on Investigations of the Committee on Government Affairs, Senate*, 95th Congress, 2d Sess. (July 20, 1978). Congressional investigation of clinical laboratories receiving Medicare and Medicaid payments concluded that approximately one dollar out of every six dollars was questionably or fraudulently obtained. SPECIAL COMM. ON AGING, FRAUD AND ABUSE AMONG CLINICAL LABORATORIES, S. REP. NO. 944, 94th Cong., 2d Sess. (1976).

13. One analyst has objected on economic grounds to criminalizing the payment of kickbacks or fee splitting. Pauly, *The Ethics and Economics of Kickbacks and Fee Splitting*, 10 BELL J. ECON. 344 (1979). He notes that the existence of kickbacks and fee splitting serve to undermine specialist monopoly power, reveal that the price has been set above the marginal cost of providing the service, and that criminalizing such payment induces physicians to perform lower quality procedures, rather than refer to a specialist. *Id.* Nonetheless, most states have outlawed fee splitting and kickbacks. See *infra* notes 314-15. The American Medical Association is also opposed to such arrangements. "Payment by one physician to another solely for the referral of a patient is fee splitting and is improper both for the physician making the payment and the physician receiving the payment. A physician may not accept payment of any kind, in any form, from any source. . . ." Judicial Council of the American Medical Association, Current Opinions, 6.04 (1986).

14. See *infra* notes 109-21 and accompanying text.

15. *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985) (emphasis added).

16. See *infra* notes 49-103 and accompanying text for a discussion of physician incentive programs and joint ventures.

17. S. REP. NO. 109, 100th Cong., 1st Sess. 27, reprinted in 1987 U.S. CODE CONG. & ADMIN. NEWS 682, 707 (1987).

18. Medicare and Medicaid Patient and Program Protection Act, Pub. L. 100-93, 101 Stat. 680 (1987).

Human Services ("HHS") to issue regulations specifying payment practices that will not be the subject of prosecution under the Fraud and Abuse statute.<sup>19</sup> This Article will examine the changes in the health care environment,<sup>20</sup> the origin and foundations of the Fraud and Abuse statute,<sup>21</sup> and the changing interpretation of the statute<sup>22</sup> to determine the appropriate limits that regulation should place on providers.<sup>23</sup> The government appears determined to use competition to control costs.<sup>24</sup> The regulations should be responsive to that mandate<sup>25</sup> to the extent there are not other compelling issues implicated.<sup>26</sup>

## II. PROSPECTIVE PAYMENT

As noted earlier, the Medicare and Medicaid programs originally utilized a retrospective fee-for-service reimbursement system.<sup>27</sup> Providers had no particular economic incentive to provide cost-efficient health care and were actually rewarded for providing inappropriate or inefficient care.<sup>28</sup> These factors helped to contribute to the phenomenal growth of the Medicare budget — from \$7.5

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19. Pub. L. 100-93 § 14, 101 Stat. 680, 697, 698 (1987).

20. See *supra* note 1 and *infra* notes 27-103 and accompanying text.

21. See *infra* notes 166-209 and accompanying text.

22. See *infra* notes 212-80 and accompanying text.

23. At present, only hospitals receive prospective reimbursement. Social Security Amendments of 1983, Pub. L. No. 98-21 §§ 601-07, 97 Stat. 65, 149-72 (1983). The analysis of this Article focuses on the effect of this form of reimbursement on the business practices of the hospital and the fraud and abuse issues such practices raise. The analysis should not be extended beyond those providers that receive prospective payment (and under certain circumstances those with whom they form joint ventures and incentive programs) without careful consideration. In particular, the discussion of the ethics of physician participation in these arrangements needs to be weighed. See *infra* notes 141-59 and accompanying text.

24. See *infra* notes 39-42 and accompanying text.

25. Logically, the desire to instill competition requires that anticompetitive restraints be removed. The mandate to instill competition is discussed briefly *infra* at notes 39-40. See also 48 Fed. Reg. 39752, 39804-07.

26. These issues include concerns about the impact of certain arrangements on physician ethics as well as provisions of various other laws. See *infra* notes 49, 141-59, 215, 314-15.

27. 8 Fed. Reg. 39752, 39754, 39804 (1983).

28. 48 Fed. Reg. 39752, 39804 (1983). Inefficient care is likely to flourish under a reimbursement system that rewards inefficiency. A cost-based system has precisely this effect. *Id.* Unnecessary or inappropriate care is subject to the same incentives. However, unnecessary care is a difficult problem to quantify. There is tremendous geographic variation in the usage of medical and surgical services. Admission rates for more than eighty percent of medical conditions are highly variable. Wennberg, *Which Rate is Right?*, 314 NEW ENG. J. MED. 310 (1986). See also Chassin, Brook, Park, Keesey, Fink, Kosecoff, Kahn, Merrick & Solomon, *Variations in the Use of Medical and Surgical Services by the Medicare Population*, 314 NEW ENG. J. MED. 285 (1986); Barnes, O'Brien, Comstock,

billion in 1970, to \$58.9 billion in 1983, to a total of \$77.7 billion in

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D'Arpa & Donahue, *Report on Variation in Rates of Utilization of Surgical Services in the Commonwealth of Massachusetts*, 254 J.A.M.A. 371 (1985).

A substantial quantity of the variation, and many clinical decisions seem to be due to practice "style," and not based on any scientific rationale. Burnum, *Medical Practice A La Mode: How Medical Fashions Determine Medical Care*, 317 NEW ENG. J. MED. 1220 (1987). Part of the problem is related to societal and legal pressures. Friedman, *The Obstetrician's Dilemma: How much Fetal Monitoring and Cesarean Section is Enough?* 315 NEW ENG. J. MED. 641 (1986).

More rigorous efforts have been made at assessing the value of previously routinely performed medical and surgical tests and interventions. See Akin, Hubbell, Frye, Rucker & Friis, *Efficacy of the Routine Admission Urinalysis*, 82 AM. J. MED. 719 (1987); Nightingale, Robotti, Deckers, Allmendinger, Lowe & Low, *Quality Care and Cost Effectiveness: An Organized Approach to Problem Solving*, 122 ARCHIVES OF SURGERY 451 (1987); and the Diagnostic Decision series published monthly in the Annals of Internal Medicine beginning with: Sox, *Probability Theory in the Use of Diagnostic Tests: An Introduction to Critical Study of the Literature*, 104 ANNALS INT. MED. 60 (1986).

Technological factors are implicated as well. Sawitz, Showstack, Chow, Schroeder, *The Use of In-Hospital Physician Services for Acute Myocardial Infarction: Changes in Volume and Complexity Over Time*, 259 J.A.M.A. 2419 (1988). During the period 1972-1982, average length of stay decreased by almost 40%, but the number of physician services doubled and total physician costs almost tripled. *Id.* The increase was primarily due to the use of more complex diagnostic technologies and the provision of coronary artery bypass graft surgery. *Id.* This result should not make one optimistic about the success of cost control measures.

However, inappropriate care clearly exists as well. A retrospective study of the implantation of permanent pacemakers in Philadelphia in 1983 revealed that 44% were indicated, 36% were possibly indicated, and 20% were not indicated. Greenspan, Kay, Berger, Greenberg, Greenspan & Gaughan, *Incidence of Unwarranted Implantation of Permanent Cardiac Pacemakers in a Large Medical Population*, 318 NEW ENG. J. MED. 158 (1988). See also Kastor, *Pacemaker Mania*, 318 NEW ENG. J. MED. 182 (1988); Dans, Cafferty, Otter & Johnson, *Inappropriate Use of the Cerebrospinal Fluid Venereal Disease Research Laboratory (VDRL) Test to Exclude Neurosyphilis*, 104 ANNALS INT. MED. 86 (1986); Kemper, *Medically Inappropriate Hospital Use in a Pediatric Population*, 318 NEW ENG. J. MED. 1033 (1988). But see Rutkow, *Unnecessary Surgery: What is It?* 62 SURG. CLIN. N. AM. 613 (1982).

A study of the records of 1,132 hospitalized adults revealed that 23% of the admissions and 34% of the hospital days were inappropriate. Siu, Sonneberg, Manning, Goldberg, Bloomfield, Newhouse & Brook, *Inappropriate Use of Hospitals in a Randomized Trial of Health Insurance Plans*, 315 NEW ENG. J. MED. 1259 (1986). An additional 17% of admissions were judged to be avoidable by using ambulatory surgery. *Id.*

Joseph Califano, the former Secretary of the Department of Health and Human Services has estimated that at least \$125 billion is wasted on unneeded medical care each year, of which \$25 billion is paid for by taxpayers. Capital Digest, 18 MODERN HEALTHCARE 26 (May 13, 1988). See also Califano, *The Health-Care Chaos*, New York Times Mar. 20, 1988 (Magazine), at 44.

However, it should be noted that at least one commentator believes that unnecessary care is only one part of the cause of increasing cost. Schwartz, *The Inevitable Failure of Current Cost Containment Strategies: Why They Can Provide Only Temporary Relief*, 257 J.A.M.A. 220 (1987). Other factors include population growth, increasing input prices for a hospital's "market basket" of goods, and the promotion and dissemination of expensive technological innovations by the Federal government. *Id.* These factors continue to operate under prospective payment and will either undermine the PPS or destroy the

1986.<sup>29</sup>

The extraordinary growth in the cost of the Medicare program, "coupled with the worsening plight of the Federal budget, combined to create a political demand for reforming Medicare's repayment system."<sup>30</sup> The result was the initiation of prospective reimbursement.<sup>31</sup> The system currently is limited to payment to hospitals for care rendered to inpatients.<sup>32</sup> Under prospective reimbursement, similar diagnoses are grouped into diagnosis related groups ("DRGs").<sup>33</sup> The number and intensity of resources required for treatment determines which diagnoses are grouped together.<sup>34</sup> A hospital is paid a set amount for each patient

stability of many hospitals. *Id.* See also Ginzberg, *A Hard Look at Cost Containment*, 316 NEW ENG. J. MED. 1151 (1987).

29. Statistical Abstract of the United States 86 (1988).

30. Vance-Bryan, *Medicare's Prospective Payment System: Can Quality Care Survive?*, 69 IOWA L. REV. 1417, 1418 (1984).

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

32. Rehabilitation, long-term, psychiatric, and children's hospitals are excluded from the prospective payment system. 48 Fed. Reg. 39752, 39754.

33. See Vladeck, *Medicare Hospital Payment by Diagnosis Related Groups*, 100 ANNALS INT. MED. 576 (1984); Dolenc & Dougherty, *DRGs: The Counterrevolution in Financing Health Care*, 15 HASTINGS CENTER REP. 19 (June 1985); Morreim, *The MD and the DRG*, 15 HASTINGS CENTER REP. 31 (June 1985) (an overview of reimbursement and its implications for hospitals, physicians, and the hospital-physician relationships).

The DRG system has also been criticized for its insensitivity to severity of illness, inappropriate classification for certain illnesses, and bias against certain procedures. See Horn, Bulkeley, Sharkey, Chambers, Horn & Schramm, *Interhospital Differences in Severity of Illness — Problems for Prospective Payment Based on Diagnosis-Related Groups (DRGs)*, 313 NEW ENG. J. MED. 20 (1985); Horn, Horn, Sharkey, Beall, Hoff & Rosenstein, *Misclassification Problems in Diagnosis-Related Groups — Cystic Fibrosis as an Example*, 314 NEW ENG. J. MED. 484 (1986); Rhodes, Krasniak & Jones, *Factors Affecting Length of Hospital Stay for Femoropopliteal Bypass — Implication of DRGs*, 314 NEW ENG. J. MED. 153 (1986); Douglass, Rosen, Butler & Bone, *DRG Payment for Long-Term Ventilator Patients — Implications and Recommendations*, 91 CHEST 413 (Mar. 1987); Douglass, Bone & Rosen, *DRG Payment for Long-Term Ventilator Patients — Revisited*, 93 CHEST 629 (1988); Nevitt, Yelin, Henke & Epstein, *Risk Factors for Hospitalization and Surgery in Patients with Rheumatoid Arthritis: Implications for Capitated Medical Payment*, 105 ANNALS INT. MED. 421 (1986).

34. Vladeck, *Medicare Hospital Payment by Diagnosis — Related Groups*, 100 ANNALS INT. MED. 576 (1984). The DRG system was based on a pilot research project at Yale University that used the International Classification Of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) as the basis for the classification scheme. *Id.* This approach has been criticized because of inherent inadequacies with the ICD-9-CM. McMahon & Smits, *Can Medicare Prospective Payment Survive the ICD-9-CM Disease Classification System?*, 104 ANNALS INT. MED. 562 (1986). See also Dolenc & Dougherty, *DRGs: The Counterrevolution in Financing Health Care*, 15 HASTINGS CENTER REP. 19 (June 1985).

admission.<sup>35</sup> The payment level is determined by the diagnosis upon admission.<sup>36</sup> In a radical departure from past government reimbursement patterns which compensated hospitals for their costs, the hospital now faces a loss if the costs for any individual patient exceed the DRG allotment for that patient.<sup>37</sup> The hospital, therefore, has an incentive to deliver health care economically and discharge patients quickly because the hospital retains any excess DRG payment over its cost.<sup>38</sup> Efficiency and cost containment were the guiding principles of prospective payment.<sup>39</sup> The administrative enactment echoes the same two themes. By shifting to prospective reimbursement, the federal government was supposed to contain its expected costs, gain control over the rate of inflation and expenditures for hospital costs, and shift a substantial financial risk to the hospitals.<sup>40</sup> Although the PPS has had a variety of effects, it has not fully met these expectations.<sup>41</sup>

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35. Social Security Amendments of 1983, Pub. L. No. 98-21, tit. VI, § 601, 97 Stat. 65, 149-63.

36. See Medicare & Medicaid Guide (CCH) ¶ 4204, at 1511-3 (July 1984).

37. "[P]rospective payment systems will change the economic incentives that influence a hospital's decisions in the use of resource inputs for each case. The profit potential inherent in this system alone should encourage hospitals to begin changing their behavior to decrease their operating costs." 48 Fed. Reg. 39752, 39805 (1983).

38. The incentive for a hospital under cost-based reimbursement is to encourage physicians to admit more Medicare patients, lengthen their stays and use more services while in the hospital. See *supra* note 9. Under this older system, the more services Medicare patients used, the more the hospital was paid. *Id.*

The PPS gives hospitals a sharply modified set of incentives. See also Dolenc & Dougherty, *DRGs: The Counterrevolution in Financing Health Care*, 15 HASTINGS CENTER REP. 19 (June, 1985). The payment level is largely independent of the number of services provided. *Id.* The shorter a patient's stay and the fewer services provided, the more likely the hospital is to make a profit on the patient. *Id.* The only incentive that remains unaltered is the incentive to admit more patients — unless of course, the hospital was so inefficient as to lose money on each of them!

39. The bill is intended to improve the Medicare program's ability to act as a prudent purchaser of services, and to provide predictability regarding payment amounts for both Government and hospitals. More important, it is intended to reform the financial incentives hospitals face, promoting efficiency in the provision of services by rewarding cost-effective practices. In contrast, the cost-based reimbursement arrangements under which Medicare has operated in the past lack incentives for efficiency. Subject to some limits on overall payment amounts, the "reasonable cost" reimbursement system simply responds to hospital cost increases by providing increased reimbursement.

H.R. REP. NO. 25, 98th Cong., 1st Sess. 132, reprinted in 1983 U.S. CODE CONG. & ADMIN. NEWS 219, 351.

40. "The new system . . . is primarily intended to provide incentives to hospitals to manage their operations in a more cost-effective manner." 48 Fed. Reg. 39752 (1983). See also 48 Fed. Reg. 39752, 39805 (1983).

41. The PPS does not appear to have dramatically slowed the increase in health care costs. In 1980-1983, average annual growth of the Medicare program costs was 16.5% while inflation was 6.5%. Anderson & Erickson, *Data Watch: National Medical Care*



Under PPS, inefficient hospitals will be unable to compete, because they will lose money on Medicare inpatients. They will have to raise their charges for non-Medicare patients to compensate, which in turn should decrease the demand for their inpatient services. Conversely, those that are efficient will be able to cross-subsidize other programs with the "profit" from Medicare patients. The PPS will punish the inefficient providers and reward the ef-

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*Spending*, 6 HEALTH AFFAIRS 96 (Fall 1987). After the institution of PPS, average annual costs for the next three years grew by 8.2% while inflation was 2.9%. *Id.* After adjusting for inflation, the PPS reduced the real rate of increase by 4.3% for inpatient hospital services. In 1985-86, costs increased by 8.4% while inflation was 1.1% and the GNP grew by 5.2%. *Id.* After adjustments for inflation and the growth in population, real costs increased by 6.3%. *Id.*

However, the PPS appears to have accelerated the decline in average length of hospital stays. The length of stay for patients 65 years old and older dropped from 9.9 days in early 1983 to 8.7 days by the third quarter of 1985. Inglehart, *Early Experience with Prospective Payment of Hospitals*, 314 NEW ENG. J. MED. 1460, 1464 (1986). A study by the National Opinion Research Center showed that 78% of physicians surveyed reported that their hospitals had encouraged early patient discharges. *Id.* The PPS was cited as the reason for this pressure. The AMA, reporting the results of their DRG monitoring project, cited the effects of PPS on length of stay and pressure to discharge early. *Id.* Senator Heinz, after attending hearings by the Senate Finance Subcommittee on Health on the effect of DRGs noted, "A number of hospitals publicly rank the performance of their doctors, with good marks and even financial bonuses going for those with shorter stay, money-saving patients, and black marks for those with the sicker, older 'DRG losers.'" *Id.* See also *infra* notes 65-77 and accompanying text.

Competition and cost-containment may also have untoward effects. Shortell & Hughes, *The Effects of Regulation, Competition, and Ownership on Mortality Rates among Hospital Inpatients*, 318 NEW ENG. J. MED. 1100 (1988). This study revealed higher death rates (6-10%) in hospitals subject to stringent cost control pressures through certificate-of-need or rate-review proceedings. *Id.* Similar results were found in hospitals subject to competition from HMOs. *Id.* The effects of PPS were not measured. Dr. William Roper, the head of the Health Care Financing Administration, has challenged the report on several grounds. 17 HEALTH POLICY WEEK 3, 4 (May 2, 1987). See also Guterman, Eggers, Riley, Greene & Terrell, *The First Three Years of Medicare Prospective Payment: An Overview*, 9 HEALTH CARE FINANCING REVIEW 67 (Spring, 1988); McCarthy, *DRGs — Five Years Later*, 318 NEW ENG. J. MED. 1683 (1988) (DRGs have resulted in an unstable and fragile hospital system; PPS is not predictable or prospective); Schramm & Gabel, *Prospective Payment: Some Retrospective Observations*, 318 NEW ENG. J. MED. 1681 (1983) (Hospitals and doctors have responded to new incentives; dire predictions about DRGs were unfounded; principles of PPS must be extended to outpatient settings).

The PPS also affects the speed of technology development and dissemination. McCarthy, *DRGs — Five Years Later*, 318 NEW ENG. J. MED. 1683, 1685 (1988); Dolenc & Dougherty, *DRGs: The Counter Revolution in Financing Health Care*, 15 HASTINGS CENTER REP. 19, 25-26 (June 1985). The experience with TPA, a drug used for the treatment of acute myocardial infarction, is an excellent case study of the problem. Haberek, *TPA Cost Crunch: Tight Controls Now, Hope for Future*, HEALTH POLICY WEEK SPECIAL REPORT (June 20, 1988). There is no DRG specifically for TPA, and reimbursement is limited to historical cost experience as reflected in the DRG. *Id.* Consequently, the use of a more expensive technology is constrained, even if it is much more effective. The hospital will bear the excess cost if it chooses to provide the therapy. *Id.*

ficent ones, thus restraining the rate of growth of the Medicare budget and creating market forces in the health care system.<sup>42</sup>

The financial incentives of the PPS do more than encourage simple efficiency:

[H]ospitals have been encouraged to strengthen referral patterns, develop additional "outreach" programs and use more preadmission and post-discharge services while decreasing inpatient length of stay. In pursuit of these objectives, hospitals have attempted to establish formal and informal linkages with other organizations, often healthcare providers, to ensure their financial survival and to better serve their patients.<sup>43</sup>

These formal and informal linkages have the potential to undermine the PPS. Cream-skimming is one possible outcome.<sup>44</sup> Some arrangements may also result in a double payment for a particular

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42. 48 Fed. Reg. 39752, 39807 (1983). But see *infra* note 44.

43. Office of Legal and Regulatory Affairs — American Hospital Association, *Medicare-Medicaid Antifraud and Abuse Amendments: Application to Hospital Activities under the Medicare Prospective Payment System 1* (Feb. 1985).

44. Cream-skimming would involve a physician admitting "DRG-winners" (patients for whom reimbursement is likely to exceed costs) to one hospital and "DRG-losers" (patients for whom the reverse is true) to another hospital. This could skew a hospital's balance sheet significantly and is one possible response to an incentive program only at the "DRG-winner" hospitals.

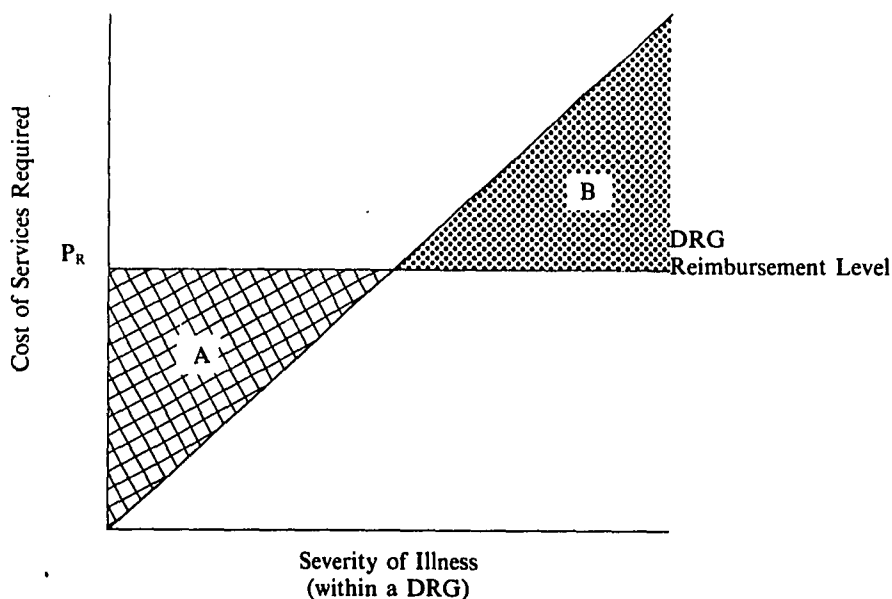
Even without an incentive program, a hospital acting in a truly competitive fashion would try to admit only patients for whom the DRG payment exceeds its costs. This might take two forms. A hospital could specialize in a few DRGs at which it was extremely efficient, or for which the payment level was too high. See Dranove, *Rate Setting by Diagnosis Related Groups and Hospital Specialization*, 18 RAND J. ECON. 417 (1987).

The other alternative is a more pure form of cream-skimming. The hospital attempts to attract only patients within a DRG class for whom the DRG payment is likely to be greater than the cost of providing care. *Id.*; Dolenc & Dougherty, *DRGs: The Counter-revolution in Financing Health Care*, 15 HASTINGS CENTER REP. 19 (June 1985). Rather than use this surplus to cross-subsidize the care rendered to other more expensive patients, the hospital simply refuses to incur that expense. A diagram may help clarify the problem:

service, resulting in increased costs to the Medicare program.<sup>45</sup>

Other arrangements are entirely consistent with the intentions of the PPS, but are in tension with the provisions of the Fraud and Abuse statute.<sup>46</sup> This tension has constrained the development of a variety of innovative incentive programs and joint ventures because of uncertainty about the limits of the law. Congressional recognition of this uncertainty prompted the passage of MMPPPA.

Regulation pursuant to MMPPPA must tread between two somewhat inconsistent aims: (1) the clear intent of Congress to control the cost of Medicare by allowing providers freedom to ma-



The intention of the DRG system is that triangle A (surplus) will equal triangle B (deficit) and thus on average, the hospital should incur expense price  $P$  for providing care to patients in a particular DRG. The smaller the hospital can make triangle B, the greater will be its surplus. This behavior is exactly what one would predict of a competitive actor, demonstrating the fallacy of attempted price fixing. See *infra* note 5. Furthermore, one would expect hospitals to compete with one another by rendering luxury services (like convenient parking, better meals, etc.) to patients in A, thus decreasing the size of triangle A. This places more pressure on the hospital to decrease or deny care to patients in B. Ironically, the "ethical" behavior of hospitals, in refusing to act like truly competitive agents, is the glue that keeps the DRG system from being completely undermined.

45. For example, if a hospital contracted with a home health care agency to provide discharge planning and the agency billed the Medicare program, this would constitute double billing. The hospital's prospective payment usually includes an allotment for such services. Teplitzky & Yampolsky, *Historical Perspectives on Joint Ventures*, in *MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW 108* (1986).

46. See *infra* notes 107-08 and accompanying text.

never as they see fit under the PPS;<sup>47</sup> and (2) the desire to control the structure and incentives for the delivery of health care through the Fraud and Abuse statute. Ultimately, the conflict centers on whether health care will be delivered on a more or less pure market system or held to a higher standard.<sup>48</sup>

### III. PHYSICIAN INCENTIVE PROGRAMS AND JOINT VENTURES

#### A. Physician Incentive Programs

The changes in the health care environment to a more competitive, market-based model are mirrored by the changes in physician incentive programs and the development of joint ventures.<sup>49</sup> Physician incentive programs originally existed to attract qualified phy-

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47. See *supra* notes 37-40, 42 and accompanying text.

48. See *infra* notes 141-59 and accompanying text. A market approach enhances efficiency, but if one lacks money, one cannot purchase the product. The growing disparities in access to health care for the poor and uninsured is a troubling consequence of the market approach. Nutter, *Medical Indigency and the Public Health Care Crisis: The Need for a Definitive Solution*, 316 NEW ENG. J. MED. 1156 (1987). Changes in Medicaid eligibility between 1975 and 1983 resulted in a decrease in the proportion of low-income Americans insured by Medicaid, [from 63% to 46%] despite a 27% increase in the number of Americans living at or below 125% of the federal poverty level. Blendon, Aiken, Freeman, Kirkman-Liff & Murphy, *Uncompensated Care by Hospitals or Public Insurance for the Poor*, 314 NEW ENG. J. MED. 1160 (1986). The number of Americans without any health insurance increased by more than 20% between 1979 and 1984. *Id.* See also Ginzberg, *Medical Care for the Poor: No Magic Bullets*, 259 J.A.M.A. 3309 (1988); Davis, *National Initiatives for Care of the Medically Needy*, 259 J.A.M.A. 3171 (1988); Dolenc & Daugherty, *DRGs: The Counter Revolution in Financing Health Care*, 15 HASTINGS CENTER REP. 19, 21-22 (June 1985).

Hospitals are faced with footing the bill for uncompensated care, and in response transfer patients without insurance to public hospitals. Schiff, Ansell, Schlosser, Idris, Morrison & Whitman, *Transfers to a Public Hospital*, 314 NEW ENG. J. MED. 552 (1986). This prospective study of 467 patients transferred to Cook County Hospital revealed that 87% were transferred because they lacked adequate medical insurance. *Id.* Only 6% had signed a consent prior to transfer. *Id.* Twenty-four percent of the patients were classified as "unstable" at the time of transfer. See also Equal Access to Health Care: Patient Dumping, H.R. REP. NO. 531, 100th Cong., 2d Sess. (1988); Relman, *Texas Eliminates Dumping: A Start Toward Equity in Hospital Care*, 314 NEW ENG. J. MED. 578 (1986).

49. Most incentive programs also raise tax (*i.e.*, inurement for an I.R.C. § 501(c)(3) corporation), antitrust, reimbursement, and state law (concerning fee splitting and corporate practice of medicine) issues as well. It is ironic that the solution of the "inurement problem," *i.e.*, showing that an incentive program benefits the tax-exempt institution is the critical element for creating a fraud and abuse violation. The antitrust implications of many of these arrangements are startling. A lock-up of referrals, even if it passed the Fraud and Abuse regulations may be subject to attack under: § 1 or § 2 of the Sherman Act, 26 Stat. 209 (1890) (codified as amended at 15 U.S.C.A. §§ 1, 2 (1982)); § 3 of the Clayton Act, 38 Stat. 730 (1914) (codified as amended at 15 U.S.C.A. § 14 (1982)); or § 5 of the Federal Trade Commission Act, 38 Stat. 717 (1914) (codified as amended at 15 U.S.C.A. § 45 (1980)).

sicians to the hospital staff.<sup>50</sup> Often they included simple benefits such as free coffee and convenient parking.<sup>51</sup> Other hospitals purchased state-of-the-art equipment to offer more treatment options.<sup>52</sup> Competition among hospitals to attract physicians, and consequently patients, was largely on the basis of such amenities.<sup>53</sup>

Gradually, incentive programs began to involve more complicated arrangements such as favorable lease terms in a medical office building owned by the hospital or the opportunity to participate in joint ventures.<sup>54</sup> These arrangements fostered cooperation and good will between the hospital and its medical staff.<sup>55</sup> Obviously, the hospital was concerned with referrals, and hoped such arrangements would generate them, but the Fraud and Abuse statute effectively forestalled any linkage between the level of incentive (or savings) and the number of referrals.<sup>56</sup>

Another commonly used arrangement attempted to induce physicians to move into under-served areas.<sup>57</sup> These arrangements include relocation incentives such as moving expenses, salary guarantees, low interest loans, and incentive payments.<sup>58</sup> In exchange, the physician was obligated to the hospital and the community for a minimum period of time.<sup>59</sup>

Some hospitals also offer malpractice insurance to members of their medical staff.<sup>60</sup> The physician gains access to insurance cov-

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50. Telephone interview with E. Frederic Bockstahler, Senior Vice President, Voluntary Hospitals of America, Inc. (August 11, 1988).

51. *Id.*

52. Robinson & Luft, *Competition and the Cost of Hospital Care, 1972-1982*, 257 J.A.M.A. 3241 (1987).

53. One result was that hospitals competed on the basis of quality rather than price. Counterintuitively, this resulted in higher health care costs in more competitive areas. *Id.* See also Luft, Robinson, Garnick, Maerki & McPhee, *The Role of Specialized Clinical Services in Competition Among Hospitals*, 23 INQUIRY 83 (Spring 1986).

54. See generally L. BURNS & D. MANCINO, JOINT VENTURES BETWEEN HOSPITALS AND PHYSICIANS: A COMPETITIVE STRATEGY FOR THE HEALTHCARE MARKET PLACE (1987).

55. *Id.*

56. See *infra* notes 104-08 and accompanying text.

57. Telephone Interview with E. Frederic Bockstahler, Senior Vice President, Voluntary Hospitals of America, Inc. (August 11, 1988).

58. *Id.*

59. The obligation usually required a minimum of hours worked per week and an agreement to stay in the area and use that hospital. *Id.*

60. Some hospitals have formed risk retention groups or captive insurance companies in order to provide lower cost liability insurance. Taravella, *Frustrated Healthcare Systems Seek Alternatives to Traditional Insurance*, 18 MODERN HEALTHCARE 30 (May 13, 1988). Other hospitals pay a portion of the physician's premium or agree to pay the deductible in the event of a claim. *Channeling can reduce premiums and malpractice claims*, 10 HOSPITAL RISK MANAGEMENT 25-31 (Mar. 1988).

erage at below-market rates. The hospital is able to coordinate the defense of claims and reduce liability exposure<sup>61</sup> while encouraging physician loyalty and continued referrals.<sup>62</sup> Other hospitals woo prominent physicians from competitors, or "promote and package" their physicians to ensure high visibility.<sup>63</sup> Physicians have also become more vocal about the services that they wish hospitals to provide.<sup>64</sup>

After the introduction of the PPS, the interests of hospitals diverged dramatically from the interests of admitting physicians.<sup>65</sup> Physicians are still paid under the traditional fee-for-service system, with payment made for each service rendered.<sup>66</sup> Consequently, the physician has little incentive to economize. The hospital receives a fixed sum per admission, but faces a substantial risk because physicians control the allocation of hospital resources to each patient.<sup>67</sup> Physicians also exercise considerable control over where patients are admitted, thus affecting the census of any

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61. *Id.*

62. Of course, requiring referrals might run afoul of the fraud and abuse statute. See *infra* notes 104-08 and accompanying text.

63. Perry, *U.S. Hospitals Wooing Superstar Physicians*, 18 MODERN HEALTHCARE 24 (Jan. 8, 1988).

64. Surveys of physicians have revealed that the top five services they would like to receive from hospitals are:

- (1) Hospital-subsidized Continuing Medical Education programs,
- (2) Physician referral service,
- (3) Market research for referral tracking/patient satisfaction,
- (4) Malpractice insurance,
- (5) Joint venture alternative delivery services.

*Id.* at 26.

65. Anderson, *Medical Profession Perspective*, in MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW 129-132 (1986).

66. See 42 U.S.C. § 1395(b)(1) (1982). Congress has made efforts to control reimbursement to physicians, including a mandatory fee freeze and the creation of a participating physician program that induces physicians to accept payment from Medicare as payment in full. Note, *Rethinking Medical Malpractice Law in Light of Medicare Cost-Cutting*, 98 HARV. L. REV. 1004, 1007 (1985).

Congress has, however, been unsuccessful in efforts to alter the formula for physician payments. Relative Value Scales, Preferred Provider Organizations (PPOs), DRGs and Capitated Care have been considered. See generally *Physician Payments: Medicare's Next Battleground*, MEDICINE & HEALTH PERSPECTIVES (Oct. 26, 1987); Robinson, *The Debate Begins over Physician Payment*, 4 HEALTHSPAN 26 (Apr. 1987); *HCFCA Staff Finds MD DRGs Problematic*, 16 HEALTH POLICY WEEK 1 (January 26, 1987); *A Medicare Physician's Relative Value Scale: Why It's Needed and How it Would Work*, 3 HEALTHSPAN 10 (Jan. 1986); Mitchell, *Physician DRGs*, 313 NEW ENG. J. MED. 670 (1985); Hadley & Berenson, *Seeking the Just Price: Constructing Relative Value Scales and Fee Schedules*, 106 ANNALS INT. MED. 461 (1987).

67. Saphier, *Cost Effectiveness Requires Cooperation*, in MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW 124 (1986).

given hospital.<sup>68</sup> If physicians fail to act in a cost-conscious manner or otherwise deliver care in an inefficient fashion, the hospital will lose significant sums of money.<sup>69</sup>

Predictably, the focus of many hospitals has become cost containment.<sup>70</sup> Many hospitals have introduced novel incentive programs to encourage physicians to practice medicine more economically.<sup>71</sup> These programs reward physicians for admissions<sup>72</sup> or for DRG savings experienced by the hospital.<sup>73</sup> Participation requires physicians to alter their practice patterns, thereby reducing the hospital's costs.<sup>74</sup> These alterations might include pre-admission testing, timely record completion, utilization review, treatment according to a pre-determined protocol, or even accelerated discharge.<sup>75</sup> Although some of these alterations may improve

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68. Physicians presently control 70% of admission decisions. Perry, *U.S. Hospitals Wooing Superstar Physicians*, 18 MODERN HEALTHCARE 24 (Jan. 8, 1988). This figure has dropped from 88% in the early 1980s. *Id.* Patients appear to control the admission decision for obstetrics, sports medicine, emergency care and mammography. *Id.* at 32. Physicians and patients share admission decisions for cancer treatment, infectious disease treatment, geriatrics, cardiology, ophthalmology, orthopedics and pediatrics. *Id.*

69. Saphier, *Cost Effectiveness Requires Cooperation*, in MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW 124 (1986).

70. Cost containment is obviously not limited to physician incentives. In response to the PPS, health care providers are forging new organizational structures and joint ventures in an effort to broaden their revenue base, share risk and cut costs. See *supra* note 43 and accompanying text.

71. Saphier, *Cost Effectiveness Requires Cooperation*, in MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW 124-25 (1986).

72. The most extreme incentive program of this sort was at Pasadena General Hospital, which paid physicians a fixed sum for every patient admitted. The U.S. Attorney believed this program was a clear violation of the Fraud and Abuse statutes and secured an indictment of the hospital and its directors. After a jury trial, the defendants were acquitted on the basis that the U.S. Attorney had failed to prove the payments were for Medicare (and not just private) patients. GAO REPORT TO THE CHAIRMAN; SUBCOMMITTEE ON HEALTH, COMMITTEE ON WAYS AND MEANS, HOUSE OF REPRESENTATIVES, MEDICARE: PHYSICIAN INCENTIVE PAYMENTS BY HOSPITALS COULD LEAD TO ABUSE (July 1986) GAO/HRD-86-103 20.

73. For a discussion of "profit" in a DRG system and the problems posed by the continued expectation of cross-subsidization within a DRG, see *supra* note 44.

74. Obviously, some of these alterations might benefit all of the parties involved. See *supra* note 28 on inappropriate and unnecessary care and *infra* note 88 on treatment associated complications. If even some of this care was eliminated, costs would be lower and patients would spend less time in the hospital.

75. See generally Saphier, *Cost Effectiveness Requires Cooperation*, in MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW 124-25 (1986). Although the Omnibus Budget Reconciliation Act of 1986 ("OBRA") contains provisions that appear to limit the effectiveness of a program that encourages early discharge or minimal care, many hospitals have made efforts to structure such arrangements with either individual physicians or with an organization of physicians. OBRA prohibits direct or indirect payments "to a physician as an inducement to reduce or limit services provided" to Medicare or Medicaid beneficiaries "under the direct care of the physician." Pub. L. No. 99-509

the quality of medical care, others have come under scrutiny by Congress and other organizations concerned about the effect of such arrangements on patient care.<sup>76</sup> The American Medical Association ("AMA") has formally disapproved of physician participation in such DRG incentive arrangements.<sup>77</sup>

Obviously, physician incentive programs provide some incentive for the physician to act in the desired fashion.<sup>78</sup> Incentives of any sort raise the problem of compliance with the "Fraud and Abuse" statute.<sup>79</sup> This statute forbids the knowing and willful solicitation or receipt of any remuneration in exchange for a referral or for ordering a service for which reimbursement may be made under Medicare.<sup>80</sup>

Payments by providers to one another for referrals or for the opportunity to provide services to patients were not acceptable to the government under a cost-based system. Such arrangements encourage over-utilization and the inflation of charges to cover such payments.<sup>81</sup> Under prospective payment, however, few such concerns apply<sup>82</sup> because the cost to the government is fixed.<sup>83</sup> In fact,

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§ 9313(c), 100 Stat. 2002, 2003 (1986). Hospitals and physicians who knowingly violate these provisions are subject to civil money penalties. *Id.* The ban applies only to physicians with direct care responsibilities. *Id.* Health maintenance organizations and other prepaid plans are not subject to the ban until January 1, 1989. *Id.* HHS has just proposed regulations to limit early discharge, largely in response to several well-publicized cases of patient "dumping." 53 Fed. Reg. 22513 (1988). See *supra* note 48 on "dumping."

76. See GAO REPORT TO THE CHAIRMAN, SUBCOMMITTEE ON HEALTH, COMMITTEE ON WAYS AND MEANS, HOUSE OF REPRESENTATIVES, MEDICARE: PHYSICIAN INCENTIVE PAYMENTS BY HOSPITALS COULD LEAD TO ABUSE; GENERAL ACCOUNTING OFFICE REPORT TO THE CHAIRMAN; July 1986 GAO/HRD-86-103.

77. See *infra* note 90.

78. Incentives might range from participation in lucrative joint ventures and direct cash payments to tokens of appreciation and free coffee. Certain commentators have been rather hyperbolic in their description of what might constitute an incentive under the criminal provisions. See *Health Care Business Deals: Kickbacks or Capitalism?* HEALTH POLICY WEEK SPECIAL REPORT 3 (Apr. 11, 1988) (a cup of coffee would be prohibited by a literal reading).

79. 42 U.S.C. § 1395nn(b) (1982), 42 U.S.C. § 1396h(b) (1982). See *infra* notes 104-08.

80. *Id.*

81. See *infra* the discussion of *Ruttenberg* at notes 256-65 and accompanying text. Referrals are extremely valuable because they provide the opportunity to obtain remuneration. Glenn, Lawler & Hoerl, *Physician Referrals in a Competitive Environment—An Estimate of the Economic Impact of a Referral*, 258 J.A.M.A. 1920 (1987). In this study of referrals from rural practitioners to university based specialists, each patient accumulated an average of \$3,000 in billings for hospital charges and professional fees within six months of the referral. *Id.* Almost half of the referrals studied led to a hospital admission. *Id.* Seventy-two percent of all the revenue accrued to the hospital. *Id.*

82. Direct payment for admissions has the potential to subvert the goals of the PPS, particularly if the admissions are profitable for the hospital. See *supra* note 44.

83. Prospective payment diminishes the ways in which the Medicare program may be



the PPS encourages hospitals to provide a broader range of services so long as they can do so efficiently.<sup>84</sup> The development of joint ventures is also encouraged by prospective payment.<sup>85</sup> The most efficient hospitals will increase their market share under the PPS.<sup>86</sup> Indeed, the government wants to encourage the movement of patients to more efficient providers because the marketplace is viewed as the most effective and rational way to allocate Medicare patients.<sup>87</sup>

The funnelling of patients to these more efficient providers may have other beneficial effects as well.<sup>88</sup> Incentive arrangements cre-

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cheated. Because the payment is fixed, overutilization of individual services actually costs the hospital money. See *supra* notes 37, 39-40. Possible forms of cheating the PPS include: DRG up-coding, also known as creep or gaming (miscategorizing an illness to obtain greater payment), or inappropriate admissions, transfers or discharges. See generally Sinborg, *DRG Creep: A New Hospital Acquired Disease*, 304 NEW ENG. J. MED. 1602 (1981). One study of 2,400 Medicare patients in California found a 23% DRG coding error rate. 16 HEALTH POLICY WEEK (Apr. 13, 1987). A more thorough study using blinded techniques revealed a 20.8% error rate in DRG coding. Hsia, Krushat, Fagan, Terbutt & Kusserow, *Accuracy of Diagnostic Coding for Medicare Patients Under the Prospective-Payment System*, 318 NEW ENG. J. MED. 352 (1988). Small hospitals had significantly higher error rates. *Id.* The study also showed that 61.7% of coding errors favored the hospital, resulting in a total overpayment of approximately \$478,000. *Id.* The study concluded that "creep" does occur in DRG coding, and estimated that \$300 million (out of \$27 billion in prospective payments) in 1985 constituted overpayments caused by coding errors. *Id.* The selective admission of patients who could be treated as outpatients or for whom DRG payment is expected to exceed costs ("DRG-winners") is another form of abusive practice. See *supra* note 44. Still another type of abuse involves the failure to provide medically necessary services (under-utilization) or early discharge from the hospital. See *supra* note 75 and accompanying text.

However, all of these abusive practices have already been addressed either by Peer Review Organizations ("PROs") which monitor the provision of services to patients pursuant to 42 U.S.C. § 1320c-5(a), civil money penalties pursuant to the Medicare and Medicaid Patient and Program Protection Act and the Civil Monetary Penalties Act, false statement statutes, or by the provisions of the Omnibus Budget Reconciliation Act of 1986. Thus, there is no need to write Fraud and Abuse regulations concerning such matters.

84. See *infra* note 43 and accompanying text.

85. *Id.*

86. This assessment is implicit in the decision to restructure "the economic incentives facing the health care system to establish market like forces." 48 Fed. Reg. 39752, 39807 (1983).

87. *Id.*

88. Prospective payment encourages the provision of services in the most cost-effective manner. See *supra* notes 39-40. This may benefit the patient as well as the taxpayer — the risk of treatment associated (iatrogenic) complications will decline as unnecessary services are eliminated. Hospitals will also seek to limit adverse events such as hospital acquired infections. See Haley, White, Culver & Hughes, *The Financial Incentive for Hospitals to Prevent Nosocomial Infections under the Prospective Payment System*, 257 J.A.M.A. 1615 (1987).

This movement of patients may also have another beneficial effect. A high volume of a particular procedure usually results in better outcomes for the individual patients.

ate significant fraud and abuse issues, but they involve liability,<sup>89</sup> ethical, and policy dimensions as well.<sup>90</sup> Finally, physician incentive payments have the potential to undermine the DRG system. Selective admission of DRG "winners,"<sup>91</sup> inappropriate transfers or discharges, and the prevention of professional review of an entire practice are possible undesirable outcomes of a DRG incentive program.<sup>92</sup>

### B. Joint Ventures

Joint ventures provide additional opportunities to enhance physician and hospital revenues and referrals. Joint ventures are a

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Bunker, Luft & Enthoven, *Should Surgery be Regionalized?*, 62 SURGICAL CLINICS N. AM. 657 (1982). One study of coronary artery bypass grafts revealed that patients at high volume hospitals had a shorter average length of stay and a decreased in-hospital mortality. Showstack, Rosenfield, Gamick, Luft, Schaffarzick & Fowles, *Association of Volume with Outcome of Coronary Artery Bypass Graft Surgery: Scheduled vs. Nonscheduled Operations*, 257 J.A.M.A. 785 (1987). High volume hospitals also had fewer patients with extended hospitalizations than low volume hospitals. *Id.*

89. The liability aspect of DRG incentive payments arises when a patient sues both hospital and physician for failure to meet the necessary standard of care. If hospitals and physicians discharge patients quicker and render fewer services as a result of an incentive program, they may be held to the prevailing standard which presumably does not involve such incentives. Increased liability is thus a direct consequence of many incentive programs. One possible solution is to use the standard of a reputable minority — *i.e.*, other providers subject to such incentives — as a more appropriate way of establishing the standard of care. This suggestion was raised with regard to the appropriate standard of care for an HMO. Bovbjerg, *The Medical Malpractice Standard of Care: HMO's and Customary Practice*, 1975 DUKE L.J. 1375. *But see* Wickline v. State, 183 Cal. App. 3d 1175, 228 Cal. Rptr. 661 (1986). This case involved the liability of a utilization control consultant who refused to approve an extended hospital stay for the plaintiff. The plaintiff sued for damages resulting from the loss of her leg which was allegedly due to the refusal to extend the hospital stay. The California Court of Appeals indicated that the standard of care expected remains unchanged, despite pressure from cost containment programs. *Id.*

90. For example, both the American Medical Association and the Institute of Medicine have expressed disapproval of DRG incentive plan payments. Reports of the Judicial Council of the American Medical Association, *Ethical Implications of Hospital-Physician Risk-Sharing Arrangements under Diagnosis Related Groups System*, 253 J.A.M.A. 2424 (1985); FOR PROFIT ENTERPRISE IN HEALTH CARE 165 (B. Gray, ed., 1980). Both bodies recognize the possibility of an adverse effect on the quality of patient care. The General Accounting Office also concluded that many DRG incentive plans "provide physicians too strong an incentive to undertreat patients." GAO REPORT TO THE CHAIRMAN, SUBCOMMITTEE ON HEALTH, COMMITTEE ON WAYS AND MEANS, HOUSE OF REPRESENTATIVES, MEDICARE: PHYSICIAN INCENTIVE PAYMENTS BY HOSPITALS COULD LEAD TO ABUSE 20 (July 1986), GAO/HRD-86-103.

91. *See supra* note 44 and accompanying text.

92. GAO REPORT TO THE CHAIRMAN, SUBCOMMITTEE ON HEALTH, COMMITTEE ON WAYS AND MEANS, HOUSE OF REPRESENTATIVES, MEDICARE: PHYSICIAN INCENTIVE PAYMENTS BY HOSPITALS COULD LEAD TO ABUSE 20 (July 1986), GAO/HRD-86-103.

complex subject because they involve a tremendous diversity of providers and plans.<sup>93</sup> Joint ventures have been undertaken for many different purposes.<sup>94</sup> Joint ventures can involve parties other than hospitals and physicians; Durable Medical Equipment ("DME") manufacturers and suppliers, pharmaceutical manufacturers, pharmacists, podiatrists, and businessmen have participated in joint ventures.<sup>95</sup> Many joint ventures raise Fraud and Abuse issues that are similar to those found in the context of physician incentive programs because the investors often refer patients to the joint venture.<sup>96</sup> Even if there is no absolute requirement for referral, participants receive an increased return for every referral they make. Thus, joint ventures implicate both the abuse<sup>97</sup> and the fraud<sup>98</sup> strands of reasoning for the statute.<sup>99</sup>

The intensely competitive and rapidly changing environment of the health care industry has forced providers to develop incentive programs and engage in joint ventures.<sup>100</sup> The introduction of the PPS accelerated the change and encouraged providers to form these arrangements.<sup>101</sup> Such arrangements have attracted attention for their potential effect on the quality of care and physician integrity<sup>102</sup> and the risk of violating the Fraud and Abuse statute.<sup>103</sup> Any regulation that attempts to clarify the enforcement of the

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93. For an overview of the types of joint ventures that have been used, see generally L. BURNS & D. MANCINO, *JOINT VENTURES BETWEEN HOSPITALS AND PHYSICIANS: A COMPETITIVE STRATEGY FOR THE HEALTHCARE MARKETPLACE* (1987).

94. Possible reasons to create a joint venture include the purchase of diagnostic equipment, the creation of emergi-centers and surgi-centers, and to provide utilization and quality review. *Id.*

95. Telephone interview with E. Frederic Bockstahler, Senior Vice President, Voluntary Hospitals of America, Inc. (August 11, 1988).

96. Adams, *Fraud and Abuse Implications of Joint Ventures*, in L. BURNS & D. MANCINO, *JOINT VENTURES BETWEEN HOSPITALS AND PHYSICIANS: A COMPETITIVE STRATEGY FOR THE HEALTH CARE MARKETPLACE* (1987).

97. *See infra* note 124.

98. *See infra* note 126.

99. *See supra* note 43 and accompanying text. *See also generally*: Roble & Mason, *The Legal Aspects of Health Care Joint Ventures*, 24 DUQ. L. REV. 455 (Winter, 1985); Adams, *Fraud and Abuse Implications of Joint Ventures*, in L. BURNS & D. MANCINO, *JOINT VENTURES BETWEEN HOSPITALS AND PHYSICIANS: A COMPETITIVE STRATEGY FOR THE HEALTHCARE MARKETPLACE* (1987); Teplitzky, *Avoiding Fraud and Abuse Problems in Joint Ventures*, 4 HEALTHSPAN 17 (Jan. 1987).

100. Saphier, *Cost Effectiveness Requires Cooperation*, in *MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW* 124 (1986).

101. *See supra* note 43 and accompanying text.

102. *See infra* notes 141-59.

103. *See Tillman, Scope of the Conference*, in *MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW* 7, 8 (1986).

Fraud and Abuse statute must take into account the diversity of approaches to the problem.

#### IV. FRAUD AND ABUSE: THE CURRENT FEDERAL STATUTE

The Fraud and Abuse provisions have had a chilling effect on the development and implementation of incentive programs and joint ventures by health care providers.<sup>104</sup> The statute prohibits the knowing and willful solicitation or receipt of any remuneration in exchange for a referral of a patient or for ordering a good or service for which payment may be made under Medicare.<sup>105</sup> The language

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104. See Burda, *Law Aimed at Curbing Medicare Fraud May Have 'Chilling Effect' on Joint Ventures*, MODERN HEALTH CARE 92 (Oct. 9, 1987); Dechene, *Implications of Physician Incentive Programs*, MERRILL'S ILLINOIS LEGAL TIMES 20, 27 (May 1987); Teplitzky, *Avoiding Fraud and Abuse Problems in Joint Ventures*, 4 HEALTHSPAN 17, 21 (Jan. 1987); Teplitzky & Yampolsky, *Historical Perspective on Joint Ventures*, in MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW 102, 105-09, 115 (1986).

105. 42 U.S.C. §§ 1395nn(b), 1396h(b) (1982).

Prior to the enactment of MMPPPA, the statute read as follows:

(b) **Illegal Remuneration**

(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 this subchapter, 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 subchapter, 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 this subchapter, 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 subchapter, 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 subchapter 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 subchapter; 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.

*Id.*

of the statute is broad and ambiguous and has been applied to a variety of situations that were not contemplated by Congress when it enacted the statute.<sup>106</sup> Furthermore, because violation of the statute is a felony, the only binding interpretations of its breadth to this point have been the infrequent criminal prosecutions in federal courts. Indictment usually occurs only when the facts are extreme and outrageous, resulting in relatively limited guidance on what sorts of normal business activity might be subject to indictment.<sup>107</sup> A technical violation of the statute could lead to prosecution although the act posed no threat to the integrity of the Medicare program.<sup>108</sup>

An instructive example on this point involves the issue of the waiver of deductibles and co-insurance payments. Medicare has a deductible and co-insurance provision which the patient is expected to pay.<sup>109</sup> Many hospitals have started waiving these co-payments and advertise this fact to attract patients.<sup>110</sup> This practice appears to violate the Fraud and Abuse statute,<sup>111</sup> but it does not immediately increase the cost to the Medicare program<sup>112</sup> and

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106. Adams, *Fraud and Abuse Implications of Joint Ventures*, in JOINT VENTURES BETWEEN HOSPITALS AND PHYSICIANS: A COMPETITIVE STRATEGY FOR THE HEALTHCARE MARKETPLACE 129, 130 (1987).

107. *Health Care Business Deals: Kickbacks or Capitalism?* HEALTH POLICY WEEK SPECIAL REPORT 3 (April 11, 1988). The issues are even more complicated because there is a substantial delay between the occurrences of an activity, investigation, indictment, trial and published opinion. Adams, *Fraud and Abuse Implications of Joint Ventures*, in JOINT VENTURES BETWEEN HOSPITALS AND PHYSICIANS: A COMPETITIVE STRATEGY FOR THE HEALTHCARE MARKETPLACE 129, 130 (1987).

108. See *infra* notes 109-13 and accompanying text.

109. See 42 U.S.C. § 1395e(a)(1-3) (1982); 42 U.S.C. § 1395e(b)(1-3) (1986); 42 U.S.C. § 13951(b) (1982); 42 U.S.C. § 1395x(y)(3) (1983); 42 U.S.C. § 1395cc(2)(A) (1986).

110. The waiver of deductibles and co-insurance has been shown to be an effective marketing tool. 16 HEALTH POLICY WEEK 3 (Feb. 16, 1987). One hospital in Arizona began offering such waivers to veterans. *Id.* Of 1,400 veterans who signed up initially for the discounts, between 20-30% have returned for subsequent care. *Id.* The success of the program led six other hospitals in Arizona, Florida, California and Oregon to start programs of their own. *Id.*

111. Waiver programs are "technically speaking, violations of the kickback provisions." Harvey Yampolsky, Assistant General Counsel, Department of Health and Human Services, HOSPITALS, May 5, 1988, at 54.

112. The existence of a waiver program costs the government no money (at least in the short term) only when the program cost at the facilities is not different. For example, if two facilities are both paid the same amount, the government is price-indifferent to the existence of a waiver program. In fact, a waiver will allow for price competition by the facilities, reflecting their respective operating efficiencies. A uniform price acts as both a floor and ceiling, deterring innovation and prolonging hospital programs beyond their market dictated life span. Kalison & Averill, *The Challenge of 'Real' Competition in*

it saves the beneficiary out-of-pocket costs.<sup>113</sup> U.S. Attorneys have

*Medicare*, 6 HEALTH AFFAIRS 47, 48 (Fall 1986). But see *infra* note 113 on the adverse long-term consequences on the level of utilization of medical services.

Furthermore, if two facilities are paid different amounts, the government should no longer be price-indifferent to the existence of a waiver program. For example, until recently, an ambulatory surgery center ("ASC") was fully paid by the government and did not have to charge a co-payment. Hospital outpatient departments that performed the same procedures were required to charge the co-payment, because the cost to the program of having surgery performed at the hospital outpatient department was far higher than at an ASC. If the hospital waived its charges, the patient would be price-indifferent but the program would not. Some figures may clarify the issue. Assume that an ASC is paid \$400 for a procedure while the hospital receives \$1,000. If the co-payment is \$200, the figures break down as follows:

	Program Cost	Beneficiary Cost
ASC	\$400	0
Hospital without waiver	\$800	\$200
Outpatient Department with waiver	\$800	0

Obviously, the existence of the co-payment will encourage ASC use, with a substantial savings for the program. Once the waiver program is in existence, that incentive is gone and the potential for increased cost to the program is substantial. See generally FEDERAL AMBULATORY SURGERY ASSOCIATION, COMMENT SUBMITTED TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.

For actual figures on one such arrangement, see *Medicare Reimbursement for Cataract Surgery: Hearings before the Subcomm. on Health of the House Comm. on Ways and Means*, 99th Cong., 1st Sess. 229, 230 (1985) (statement of Phil Hessburg M.D.).

In the interim, Congress has "leveled the playing field" between hospital outpatient departments and ASCs, providing for a co-payment to the ASC and reducing the amounts paid to hospital outpatient departments. See Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509 § 9343, 100 Stat. 2039-2042 (1986). Although hospital outpatient surgery will soon be paid on a prospective basis, it will be higher than the ASC rate to compensate for the higher fixed costs of a hospital. *Id.* The playing field is somewhat more level, but the different program costs should make the government want to encourage ASC usage by patients.

113. It is widely expected that the forthcoming regulations will legalize the routine waiver of co-insurance and deductible for services rendered under the PPS. *Government Will Examine Waiver Programs*, HOSPITALS (May 5, 1988) at 54. Services that are compensated under a cost-based system are unlikely to receive the same treatment. *Id.*

The ability of certain hospitals to engage in routine waiver suggests that the DRG payment is too high and provides further evidence that some hospitals are operating more efficiently than others.

Legalization of routine waiver seems both politically sensible and superficially beneficial to all parties. Unfortunately, from an economic standpoint, it eliminates one of the best hopes for controlling health care costs and encouraging price-sensitive shopping by patients. In fact, Congress hoped to create those incentives when it provided for co-insurance and deductibles. "The co-insurance requirement was established by Congress as an incentive to patients to be cost conscious." Letter from Stephen S. Trott to Richard P. Kusserow (October 30, 1985) (discussing waiver of co-payments and possibility of immunization from prosecution) in MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW 57 (1986).

It is well established that the existence of a co-insurance payment or deductible de-

not been eager to prosecute hospitals that waive the co-payment.<sup>114</sup> The Department of Justice has refused to instruct U.S. Attorneys that prosecution is unwarranted for waiving deductibles and co-insurance, explaining that the executive branch could not prospectively immunize conduct that the legislative branch had deemed a criminal offense.<sup>115</sup> They have also refused to issue guidelines on how to handle such cases.<sup>116</sup> Observing that no relief was forth-

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creases utilization. Fischer, Strobino & Pinckney, *Utilization of Child Health Clinics following Introduction of a Copayment*, 74 AM. J. PUB. HEALTH 1401 (1984); Shapiro, Ware & Sherbourne, *Effect of Cost Sharing on Seeking Care for Serious and Minor Symptoms: Results of a Randomized Controlled Trial*, 104 ANNALS INT. MED. 246 (1986); Helms, Newhouse & Phelps, *Copayments and Demand for Medical Care: the California Medicaid Experience*, 9 BELL J. ECON 192 (1982). *But see* Siu, Sonneberg, Manning, Goldberg, Bloomfield, Newhouse, Brook, *Inappropriate Use of Hospitals in a Randomized Trial of Health Insurance Plans*, 315 NEW ENG. J. MED. 1259 (1986) (cost-sharing did not selectively diminish inappropriate usage).

The existence of co-insurance and deductibles does not appear to dramatically decrease the health status of patients. Brook, Ware, Rogers, Keller, Davies, Donald, Goldberg, Lohr, Masthay & Newhouse, *Does Free Care Improve Adults' Health?* 309 NEW ENG. J. MED. 1426 (1983) (Only functional far vision and blood pressure improved of 11 health status indicators); Keller, Sloss, Brook, Operkalski, Goldberg & Newhouse, *Effects of Cost Sharing on Physiological Health, Health Practices, and Worry*, 22 HEALTH SERVICES RESEARCH 279 (1987) (except for patients with hypertension or vision problems, effects of cost sharing on health were minor). Pediatric patients, for whom parental concern is likely to result in increased attention to health, showed comparable results. Leibowitz, Manning, Keeler, Duan, Lohr & Newhouse, *Effect of Cost-Sharing on the Use of Medical Services by Children: Interim Results from a Randomized Controlled Trial*, 75 PEDIATRICS 942 (1985); Valdez, Brook, Rogers, Ware, Keeler, Sherbourne, Lohr, Goldberg, Camp & Newhouse, *Consequences of Cost-Sharing for Children's Health*, 75 PEDIATRICS 952 (1985).

*But see* Greenwald, *HMO membership, Copayment, and Initiation of Care for Cancer: a Study of Working Adults*, 77 AM. J. PUB. HEALTH 461 (1987) (1.25 month delay from suspicion to definitive diagnosis and .83 month delay from diagnosis to treatment in patients with copayment); Wallen, Roddy & Meyers, *Male-Female Differences in Mental Health Visits under Cost-Sharing*, 21 HEALTH SERV. RES. 341 (1986) (copayment may reduce necessary visits).

The PPS encourages the hospitalization of patients with minor short-term illnesses for whom DRG payment is likely to exceed costs. *See supra* note 44. These are precisely the patients who are likely to be deterred from seeking hospitalization if they must pay a deductible and co-insurance. Thus, the existence of co-insurance and a deductible complement the cost-saving activity of the PPS. Eliminating them would be foolish from a cost-containment point of view.

114. No enforcement of the provisions has occurred "because waivers are viewed as 'victimless crimes' and are low priorities for an understaffed government enforcement team." Harvey Yampolsky, Assistant General Counsel, Department of Health and Human Services, *HOSPITALS* (May 5, 1988) at 54. *See also infra* note 116.

115. Letter from Richard P. Kusserow, Inspector General — HHS to Stephen S. Trott (Assistant Attorney General) (April 17, 1985); and letter from Stephen S. Trott to Richard P. Kusserow (October 30, 1985) (discussing waiver of co-payments and possibility of immunization from prosecution) *reprinted in* MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW 49-59 (1986).

116. A U.S. Attorney in Jackson, Mississippi, threatened to prosecute the Biloxi Re-

coming from the executive branch, one hospital attempted to use the judicial branch to enjoin another hospital from waiving co-payments. The court declined to issue an injunction, stating it was not appropriate to "enjoin the commission of a crime," and that the court had to defer to the executive and legislative branches of government.<sup>117</sup> The Seventh Circuit Court of Appeals recently upheld the trial court's denial of an injunction.<sup>118</sup>

Enforcement of the Fraud and Abuse statutes is frequently a function of the discretion of the local U.S. Attorney and unpredictably turns on parochial considerations.<sup>119</sup> Complaints from competitors or persons excluded from the incentive program or joint venture may prompt investigation.<sup>120</sup> Needless to say, the stakes are very high. In a recent case, the defendant was sentenced to six months in jail and ordered to pay a one hundred thousand dollar fine, although the indictment only alleged sixteen hundred dollars worth of services.<sup>121</sup>

The passage of MMPPPA creates concurrent civil authority in the Secretary of HHS to issue regulations specifying legal payment arrangements.<sup>122</sup> This new authority should help eliminate the uncertainty that accompanies the current statute and result in a nation-wide policy towards innovative reimbursement arrangements.

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gional Medical Center for waiving deductibles of Medicare beneficiaries. *HEALTH CARE FINANCIAL MANAGEMENT* 7 (July 1987). The hospital elected to discontinue the program rather than face prosecution. *Id.* The U.S. Attorney involved subsequently requested guidelines from the Department of Justice on handling such cases, but has yet to receive any response. 16 *HEALTH POLICY WEEK* 4 (Oct. 19, 1987).

117. *West Allis Memorial Hosp. v. Bowen*, Civil Action No. 87-C-0053 (E.D. Wis. May 28, 1987). *See also* 16 *HEALTH POLICY WEEK* 3 (Feb. 16, 1987).

118. *West Allis Memorial Hosp. v. Bowen*, No. 87-1974 (7th Cir. July 14, 1988).

119. This point was made quite explicitly by Steven Trott, the Assistant Attorney General:

The Department of Justice does not have the resources to prosecute every violation of the criminal code. A determination to prosecute represents a policy judgment that the fundamental interests of society require the application of the criminal laws to a particular set of circumstances, recognizing both that serious violations of federal law must be prosecuted and that prosecution entails profound consequences for the accused whether or not a conviction ultimately results. In almost all circumstances, this discretion is exercised on a case by case basis.

Letter from Steven S. Trott to Richard P. Kusserow (Oct. 30, 1985) in *MEDICARE FRAUD AND ABUSE: UNDERSTANDING THE LAW* 58 (1986).

120. In *United States v. Greber*, discussed subsequently, an anonymous tip (eventually revealed as originating from a competitor) resulted in the indictment and conviction of Dr. Greber. Gregory P. Miller (prosecutor in *Greber*), *The Greber Case*, in *MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW* 13 (1986).

121. *Id.* at 16.

122. Medicare and Medicaid Patient and Program Protection Act, Pub. L. 100-93 § 14, 101 Stat. 680, 697 (1987).



## V. RATIONALE FOR THE FRAUD AND ABUSE STATUTE

Two strands of reasoning form the foundation for the Fraud and Abuse statute. The more obvious one is a desire to avoid waste and increased cost. In fact, the legislative history is replete with references to profiteering and the taxpayer as victim.<sup>123</sup> The definition of abuse is a direct outgrowth of this perspective.<sup>124</sup> Indeed, much of the Medicare Intermediary and Carriers Manuals are concerned with detecting and preventing over-utilization and unnecessary medical care.<sup>125</sup>

The second strand of reasoning is captured by the definition of fraud.<sup>126</sup> In the Intermediary Manual, kickbacks are dealt with under the fraud provisions.<sup>127</sup> Although kickbacks have the potential to increase the cost of the Medicare program, that is not the fundamental issue.<sup>128</sup> Rather, the existence of the payment per se is an affront to the character of the Medicare program.<sup>129</sup> The desire to have an honestly run program is echoed throughout the legislative history, and was cast in sharp words by the Seventh Circuit in *United States v. Ruttenberg*<sup>130</sup>

*[I]t should be noted that the law does not make increased cost to the government the sole criterion of corruption. . . . Nor need Congress have spelled out duties, beyond the duty of avoiding receipt and payment of kickbacks. A compassionate people have established and paid for a program of care for the aged among them. Nothing in that program gave to its empowered and privileged conductors carte blanche to manipulate within its fixed costs*

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123. "In addition, it is the American taxpayer who pays the price for the misuse of funds in such federally financed programs." 123 Cong. Rec. H30287 (statement of Rep. Thone); "The taxpayers suffer because they expect the money they have put into the system will be used for the purposes it was intended. But instead, the money is abused and the taxpayers are cheated." 123 Cong. Rep. S31770 (statement of Sen. Dole).

124. "Abuse" means provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary cost to the Medicaid program. 42 C.F.R. § 455.2 (10-1-86 Edition).

125. See *infra* note 290.

126. "Fraud" means an intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law. 42 C.F.R. § 455.2 (10-1-86 edition).

127. See *infra* note 290.

128. See generally *infra* notes 185-86, 262-63 and accompanying text.

129. *Id.*

130. 625 F.2d 173, 177 (7th Cir. 1980).

...<sup>131</sup>

The statute allows for lowered costs through normal business arrangements by exempting discounts, so long as they are properly disclosed and reflected in the cost.<sup>132</sup> The report of the House Ways and Means Committee noted that Congress wanted to "encourage providers to seek discounts as a good business practice which results in savings to [the] Medicare and Medicaid program."<sup>133</sup> However, not all "good business practices" are acceptable.<sup>134</sup> Even if a physician incentive program lowered costs to the Medicare program, the structure of the arrangement could nevertheless constitute a fraud.<sup>135</sup>

Whether the preceding analysis should continue to apply now that the PPS is the law is a complex question. Certainly, abuse as a rationale for the statute has lost most of its viability because there is relatively little the hospital can do to increase the cost to the Medicare program.<sup>136</sup> Unnecessary care costs the hospital money, and not the government. Fraud as a rationale was also attenuated by the introduction of the PPS. After the introduction of the PPS, payments to physicians might be for quite legitimate purposes.<sup>137</sup> The difficulty is that the PPS encourages hospitals to experiment with ways to maximize cost-effective care, thus increasing the profit to the hospital.<sup>138</sup> Inefficient hospitals will lose money on the fixed-rate DRG payment, and either reform themselves or go out of business.<sup>139</sup> At the very least, hospitals are expected to manipu-

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131. *Id.* (emphasis added) See *infra* notes 256-65 and accompanying text for a discussion of *Ruttenberg*.

132. Pub. L. No. 95-142, 91 Stat. 1175, 1182 codified at 42 U.S.C. § 1395nn(b)(3)(A) (1982).

133. H.R. REP. NO. 231, 92d Cong., 2d Sess. (1977), reprinted in 1977 U.S. CODE CONG. AND ADMIN. NEWS, 3039, 3056.

134. See *infra* notes 156-57 and accompanying text.

135. This is a paradoxical result given the recent emphasis on cost containment and the incentives faced by the hospital under prospective reimbursement. However, Congress also enacted § 9313(c) of OBRA. See *supra* note 75. This statute targets physician incentive plans and imposes civil money penalties for offering, soliciting or receiving payment as an inducement to reduce or limit services to Medicare or Medicaid patients. So long as the incentive program aims at efficiency and not limitation of services, it should not represent a violation of this statute.

136. See *supra* notes 44 and 83 for a description of the ways the system can be cheated or manipulated.

137. It turns out to be difficult to discriminate between payment for referrals and payment for a legitimate business purpose, especially since ensuring a flow of referrals is a legitimate business purpose in itself. The appropriate test, if the policy is to discriminate payment for legitimate services from payment for referrals, is that of *United States v. Lipkis*, 770 F.2d 1447 (9th Cir. 1985). See *infra* note 358.

138. See *supra* notes 37-40, 43.

139. See *supra* note 42.

late the structure of health care delivery within the fixed costs; the precise result which the Seventh Circuit in *Ruttenberg* understood the Fraud and Abuse statute as designed to prevent.<sup>140</sup>

Is there, then, any foundation for the fraud rationale, and therefore for the Fraud and Abuse statute as a whole? One might begin with those who have criticized physician involvement in joint ventures and incentive programs. Critics point to the dangers of self-referral in inflating costs and providing unnecessary care.<sup>141</sup> Some evidence supports their objections.<sup>142</sup> Others point to the conflict of interest implicit in such entrepreneurial arrangements.<sup>143</sup> The financial self-interest of physicians encourages participation in such arrangements, but there is widespread concern about the effect of such arrangements on physician ethics and the nature of professional duty.<sup>144</sup>

140. See *supra* note 131 and *infra* notes 256-65 and accompanying text.

141. Relman, *Dealing with Conflicts of Interest*, 313 NEW ENG. J. MED. 749 (1985); FOR PROFIT ENTERPRISE IN HEALTH CARE 151 (B. Gray, ed., 1986).

142. The Institute of Medicine concluded that:

Empirical studies do not yet exist on the impact on patient care decisions of new forms of physician entrepreneurship or of incentive bonus plans. However, the survey evidence that does exist is adequate to confirm the common-sense conclusion that investments and economic arrangements that reward physicians financially for making certain patient care decisions (ordering lab tests) will bias physicians in favor of making such decisions.

FOR PROFIT ENTERPRISE IN HEALTH CARE 158 (B. Gray, ed., 1986).

A study of laboratory test usage that compared physician owners and nonowners found that physician owned laboratories were responsible for between 35-375% more laboratory tests per recipient than were non-owners. Higher aggregates were found in physician owned laboratories in both the number of tests per referred recipient and the average payment per recipient. MEDICAL SERVICES ADMINISTRATION, MEDICAID MONITORING SECTION, STATE OF MICHIGAN DEPARTMENT OF SOCIAL SERVICES, UTILIZATION OF MEDICAID LABORATORY SERVICES BY PHYSICIANS WITH/WITHOUT OWNERSHIP INTEREST IN CLINICAL LABORATORIES, 1981.

See also Luft, *Economic Incentives and Clinical Decisions* in THE NEW HEALTH CARE FOR PROFIT: DOCTORS AND HOSPITALS IN A COMPETITIVE ENVIRONMENT 103 (B. Gray ed., 1983).

143. Relman, *Dealing with Conflicts of Interest*, 313 NEW ENG. J. MED. 749 (1985).

144. No system of reimbursement is immune from incentives that may run counter to the physicians' fiduciary duty. FOR PROFIT ENTERPRISE IN HEALTH CARE 153 (B. Gray, ed., 1986). Fee for service rewards overutilization and unnecessary care. See *supra* notes 28 and 39. However, the growing amount of physician entrepreneurialism has aroused concern about its effect on the quality of care and the nature of medical professionalism. See *infra* notes 148-51. The Institute of Medicine has noted:

All compensation systems — from fee-for-service to capitation or salary — present some undesirable incentives for providing too many services, or too few. No system will work without some degree of integrity, decency, and ethical commitment on the part of professionals. Inevitably, we must presume some underlying professionalism that will constrain the operation of unadulterated self-interest. The question is not to find a set of incentives that is beyond criticism, but to seek arrangements that encourage the physician to function as a

The AMA has concluded that physicians may ethically invest in facilities and share profits with hospitals or pharmaceutical or equipment manufacturers, provided that the arrangements are lawful, do not lead to overutilization or improper care of patients, are disclosed in advance to patients, and do not involve profit sharing with institutions being paid under the DRG system.<sup>145</sup> The AMA has reaffirmed that physicians must put the needs of their patients above economic self-interest, but has concluded that participation in such enterprises was not necessarily unethical.<sup>146</sup> The American College of Physicians, however, has concluded that "the physician must avoid any personal commercial conflict of interest that might compromise his loyalty and treatment of the patient."<sup>147</sup>

Criticisms of physician entrepreneurialism usually draw out the distinction that medicine is a profession, rather than a business,<sup>148</sup>

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professional, in the highest sense of that term. Certain changes that are occurring in our increasingly entrepreneurial health care system could undermine patients' trust in their physicians and society's trust in the medical profession. For those who believe that the professionalism of the physician is an essential element in ensuring the quality of health care and the responsiveness of institutions to the best interests of patients, an important question is whether that professionalism will be undermined by the increasingly entrepreneurial health care market in which physicians play a major part.

FOR PROFIT ENTERPRISE IN HEALTH CARE 153 (B. Gray ed., 1986).

145. Reports of the Judicial Council of the American Medical Association, *Conflict of Interest — Guidelines* 253 J.A.M.A. 2425 (1985). See also *infra* note 150.

146. Specifically, the AMA noted, "physician ownership interest in a venture with the potential for abuse is not in itself unethical." *Id.* For an overview of the AMA's evolving position with respect to physician entrepreneurialism, see Veatch, *Ethical Dilemmas of For-Profit Enterprise in Health Care* in *THE NEW HEALTH CARE FOR PROFIT: DOCTORS AND HOSPITALS IN A COMPETITIVE ENVIRONMENT* 125 (B. Gray ed., 1983).

147. Ad Hoc Committee on Medical Ethics of the American College of Physicians, *History of Medical Ethics, The Physician and the Patient, the Physician's Relationship to Other Physicians, the Physician and Society*, 101 *ANNALS INT. MED.* 129 (1984).

148. The distinction is concisely stated as follows:

The contradiction between professionalism and the rule of the market is longstanding and unavoidable. Medicine and other professions have historically distinguished themselves from business and trade by claiming to be above the market and pure commercialism. In justifying the public's trust, professionals have set higher standards of conduct for themselves than the minimal rules governing the marketplace and maintained that they can be judged under those standards only by each other, not by laymen. The ideal of the market presumes the "sovereignty" of consumer choices; the ideal of a profession calls for the sovereignty of its members' independent, authoritative judgment. A professional who yields too much to the demands of clients violates an essential article of the professional code: Quacks, as Everett Hughes once defined them, are practitioners who continue to please their customers but not their colleagues. This shift from clients to colleagues in the orientation of work, which professionalism demands, represents a clear departure from the normal rule of the market.

P. STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 23 (1982).

which is bound by a code of ethics.<sup>149</sup> One participant in the Institute of Medicine Committee on Implications of For-Profit Enterprise in Health Care noted:

Physicians have always been in the business of trying to make a profit. Indeed, medicine would not have survived and prospered were that not the case, for it would otherwise have become a hobby pursued solely by persons of independent means. Nonetheless, medicine has been—and should remain—something more than a business. It should continue to be a profession guided by an ethical code whose ideals diverge from the stan-

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149. See generally L. Kass, *Professing Medically: The Place of Ethics in Defining Medicine in TOWARD A MORE NATURAL SCIENCE: BIOLOGY AND HUMAN AFFAIRS* 211 (1985). Consider also three statements of the nature of professionalism, ranging over almost 800 years: "Historically, there are three ideas involved in a profession: organization, learning, i.e., pursuit of a learned art, and a spirit of public service. These are essential. A further idea, that of gaining a livelihood is involved in all callings. It is the main if not the only purpose in the . . . money-making callings. In a profession it is incidental." R. POUND, *THE LAWYER FROM ANTIQUITY TO MODERN TIMES* 6 (1953).

In about 1190, Maimonides' Prayer admonished "Do not allow thirst for profit, ambition for reknown and admiration, to interfere with my profession for these are the enemies of truth and can lead me astray in the great task of attending to the welfare of your creatures." House of Delegates of the American Medical Association, *Conflict of Interest — Guidelines: Report of the Judicial Council of the American Medical Association* (1984).

William Osler warned "Always seek your own interests, make of a high and sacred calling a sordid business, regard fellow creatures as so many tools of trade, and, if your heart's desire is for riches they may be yours; but you will have bartered away the birthright of a noble heritage, traduce the physician's well deserved title of the Friend of Man, and falsified the best traditions of an ancient and honorable guild." W. Osler, *Teacher and Student*, in *AEQUANIMITAS WITH OTHER ADDRESSES* 40-41 (1932). There is thus a strong historical foundation for questioning physician entrepreneurialism on ethical grounds. Indeed, the concept of a conflict of interest requires the existence of a profession to which one owes certain obligations. See *supra* note 148. See also *Editorial*, 31 *PERSPECTIVES IN BIOLOGY AND MED.* 157 (Winter, 1988).

However, the view that business is devoid of ethics has been criticized. Shore & Levinson, *On Business and Medicine*, 313 *NEW ENG. J. MED.* 319 (1985). Yet, consider the legendary response of William H. Vanderbilt, when a reporter asked him why he did not consider public convenience in the running of his trains. "The public be damned," he replied. "I'm working for my stockholders."

Consider also this argument, typical of the Law and Economics approach:

A firm may also find it advantageous to violate a law deliberately and pay the penalty for the same reason that an individual in some cases may prefer to breach a contract and pay damages. Because the gains from breach or violation presumably exceed the social costs (as reflected in the penalty), compliance with the statute or contract is undesirable from a personal as well as a social perspective. The optimal level of violations of law, therefore, is not zero.

Fischel, *The Corporate Governance Movement*, 35 *VAND. L. REV.* 1259, 1268-71 (1982).

See also *Interview with Milton Friedman*, *PLAYBOY MAG.* Feb. 1973, at 59, reprinted in *R. HAMILTON, CORPORATIONS* 524 (1986).

dards of the marketplace.<sup>150</sup>

This distinction was one that was respected and followed by the drafters of the Fraud and Abuse statute: the 1977 amendments target "certain practices that [had] long been regarded by professional organizations as unethical . . ." <sup>151</sup> Furthermore, the 1977 amendments provided that discounts, so long as properly disclosed, were exempt.<sup>152</sup> This "good business practice"<sup>153</sup> is a rather narrow provision; not all good business practices are allowed.<sup>154</sup> Professional ethics rather than the standards of the marketplace set the level of legality.<sup>155</sup>

HHS appears to have lost sight of the distinction between a profession and a business, particularly when it suggested, that "the intent of these provisions is not to penalize individuals or entities participating in legitimate business transactions."<sup>156</sup> It is clearly a

150. Capron, *Physicians as Entrepreneurs: Drawing the Bottom Line*, U.S.C. NEWS AND FEATURES, 0886043 p. 4.

151. H. R. REP. NO. 393, 95th Cong., 1st Session. reprinted in 1977 U.S. CODE CONG. AND ADMIN. NEWS 3039, 3055.

152. Pub. L. No. 95-142, 91 Stat. 1175, 1182 (codified at 42 U.S.C. § 1395nn(b)(3)(A) (1982)).

153. See *supra* note 133.

154. See *infra* notes 156-57 and accompanying text.

155. See *infra* note 186 and accompanying text.

156. Letter from Don Nicholson, Director, Office of Program Integrity, HHS to Hon. Leon Panetta (Oct. 30, 1978) in S. Teplitzky, *Avoiding Fraud and Abuse Problems in Joint Ventures*, 4 HEALTHSPAN 17 (Jan. 1987).

The Federal Trade Commission's Bureaus of Competition, Consumer Protection, and Economics ("FTCB") seem to have missed the point as well. Concerned solely with the cost to the program, the FTCB ignores entirely the legislative history of the statute. See *infra* note 186. The arguments against physician entrepreneurialism are also ignored. See *supra* notes 141-55 and accompanying text. The FTCB bases its assessment solely on competition and cost-saving. Comments of the Federal Trade Commission's Bureaus of Competition, Consumer Protection and Economics concerning the Development of Regulations Pursuant to the Medicare and Medicaid Anti-Kickback statute.

FTCB also argues that physicians should be able to refer patients to facilities in which they have an ownership interest, and consequently derive income from the referral. *Id.* There are a variety of sound reasons for allowing some forms of equity interest, but FTCB argues, in an extraordinary fashion, that: 1) practitioners will be best able to identify particular health care needs; and 2) investment interest will lead to a stronger, more permanent working relationship, and consequently higher quality care. *Id.* Efficient capital market theory eliminates the first point — anyone can identify the need. If physicians are the only ones to invest, it is because by referring only to themselves they ensure a higher than expected rate of return. Far from increasing competition, the FTCB will foreclose it. As for the second point, other things being equal, one is more likely to refer to an inefficient or inadequate facility when one has an ownership interest in it.

Finally, FTCB acknowledges that allowing referrals to facilities where a physician has an ownership interest may increase the risk of unnecessary, inappropriate, or more expensive care. *Id.* However, FTCB argues that arrangements that create this risk are common in the health care field. *Id.* Although conflicts of interest are not uncommon (See

legitimate business transaction to pay a commission for the referral of business. Providing customers is, after all, what business arrangements are supposed to accomplish. It is just as clearly a statutory violation when it involves patients and Medicare money.<sup>157</sup>

Although the government has chosen to contain health care costs through competition, the limits of that mandate are not straightforward. Unchecked physician entrepreneurialism will certainly alter the character of the medical profession.<sup>158</sup> The legislative history of the Fraud and Abuse statutes clearly shows deference to the medical profession's determination of ethical conduct.<sup>159</sup> At the same time, claims of professional privilege or ethics generally are accorded little recognition,<sup>160</sup> particularly as they

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*infra* note 147), this argument is a touch disingenuous. The whole point of the process of regulation is to confront such conflicts, not celebrate them.

157. See *supra* note 105. See also: Teplitzky & Yampolsky, *Historical Perspective on Joint Ventures*, in *MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW* 102-103 (1986).

Congress has continued to foreclose "legitimate business transactions" by physicians. Investing in a Home IV (IntraVenous) therapy provider is now prohibited if the physician refers to the provider. 17 HEALTH POLICY WEEK 1 (July 4, 1988). Representative Stark, Chairman of the House Ways & Means Health Subcommittee wants to ban all such business interests by physicians who refer Medicare patients. *Id.* See H.R. 5198, 100th Cong., 2d Sess. (1988) (Ethics in Patient Referrals Act).

158. Relman, *Practicing Medicine in the New Business Climate*, 316 NEW ENG. J. MED. 1150 (1987); Fuchs, *The Counterrevolution in Health Care Financing*, 316 NEW ENG. J. MED. 1154 (1987); Relman, *Dealing with Conflicts of Interest*, 313 NEW ENG. J. MED. 749 (1985); Relman, *The new Medical — Industrial Complex*, 303 NEW ENG. J. MED. 963 (1980); *Physicians and Entrepreneurism in Health Care*, in *FOR PROFIT ENTERPRISE IN HEALTH CARE* (B. Gray, ed., 1986).

159. See *infra* note 169.

160. Antitrust law has been the principal weapon against professionalism. See e.g., *Am. Medical Ass'n*, 94 F.T.C. 701 (1979) affirmed as modified, 638 F.2d 443 (2d Cir. 1980), affirmed by an equally divided Court, 455 U.S. 676 (1982); *Goldfarb v. Virginia State Bar*, 421 U.S. 773 (1975); *Nat'l Soc'y of Professional Eng'g v. United States*, 435 U.S. 679 (1978); *Arizona v. Maricopa County Medical Soc'y*, 457 U.S. 332 (1981).

The language of these opinions often contain suggestions that ethical restraints might be allowed despite their anticompetitive effect, because of the nature of a profession. A footnote in *Goldfarb* states:

It would be unrealistic to view the practice of professions as interchangeable with other business activities, and automatically to apply to the professions antitrust concepts which originated in other areas. The public service aspect, and other features of the profession, may require that a particular practice, which could properly be viewed as a violation of the Sherman Act in another context, be treated differently.

*Goldfarb*, 421 U.S. at 788.

The Court had previously recognized "that in some instances the State may decide that 'forms of competition usual in the business world may be demoralizing to the ethical standards of a profession.'" *United States v. Oregon State Medical Soc'y*, 343 U.S. 326, 336 (1952).

A concurrence in *Professional Engineers* noted "that there may be ethical rules which

raise issues of antitrust law.<sup>161</sup> A variety of ill effects may attend an increase in physician entrepreneurialism, although this is controversial.<sup>162</sup> The Fraud and Abuse statute has restrained physi-

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have a more than *de minimis* anticompetitive effect and yet are important in a profession's proper ordering. . . ." *Professional Engineers*, 435 U.S. at 700, 701.

Significantly, despite these reservations, restraints that serve ethical purposes have been attacked under antitrust law as well. *Koefoot v. Am. College of Surgeons*, 652 F. Supp. 882 (N.D. Ill. 1986). Although the restraint was upheld, the court refused to recognize either a defense of concern for patient welfare or a claim that a patient care motivation confers a procompetitive advantage on the "marketplace." *Koefoot*, 652 F. Supp. at 900.

On balance, the black letter law is succinctly stated as follows: "Antitrust law does not, as a general rule tolerate competitor collaboration simply because it serves worthy purposes, professional or otherwise. Instead the legal inquiry . . . focuses on whether a particular collaboration is compatible with the maintenance of competition in the market as a whole." Havighurst, *Doctors and Hospitals: An Antitrust Perspective on Traditional Relationships*, 1984 DUKE L.J. 1095. *But see Note, Rethinking the Rule of Reason: From Professional Engineers to NCAA*, 1984 DUKE L.J. 1297.

161. The FTC has previously indicated that professional organizations may adopt reasonable ethical codes designed to protect the public. American Academy of Ophthalmology, 101 F.T.C. 1018 (1983) (advisory opinion). However, ethical canons that prohibit participation in entrepreneurial activity might raise antitrust issues, if deemed to be anticompetitive.

Such self-regulatory activity serves legitimate purposes and in most cases can be expected to benefit, rather than injure, competition and consumer welfare. However, private ethics restrictions on competitive conduct that are broader than necessary to protect the public are suspect under the antitrust laws. For example, a reasonable ethical rule that was designed to prevent deception and that required physicians to disclose potential conflicts of interest (such as equity interests in health care facilities to which physicians refer patients) probably would not raise antitrust problems. But if an ethics rule prohibited physicians from having any ownership interest in a facility to which they referred patients, antitrust questions would be raised, since the rule would probably be overly broad as a means of preventing deceptive behavior or other abuses.

Costilo, *Antitrust Enforcement in Health Care: Ten years after the AMA Suit*, 313 NEW ENG. J. MED. 901 (1985). Contrast this with the editor of the New England Journal of Medicine who wrote,

The kind of freewheeling business competition envisioned by antitrust lawyers is simply not compatible with the ethical obligations of doctors to their patients. . . . The patient's (*i.e.*, "consumer's") interest is best served by unbiased professional medical advice that can help guide him through the complex medical "market," but physicians who have strong economic ties to particular medical facilities, services, and products are not in the best position to give such advice. . . . It is only when physicians act as 'double agents' that ethical questions arise — when they serve as agents for their patients and as agents for businesses seeking to sell products and services to their patients.

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

162. Proponents of physician entrepreneurialism point to the fact that conflicts of interest are ubiquitous. For a cross section of such opinions, *see generally Letters, Conflicts of Interest and the Physician Entrepreneur*, 314 NEW ENG. J. MED. 250-53 (1986). For example, the basic principle of a capitated or gate keeper arrangement is to reward physicians for denying care. *Id.* Others point to the fact that nonphysicians will capture the "market" and then dictate the quality and cost of medical care without concern for



cian entrepreneurialism in the past by its vagueness.<sup>163</sup> Whether the statute should continue to do so in the future requires the weighing of the aforementioned ethical concerns against the trend to treat health care as a market like any other.<sup>164</sup>

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professional values. *Id.* In fact, individual clinical decisions are increasingly influenced by non-physicians. Economic incentives are only one form of pressure brought to bear in the name of cost-containment. Caper, *Solving the Medical Care Dilemma*, 318 NEW ENG. J. MED. 1535 (1988). See also Relman, *Salaried Physicians and Economic Incentives*, 319 NEW ENG. J. MED. 784 (1988); Bock, *The Pressure to Keep Prices High at a Walk-in Clinic: A Personal Experience*, 319 NEW ENG. J. MED. 785 (1988); Scovern, *Hired Help: A Physician's Experiences in a For-Profit Staff-Model HMO*, 319 NEW ENG. J. MED. 787 (1988).

163. S. REP. NO. 109, 100th Cong., 1st Sess. 27, reprinted in 1987 U.S. CODE CONG. & ADMIN. NEWS 682, 707 (1987).

164. Both Federal reimbursement and antitrust policy begin with the proposition that health care is a competitive industry to be guided by market forces. See *supra* notes 36-38. See also *supra* note 146. Marketing and advertising is one hallmark of a competitive industry. Cf. Strum, *Innovative Advertising Becoming Vital in an Increasingly Competitive Market*, 18 MODERN HEALTHCARE 33 (June 10, 1988). Yet, consider the Supreme Court's treatment of commercial speech by the professions. *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976); *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977); *American Medical Ass'n*, 94 F.T.C. 701 (1979) *affirmed as modified*, 638 F.2d 443 (2d Cir. 1980), *affirmed by an equally divided court*, 455 U.S. 676 (1982). The Court was quite cautious in extending the protections of the First Amendment to professional advertising. The Courts' hesitation, as it readily admits, is due to the nature of a profession. "Physicians and lawyers, for example, do not dispense standardized products; they render professional services of almost infinite variety and nature, with the consequent enhanced possibility for confusion and deception if they were to undertake certain kinds of advertising." *Virginia State Board of Pharmacy*, 425 U.S. 748, 773 (1976) (emphasis in original).

A concurrence noted,

that the advertisement of professional services carries with it quite different risks from the advertisement of standard products. The Court took note of this in *Semler, v. Oregon State Board of Dental Examiners*, 294 U.S. 608, 612 (1934) in upholding a state statute prohibiting entirely certain types of advertisement by dentists. The legislature was not dealing with traders in commodities, but with the vital interest of public health, and with a profession treating bodily ills and demanding different standards of conduct from those which are traditional in the competition of the market place. The community is concerned with the maintenance of professional standards which will insure not only competency in individual practitioners, but protection against those who would prey upon a public peculiarly susceptible to imposition through alluring promises of physical relief. And the community is concerned in providing safeguards not only against deception, but against practices which would tend to demoralize the profession by forcing its members into an unseemly rivalry which would enlarge the opportunities of the least scrupulous.

*Virginia State Board of Pharmacy*, 425 U.S. at 774, 775 (Burger, concurring).

A dissent by Justice Rehnquist criticized the holding.

The Court concedes that legislatures may prohibit false and misleading advertisements, and may likewise prohibit advertisements seeking to induce transactions which are themselves illegal. In a final footnote the opinion tosses a bone to the traditionalists in the legal and medical professions by suggesting that

## Finally, it should be remembered that the Fraud and Abuse stat-

because they sell services rather than drugs the holding of this case is not automatically applicable to advertising in those professions. . . .

Nothing we know about the acquisitive instincts of those who inhabit every business and profession to a greater or lesser extent gives any reason to think that such persons will not do everything they can to generate demand for these products in much the same manner and to much the same degree as demand for other commodities has been generated.

*Virginia State Board of Pharmacy*, 425 U.S. at 785, 788, 789. (Rehnquist, dissenting).

The Court took a further step in extending first amendment protection to commercial speech by professionals in *Bates*, 433 U.S. 350 (1977), despite misgivings about the misleading effects of advertising.

Advertising by physicians has also been upheld. See *American Medical Ass'n*, 94 F.T.C. 701 (1979) *affirmed as modified*, 638 F.2d 443 (2d Cir. 1980), *affirmed by an equally divided Court*, 455 U.S. 676 (1982). However, the Court has recently held that commercial speech relating to legal conduct may be banned. *Posadas de Puerto Rico Assocs. v. Tourism Co. of Puerto Rico*, 478 U.S. 328 (1986). This decision raises the possibility that the earlier closely split decisions on "professional-commercial" speech might be reexamined.

Just prior to publication, the Supreme Court decided *Shapero v. Kentucky Bar Association*, 108 S.Ct. 1916 (1988), upholding by a 6-3 vote petitioner's constitutional right to mail targeted direct solicitation to potential clients. The dissent sounds on the same themes as previously noted:

One distinguishing feature of any profession, unlike other occupations that may be equally respectable, is that membership entails an ethical obligation to temper one's selfish pursuit of economic success by adhering to standards of conduct that could not be enforced, either by legal fiat or through the discipline of the market.

Like physicians, lawyers are subjected to heightened ethical demands on their conduct towards those they serve. These demands are needed because market forces, and the ordinary legal prohibitions against force and fraud, are simply insufficient to protect the consumers of their necessary services from the peculiar power of the specialized knowledge that these professionals possess.

*Shapero*, 108 S. Ct. 1916, 1929-30 (O'Connor, dissenting).

The heart of the dissent implicates physician advertising, physician entrepreneurialism, and the proper role of the market in health care. It is neatly stated as follows: "[t]he roots of the error in our attorney advertising cases are a defective analogy between professional services and standardized consumer products. . . ." *Id.* at 1928. If professional services are not analogous to consumer products, ethical restraints would be both necessary and appropriate in tempering the "selfish pursuit of economic success." *Id.* at 1929. As Justice O'Connor notes,

[t]here are sound reasons to continue pursuing the goal that is implicit in the traditional view of professional life. Both the special privileges incident to membership in the profession and the advantages those privileges give in the necessary task of earning a living are means to a goal that transcends the accumulation of wealth. That goal is public service. . . ."

*Id.* at 1929-30. Far from being a conspiracy against the laity, as George Bernard Shaw labeled all professions, this view of professionalism depends heavily on the character and integrity of its professionals. Whether they can remain worthy of such regard, when subjected to tremendous incentives to act otherwise, is another matter.

For a medical perspective on the dangers and difficulties of physician advertising, see Margo, *Selling Surgery*, 314 *NEW ENG. J. MED.* 1575 (1986); Read & Ratzan, *Yellow Professionalism: Advertising by Physicians in the Yellow Pages*, 316 *NEW ENG. J. MED.*

ute was designed to safeguard the integrity of the Medicare program and to protect patients and taxpayers from profiteering and abusive practices.<sup>165</sup> The statute was never intended to affect the structure of health care delivery in isolation from these goals. The Fraud and Abuse statute was never an end in itself—merely a means to another end.

## VI. HISTORY OF THE FRAUD AND ABUSE FEDERAL STATUTE

### A. *The 1972 Statute*

Congress originally enacted the Fraud and Abuse provisions as part of the Social Security Amendments of 1972.<sup>166</sup> The statute explicitly listed the prohibited practices to be kickbacks, bribes, or rebates.<sup>167</sup> No specific intent was required, and violation was a misdemeanor.<sup>168</sup> The statute targeted both increased cost to the Medicare program and unethical behavior.<sup>169</sup>

### B. *The 1977 Amendments*

Congress subsequently broadened the statute through the Medicare and Medicaid Antifraud and Abuse Amendments.<sup>170</sup> The same evils of increased cost and unethical behavior that were the moving force behind the 1972 Fraud and Abuse statute are again omnipresent.<sup>171</sup> The statute now included the solicitation or receipt of *any* remuneration, whether direct or indirect, overtly or covertly, in cash or in kind.<sup>172</sup> Violation of the statute became a felony, subject to increased penalties.<sup>173</sup> Two exceptions to the statute were created. Discounting was encouraged as a "good busi-

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1315 (1987). Advertising prescription drugs directly to the public poses similar dilemmas. See Cohen, *Direct to the Public Advertisement of Prescription Drugs*, 318 *NEW ENG. J. MED.* 373 (1988).

165. See *infra* notes 169, 177-80, 184-87 and accompanying text.

166. Pub. L. No. 92-603 § 242(b), 86 Stat. 1329, 1419 (1972).

167. *Id.*

168. *Id.*

169. H.R. REP. NO. 231, 92d Cong., 2d Sess., reprinted in 1972 U.S. CODE CONG. AND ADMIN. NEWS, 4989, 5093. The legislative history shows that Congress was concerned about "certain practices which have long been regarded by professional organizations as unethical, as well as unlawful in some jurisdictions, and which contribute appreciably to the cost of the medicare and medicaid programs." *Id.*

170. Pub. L. No. 95-142 § 4, 91 Stat. 1175 (1977).

171. H.R. REP. NO. 393, 95th Cong., 1st Sess., reprinted in 1977 U.S. CODE CONG. AND ADMIN. NEWS 3039, 3047, 3055. Compare *supra* note 169 on the 1972 Fraud and Abuse Statute with *infra* notes 182-86 and accompanying text on the 1977 Amendments.

172. 42 U.S.C. § 1396h(b)(1) (1977).

173. *Id.*

ness practice"<sup>174</sup> that decreased costs to the Medicare program.<sup>175</sup> Payments pursuant to *bona fide* employment relationships were the second exemption.<sup>176</sup>

The legislative history of the bill reveals that the problem of fraud and abuse was thought to be a generalized one. The House Ways and Means Committee issued a report stating that the problem of fraud and abuse was pervasive.<sup>177</sup> The most flagrant abuses were noted in Medicaid mills<sup>178</sup> which inflated billings through a variety of practices.<sup>179</sup> The mills were the most egregious offend-

174. H.R. REP. NO. 393, 95th Cong., 1st Sess., *reprinted in* 1977 U.S. CODE CONG. AND ADMIN. NEWS, 3039, 3056.

The bill would specifically exclude the practice of discounting or other reductions in price from the range of financial transactions to be considered illegal under Medicare and Medicaid, but only if such discounts are properly disclosed and reflected in the cost for which reimbursement could be claimed. The committee included this provision to ensure that the practice of discounting the normal course of business transactions would not be deemed illegal. In fact, the committee would encourage providers to seek discounts as a good business practice which results in savings to Medicare and Medicaid program costs.

*Id.*

175. 42 U.S.C. § 1396h(b)(3)(A) (1982).

176. 42 U.S.C. § 1396h(b)(3)(B) (1982).

177. H.R. REP. NO. 393, 95th Cong., 1st Sess., *reprinted in* 1977 U.S. CODE CONG. AND ADMIN. NEWS 3039, 3047. Other commentators noted such activities were not limited to one class of providers or treatment setting. 123 Cong. Rec. S31770 (statement of Sen. Dole). *See also infra* note 185.

178. A Medicaid mill derives its primary business from treating welfare patients. Such facilities are usually operated out of storefronts. In New York, seven percent of Medicaid physicians received fifty percent of Medicaid funds for physician services. Similar patterns were found in Illinois, California, New Jersey, and Michigan. STAFF OF SUBCOMM. ON HEALTH OF HOUSE COMM. ON WAYS AND MEANS AND OF HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, 95TH CONG., 1ST SESS., FRAUD AND ABUSE IN THE MEDICARE AND MEDICAID PROGRAMS (1977).

179. These practices include:

- (1) "ping-ponging"—referring of patients from one practitioner to another within the facility even though there is no medical reason for doing so;
- (2) "ganging"—billing for multiple services to relatives who accompany a family member who alone had sought treatment at the mill;
- (3) "upgrading"—billing for a service more extensive than that actually provided;
- (4) "steering"—directing a patient to a particular pharmacy, a violation of the Medicaid program's policy of freedom of choice; and
- (5) billing for services not rendered—either adding services not performed onto an invoice carrying legitimate billings or submitting a totally fraudulent claim.

Other documented violations included billings for work performed by others or by unlicensed practitioners; making multiple copies of Medicaid cards, apparently for multiple or fictitious billing; soliciting, offering, or receiving kick-backs; billing twice or more for the same service; and billing both Medicare and Medicaid for the same service.

STAFF OF SUBCOMM. ON HEALTH OF HOUSE COMM. ON WAYS AND MEANS AND OF

ers, but Congress recognized that clinical laboratories, nursing homes, and independent practitioners had also engaged in fraudulent and abusive activities.<sup>180</sup> Thus, Congress aimed at the underlying problem in the broadest way possible.<sup>181</sup>

Congress intended the amendments to broaden the reach of the statute to cover all payments, no matter how they might be characterized.<sup>182</sup> Congress distinguished between fraud and abuse, although the amendments were intended to address both problems.<sup>183</sup> The debates on the floor of Congress underline the seriousness of the problem:

Medicare and Medicaid fraud and abuse are diseases, and are insidious and potentially fatal processes that may serve to destroy these programs. Those who are adversely affected by these abuses are the recipients, the health care providers and the taxpayers.

The recipients, those who are the poor, the aged, and the disabled of our society suffer because fraud and abuse takes the money needed for services to these people, and puts it into the hands of the unscrupulous whose sole purpose is an increase in their own wealth. . . .

The taxpayers suffer because they expect that money they have put into the system will be used for the purposes it was intended. But instead, the money is abused and the taxpayers are cheated.<sup>184</sup>

Congress was concerned with both the increased cost to the Medicare program of fraudulent and abusive practices, and with having an honestly run program.<sup>185</sup> The integrity and ethical character of

HOUSE COMM. ON INTERSTATE AND FOREIGN COMMERCE, 95TH CONG., 1ST SESS., FRAUD AND ABUSE IN THE MEDICARE AND MEDICAID PROGRAMS 3 (1977).

180. H.R. REP. NO. 393, 95th Cong., 1st Sess., *reprinted in* 1977 U.S. CODE CONG. AND ADMIN. NEWS 3039, 3047-50.

181. *See infra* note 189 and accompanying text.

182. "The bill would define the term 'any remuneration' broadly to encompass kick-backs, bribes, or rebates which may be made directly or indirectly, overtly or covertly, in cash or in kind. . . ." H.R. REP. NO. 393, 95th Cong., 1st Sess., *reprinted in* 1977 U.S. CODE CONG. AND ADMIN. NEWS 3039, 3056.

183. H.R. REP. NO. 393, 95th Cong., 1st Sess., *reprinted in* 1977 U.S. CODE CONG. AND ADMIN. NEWS 3039, 3050.

184. 123 CONG. REC. S31770 (statement of Sen. Dole).

185. [A]s numerous studies have confirmed, fraudulent and abusive practices associated with health care services financed by the Medicare and Medicaid programs have become more and more pervasive and serious. What concerns me greatly is that those who do so desperately need the medical services provided by these programs, the poor and elderly, are not receiving these services when abuse and fraud in the system divert program moneys. In addition, it is the American taxpayer who pays the price for the misuse of funds in such federally financed programs.

Fraudulent and abusive activities weaken the financial stability of local and

the medical profession was also at issue.<sup>186</sup>

The amendments were intended to alleviate problems encountered with enforcement of the existing law,<sup>187</sup> particularly those of vagueness.<sup>188</sup> The committee that drafted the legislation agreed that there were problems with vagueness and broadened the statutory language to cover all such arrangements:

In broadening these criminal provisions, your committee sought to make clear that kickbacks are wrong no matter how a transaction might be constructed to obscure the true purpose of a payment . . . . We are in a complex area where right and wrong are often clouded with shades of gray. In such situations, the committee stresses the need to recognize that the substance rather than simply the form of a transaction should be controlling.<sup>189</sup>

### C. The 1980 Amendment

Congress next amended the statute through the Omnibus Reconciliation Act of 1980.<sup>190</sup> This amendment added the requirement of a specific intent.<sup>191</sup> To be convicted, all offenses must be committed "knowingly and willfully."<sup>192</sup>

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State governments where already stretched budgets must be readjusted to meet commitments for medical assistance programs.

123 CONG. REC. H30287 (statement of Rep. Thone).

186. The same concern with ethical integrity that marked the passage of the 1972 Fraud and Abuse statute recurs here. "[T]he activities of those who seek to defraud these programs unfairly calls into question [the] honesty and integrity of the vast majority of practitioners and health care institutions." H.R. REP. NO. 393, 95th Cong., 1st Sess., reprinted in 1977 U.S. CODE CONG. AND ADMIN. NEWS 3039, 3047. The same report subsequently notes that the law will provide "specific penalties under the medicare and medicaid programs for certain practices that had long been regarded by professional organizations as unethical. . . ." H.R. REP. NO. 393, 95th Cong., 1st Sess., reprinted in 1977 U.S. CODE CONG. AND ADMIN. NEWS 3039, 3055.

The debates in Congress underscore the point. "The health care providers suffer because the names of many good practitioners are needlessly blackened, and their professionalism questioned, because of a few who are unethical." 123 CONG. REC. S51987 (statement of Sen. Dole). "[What is] perhaps most alarming, such abuses unjustly call into question the honesty and integrity of all practitioners and health care institutions." 123 CONG. REC. H30282 (statement of Rep. Thone).

187. Rep. Ullman stated "There is need to strengthen the Government's hand in combating fraud and abuse and that is what this legislation would do." 123 CONG. REC. H30279 (statement of Rep. Ullman).

188. Senator Church noted that "U.S. attorneys . . . testified that the language of the Medicare/Medicaid fraud statute needs clarification. New language will help better define what constitutes an illegal 'kickback' or rebate." 123 CONG. REC. S31772 (statement of Sen. Church).

189. 123 CONG. REC. 30280 (statement of Rep. Rostenkowski).

190. Pub. L. No. 96-499, 94 Stat. 2599 (1980) codified at 42 U.S.C. § 1395nn(b)(1).

191. *Id.*

192. *Id.* Congress added the requirement because, "[t]he Committee is concerned that criminal penalties may be imposed under current law to an individual whose con-

### D. The 1987 Amendment

Until recently, the statute remained in this form, despite periodic efforts by Congress at amendment. MMPPPA was enacted on August 18, 1987.<sup>193</sup> The concern with waste and over utilization that marked the passage of the 1977 amendments is again present in the legislative history of this most recent enactment.<sup>194</sup>

The MMPPPA addresses four principal aspects of fraud and abuse enforcement in federal health programs. Only two of these aspects are material to this discussion: the increase in the authority of the Secretary of HHS to impose penalties, including exclusion<sup>195</sup> and civil monetary penalties;<sup>196</sup> and the provision for issuance of regulations covering the criminal anti-kickback statute.<sup>197</sup>

The civil penalty provisions allow the Secretary of HHS to exclude providers<sup>198</sup> and impose substantial fines<sup>199</sup> for violations of

duct, while improper, was inadvertent. Accordingly, the section clarifies current law to assure that only persons who knowingly and willfully engage in the proscribed conduct could be subject to criminal sanctions." H.R. REP. NO. 1167, 96th Cong., 2d Sess., reprinted in 1980 U.S. CODE CONG. AND ADMIN. NEWS 5526, 5572.

193. Pub. L. 100-93 101 Stat. 680 (1987).

194. Senator Packwood, who is the ranking minority member of the Committee on Finance, and a member of the Subcommittee on Health, concluded his remarks on the floor of the Senate regarding the MMPPPA as follows: "[w]hen fraud and financial abuse occur in Government health care programs, American taxpayers are the victims. . . . This cannot be tolerated." 133 CONG. REC. S105378 (daily ed. July 23, 1987) (statement of Sen. Packwood).

195. Exclusion from the program virtually precludes payment for any services rendered by the provider. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. 100-93, §§ 8, 10, 101 Stat. 680, 692-96 (1987). MMPPPA provides for both mandatory and permissive exclusion, depending on the circumstances. Medicare and Medicaid Patient and Program Protection Act, Pub. L. 100-93, §§ 2, 7, 101 Stat. 680-86, 691-92 (1987). Exclusion may now be imposed against a person who has been assessed with a civil monetary penalty. Medicare and Medicaid Patient and Program Protection Act, Pub. L. 100-93, § 3, 101 Stat. 680, 686-88 (1987).

196. The Secretary of HHS has the authority to impose a civil monetary penalty (of up to \$2,000 per item or service) plus an assessment of twice the amount claimed on any person who files a claim for a medical or other item or service that the person knew or had reason to know was not provided as claimed. S. REP. NO. 109, 100th Cong., 1st Sess. 14, reprinted in 1987 U.S. CODE CONG. AND ADMIN. NEWS 682, 695. See also Meyer & Orbovich, CIVIL MONEY PENALTIES IN MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW 135-47, 180-190 (1986). MMPPPA expands the grounds on which penalties may be based. S. REP. NO. 109, 100th Cong., 1st Sess. 14, reprinted in 1987 U.S. CODE CONG. AND ADMIN. NEWS 682, 695.

197. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. 100-93 § 14, 101 Stat. 680, 697-98 (1987).

198. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. 100-93, § 2, 101 Stat. 680-86 (1987). Interestingly, this provision can be enforced "without the necessity of imposing a civil monetary penalty or obtaining a criminal penalty or obtaining a criminal conviction." S. REP. NO. 109, 100th Cong., 1st Sess. 10, reprinted in

the anti-kickback statute. With this concurrent civil authority, HHS can enforce the anti-kickback statute without the concurrence of the U.S. Attorney,<sup>200</sup> as was necessary for indictment under the criminal statutes. Civil provisions also require a lower burden of proof than criminal sanctions.<sup>201</sup> HHS is planning to create a specific group of Administrative Law Judges who will hear only civil money penalties cases against providers.<sup>202</sup> As a result of these changes, providers can anticipate a markedly increased level of scrutiny and prosecution of less extreme cases than was undertaken previously.<sup>203</sup>

The bill also modifies the criminal provisions by directing the Secretary of HHS, in consultation with the Attorney General, to promulgate regulations specifying payment practices that will not be the subject of criminal or civil prosecution<sup>204</sup> under (new) Sections 1128B(b) and 1128b(7) of the Social Security Act.<sup>205</sup> The Secretary of HHS is also directed to publish preliminary regulations one year after enactment to allow sufficient time for public comment,<sup>206</sup> although the deadline will not be met.<sup>207</sup> The regulations were to be published in final form two years after enactment

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1987 U.S. CODE CONG. AND ADMIN. NEWS 682, 690 (1987). The Senate Finance Committee intended that exclusions under this provision would require only the burden of proof customary with administrative proceedings, although some special due process protection was provided. S. REP. NO. 109, 100th Cong., 1st Sess. 10, *reprinted in* 1987 U.S. CODE CONG. AND ADMIN. NEWS 682, 690, 692-94 (1987).

199. *See supra* note 196.

200. Address by Robert W. McCann at the National Health Lawyers Association Conference on Fraud and Abuse: Understanding the Law (Oct. 5, 1987).

201. *See supra* note 198.

202. Address by D. McCarty Thornton, Office of the General Counsel, Inspector General Division, HHS, at the National Health Lawyers Association Conference on Fraud and Abuse: Understanding the Law (Oct. 5, 1987).

203. Address by Robert W. McCann at the National Health Lawyers Association Conference on Fraud and Abuse: Understanding the Law (Oct. 5, 1987).

204. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. 100-93 § 14, 101 Stat. 680, 697-98 (1987).

205. MMPPPA recodifies the Fraud and Abuse provisions into section 1128 B of the Social Security Act. Medicare and Medicaid Patient and Program Protection Act, Pub. L. 100-93, § 4, 101 Stat. 680, 688-689 (1987). *See also* S. REP. NO. 109, 100th Cong., 1st Sess. 27, *reprinted in* 1987 U.S. CODE CONG. AND ADMIN. NEWS 682, 698 (1987). The new exclusion provision is found at section 1128 b(7).

206. S. REP. NO. 109, 100th Cong., 1st Sess. 27, *reprinted in* 1987 U.S. CODE CONG. AND ADMIN. NEWS 682, 708 (1987).

207. The statute was passed on August 18, 1987, making the deadline August 19, 1988. The request for public comment in shaping the proposed regulations was published on October 19, 1987. 52 Fed. Reg. 38794 (1987). Richard P. Kusserow, the Inspector General of HHS recently stated: "we don't anticipate completing that process [rulemaking] until after the summer." *IG Seeks Clearer Regulations on Fraud and Abuse*, HOSPITALS May 20, 1988, at 79. At the time of publication, no regulations had been issued.



of the amendments.<sup>208</sup>

Congress clearly recognizes that the present Fraud and Abuse statute frustrates the efforts of hospitals and physicians to come up with innovative ways of delivering quality medical care. "[T]he breadth of the [Fraud and Abuse] statutory language has created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are prescribed."<sup>209</sup> Regulation will provide greater confidence in the legality of certain joint ventures and physician incentives, and should simplify compliance with the law.

#### VII. JUDICIAL INTERPRETATION OF THE FRAUD AND ABUSE STATUTE

There have been no judicial opinions that address the Fraud and Abuse statute in the context of legitimate business arrangements.<sup>210</sup> Most of the cases that have been decided involve a more or less thinly veiled kickback.<sup>211</sup> Nevertheless, a review of the existing judicial opinions should help clarify how the existing statute has been interpreted by the few courts confronted with its enforcement.

The trend of the case law has been curious. In the first two decided cases, the statute was construed extremely narrowly and literally.<sup>212</sup> Subsequently, the statute was given a more expansive reading.<sup>213</sup> Congressional broadening of the fraud and abuse provisions in 1977 also simplified enforcement.<sup>214</sup> Other federal statutes are also available for prosecuting conduct that constitutes fraud and abuse.<sup>215</sup>

In *United States v. Zacher*,<sup>216</sup> a nursing home administrator charged the families of Medicaid patients four dollars per day over

208. S. REP. NO. 109, 100th Cong., 1st Sess. 27, reprinted in 1987 U.S. CODE CONG. AND ADMIN. NEWS 682, 708 (1987).

209. S. REP. NO. 109, 100th Cong., 1st Sess. 27, reprinted in U.S. CODE CONG. AND ADMIN. NEWS 682, 707 (1987).

210. See *supra* note 107.

211. See *infra* notes 216-80 and accompanying text.

212. See *infra* discussion of *Zacher* and *Porter*.

213. See *infra* discussion of *Hancock*, *Tapert*, *Ruttenberg* and *Greber*.

214. See *supra* notes 170-89 and accompanying text.

215. See MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW 25-31 (1986) for a list of the statutes that could be utilized. These include mail fraud, conspiracy, false statement, civil money penalties and so on. In a typical prosecution, one provider was indicted for mail fraud (11 counts), false statements to an agency of the United States (6 counts), aiding and abetting (11 counts) and offer and payment of illegal kickbacks (5 counts). See *infra* notes 266-80 and accompanying text for a description of the case.

216. 586 F.2d 912 (2d Cir. 1978).

and above their Medicaid allotment.<sup>217</sup> This sum brought the daily rate up to that paid by private patients. A grand jury indicted Zacher for receiving bribes and kickbacks in violation of the 1972 Medicaid statute.<sup>218</sup> The kickback charges were dismissed and the jury convicted Zacher of receiving bribes.<sup>219</sup> On appeal, the United States Court of Appeals for the Second Circuit reversed, holding that a "bribe" requires something beyond a simple payment.<sup>220</sup> Bribery must involve an element of corruption and the violation of a public trust or duty.<sup>221</sup>

The finding in *Zacher* that there was no element of corruption was drawn from the consequences of the payment and not innate considerations of the substance of the transaction: "The payments to Zacher did not increase the cost to the government of patient care, decrease the quality of patient care purchased by the government or involve the misapplication of government funds."<sup>222</sup> This narrow reading of the Fraud and Abuse statute was explicitly rejected by Congress with the 1977 amendments to the statute.<sup>223</sup>

In *United States v. Porter*,<sup>224</sup> a group of physicians sent blood samples of Medicare patients to a laboratory which paid the physicians a "handling fee."<sup>225</sup> After receiving payment from Medicare, the laboratory sent the fee to the physicians.<sup>226</sup> The U.S. Attorney characterized these payments as bribes, kickbacks, or rebates and indicted the physicians and the laboratory owner for violation of the 1972 Medicare statute, mail fraud, and conspiracy.<sup>227</sup>

The defendants were found guilty,<sup>228</sup> but on appeal the Fifth Circuit reversed.<sup>229</sup> The court concluded that no bribe had taken place based on the same analysis as the *Zacher* opinion.<sup>230</sup> Then, in an extremely literal reading of the definition of kickback, the court concluded there had been no kickback.<sup>231</sup> The court ex-

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217. *Id.* at 913.

218. *Id.* at 914.

219. *Id.* at 913.

220. *Id.* at 916.

221. *Id.* at 915.

222. *Id.* at 916.

223. *See supra* notes 170-76, 182-83 and accompanying text.

224. 591 F.2d 1048 (5th Cir. 1979).

225. *Porter*, 591 F.2d at 1051.

226. *Id.*

227. *Id.*

228. *Id.* at 1050.

229. *Id.*

230. *Id.* at 1053, 1054.

231. *Id.* at 1054 (emphasis in original) ("the return to an earlier possessor of part of a sum received").

tended dicta in *Zacher* to conclude that a kickback, "involve[s] a corrupt payment or receipt of payment in violation of the duty imposed on providers of services to use federal funds only for intended purposes and only in the approved manner."<sup>232</sup> After determining there had been no fraud, the court dismissed the conspiracy count.<sup>233</sup> The court defined the breadth of a fraud indictment under the Medicare statute<sup>234</sup> by reference to *Hammerschmidt v. United States*<sup>235</sup> and *Dennis v. United States*.<sup>236</sup> The Fifth Circuit went on to add that the receipt of handling fees by the defendants did not defraud the government of the right to have an honestly run program or constitute interference with its lawful

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232. *Id.* (quoting *Zacher*, 586 F.2d at 916).

233. *Porter*, 591 F.2d at 1057.

234. *Porter* was prosecuted under the 1972 Medicare statute, which was not as broad as the present statute. *See infra* notes 170-209 and accompanying text for a description of the amendments that have since been made to the statute. In fact, the *Porter* court took judicial notice of the fact that amendments had been made to the statute in 1977 and noted,

Our conclusion that 42 U.S.C. § 1395nn(b) did not make criminal the acts charged in the indictment is strengthened, if not absolutely compelled, by events subsequent to the indictment period. In 1977 . . . Congress completely changed the wording of the statute and made the description of the crime much more specific. The legislative history clearly indicates that the reason for this substantial alteration of the wording was the fact that Congress and many United States Attorneys believed "that the existing language of these penalty statutes [42 U.S.C. §§ 1395nn and 1396h] is *unclear and needs clarification*." H.R. Rep. No. 95-393(II), 95th Cong., 1st Sess. 53 (1977), *reprinted in* [1977] U.S. Code Cong. and Admin. News, pp. 3039, 3055 (emphasis added).

If the meaning of the 1972 version of 42 U.S.C. § 1395nn(b) was not clear and precise to the Congress and to United States Attorneys charged with enforcing the law, then we are hard put to say, with that degree of confidence required in a criminal conviction, that these defendants were given clear warning by that statute that their conduct was prohibited by it, thus amounting to a criminal act.

*Porter*, 591 F.2d at 1054.

235. 265 U.S. 182 (1924). "To conspire to defraud the United States means primarily to cheat the government out of property or money, but it also means to interfere with or obstruct one of its lawful governmental functions by deceit, craft or trickery, or at least by means that are dishonest. It is not necessary that the government shall be subjected to property or pecuniary loss by the fraud, but only that its legitimate official action and purpose shall be defeated by misrepresentation, chicane, or the overreaching of those charged with carrying out the governmental intention." *Id.* at 188. *Hammerschmidt* involved an indictment under the general fraud statute. 18 U.S.C. § 37 (1982). The Fifth Circuit appears to have simply applied it as precedent, presumably reasoning that fraud is fraud.

236. 384 U.S. 855 (1966). *Dennis* held that a conspiracy to defraud was "any conspiracy for the purpose of impairing, obstructing, or defeating the lawful function of any department of government." *Id.* at 861 (quoting *Haas v. Henkel*, 216 U.S. 462, 479, *quoted in* *United States v. Johnson*, 383 U.S. 169, 172). *Dennis*, like *Hammerschmidt*, involved a case under the general fraud provisions of 18 U.S.C. § 37 (1982).

functions.<sup>237</sup>

Subsequent cases rejected the approach of *Zacher* and *Porter*. In *United States v. Hancock*,<sup>238</sup> several chiropractors were indicted under the 1972 statute for soliciting handling fees from laboratories to which they sent work.<sup>239</sup> After pleading *nolo contendere*,<sup>240</sup> they appealed the sufficiency of the indictments, based on the reasoning of *Zacher* and *Porter*.<sup>241</sup> The Seventh Circuit upheld the convictions<sup>242</sup> after accepting a broader definition of kickback than the Fifth Circuit had in *Porter*.<sup>243</sup> The government alleged that the "defendants received kickbacks 'for referring Medicare and Medicaid recipients' blood and tissue specimens . . .,"<sup>244</sup> rather than that there was any increased cost to the Medicare and Medicaid program. The element of corruption was evidenced by the referral of patients in exchange for payments.<sup>245</sup> Thus, unlike the Second Circuit in *Zacher*, the Seventh Circuit looked to the substance of the transaction, rather than its consequences, to assess its nature. The court, however, noted both the potential for increased cost and for diversion of federal funds.<sup>246</sup>

In *United States of America v. Weingarden*,<sup>247</sup> the defendants were indicted under the 1972 Fraud and Abuse Medicaid statute for soliciting and receiving kickbacks in a scheme similar to

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237. *Porter*, 591 F.2d at 1055.

238. 604 F.2d 999 (7th Cir. 1979).

239. *Id.* at 1001.

240. "Latin phrase meaning 'I will not contest it'. . . . The defendant does not admit or deny the charges, though a fine or sentence may be imposed pursuant to it. The principal difference between a plea of guilty and a plea of *nolo contendere* is that the latter may not be used against the defendant in a civil action based upon the same acts." BLACK'S LAW DICTIONARY 945 (5th ed. 1979).

241. *Hancock*, 604 F.2d at 1001.

242. *Id.* at 1002.

243. "The court in *Porter* also construed the term kickback to mean 'the secret return to an earlier possessor of part of a sum received.' 591 F.2d at 1054. We cannot agree that the term kickback is limited to a return of funds to an earlier possessor. The term is commonly used and understood to include 'a percentage payment . . . for granting assistance by one in a position to open up or control a source of income,' Webster's Third New International Dictionary (1966), and we think it was used in the statute to include such a payment. . . . To the extent our conclusions are inconsistent with the *Porter* case, we decline to follow it." *Hancock*, 604 F.2d at 1002.

244. *Hancock*, 604 F.2d at 1001 (emphasis in original).

245. "[T]he element of corruption is found in this allegation that the defendants received payments in return for their decision to send specimens to ChemTech." *Id.* at 1001.

246. "The potential for increased costs to the Medicare-Medicaid system and misapplication of federal funds is plain, where payments for the exercise of such judgments are added to the legitimate costs of the transaction." *Id.* at 1001.

247. 468 F. Supp. 410 (E.D. Mich. 1979).

*Porter*.<sup>248</sup> The defendants filed a motion to dismiss the indictment, citing the reasoning of *Porter*.<sup>249</sup> The court declined to follow any of the reasoning in *Porter* and reformulated the definition of kickback along the same lines as the court in *Hancock*.<sup>250</sup> The court in *Weingarden*, like the *Hancock* court, also took issue with *Porter* for its holding that no interference with a governmental function had taken place.<sup>251</sup>

The defendants subsequently pleaded guilty and were convicted.<sup>252</sup> They appealed their convictions in *United States v. Tapert*.<sup>253</sup> The court affirmed the convictions after adopting the definition of kickbacks applied by the Seventh Circuit in *Hancock*.<sup>254</sup> In a concurrence, Judge Jones stressed that "[t]he United States has an important interest in securing the honest administration of federally funded programs."<sup>255</sup>

In *United States v. Ruttenberg*,<sup>256</sup> nursing home owners solicited and received monthly fees from a druggist for the opportunity to provide drugs and pharmaceutical services to nursing home residents.<sup>257</sup> The defendants were indicted under the 1972 Fraud and Abuse statute and pleaded guilty.<sup>258</sup> The defendants subsequently filed for a *writ of error coram nobis*,<sup>259</sup> relying on the reasoning in *Zacher* and *Porter*.<sup>260</sup> The defendants denied the controlling influence of *Hancock* by asserting that, "the fee agreement in *Hancock* raised costs to the Medicare system, whereas the government's election to fix the price of drugs and pharmaceuticals precludes that result."<sup>261</sup>

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248. The facts are elliptically presented in *Weingarden*, 468 F. Supp. at 411. A fuller description of the arrangement is found in *United States v. Tapert*, 625 F.2d 111, 113-14 (6th Cir. 1980).

249. *Weingarden*, 468 F. Supp. at 412.

250. In fact, both *Weingarden* and *Hancock* quote the Webster's Third New International Dictionary definition of kickback. Compare *supra* note 243 with *Weingarden*, 468 F. Supp. at 413.

251. *Weingarden*, 468 F. Supp. at 414.

252. *Tapert*, 625 F.2d at 113.

253. 625 F.2d 111 (6th Cir. 1980).

254. *Id.* at 121.

255. *Tapert*, 625 F.2d at 121 (Jones, J., concurring) (citing *United States v. Thompson*, 366 F.2d 167 (6th Cir. 1966)).

256. 625 F.2d 173 (7th Cir. 1980).

257. *Id.* at 174.

258. *Id.* at 175.

259. "A writ to bring before the court that pronounced judgment errors in matters of fact which had not been put in issue or passed and were material to validity and regularity of legal proceeding itself." BLACK'S LAW DICTIONARY 487 (5th ed. 1979).

260. *Ruttenberg*, 625 F.2d at 175.

261. *Id.* at 176. The prosecutor in *Ruttenberg* disputed the existence of any increased

The Seventh Circuit, which had previously decided *Hancock*, had no difficulty dismissing the arguments of the defendants in one paragraph and a sharply worded footnote:

*Whether costs were directly and immediately increased by those particular payments, however, is irrelevant. The potential for increased costs if such "fee" agreements become an established and accepted method of business is clearly an evil with which the court was concerned and one Congress sought to avoid in enacting § 1396(b)(1).<sup>262</sup>*

The footnote in the opinion went on to add:

*Though we are concerned with the law, not the ethics of the medical profession, United States v. Porter, 591 F.2d at 1058, it should be noted that the law does not make increased cost to the government the sole criterion of corruption. In prohibiting "kickbacks," Congress need not have spelled out the obvious truisms that, while unnecessary expenditure of money earned and contributed by taxpaying fellow citizens may exacerbate the result of the crime, kickback schemes can freeze competing suppliers from the system, can mask the possibility of government price reductions, can misdirect program funds, and, when proportional, can erect strong temptations to order more drugs and supplies than needed.<sup>263</sup>*

The Seventh Circuit refused to grant the requested writs, thus affirming the convictions of all defendants.<sup>264</sup> The analysis of *Porter* and *Zacher* was explicitly rejected again, and the *Hancock* definition of kickback was reaffirmed.<sup>265</sup> Increasing the cost to the program was now only one of many corrupt practices.

The most recent and most broadly worded case is *United States v. Greber*.<sup>266</sup> *Greber* involved an osteopath who paid "interpretation fees"<sup>267</sup> to physicians who referred patients for Holter monitoring<sup>268</sup> to his company.<sup>269</sup> The referring physician had to sign a

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costs in *Hancock*. No allegation of increased cost was made in the indictment for *Hancock*. See *supra* note 244 and accompanying text. Appellants relied on the language of the opinion quoted *supra* in note 246.

262. *Id.* at 176, 177 (emphasis added).

263. *Ruttenberg*, 625 F.2d at 176, 177 (emphasis added).

264. *Id.* at 177.

265. *Id.* This definition was subsequently adopted in *United States v. Perlstein*, 632 F.2d 661 (6th Cir. 1980) and *Bethune Plaza, Inc. v. Department of Public Aid*, 90 Ill. App. 3d 1133 414 N.E. 2d 183 (1st Dist. 1980).

266. 760 F.2d 68 (3d Cir. 1985).

267. *Id.* at 70. The payments were also characterized at various times as consulting fees, *id.*, and referral fees. Miller, *The Greber Case*, in *MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW 15* (1986).

268. "A technique for long-term recording of electrocardiographic signals continuously on magnetic tape, and replaying it at rapid speed for scanning and selection of

line at the bottom of the official report to receive his fee.<sup>270</sup> The defendant was indicted for mail fraud, Medicare fraud under the 1980 Fraud and Abuse statute, and violation of the false statement statutes.<sup>271</sup> At trial, "[t]he judge . . . charged that even if the physician interpreting the test did so as a consultant to Cardio-Med, that fact was immaterial if a purpose of the fee was to induce the ordering of services from Cardio-Med."<sup>272</sup>

On appeal, the defendant contended that it was necessary to show that the *only* purpose of the fee was to induce referrals to prove a violation.<sup>273</sup> The government replied that Congress had intended to combat financial incentives to physicians for ordering particular services patients did not require.<sup>274</sup> That a payment might have a legitimate purpose in addition was irrelevant.<sup>275</sup>

In a broadly worded opinion, the court in *Greber* held that: "the district court correctly instructed the jury. If the payments were intended to induce the physician to use Cardio-Med's services, the statute was violated, even if the payments were also intended to compensate for professional services."<sup>276</sup> The Third Circuit affirmed the conviction on all counts.<sup>277</sup> The prosecutor in *Greber*

significant but fleeting changes that might otherwise escape notice." Stedman's Medical Dictionary 885 (24th ed.) The patient typically wears the monitor for eight to twenty-four hours. Noble & Zipes, *Techniques of Long-Term Continuous Electrocardiographic Recording*, in *THE HEART* 1720 (J. Hurst ed. 1986). The electrocardiogram is scanned to assess the frequency of arrhythmias. *Id.* See also Morganroth, *Ambulatory Holter Electrocardiography: Choice of Technologies and Clinical Uses*, 102 *ANNALS INT. MED.* 73 (1985).

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

270. Miller, *The Greber Case*, in *MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW* 13 (1986).

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

272. *Id.* at 71 (emphasis added).

273. *Id.*

274. *Id.*

275. The court subsequently agreed with the government's position:

Even if the physician performs some service for the money received, the potential for unnecessary drain on the Medicare system remains. The statute is aimed at the inducement factor.

The text refers to 'any remuneration.' That includes not only sums for which no actual service was performed but also those amounts for which some professional time was expended. 'Remunerates' is defined as 'to pay an equivalent for service.' Webster Third New International Dictionary (1966). By including such items as kickbacks and bribes, the statute expands 'remuneration' to cover situations where no service is performed. That a particular payment was a remuneration (which implies that a service was rendered) rather than a kickback, does not foreclose the possibility that a violation nevertheless could exist.

*Greber*, 760 F.2d at 71.

276. *Greber*, 760 F.2d at 71, 72.

277. *Id.* at 73.

subsequently noted that overutilization was the key to establishing criminal intent:

If a suspicious financial relationship is accompanied by overutilization, it can be inferred that the reason for the overutilization is the financial benefit to the referring physician. Or, one might say that if there was no financial benefit to the physician, why would he or she engage in overutilization.<sup>278</sup>

*Greber* represents the culmination of a trend to an expansive reading of the fraud and abuse statutes. Although the case has not yet been used as precedent for this broad interpretation of the statute, it seems clear that prosecution of fraud and abuse will be more straightforward after *Greber*.<sup>279</sup> As the court in that case concluded, "if one purpose of the payment was to induce future referrals the Medicare statute has been violated, even if the payment has a legitimate purpose as well."<sup>280</sup>

### VIII. ADMINISTRATIVE INTERPRETATIONS

The application of the Fraud and Abuse statutes to legitimate business arrangements is riddled with uncertainty.<sup>281</sup> Between 1977 (when the kickback provisions were added to the statute) and 1981, the Office of Program Integrity of the Health Care Financing Administration ("HCFA") issued a number of letters and opinions in response to specific inquiries.<sup>282</sup> In 1981, the agency decided that it was inappropriate to aid in the interpretation of a criminal statute.<sup>283</sup> Since then, the Inspector General has maintained that interpretation is the province of the judiciary.<sup>284</sup>

HHS, while drafting regulations, adopted the Congressional definition of fraud — an intentional deception or misrepresentation designed to obtain an unauthorized benefit.<sup>285</sup> This definition includes by reference the decision of the Supreme Court in *Ham-*

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278. Miller, *The Greber Case*, in *MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW* 16 (1986). Obviously, under a prospective payment system, the incentives are quite different. See *supra* note 38.

279. "Other prosecutions similar in nature to *Greber* are to be expected. This is a growth area for federal prosecutors; they like the *Greber* decision, and are happy to have a case this broad as precedent." Miller, *The Greber Case*, in *MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW* 17 (1986).

280. *Greber*, 760 F.2d at 69 (emphasis added).

281. Schorr, *Health Care Business Deals: Kickbacks or Capitalism?* HEALTH POLICY WEEK SPECIAL REPORT 3 (Apr. 11, 1988).

282. *MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW* 9, 10 (1986).

283. *MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW* 10 (1986).

284. *Id.*

285. See *supra* note 126.



*merschmidt*<sup>286</sup> and in *Dennis*.<sup>287</sup> In contrast, abuse seems more related to overutilization. It is defined by HHS as behavior that is inconsistent with sound fiscal, business, or medical practice and consequently increases the cost to the Medicare program.<sup>288</sup>

The Medicare manuals<sup>289</sup> provide more specific examples to aid in the identification of fraud and abuse.<sup>290</sup> It is notable that kick-backs occupy their own category and are not linked with other

286. See *supra* note 235.

287. See *supra* note 236.

288. See *supra* note 124.

289. These manuals are provided by HCFA to intermediaries and carriers who respectively administer the payments to hospitals and physicians. The manuals contain guidelines for all aspects of the Medicare program.

290. According to the Medicare Carriers Manual,

Situations that suggest the possibility of a deliberate attempt to claim benefits illegally include, but are not limited to the following:

1. A complaint or other report that a claim was submitted for supplies or services that were not provided.
2. A physician's bill which appears to have been altered.
3. An indication that there may be deliberate application for duplicate reimbursement.
4. Use of another person's Medicare card.
5. Any false representation with respect to the nature of charges for services rendered, identity of recipient of services, date of receipt of services, etc.
6. A claim for uncovered services billed as services which are covered, e.g., routine foot care billed as a more involved form of foot care to obtain reimbursement as a covered service.
7. Claims involving collusion between the supplier and the recipient resulting in higher costs or charges to the Medicare program.
8. Soliciting, offering, or receiving a kickback, bribe, or rebate.

#### IDENTIFYING POSSIBLE ABUSE SITUATIONS

The type of abuse to which Medicare is most vulnerable is over-utilization of medical and health care services. Other types of abuse include but are not limited to the following:

1. Excessive charges for services or supplies.
2. Claims for services not medically necessary, or if medically necessary, not to the extent rendered. (For instance, a battery of diagnostic tests is given whereas, based on diagnosis, only a few are needed.)
3. Breach of assignment which results in the beneficiary's being billed for amounts disallowed by the carrier on the basis that such charges exceeded the "reasonable charge" criteria. (See also § 11027 as regards breach of assignment situations which are classified as fraud.)
4. Separate schedule of charges for Medicare and non-Medicare patients.
5. The technique of billing based on "gang visits." (For example, a physician visits a nursing home, walks through the facility, and bills for 20 nursing home visits, without rendering any specific service to individual patients.)

#### MEDICARE CARRIERS MANUAL HIM — 14 §§ 11004, 11005.

According to the Medicare Intermediary Manual,

Situations which could suggest the possible existence of fraud would include:

1. Billings for services, supplies or equipment which were not rendered to, or used for, Medicare beneficiaries;
2. Billings for supplies or equipment which are clearly unsuitable for the pa-

activities that directly increase the program costs. The only other source of guidance from administrative agencies has been intermediary letters<sup>291</sup> from HHS and HCFA.<sup>292</sup> Unfortunately, as with the judicial opinions,<sup>293</sup> these letters have "dealt for the most part with extreme fact situations where the answers are more or less obvious."<sup>294</sup> In 1984, HCFA issued an Intermediary Letter relating to fees paid by DME suppliers to respiratory therapists.<sup>295</sup> The

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tient's needs or are so lacking in quality or sufficiency for the purpose as to be virtually worthless;

3. Flagrant and persistent over-utilization of medical or paramedical services with little or no regard for results, the patient's ailments, condition, medical needs or the doctor's orders;

4. Claiming of costs for noncovered or nonchargeable services, supplies or equipment disguised as covered items;

5. Material misrepresentations of dates and descriptions of services rendered, or of the identity of the recipient or the individual who rendered the services;

6. Duplicate billing which appears to be deliberate. This includes billing the Medicare program twice for the same services or billing both Medicare and the beneficiary for the same services;

7. Arrangements by providers with employees, independent contractors, suppliers and others which appear to be designed primarily to overcharge the health insurance program with various devices (commissions, fee splittings) used to spin off or conceal illegal profits;

8. Charging to the health insurance program by subterfuge, costs not incurred or which were attributable to nonprogram activities, other enterprises or personal expenses of principals;

9. Deliberately providing, or receiving health insurance benefits on the Medicare account of another individual;

10. Persistently and deliberately billing beneficiaries rather than Medicare for covered services;

11. Providers concealing business activities which would prevent them from complying with the provisions of the Provider Agreement (SSA-1561);

12. Falsifying provider records in order to meet or continue to meet the Conditions of Participation. The regional office will report this situation to the state agency for an appropriate action regarding the provider's certification;

13. Soliciting, offering, or receiving a kickback, bribe or rebate.

MEDICARE INTERMEDIARY MANUAL HIM-13 § 3462.

291. Intermediary Letters are policy statements from HCFA to carriers and intermediaries. They are intended to alert carriers and intermediaries to activities which they should report to HCFA if discovered.

292. The mission of the Health Care Financing Administration is to administer the Medicare and Medicaid programs and related provisions of the Social Security Act in a manner which (1) promotes the timely and economic delivery of appropriate quality health care to eligible beneficiaries, (2) promotes beneficiary awareness of the services for which they are eligible and improves the accessibility of those services, and (3) promotes efficiency and quality within the total health care delivery system.

Medicare and Medicaid Guide (CCH) ¶ 13,170 (1988).

293. See *supra* note 216-280 and accompanying text.

294. Tillman, *Scope of the Conference in MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW* 11 (1986).

295. HCFA Intermediary Letter No. 84-9, Suppliers of Durable Medical Equipment

Letter is quite explicit that finder's fees paid to respiratory therapists for referring patients in need of home oxygen therapy violates the Fraud and Abuse statute.<sup>296</sup> That assessment is clearly within the provisions of the statute and to go only so far would be noncontroversial. But the Letter further stated that payment of a reasonable fee to the respiratory therapist for setting up the equipment, instructing the patient in its use, and performing routine maintenance on it was also a violation.<sup>297</sup> HCFA thus refused to differentiate between legitimately compensated service and the inducement of a referral, and focused on the opportunity to generate a fee.

The opportunity to generate a fee is itself a form of remuneration. The offer or receipt of such fee opportunities is illegal if intended to induce a patient referral. Thus, a supplier who induces patient referrals by offering therapists fee-generating opportunities is offering illegal remuneration, even if the therapist is paid no more than his or her usual fees.<sup>298</sup>

This Intermediary Letter caused a great deal of comment and concern because of the broad sweep of the ruling.<sup>299</sup> DME suppliers rely on such arrangements for education of the patient and maintenance of the equipment.<sup>300</sup> In fact, many areas of the health care industry, like most businesses, depend on providers and suppliers giving each other the "opportunity to generate a fee."<sup>301</sup> Joint ventures, in particular, are directly analogous.<sup>302</sup>

HCFA retreated from this extreme position in a subsequent Program Memo.<sup>303</sup> The Memo deleted the language quoted above and noted that the legality of any particular arrangement could not be assessed "without consideration of the relevant factors and practice patterns."<sup>304</sup> The Program Memo then lists a number of factors that must be considered in characterizing the nature of the oppor-

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Offering "Finders" and "Referral" Fees, (Sept. 1984), *reprinted in Medicare and Medicaid Guide (CCH)* ¶ 34,127.

296. *Id.*

297. *Id.*

298. *Id.*

299. Adams, *Fraud and Abuse Implications of Joint Ventures*, in L. BURNS & D. MANCINO, *JOINT VENTURES BETWEEN HOSPITALS AND PHYSICIANS: A COMPETITIVE STRATEGY FOR THE HEALTHCARE MARKETPLACE* 129, 135 (1987)

300. *Id.*

301. *Id.*

302. *Id.* See also *supra* notes 93-99 and accompanying text.

303. HCFA Program Memo (Carriers) B85-2, *Suppliers of Durable Medical Equipment Offering "Finders" and "Referral" Fees*, (April 1985), *reprinted in Medicare and Medicaid Guide (CCH)* ¶ 34,544.

304. *Id.*

tunity to generate a fee.<sup>305</sup> The factors are an attempt to differentiate compensation for needed services from an inducement to refer.<sup>306</sup>

Although HCFA has retreated from its extreme position, the language of the Intermediary Letter is still similar to that subsequently used in *Greber*.<sup>307</sup> As HCFA correctly pointed out, prior to MMPPA it could not properly judge the legality of a payment arrangement or immunize a payment from prosecution.<sup>308</sup> After MMPPA, civil enforcement is under the sole direction of the Secretary of HHS.<sup>309</sup> The concurrence of a U.S. Attorney is no longer necessary to enforce the Fraud and Abuse statute.<sup>310</sup> The criminal requirement of intent is also not necessary for a civil action. Thus, an administrative agency now has significant power in determining how and against whom the law will be enforced.<sup>311</sup> Despite the broad language of the statute, prosecution has involved only the most extreme conduct, where an obvious kickback and overutilization could be proven.<sup>312</sup> However, the broadened authority of the Secretary to impose civil sanctions suggests that more vigorous enforcement is in the offing.<sup>313</sup>

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305. *Id.* The factors that HCFA identified as important in characterizing the inducement factor are as follows:

1. whether the therapist provides service to the DME supplier only for those patients which he refers;
2. whether the supplier uses therapists to install and service equipment for patients not referred by therapists;
3. whether there are unusual geographic or medical reasons for using therapists in certain cases;
4. how similar equipment is installed and maintained by other suppliers in the area.

*Id.*

306. *Id.*

307. *See supra* notes 266-80 and accompanying text.

308. *See supra* note 284.

309. Burda, *Law Aimed at Curbing Medicare Fraud May Have 'Chilling Effect' on Joint Ventures*, 17 MODERN HEALTHCARE 92 (Oct. 9, 1987).

310. *Id.*

311. For example, a physician who participated in a payment arrangement that the U.S. Attorney refused to indict upon, or failed to meet the standard of proof for criminal conviction could still be excluded from the Medicare program or face civil monetary penalties under the authority granted the Secretary of HHS. Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-109 § 2, 101 Stat. 680, 690 (1987).

312. *See supra* notes 107, 210-80 and accompanying text.

313. Burda, *Law Aimed at Curbing Medicare Fraud May Have 'Chilling Effect' on Joint Ventures*, 17 MODERN HEALTHCARE 92 (Oct. 9, 1987).

## IX. STATE FRAUD AND ABUSE PROVISIONS

Many states have enacted laws relating to Medicaid fraud, fee-splitting, or patient referral.<sup>314</sup> These statutes are often as broad or broader than the federal provisions.<sup>315</sup> The variation in the state statutes complicates the problem of federal regulation. If the state statutes prove to be more restrictive than the federal regulations,

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314. Not all states have statutes that deal specifically with the fraud and abuse problem. The list below is of statutes that relate specifically to enforcement of the Medicaid regulations.

Alabama: ALA. CODE § 22-1-11 (1975); Arkansas: ARK. STAT. ANN. § 41-4401 (1985); California: CAL. WELF. & INST. CODE § 14107.2 (West 1980); Colorado: COLO. REV. STAT. § 26-1-127 (1982); Connecticut: CONN. GEN. STAT. ANN. § 17-134a (West 1958); Florida: FLA. STAT. ANN. § 409.2664, (1980); Hawaii: HAWAII REV. STAT. § 346.43.5 (1985); Kentucky: KY. ANN. REV. STAT. §§ 194.505 (6,7) 205.850 (Michie, 1982); Louisiana: LA. REV. STAT. ANN. § 14.70.1 (West 1979); Massachusetts: MASS. GEN. LAWS ANN. ch. 118 E, § 21A, B, D, E (West 1980); Michigan: MICH. COMP. LAWS ANN. § 400.604 (West 1986); MICH. STAT. ANN. § 1415 (1101) (Callaghan 1985); Mississippi: MISS. CODE. ANN. § 43-13-201 (1986); North Carolina: N.C. GEN. STAT. § 108A-63 (1978); Ohio: OHIO REV. CODE ANN. § 5111.03 (Anderson 1981); Rhode Island: R.I. GEN. LAWS § 40-8.2-3 (1984); Utah: UTAH CODE ANN. § 26-20-4 (1984); Vermont: VT. STAT. ANN. tit. 33, § 2581 (1977); Virginia: VA. CODE § 32.1-315 (1985); Washington: WASH. REV. CODE ANN. § 74.09.210 (1979); West Virginia: W. VA. CODE § 9-7-5 (1984); Wisconsin: WIS. STAT. ANN. § 49.49(2) (West 1986).

The states also regulate physicians through licensing. Most states have statutory language relating to kickbacks, fee splitting and other unprofessional conduct. Those statutes that could refer to the fraud and abuse problem are listed below.

Florida: FLA. STAT. ANN. § 458.331(j) (1980); Illinois: ILL. ANN. STAT. ch. 111 § 4433(14) (1976); Michigan: MICH. COMP. LAWS ANN. § 333.16221 (d(ii)); New York: N.Y. EDUC. LAW § 6509 (McKinney 1977); Texas: TEX. STAT. ANN. art. 4495b § 3.07(c) (1981); Washington: WASH. REV. CODE ANN. § 19.68.010.

However, at least one court has held that the "acceptance of rebates or kick-backs is not within the proscription of 'unprofessional conduct' as that term is used. . . ." Lester v. Dept. of Professional of Occupational Regulations, State Board of Medical Examiners of Florida, 348 So. 2d 923 (Fla. Dist. Ct. App. 1977).

It has also been suggested that the theft or fraudulent schemes statutes might apply to the fraud and abuse problem. A typical example is ARIZ. REV. STAT. ANN. § 13.2311 (1956).

315. Michigan expressly prohibits referral to a facility in which the physician has a financial interest. The statute prohibits the "promotion for personal gain of an unnecessary drug, device, treatment, procedure, or service, or directing or requiring an individual to purchase or secure a drug, device, treatment, procedure, or service from another person, place, facility, or business in which the licensee has a financial interest." MICH. COMP. LAWS ANN. § 400.604(4) (West 1986). California has a statute almost as broad. California prohibits "the offer, delivery, receipt or acceptance, by any person licensed under this division of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest or co-ownership in or with any person to whom such patients, clients or customers are referred." CAL. BUS. & PROF. CODE § 650 (West 1986). Other statutes classify some incentive arrangements as "unprofessional conduct" and may discipline and revoke the license of physicians who participate. See *supra* note 314.

then many arrangements that are acceptable under federal law will still be prohibited. Federal regulation should be sensitive to local considerations but it should not be bound by them. Although the competitive environment affects all states, an individual state can decide that it still wishes to prohibit certain forms of joint ventures or incentive programs. This problem of federalism is best dealt with by the individual providers that are affected.

Many states have a Medicaid fraud unit which enforces the relevant criminal statutes. Such fraud units have been very successful and are a popular and effective enforcement device.<sup>316</sup> Many states provide a mechanism for obtaining advisory opinions about the legality of any proposed program.<sup>317</sup> Federal regulation that allowed a program would probably influence the state official who had to issue the opinion. Thus, federal regulation might affect the diversity of state regulation as well. California used this mechanism of advisory opinions to determine that DRG physician incentive programs are legal.<sup>318</sup> The California Board of Medical Quality Assurance reviewed the application of section 650<sup>319</sup> to a plan that pays physicians for profitable admissions. The Board concluded that because payment was not tied to referral, there was no violation.<sup>320</sup> Although this finding would allow DRG physician incentive programs, it appears to preclude direct payment for admissions or joint ventures that require a specific number of referrals to participate.

## X. REGULATORY SUGGESTIONS

The legislative history of MMPPPA reveals that Congress was concerned "that the breadth of [the 1980] statutory language has created uncertainty among health care providers as to which com-

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316. See generally I. GARDINER & T. LYMAN, *THE FRAUD CONTROL GAME: STATE RESPONSES TO FRAUD AND ABUSE IN AFDC AND MEDICAID PROGRAMS* (1984).

317. Adams, *Fraud and Abuse Implications of Joint Ventures*, in L. BURNS & D. MANCINO, *JOINT VENTURES BETWEEN HOSPITALS AND PHYSICIANS: A COMPETITIVE STRATEGY FOR THE HEALTHCARE MARKETPLACE* 139 (1987).

Depending on state law, these opinions are not likely to be binding on courts, but they are likely to be binding or carry great weight with state officials, including prosecutors who might be charged with enforcement of the underlying state statutes. Such opinions may have to be requested by specified state elected or appointed officials.

*Id.*

318. California Hospital Association News, Oct. 11, 1985.

319. See *supra* note 315 and accompanying text.

320. California Hospital Association News, Oct. 11, 1985.

mercial arrangements are legitimate and which are prescribed."<sup>321</sup> No regulations had been issued to give guidance to health care providers, essentially because the 1980 statute provided for criminal sanctions.<sup>322</sup> MMPPA directs the Secretary of HHS to draft regulations with the assistance of the Attorney General.<sup>323</sup> Congress specifically provides for consultation with "affected provider[s], practitioner[s], supplier[s], and beneficiary representative[s],"<sup>324</sup> thus emphasizing that the regulations are meant to be responsive to the realities of the health care environment as experienced by participants.

The charge to issue regulations is broad and provides for both generic and specific criteria. "The rules will, to the extent practical, contain criteria relative to prevalent controversies or ambiguities under the law in addition to any generic criteria that might apply to business arrangements generally."<sup>325</sup> The specific criteria are directed toward "present controversies or ambiguities under the law."<sup>326</sup> These include issues that have been recognized and provider arrangements that have been proposed or implemented. Generic criteria, on the other hand, are designed to "apply to business arrangements generally,"<sup>327</sup> providing guidance as to the legality of a proposed arrangement. The availability of generic criteria should simplify strategic planning, lessen the risks of prosecution, and allow providers to maneuver within the boundaries of a known law,<sup>328</sup> while allowing for general supervision of the forms

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321. H. R. REP. NO. 85, Part 2, 100th Cong., 1st Sess. 27 (1987).

322. *Id.* See also *supra* note 284 and accompanying text.

323. Medicare and Medicaid Patient and Program Protection Act, Pub. L. 100-93 § 14, 101 Stat. 680, 697-98.

324. *Id.* The regulations should incorporate both the economic interests of the providers in competing successfully, as well as their assessment of ethical and unethical behavior. See *supra* notes 141-159 and accompanying text.

The comments filed with HHS in anticipation of the proposed fraud and abuse regulations provide a fascinating overview of different approaches to the problems created by the statute. Over eight hundred pages of comments discuss issues faced daily by providers and health care lawyers. Ethics is discussed in the same sentence as criminal behavior. Claims of acting in the public interest are frequent. The comments are available from the Inspector General's Office. Wary readers are advised to follow Queen Gertrude's advice in analyzing comments that "protest too much, methinks." W. Shakespeare, HAMLET Act III, Scene 2.

325. H.R. REP. NO. 85, Part 2, 100th Cong., 1st Sess. 27 (1987).

326. *Id.*

327. *Id.*

328. That the law should be clear should not be at issue. If the intent is to exclude some of these arrangements on ethical grounds (*see infra* notes 131-141 and accompanying text), then the appropriate means of so doing is to enact a regulation that specifically prohibits such conduct. Ambiguous provisions have the effect of chilling such arrangements, yet the barrier is in the ambiguity rather than in the law.

of health care delivery. Congress also provided for the expected changes in the health care environment.<sup>329</sup> In addition, the legislative history contains the cryptic comment that the law must be updated so as not to impede "legitimate and beneficial activities."<sup>330</sup>

Congress provided for both specific practice criteria and generic criteria.<sup>331</sup> The former is, of course, dependent on those payment arrangements that have been used or envisioned. One cannot promulgate a specific regulation covering a practice that has never been suggested. The Inspector General's Office appears to favor only the use of specific practice criteria, with presumptive invalidity of any arrangement not mentioned.<sup>332</sup>

The difficulty with this approach should be obvious. The legislative history is clear that generic criteria, "to the extent practical," are to be promulgated.<sup>333</sup> Presumptive disapproval of a non-listed arrangement is clearly not compatible with this Congressional intent<sup>334</sup> because it reads the requirement for generic criteria out of

Vague laws offend several important values. First, because we assume that man is free to steer between lawful and unlawful conduct, we insist that law give the person of ordinary intelligence a reasonable opportunity to know what is prohibited, so that he may act accordingly. Vague laws may trap the innocent by not providing fair warning. . . . Uncertain meanings inevitably lead citizens to "steer far wider of the unlawful zone" . . . than if the boundaries of the forbidden areas were clearly marked.

Grayned v. City of Rockford, 408 U.S. 104, 109 (1971) (footnotes omitted). See also Papachristou v. City of Jacksonville, 405 U.S. 156 (1972).

329. H.R. REP. NO. 85, Part 2, 100th Cong., 1st Sess. 27 (1987).

[A] mechanism for periodic public input is necessary to ensure that the regulations remain relevant in light of changes in health care delivery and payment. . . . Accordingly, the Committee expects that the Secretary will formally re-evaluate the anti-kickback regulations on a periodic basis and, in so doing, will solicit public comment at the outset of the review process.

*Id.*

330. *Id.* This comment provides little guidance, as what is legitimate and beneficial (and for whom) is precisely what is at issue in framing such regulations. Too broad a definition begs the issue of professional ethics discussed *supra* at notes 131-41 and accompanying text. Too narrow a definition precludes some cost containment measures.

331. H.R. REP. NO. 85, Part 2, 100th Cong., 1st Sess. 27 (1987).

332. Burda, *Law Aimed at Curbing Medicare Fraud May Have 'Chilling Effect' on Joint Ventures*, 17 MODERN HEALTHCARE 92 (Oct. 9, 1987).

The rules will clear up longstanding confusion over what constitutes violation of the law. . . . If a type of payment practice or joint venture is not on the list, it is illegal. Any new payment practices or joint venture structures can be added to the list if they are shown not to harm Medicare or Medicaid beneficiaries.

*Id.*

333. H.R. REP. NO. 85, Part 2, 100th Cong., 1st Sess. 27 (1987).

334. "The fundamental rule of statutory construction is to ascertain and, if possible, give effect to the intention or purpose of the legislature as expressed in the statute." 82 C.J.S. *Statutes* § 321.



the legislative history. Furthermore, it is fundamentally inconsistent with the realities of the health care environment that prompted the enactment of MMPPPA. The Congressional mandate to providers is to compete with one another by developing new and innovative approaches to the efficient provision of cost-effective care.<sup>335</sup> Presumptive disapproval freezes the health care system in its tracks and precludes any speedy response to the changing competitive environment. Although Congress provided for periodic updating of the regulations, the regulatory process is slow and clumsy.<sup>336</sup> Innovative thinking would be stifled and competition would suffer if every idea had to await the next rules drafting period for approval. Any competitive advantage from an innovative arrangement would be dissipated because all competitors would have simultaneous access to the same information about newly approved arrangements.

Creating a list of approved payment practices is worse than useless. Unless one is willing to copy the approved arrangement, there is some risk of prosecution. Any deviation might be sufficient to eliminate the protections of a specific practice criterion. Few providers would be willing, no matter how similar their circumstances (in itself an unlikely event) to duplicate another provider's arrangement. Every contract, and every discount, and every employee's duties are implicitly involved in assessing if one falls within a specific practice criteria.

Obviously, the regulations should provide specific practice criteria for payment practices and joint ventures that have been introduced or envisioned. These might include waiver of co-payments, group purchasing arrangements, ownership interests in health care facilities, and payments by DME suppliers and home health care agencies. However, the regulations should also provide generic criteria — the philosophic underpinning for the determination of specific provisions — for the assessment of novel and innovative joint ventures and incentive programs. The Congressional mandate is not sufficiently served without generic criteria. If one does not know the rules, it is difficult to play the game.

The publication of generic criteria does not prevent the Secretary from determining that a specific practice constitutes a viola-

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335. Evidence for this mandate is the widespread support for the prospective payment system, the Congressional desire to contain the growth of health care costs, and the provision for generic criteria in regulation pursuant to MMPPPA.

336. For example, MMPPPA will require at least two years before the final regulations are available. H.R. REP. NO. 85, Part 2, 100th Cong., 1st Sess. 27 (1987).

tion of the statute, even though there was no specific prohibition in the regulations. This will ensure a good faith reading of the generic criteria and will allow the Secretary to eliminate fraudulent or abusive practices without constraining the development of new and innovative arrangements.

Not all providers are reimbursed under the PPS. Only hospitals currently receive prospective payment.<sup>337</sup> Physicians, home health care agencies, DME suppliers, clinical laboratories, and other providers and facilities are paid under the older fee-for-service system.<sup>338</sup> Any generic criteria must account for the existence of this dual system for reimbursement and accommodate arrangements between providers in each system. Further, the generic criteria must account for the ethical constraints on physicians.<sup>339</sup> We suggest several potential generic criteria, and note some of the advantages or disadvantages of each.

#### A. *No Increased Cost: Not Illegal*

This criterion is clearly inadequate. Under a cost-based reimbursement system, this criterion helps to constrain abusive practices such as over-utilization.<sup>340</sup> Nonetheless, it is clearly not responsive to fraudulent practices such as kickbacks or bribes. Further, the criterion is founded on a misapprehension of the evils of the proscribed conduct, a view that was clearly and convincingly rejected by the Seventh Circuit in *United States v. Ruttenberg*.<sup>341</sup> Quality of care issues may also arise; consider the danger of referral to a marginal institution that offers substantial incentive payments. Providers that receive prospective payment are left to their own devices if this criterion is adopted, because almost no action they take could increase the cost to the government.<sup>342</sup> Finally, this criterion is not responsive to the ethical implications of physi-

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337. See *supra* note 23.

338. This generalization does not include health maintenance organizations ("HMOs") that contract with Medicare to provide all necessary care to beneficiaries at a fixed price. There have also been efforts at reforming Medicare payment to physicians. See *supra* note 66.

339. See *supra* notes 141-59 and accompanying text.

340. See *supra* notes 28, 124-25, 246.

341. See *supra* notes 262-63 and accompanying text. See also discussion of *Hammerschmidt* and of *Dennis*, *supra* at notes 235-36.

342. But see *supra* note 42. Even if adopted, this exemption for hospitals paid under the PPS cannot be indefinitely expanded. If a hospital structures an arrangement so that the Medicare program can be billed twice for the same episode of treatment, then that structure would likely violate the Fraud and Abuse statute even though a provider paid by the PPS was involved. See *supra* note 45.

cian participation in such arrangements.<sup>343</sup>

*B. If the Activity is in Keeping with the Common and Accepted Practices in the Hospital and Health Care Field — i.e., if it is a Reasonable and Legitimate Business or Medical Activity: Not Illegal*

This criterion is better than the previous one but it raises both definitional and philosophic problems. The definition of reasonable and legitimate is, after all, what is at issue. How does one measure such a thing? Expert testimony? Survey research? Gut instinct? More problematic is that the criterion does not allow for the development of new and innovative arrangements. All activities are measured against what has been done in the past — a result that is fundamentally at odds with current conditions and with Congressional intent.<sup>344</sup>

Although this criterion avoids some of the ethical difficulties previously discussed by incorporating such a standard, it raises other issues. A reasonable and legitimate activity in the business field may not be so in the medical field. Congress provided for the exemption of discounting in the 1977 Fraud and Abuse statute, but it did not allow many other forms of normal business activity, emphasizing that the health care field is held to a different standard.<sup>345</sup> The canon of ethics that is accepted by most providers will be imposed on those less inclined to follow any higher standard.<sup>346</sup> Yet,

343. See *supra* notes 141-59 and accompanying text.

344. See *supra* notes 30-43 and accompanying text.

345. See *supra* notes 156, 174-86 and accompanying text.

346. Of course, this assumes that most providers are at the "right" level of ethical conduct. Ethical canons alone are not sufficient to ensure ethical conduct, as any sanctions they impose might run afoul of the antitrust laws:

Although an ethical canon may serve to discourage some physicians from getting involved in conflict situations, it cannot deter those who are strongly inclined toward entrepreneurship. Indeed, it is an irony of ethical canons that they discourage only the most conscientious and reputable physicians — the very ones least likely to abuse their trust — from embarking on questionable paths.

Havighurst, *Letter*, 314 *NEW ENG. J. MED.*, 251 (1986).

Another difficulty with this approach (i.e., incorporating the assessments of regulated parties as the standards for regulation), is the problem of delegation, most definitively explored in *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935). As a constitutional doctrine, non-delegation has fallen on hard times, despite some recent evidence of reexamination. See *Industrial Union Department, AFL-CIO v. Am. Petroleum Inst.*, 448 U.S. 607, 672-688 (1979) (Rehnquist, J., concurring in judgment).

As a policy matter, however, non-delegation is an important concept. It prevents some market participants from dictating the rules which all participants must follow. Recent theories of agency "capture" are the modern counterpart of the non-delegation doctrine.

the Congressional directive to "consult with affected provider[s], practitioner[s], supplier[s] and beneficiary representatives before publishing proposed rules,"<sup>347</sup> indicates that current practice provides some guidelines to the boundaries of ethical and legal conduct.<sup>348</sup>

*C. No Objection by the Inspector General: Not Illegal*

This criterion could operate either retrospectively or prospectively. Retrospective review would allow for experimentation by providers and the Inspector General could choose those programs it deemed inconsistent with the spirit and integrity of the Medicare program. This approach has two problems: it fails to protect the beneficiary population in the interim, and it provides no guidance to providers as to the appropriate limits of legal conduct. Their planning and marketing will be adversely affected by the inherent uncertainty of their arrangements.<sup>349</sup>

Prospective review is somewhat better than retrospective review because it avoids some of the inherent uncertainty associated with retrospective review. Unfortunately, it suffers from other defects. If approval requires awaiting the next rules-drafting period, there will be lengthy delays before new arrangements may be instituted. The simultaneous release of information about specific legal arrangements will destroy whatever competitive advantage the innovator would have derived from being the first to invent a new arrangement. The incentives for innovation are radically skewed by precluding any profit from innovation.<sup>350</sup> HHS could provide private letter rulings analogous to those used by the Internal Revenue Service.<sup>351</sup> This would minimize uncertainty, provide ongoing review of appropriate practices, and simplify the updating of "specific practice" regulation. Logically, such private letter rulings

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See Sunstein, *Constitutionalism after the New Deal*, 101 HARV. L. REV. 421. For a general discussion of agency capture theories, See SCHOLZMAN & TIERNEY, ORGANIZED INTERESTS AND AMERICAN DEMOCRACY (1986).

347. H.R. REP. NO. 85, Part 2, 100th Cong., 1st Sess. 27 (1987).

348. See *supra* notes 141-59, 186 and accompanying text.

349. Obviously, the government can at any time choose to prosecute an arrangement that had previously been ignored, winked at, or acquiesced in. *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 225-27 (1940). This inherent uncertainty would chill innovation — precisely the opposite from what was intended to result from generic criteria. See *supra* notes 310-14 and accompanying text.

350. In fact, the constitution provides for protecting the "Right" of inventors to their discoveries, "to promote the progress of Science and the Useful Arts." U.S. CONST. art. I, § 8.

351. The Internal Revenue Service provides these rulings pursuant to the broad grant of authority in I.R.C. § 7805 (1982).

should be protected from disclosure for a limited period of time. This would encourage innovation that results in a competitive advantage, yet allow for dissemination of new approaches to cost-containment.<sup>352</sup> Any such arrangement should leave providers free to experiment with reimbursement arrangements. Refusal to submit an arrangement for approval might be deemed to constitute the knowing and willful element of intent if an arrangement was subsequently determined to violate the statute.

#### D. *No Objection by the Patient: Not Illegal*

This criterion is deeply problematic. If a patient fully and freely agrees to some arrangement, what business is it of anyone? Respect for the patient's autonomy and his right to contract freely should preclude any officious intermeddling by the government.<sup>353</sup> Yet, this argument does little justice to the problem. Generally, one may not consent to the commission of a crime, nor may consent be brought as a defense.<sup>354</sup> The government and the profession of medicine both have an interest in those arrangements that are made.<sup>355</sup> Thus, even if it could be shown that the patient understood all the implications of an arrangement, simple consent is not sufficient.<sup>356</sup> Interestingly, consent might cure some, but not

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352. This is precisely the approach used by the patent office. Inventors are granted a temporary monopoly in exchange for disclosing their invention.

353. This philosophy is more commonly known as freedom of contract. Borrowed largely from the work of John Locke and John Stuart Mill, it is a powerful undercurrent in most legal scholarship. "[F]reedom of contract tends both to advance individual autonomy and to promote the efficient operation of labor markets." Epstein, *In Defense of the Contract at Will*, 51 U. CHI. L. REV. 947 (1984). See also generally *Medical Malpractice: Can The Private Sector Find Relief*, 49 LAW AND CONTEMP. PROBS. 143-223, 243-305 (1986) for an example of freedom of contract principles in action.

354. W. LAFAVE & A. SCOTT, *HANDBOOK ON CRIMINAL LAW* 408 (1972). "The explanation most commonly given for this rule is that a criminal offense is a wrong affecting the general public, at least indirectly, and consequently cannot be licensed by the individual directly harmed." *Id.* "For it is the public, not a complainant, that is injured by the commission of a crime." *People v. Brim*, 199 N.Y.S.2d 744, 748 (1960) (citing *People v. Quill*, 11 Misc. 2d 512, 513, 177 N.Y.S.2d 380, 382) (1958)).

355. See *infra* notes 141-59 and accompanying text.

356. Interestingly, California requires written disclosure of physician financial interest in facilities to which they refer patients. Cal. Bus. & Prof. Code § 654.2 (West 1986). The physician must also inform the patient that they do not have to use the facility that the physician selects. *Id.* Federal law requires disclosure to the Secretary of HHS of ownership interest in a facility to which the physician refers patients. 42 U.S.C. § 1320a-3 (1982).

However, disclosure is not a panacea, as it undermines the very values of professionalism it was designed to protect. Morreim, *The MD and the DRG*, 15 HASTINGS CENTER REP. 30, 35 (June 1985). A loss of trust in the physician will inevitably result. *Id.* One would have hoped that consumer protective legislation would not be required for the doctor-patient relationship.

all of the antitrust implications of these arrangements.<sup>357</sup>

*E. No Harm to the Program or its Beneficiaries: Not Illegal*

Harm, of course, requires some specific standards for assessment. Possible standards include: (1) Any arrangement that results in increased cost to the program for items or services provided results in a harm; (2) Any arrangement that results in the furnishing of a medically unnecessary item or service results in a harm; (3) Any arrangement that results in quality of care that does not meet professionally recognized standards of care results in a harm; (4) Any arrangement that results in the failure to provide a medically necessary item or service results in a harm; (5) Any arrangement that compensates a physician for services rendered to another provider, so long as the service is necessary and the compensation is reasonable, does not result in a harm.<sup>358</sup>

The first three standards should be relatively noncontroversial,

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357. An antitrust objection could be made that the arrangement was a contract, combination, or conspiracy in restraint of trade (specifically, a "tying violation") under the Sherman Act 15 U.S.C. § 1 and Clayton Act 15 U.S.C. § 15 or an unfair or deceptive act or practice in commerce under the FTC Act 15 U.S.C. § 50. A tying arrangement has been defined:

as an agreement by a party to sell one product but only on the condition that the buyer also purchases a different (or tied) product, or at least agrees that he will not purchase that product from any other supplier. Where such conditions are successfully exacted competition on the merits with respect to the tied product is inevitably curbed. Indeed "tying agreements serve hardly any purpose beyond the suppression of competition." *Standard Oil Co. of California v. United States*, 337 U.S. 293, 305-306 (1948). They deny competitors free access to the market for the tied product, not because the party imposing the tying requirements has a better product or a lower price but because of his power or leverage in another market. At the same time buyers are forced to forego their free choice between competing products.

*Northern Pacific Railroad Co. v. United States*, 356 U.S. 1, 5-6 (1957).

If a patient fully and freely consented, presumably there could not be a tie as there has been no "forcing" or leverage of market power. A tying violation requires market power in the tying product (physician referrals) which most providers do not have. *Jefferson Parish Hosp. District No. 2 v. Hyde*, 466 U.S. 2, 14 (1983). On "tying" violations generally, see L. SULLIVAN, *HANDBOOK OF THE LAW OF ANTITRUST* 431-471 (1977). Indeed, there has been criticism of the basic principle of "tying violations" on economic grounds. R. POSNER & F. EASTERBROOK, *ANTITRUST* 802 (1982) (sellers will not engage in such conduct as they can already extract the full monopoly profit from the tying item). Nevertheless, the FTC antitrust suit would presumably not be waived by consent, as the conduct could still be deemed unfair or deceptive.

358. The test for reasonableness should probably be that suggested in dicta in *United States v. Lipkis*, 770 F.2d 1447 (9th Cir. 1985). In that case, the court noted in regard to a payment "the fair market value of these services was substantially less than the compensation . . . and there is no question that ALS was paying for the referrals as well as the described services." *Id.* at 1449. The *Lipkis* test is a narrowing of the *Greber* holding. In *Greber* a reasonable payment was still illegal if "one intention of the payment is to induce

because they merely incorporate the present obligations of all providers to Medicare patients.<sup>359</sup> The fourth standard will address the abusive practice of underutilization. It presumably will foreclose the attractiveness of many DRG incentive programs, especially because it complements the OBRA provision<sup>360</sup> and provides an alternative to pursuing the consequences of such arrangements with peer review sanctions.<sup>361</sup>

The fifth standard will delineate the acceptable boundaries of physician conduct, given the ethical concerns discussed previously.<sup>362</sup> Physicians must provide real and necessary service to another provider. The resulting compensation must be reasonable. Payment for referral alone is forbidden. There must, however, be some common sense limitations here as well.<sup>363</sup> This may preclude some physician entrepreneurialism, but it definitively allows those arrangements that meet the standard.

When taken together, these standards incorporate the cost-containment goals, yet safeguard the ethical integrity of the medical profession. The standards are protective of physician integrity — to the paternalistic extent of precluding participation in many profitable activities. Yet, the legislative history and the nature of professionalism argue against any other result.<sup>364</sup>

The generic criteria that are adopted should probably be some combination of the standards listed in proposals B, C, and E above. This will allow providers sufficient flexibility in the development

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a referral." *Greber*, 760 F.2d at 71. *Lipkis* suggests that inducement is manifested by disproportionality of service and payment rather than payment *per se*.

359. 42 U.S.C. § 1320 c-5 (1982).

360. *See supra* note 75.

361. *See supra* note 83.

362. *See supra* notes 141-59 and accompanying text.

363. For example, a physician who owned one share of stock in a company from which his patients bought medical supplies should not be subject to the statute.

364. In this context, it is interesting to note that when DRGs were introduced, critics noted that hospitals would be encouraged to discharge patients "quicker and sicker." The standard response was that the ethical integrity and professionalism of physicians would preclude that result. A redefinition of the relationship between hospital and physician was expected, but

in the final analysis physicians must not voluntarily compromise the quality of care they offer their patients in order to conserve society's costs. Let society (or the hospital) defend its interests while the physician defends the patient's. . . . Overall, then, physicians' cost control efforts should aim to comply responsibly with the spirit as well as the letter of society's cost-control policies — neither neglecting their hospitals' fiscal welfare nor single-mindedly promoting their hospitals' maximal economic benefit. Throughout, however, physicians' allegiance to their patients must still assume a primacy in any morally acceptable response to economic constraints.

Morreim, *The MD and the DRG*, 15 HASTINGS CENTER REP. (June, 1985) 30, 31, 33-34.

and assessment of innovative arrangements while still providing guidelines as to which results are acceptable and which are proscribed. The publication of generic criteria leaves the initial experimentation and determination of payment arrangements to providers, yet this is precisely what Congress intended by enacting the PPS.

## XI. CONCLUSION

The framing of regulations pursuant to MMPPPA offers a unique opportunity for clarifying the ambit of the Fraud and Abuse statute. A review of the history of the statute has revealed that fraud was distinguished from abuse although both were perceived as attacks on the fiscal and ethical integrity of the Medicare program.<sup>365</sup> The introduction of the PPS and other changes in the health care environment changed the situation dramatically. Providers are now encouraged to forge new relationships and to operate more efficiently, so as to lower costs. In other words, providers are encouraged to drive inefficient competitors from the marketplace. Yet the narrowness of the exemptions under the 1977 Fraud and Abuse statute indicates that the health care industry is to be held to a higher standard than "business as usual."<sup>366</sup> Choosing the correct generic criteria requires the balancing of cost containment with ethical concerns. The regulators must be responsive to each of these demands, yet conscious of the tension between them.<sup>367</sup>

Enforcement based on outdated principles is counterproductive and will impede the restructuring of the health care industry along more efficient and cost-effective lines. Congress has demonstrated its intent to encourage the efficient and cost-effective provision of health care to Medicare beneficiaries. The new regulations should allow for innovation and should not impede legitimate and beneficial activities. HCFA previously has intimated that such activities are not subject to prosecution. Yet, the effects of the Fraud and Abuse statutes has been to cast doubt on precisely such behavior.

It is clear that the structure of an arrangement can violate the

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365. See *supra* notes 169, 177-89, 194 and accompanying text.

366. See *supra* notes 141-59 and accompanying text.

367. That there is tension between these two goals seems obvious. Skeptics should consult notes 141-59 and accompanying text. Those who remain firm advocates of "business as usual" should ponder the position of one attorney who asked, "If there's no possibility of 'churning' patients through unneeded tests, what's the matter with an honorable, reputable M.D. making the money?" 17 HEALTH POLICY 1 (July 14, 1988). Does not this response beg the question? Will honor or reputation long remain when a profession is placed in such a conflict of interest?



1980 Fraud and Abuse statute even in the absence of over- or under-utilization. Whether that should continue to be the case seems justifiable only for ethical reasons, especially because the health care financing system now relies on "competition" to ensure efficient and cost-effective care.<sup>368</sup> At the very least, the strand of reasoning captured by the definition of fraud has lost much of its viability and should probably be narrowed.<sup>369</sup>

Thus, the new guidelines from HHS should provide both specific safe harbors as well as generic criteria against which proposed incentives may be measured. By including these generic criteria, the government unleashes the ingenuity of providers to experiment with linkages and other innovative arrangements in keeping with the purpose of the PPS. A narrow definition of "safe harbors" for payment practices will stall incentive programs in existing patterns and will force the Inspector General to issue frequent updates on acceptable payment arrangements. This process would be time-consuming and unsatisfactory. Worse still, it is fundamentally inconsistent with the intent of Congress to control health care costs through the "competitive" forces of the marketplace.<sup>370</sup> The ingenuity of providers to maneuver within the PPS will be severely compromised if HHS refuses to provide generic criteria.

In this new era of "competition" in health care, the Fraud and Abuse statutes are in large part a superannuated remnant of regulatory control. Absent clear evidence of harm to the program, its beneficiaries, or compelling ethical arguments, the regulations should allow providers the flexibility to provide quality care in an efficient and cost-effective manner.

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368. The quote marks around "competition" are used deliberately. Irony aside, it is difficult to square price-fixing, which the DRGs are, with any principle of competition. Yet, true competition has its own problems. See *supra* notes 5, 41, 44.

369. See *supra* notes 136-40.

370. See *supra* note 368. For simplicity, future use of "competition" will include quotation marks.