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### Curing the Health Care Industry: Government Response to Medicare Fraud and Abuse

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## COMMENTS

### CURING THE HEALTH CARE INDUSTRY: GOVERNMENT RESPONSE TO MEDICARE FRAUD AND ABUSE

#### I. INTRODUCTION

In 1983, Congress enacted legislation that changed the form of Medicare reimbursement for inpatient services from a direct cost reimbursement system to a prospective payment system (PPS).<sup>1</sup> Under the direct cost reimbursement system, the federal government reimbursed a hospital for the actual dollar amount the Medicare patient cost the hospital. The only requirement imposed on a hospital was that the cost for the treatment be reasonable.<sup>2</sup> In order to cut the high cost of the Medicare program, the federal government established the PPS. Under the PPS, a hospital is only reimbursed a fixed, predetermined sum for the treatment rendered. This sum is determined by the "average cost of treating a patient in a particular Diagnostic-Related Group (DRG),"<sup>3</sup> regardless of the Medicare patient's actual cost to the hospital. Thus, if a Medicare patient's cost to the hospital exceeds the prospective payment, the hospital loses money. As a result, a greater need for hospital efficiency and expansion arose in order for hospitals to increase their revenue base and profit margin.<sup>4</sup>

In order to improve efficiency, reduce costs, and increase revenue, hospitals have embarked upon various ventures. These ventures include physician

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1. Social Security Amendments of 1983, Pub. L. No. 98-21 § 60-107, 97 Stat. 65, 149-72 (1983). For an account of the Medicare system surrounding the change to and enactment of PPS, see generally Hyman and Williamson, *Fraud and Abuse: Regulatory Alternatives in a "Competitive" Health Care Era*, 19 LOY. U. CHI. L.J. 1133, 1136-43, 1166-69 (1988); see also Comment, *The Medicare-Medicaid Anti-Fraud and Abuse Amendments: Their Impact on the Present Health Care System*, 36 EMORY L.J. 691, 691-727 (1987) [hereinafter Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*].

2. See Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 701.

3. *Id.* at 703; see also Hyman and Williamson, *supra* note 1, at 1138-1143.

4. Increasing a hospital's revenue base is a concern for both a for-profit and not-for-profit hospital. In order to survive, each type of hospital must remain financially viable through effectively employing their existing revenue. Although this Comment will focus on for-profit hospitals, not-for-profit hospitals conceivably could still be affected by the addressed issues surrounding the hospital's increase of its revenue base and profit margin.

incentive plans,<sup>5</sup> hospital-physician joint ventures,<sup>6</sup> and physician recruitment programs.<sup>7</sup> If these revenue enhancing plans are not carefully structured and implemented, both the hospital and the physicians involved in the plan run the risk of violating the Medicare fraud and abuse laws,<sup>8</sup> under which it is illegal to knowingly solicit or receive any form of remuneration in return for the referral of patients.

The clear language of the anti-kickback provision,<sup>9</sup> broad judicial inter-

5. Physician incentive plans are programs set up within a hospital through which hospitals reward physicians for their cost-conscious behavior in administering patient care. See *infra* notes 56-78 and accompanying text.

6. Hospital-physician joint ventures are contractual arrangements between hospitals and physicians where the participating parties exchange their services in the delivery of health care to the community. See *infra* notes 79-96 and accompanying text.

7. Physician recruitment programs are set up by hospitals to recruit and obtain outstanding physicians for the hospital's own affiliation. See *infra* notes 97-99 and accompanying text.

8. 42 U.S.C. § 1320a-7b(b) (Supp. 1988) (recodifying 42 U.S.C. § 1395nn(b)(1982)). Medicare, Title 18 of the Social Security Act, provides health insurance "for the elderly over 65 who were eligible for social security benefits and for certain disabled persons." Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 696 (footnote omitted). Medicaid, Title 19 of the Social Security Act issues payments in the form of grants to the states to provide health insurance for the medically indigent. *Id.* (The structuring and intricacies of the two forms of governmental medical insurance are beyond the scope of this Comment. For a further, in depth analysis of the structure of the two forms of governmental medical insurance, see *id.* at 696-99.). The substance of the Medicare and Medicaid anti-kickback provisions are substantially similar; however, for simplicity this Comment focuses primarily on Medicare fraud and abuse.

9. 42 U.S.C.A. 1320a-7b(b) states:

(b) Illegal remunerations

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

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

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under subchapter XVIII of this chapter or a State health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined (not more than \$25,000 or imprisoned for not more than five years, or both.

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

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

(B) to purchase, lease, order, or arrange for or recommend purchasing, leas-

pretation of the enforcement provision,<sup>10</sup> and sufficient declination of the prosecution of kickback violations by the Department of Justice (DOJ)<sup>11</sup> have fostered an air of uncertainty within the health care and legal communities as to the scope of the Medicare anti-kickback provisions. Hospitals have weighed the illegality of their conduct against the probability of prosecution<sup>12</sup> for various cost-effective arrangements. After assessing that

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ing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under subchapter XVIII of this chapter or a State health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

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

- (A) a discount or other reduction in price obtained by a provider of services or other entity under subchapter XVIII of this chapter or a State health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under subchapter XVIII of this chapter or a State health care program;
- (B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;
- (C) any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under subchapter XVIII of this chapter or a State health care program if—
  - (i) the person has a written contract, with each such individual or entity which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and
  - (ii) in the case of an entity that is a provider of services (as defined in section 1395x(u) of this title, the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity; and
- (D) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 . . . .

10. *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), *cert. denied*, 447 U.S. 988 (1985). To date *Greber* is the most elaborate judicial determination of the Medicare anti-kickback provisions. In *Greber*, the court determined that even if payments from a health care entity to a physician participating in the Medicare reimbursement system were made in compensation for services rendered, the Medicare anti-kickback provision was violated if the payments were made to induce future referrals. *Id.* at 72. This broad interpretive holding is supported in a subsequent case. See *United States v. Lipkis*, 770 F.2d 1447 (9th Cir. 1985). For a more detailed discussion, see *infra* text accompanying notes 32-48.

11. See Volk, *Medicare/Medicaid Fraud and Abuse in the Reimbursement System*, 6 WHITTIER L. REV. 857, 858 (1984).

12. See Kusserow, *OIG Mission, Staff, Record*, in *MEDICARE FRAUD AND ABUSE: UNDERSTANDING THE LAW* 46 (1986).

probability, some hospitals in tight financial situations have proceeded into revenue enhancing areas that may constitute technical violations of the law.<sup>13</sup> The real impact of hospitals engaged in these technically illegal practices of raising revenue is that they are driving hospitals who are strictly observing the letter of the Medicare fraud and abuse laws out of business.

The rendering of competent, legal advice to the affected hospitals and physicians becomes an issue for health lawyers when the scope of these laws and regulations are unclear. Ethically, lawyers cannot advise their hospital and physician clients to enter business arrangements that violate the law even though the risk of prosecution may be slight. The other option lawyers have is to advise their hospital and physician clients to follow the strict letter of the law. This latter option, however, may cause hospitals and physicians to forego possible advantageous business arrangements that may increase their cost effectiveness, their revenue bases, and ultimately their ability to deliver health care services.

In response to the growing uncertainty within the health law field, Congress enacted the *Medicare and Medicaid Patient and Program Protection Act of 1987* ("1987 Act").<sup>14</sup> The 1987 Act broadens the enforcement power of the anti-kickback statutes by expanding the disciplinary authority to the Office of Inspector General (OIG) within the Department of Health and Human Services (HHS).<sup>15</sup> Furthermore, the 1987 Act mandates that HHS issue final regulations by August of 1989, exempting from disciplinary action certain business practices of hospitals and physicians.<sup>16</sup> This enactment and

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13. The Medicare anti-kickback provision prohibits both the offering and receiving of any form of remuneration. This broad statutory language incorporated not only clearly abusive and violative kickback practices, but also nonabusive practices such as providing free cups of coffee to a hospital's staff. Gaynor and Decator, *Joint Ventures and Medicare-Medicaid Fraud and Abuse Laws*, 41 TRUSTEE 23 (Apr. 1988). Although these two examples are on opposite ends of the spectrum of the Medicare fraud and abuse laws, they illustrate the sweeping effect of the provisional language. Within this wide scope of the law are many legitimate, financially necessary, non abusive arrangements between hospitals and physicians.

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

15. *Id.* § 2, 101 Stat. 680, 681-82 (codified at 42 U.S.C.A. § 1320a-7(b)(7) (Supp. 1988)). Previously enforcement was a criminal matter and authority existed solely with DOJ. Now HHS has the civil authority to exclude the violating hospital from participation in the Medicare and Medicaid systems. This exclusion would disallow any federal reimbursement of hospital cost for treatment rendered and thwart some hospitals' efforts to increase their revenue base.

16. 1987 Act, § 14, 101 Stat. 680, 697. Proposed regulations were issued on January 23, 1989 with a comment period extending until March 24, 1989. See 54 Fed. Reg. 3088 (1989) (to be codified 42 C.F.R. pt. 1001). HHS will review the comments and issue final regulations in August 1989. Interested practitioners should be aware of this date; however the proposed regulations were supposed to be issued in August, 1988 and were not issued until five months later. Therefore a constant watch of HHS action is essential to acquiring knowledge of these final regulations.

subsequent promulgation of exemptions demonstrate a governmental response aimed at curing the uncertainty and fostering a more efficient and market-responsive health care industry.

This Comment outlines and analyzes the 1987 Act's expansion of government enforcement authority under the Medicare fraud and abuse laws. Subsequently, an analysis of the wide array of business arrangements illustrates the complexity of the fraud and abuse concerns. Finally, the issuance of proposed regulations and further congressional guidance provides the health care industry with a semblance of certainty and continuity in this unclear area. This Comment concludes that the 1987 Act commences a curative governmental response to the uncertainty within the health care industry and fosters eventual growth and development throughout the health law field.

## II. THE MEDICARE AND MEDICAID PATIENT AND PROGRAM PROTECTION ACT OF 1987

The 1987 Act performs three functions regarding kickbacks within the Medicare system: consolidation of enforcement provisions; expansion of disciplinary authority; and regulation from which guidelines may be derived.

### A. Consolidation of Enforcement Provisions

Prior to the 1987 Act, the Medicare anti-kickback provision was found in section 1877(b) of the Social Security Act.<sup>17</sup> The provision prohibited any individual or entity from soliciting or receiving any remuneration in return for patient referrals, as well as from offering or paying any remuneration to induce these referrals. Violation of this statute constituted a felony with the imposition of a fine not to exceed \$25,000, or a prison term no longer than five years, or both.<sup>18</sup> Statutory exemptions to the anti-kickback provision included practices first, where a discount in price was obtained by a provider of services "if the reduction in price [was] properly disclosed and appropriately reflected in the costs claimed,"<sup>19</sup> second, where a bona fide employment relationship existed and an employer made a payment to an employee for Medicare related items or services,<sup>20</sup> and third, where a vendor of goods made a payment to an individual or entity acting as a group purchasing organization when the amount of the payment had been contractually set

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17. Social Security Act, § 1877(b), 42 U.S.C. § 1395nn(b) (1982) dealt solely with Medicare fraud and abuse. It contained substantially the same effectual language with regard to the Medicare program as does the recodified version of 42 U.S.C.A. § 1320a-7b(b) (Supp. 1988).

18. 42 U.S.C. § 1395nn(b) (1982).

19. 42 U.S.C. § 1395nn(b)(3)(A) (1982).

20. *Id.* at § 1395nn(b)(3)(B):

and proper disclosure was evident.<sup>21</sup>

The Medicaid anti-kickback provision contained substantially identical language.<sup>22</sup> These provisions were spread throughout the Social Security Act. While maintaining the same effectual language and enforcement power, the 1987 Act consolidated these provisions.<sup>23</sup> While the simplification and unification of these enforcement provisions did not affect the distribution of health care services, it was a constructive step toward clarifying complex legislation.

### B. Expansion of Authority

Prior to the 1987 Act the only enforcement for the Medicare anti-kickback provision was criminal prosecution initiated by the DOJ. The 1987 Act expands to HHS the authority to impose penalties for kickback payments.<sup>24</sup> In addition to criminal penalties, which are still contained in the anti-kickback provision, the Secretary of HHS has the authority to exclude from the Medicare program any individual or entity which he determines has engaged in prohibited conduct relating to the giving or receiving of kickbacks for patient referrals.<sup>25</sup> The basis for this enforcement authority is the broad anti-kickback language of the Social Security Act.<sup>26</sup> Furthermore, the standard of judicial review is lower than that of a criminal proceeding.<sup>27</sup> The legislative history states that "the burden of proof requirements under this authority would be those customarily applicable to administrative

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21. *Id.* at § 1395nn(b)(3)(C).

22. Social Security Act § 1909(b), 42 U.S.C. § 1396h(b) (1982).

23. 1987 Act § 4, 101 Stat. 680, 688-89. Social Security Act § 1877(b), 42 U.S.C. § 1395nn(b) was repealed and replaced by Social Security Act, § 1128B, 42 U.S.C.A. § 1320a-7b(b) (Supp. 1988). Even though enforcement of the anti-kickback provisions are contained within the same section, the actual enforcement procedure is different. The focus of this Comment is limited to fraud and abuse within the Medicare system. Health lawyers should be aware of the differences with regard to eligibility requirements, payment structure, and enforcement proceedings of each system. To obtain the required knowledge of the Medicaid insurance system, investigation of each individual state's health care program is essential.

24. 1987 Act at § 2(b)(7), 101 Stat. 680, 681-82 (codified at 42 U.S.C. § 1320a-7(b)(7) (Supp. 1988)).

25. *Id.* Exclusion would be a preclusion of any Medicare payment issued for any services rendered by a provider of health care. 1987 Act, § 8(c), 101 Stat. 680, 692-93, amending section 1862 of the Social Security Act, 42 U.S.C. 1395y(e) (1982); 1987 Act, § 10, 101 Stat. 680, 696.

26. Social Security Act § 1128B, 42 U.S.C.A. § 1320a-7b(b) (Supp. 1988).

27. See 1987 Act, § 2(f), 101 Stat. 680, 685. The standard of proof in a criminal proceeding is that the evidence must be proven "beyond a reasonable doubt." In *Steadman v. SEC*, 450 U.S. 91 (1981), the Supreme Court stated that evidence presented in agency proceedings, absent any congressional mandate as to the required standard of proof, must only be proven by a preponderance of the evidence, not a heightened level of scrutiny. *Id.* at 104.

proceedings.”<sup>28</sup>

With this broad grant of enforcement authority, special due process requirements are imposed. Rather than pre-hearing exclusion, “any individual or entity that is the subject of an adverse determination under subsection (b)(7) [Permissive Exclusion for Fraud, Kickbacks, and other Prohibited Activities] shall be entitled to a hearing by an administrative law judge . . . before any exclusion based upon the determination takes effect.”<sup>29</sup> The legislative history specifies the reasoning behind this special review:

The Committee bill includes this special protection requiring a pre-exclusion independent fact finding because some of the grounds for exclusion under section 1128(b)(7) [section 2(b)(7) of the 1987 Act], particularly the anti-kickback provisions of section 1128B, may involve practices that require adjudication to determine whether the requisite criminal intent existed to “knowingly and willfully” violate the standards.<sup>30</sup>

This special review would not apply in an instance where the Secretary determines that a delay in exclusion would harm “the health or safety of individuals receiving services.”<sup>31</sup>

The lower burden of proof associated with exclusionary proceedings, and the expansion of authority to HHS, suggest an increase in disciplinary actions in the future. This increase would provide an opportunity to formulate guidelines from which the health law field may determine which type of practices would be penalized. As a result, the 1987 Act has enabled clearer standards to be formed, thereby providing some certainty within this area of health care.

### C. Judicial Interpretation-United States v. Greber

Prior to the 1987 Act, the scope of the Medicare anti kickback provisions included a “wide range of practices within the healthcare industry—from paying physicians a ‘bounty’ for each referred patient, which is clearly prohibited, to providing free coffee to medical staff members.”<sup>32</sup> In *United States v. Greber*,<sup>33</sup> the court held that if payments were made to a physician

28. 1987 Act, S. Rep. No. 100-109, 100th Cong., 1st Sess. 10, *reprinted in* 1987 U.S. CODE CONG. & ADMIN. NEWS 682, 690 (1987).

29. 1987 Act, § 2(f)(2), 101 Stat. 680, 685, 42 U.S.C.A. § 1320a-7(f)(2) (Supp. 1988).

30. 1987 Act, S. Rep. No. 100-109, 100th Cong., 1st Sess. 13, *reprinted in* 1987 U.S. CODE CONG. & ADMIN. NEWS 682, 683 (1987).

31. *Id.*, *reprinted in* 1987 U.S. CODE CONG. & ADMIN. NEWS 682, 694 (1987).

32. Gaynor and Decator, *supra* note 13.

33. 760 F.2d 68 (3d Cir. 1985), *cert. denied*, 447 U.S. 988 (1985). *Greber* provides the most recent insight into the enforcement power under the Medicare anti-kickback provision. For a further in depth analysis of the *Greber* decision and its impact on potential physician



to induce future patient referrals, even if the payments were in compensation for actual services rendered by the physician, the Medicare anti-kickback provision had been violated by both parties.<sup>34</sup> *Greber* involved a diagnostic services company (Cardio-Med, Inc.) which provided physicians with a Holter-Monitor.<sup>35</sup> After Cardio-Med had analyzed the data received from the monitored patient, it would bill Medicare for this service and return the data to the physician along with a portion of the Medicare fee supposedly for interpretation fees which the physician would perform after receiving the data.<sup>36</sup> These interpretation fees were provided to physicians even though Cardio-Med already had interpreted and evaluated the data.<sup>37</sup> Because the physician would receive a benefit from the arrangement, there was an incentive for the physician to retain an ongoing relationship with Cardio-Med for their services. Although the defense argued that the funds were for professional services rendered, the court, in adopting the broadest interpretation of the Medicare anti-kickback statute to date, found that where an intent to receive future referrals exists, the statute has been violated.<sup>38</sup>

The problem endemic to all of these fraud and abuse cases is proving the element of intent. In the *Greber* case sustaining this burden was relatively easy for two reasons. First, the investigators found that Dr. Greber had testified in an earlier civil case regarding the Holter Monitor that "if he did not make this payment [from Medicare funds already received], physicians would not select his company."<sup>39</sup> This statement exemplified an actual, discernable intent on the part of Dr. Greber to retain future referrals from the physicians. Second, the *Greber* arrangement contained a "potential for unnecessary drain on the Medicare system,"<sup>40</sup> or overutilization.

The *Greber* court's broad interpretation of the Medicare anti-kickback

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incentive plans and joint ventures, see Case-Comment, *United States v. Greber: A New Era in Medicare Fraud Enforcement?*, 3 J. CONTEMP. HEALTH L. & POL'Y 309, 322-26 (1987); see also, Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, 721-24.

34. *Greber*, 760 F.2d at 72.

35. *Id.* at 70. This device was worn for 24 hours by the patient and would record the cardiac activity. A technician scanned the tape and recorded the data in a diary. *Id.*

36. *Id.*

37. *Id.*

38. Miller, *The Greber Case*, in MEDICARE FRAUD AND ABUSE: UNDERSTANDING THE LAW 16, 33 (1986).

39. *Id.* at 15.

40. *Greber*, 760 F.2d at 71. Gregory P. Miller, the prosecutor in the *Greber* case, suggests that overutilization is the key to establishing 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". Miller, *supra* note 38, at 16.

provisions provided prosecutors at DOJ with a vast area of enforcement.<sup>41</sup> If a relationship fell within the broad reach of the provision, it would be subjected to increased scrutiny.<sup>42</sup> Overutilization is one indicator to detect fraud. Additionally, competing health care providers may inform HHS or the Federal Bureau of Investigation (FBI) of illegal financial arrangements that should be prosecuted.<sup>43</sup>

The issue of subjecting to close scrutiny, and possible criminal prosecution, persons and entities involved in legitimate financial arrangements that accrue no cost on the government has arisen due to a conflict these arrangements have with the Medicare fraud and abuse laws.<sup>44</sup> Furthermore, providing competent legal advice to a hospital or medical practitioner becomes a legal as well as an ethical issue when the legal community is uncertain as to what type of arrangement is covered by the law. Under a different, more legitimate business arrangement, the courts might determine that the payment and referral devices are too remote to violate the anti-kickback provision and distinguish the *Greber* case.<sup>45</sup> However, another judicial decision defining this specific issue has not been prevalent since *Greber*.<sup>46</sup> Given this uncertainty, lawyers cannot possibly advise their clients of all the potential ramifications of the anti-kickback provision.<sup>47</sup> Because the anti-kickback provision exclusively involved a criminal prosecution of violators, HHS could not offer any sufficient assistance in delineating potential problem business arrangements.<sup>48</sup> Ultimately, the guidelines rested with the courts. The law as to physician incentive plans, joint ventures, and physician recruitment

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41. Miller, *supra* note 38, at 17.

42. *Id.* at 33.

43. *Id.* at 15. The issues of overutilization and cost-effectiveness aid the court in determining the legitimacy of the arrangement, but in no way are they conclusive. *Id.* at 16.

44. See Social Security Act, § 1877(b), 42 U.S.C. § 1395nn(b) (1982).

45. See Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 724.

46. Miller, *supra* note 38, at 18: *but see* United States v. Lipkis, 770 F.2d 1447 (9th Cir. 1985), where it was found that defendant received kickback payments in exchange for Medicare referrals, even though such payments also included "compensation for specimen collection and handling services." *Id.* at 1449. The appeal, however, focused upon two issues involving false statements relating to the investigation of the kickbacks. *Id.* at 1448.

47. Miller, *supra* note 38, at 18.

48. See Tillman, *Scope of the Conference*, in *MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW* 10 (1986); *see also* the common language used in HHS advisory letters to providers after the *Greber* decision:

Sections 1877 and 1909 are criminal provisions and as such, no one within the Department has the authority to offer legal advice as to the applicability of the provisions to particular factual situations. Rather, only the Department of Justice and the individual offices of United States Attorneys have the discretion to decide whether or not to prosecute a particular case, and only a court may rule on the applicability of the law to the particular case before it. Nevertheless, having reviewed the descrip-

programs was ambiguous. Prior to 1987 there existed a need for clarification of the Medicare fraud and abuse laws after the *Greber* decision. The 1987 Act was designed to clarify some of the ambiguity that had existed. While it does not completely solve all areas of uncertainty, it is a first step in the right direction.

#### D. Promulgation of Guidelines

The 1987 Act provides the health care community with the opportunity to acquire advice that is more than mere speculation. These guidelines will take the form of issued regulations, or safe harbors.<sup>49</sup> These regulations invite public comment and provide HHS with the opportunity to promulgate exemptions that are in concert with the pulse of the health law field. Additionally, advice could come from specific, fact sensitive, private letter rulings addressed to the concerned parties analogous to those issued by the Internal Revenue Service (IRS)<sup>50</sup> or the Securities Exchange Commission (SEC). Under this form of regulation, although not mentioned in the proposed regulations, health lawyers and affected health care providers would be able to obtain current, substantive advice on specific, proposed health distributing arrangements. The employment of such a mechanism within HHS, who would operate in consultation with DOJ, would be consistent with the congressional purpose of abating the past uncertainty in this area.

The relevant legislative history of the 1987 Act indicates the frustration existing within the health care industry:

It is the understanding of the committee that the breadth of [prior] statutory language has created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed. Neither the Attorney General nor the Inspector General of the Department of Health and Human Services has issued any regulations which would offer guidance to health

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tions of the proposed arrangements set out in your letter, I can provide you with some *general guidance that may be helpful to you*.

Letter from Robin Epstein Schneider, Attorney, Inspector General Division of HHS, January 6, 1986, and December 30, 1985 (emphasis added).

49. See *infra* notes 100-126 and accompanying text. Even if the final regulations do not provide anything more than the obvious business arrangement exemptions from Medicare exclusion or prosecution, the existence of exemptions themselves, combined with an ongoing input into the rulemaking process improves the health care community in this area of law.

50. See Hyman and Williamson, *supra* note 1, at 1191-1192, where the authors argue for the logical and beneficial employment of a private letter ruling mechanism within HHS. The authors propose that this employment would not only provide ongoing review of business arrangements, but also encourage innovation through limited disclosure of the specific ventures.

care providers in this regard.<sup>51</sup>

The 1987 Act provides an opportunity to establish clearer standards through an administrative rulemaking process. The legislative history states:

The committee expects that the Secretary will consult with affected provider, practitioner, supplier, and beneficiary representatives before publishing proposed rules, and that the rules will, to the extent possible, contain criteria relative to prevalent controversies or ambiguities that might apply to business arrangements generally.<sup>52</sup>

The legislative history also states that the intent of Congress is to have HHS receive constant public input so as to allow the regulations to remain current and relevant.<sup>53</sup> This rulemaking process is essential in maintaining the curative effect of the 1987 Act. Absent constant updating, innovative, efficient, and non-abusive ventures will be thwarted in their implementation. As a result, the frustration existing prior to the 1987 Act in the health care community would be revisited.

Through the enactment of the 1987 Act, Congress has constructively enabled the health care community to move forward. The 1987 Act has not limited the *Greber* application *per se*, rather it has allowed HHS, which is theoretically more in touch with the health care community than DOJ, to enforce the anti-kickback provision at an administrative level.<sup>54</sup> The 1987 Act also has addressed the issue of differing fact patterns from that in *Greber* in its mandate of HHS in consultation with DOJ to promulgate rules exempting specific business arrangements from enforcement proceedings. Depending upon the HHS determination in its final regulations, the broad *Greber* interpretation of the Medicare anti-kickback provision may be narrowed.<sup>55</sup>

### III. DEVELOPMENT OF REVENUE ENHANCING ARRANGMENTS

#### A. Physician Incentive Plans

One of the ways hospitals have increased their revenue base is through the implementation of physician incentive plans. These plans seek to develop

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51. 1987 Act, H.R. Rep. No. 100-85, 100th Cong., 1st Sess., 27.

52. *Id.*

53. *Id.*

54. See 1987 Act, § 2(f), 101 Stat. 680, 685, 42 U.S.C.A. § 1320a-7(f) (Supp. 1988).

55. The issuance of the proposed regulations, see *infra* notes 100-126, illustrate that although the *Greber* decision has not been narrowed significantly, some instances, such as the selling of a retiring or relocating physician's practice to a hospital, will exist thereby narrowing somewhat the broad scope of possible violations that existed under *Greber*.

cost-conscious behavior among the physicians affiliated with the hospital.<sup>56</sup> Commonly, these plans take the form of cash payments to the physician for his effort in successfully reducing the hospital's cost of the inpatient services.<sup>57</sup> Such plans have been formulated in response to the "growing recognition in society that if the health care industry is to function more effectively, it must do so through cooperation [between hospitals and physicians]."<sup>58</sup> Hospitals realize that their success under the PPS largely depends upon the behavior of the physicians because "physicians control approximately sixty to eighty percent of the hospital's costs,"<sup>59</sup> and "physicians' use of [the hospital's] ancillary services and discharge decisions often determine whether the hospital can meet its PPS target."<sup>60</sup> Although arguably financially necessary, these plans pose serious legal as well as medical ethics issues to the hospitals and physicians.

In order for a particular hospital's physician incentive plan to fall within the scope of the Medicare anti-kickback provision, the hospital's intent behind providing benefits to the physician must be to induce the referral of patients to that hospital.<sup>61</sup> It may be established that if the incentive plan is aimed at cost efficiency and the use of the hospital's ancillary services, such as nursing homes, and not tied directly to patient referrals, then arguably the plan falls outside the scope of the anti-kickback provision. The broad language of *Greber* does not apply to the specific physician incentive plan fact pattern, and "[should] not be blindly applied to incentive plans."<sup>62</sup> If there is no harm to the Medicare program and cost efficiency is achieved through these incentive plans, then the health care community is benefited.

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56. Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 711.

57. Physician incentive plans may also take the form of group purchasing agreements for medical office supplies, computer list networks, loan programs, IPA programs, group marketing and promotional campaigns, physician referral services, medical liability and malpractice insurance, medical office evaluation, continuing education subsidies, medical office training sessions, offices of physician relations program, as well as other individualized, innovative plans. Bulger, *Physician Incentive Programs Strengthens Bonds*, HEALTHCARE FIN. MGMT. 68 (July, 1988). See also Fraiche, *Definition of Issues*, in PHYSICIAN RECRUITMENT, RETENTION & INCENTIVES 6 (1988).

58. Saphier, *Cost Effectiveness Requires Cooperation*, in MEDICARE FRAUD & ABUSE: UNDERSTANDING THE LAW 124 (1986). Under PPS, physicians are still paid on a fee for service basis, while hospitals are paid a fixed sum. In order to survive, hospitals must instill cost-conscious behavior in physicians. See Hyman and Williamson, *supra* note 1, at 1146.

59. Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 732.

60. Richman, *Physician Incentive Plan Study May Give Guidance*, 15 MOD. HEALTH CARE 48, (July 19, 1985).

61. Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 733.

62. *Id.* at 735.

It has been suggested that particular incentive plans may encourage physicians to admit the "easy" cases, e.g. those cases which most likely produce a profit, to hospitals which have an incentive program, while sending the "complicated" cases to hospitals where no incentive plan exists. Theoretically, this argument makes sense, but in reality physicians generally do not work this way, thereby negating the commonness of this practice.<sup>63</sup> If the hospital plan is aimed at the actual practice patterns of physicians in the hospital, and not at the actual referral patterns of the physician, then there seems to be no apparent conflict with the Medicare anti-kickback provision.<sup>64</sup>

An example of a particular physician incentive plan which was under investigation by the HHS in 1985 was DRG incentives offered by Paracelsus Health Care Corporation in fourteen California hospitals.<sup>65</sup> The plan stated that "[i]f Medicare payments for a physician's patients are above a set percentage (70-75%), the physician is paid a percentage of the difference; payments are figured on a monthly basis."<sup>66</sup> It was determined by the General Accounting Office (GAO) that "the incentives [were] too strong for physicians to underprovide services or admit patients to the hospitals who might

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63. Saphier, *supra* note 58, at 126-127. The American Medical Association's House of Delegates adopted guidelines relating to physician ownership interest in commercial venture. "When a physician's commercial interest conflicts so greatly with the patient's interest so as to be incompatible, the physician should make alternative arrangements for the care of the patient." Fraiche, Anthony, Devlin and Kahn, *Overview: Industry Panel*, in PHYSICIAN RECRUITMENT, RETENTION & INCENTIVES 3 (1988). See generally *Oath of Hippocrates* quoted in 4 ENCYCLOPEDIA OF BIOETHICS 1731 (1978), where it is stated that physicians convenant to uphold above anything else the medicinal value of the medical profession. For a thought-provoking analysis of self-interest and virtue in the medical profession see Pellegrino, *Character, Virtue, and Self-Interest in the Ethics of the Professions*, 5 J. CONTEMP. HEALTH L & POL'Y 53 (1989). But see Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, where it is argued that although it may be impractical on the part of the physician to split his admissions between hospitals based on economic reasons, it is not impractical for a physician to opt to admit his patients to a hospital which has an existing incentive plan as opposed to a hospital that does not, provided both hospitals are equal as to the quality of care administered. *Id.* at 735.

64. See Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 735. An ethical conflict would exist, however, if the quality of patient care was sacrificed for the economic interest of the hospital or the physician. To avoid this conflict each physician incentive plan must be implemented with adequate safeguards protecting the quality of care offered. Cost efficiency is not *per se* unethical. In fact cost efficiency within the hospital increases the hospital's revenue base and allows a hospital to continue to provide competent medical services to the community. A physician incentive plan implemented with proper ethical and legal safeguards will benefit the health care community.

65. Cleveland, *Prospective Payment Issues*, in FRAUD AND ABUSE: UNDERSTANDING THE LAW 9 (1987).

66. *Id.* at 9-10.

not need hospitalization.”<sup>67</sup> Specific objections to the plan were that the time period for determining the payment to physicians was too short; a strong incentive existed for a physician to admit only the less costly patients to one hospital while admitting the more costly patients to hospitals without an incentive plan; and no counter mechanism was employed to retain the high quality of care within the hospital.<sup>68</sup> However, these findings suggest that the implementation of a physician incentive plan with a longer, fixed payment schedule and a mechanism to maintain the high quality of care would be acceptable to HHS under the anti-kickback provision.

The American Medical Association (AMA) agreed with the GAO finding and further adhered to the position that a hospital with an incentive plan earns profits at the expense of the hospitals in the same area that do not have incentive plans.<sup>69</sup> Although this position is aimed at promoting fairness within the health care industry, this fact alone should not have any effect on the “propriety of the arrangement.”<sup>70</sup> Theoretically, the problem could be easily remedied because adversely affected hospitals could respond to their competition by implementing an incentive plan of their own;<sup>71</sup> but because no guidelines existed, such an adoption was inherently risky. Hospitals, caught in a competitive vortex, would find themselves weighing the illegality of proposed conduct against the probability of prosecution, and implementing technically illegal physician incentive plans<sup>72</sup> merely to remain competitive within their health care marketplace. The reality appears to be that if a hospital does not engage in some type of incentive plan, it is operating at a competitive disadvantage and runs the risk of being put out of business by competing area hospitals that provide an incentive plan for their physicians. While the 1987 Act provides some guidance to hospitals, the need for additional, workable guidelines in this area is evident.

In structure or implementation, some physician incentive plans may run counter to medical ethics standards. The Institute of Medicine expressed its disapproval of DRG incentive payments by stating that “such incentive plans place the physician in an unnecessary and unacceptable conflict of interest.”<sup>73</sup> This conflict of interest arises when the pressure from hospital

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67. *Id.* at 10.

68. *Id.*

69. Richman, *supra* note 60, at 48; see also Hyman and Williamson, *supra* note 1, at 1149 n.90.

70. Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 735.

71. *Id.*

72. See Kusserow, *supra* note 12, at 46.

73. Institute of Medicine, *FOR-PROFIT ENTERPRISE IN HEALTH CARE*, (Gray ed. 1986) quoted in Cleveland, *supra* note 65, at 12.

management to increase efficiency "may compromise the physician's primary role as an independent patient advocate and detrimentally affect the quality of patient care."<sup>74</sup> Such a compromise in quality of care raises serious doubts as to the sanctity of the patient-physician relationship.<sup>75</sup> But if there was no compromise in patient care, an ethical dilemma would not exist, and the particular incentive plan could be beneficial to the health care industry.

Prior to 1987, no guidelines existed with regard to physician incentive plans. Even the findings of the GAO in the Paracelsus example were merely suggestions, not criminal findings. DOJ had not enforced the illegal remuneration statute since *Greber*,<sup>76</sup> and it was the only body from which guidelines for the anti-kickback provision could have come. The anti-kickback provision of the Medicare fraud and abuse laws was developed in response to the abuses within the Medicare system under direct cost reimbursement, not under the PPS. "Thus, the law generally has been applied only against fairly blatant kickback or referral fee mechanisms."<sup>77</sup> Differing points of view exist on the implementation of incentive plans,<sup>78</sup> but until guidelines are finally issued, hospitals and physicians must be careful in formation of their plans because, as witnessed in the Paracelsus example, the plan may still be confronted with skepticism. HHS' issuance of final regulations in response to these issues will begin to provide the needed guidance under which hospitals, physicians, and health lawyers can operate.

### B. Joint Ventures

#### Hospital-physician joint ventures and hospital acquisition of physician

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74. Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 712. See CURRENT OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, § 4.05 (1986) *quoted in* Fraiche, Anthony, Devlin and Kahn, *supra* note 63, at 4:

Under no circumstance may the physician place his own financial interest above the welfare of his patients. The prime objective of the medical profession is to render service to humanity; reward or financial gain is a sub-ordinate consideration. For a physician to unnecessarily hospitalize a patient or prolong a patient's stay in the health facility for the physician's financial gain would be unethical. If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit.

75. Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 712.

76. *But see Lipkis*, 770 F.2d at 1448-49, where the court found that the defendant had received anti-kickback payments, however the illegal remunerations provision (42 U.S.C. § 1395nn(b)) of the Medicare fraud and abuse laws was not enforced, rather the court focused on the making of false statements provision (42 U.S.C. 1395nn(a)) of these laws.

77. Dechene, *Physician Incentive Programs: Are They Legal?* 4 HEALTH SPAN 3, 4 (Jan. 1987).

78. See *supra* notes 69-75 and accompanying text.



practices establish a form of vertical integration and an alternative source of revenue for hospitals. The ensuing relationship between the hospital and physician is modified just as it was under physician incentive plans; however, these joint venture arrangements pose clearer potentially technical violations than do the physician incentive plans. Conceivably, joint ventures "develop multiple sources for inpatient referrals."<sup>79</sup> The intent of the hospitals participating in a joint venture is to preserve their existing patient base, to obtain a referral stream, and to increase their "ability to compete with alternative health care delivery systems."<sup>80</sup> "Hospitals are trying to expand the services that they furnish to the community, to vertically integrate, and to ensure proper access and quality care to the people in their community, but they are not going to do it at a [financial] loss."<sup>81</sup> Furthermore, a joint venture contractually links the hospital and the physician. The hospital-physician relationship is solidified through this arrangement, from which future patient referrals are more likely to result.<sup>82</sup>

The intent to increase the hospital's patient referral stream technically violates the broad prohibition of the Medicare anti-kickback provision.<sup>83</sup> "Referral levels or revenue generated from the referrals cannot be a requirement for the joint venture arrangement. Nor can the venture distribute funds based upon the number of referrals or calculated as a percentage of revenue generated from referrals."<sup>84</sup> Under this interpretation, the survival of joint venture arrangements is tenuous. Prior to any HHS regulation, the structuring of a joint venture could only focus on the minimization of investigation or liability of the participating hospital and physician. The joint venture contract could not expressly mention the referral requirement. Although the intent to provide referrals was present, it was left unwritten and only anticipated, thereby making it difficult for the government to prove a hospi-

79. Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 709.

80. Jacobs and Rubin, *Institutional Purchases of Professional Practices*, in *PHYSICIAN RECRUITMENT, RETENTION & INCENTIVE 1* (1988). Physicians also have their own incentives to enter into joint ventures such as a favorable selling price, avoidance of medical insurance costs, and avoidance of business and administrative risks. *Id.* Each incentive varies as to the actual needs of the physicians. For an in depth analysis of the advantages of forming joint ventures, see Barkley, *Hospital-Physicians Joint Ventures: An Expanding Field*, *CAL. BUS. L. PRAC.* 113 (Spring 1987). For further guidance in forming joint ventures and purchasing physician practices see Sollins, *Purchasing Physician Practices: Legal and Regulatory Concerns*, *HEALTH-CARE FIN. MGMT.* 56 (Jan. 1988).

81. Teplitzky and Yampolsky, *Historical Perspective on Joint Ventures*, in *MEDICARE FRAUD AND ABUSE: UNDERSTANDING THE LAW* 102 (1986).

82. Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 711.

83. 42 U.S.C.A. § 1320a-7b(b) (Supp. 1988).

84. Teplitzky and Yampolsky, *supra* note 81, at 111.

tal's or physician's violation of the anti-kickback statute.<sup>85</sup>

To avoid a statutory violation, the anticipated patient referral stream generated by the joint venture must be coupled with legitimate medical reasons for the referral, as well as no overutilization of Medicare funds. As evidenced in *Greber*, the courts and HHS are likely to characterize an unreasonably high rate of return on a physician's investment as resulting from overutilization, and hold the joint venture as violative of the anti-kickback provisions of the Medicare fraud and abuse laws.<sup>86</sup> Also, in order to avoid a technical violation, the parties to the joint venture must share the financial and business risks.<sup>87</sup> Although a lawyer, in structuring a joint venture, can minimize the inherent legal and financial risks of joint ventures, as shown by *Greber*, "no venture is completely risk free."<sup>88</sup> It is unethical for a lawyer to advise a client to proceed with a joint venture which is technically illegal and where the client runs the risk of being criminally prosecuted for his activity.<sup>89</sup>

An appropriately structured joint venture potentially "promotes new forms of health care delivery in an efficient manner."<sup>90</sup> An immediate benefit of such a joint venture is that participating hospitals can alleviate the financial burden of physicians in purchasing expensive medical equipment on credit which becomes obsolete before the physician has even made full payment.<sup>91</sup> Another benefit of the joint venture is that a hospital may provide the physician with access to a competent staff which in turn, allows the physician to be more competitive within his health care market.<sup>92</sup> From this perspective, the Medicare fraud and abuse laws have thwarted this type of legitimate business arrangement which aids the health care community. But again, the same medical, legal, and ethical issues develop with joint ventures as were discussed with physician incentive plans.<sup>93</sup> These issues could be

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85. See *id.* at 105.

86. Gaynor and Decator, *supra* note 13, at 27.

87. See Barkley, *supra* note 80, at 115.

88. Teplitzky and Yampolsky, *supra* note 81, at 105.

89. See MODEL CODE OF PROFESSIONAL RESPONSIBILITY EC 7-5 (1981), where "[a] lawyer should never encourage or aid his client to commit criminal acts or counsel his client on how to violate the law and avoid punishment therefor." (Footnote omitted). See also *id.* DR 7-102(A)(7) (1981), where in the representation of his client, a lawyer shall not "[c]ounsel or assist his client in conduct that the lawyer knows to be illegal or fraudulent."

90. Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 744.

91. See Barkley, *supra* note 80, at 115.

92. See Teplitzky, *Hospital/Physician Joint Ventures*, in PHYSICIAN RECRUITMENT, RETENTION AND INCENTIVES 3 (1988).

93. See *supra* notes 63-75 and accompanying text.

solved partially if the government provided workable guidelines which outlined legitimate arrangements as exempt from enforcement proceedings.

Prior to the 1987 Act the major problem was that no single voice of the government could speak with authority or what might happen in any given case.<sup>94</sup> "A criminal law is supposed to be absolutely clear—which is why the agency ha[d] no authority to issue regulations on it. Many arrangements, however, involve a circumstance that might be technically illegal, but which most people presume [was] not going to be prosecuted."<sup>95</sup> Problems arose similar to physician incentive plans in the design of joint venture arrangements. Innovation was stymied because hospitals and physicians were weighing the illegality of their venture against the probability of prosecution and entering into technically illegal ventures.<sup>96</sup>

Prior to the 1987 Act and the increased advisory role of HHS, the formation of joint ventures had to reflect a valid business purpose resulting in no over-compensation to either party, equal risk sharing, disclosure of all ownership interests, and the offer or receipt of benefits was not connected with the number of patient referrals. As evidenced in the discussion of physician incentive plans, workable guidelines had to be provided to the health care industry so as to promote clarity and a sense of certainty within this area of the health law field.

### C. Physician Recruitment Programs

Physician recruitment programs derive from the same premise as physician incentive plans and joint ventures. If any form of remuneration is given to the recruited physician as an inducement to make Medicare referrals to the hospital, then technically the recruitment program has violated the

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94. Teplitzky and Yampolsky, *supra* note 81, at 105-06.

95. *Id.* at 106.

96. *Id.* at 107. Joint ventures are complex business arrangements between hospitals, physicians, laboratories and other individuals within the health care community. Each arrangement must consider the legality of each of the facets presented. Many additional issues surrounding the formation of a joint venture are not addressed in this Comment but must be considered when implementing a joint venture. These include tax, antitrust, the corporate practice of medicine and whether a general or limited partnership should be formed. See generally Sollins, *supra* note 80; Barkley, *supra* note 80; Teplitzky, *supra* note 92; Jacobs and Rubin, *supra* note 80. See also Roble, *Corporate Law Issues*, in PHYSICIAN RECRUITMENT, RETENTION & INCENTIVES (1988); Bromberg and Hagues, *Physician Investment Opportunities*, in PHYSICIAN RECRUITMENT, RETENTION & INCENTIVES (1988); Stewart, *Physician Recruitment and Contracting Strategies: Playing the Jeopardy Game*, in PHYSICIAN RECRUITMENT, RETENTION & INCENTIVES (1988); Cassidy and Wynstra, *Recruitment Strategies*, in PHYSICIAN RECRUITMENT, RETENTION & INCENTIVES (1988); Cowan, *Medical Staff Issues*, in PHYSICIAN RECRUITMENT, RETENTION & INCENTIVES (1988).

Medicare anti-kickback provision.<sup>97</sup> Physician recruitment programs vary. Some examples of hospital offerings to physicians are as follows: "guaranteed minimum salaries; free or rent reduced office space; opportunities to become limited partners in a venture such as a medical office building; equity interest in the hospital; housing; cars; or financial resources for the physician to develop satellite clinics."<sup>98</sup> Again, in these instances, the recruitment program must be carefully scrutinized prior to implementation so as to avoid the program falling under the broad interpretation of *Greber*.

The variety of physician recruitment programs, however, differ from the specific factual situation in *Greber*. The benefits of such programs should not be overlooked or minimized. These programs not only can recruit good physicians to rural communities where the physician would not otherwise practice, but they also can attract outstanding physicians to the hospital's in house medical staff and thereby increase the quality of care offered by the hospitals to their communities. But, because of the potential technical illegalities, the Medicare fraud and abuse laws again thwarted such legitimate and aiding medical arrangements. As of 1986 no guidelines were forthcoming from DOJ.<sup>99</sup> This frustration certainly was not within the congressional purpose of the Medicare program. A clarification of the congressional intent was needed.

#### IV. POTENTIAL SAFE HARBORS

Through the enactment of the 1987 Act, Congress mandated that HHS issue guidelines, in the form of regulations, by August, 1989. Proposed regulations, or safe harbors, were issued on January 23, 1989<sup>100</sup> with a comment period ending on March 24, 1989. HHS has proposed certain areas that, if finalized, would be deemed exempt from criminal prosecution and administrative exclusion from the Medicare program. These exemptions exhibit an initial governmental response to the uncertainty under the Medicare fraud and abuse laws.

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97. See Comment, *Medicare—Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 730.

98. *Id.* at 727-28. Similar to joint ventures and physician incentive plans, each type of recruitment program depends upon the individual needs of the participants. For differing strategies see generally Fraiche, *supra* note 57, 3-4; see also Stewart, *Physician Recruitment and Contracting Strategies: Playing the Jeopardy Game*, in PHYSICIAN RECRUITMENT, RETENTION & INCENTIVES (1988); Cassidy and Wynstra, *Recruitment Strategies*, in PHYSICIAN RECRUITMENT, RETENTION & INCENTIVES (1988); Cowan, *Medical Staff Issues*, in PHYSICIAN RECRUITMENT, RETENTION & INCENTIVES (1988).

99. Cohen, *Bed Reservation Agreements*, in MEDICARE FRAUD AND ABUSE: UNDERSTANDING THE LAW 195 (1986).

100. See 54 Fed. Reg. 3088 (1989) (to be codified 42 C.F.R. pt. 1001).

### A. Investment Interests

Under this proposed safe harbor, HHS has determined that certain investment interests, such as interest in publically owned hospitals, clinical laboratories, and other health care services to which patients may be referred, are exempt from criminal prosecution and exclusion from the Medicare program, if the interested parties meet certain conditions.<sup>101</sup> The investment interest must be in a large public corporation "so that the return on investment is, at most, tangentially related to any referrals of items or services made by a shareholder . . . ."<sup>102</sup> Under this proposed safe harbor, only large public corporations are exempt from enforcement proceedings. Other smaller, legitimate arrangements, although technically violating the anti-kickback provision, are still subject to the broad enforcement language of the Medicare fraud and abuse laws. The only distinctive differences between the two investment interests is the size of the corporation and the increased potential for reflected referral payments. Both type of arrangements may provide the same amount of benefit to the community. Smaller, legitimate, privately owned health care entities would not be exempt from prosecution or exclusion from Medicare, thereby precluding the development of innovative arrangements. Therefore this limited "safe harbor" alone does not provide any substantial form of guidance for health lawyers, hospitals, and physicians because many arrangements still remain subject to enforcement proceedings even though they are legitimate and beneficial.

HHS is considering crafting additional investment interest "safe harbors" for certain limited partnerships and managing partnerships. If the investment interest is in a limited partnership where "a bona fide opportunity to invest is made on an equal basis to people in a position to make referrals as well as others, where there has been disclosure to a referred patient, and where payments are not related to referrals . . . ."<sup>103</sup> then a possible safe harbor may exist. If the investment interest is in managing partnerships, the payments must not reflect referrals, and disclosure of the interest to the referred patient must exist.<sup>104</sup>

Although broadly worded, the existence of this safe harbor, including exempt limited and managing partnerships, would enable health lawyers to advise hospitals and physicians about proposed revenue enhancing plans with more certainty and less ambiguity. Each of the required standards

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101. 54 Fed. Reg. at 3090; *Anti-kickback Safe Harbors: Small*, 17 HEALTH POL. WEEK 1-2 (Aug. 1, 1988).

102. 54 Fed. Reg. at 3090.

103. *Id.*

104. *Id.*; see also *Anti-kickback Safe Harbors: Small*, *supra* note 101, at 2.

must be met for a venture to be exempt from prosecution and exclusion from Medicare.<sup>105</sup> If any incremental step in the formation of an investment interest type arrangement is not fulfilled, the exemption will not be granted.<sup>106</sup> To avoid an inadvertant technical illegality requires having knowledge of the specific criteria required for the exemption. Once this knowledge is obtained, health lawyers may structure and implement revenue enhancing ventures with more certainty. Development within the health care community, however, will only result if HHS constantly updates and substantiates this safe harbor.

Physician incentive plans, hospital-physician joint ventures, and physician recruitment programs may offer the physician a type of investment interest that would aid the health care industry by effectively and efficiently increasing the quality of care. In lieu of bonuses or benefits, hospitals may offer physicians participating in incentive plans and recruitment programs, or forming joint ventures, the opportunity to invest in ownership of the hospital.<sup>107</sup> Under this investment interest safe harbor, if shares in the hospital, which is a large public corporation, are not offered to the general public, or fail to meet the minimum standards applied by HHS, then that particular venture will not be exempt from prosecution or exclusion.<sup>108</sup> However, a non-exempt venture, which does not abuse the Medicare system, increases efficiency, and improves the quality of care offered, should not be *per se* illegal.

The standards requiring that investments be offered in large public corporations and that full disclosure be made to the patient of any economic interest preserve the general intent of the law, which is to prohibit illegitimate payments based upon patient referrals and to eliminate decreasing quality of medical care.<sup>109</sup> Structured and implemented ventures that do not meet these standards should only be presumed to be illegal. This presumption of illegality is in accord with the congressional intent of the 1987 Act, which requires special due process proceedings for any exclusion relating to kickbacks.<sup>110</sup> This proceeding allows an attorney to rebut the presumption of illegality while informing and educating HHS of legitimate, innovative ventures previously not considered when HHS was developing the safe harbors. As a result, HHS will remain in touch with the developing health care com-

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105. 54 Fed. Reg. at 3089.

106. *Id.*

107. See generally Koska, *Physicians Now Looking to Purchase Hospitals*, 62 HOSPITALS 81 (Aug. 20, 1988); Teplitzky, *supra* note 92 at 16.

108. 54 Fed. Reg. at 3094

109. See 1987 Act, S. Rep. No. 100-109, *supra* note 28, at 1, reprinted in 1987 U.S. CODE CONG. & ADMIN. NEWS 682.

110. See *supra* notes 29-31 and accompanying text.

munity. Therefore, further guidance is accomplished with increased certainty and continuity throughout this area of health care.

### *B. Space and Equipment Rental*

Space rental agreements are usually between laboratories or other diagnostic services and physicians. The labs provide the physician with rental payments for the use of the physician's office, from which patients may be referred to the lab.<sup>111</sup> An exemption exists in such an arrangement if the rental agreement is periodic, in writing, and periodic intervals are "set in advance in the lease rather than allowed to vary . . . on the basis of the number of referred patients to be served at the premises."<sup>112</sup> Secondly, the lease must be for "at least one year so it cannot be readjusted every month based on the number of referrals . . . ."<sup>113</sup> Third, any charge must reflect the fair market value of the service.<sup>114</sup>

Similarly, the rental of office equipment to a physician is provided as a another possible safe harbor. The same conditions apply to equipment rental as apply to space rental.<sup>115</sup> As previously mentioned, hospitals can alleviate some of the inherent financial risk for the physician who purchases or rents highly priced and technical equipment.<sup>116</sup> Normally, individual physicians, or small practices do not have the time or the capital to establish a diagnostic laboratory which could provide analyses of patient data similar to the type a hospital or lab might have. In the health care industry, diagnostic and laboratory equipment also becomes obsolete so quickly that sole ownership of equipment by individual physicians or small practices is inefficient and not financially viable.<sup>117</sup> By allowing certain non-abusive hospital-physician arrangements to be implemented, HHS has begun to foster the growth of an efficient and an improved quality health care delivery system. Again, if any one of the conditions for the space rental and equipment rental safe harbors are not strictly adhered to by participants, HHS will not exempt the arrangement. But, continued growth and a better allocation of medical resources would be guaranteed only if HHS constantly updates these safe harbors to include future, innovative, rental arrangements that produce efficient use of health care resources.

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111. 54 Fed. Reg. at 3090; *Anti-kickback Safe Harbors: Small*, *supra* note 101, at 2.

112. 54 Fed. Reg. at 3091.

113. *Id.*

114. *Id.*

115. *Id.*; see also *Anti-kickback Safe Harbors: Small*, *supra* note 101, at 2.

116. See Barkley, *supra* note 80, at 115.

117. See *id.*

*C. Personal Services/Management Contracts*

In personal service contracts and management contracts, an arrangement exists under which mutually beneficial services are performed by both the participating hospital and physician.<sup>118</sup> HHS has attempted to extend a safe harbor to these arrangements but only if safeguards and conditions exist to ensure that within these contractual arrangements, the opportunity to provide financial incentives to the physician, for the purpose of inducing patient referrals to the hospital, is limited.<sup>119</sup>

Usually, the personal services and management contracts function through the implementation of a vehicle such as a physician recruitment program or a hospital-physician joint venture. The intent of such an arrangement is to solicit physicians who are specialists and who can perform their expertise either within the hospital, as a head of a specialized department, or within the extended rural communities served by the hospital. The quality of a hospital's medical staff is directly related to the quality of care and services that are provided by that hospital. Any program which successfully recruits specialists as well as quality general physicians to practice in rural communities extends a higher quality of care and services to areas which otherwise could not enjoy such care and services. Additionally, these solicitations increase the revenue base of the hospital by increasing patient referrals; however, these referrals are brought about primarily by an increased quality of care and services emanating from the hospital, not from improper financially induced patient referrals. As long as the financial inducements are not centered upon the acquisition of the physician's patient referrals, but rather centered on an increased and extended quality of medical care and services the intention of the Medicare program is met.

The business aspect of these arrangements is to make money. If these ventures do not enhance a hospital's profitability through the increased quality of medical care and services offered to the community, the hospital will not enter into the venture.<sup>120</sup> A reasonable rate of return for the hospital's participation in the venture is necessary for the hospital to remain financially viable. The competitive health care market will not allow a hospital to perform such services uncompensated. The same unwritten intimations of producing referrals for money will be present in the implementation of these contracts; however, HHS should issue substantial recommendations that will provide further guidance as to what type of personal services or management contracts will be exempt from prosecution and exclusion from Medicare.

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118. 54 Fed. Reg. at 3091.

119. *Id.*

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



HHS now has the authority to issue standards that will continue to provide certainty as to how to set up legitimate personal service and management contracts. The implementation of this safe harbor and the expanded authority of HHS begins to cure the uncertainty that has plagued innovation in the health care industry.

#### D. Sales of Practice

As previously discussed, in order for hospitals to increase their revenue base, the purchase of physician practices has become a lucrative business venture.<sup>121</sup> HHS has attempted only to extend a safe harbor to these purchases where the selling physician is retiring or not continuing to practice medicine on that hospital's staff, or "some other event that removes the physician from the practice of medicine or from the service area in which he or she was practicing . . . ."<sup>122</sup>

The rationale behind this proposed safe harbor is that a retiring or exiting physician will not be in the position to make ongoing referrals.<sup>123</sup> He is no longer practicing medicine, and no drain on the Medicare system would exist. In a purchase where the practicing physician remains in contact with the purchasing hospital, the potential for kickbacks exists.<sup>124</sup> This type of arrangement conflicts with the anti-kickback provisions of section 1128 of the Social Security Act, and is intended to be prohibited.<sup>125</sup>

If this proposed safe harbor becomes a final regulation, HHS will have narrowed the broad enforcement power of the anti-kickback provisions. HHS has established an area where the legitimate hospital purchase of a retiring or relocating physician's practice is an efficient recycling of medical resources.<sup>126</sup>

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121. See Wolfe, *Patients for Sale*, Wash. Post, Oct. 4, 1987, at C5, col. 3.

122. 54 Fed. Reg. at 3091.

123. *Id.*

124. *Id.*

125. *Id.*

126. *Id.* Other possible safe harbors exist for the practice of referral services. The professional not-for-profit societies that provide a patient referral to hospital in return for a service fee to cover costs would specifically be exempted, provided abuse does not result, such as an overly high participation fee. 54 Fed. Reg. at 3091. In the case of profit making referral services, the service fee should reflect a fair market value and not be tied to referrals to minimize any risk of nonexemption from prosecution and exclusion. Companies which offer warranties to induce the use and purchase of their equipment do not pose a service abuse problem and therefore quite possibly may be specifically included as a safe harbor. 54 Fed. Reg. at 3092. Provided, that the warranty is issued at the time of sale, and is solely "related to workmanship and performance [of the product] for a specified period of time." *Anti-kickback Safe Harbors: Small, supra* note 101, at 3. Furthermore, the warranty only offers recovery from reasonable economic loss, such as the purchase price. See *id.*

Discounts on medical goods and services, statutorily mandated, may also be considered safe

## V. CONCLUSION

Congress has recognized the thwarting of complex, legitimate business ventures within the health care industry due to the uncertainty that existed under the Medicare fraud and abuse laws. The 1987 Act's expansion of disciplinary authority to HHS and mandate of promulgating final regulations by August, 1989 provide the impetus for growth in the health care industry. For the 1987 Act to be most effective, HHS must continue to receive input and update the issued safe harbors. The issuance of safe harbors provides some semblance of guidance and certainty. Subsequent updating will provide the continuous development of an efficient and improved health care delivery system. The 1987 Act and subsequent regulation by HHS demonstrate the increased governmental commitment to responding and curing the health care industry under the Medicare fraud and abuse laws.

Although Congress and the HHS have responded and begun to clarify the uncertainty that existed within the health care industry prior to the 1987 Act, many ambiguous areas involving physician incentive plans, joint ventures, and physician recruitment programs still exist. HHS should provide more substantial advice to the affected participants in these health care arrangements. This advice can come from constant updating of the safe harbors, or from possible advisory letters similar to those in the IRS and SEC.<sup>127</sup> Health lawyers consulting hospitals and physicians must carefully implement revenue enhancing programs that do not rely on the inducement of patient referrals. The curative effect of the 1987 Act will not be immediately evident. For that reason, the thwarting, broad enforcement power of

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harbors. 54 Fed. Reg. at 3092. Furthermore hospital's practice of waiving the collection Part A co-insurance payments and deductibles may possibly form another safe harbor. *Id.*; Holthaus, *HHS Outlines "Safe Harbor" Business Practices*, 62 HOSPITALS 53 (October 5, 1988.) This HHS opinion was a reversal from earlier drafts issued in summer of 1988. Richard Kuserow stated that this specific hospital practice, used to attract Medicare patients, "while technical violations of the kickback provision do[es] not warrant prosecution." Holthaus, *HHS Outlines "Safe Harbor" Business Practices*, at 53. Although this is not included as a proposed safe harbor, comments were solicited, and this type of hospital practice may become a final regulation. For a discussion outlining the structure of the Medicare program, see Comment, *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, *supra* note 1, at 696-699. For an in depth analysis of the waiving of co-insurance payments by hospitals, see Hyman and Williamson, *supra* note 1, notes 110-114 and accompanying text.

In an earlier HHS draft of proposed safe harbors, "physician recruitment programs" were included as a potential safe harbor. In the subsequent promulgation of proposed safe harbors, this type of hospital arrangement was deleted. As presented throughout this paper, properly structured physician recruitment programs serve a viable and beneficial purpose in fostering better health care. This type of hospital-physician relationship should be reconsidered and implemented as a safe harbor in the final promulgation of exemptions.

127. See *supra* note 50 and accompanying text.

the anti-kickback provisions of the Social Security Act is the law.<sup>128</sup> If lawyer's implement ventures following the proposed regulations, the likelihood of prosecution or exclusion will be minimized.

*Francis J. Hearn, Jr.*

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128. The practicing health lawyer should also remain aware of other forms of legislation that will affect this sensitive area within the health care industry. Congressman Stark introduced the *Ethics in Patient Referrals Act of 1989* (Stark Bill) on February 9, 1989. This introduction illustrates that Congress is not finished curing the health care community. For this reason, health lawyers must not only be aware of HHS developments, but also congressional and DOJ action as well.

The following material is available through the National Health Lawyers Association in Washington, D.C.: *MEDICARE FRAUD AND ABUSE: UNDERSTANDING THE LAW* (1986); *FRAUD AND ABUSE: UNDERSTANDING THE LAW* (1987); and *PHYSICIAN RECRUITMENT, RETENTION & INCENTIVES* (1988).