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The Medicare and Medicaid Anti-Kickback Statute: Safe Harbors Eradicate Ambiguity

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THE MEDICARE AND MEDICAID ANTI-KICKBACK STATUTE: "SAFE HARBORS" ERADICATE AMBIGUITY

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I. INTRODUCTION

Fraud and abuse are pervasive problems in the Medicare and Medicaid programs, the solution to which has eluded Congress for many years. Although congressional investigators estimate that only 5% of program providers participate in fraudulent activity, that percentage translates into a loss of $40 billion a year, approximately 10% of all U.S. medical costs.1 It is only in the last twenty years that Congress has taken affirmative steps to eradicate this evil through legislative efforts collectively known as the Medicare and Medicaid

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1Jack Anderson & Donald Robinson, Isn't it Time To Clean Up Medicare, PARADE MAGAZINE, November 8, 1992 at 8. Congressional investigators estimate that fraud and abuse account for more than 10 percent of all U.S. medical costs- as much as $40 billion a year.
Anti-kickback Statute (hereinafter "MMAKS"). Since the enactment of the MMAKS in 1972, the Office of the Inspector General (hereinafter "OIG"), a


(b) Illegal remunerations

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

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

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

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

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

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

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under subchapter XVIII of this chapter or a State health care program,

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

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

(A) a discount or other reduction in price obtained by a provider of services or other entity under subchapter XVIII of this chapter or a State health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by 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
division of the Department of Health and Human Services (hereinafter "HHS"),
has been charged with safeguarding the integrity of the Medicare and Medicaid
programs. Since then, the OIG has secured over 500 convictions, judgments,
and settlements under the MMAKS.3

Recent developments, including the introduction of the prospective
payment system (hereinafter "PPS"), have led federally funded medical
providers to argue that the broad judicial interpretation applied to the MMAKS
has left them disadvantaged in a competitive health care market. Moreover,
health care providers contend that Congress' latest attempt at clarifying the
MMAKS, the Medicare and Medicaid Patient and Program Protection Act of
1987 (hereinafter "MMPPPA"), provides little guidance for MMAKS
compliance.4 As a result, program participants insist that they have no recourse
other than to enter into joint ventures and business arrangements in violation
of the MMAKS.5

This argument, taken in light of the purpose and judicial interpretation of
the MMAKS, in conjunction with the MMPPPA's finalized regulations, is
patently erroneous. The MMAKS was enacted to specifically address the use
of federal health care funds.6 Although initially weak in curbing fraud and
abuse, the MMAKS has since been modified and augmented, resulting in
greater clarity and an increased number of convictions. Furthermore, the
MMPPPA regulations provide clear and concise language for MMAKS
compliance.7 These regulations, more commonly known as "safe harbors,"

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Although prosecutions have been few, the OIG has received more than 1,250 allegations
of violations of the anti-kickback statute since 1987. After screening the allegations, the
OIG opened some 800 cases. Id.


5 Howard Lankin, Most Joint Ventures Unlikely to be in a Safe Harbor, Am. Med. News,

6 Carrie Valiant, HHS Inspector General Publishes Final Safe Harbor Regulations, 17

provide detailed explanations of exempt business arrangements that would otherwise be subject to prosecution.

This Note will briefly explore the history of the Medicare and Medicaid programs including the introduction of the PPS. Next, the Note will detail the legislative history surrounding the adoption of the MMAKS and the judicial interpretation applied to its elements. The Note will follow with an analysis of the purpose, goals, and disagreements relating to the MMPPPA's "Safe Harbor" regulations, resolving their alleged ambiguity against the medical profession. Finally, the Note will advocate support of the recently proposed Health Care Cost Containment and Reform Act of 1992 with emphasis on increasing the budget and size of the staff within the Office of the Inspector General.  

II. BACKGROUND

A. History of Medicare and Medicaid Programs

The Medicare and Medicaid programs were the result of governmental efforts to establish additional public health care for the elderly and poor. As codified in Title 18 and 19 of the Social Security Act respectively, these programs provide reimbursement to health care providers for medical services rendered to qualified candidates.

The payment system of the Medicare and Medicaid programs has been reformed several times in an attempt to curtail the spiraling cost of health care. Formerly, payment to providers was accomplished through a retrospective cost reimbursement program (hereinafter "RRP"). As a result of this payment system the provider of health care services received reimbursement under Part A based on reasonable costs.

Medicare Part A provides basic protection against the costs of hospital, related post-hospital, home health services, and hospice care services. Part A covers inpatient hospital care, skilled nursing facility services, outpatient rehabilitation facilities. Beneficiaries include persons over the age of 65 and disabled persons entitled to Social Security benefits. A physician is not usually reimbursed by Medicare directly, instead it is through a third party intermediary which is a third party private insurance plan acting under contract with the Department of Health and Human Services. Effective 1983, the provider of health care services received reimbursement under Part A based on reasonable costs.

Medicare Part B provides supplementary health insurance coverage to Part A and largely covers physician services. Other covered services include durable medical equipment, ambulatory surgical center services, and hospital outpatient services. Part B is voluntary program available to those who are eligible for Part A. Financing is provided by monthly premiums paid by enrollees and by general federal revenues. This
method, providers were actually rewarded for inappropriate or inefficient care. Due to the extraordinary growth and cost of the programs, combined with the ever-increasing federal budget, regulatory and congressional efforts resulted in shifting reimbursement to the PPS.

Under this plan, a hospital or medical facility is only reimbursed a fixed, predetermined sum for treatment rendered, regardless of the actual cost of the medical service provided to the patient. The payment for services is based on a categorized listing encompassing 470 illnesses known as diagnostic related groupings (hereinafter "DRG's"). This can cause a hospital or other medical service to face a loss if the costs for an individual patient exceeds the allotted DRG amount. As a result of PPS, medical services are provided with the incentive to deliver health care economically and to discharge patients quickly in order to retain any excess payment.

Nonetheless, today's medical providers argue that current medical care competition and the PPS shift such a substantial financial burden to participating health care facilities that efficiency requires expansion of clientele and services to increase revenue and profit margin. Many of these revenue enhancement schemes involve fraudulent activity. These fraudulent arrangements, formulated by medical providers to gain revenue, sacrifice program integrity and taxpayer monies. This is the conduct which runs afoul of the MMAKS' legislative intent and statutory prohibitions. An analysis of the legislative history surrounding the adoption of the MMAKS demonstrates congressional efforts to eradicate fraud and abuse.

B. Legislative History

Since their creation in 1965, the Medicare and Medicaid programs have been the target of numerous fraudulent schemes. Prior to 1972, the Social Security Act contained only one penalty provision relating to the making of false

insurance generally covers 80% of a physician's reasonable charge. Administration of the program is again through a third party fiscal agent termed a carrier. Id.


Hearn, supra note 11, at 175.

Id.

Id.

Id.

See generally HIA, supra note 9.
statements or misrepresentations of material fact. As such, the Social Security Act's limited language hindered prosecutorial efforts. Accordingly, Medicare and Medicaid fraud was prosecuted under federal statutes prohibiting conspiracies to defraud the government and prohibiting mail fraud. Unfortunately, these statutes required the government to prove, beyond a reasonable doubt, that the prohibited acts were done "knowingly" and/or "willfully."

In an attempt to directly combat fraud and abuse in the Medicare and Medicaid programs, Congress enacted the MMAKS as part of the Social Security Amendments of 1972. These sections (hereinafter "Original MMAKS") eliminated two prosecutorial problems while providing prosecutors with an enforcement tool more specifically tailored to the medical profession. First, the scope of prohibited conduct was expanded to include soliciting, offering or accepting kickbacks, bribes, or rebates. Secondly, these

19 42 U.S.C. §1307(a) (1982) provides:

[Whoever, with the intent to defraud any person, shall make or cause to be made any false representation concerning the requirements of this chapter, subchapter E of Chapter 1 or subchapter A, C, or E of Chapter 9 of the Internal Revenue Code of 1939, or of any rules or regulations issued thereunder, knowing such representation to be false, shall be deemed guilty of a misdemeanor, and, upon conviction thereof, shall be punished by a fine not exceeding $1,000, or by imprisonment not exceeding one year, or both.]

20 See 18 U.S.C. §1341 (1994) (Mail Fraud Statute); 18 U.S.C. § 371 (1994) (Conspiracy to Defraud Gov't). The 1972 versions of each statute are equivalent to the current versions of each with respect to claims or prosecutions that would have been brought under the 1972 version.

21 Id.

22 Original MMAKS, supra note 2. §1877(b) of the Act provides:

[Whoever furnishes items or services to an individual for which payment is or may be made under this title and who solicits, offers, or receives any-
(1) kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment, or
(2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services shall be guilty of a misdemeanor and upon conviction shall be fined not more than $10,000 or imprisoned for not more than one year, or both.]

§1909(b) of the Act provides:

[Whoever furnishes items or services to an individual for which payment is or may be made in whole or in part out of Federal funds under a State plan approved under this title and who solicits, offers, or receives any-
(1) kickback or bribe in connection with the furnishing of such items or services or the making or receipt of such payment, or
(2) rebate of any fee or charge for referring any such individual to another person for the furnishing of such items or services shall be guilty of a misdemeanor and upon conviction shall be fined not more than $10,000 or imprisoned for not more than one year, or both.]

23 Id.
sections eliminated the requirement that the prohibited conduct be performed "knowingly" and/or "willfully," thereby holding violators strictly liable.\textsuperscript{24}

Although the Original MMAKS lacked a mens rea element, relieving the prosecution of proving its greatest impediment to conviction, fraud and abuse continued to escalate in the programs. As a consequence of extensive fraudulent activities, Congress enacted the Medicare and Medicaid Anti-Fraud and Abuse Amendments in 1977 (hereinafter the "Amended MMAKS").\textsuperscript{25} The express purpose of the Amended MMAKS was to strengthen the capacity of the government to detect, prosecute, and punish fraudulent activities under the Medicare and Medicaid programs.\textsuperscript{26}

The Amended MMAKS expanded and clarified the scope of the Original MMAKS' terminology by prohibiting the solicitation or receipt of "any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or kind."\textsuperscript{27} To further encourage statutory compliance, the penalty for a violation was elevated to a felony, punishable by a fine of up to $25,000 and/or imprisonment for not more than five years.\textsuperscript{28}

Despite the overriding desire to eradicate fraudulent activity, Congress created two prosecutorial exceptions designed to foster competition and good business practices among medical providers. These exemptions amounted to discounts within and payments pursuant to bona fide employment relationships.\textsuperscript{29} Overall, the statutory provisions were intended to effectuate vigorous prosecutions in light of a serious and pervasive fraud problem.

In 1980, Congress, realizing the potential for prosecuting individuals whose conduct, while improper, was inadvertent, enacted the Omnibus Reconciliation Act of 1980 (hereinafter "ORA"). The ORA required, among other things, that the prohibited conduct be performed "knowingly and willfully" before it be deemed a violation of the MMAKS.\textsuperscript{30} Ironically, the addition of this element reinstated the very element eliminated by the Original

\textsuperscript{24} Id. (absence of "knowingly" and/or "willfully" language).

\textsuperscript{25} Amended MMAKS, supra note 2, § 1877(b) (current version codified at 42 U.S.C. § 1320a-7b(b)).

\textsuperscript{26} See generally Joseph T. Sebastianilli, Health Care in the 90's and Beyond: Practice Structure, Competition, Government Regulation, and Malpractice Concerns, A.L.I., September 14, 1989, at 97. "Fraud in these health care programs adversely impacts on all Americans, who must bear the financial burden from misuse of funds and diverts funds from those most in need, the elderly and poor." Id.

\textsuperscript{27} 42 U.S.C. § 1395 (1977) (emphasis added), recodified as 42 U.S.C. § 1320a-7b(b)(1994) by MMPPPA, supra note 4. For a detailed discussion of what payment arrangements qualify as remunerations, see discussion, part III. B. 2, infra.

\textsuperscript{28} 42 U.S.C. § 1320a-7b(b) (1994).


\textsuperscript{30} ORA of 1980, supra note 2.
MMAKS as an impediment to successful prosecution.\textsuperscript{31} So, although Congress’ actions evidence an obvious intent to increase the enforceability of the MMAKS, it in fact compromised its position by requiring a mens rea element to be proven in each case.

In the years following the introduction of the PPS, a dramatic increase in the number of complaints from medical providers culminated in the enactment of the MMPPPA in 1987.\textsuperscript{32} The purpose of the Act, like the Amended MMAKS, was to clarify those arrangements permissible under the MMAKS.\textsuperscript{33} The MMPPPA mandated, among other things, that the Secretary of Health and Human Services promulgate regulations (conventionally labelled "safe harbors") designating certain payment practices and business arrangements as exempt from criminal prosecution.\textsuperscript{34} An in-depth discussion of the past case law interpreting the MMAKS is necessary for a full understanding and application of these recently-enacted safe harbors.

III. JUDICIAL INTERPRETATION OF THE ANTI-KICKBACK STATUTE

A. Original Kickback Statute

With the exception of two early cases, federal courts have been consistent in their interpretation of the MMAKS.\textsuperscript{35} Judicial construction of the 1972 statute primarily focused on the appropriate definition of the terms "kickback" and "bribe." \textit{United States v. Zacher,}\textsuperscript{36} one of these early exceptions, is illustrative of the problems faced by prosecutors under the narrow judicial interpretation applied to the limited language of the Original MMAKS. In \textit{Zacher}, the defendant operated a nursing home and charged all patients $29 per day. Medicaid, regardless of the actual cost to the facility, would reimburse the operation only $25 per day. Consequently, Zacher admitted Medicaid patients on the understanding that they or their families would either supplement Medicaid by paying the $4 difference, or would forgo treatment.\textsuperscript{37}

The government initially secured a conviction, arguing that the supplementary payments required by the facility during the years of 1973 and 1974 were bribes in violation of 42 U.S.C. § 1396h(b) (formerly §1909(b) as

\textsuperscript{31}See Original MMAKS, \textit{supra} note 2.

\textsuperscript{32}MMPPPA, \textit{supra} note 4. See also 42 U.S.C. § 1320a-7(b)(E) (1994).

\textsuperscript{33}Sebastenilli, \textit{supra} note 25, at 97-98. "Purpose of amendments: a. clarify and restructure those provisions in existing law which define types of financial arrangements and conduct to be classified as illegal under medicare/medicaid." \textit{Id}

\textsuperscript{34}MMPPPA, \textit{supra} note 2, § 14.


\textsuperscript{36}Zacher, 586 F.2d 912 (2nd Cir. 1978).

\textsuperscript{37}Id.
The Second Circuit reversed the defendant’s conviction, holding that in the absence of any misapplication of government funds increasing the cost of the programs, or any definitive interpretation of the statutory language, the traditional common law understanding of the word "bribe" should be utilized. Accordingly, Zacher was acquitted because his intent was not "corrupt."

Within a year of Zacher, the Fifth Circuit, in *United States v. Porter*, reversed a fraud conviction based on a narrow definition applied to another statutory term, "kickback." In *Porter*, the defendant physicians, rather than bill Medicare directly or use an inexpensive computerized facility, would send blood samples to a manual laboratory operated by Porter. Porter in turn paid the defendant physicians up to $35 of the total $214 reimbursement he received from Medicare. The defendant physicians, in cooperation with Porter, set up a dummy corporation to act as a conduit between the laboratory and doctors for the sole purpose of distributing the payments. The defendants then claimed that these payments represented legitimate "handling fees." This was a case of first impression for the Fifth Circuit. The court, using reasoning similar to that in *Zacher*, stated that in the absence of any definitive statutory guidance, a kickback

"[i]n ordinary parlance... is a secret return to an earlier possessor of part of a sum received...[and further] involves a corrupt payment or receipt of payment in violation of the duty imposed by Congress on providers of services to use federal funds only for intended purposes and only in the approved manner."

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38Id. at 916.

39Id.

[C]ourts have consistently understood the word "bribe" to encompass acts that are *malum in se* because they entail either a breach of trust or duty or the corrupt selling of what our society deems not to be legitimately for sale...It is this element of corruption that distinguishes a bribe from a legitimate payment for services.

Id.

40*United States v. Porter*, 591 F.2d 1048 (5th Cir. 1979). Porter's activities occurred during a 3-year span from 1973 to 1975. Further, Porter was under no statutory duty to use automated services, as opposed to the selected manual hand-operated services, and consequently did not violate the statutory proscriptions by receiving a portion of a lawful Medicare payment to a laboratory for his referral of patients. *Id.* at 1054.

41*Id.* at 1051. The Court upheld a doctor's right to receive "handling fees" from laboratory and classified the payment as a legitimate arrangement rather than unacceptable kickbacks. *Id.* at 1054.

42*Id.* at 1053. As opposed to *Zacher's* Medicaid charge pursuant to 42 U.S.C. § 1396h(b), *Porter* was charged under the Medicare provision of § 1395nn(b).

43*Id.* at 1054.
Applying this reasoning, the Fifth Circuit determined that no kickback existed. The defendants' activities were not found to fall within the meaning of the statute because: (1) the funds being received were not funds being returned to an earlier possessor, (2) the defendants were not public officials having their judgment corrupted, and (3) the defendants were not persons on whom Congress had imposed a statutory duty.\textsuperscript{44}

The court's narrow construction asserted, in effect, that once the laboratory received a lawful fee, the Original MMAKS seemed to impose no restrictions on what the lab could do with the payment. Therefore, the defendants' characterization of the kickback as a "handling fee" was legitimate.\textsuperscript{45} Moreover, although the \textit{Porter} activity transpired over a three-year-period prior to 1977, the court relied on the legislative intent of the Amended MMAKS as a foundation for defendants' acquittal.

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 . . . is unclear and needs clarification." If the meaning of the 1972 version of 42 U.S.C. § 1395nn(b) was not clear and precise to the Congress and to the United States Attorneys charged with enforcing the law, we are hard put to say, with that degree of confidence required in a criminal conviction, that these defendants were given clear warning by the statute that their conduct was prohibited by it, thus amounting to a criminal act.\textsuperscript{46}

The flaws of the Original MMAKS, illustrated by this legislative analysis, virtually mandated the \textit{Porter} result. The \textit{Porter} decision became a powerful tool in defense of Medicare and Medicaid cases arising before the Amended MMAKS took effect. Defense attorneys relied upon \textit{Porter} to argue that a "kickback" cannot refer to a payment made to a party other than the party who initially transferred the sum to the payor.\textsuperscript{47} This interpretation, however, did not prevail in subsequent decisions. Instead, the judiciary, acknowledging the myriad of ways in which fraudulent kickback schemes could be accomplished, turned to the intent with which the defendants' conduct was undertaken, the substance of the transaction, and a broader interpretation of the MMAKS' elements for subsequent determinations. A series of decisions in the Sixth and Seventh Circuits exemplifies this trend.\textsuperscript{48}

\textsuperscript{44}Id.
\textsuperscript{45}591 F.2d at 1054.
\textsuperscript{46}Id. (citations omitted).
\textsuperscript{47}Id.
\textsuperscript{48}See United States v. Perlstein, 632 F.2d 661 (6th Cir. 1980); United States v. Tapert, 625 F.2d 111 (6th Cir.), cert. denied, 449 U.S. 1034 (1980); United States v. Ruttenberg, 625 F.2d 173 (7th Cir. 1980); United States v. Hancock, 604 F.2d 999 (7th Cir. 1979).
In *United States v. Hancock*, the defendant chiropractors prepared and sent tissue samples to a clinical laboratory for testing. The laboratory would then bill Medicaid directly for its services and include in the bill the cost of the preparation services performed by the defendants. Upon receiving reimbursement from Medicaid, the laboratory paid the defendants for their preparation or "handling fees." Although similar to the *Porter* scheme, the Seventh Circuit rejected the Fifth Circuit's interpretation of the term "kickback" and reversed the lower court's ruling. The court applied a common usage to the term, designating it as a "percentage payment for ... granting assistance by one in a position to open or control a source of income." The defendants, as the court described, were undoubtedly able to control the payment of federal funds to the laboratory by sending Medicare or Medicaid patient tissue specimens to the laboratory.

In addition, the Seventh Circuit agreed with the *Zacher* court, stating that the intent behind the 1972 statute was to decrease the costs to the Medicare/Medicaid programs by reducing fraud and abuse. Accordingly, the *Hancock* payment scheme, adding an alleged "handling fee" to the legitimate cost of the transaction, was the sort of "evils Congress sought to prevent by enacting the kickback statutes." Thus, the potential for increased program costs was the equivalent of the corrupt element announced in *Zacher*, and the allegation that the defendants received payments in return for their decision to send specimens to Chem-Tech satisfied it.

In *United States v. Ruttenberg*, the Seventh Circuit adopted the *Hancock* analysis, finding that payments from a pharmaceutical service to a nursing home for the opportunity to sell its drugs were kickbacks in violation of the Original MMAKS. The court stated that Congress' adoption of the term "kickback" was fully understood by Congress itself and the public to "mean the transfer back to one having control of the original payment."

49 604 F.2d at 999. Hancock's activities took place prior to the 1977 amendments, although the ruling came after.

50 Id. at 1001.

51 Id. at 1002.

52 Id. (citing WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1966).

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

54 Id.

55 *Ruttenberg*, 625 F.2d at 177. Ruttenberg's activities, similar to *Hancock's*, took place before the 1977 amendment even though the ruling came after.

56 Id.

Though we are concerned with the law, not the ethics of the medical profession ... it should be noted that the law does not make increased cost to the government the sole criterion of corruption ... [N]or need Congress have spelled out duties, beyond the duty of avoiding receipt and payment of kickbacks.

Id. at 177, n.9 (citations omitted).
The Ruttenberg defendants attempted to distinguish their case from that of Hancock. The defendants maintained that their pharmaceutical arrangement posed no increased costs to the federal assistance programs due to government price fixing.\(^5\) The Seventh Circuit rejected this argument and asserted that even if the payments made by druggists to nursing home operators were not paid out of federal funds, but were merely gifts from the druggists' profits, the payments would still be kickbacks proscribed by the statute.\(^5\) "Whether costs were directly and immediately increased by those particular payments, however, is irrelevant. The potential for increased costs if such 'fee' agreements became an established method of business is clearly an evil with which the court was concerned and one Congress sought to avoid in enacting" the statute.\(^5\)

B. The Current Anti-kickback Statute: Clarification from the 1977 Fraud and Abuse Amendments

Congress' most encompassing attempts at clarifying the statutory terms of the MMAKS by adoption of the 1977 Anti-Fraud and Abuse amendments (Amended MMAKS), the ORA of 1980, and the MMPPPA of 1987 resulted in apparently few, but substantially important changes to the Original MMAKS.\(^6\) Before proceeding to a discussion of the MMPPPA and what arrangements qualify for safe harbor protection, an analysis of the MMAKS' current statutory language is imperative.

The current MMAKS sets forth four elements that must be found before a violation can occur.\(^6\) The first element is that the remuneration must be made in return for, or in order to induce the referral of, Medicare or Medicaid business.\(^6\) The second element that must be found before a violation of the

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\(^5\) Id. at 176.

\(^5\) Id. at 177. Ruttenberg in effect ruled that all that was required under the statute was a payment of a kickback to those in control of federal funds. The referring or receiving of a portion of those federal funds for the "opportunity" to provide services was the equivalent of a non-approved use and therefore a kickback within the language of the statute.

\(^5\) Ruttenberg, 625 F.2d at 177.

\(^6\) See Amended MMAKS, ORA of 1980, and MMPPPA of 1987, supra note 2. The ORA of 1980 added the requirement of specific intent. For one to be convicted, all offenses must be done knowingly and willfully. See 42 U.S.C. § 1320a-7b(b) (1994).

\(^6\) 42 U.S.C. § 1320a-7b(b) (1994) Illegal Remunerations sets forth four elements:
1.) Knowingly and Willfully soliciting or receiving
2.) any remuneration . . .
3.) in return for referring . . .
4.) for which payment is made by Medicare or Medicaid.

Elements three (3) and four (4) as listed, and termed one (1) and two (2) within the text, are so basic and obvious when met as to require no further discussion.

\(^6\) Id. § 1320a-7b(b)(1)(A), 2(A).
current statute can occur is that the service, item, good, or facility must be paid for in whole or part by Medicare or Medicaid.63

The other two elements, the mens rea element and the "remuneration" element, have been the subject of considerable judicial interpretation and, for clarification, will be addressed individually.

1. The Mens Rea Element: "Knowingly and Willfully"

The current MMAKS provides that the prohibited act must be done "knowingly" and "willfully."64 This element was inserted in 1980 as a result of congressional intent to facilitate legitimate competitive activity.65 In the context of the statute, the Medicare Intermediary Manual defines "knowingly" as "the accused person is aware that a particular act would constitute a deception or misrepresentation, but nevertheless proceeds to do it."66 "Willfully" is defined as actions done "voluntarily, purposefully, deliberately and intentionally...."67

The intent element is the most important, disputed, and difficult element to prove in all cases arising under the current MMAKS. In the seminal case of United States v. Greber,68 the defendant, an osteopathic physician and president of Cardio-Med Laboratory, Inc., provided physicians with heart monitoring services for their Medicaid and Medicare patients. After removing the monitors and analyzing and interpreting the data, Cardio-Med would bill Medicare for the service and return the report, together with a 40% portion of the Medicare reimbursement. The reimbursement was termed an "interpretation fee" even though in most cases, the physicians merely signed the reports previously translated and interpreted by Cardio-Med Analysts.69

The defendants claimed that this payment scheme was legitimate since Medicare allowed reimbursement and/or payment for physician interpretation and evaluation.70 "Absent a showing that the only purpose behind the fee was to improperly induce future referrals," the defendants

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63Id. § 1320a-7(b)(1)(B)-(2)(B). This element is included in the provision to exclude from prosecution activities which are associated with privately insured patients as opposed to patients or recipients of Medicare and Medicaid.

64Id. at § 1320a-7(b) 1-2.

65ORA, supra note 2.


67Id.


69760 F.2d at 70.

70Id. at 69-70. The court asserted that even if Medicare allowed for Medicare reimbursements, the fixed percentage paid to the defendant was still violative of Medicare's allotted service reimbursement.
argued that "compensating a physician for services actually rendered could not be a violation of the statute."\textsuperscript{71}

The Third Circuit, in an expansive and comprehensive decision, rejected this argument and affirmed the defendants' convictions. The court held that if payments were made to a physician to induce future patient referrals, even if the payments were in compensation for actual services rendered by the physician, known as fee splitting, the MMAKS had been violated by both parties.\textsuperscript{72} In other words, if one purpose of the remuneration was to induce a referral, then even if the remuneration was intended to primarily provide compensation for professional services, the provider would have violated the statute.\textsuperscript{73}

The Greber court declared the test for business impropriety as the subjective purpose for which the business participants' referrals were made.\textsuperscript{74} Overutilization, one indicator to detect fraud, was the key in establishing criminal intent in Greber.\textsuperscript{75} "If a suspicious financial arrangement 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."\textsuperscript{76}

The Greber court's decision reflects a broad, although not inappropriate, interpretation of the intent element. The court stated that the language and purpose of the statute support the government's view in contrast to the defendants' argument.\textsuperscript{77} "[C]ongress intended to combat financial incentives to physicians for ordering particular services patients did not require . . . [t]he statute is aimed at the inducement factor and the potential for unnecessary drain on the Medicare system . . . ."\textsuperscript{78}

2. The "Remuneration" Element

The second disputed requirement for a violation of the MMAKS to occur is that the prohibited conduct must involve a solicitation, receipt, offer, or pay-
ment of any "remuneration (including any kickback, bribe or rebate)." The remuneration can be direct or indirect, overt or covert, in cash or kind. The addition of the "remuneration" element resolved the controversy under the Original MMAKS concerning the definitive scope of the terms "kickback" and "bribe." Cases following the enactment of the Amended MMAKS are illustrative of this trend.

In United States v. Stewart Clinical Laboratory, the Ninth Circuit, although reversing a conviction under the 1977 provision, stated that "[t]he amendments effectively eliminated any problems presented by the distinction between a kickback or bribe and rebate . . . , by making illegal all forms of improper remuneration." Thus, the provision now reaches any type of transaction involving payment for referrals.

The Greber court endorsed the Stewart decision, relying on the intent of the Amended MMAKS and its prior application in Hancock. The court clearly defined "remunerate[s]" as "to pay an equivalent for service." The Greber court asserted that by adding this term, Congress intended to expand the coverage of the statute to situations where no service was rendered. The court stated that the text refers to "any remuneration," which includes not only amounts for which professional time was expended, but to those amounts for which no actual service was performed. While the Stewart and Greber decisions clearly illustrate the breadth of the Amended MMAKS, medical providers continue to quarrel over the statute's ability to guide them toward legitimate business arrangements.

C. Rejection of the Medical Profession's Argument

The ease with which a conviction was obtained in Greber is not supportive of the argument that the statute is ambiguous and provides little guidance for
legitimate competitive practices. The Greber decision does not support any claim that the amendments have unfairly constrained medical providers' ability to create legitimate arrangements. In Greber, proving the intent element was relatively easy. First, investigators found that Dr. Greber had testified at an earlier civil case to the effect that "[i]f the doctor didn't get his consulting fee, [from the medicare funds already received], he wouldn't be using our service. So the doctor got a consulting fee." This statement undoubtedly exemplified an actual discernible intent on the part of the defendant to retain future referrals from physicians. Secondly, Greber's utilization of the kickback arrangement, over a two year period, contained a clear potential for the unnecessary drain on the Medicare system.

Furthermore, the very effect of adding a mens rea element to the MMAKS can only lead to complicated prosecutions resulting in a lack of convictions. This outcome is directly at odds with the deterrent/punishment intent behind the statute. Moreover, the U.S. Attorney's office, in cooperation with the Inspector General's Office, has the discretion to prosecute. Under a different, more legitimate remuneration arrangement, the prosecutors and courts may determine that the payment and referral devices are too remote to violate the Statute, distinguishing it from Greber and criminal sanctions.

The aforementioned problems manifest the difficulties in detecting and punishing fraudulent activities. The addition of the mens rea element was a prosecutorial sacrifice to placate medical providers who maintain they have no other alternative but to utilize prohibited arrangements and practices to remain efficient. The resultant alterations in the statutory language assist providers in avoiding prosecutions, not promoting them. Medical providers should not be condemning the legislative history of MMAKS. Hospitals, physicians and other medical providers should be applauding congressional efforts for striking a balance in an area so critical and complex that less than complete detection of fraudulent activity will ultimately result in drastic detrimental effects in the application and continuance of the government-based programs.

In summation, the MMAKS contains broad, but precise, language intended to effectuate vigorous prosecutions of fraudulent financial arrangements. The several court decisions mentioned earlier clearly illustrate this point. However, with the introduction of the PPS in 1983, cries from medical providers for further exemptions from the MMAKS began to surface. Congress, recognizing that some aspects of PPS regulation could possibly cause inefficient medical

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866760 F.2d at 70.
In addition, defendant told physicians at the hospital that the Board of Censors of the Philadelphia County Medical Society had said the referral fee was legitimate if the physician shared the responsibility for the report. Actually, the Society had stated that there should be separate bills because "for the monitor company to offer payment to the physicians...is not considered to be the method of choice." Id.

87Id. at 71.

88Hearn, supra note 11, at 175.
care, but acknowledging the fact that more complex and deceiving arrangements were forthcoming, ratified the MMPPPA. The MMPPPA was the culmination of congressional intent to close the gaps of the Amended MMAKS. This purpose is also achieved by MMPPPA mandating the Secretary of HHS to define business arrangements that would be exempt from criminal prosecution. Our attention will now turn to an examination of these exemptions, more conventionally labelled safe harbors.

IV. RESPONSE TO UNCERTAINTY-SAFE HARBORS ENACTED

Since the enactment of the Amended MMAKS, concern has arisen among a number of health care providers that many relatively innocent, and even beneficial, commercial arrangements may be subject to criminal sanctions. As a result of broad judicial interpretation applied to the Amended MMAKS and the 1982 adoption of the PPS, medical providers contend that they are forced into adjusting operations through capital pooling and horizontal integration to remain competitive and efficient. Expansion into new forms of health care delivery may enable hospitals and other provider facilities to develop multiple sources of revenue.

While this may be true, such arrangements increase the temptation to improve profits under the guise of providing convenient patient services. Notwithstanding this reality, Congress, in an effort to appease medical providers by ensuring greater certainty concerning MMAKS compliance, ordered the Secretary of the Department of HHS to issue regulations clearly defining legal business arrangements.

The MMPPPA specifically provides two sections clarifying the Amended MMAKS. Section two (2) authorizes the Office of the Inspector General to exclude an individual or entity from participation in either program upon a determination that the party engaged in a prohibited remuneration scheme. This new sanction was intended to provide an alternate civil remedy, short of

89 MMPPPA, supra note 4, § 14(a).

90 Id. See also 42 U.S.C. § 1320a-7b(b)(3)(E) (1994).


92 MMPPPA, supra note 2, § 14. Generally the provisions provide safe harbors for:

1) investments or ownership by referral sources,
2) space rental/lease arrangements,
3) equipment rentals/lease,
4) personal services/management contracts,
5) sale of physicians practices,
6) referral services,
7) discounts,
8) employee and group purchasing organizations,
9) waiver of co-insurance deductible amounts, and
10) warranties.

93 Social Security Act § 1128(b)(7), 42 U.S.C. § 1320a-7(b).
criminal prosecution, that would be an effective way of regulating abusive business practices. Section fourteen (14), which will be the focus of this part of the article, mandated the promulgation of regulations specifying those payment practices that would not be subject to criminal prosecution under §1128(b) of the Social Security Act. Although the rules were supposed to be handed down within a year of the MMPPPA's enactment, several subsequent revisions and rescission for clarification delayed their final effective date until July 1991.

In all, the rules name some ten safe harbors where physicians and other providers can take haven without fear of prosecution. They cover a diverse set of arrangements, including investments, sale of practices, employment contracts, equipment rentals, space rentals/leases, personal service contracts, discounts, warranties, and waiver of Medicare co-payments. Perhaps the greatest attention has focused on the safe harbors for investment interests and space or equipment rental.

A. Investment Interests

The Secretary of HHS formulated this exception intending to demonstrate that the HHS did not want to bar all investments by physicians in other health care facilities to which they refer patients. Under this regulation, the safe harbor is intended to shelter two basic situations. The first situation involves investment by physicians and other providers in large publicly-held entities. The second situation involves small entities, more specifically joint ventures. It is this second situation that has given medical providers the most trouble, because unlike the first situation, a safe harbor provision was not provided for smaller entities in the earlier draft.

94 Social Security Act § 1128(b), 42 U.S.C. § 1320a-7(b).


96 See MMPPPA, supra note 4.

97 Id.


99 Id.

100 Id.

101 53 Fed. Reg. 51,856 (to be codified at 42 C.F.R. § 1001). This is only a proposal at this time with possible requirements of:

a. Bona fide opportunity to invest is made on an equal basis to referral and non-referral sources;

b. no referral requirement;

c. payments not related to referrals; and

d. ownership interest is disclosed.

Final regulations were handed down in July 1991 in similar form.
Because of significant business investment activity in joint enterprises, the final regulations added a safe harbor provision to cover small entities.\textsuperscript{102} The first type of investment interest requires, among other things, "that the opportunity to invest be open to investors regardless of whether they are in a position to make referrals."\textsuperscript{103} In addition, investors would receive a return proportionate to their investment which could not be in relation to the volume or value of referrals provided to the investment.\textsuperscript{104} The second type of investment involves "situations where the investor has a significant management role in the entity," including certain limited partnerships and managing partnerships.\textsuperscript{105} Like the first situation, investors would receive a return proportional to their investments not predicated on referrals to the investment.\textsuperscript{106}

The addition of this safe harbor enables health care attorneys to advise hospitals and other medical provider clients about proposed revenue enhancing arrangements with greater clarity. Since the regulatory language is narrow and each of the requirements must be met for compliance, a health care provider can structure and implement revenue enhancing ventures in harmony with the statutory requirements consistently and fairly.

\textbf{B. Space and Equipment Rentals}

One of the many controversies surrounding the MMAKS involves the rental of space or medical equipment owned by another health provider. Space rentals are usually between laboratories or other diagnostic services and physicians. The laboratories or diagnostic facilities provide physicians with rental payments for the use of the physician's office, from which patients may be referred to the lab.\textsuperscript{107} A Safe Harbor exemption exists for such an arrangement if the rental agreement meets several requirements including having a periodic agreement of at least one year in writing.\textsuperscript{108} Furthermore, the rental payment must be set in advance and cannot be founded on the number of referred patients to be served on the premises.\textsuperscript{109} Finally, the rental charge must reflect

\textsuperscript{103}See Tempkin, \textit{supra} note 95, at 13.
\textsuperscript{104}Id.
\textsuperscript{105}Id.
\textsuperscript{106}Id. at 13.
\textsuperscript{107}See Tempkin, \textit{supra} note 95, at 13.
\textsuperscript{109}Id.
the fair market value of the space. The same conditions apply to equipment rental as apply to space rental.

Most providers find that the ambiguity of this provision lies in the regulatory terms "fair market value." The view that this safe harbor does not furnish clear guidance is not shared by the OIG, the HHS Department charged with enforcing the regulations. The Secretary of HHS created this provision fully aware of sham lease arrangements in which rented space may not be large enough or otherwise suitable to perform the services for which the rent was paid. The provision, however, is conclusive and dictates that fair market value be defined as the "[v]alue for . . . general commercial purposes, not reflecting additional value attributed by either party because of proximity to referrals." Accordingly, fraudulent lease arrangements may take the form of a diagnostic laboratory service paying a physician a rental payment for leasing a portion of the physician's building, often a closet not intended for use, although doing so in order to obtain the referrals. In such a situation, if the physician refers her or his patients to that laboratory or diagnostic facility, the rent is considered a remuneration and hence a violation of the statute.

The creation of this exemption recognizes the ability of hospitals and corporate medical providers to alleviate the inherent financial risks for individual medical providers who rent space or highly-priced medical equipment. By allowing non-abusive hospital-physician arrangements, the HHS is fostering the growth of an efficient health care delivery system, not curtailing it. In light of the devastating troubles federally funded medical assistance programs are currently enduring, medical providers should reevaluate their contentions with the HHS's and OIG's efforts to accommodate the medical profession's so-called "competitive plight."


111 Id.

112 Teresa Hudson, Narrow 'Safe Harbors' May Create Tough Choices for Hospitals, HOSPITALS, Oct. 5, 1991, at 32. "We believe these regulations dramatically increase the level of guidance to the health care sector," says Thomas S. Crane, an OIG attorney and principal author of the 'Safe Harbors.' "This is the first time providers will know with certainty how to structure a business arrangement that will not violate the Statute."

Id.

113 Id.

114 42 C.F.R. § 1001.952.


116 Id. This provision, unlike its predecessor, deleted the prohibition of considering in the rental price the intended use of the space, thereby allowing leeway in generating fair market value for rented space.

117 Id.
Congress’ latest attempt to control fraud and abuse in the federally funded medical assistance programs, H.R. 5502, the Health Care Cost Containment and Reform Act of 1992, was favorably reported by the Subcommittee on Health of the Committee on Ways and Means to the full Committee on Ways and Means, U.S. House of Representatives, on July 1, 1992. Among other things, the measure would require the Secretary of the HHS to establish and coordinate a national health care fraud-control program to restrict fraud and abuse in private and public health care programs. More importantly, the fraud and abuse staff within the OIG would be increased to administer the national health care fraud-control program. The bill authorizes an increase in the OIG budget of $250 million in 1994, $300 million in 1995, $350 million in 1996, and $400 million in 1997. Finally, the bill would establish more severe criminal penalties and possible fines including triple damages for accepting kickbacks for violating the MMAKS.

VI. CONCLUSION

While it may be unclear as to whether fraud and abuse thrives at the same level as it has previously, one thing is clear, and that is the purpose and language of the MMAKS. Congress enacted the MMAKS for the specific purpose of combatting fraudulent remuneration schemes that, directly or indirectly, increase the overall cost of federally funded medical assistance programs. The subsequent acts and amendments to the MMAKS, in contrast to the arguments put forth by health care providers, have brought clarity and precision to its prohibitions. Further, Congress, recognizing the possibility of thwarting legitimate business ventures in the health care industry, has provided additional guidance by detailing transactions in which medical providers can engage without fear of prosecution. If medical providers follow the 'Safe Harbor' regulations and proscriptions of the MMAKS, the likelihood of prosecution will be minimized.

It is only through legislative efforts such as these that the evil of fraud and abuse in federal and state funded medical assistance programs can be eradicated. As long as prosecutors are flooded with higher priority cases that


119 Id. at 8. The bill would provide that any physician participating in a public or private health care program could not refer patients to other health care providers who provide certain specified services with which the physician has a financial relationship. Id.

120 Id.

121 Id.

122 Id.
attract more community interest and support, there will continue to be a lack of convictions.

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