# TABLE OF CONTENTS

INTRODUCTION ......................................................... 1  
FINDINGS ................................................................. 3  
RECOMMENDATIONS ..................................................... 5  
APPENDIX A. HCFA Comments  
APPENDIX B. AHA Comments  
APPENDIX C. CAP Comments
INTRODUCTION

PURPOSE

This management advisory report (MAR) alerts you to potential violations of the anti-kickback statute (statute), section 1128B(b) of the Social Security Act (42 U.S.C. section 1320a-7b(b)). We have identified potential violations in the financial arrangements between some hospitals and hospital-based physicians because these agreements appear to require physicians to pay more than the fair market value for services provided by the hospitals. We are continuing to pursue illegal arrangements where referring physicians receive kickbacks from hospitals. This MAR focuses on arrangements in which hospitals receive suspect remuneration from physicians.

BACKGROUND

Hospital-based physicians include specialists such as anesthesiologists, pathologists, and radiologists. Each of these specialties is dependent on their position at the hospital to obtain referrals from other specialists practicing at their hospital. In addition, hospitals often perform a variety of services for these physicians. In turn, the hospitals are dependent on the hospital-based physicians because they provide essential services to the hospitals. Some hospitals have reduced payments to hospital-based physicians, and some are requiring payments from those physicians ostensibly to reimburse the hospital for the services it performs, or for other purposes, such as "contributions" to a capital fund.

Medicare pays for the services of hospital-based physicians in a variety of ways. Usually, Medicare pays physicians directly for the services delivered. However, when pathologists perform clinical laboratory services for hospital inpatients under Part A, some portion of Medicare's prospective payment amounts to the hospital is for that pathology service. Medicare Part B payments for anatomic pathology services are more complicated. Technical and professional components are paid separately. The former go directly to hospitals and the latter to the pathologist.

Legal Criteria

Section 1128B(b) makes it illegal to offer, pay, solicit, or receive remuneration for referring patients or for arranging for or recommending the ordering of any service payable under Medicare or Medicaid. The statute is very broad, covering indirect or covert forms of remuneration, bribes, kickbacks, and rebates as well as direct or overt ones. Unlike most applications of the statute concerning Medicare compensation arrangements, the focus here is on remuneration made to hospitals from physicians.

The case law makes clear that the statute's proscriptions apply to those who can materially influence the flow of Medicare and Medicaid business. Hospitals are in
such a position with respect to hospital-based physicians, since they typically can name who will be the recipient of the flow of business generated at the hospital. The use of influence to steer health care business was the subject of a case decided in the First Circuit, U.S. Court of Appeals. In United States v. Bay State Ambulance and Hospital Rental Service, Inc., 874 F.2d 20, 33 (1st Cir. 1989) a hospital employee, John Felci, was convicted of receiving illegal payments to influence the hospital’s decision as to which ambulance company should receive the hospital’s ambulance contract.

Three other significant cases have interpreted the statute. In United States v. Greber 760 F.2d 68, 69 (3rd Cir.), cert. denied, 474 U.S. 968 (1985) the Court held that, "if one purpose of the payment was to induce future referrals, the Medicare statute has been violated." The reasoning in Greber was adopted by the Ninth Circuit Court of Appeals in the United States v. Ka's 871 F.2d 105 (9th Cir. 1989.) In Kats the Court found that the statute is violated unless the payments are incidentally attributable to referrals.

In United States v. Lipkis 770 F.2d 1447 (1985), the Ninth Circuit Court of Appeals reviewed an arrangement between a medical management company which provided services to a physician’s group and a clinical laboratory. The laboratory returned 20 percent of its revenues obtained from the physician group’s referrals to the management company. The defendants alleged that these payments represented fair compensation for "specimen collection and handling services." Ibid. at 1449. The court rejected this defense, noting "the fair market value of these services was substantially less than the [amount paid], and there is no question [the laboratory] was paying for referrals as well as the described services." Ibid. Thus, applying the reasoning of the Ninth Circuit Court of Appeals in Lipkis, an inference can be drawn that illegal remuneration occurs when a contract between a hospital and hospital-based physicians calls for the rental of space or equipment or provision of professional services on terms other than fair market value.

If a provider's conduct falls within the purview of the statute, it can be prosecuted unless the conduct meets a statutory exception or regulatory "safe harbor." 56 Fed. Reg. 35952 (July 29, 1991).
FINDINGS

Given the relationship between a hospital and its hospital-based physicians, contracts which require the hospital-based physicians to split portions of their income with hospitals are suspect, although not per se violations of the statute. In some cases that we have reviewed, there is little basis to require hospital-based physicians to turn over a percentage of their earnings to the hospital. In addition, under Lipkis, a court may draw the inference that a direct payment from a hospital-based physician to a hospital is made for an illegal purpose when the amount of the payment cannot be justified based on the amount of services the hospital renders under the contract with the physician.

We have reviewed agreements that provide payments or remuneration to hospitals far in excess of the fair market value of the services provided by them. Because these arrangements may violate the statute, disclosure of the terms of these agreements are rare. Therefore, it is very difficult to establish the prevalence of these agreements. Several medical societies and anonymous parties have shown us the following contract provisions without identifying names and locations:

- A hospital provides no, or token, reimbursement to pathologists for Part A services in return for the opportunity to perform and bill for Part B services at that hospital.
- Radiologists must pay 50 percent of their gross receipts to a facility’s endowment fund.
- Thirty-three percent of all profits above a set amount must be paid by a radiology group to a hospital for its capital improvements, equipment, and other departmental expenditures.
- A radiologist group was required to purchase radiology equipment and agreed to donate the equipment to the hospital at the termination of the contract. The hospital has an unrestricted right to terminate the contract at any time.
- When net collections for a radiology group exceed $230,000, 50 percent is paid to the hospital, and the hospital reserves the right to unilaterally adjust the distributions if it determines that the physician group has not fulfilled the terms of the contract.
- A radiologist group pays 25 percent of the profits exceeding $120,000 to the hospital for capital improvements. Fifty percent of the profits exceeding $180,000 go to this purpose.
- A radiology group pays for facilities, services, supplies, personnel, utilities, maintenance, and billing services furnished by the hospital on a fee schedule.
that begins at $25,000 for 1989, and rises to $100,000 by 1993. Payments are
due only if the radiologist's gross revenue exceeds $1,000,000 in the previous
year.

A determination of whether these agreements are illegal requires an entire review of
the contract and the relationship between the parties. In addition, it is recognized that
at some income levels, agreements which require physicians to turn over a percent of
their income over a threshold amount, may approximate the fair market value of the
services the hospital provides. This fact may diminish our enforcement concerns.

All of these examples appear to violate the statute because they provide compensation
to the hospitals that exceeds the fair market value of the services the hospitals provide
under the contracts. It also appears the remuneration is intended to provide the
hospital-based physician with referrals from the other physicians on the hospital's
medical staff.

These potentially illegal financial arrangements may have several unfortunate results.
Hospitals may award the exclusive contract based on improper financial considerations
instead of on traditional considerations centering on the professional qualifications of
the physician. In addition, the remuneration gives hospitals a financial incentive to
develop policies and practices which encourage greater utilization of the services of
hospital-based physicians payable under Medicare Part B. Hospital-based physicians
faced with lowered incomes may also be encouraged to do more procedures in order
to offset the payments to the hospitals. These problems are among the recognized
purposes of having the anti-kickback statute on the books in the first place.

Illegal arrangements may also complicate the development and updating of physician
fee schedules. Physician practice costs could be artificially inflated by hospitals and
physicians that enter into arrangements not based on fair market values.
RECOMMENDATIONS

The HCFA should instruct its intermediaries to: (1) notify hospitals about potential legal liability when they enter into agreements not based on the fair market value of necessary goods and services exchanged; and (2) refer cases similar to the examples given above, or any other suspect arrangements to the OIG for possible prosecution or sanctions.

To avoid potential legal liability, all contracts between hospitals and hospital-based physicians should comply with all the safe harbor provisions that may apply under the contract between the parties. Of particular importance are the safe harbors that protect payments for personal services and management contracts and for services of bona fide employees. 42 CFR §§ 1001.952(d) and (j); 56 Fed. Reg. 35985, 35987. It is noted that in some of the safe harbor provisions, we require that payments must be consistent with "fair market value." The regulation explicitly provides that safe harbor protection is not available where any part of the payment takes into account the volume or value of referrals or business otherwise generated by either party. This restriction is necessary because such payments directly violate the statute.

HCFA and Industry Comments on Earlier Version

In response to an earlier draft of this report, we received comments from HCFA, the American Hospital Association (AHA), and the College of American Pathologists (CAP). The HCFA comments are included in appendix A. The AHA comments are included in appendix B, along with our response to these comments, and AHA's views on our response. The CAP comments are included in appendix C.

In response to these comments, we have (1) clarified the legal basis for our discussion and (2) deleted our recommendation that carriers identify suspect arrangements.
APPENDIX A

HCFA Comments
Memorandum

MAY 2 1991

From Gail R. Wilensky, Ph.D. ( Administrator

Subject OIG Management Advisory Report: "Financial Arrangements Between Hospitals and Hospital-Based Physicians," OEI-09-89-00330

To The Inspector General Office of the Secretary

We have reviewed the subject management advisory report which alerts HCFA to potential violations of the anti-kickback statute of the Social Security Act. The report identifies as potential violations those financial arrangements between hospitals and hospital-based physicians which either require physicians to pay more than the fair market value for services provided by the hospitals or which compensate physicians for less than the fair market value of goods and services that they provide to hospitals.

The report recommends that HCFA instruct its contractors to (1) notify physicians and hospitals about the potential legal liability when they enter into agreements not based on the fair market value of necessary goods and services exchanged; and (2) refer identified cases to OIG for possible prosecution or sanctions. Our comments on these recommendations, as well as technical comments on the report, are attached.

Thank you for the opportunity to comment on this management advisory report. Please advise us whether you agree with our position on the report's recommendations at your earliest convenience.

Attachment
OIG Recommendation 1

HCFA should instruct its contractors to notify physicians and hospitals about potential legal liability when they enter into agreements not based on the fair market value of necessary goods and services exchanged.

HCFA Response

We do not disagree with a recommendation that physicians and hospitals be notified of the potential legal consequences that can follow a violation of the anti-kickback provisions. However, OIG, not HCFA, is responsible for monitoring compliance with the anti-kickback statute, investigating potential violations, and initiating legal action against parties to alleged illegal kickbacks. Therefore, we believe that it would be more appropriate for the OIG to issue this warning as a fraud alert, rather than placing this responsibility on the Medicare contractors.

OIG Recommendation 2

HCFA should instruct its contractors to refer identified cases to OIG for possible prosecution or sanctions.

HCFA Response

We believe that it would not be meaningful for HCFA to attempt to implement the above recommendation on the basis of the very limited information given in OIG's report. The report gives no suggestions as to what procedures the contractors should use to detect and identify violations in the arrangements between hospitals and hospital-based physicians. This poses particular difficulties now that the contractors, with the move away from cost-based reimbursement, no longer routinely audit the agreements between hospitals and physicians.

More importantly, no regulations have been issued to define what specific agreements would be illegal under the anti-kickback statute. Moreover, the criteria discussed in the report cannot be easily applied to a concrete analysis of
specific agreements, and the report draws no clear line between legal and illegal arrangements. For example, the report describes an arrangement where a hospital provides no, or token, payback to pathologists for Part A services in return for the opportunity to perform Part B services at that hospital. OIG gives this as an example of a possible violation of the anti-kickback statute. However, it is unclear from this report how such an arrangement is to be distinguished from those in which a physician provides other types of services to a hospital in connection with the physician's admitting privileges. Physicians have routinely furnished services to hospitals, such as serving on committees, performing administrative functions or supporting a hospital's graduate medical program, in return for admitting privileges and the right to practice at those hospitals. Without clearer and more specific legal criteria, we would be reluctant to ask the contractors to take on the responsibility of actively attempting to identify violations of the anti-kickback statute. However, contractors do already operate under an instruction to report any activities they come across while carrying out their audit function that they believe to be potentially illegal.

General Comments

- HCFA is currently developing demonstrations which involve innovative financial arrangements between hospitals and hospital-based physicians. For example, the Medicare Participating Heart Bypass Center and the Cataract Surgery Alternate Payment demonstrations will test the concept of a negotiated bundled payment combining hospital, facility, and physician services for coronary artery bypass grafts (CABG) and cataract procedures, respectively. OIG representatives actively participated in the design of each of these demonstrations and have assured HCFA that they do not consider either of them to be in violation of the anti-kickback statute. Also, under HCFA's point-of-service proposal, contractors will establish and run preferred provider networks. These contractors will negotiate financial agreements for high volume procedures such as CABG. OIG should make clear in this report that such arrangements would not constitute a potential violation of the anti-kickback statute.

- The American Hospital Association (AHA) has sent us a copy of their March 11, 1991 letter to OIG concerning this report. AHA claims that OIG did not take the hospital perspective into account when drafting the report. The letter raises several important points which should be addressed by OIG in the final report.
Technical Comments

0 We believe that the background discussion of hospital-based pathologists on pages 1 and 2 is vague, and even misleading, when it explains how Medicare pays for the clinical laboratory services pathologists perform for hospital inpatients. Generally, pathologists do not order, perform or interpret the findings of clinical laboratory tests. The pathologist's role in connection with these services is supervisory in nature and the associated costs are payable as a service to the hospital, either through the diagnosis related group (DRG) payment or on a reasonable cost basis in hospitals excluded from the prospective payment system (PPS). The report's description of payments for the technical component of anatomic pathology services implies that a separate payment is made to the hospital rather than indicating that payment for the technical component is made through the DRG amounts.

0 We also believe that the report should address the practical differences in Medicare's ability to respond to the recirculation of physicians' fee revenue in PPS hospitals as compared with hospitals in which inpatient services are payable on a reasonable cost basis.
A fraud and abuse analysis is inappropriate because contracts between hospitals and hospital-based physicians do not result in overutilization of Medicare services.

The Office of the Inspector General is charged with investigating potential violations of the Medicare fraud and abuse "anti-kickback" statute. The purpose of the anti-kickback law is to prevent overutilization of Medicare services, thereby preventing unnecessary expenditures of federal funds. Inducement of overutilization as a result of financial arrangements triggers involvement by the Inspector General in those arrangements.

AHA does not understand how hospital contracts with hospital-based physicians such as those described in the report can be viewed as encouraging overutilization of services. In order to apply a fraud and abuse analysis, the OIG would need to show that: 1) hospitals refer patients to hospital-based physicians, and are able to order services for patients; 2) hospitals (rather than other physicians) have the ability to drive the volume of hospital-based physician services utilized; and 3) hospitals refer more patients to the hospital-based physicians, directly or indirectly, as a result of contracts with the physicians.

The reality of delivering hospital-based physician services reveals that these premises are not true. With regard to a hospital's ability to refer patients, the advisory report itself states that specialists obtain referrals from other physicians within the hospital environment. The hospital's role in ordering hospital-based physician services is tenuous. For example, emergency room physicians treat patients (and order additional necessary services) as individuals present at the emergency room; the patients are not referred to the emergency physicians.

We believe that incentives for overutilization do not exist because contracts with hospital-based physicians do not impact utilization. Consequently, the arrangements referenced in the report do not result in unnecessary costs to the Medicare program. "The following words of an AHA member hospital administrator illustrate our position:

Why, pray tell, should the Federal Government care about this issue when there is no direct relationship between patient flow and hospital-based physicians in connection with these contracts, nor indeed will the Federal Government be spending one nickel more whether the physicians agree to provide support to hospitals or whether they do not."
B. The advisory report offers no evidentiary basis for a potential fraud and abuse violation.

The advisory report offers no evidence of overutilization, or even suspected overutilization, in connection with hospital-based physician contracts. While the report states that the contracts give hospitals "a financial incentive to develop policies and practices which encourage greater utilization of the services of hospital-based physicians," it presents no basis for that conclusion and includes no examples of such potentially abusive practices.

AHA is aware of studies documenting higher utilization by referring physicians who own the equipment or facilities furnishing the referred services as compared to physicians who do not; however, AHA is not aware of similar studies on hospital-based physicians. Moreover, the report does not show any relationship between volume of services where such arrangements exist as compared to volume where other physician compensation arrangements exist, or where a hospital purchases its services outside the hospital (for example, from a free-standing laboratory or imaging facility).

The Office of Inspector General's authority to investigate financial relationships between hospitals and physicians is predicated upon overutilization of Medicare services resulting from a violation of the anti-kickback law. Absent evidence of potential overutilization, AHA believes that interference in the hospital/physician contracting relationship is inappropriate.

C. The advisory report fails to offer a hospital perspective on hospital-based physician contracts.

The advisory report indicates that the OIG's analysis is based upon contract provisions furnished by "several medical societies and anonymous parties." Such a one-sided perspective on business arrangements that allegedly violate the fraud and abuse laws does not substantiate the accusations made in the report. In November 1990, AHA initiated a meeting with OIG staff to discuss the issue of hospital-based physician contracts. At that meeting, AHA staff was informed that the OIG was developing a memorandum to HCFA and was assured that the hospital perspective would be considered, yet that perspective is not reflected in the report.
OIG staff has indicated to AHA that it has no basis for knowing to what extent the arrangements referenced in the memorandum actually exist within the hospital field. We understand that the medical societies and other parties who provided the OIG with examples of contractual provisions are neither willing to make the entire contracts public, nor willing to participate in a survey to determine the extent and nature of the contracts. Indeed, the advisory report itself states that disclosure of the terms of these agreements is "rare." One must question the motives of parties who are willing to provide only partial information on arrangements being characterized as potentially illegal.

In fact, hospitals generally need to accommodate hospital-based physicians, especially in rural areas, in order to keep physicians available and maintain necessary medical coverage for services. For example, some hospitals must guarantee physicians a minimum number of visits or revenue due to a limited pool of potential patients. In addition, physicians often desire percentage arrangements in order to avoid excessive expenses during "slow" months, and occasionally demand more in contract negotiations than a hospital would normally provide for hospital-based services. Physicians who do not obtain desired terms are free to, and frequently do, choose to operate freestanding facilities rather than be hospital-based. Respective parties' "bargaining positions" depend entirely on circumstances and locale and cannot be generalized.

The advisory report lists teaching physicians among the hospital-based specialists whose arrangements are potentially illegal. As a common practice in most teaching facilities, revenues generated for patient care services are paid into physician fee pools from which physicians are compensated and the medical centers receive funds. HCFA has addressed the issue of physician fee pools in the context of Medicare reimbursement at various times over the past 25 years. (See, for example, Intermediary Letters 372 and 70-2, HCFA Memorandum of October 1979 to Chicago Regional Medicare Director, HCFA Letter of February 1980 to Blue Cross Association, and HCFA Letter of May 1984 in response to questions concerning fee pools in the teaching setting.) In none of those instances was the suggestion of a fraud and abuse violation raised. To now question the legality of such arrangements would be to suggest that some of this country's premier health institutions have been engaged in criminal conduct for years.

Finally, the release of the advisory report is having an immediate and detrimental effect on hospital/physician relationships—which only hints at the disruption that would
result if further action is taken without consideration of the hospital position. Some physicians have already been instructed that "[u]se of the document should effectively serve to:counter hospital kickback demands during contract negotiations or renegotiations." (See Letter dated February 13, 1991 from American College of Radiology to members.) Even if research reveals evidence of potentially abusive arrangements between hospitals and hospital-based physicians, the expansive net cast by the OIG report would encompass countless contracts which have no effect on the Medicare program.

D. The government has addressed the issue of hospital revenues from hospital-based physicians' services extensively in the past and has never viewed these arrangements as potential fraud and abuse violations.

The report states that hospitals "recently" began to view hospital-based physicians as "potential new revenue sources." AHA does not understand the basis for this accusation, in light of the Medicare program's 25 year history of recognizing circumstances under which hospital-based physicians' patient care revenues may accrue to the benefit of hospitals. Since the inception of the Medicare program in 1966, hospitals have received revenues from their hospital-based physicians' services, and the Medicare program has been aware of and has interpreted the implications of such revenues. Yet the January 1991 OIG memorandum represents the first instance of such revenues being viewed as potential violations of the fraud and abuse statute (which was enacted in 1972 and amended with the anti-kickback provisions in 1977).

Government communications both before and after enactment of the anti-kickback provisions have addressed questions about hospital-based physician arrangements without ever questioning the legality of those arrangements under the fraud and abuse laws. In addition, HCFA has published both proposed and final regulations that clearly show the government was aware of hospital benefit due to hospital-based physician revenues, and, nevertheless, clearly reflect no fraud and abuse concerns.

For example, a 1984 letter from HCFA's Director of the Division of Audit and Payment Policy addressed an arrangement under which physicians pay to hospitals amounts unrelated to the hospital's operating or capital costs for their use of the hospital. (Letter dated November 14, 1984, Ref. No. FQA-581.) Another letter from HCFA's Bureau of Eligibility, Reimbursement and Coverage to the American College of Radiology discussed hospital initiatives to require radiology groups and other
physicians to return to the hospital some portion of their professional revenues. (Letter dated November 15, 1986.) In neither of these communications, which respond to open inquiries by providers and other interested individuals, does a government official raise fraud and abuse concerns.

Even more illustrative is the fact that HCFA regulation notices have discussed payments to hospitals by hospital-based physicians without considering whether these payments are illegal under the anti-kickback statute. The 1983 regulations entitled "Payment for Physician Services Furnished in Hospitals, Skilled Nursing Facilities and Comprehensive Outpatient Rehabilitation Facilities" reflect that eight years ago, the government was aware that some hospitals were charging hospital-based physicians for billing services, office expenses, and personnel.

In addition, HCFA was aware that the hospitals' charges to their hospital-based physicians were in some cases based on a percentage of the physicians' collections. This fact contradicts the 1991 OIG report's recommendation that "contracts between hospitals and hospital-based physicians should: ...be unrelated to physician income or billings." In the 1983 rules HCFA reiterates its earlier position, within the context of physician compensation allocation, that physicians and hospitals are "free to negotiate the kind of financial agreement, such as salary, fees or compensation based on a percentage of either gross or net charges, that best suits their circumstances." (Vol. 48, No. 42, Fed. Reg. at p. 8924-8925.) Indeed, the final regulations themselves recognize that payments may be returned by a hospital-based physician to the hospital. (See 42 C.F.R. Sec. 405.481(d)(2).)

The government more recently recognized that hospital-based physicians may return a portion of their patient care revenues to their hospitals in HCFA regulations proposed on February 7, 1989. In the preamble to the proposed rule, HCFA addresses both provider/physician agreements under which physicians return a portion of the realized charge revenue to providers and agreements under which providers retain a portion of revenues received. HCFA states the following in its discussion of allocation of compensation costs:

The revenues received by the provider in either of these situations might be utilized by the provider or related organization to defray the costs of medical educational activities, patient care, or nonpatient care related activities, including the costs of services furnished by physicians in these areas. (Vol. 54, No. 24, Fed. Reg. at p. 5955.)
AHA offers the foregoing historical examples to show that arrangements under which hospitals may benefit from hospital-based physician revenues are not a "new" idea, as the advisory report indicates. The government has addressed these arrangements in the Medicare reimbursement context numerous times in the past, without identifying fraud and abuse concerns. Neither Congress nor HCFA contemplated that financial arrangements whereby hospital-based physicians provide revenues to their affiliated hospitals constitute "kickback" schemes under the fraud and abuse laws.

E. Even if such arrangements were found to be potential violations of the fraud and abuse law, the OIG should publish notice of such a change and allow all providers an opportunity to comment.

Even if possible fraud and abuse violations could be validated, it would be appropriate for the OIG to adhere to certain administrative procedures before declaring such arrangements potentially illegal. The history of financial arrangements between hospitals and hospital-based physicians described above shows that the recommendations in the advisory report, if followed, would represent a drastic change in government policy. Moreover, any possible abuse resulting from such arrangements would be minimal, while the potential sanctions are severe. If HCFA is to view these long-standing arrangements in a new light, the appropriate action for the OIG would be to gather evidence of abuse, provide notice to the health care community, and allow an opportunity for providers (hospitals and physicians alike) to comment on these allegedly suspect arrangements.

Congress enacted the anti-kickback provisions of the fraud and abuse statute in 1977. In 1987, Congress directed the Office of the Inspector General to provide guidance in interpreting the statute as it relates to provider arrangements involving Medicare services. The Department of Health and Human Services responded to that directive by proposing "safe harbor" regulations, which have yet to be issued in final form. Hospital-based physician contracts, as a broad category of potentially violative arrangements, were not addressed in those proposed regulations. The OIG's use of a management advisory report to notify the health care community that an expansive group of agreements potentially violates the law raises questions of due process, equal protection, and proper administrative procedure. AHA believes that hospitals and other providers deserve at least as much opportunity, and the
proper forum, to comment on these arrangements as investor/referring physicians (and other providers) have been given in conjunction with the investment "safe harbors" proposed by the OIG.

Conclusion

In the March 5, 1991 meeting between the OIG and members of the health care community, you indicated a willingness to work openly and cooperatively with providers. AHA offers its assistance in resolving any questions you may have about agreements between hospitals and hospital-based physicians, and would like to arrange a meeting with you and your staff to follow up on this issue.

If you or members of your staff have any questions, please contact Cae-lynn DeMartino (202/638-1100) in our Washington office, or John Steiner (312/280-6510) in our Chicago office.

Sincerely yours,

Paul C. Rettig
Executive Vice-President

cc: Louis Sullivan, M.D.
Secretary, Department of Health and Human Services

Gail R. Wilensky, Ph.D.
Administrator, Health Care Financing Administration

Michael Mangano
Office of Inspector General
Mr. Paul C. Rettig  
Executive Vice-President  
American Hospital Association  
50 F Street, N.W.  
Washington, D.C. 20001

Dear Mr. Rettig:

Thank you for your letter of March 11, 1991, expressing various concerns of the American Hospital Association regarding the Office of Inspector General's management advisory report ("MAR") "Financial Arrangements Between Hospitals and Hospital-Based Physicians." We appreciate hearing from you, and we welcome this opportunity to respond to your concerns.

As you know, this MAR states our conclusion that some financial arrangements between hospitals and hospital-based physicians (such as radiologists, pathologists and anesthesiologists) may violate the criminal anti-kickback statute, 42 U.S.C. 1320a-7b(b), putting both the hospital and the physician in question at risk. The MAR focuses on those arrangements which require such physicians to pay more than fair market value for items or services provided by the hospitals, or which compensate physicians for less than the fair market value of goods and services that they provide to hospitals.

Chief among your concerns are the propositions that the arrangements in question (1) are not covered by the statute at all since hospitals do not "refer" patients, and (2) have not been shown to result in overutilization, and in fact cannot result in overutilization. You further state (3) that the MAR is inappropriate in view of numerous issuances by the Health Care Financing Administration ("HCFA") in this subject matter area, and (4) that the MAR should be the subject of notice and comment procedures of the Administrative Procedure Act.

To summarize our views on these propositions, we firmly believe that in these arrangements, hospitals are in a position to "refer" Medicare and Medicaid business within the meaning of the statute. Second, the statute does not require proof of overutilization because Congress made the judgement that the programs should not be subject to the risk of overutilization created by practices which violate the anti-kickback statute. Third, the pronouncements of HCFA relating to reimbursement...
issues are irrelevant to the issue presented because they do not purport to address fraud or abuse issues. The Secretary has delegated the responsibility for enforcing this statute to the Office of Inspector General ("OIG"), and we are serving one of our primary statutory functions in alerting HCPA and the public at large to potentially unlawful practices. Finally, the MAR does not attempt to establish a binding rule of law, which would require notice and comment procedures of the Administrative Procedure Act. The MAR addresses the application of a criminal statute to a particular course of conduct, a matter which is not appropriate for public notice and comment procedures.

As you know, the anti-kickback statute prohibits the knowing and willful solicitation or receipt of remuneration (directly or indirectly, overtly or covertly) in return for the referral of business paid for by Medicare or Medicaid. There can be no question that a hospital is subject to the anti-kickback statute when it solicits or receives remuneration in exchange for directing the flow of business generated at the hospital. Of course, it is the physicians practicing at the hospital (e.g., surgeons, neurologists, etc.) who order radiologist, anesthesiologist and pathologist services for particular patients. However, it is generally the hospital which chooses which radiologist, anesthesiologist or pathologist will perform those services.

The case law interpreting the anti-kickback statute makes it clear that the statute's proscriptions apply to those who can materially influence the flow of Medicare and Medicaid business. It is not necessary for a violator to actually order the service in question. The case of United States v. Bay State Ambulance and Hospital Rental Services, Inc., 874 F.2d 20 (1st Cir. 1989) involved an ambulance company which desired to renew an existing contract with a hospital. The ambulance company gave remuneration to one John Felci, a hospital employee. As one member of the hospital's "bid" committee which made its recommendation to the hospital's CEO, Felci subsequently voted to recommend approval of the contract to that ambulance company. The ambulance company and Felci were convicted of kickback violations. It is important to note that Felci neither generated the "order" to obtain a contract for an ambulance company, nor did he control the decision on the award of the contract. What the ambulance company did was pay Felci to exercise what influence he had over the flow of program business.

Similarly, hospitals are in a position to influence the flow of business to be performed by hospital-based physicians, since they typically can name who the recipient(s) (i.e., the radiologist, anesthesiologist or pathologist) of that business will be. If a hospital were to extract $5 from a radiologist for every x-ray performed at the hospital, there can be no doubt whatever that a kickback offense has been committed. Yet, in many of the
arrangements we have recently observed and described in detail in the MAR, practices similar in effect to this obvious kickback are occurring.

You also take issue with the MAR because you contend that contracts between hospitals and hospital-based physicians do not result in demonstrable overutilization of Medicare services. While preventing overutilization is unquestionably one of the purposes of the anti-kickback statute, your letter implies that proof of overutilization is an element of the offense. However, the anti-kickback statute does not require such proof to establish a violation. (See: Bay State, Id. at 32, n.21) One reason is that overutilization is notoriously hard to police and to prove. Another reason is that Congress was not only concerned with prohibiting arrangements which lead to demonstrable overutilization, but also with prohibiting arrangements which have the potential for causing overutilization. In other words, Congress made the assumption that health care providers would respond to financial incentives, and the potential for overutilization clearly exists whenever a party is being paid for the referral of program-related business. Our health care programs and their beneficiaries should not be subject to this increased risk of overutilization.

Again, by selecting the physician who will serve as the hospital's radiologist, pathologist, anesthesiologist, etc., the hospital is in the position of determining which physician will receive the referrals of the hospital's program-related business. The underlying concern expressed in the MAR is that some hospitals use this position of power to create situations which can cause overutilization. For example, if a hospital receives 50 percent of a hospital-based radiologist's billings over $250,000, the hospital has a strong incentive to do whatever it can to increase the use of those services in the hospital. The hospital can, by subtle or not-so-subtle means, cause that to happen. For instance, under the guise of "defensive medicine," the hospital could encourage the increased use of diagnostic x-rays.

In addition, where such an arrangement is initially imposed on a radiologist, the arrangement could potentially cause a radiologist to attempt to increase the amount of services he/she renders in order to make up the lost income. Radiologists could accomplish this through normal consultation with the other physicians practicing in the hospital, e.g., suggesting or encouraging additional radiological services.

With regard to your discussion of HCFA's regulations and other issuances, enforcement of the anti-kickback statute is primarily the responsibility of OIG. The HCFA issuances do not purport to address fraud and abuse issues in general or kickback concerns in specific. On the other hand, it is OIG's obligation to respond
to potential kickback violations as they come to our attention. It appears that changing conditions in the health care industry have led to the recent proliferation of contracts between hospitals and hospital-based physicians which cause kickback concerns. We would be remiss if we failed to address a potential legal violation which is potentially harmful to our health care programs and their beneficiaries.

With regard to your concerns that the MAR does not include the hospital industry's perspective and should have been published with opportunity for notice and comment, we must point out that the MAR is not a regulation interpreting the anti-kickback statute, like the "safe harbor" regulations. Rather, the MAR is designed to furnish notice to HCFA and the public regarding a significant problem area under the anti-kickback statute. It is, of course, one of OIG's central duties under the Inspector General Act of 1978, 5 U.S.C. App 3, to notify the Department and the public about possible violations of criminal law. The point of this document was not to present various perspectives in an attempt to gain consensus, but rather, to exercise our law enforcement functions to call attention to an abuse which we believe has the potential for causing harm. An alternate way of giving the provider community notice would be simply to initiate prosecutions or exclusion actions. We are quite sure that the provider community would prefer to have notice of our views first in the form of a MAR or a Fraud Alert.

Again, the touchstone for analysis in the MAR is that the concept of fair market value should govern remuneration which flows from hospital-based physicians to the hospital. It is hard to understand why this is a radical or onerous concept, particularly if it is necessary to effectuate the intent of Congress as expressed in a criminal statute.

I hope this letter adequately explains our response to your concerns with regard to the MAR. If you wish to discuss this matter further, please contact D. McCarty Thornton, Chief Counsel to the Inspector General at (202) 619-0135.

Sincerely yours,

R.P. Kusserow

Richard P. Kusserow
Inspector General

cc: Gail R. Wilensky, Ph.D.
Administrator,
Health Care Financing Administration
September 6, 1991

RE: Financial Arrangements Between Hospitals and Hospital-Based Physicians 09-59-00330

Dear Mr. Kusserow

Thank you for providing us with a draft of the OIG management advisory report (MAR) on financial arrangements between hospitals and hospital-based physicians (HBPs), and for the opportunity to share our comments with you.

At the July 12, 1991 meeting between your office and health care field representatives, AHA and other hospital groups raised several fundamental issues concerning relationships between hospitals and hospital-based physicians. We are disappointed that the revised MAR, while addressing some minor points, does not contain any substantive changes reflecting those concerns. Hospitals and the OIG essentially view hospital/HBP relationships differently: where the OIG sees a potential fraud and abuse scheme, hospitals see an agreement to enter into a mutually dependent relationship.

First and foremost, we believe that the underlying premise in the MAR is misguided. As AHA and others indicated at the July 12 meeting, the notion that hospitals direct the flow of business in a manner which violates the fraud and abuse statute reflects a misunderstanding of the traditional hospital/hospital-based physician relationship. Most HBPs request and receive exclusive contracts to provide services at a hospital; hospitals must provide the contracts to obtain health care for their patients. The underpinnings of the MAR, which must be accepted if a kickback analysis is to apply, are that hospitals enter these agreements and thereby "name who will be the recipient of the flow of business" (in effect, refer patients to the physicians) in exchange for any payments to the hospital from revenues generated by virtue of the contract, and that the volume of "business" varies depending on the nature of the financial relationship. We flatly reject these premises.
Second, the revised MAR fails to fully acknowledge that the relationship between hospitals and hospital-based physicians is mutually dependent, and that, more often than not, hospitals find it necessary to accommodate physicians' financial requests in order to secure needed physician services for their patients. (The MAR states that hospitals are "somewhat dependent" on HBPs, but goes on to discuss how hospitals have reduced compensation or obtained additional payments from the physicians. Yet the MAR fails to discuss the other side of the equation, namely, the increased demands many physicians are placing on hospitals in light of changing physician payment schemes and economic conditions.) The MAR assumes that hospitals hold the bargaining power and that HBPs, dependent upon the hospitals, must accede to hospital demands in order to ensure a viable practice. This perception does not reflect the reality of furnishing health care services.

Third, with one exception, the examples of agreements listed in the MAR are identical to those in the original draft. As discussed at the July 12 meeting, assessment of these provisions is simply impossible without complete information about the agreements. Nowhere does the MAR identify what services the hospitals provided to physicians in exchange for the payments indicated. Rather, the MAR categorically states that the payments are "far in excess of the fair market value of the services provided," without presenting any evidence of this. (AHA repeatedly has requested the opportunity to review the contracts, with identifying information deleted, but the OIG repeatedly has refused.) In light of the OIG's acknowledgement that review of the entire contract is necessary and that percentage amounts may approximate fair market value, presenting these provisions in isolation is, at the very least, misleading.

Finally, the revised MAR, like the original draft, indicates that the remuneration in the arrangements listed "gives the hospitals a financial incentive to develop policies and practices which encourage greater utilization" of services. In response to questions about this statement, OIG staff stated that they know of no examples or incidents in which such hospital policies exist. Neither does AHA.

AHA appreciates the opportunity to provide these comments and the OIG's willingness to attach our March 11 letter and this letter as appendices to the final MAR. If you or members of your staff have any questions or wish to discuss our comments further, please contact Gaelynn DeMartino in our Washington office (202/638-1100) or John Steiner in our Chicago office (312/280-6510).
February 22, 1991

Richard P. Kusserow
Inspector General
Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

RE: Management Advisory Report

Dear Mr. Kusserow:

The College of American Pathologists strongly supports and endorses your January 31, 1991, Management Advisory Report relating to hospital arrangements with hospital-based physicians (HBP). The report highlights a problem of growing significance under the Medicare program. A growing number of hospitals have improperly retained the portion of DRG payments which covers the Part A services of HBP in return for granting the hospital "franchise" to the HBP. Other hospitals are charging HBP for supplies and services that are hospital operating costs covered under Part A and paid through the DRG rate. The wide distribution of the Management Advisory Report, combined with enforcement actions against those hospitals which require HBP to provide free or deeply discounted Part A services, should help curb this abuse of the Medicare program.

Pathologist directors of hospital laboratories spend a significant amount of time and effort in providing services that are needed to assure that quality laboratory services are available to patients. Clinical pathology services of general benefit to patients (e.g., quality control, assuring laboratory compliance with federal and state standards) are to be paid through Part A. Increasingly, a growing number of hospitals have eliminated all or most of the compensation paid to the pathologists for these important Part A services. Some hospitals extract remuneration from the pathologist in the form of free or deeply discounted clinical pathology services. The hospital demands this remuneration in exchange for the pathologist's "franchise" to provide and bill for anatomic pathology services for hospital patients. The College has long argued that these arrangements are a potential violation of the fraud and abuse provision, 42 USC §1320a-7b(b). The College strongly supports OIG's commitment to scrutinize and attack such improper arrangements.

In addition to the fraud and abuse concerns, there are a number of public policy issues posed by these arrangements. First, pathologists' ability to assure that quality laboratory services are available to patients is severely compromised. Services that are essential to the appropriate diagnosis and treatment of patients are placed at severe risk because adequate resources to support their provision are withheld.

Second, hospitals which refuse to pay for clinical pathology services profit unduly under the DRG prospective payment system. As explicitly recognized in the Management Advisory Report, a portion of Medicare's DRG payments to the hospital are for clinical pathology services. Since Medicare is
paying for clinical pathology, a hospital that refuses to pay pathologists a fair amount for these services plainly is extracting an inappropriate profit at the expense of the pathologists.

Third, the arrangements discussed in the Management Advisory Report effectively unbundle services that are covered by DRG payments. The hospital forces pathologists inappropriately to incur costs that, under the Medicare program and common practice, are the responsibility of the hospital. The College believes that such hospital arrangements amount to the unbundling of services that are reimbursed by the DRG program in violation of 42 CFR §412.50.

In order to eliminate the abuses associated with hospitals forcing pathologists to provide free or deeply discounted clinical pathology services or to pay for "support services" already paid through Part A, the College recommends that the OIG prosecute hospitals that persist in maintaining abusive arrangements. Pathologists and the College have vigorously opposed these abusive arrangements for years. Prior to the issuance of the Management Advisory Report, some pathologists were forced to accept one-sided contracts from hospitals. The College strongly believes that the OIG should not prosecute those HBPs who are forced by the hospital to enter into these arrangements.

Once again, the College endorses your January 31, 1991, Management Advisory Report. Wide dissemination of the report, together with enforcement actions against hospitals that continue to engage in the proscribed behavior, should help eliminate the abusive arrangements.

Sincerely,

[Signature]
Loyd R. Wagner, MD
President

LRW/mps

cc: Gail Wilensky, PhD

LETTERS/04/03.00
The attached management advisory report alerts you to the existence of arrangements between some hospitals and hospital-based physicians which potentially may be inappropriate and illegal under the Medicare and Medicaid anti-kickback statutes, section 1128B(b) of the Social Security Act. We are continuing to pursue illegal arrangements where referring physicians receive kickbacks from hospitals.

We recommend that you notify intermediaries about this problem and suggest that they refer identified cases to the Office of Inspector General. We suggest that the following language be used in that notification:

"Please notify hospitals about potential legal liability under the anti-kickback statute when they enter into agreements with physicians not based on the fair market value of the goods and services exchanged. The Office of Inspector General has identified situations that may be illegal when hospitals contract with hospital-based physicians.

To avoid potential legal liability, all contracts between hospitals and hospital-based physicians should comply with all the safe harbor provisions that may apply under the contract between the parties. Of particular importance are the safe harbors that protect payments for personal services and management contracts and for services of bona fide employees, 42 CFR §§ 1001.952(d) and (i); 56 Fed. Reg. 35985, 35987. It is noted that in some of the safe harbor provisions, we require that payments must be consistent with 'fair market value.' The regulation explicitly provides that safe harbor protection is not available where any part of the
payment takes into account the volume or value of referrals or business otherwise generated by either party. This restriction is necessary because such payments directly violate the statute."

We appreciate the Health Care Financing Administration's comments on the earlier version of this report and the cooperation of your staff in finalizing this report. We hope that you will find this report and its recommendations acceptable.

In accordance with the requirements of the departmental conflict resolution process, please submit within 60 days your plan to implement the recommendations or explain why it is not possible to do so. If you have any questions, please contact me or have your staff contact Penny Thompson at PTS 646-3138.