

MEDICARE SELF-REFERRAL LAWS

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES
ONE HUNDRED SIXTH CONGRESS
FIRST SESSION

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MAY 13, 1999
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Serial 106-54
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MEDICARE SELF-REFERRAL LAWS

THURSDAY, MAY 13, 1999

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 1:02 p.m., in room 1100, Longworth House Office Building, Hon. William Thomas (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE

CONTACT: (202) 225-3943

May 4, 1999

No. HL-5

Thomas Announces Hearing on Medicare "Self-Referral" Laws

Congressman Bill Thomas (R-CA), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on the Health Care Financing Administration's (HCFA) implementation of the Medicare self-referral laws and its impact on the health care marketplace. The hearing will take place on Thursday, May 13, 1999, in the main committee hearing room, 1100 Longworth House Office Building, beginning at 1:00 p.m.

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

"Self-referral" is the term used to describe the situation where a physician or other provider refers a patient to a medical facility in which the physician has a financial interest. In the Omnibus Budget Reconciliation Act of 1989 (OBRA 89, P.L. 101-508), the Congress passed what became known as "Stark I" after the main sponsor, Rep. Pete Stark (D-CA). Under that law, in general, if a physician has a financial relationship with a clinical laboratory, that physician cannot make a referral to the laboratory for the furnishing of services for which Medicare pays. The Omnibus Budget Reconciliation Act of 1993 (OBRA 93, P.L. 103-66) extended the law to apply to referrals for 10 "designated health services" in addition to clinical laboratory services. This law became known as "Stark II." Five years after passage of Stark II, on January 9, 1998, HCFA issued a *proposed rule* to implement it. Today, after an additional 17 months, HCFA seems no closer to issuing a *final rule* on the Federal statute.

The guiding principle for the self-referral laws was to prevent physicians from inappropriately referring patients based on the potential for financial gain. Yet, the health care delivery system has changed profoundly since passage of the first self-referral laws. Since 1989, the health care system has rapidly moved away from the traditional fee-for-service way of delivering medical care. Today, the health care system has moved towards a more coordinated, integrated approach.

The Balanced Budget Act of 1995 (BBA95) included several amendments to the self-referral laws. The two major changes were the repeal of the prohibitions based on compensation arrangements and the revision of the list of facilities subject to the ban. BBA95 was vetoed by President Clinton on December 6, 1995.

In announcing the hearing, Chairman Thomas stated: "Physicians and hospitals are subject to a bewildering array of overlapping State and Federal statutes. Many of the steps physicians and hospitals take to integrate their practices are subject to a multitude of laws, including self-referral law, anti-kickback law, Federal tax law regulating the conduct of tax-exempt organizations, State referral bans, corporate practice of medicine prohibition and the Federal False Claims Act. The fact

that it has taken the HCFA more than 6 years to put out a final rule is further evidence that these laws are in need of an overhaul.”

FOCUS OF THE HEARING:

The hearing will focus on implementation of existing self-referral statutes and on areas for reform. The Subcommittee will also consider proposals put forward by the Administration and Members of Congress.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Any person or organization wishing to submit a written statement for the printed record of the hearing should submit six (6) single-spaced copies of their statement, along with an IBM compatible 3.5-inch diskette in WordPerfect 5.1 format, with their name, address, and hearing date noted on a label, by the close of business, Thursday, May 27, 1997, to A.L. Singleton, Chief of Staff, Committee on Ways and Means, U.S. House of Representatives, 1102 Longworth House Office Building, Washington, D.C. 20515. If those filing written statements wish to have their statements distributed to the press and interested public at the hearing, they may deliver 200 additional copies for this purpose to the Subcommittee on Health office, room 1136 Longworth House Office Building, at least one hour before the hearing begins.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All statements and any accompanying exhibits for printing must be submitted on an IBM compatible 3.5-inch diskette in WordPerfect 5.1 format, typed in single space and may not exceed a total of 10 pages including attachments. Witnesses are advised that the Committee will rely on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. A witness appearing at a public hearing, or submitting a statement for the record of a public hearing, or submitting written comments in response to a published request for comments by the Committee, must include on his statement or submission a list of all clients, persons, or organizations on whose behalf the witness appears.

4. A supplemental sheet must accompany each statement listing the name, company, address, telephone and fax numbers where the witness or the designated representative may be reached. This supplemental sheet will not be included in the printed record.

The above restrictions and limitations apply only to material being submitted for printing. Statements and exhibits or supplementary material submitted solely for distribution to the Members, the press and the public during the course of a public hearing may be submitted in other forms.

Note: All Committee advisories and news releases are available on the World Wide Web at [HTTP://WWW.HOUSE.GOV/WAYS_MEANS/](http://WWW.HOUSE.GOV/WAYS_MEANS/).

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202-225-1721 or 202-226-3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman THOMAS [presiding]. The Subcommittee will please come to order.

Today, we revisit the issue of the Federal Government's physician self-referral laws. Few laws have been as vexing for physicians and hospitals, and I dare say, apparently for bureaucrats as well. The cost of complying with this daunting law is considerable and has an impact on seniors' ability to gain access to coordinated systems of medical care. And, after all, that is what we are supposed to be focusing on, the ability of seniors to get care.

Self-referral is the term used to describe the situation where a physician refers a patient to a medical facility in which the physician has a financial interest.

The first legislative measures aimed at the potential problem of self-referrals were passed as part of the 1989 Budget Reconciliation Act. That statute applied only to physicians and clinical laboratories. In 1993, the self-referral ban was extended to 10 other designated health services, including, for example, hospital services, outpatient drugs, durable medical equipment, and home health services.

Five years after passage of the second self-referral law, HCFA finally published a proposed rule in 1998. Today, after yet another year, HCFA seems no closer to issuing a final rule on self-referral law.

I have been told that a final rule is a week or so away, or a year or so away, or, fill in the blank.

The guiding principle for the self-referral laws was to prevent physicians from inappropriately referring patients based on the potential for financial gain. These laws were meant to provide a bright-line test, and yet we are further from clarity in this area of the law than probably any other area of health policy.

At a time when physicians and hospitals are subject to heightened scrutiny by Federal investigators, they have a right to know, I think, what the law is. One legal writer paraphrased Sir Thomas Moore when talking about the self-referral laws, he said, "It is unjust to bind the people by a set of laws that are too many to be read and too obscure to be understood."

To further complicate matters, physicians and hospitals are subject to a bewildering array of overlapping State and Federal statutes. Many of the steps physicians and hospitals take to integrate their practices are subject to Federal self-referral as well as a multitude of other Federal and State laws, including the Federal anti-kickback law, Federal False Claims Act, Federal tax-exempt law, and the State self-referral bans.

Representatives from the Health Care Financing Administration and the Office of Inspector General will testify today that the self-referral laws are a weapon in the Federal Government's arsenal against fraud and abuse. And yet not a single case has been prosecuted under the self-referral laws. The Federal Government has used non-compliance with these laws as a threat, but it has never once prosecuted a case.

And this tells me two things. First, I mean, the law is not really an effective weapon in the fight against fraud and abuse; otherwise

the Inspector General and the Justice Department would have made enforcement of the self-referral laws a priority as they have with the False Claims Act and the Federal anti-kickback statute.

Second, since Federal investigators use the self-referral law to threaten physicians and hospitals, even though the status of the law is unclear, that seems to me a tacit admission that compliance is virtually impossible and that it only serves as a means to bully providers.

While today we will be considering the various options of reforming self-referral law, let me remind everyone that over the past several years this Subcommittee has built a pretty good record on fighting Medicare fraud and abuse. In both the Health Insurance Portability and Accountability Act of 1996, HIPAA, and in the Balanced Budget Act of 1997, we have stiffened penalties, beefed up the resources of both the Inspector General and HCFA.

Today, we have enacted 65 statutory provisions to preserve the integrity of the Medicare Trust Funds, and I would ask unanimous permission to put in the 65 concrete steps that we have used to fight waste, fraud, and abuse.

[The information follows:]

65 Concrete Steps to Fight Health Care, Waste, Fraud, and Abuse

SUMMARY OF HIPAA OF 1996 AND BBA OF 1997 ANTI-FRAUD

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)

1. Provides significant new funding to combat waste, fraud, and abuse: Over \$5 billion through 2003 appropriated to fight fraud and abuse through the new Health Care Fraud and Abuse Control and the Medicare Integrity Programs.

2. Increases the number of investigators on the street by 31 percent: New programs have resulted in increasing the number of full-time federal investigators fighting health care fraud and abuse from 1,187 to 1,553 in the past two years.

3. Expands Medicare and Medicaid fraud and abuse penalties: Makes Medicare and Medicaid program-related fraud penalties applicable to other federal health care programs, such as the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS).

4. Increases civil penalties for fraud and abuse: Increases civil monetary penalties for health care fraud and abuse from \$2,000 to \$10,000 for each item and service subject to a violation.

5. New penalties for illegally retaining ownership or control in a health care entity: Imposes new civil monetary penalties on individuals excluded from Medicare or State health care programs who maintain ownership or control interest in entities participating in Medicare or Medicaid.

6. New penalties for improper billing: Imposes new civil monetary penalties against persons who submit bills for more expensive services than provided or for services that are not medically necessary.

7. New penalties for improper inducement: Imposes new civil monetary penalties against persons offering improper financial incentives to induce beneficiaries to obtain services from a particular provider or supplier.

8. New penalties for false certification of home health services: Imposes new civil monetary penalties of the greater of \$5,000 or three times the amount incorrectly paid for false certification by a physician of the need for home health services.

9. Adds new criminal penalties for fraud and abuse: New federal criminal penalties for fraud and abuse violations specifically related to both the private market and public health care programs are added to Title 18 of the United States Code.

10. New penalties for health care theft or embezzlement: Provides for fines and/or imprisonment of up to 10 years for theft or embezzlement relating to health care programs.

11. New penalties for false statements: Provides for fines and/or imprisonment of up to 5 years for false statements relating to health care matters.

12. New penalties for obstruction of justice: Provides for fines and/or imprisonment of up to 5 years for obstruction of criminal health care investigations.

13. New penalties for money laundering: Specifically makes it a crime to launder money that comes from the commission of a federal health care offense.

14. Injunctive relief in health care offenses: Authorizes injunctive relief and freezing of assets in cases involving federal health care offenses.

15. New authority to issue subpoenas: Authorizes the issuance and enforcement of subpoenas of records and testimony by the Attorney General for investigation of health care offenses.

16. New forfeiture authority: Authorizes the forfeiture of property related to the commission of a health care offense, with amounts recovered to be deposited into the hospital insurance trust fund.

17. New penalties for wrongful disclosure of confidential health information: Provides that obtaining, disclosing, or using individually identifiable health information is punishable by fines of up to \$50,000 and/or imprisonment of up to one year, with additional fines of up to \$250,000 and up to 10 years imprisonment for the intent to sell or transfer such information for commercial advantage, personal gain, or malicious harm.

18. New mandatory exclusion from participation in Medicare and State health programs for felonies: Adds new mandatory exclusions from Medicare and Medicaid for felony convictions related to health care fraud or controlled substances.

19. New permissive exclusion authority for misdemeanors: Authorizes new discretionary exclusions from Medicare and Medicaid for misdemeanor convictions related to health care fraud or controlled substances.

20. New mandatory minimum exclusionary periods: Establishes a 3-year minimum exclusionary period for criminal misdemeanors related to health care fraud or controlled substances or conviction of obstruction of a health care investigation, and a minimum exclusionary period due to license revocation or suspension commensurate with the length of such revocation or suspension.

21. New permissive exclusion of individuals with ownership or control interest in sanctioned entities: Adds new permissive exclusion from Medicare and Medicaid for individuals who have an ownership or control interest, or who are managing employees, of a sanctioned entity.

22. New sanctions against practitioners for failure to comply with quality requirements: Establishes a one-year minimum exclusionary period for practitioners who fail to meet Medicare or Medicaid quality standards or who fail to complete peer review corrective action plans.

23. Establishes the new Fraud and Abuse Control Program: This program coordinates federal, state, and local law enforcement efforts against fraud and abuse in federal and private health care programs.

24. Establishes the new Medicare Integrity Program: This program authorizes the Department of Health and Human Services (HHS) to enter into contracts with private entities with expertise in rooting out waste, fraud, and abuse to perform audits and reviews of provider payments.

25. Establishes the new Beneficiary Incentive Program: This program provides incentives for beneficiaries to ferret out waste, fraud and abuse by authorizing the Secretary of HHS to share monetary recoveries with beneficiaries reporting health care fraud and abuse.

26. New data for law enforcement: Establishes the Health Integrity and Protection Data Bank to report final adverse actions against health care providers.

27. Provides guidance to providers seeking to comply with the law: Requires the Secretary of HHS to issue binding advisory opinions regarding whether a proposed transaction would violate the anti-kickback rules.

28. Provides additional funds for investigation and re-certification: Authorizes the Health Care Financing Administration to collect fees from physicians to cover the costs of investigation and issuance of program identifiers.

The Balanced Budget Act of 1997 (BBA)

29. Three strikes and you are out: Requires that providers convicted of three program-related offenses be excluded permanently from Medicare and other federal health programs, and that providers convicted of two program-related offenses be excluded from federal health programs for at least 10 years.

30. Excludes convicted felons from Medicare: Authorizes the Secretary to refuse to enter into provider agreements with persons or entities convicted of prior felonies.

31. Excludes practitioners and entities excluded from Medicare from an health care programs: Expands the scope of Medicare exclusions to include exclusion from all other federal and state health care programs, other than the Federal Employees Health Benefit Program

32. Clearly identifies Medicare providers: Requires providers to provide the Secretary with their Social Security Number or Employer Identification Number as a condition of participation in the Medicare program.

33. Prevents transfer of illicit businesses to family members: Authorizes the Secretary to exclude entities from the Medicare program in which ownership or control is transferred to immediate family members in anticipation of, or following, a conviction or exclusion action.

34. Further increases civil penalties: Imposes new civil monetary penalties of up to \$50,000 per act for providers who violate anti-kickback rules.

35. Penalizes providers who do businesses with other providers excluded from Medicare: Imposes new civil monetary penalties on providers who hire or contract with persons or entities the provider "knows or should know" have been excluded from the Medicare program.

36. New sanctions for providers not reporting to data bank: Imposes new civil monetary penalties for failure to report adverse fraud actions to the Health Integrity and Protection Data Bank.

37. \$50,000 surety bonds for certain Medicare providers and suppliers: Requires home health agencies, durable medical equipment suppliers, CORFs, and rehabilitation agencies to post surety bonds of at least \$50,000 and to disclose ownership and control information.

38. Expansion of \$50,000 surety bond requirement: Provides authority to the Secretary to extend surety bond requirements to other Part A and Part B providers.

39. Itemized bills for services: Requires providers to furnish beneficiaries with itemized bills for Medicare services upon request.

40. Sanctions for failure to provide itemized bills: Imposes civil monetary penalties of up to \$100 for failure of providers to respond to beneficiaries' request for itemized bills.

41. Toll-free hotline for beneficiaries to fight waste, fraud and abuse: Requires the Inspector General to establish a toll-free hotline for Medicare beneficiaries to report fraud and billing irregularities.

42. Disclosure to beneficiaries of provider financial interest: Requires hospitals to disclose to beneficiaries requiring post-acute care any provider in which the hospital has a financial interest.

43. Maintenance and disclosure of information on post-hospital home health agencies and other entities: Requires hospitals that have a financial interest in a home health agency or other entity to which they refer beneficiaries to disclose to the Secretary and the public the nature of the financial interest, the number of individuals discharged from the hospital requiring home health services, and the percentage of those individuals who receive home health care from the related provider.

44. Disclosure of ownership information for durable medical equipment suppliers: Prohibits the Secretary of HHS from issuing or renewing provider numbers for DME suppliers unless the supplier provides the Secretary on a continuing basis with full and complete information about the identity of each person with an ownership or control interest in the supplier or in any subcontractor in which the supplier has an ownership interest.

45. New authority to prevent Medicare overpayment: Provides the Secretary with new authority to reduce Medicare reimbursement where the current payment amount is grossly excessive and inherently unreasonable.

46. New sanctions for durable medical equipment suppliers who engage in coercive or abusive practices: Authorizes the Secretary of HHS to establish sanctions, including program exclusions, for DME suppliers who engage in sales practices designed to coerce beneficiaries to purchase "upgraded" durable medical equipment.

47. Better direction for providers: Requires the Secretary to issue advisory opinions regarding the physician self-referral rules.

48. Home health payment changes to reduce waste and abuse: Requires the Secretary to move from "cost-based" reimbursement to a prospective payment systems for home health agencies by October 1, 1999.

49. Better data on home health visits to prevent waste and abuse: Requires that home health claims contain the identification number for the prescribing physician and information on length of service (as measured in 15 minute increments).

50. Ends payment advances for home health agencies: Eliminates periodic interim payments to home health agencies.

51. Better definition of skilled nursing and home health benefits: Includes statutory definition of "part-time" and "intermittent" skilled nursing and home health aide services.

52. Prevents abuse of home health benefits: Requires the Secretary to conduct a study to clarify when a beneficiary is "homebound."

53. Prevents home health agency payment abuses: Requires home health agencies to submit claims on the basis of the location where a service is actually furnished, and not where the home health agency billing office is located.

54. Prevents unnecessary use of home health agency services: Authorizes the Secretary to establish national guidelines to prevent unnecessary billing for home health services.

55. Prevents unnecessary use of home health agency services: Clarifies that a person could not qualify for Medicare's home health benefit on the basis of their simply needing a nurse to draw a blood sample.

56. Skilled nursing payment changes to reduce waste and abuse: Requires the Secretary to replace "cost-based" reimbursement with a prospective payment system for skilled nursing facility services by July 1, 1998.

57. Prevents unnecessary ordering of equipment and supplies: Eliminates Medicare payments for unnecessary durable medical equipment and supplies by requiring nursing homes to use consistent coding and directly bill for these services.

58. Requires additional diagnostic information for better accountability: Includes non-physician practitioners in the requirement to provide diagnostic codes when ordering items or services to be furnished by another health entity.

59. Better data on skilled nursing visits to prevent waste and abuse: Requires physicians who visit patients in nursing homes to include the facility's identification number on their claim to make detection of inappropriate visits easier to track.

60. Annual audit to protect against fraud in the Medicare+Choice program: Requires the Secretary of HHS to conduct an annual audit of the financial records of at least one-third of Medicare+Choice organizations offering Medicare+Choice plans and for the General Accounting Office to evaluate the results of such audits.

61. New right to inspect, audit, and evaluate the quality of services provided by Medicare+Choice contractors: Provides authority to the Secretary of HHS to inspect and evaluate the quality, appropriateness, and timeliness of services provided under a Medicare+Choice plan and the solvency and capacity of such plan.

62. Expansion of sanctions to protect beneficiaries enrolled in Medicare+Choice plans: Makes the same sanctions applicable to physicians and entities improperly billing beneficiaries under traditional fee-for-service Medicare applicable to physicians and entities improperly billing beneficiaries enrolled in Medicare+Choice plans.

63. New sanctions for Medicare+Choice Plans to protect beneficiaries: Authorizes new intermediate sanctions, including civil monetary penalties, for Medicare+Choice organizations that fail to provide medically necessary items or services, impose excess premiums, deny or discourage enrollment by eligible individuals, furnishes false information to beneficiaries or the Secretary of HHS, employs or contracts with excluded providers, or fails to comply with Medicare+Choice consumer protections and balance billing limitations.

64. Additional penalties for Medicare+Choice organizations failing to meet contract terms: Imposes additional civil monetary penalties for Medicare+Choice organizations that substantially fail to fulfill their contract with the Medicare program, carry out the contract in a manner inconsistent with the efficient administration of the Medicare program, or no longer meet conditions of participation in the Medicare+Choice program.

65. New exclusionary authority for Medicare+Choice organizations: Authorizes the Secretary to terminate contracts with Medicare+Choice organizations in accordance with formal investigation and compliance procedures.

Chairman THOMAS. I would also like to remind everyone that a number of other people have called for simplification of these statutes, including, I might add, my friend and distinguished Ranking Member, Mr. Stark. In July 1998, he issued a press release and a letter to the Institute of Medicine asking for input on, "fundamentally simpler ways to prevent abuse in referrals." And I would ask unanimous consent to place that in the record as well.

[The information follows:]

Stark Seeks Ideas for Improvement and Simplification of Referral Laws

Citing complexity of the laws and regulations governing physician referrals to services in which the physician has an ownership or compensation arrangement,

Rep. Pete Stark (D-CA) is calling for ideas on how to stop referral abuses while simplifying the rules on doctors.

“Numerous studies have shown that when doctors have an ownership or compensation arrangement with an ancillary service, they tend to order more services and more expensive services,” said Stark. “It is an abuse of the Medicare Trust Fund, the taxpayer, and the patient who is subjected to questionable and unnecessary tests.”

“Stopping these abuses—which include the abuse of hospitals which have an ownership interest in downstream services—is complex,” said Stark. “I am asking the health community for ideas on how we can improve and simplify the current laws without opening Medicare to abuse.”

Stark released a letter he sent to the Institute of Medicine outlining possible ideas to improve the referral rules.

“The Institute will probably not be able to do work in this area without appropriate funding,” said Stark. “But I hope that the ideas I’ve raised in the letter will encourage others to offer suggestions directly to me on ways to improve this area of Medicare law without weakening our efforts against abuse of the program.”

[The letter follows:]

June 8, 1998

Dr. Kenneth I. Shine, M.D.
President, Institute of Medicine
Washington, D.C.

Dear Dr. Shine:

In the mid-80s, the Institute of Medicine helped start the national debate on the ethical issue of physician referral of patients to services from which the physician could profit. Nearly fifteen years later, the regulation of referrals remains a difficult issue, and new issues involving referrals by hospitals and other institutions to post-acute care services have developed.

A series of laws have been passed that tried to address the physician referral conflict of interest. Five years after the last of these laws was passed, the Health Care Financing Administration has finally issued proposed rules to implement those laws. The regulations are controversial, with many individual doctors and groups complaining that they will interfere with the delivery of efficient and ethical medical care, increase costs, and micro-manage doctors’ offices. Yet we know from past studies and certain on-going investigations that the problem of abusive referral is a real problem—one that abuses the public as both patient and as taxpayer. There is also some evidence that areas where the law was not applied have been subject to abuse and that ethical issues also arise in hospital referrals. In the meantime, staff at HCFA have indicated that to process the comments they are receiving on the regulation will require at least another year, and possibly more, before final regulations can be issued. In short, the controversy drags on and many providers who seek to do the right thing find themselves caught in uncertainty.

Therefore, I request that the Institute of Medicine convene a work group, hopefully late this summer, on the issue of how best to address referral problems and whether there may be a way to reach consensus on fundamentally simpler ways to prevent abuse in referrals. Specifically, would it be possible to:

- eliminate a number of the designated health services in the physician referral laws, and replace them with a system where a doctor may refer for the service, but through the use of actual acquisition cost or other payment changes, remove excessive financial incentives to over-refer and over-test? A related question is whether physician practice expense payments are sufficient to make profit margins on in-office services unnecessary?

- allow a physician to have any ownership or compensation arrangement the physician desires in exchange for accepting a “normative practices screen.” Under this approach, a physician could have, for example, an ownership interest in a lab partnership, but if he or she does not exceed the norms of testing (adjusted by specialty, severity of patient, etc.) of those with no ownership or compensation relationship, then there would be no problem. If the norm were exceeded, however, there would be potential recovery with penalty by the public insurers (Medicare/Medicaid), if practices were found to be without clinical indication.

- other ways to simplify the current Physician Referral laws without abandoning their ability to stop the abuses documented in the late 1980's and early 1990's?
- ways to address the problem of referral by institutions?

Thank you for your consideration of this request. I would like to work with you on how such a Working Group could include the key physician organizations and develop a consensus for improvement of the regulations or amendments to the law.

Sincerely,

PETE STARK
Member of Congress

Chairman THOMAS. But with all due respect, we may be asking the wrong question. The law says that a physician who owns an interest in a clinical laboratory cannot refer a patient to the clinical laboratory and then bill Medicare. But, if that same physician purchases that same lab equipment and, instead, puts it in his or her own office, that same physician can bill Medicare all he or she wants without self-referral problems.

Asking about referral patterns and asking the Federal regulators to micro-manage physicians practices may be pointless or impossible, when the real issue is not referrals but the appropriateness of the medical care provided.

Members of the Subcommittee can agree, I hope, that the overarching goal is to provide to our seniors the proper medical care in the proper setting. The healthcare delivery system today is very different from when the first self-referral laws were considered now a decade ago.

For example, the emergence of utilization review and other coordinated-care models in both managed care and fee-for-service provided, are, I believe, a more appropriate method of checking any potential abuses with regard to self-referrals.

And prior to recognizing the panel, I will turn the mike over to the gentleman from California, Mr. Stark.

Mr. STARK. Thank you, Mr. Chairman. I am not sure I ever would have chosen to have my name associated with this law. I would much rather be known for extending health insurance to the uninsured. But I don't have that much choice.

I would note that the impetus for this law started with antifraud officials in the Reagan Administration and then was continued by those in the Bush Administration. It was a bipartisan effort to fight waste, fraud and over-utilization in the Medicare system. And it was proven that those problems existed and still exist today.

In spite of the problems with the law, it's been a success. As the OIG will testify, we have prevented billions of dollars worth of business deals which would have ended up abusing patients through over-testing and unnecessary services. And in this sense, the law has been self-enforcing.

In other ways, the complexity of the law has been an embarrassment. The law purports to be simple: Don't create temptation to make a medical judgment based on the money you get. That ought to be the golden rule, like the AMA code of ethics against referral.

But it is the medical shysters, and the exemptions designed to allow people to end-run the law and make money in special situations that have made the law complicated. Every time we have attempted to define the law's parameters, we have just created an op-

portunity for unscrupulous attorneys to create a loophole based on our exemptions. And the beat goes on.

As we try and make the law more definitive, this creates ways to get around it. And now there are even new issues, where you have hospitals buying referrals.

I don't know what that does for medical care. I will tell you this, it steals the taxpayers' money.

We have a court case that was outlined in the healthcare fact sheet we got this morning of a doctor who was brought to a town by a hospital. Let's assume there is more than one hospital. I don't know. He was given a \$20,000-a-month guarantee—that is \$240,000 a year—\$15,000 in moving expenses, \$10,000 in a signing bonus, and 25,000 bucks a year in free office rent.

Now that all ends up being paid for by the taxpayers through Medicare. And I don't know that if anybody tries to tell me with a straight face that that hospital just did this out of the goodness of their heart, not anticipating that they were going to get referrals from this doctor, then I think you have got to believe in the tooth fairy and the boiling seas.

There are thousands more examples. If this money had come from a pharmaceutical company, we would say, "Oh my goodness, they are giving this doc all this money to use their pharmaceuticals," which does happen, I might add. The oncology profession has quadrupled their fees through the high markups of drugs which they think only they can administer. And Medicare is paying the bill, and I know no way that the patients are advantaged by the extra profits these doctors are making on the pharmaceuticals. And I can assure you the taxpayers are being disadvantaged.

Now, I suspect that a doctor in jail would have the same meritorious effect that one of our colleagues in jail would have, and that we would all clean up our act and they will as well. We are seeing it with Columbia. My hope is that Columbia executives will rot in jail for a while, and then we won't have to do so much legislating because other hospital executives will get the message that if you steal from the Government, you do hard time.

So this is basically a bunch of specialists, and mostly their attorneys, dreaming up ways to get money to which they are not entitled. And it is difficult to write laws to keep abreast of people who have creative genius in stealing money from the Government.

We have, in the tax field, as we all know, a new loophole every year created by some creative genius who is figuring out a way to get around the law. And it is why the Tax Code is this thick. Not because we decided to make it complicated. It is because of the innate greediness of those who don't want to pay their fair share.

So it is, and we will hear from the Government about the number of pending fraud cases and the fact that we ought to give HCFA some more money to go after these people and round them up. Perhaps if they found that they would go to jail if they steal or harm our patients by over-utilization of services, or, on the managed-care side, under-utilization, that the profession would self-police.

But I do not think that the answer is just every time it is inconvenient for some physician to not get all the money to which they

feel they are entitled, to send their lawyers here to bleed all over the place and say the law is complicated.

I just say, don't take the money. You make enough money as a physician just getting the fee to which you are entitled. And when you start to branch out—if you want to go into another business—quit billing Medicare for your medical practice and go into the other business. It's a free country.

But I do not see that we ought to encourage under any circumstances the bundling of services or the increase in the provision of services. And I agree with the Chair, we shouldn't allow a lot of physicians to buy the equipment and operate it in their office if it isn't good medical practice.

That is beyond the ability of this Committee to determine, but my sympathies lie largely with the Inspector General's Office and the bureaucrats who are overworked and underpaid in trying to keep ahead of a group who use their ill-gotten gains to hire fancy attorneys and accountants to get around the laws.

So we will hear today from the bleeding hearts about they aren't making enough money off Uncle Sam, and I look forward with great interest to their protestations.

[The opening statement of Hon. Jim Ramstad follows:]

Statement of Hon. Jim Ramstad, a Representative in Congress from the State of Minnesota

Mr. Chairman, thank you for calling this important hearing on the Medicare self-referral laws.

As elected government officials, we try to solve problems that are brought to us by our constituents. Many times we are able to help, and that is our job. Some other times, however, we may overshoot our mark and actually enact legislation that unintentionally causes a series of other problems. It is then our responsibility to revisit our efforts and undo as much of the damage as we can.

Such is the case before us today. While the self-referral laws were intended to remove potential conflicts of interest from physician decision making, we are seeing that they are actually raising health care costs, interfering in the practice of medicine and disrupting the development of new, innovative approaches for delivering health care services to America's seniors.

In addition, it is my understanding that hospitals and physicians are subject to a myriad of other over-lapping federal and state laws that are also aimed at rooting out fraud, abuse and kickbacks within the health care system. This prompts one to consider whether these laws, with all their unintended and problematic consequences, are appropriate and necessary anyway.

The famous health care creed is "first do no harm." If our policies are doing more harm than good, it is imperative that we as health care policy makers find ways to fix them.

Thank you again, Mr. Chairman, for calling this important hearing. I look forward to hearing from today's witnesses on ways we can provide relief from any unnecessary government rules and regulations without compromising the integrity of the Medicare system.

Chairman THOMAS. A public service announcement. This doesn't necessarily apply to the panel I am about to introduce. From the Health Care Financing Administration, we have gotten Kathleen Buto, who has been a long-time professional in this area, a civil service servant who has been through a number of administrations, and we look forward to her testimony.

We also have Mr. McCarty Thornton, who is back with us again from the Office of Counsel to the Inspector General and has been involved, directly with the question of medical integrity.

So, any written testimony will be a part of the record, and you can address this in any way you see fit. Start with Ms. Buto, and then go to Mr. Thornton.

STATEMENT OF KATHLEEN A. BUTO, DEPUTY DIRECTOR, CENTER FOR HEALTH PLANS AND PROVIDERS, HEALTH CARE FINANCING ADMINISTRATION

Ms. BUTO. Thank you very much, Chairman Thomas, Congressman Stark and distinguished Subcommittee Members. Thank you for inviting us to discuss limits on physician self-referral.

These limits are based on numerous studies, as others have already pointed out, showing that physicians made far more referrals when they had a financial interest in a testing or treatment facility. They were enacted in law with leadership from this Subcommittee to prevent increased costs and potential harm to beneficiaries from unnecessary treatments.

However, important exceptions to these limits are needed to protect beneficiaries' access to care and to take into account the many detailed financial arrangements in today's healthcare delivery system.

Adequately defining these exceptions and determining whether new exceptions are warranted has proven to be a daunting task. We have spent a great deal of time meeting and talking with industry associations, individual providers, and their attorneys in an effort to deal fairly and proactively with the many issues subject to interpretation. And we are continuing to do so.

We have taken steps in our proposed rules to clarify the law and create appropriate flexibility. One of the most important steps establishes that compensation arrangements are generally permissible as long as they meet fair-market value standards, further a legitimate business purpose, and are not tied to the volume or value of physician referrals.

This exception goes a long way in simplifying the policy under the law. Our proposed rules also significantly limit the information that physicians are required to report for financial relations related to the 10 new designated services added to the law in 1993.

We are not asking physicians to submit information regarding these financial relationships, as we did for clinical lab services. Instead, physicians need only keep on file the kind of information that they would normally maintain to meet IRS, SEC, and other Medicare and Medicaid rules. This would be sufficient to demonstrate compliance in the event of a complaint investigation or a spot audit.

No other type of enforcement actions will be taken until outstanding questions are resolved and a final rule is published.

We continue to evaluate the 12,800 comments we have received on the proposed rules and are open to ideas to further simplify the regulations and the law itself in ways that do not undermine its intent. We are considering a wide range of clarifications and other suggestions to determine whether they would meet the statutory

requirement that exceptions not create a risk of program or patient abuse.

But we must take care to uphold the law's intent and prevent arrangements that would increase cost to taxpayers and subject beneficiaries to possible harm from unnecessary tests and procedures.

I am pleased that we were able to issue, pretty much in record time, an interim final rule with comment to implement the advisory opinion provisions in the Balanced Budget Act and that we have already begun to process a number of requests for advisory opinions. Some 20 have been received, and we have issued two opinions. Currently we are looking at about eight that remain in the workload.

We greatly appreciate the good-faith efforts made by physicians to comply with the law and to work with us to address the issues that it raises. We look forward to continuing to work with these groups and with the Subcommittee to resolve remaining issues.

I thank you for holding this hearing, and I am happy to answer your questions.

[The prepared statement follows:]

Statement of Kathleen A. Buto, Deputy Director, Center for Health Plans and Providers, Health Care Financing Administration

Chairman Thomas, Congressman Stark, distinguished Subcommittee Members, thank you for inviting us to discuss limits on physician self-referrals for Medicare and Medicaid beneficiaries. These limits were enacted into law, with leadership from this Subcommittee, to prevent increased program costs and potential harm to beneficiaries from unnecessary tests and treatments. They are based on numerous studies showing that physicians made far more referrals when they had a financial interest in a testing or treatment facility. Some studies also found higher prices and lower quality with self-referrals. The American Medical Association has declared self-referral unethical in most instances.

Self-referral limits play an important role in bolstering our successful efforts against fraud, waste, and abuse. However, we would all agree that we must take great care in translating this important legislation into policy. Important exceptions are needed to protect beneficiaries' access to care, and we must take into account the many detailed financial arrangements in today's health care delivery system. We would also all agree that physicians and other health care entities have by and large made a good faith effort to comply with the law without final regulations to clarify many issues.

We have taken steps in our proposed regulations to clarify the law and create appropriate flexibility. One of the most important provisions establishes that referrals to an entity with which a physician has a compensation arrangement are generally permissible as long as the compensation is at "fair market value," furthers a legitimate business purpose, and is not tied to the volume or value of physician referrals. This exception goes a long way in simplifying the policy under the law.

We are evaluating the 12,800 comments we received on these proposed regulations, and are open to ideas to further simplify the regulations and the law itself in ways that do not undermine its intent. But we must take care to uphold its intent and prevent arrangements that would increase costs to taxpayers and subject beneficiaries to possible harm from unnecessary tests and procedures.

BACKGROUND

Concern about the ethical risks inherent in physician self-referral dates back at least to a 1986 Institute of Medicine study. A 1989 HHS Inspector General study documented that physicians who owned or invested in independent clinical laboratories referred Medicare patients for 45 percent more laboratory services than did physicians who did not have such financial interests. In 1991, the American Medical Association Council on Ethical and Judicial Affairs concluded that physicians should not refer patients to a health care facility outside their office at which they do not directly provide services and in which they have a financial interest. And in 1992, the American Medical Association House of Delegates voted to declare self-referral unethical in most instances.

Limits on self-referral were first enacted into law as part of the Omnibus Budget Reconciliation Act of 1989. The law took effect January 1, 1992. It bars referral of Medicare patients to clinical laboratories by physicians who have, or whose family members have, a financial interest in those laboratories. The Omnibus Reconciliation Act of 1993 expanded the scope of the ban on self-referral to 10 additional designated health services, including:

- physical therapy;
- occupational therapy;
- radiology services;
- radiation therapy services and supplies;
- durable medical equipment and supplies;
- parenteral and enteral nutrients, equipment and supplies;
- orthotics, prosthetics, and prosthetic devices and supplies;
- home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services.

The 1993 law also expanded and clarified exceptions, and applied the referral limits to Medicaid. Provisions related to the new designated health services were effective January 1, 1995.

The self-referral law works differently from the law against kickbacks, which was enacted as part of the Social Security Amendments of 1972. Enforcement of the anti-kickback law requires proof of “knowing” and “willful” illegal remuneration, such as bribes or rebates, for patient referrals, and it can result in criminal sanctions. Self-referral laws, on the other hand, are generally self-enforcing. The simple existence of an improper financial relationship is subject to loss of Medicare payment or a civil fine. This creates a powerful incentive to proactively comply with the law through due diligence efforts to avoid financial arrangements that may unethically lead to substantial increases in use of services. The law’s preventive nature makes a highly effective contribution to our increasingly successful efforts to protect Medicare and Medicaid program integrity.

EXCEPTIONS

As mentioned above, the law includes many important exceptions. It also gives the Health and Human Services Secretary authority to create new exceptions through regulations as long as they do not create a risk of program or patient abuse. One of the most important exceptions is for most services physicians provide in their own offices or through their group practices. There are more than a dozen additional exceptions, including ones for managed care plans, rural providers, and isolated financial transactions.

Adequately defining these exceptions and determining whether new exceptions are warranted has proven to be a daunting task. We have spent a great deal of time meeting and talking with industry associations, individual providers, and their attorneys in efforts to deal fairly and proactively with the many issues subject to interpretation. We are continuing these efforts.

REGULATIONS

We published proposed regulations for the clinical laboratories referral ban on March 11, 1992, and a final rule with comment period on August 14, 1995. These regulations have been in effect since September 13, 1995.

We published proposed regulations for the other designated services on January 9, 1998. These proposed regulations were generally well received. The American Hospital Association has said they make it easier for physicians and hospitals to work together in integrated systems. The proposed regulations include several clarifications and create new exceptions, providing flexibility for physicians while not compromising the intent of the law. They:

- create a “fair market value” exception to make clear that compensation arrangements are generally permissible as long as they are at fair market value, further a legitimate business purpose and are not tied to the volume or value of physician referrals. Physicians must simply put in writing the terms of their arrangements, the items or services the physician will provide, and the time period involved. The agreement must be commercially reasonable and not based on the volume or value or referrals made, and must comply with the anti-kickback statute;
- state that token gifts, such as free parking at a hospital, are allowed as long as the value is \$50 or less with an annual maximum of \$300 and there is no direct link to patient referrals.
- clarify that physicians can provide crutches to patients as long as the physicians do not profit;

- allow for discounts as long as they are passed along to the patient or insurer with no benefit to the physician;
- clarify that a financial transaction qualifies for the “isolated” exception only if another financial relationship does not occur within six months; and
- clarify an exception for recruitment payments made by hospitals to encourage physicians to relocate to the hospital’s geographic area, and invite comments on how that geographic area should be defined.

The Omnibus Reconciliation Act of 1997 instructed the Health Care Financing Administration to issue, upon request, advisory opinions as to whether particular arrangements would violate self-referral policy. We published a final regulation implementing this provision January 9, 1998. To date, we have issued two such advisory opinions and are working on several others.

REPORTING AND ENFORCEMENT

Our proposed regulations also significantly limit the information that physicians are required to report for financial relations related to the 10 new designated services. Also, we are not asking physicians to submit information regarding these financial relationships as we did for clinical laboratory services. Instead, physicians need only keep on file the kind of information that they would normally maintain to meet Internal Revenue Service, Securities Exchange Commission, and other Medicare and Medicaid rules. This would be sufficient to demonstrate compliance in the event of a complaint investigation or spot audit. No other type of enforcement actions will be taken until outstanding questions are resolved and a final rule is published.

CONCLUSION

While the general response to our proposed regulations was positive, many outstanding issues remain. We extended the public comment period by two months in order to provide more time for interested parties to respond. The public comment period closed on March 10, 1998. We are reviewing the 12,800 comments we received and continuing to evaluate how we should address the many concerns that have been raised in final regulations. Many comments involve issues related to physicians in multi-specialty group practices and to a requirement in the law for direct supervision by physicians of services provided in physician offices. We are considering a wide range of clarifications and other suggestions to determine whether they can be addressed through regulations and would meet the statutory requirement that exceptions not create a risk of program or patient abuse.

We greatly appreciate the good faith efforts made by physicians to comply with the law and to work with us to address the many issues raised by this complex legislation. We look forward to continuing to work with physician groups and this Subcommittee to resolve remaining issues. I thank you for holding this hearing, and I am happy to answer your questions.

Chairman THOMAS. Thank you very much, Ms. Buto. Mr. Thornton.

STATEMENT OF D. McCARTY THORNTON, CHIEF COUNSEL TO THE INSPECTOR GENERAL, OFFICE OF THE INSPECTOR GENERAL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. THORNTON. Thank you, Mr. Chairman. In 1989, OIG conducted the very first study on physician ownership from healthcare entities to which they make referrals. We found that patients of referring physicians who own or invest in clinical labs receive 45 percent more of such services than all Medicare patients in general.

Nine more studies have appeared in the professional literature, including four in the *New England Journal of Medicine* and three in the *Journal of the American Medical Association*. They support and expand on our original 1989 findings, often finding significant

increases in utilization where there is a financial reward for doing so.

The studies have been subject to criticism, in that most of them do not measure other factors, such as whether the additional referrals are medically necessary. However, it should be noted that some of the studies do address such issues.

For example, the 1992 study in the *New England Journal* found that self-referring physicians ordered medically unnecessary MRI scans about 36 percent of the time more often than physicians making referrals where they had no financial arrangement.

While these studies may not be conclusive, taken as a whole, they strongly support, we believe, the proposition that many physicians respond to financial rewards for ordering ancillaries.

Now, before the enactment of section 1877, which I will refer to as “the section,” the only statute available to handle the self-referral issue was the anti-kickback statute, a broadly-worded statute which requires proof of “knowingly and willfully” paying anything of value to induce the referral of Federal program business. It was and is very unrealistic to rely on the anti-kickback statute as a means to control self-referral.

The difficulty in proving knowing and willful behavior cannot be underestimated, as it requires proof of the mental thoughts and motivations of particular human beings.

The serious limitations of the anti-kickback statute can be illustrated by our case against the Hanlester Network, where we had, we thought, very strong evidence of intent to pay for referrals. For example, only physicians in a position to refer were solicited for investments in the labs. And the numbers of shares offered to each physician were related to the expected amount of referrals from each doctor.

The labs harassed investors if referrals were lower than expected and even expelled some investors who did not refer enough. However, when our case reached the Ninth Circuit, they disagreed and vacated our case.

By contrast, the section is a condition of Medicare and Medicaid payment with no mental element. I note that the Hanlester joint ventures that I just spoke of were formed before the section went into effect. Under the section, section 1877, none of the complicated evidence I described regarding intent would be needed.

Under the section, billings for clinical lab services ordered by physician-investors were as of then not payable. Very simple.

While the section contains areas of ambiguity, it has established certain core principles for Medicare and Medicaid providers which we believe have been a great benefit to the programs. Most of these principles are relatively clear and unambiguous. For example, under the section, one cannot bill the programs for a designated health service from a joint venture owned by a disparate group of physician-investors.

Similarly, one cannot enter a personal-services contract with a referring physician for more than fair-market value. Nor can the compensation vary according to the volume or value of referrals.

These core principles have been largely effective. For example, while questionable joint ventures were proliferating in the late eighties and early nineties, they are much less common today.

Much of the credit for this development must be given to the section.

Another positive feature of the section is that it is, to a large degree, self-enforcing. Healthcare companies being purchased, merged, or refinanced, which has certainly been a predominant trend in this decade, are legally required to undergo a due-diligence examination, including an examination of current contracts with physicians and ancillary providers.

To sum up, the research on physician behavior indicates that financial incentives do increase the rate at which physicians order items and services, although, obviously, this does not apply to every physician.

It may now be appropriate to revisit the section, to assess whether its objectives could be achieved with simpler provisions. It would also be appropriate to determine if there are any significant loopholes.

Our recommendation is that whatever changes are considered, the section should continue to function as a bulwark against inappropriate incentives to physicians.

Thank you, sir.

[The prepared statement follows:]

Statement of D. McCarty Thornton, Chief Counsel to the Inspector General, Office of the Inspector General, U.S. Department of Health and Human Services

Good morning Mr. Chairman and members of the Subcommittee. I am D. McCarty Thornton, Chief Counsel to the Inspector General for the Office of Inspector General (OIG) at the Department of Health and Human Services. We appreciate the opportunity today to address the law concerning physician self referral, i.e, situations where physicians obtain financial incentives which may increase their ordering of items and services paid by Federal health care programs.

Much has been learned since 1989 about the issue of self-referral, when it became a matter of attention by this committee and the Congress, and by our office. We suspected then-that physician referral of patients to health care entities like clinical laboratories with which they have a financial interest creates a situation where the financial reward can insinuate itself into patient care, and possibly lead to inappropriate use of medical services. Now we are convinced that self referral has consequences in the real world. Our own law enforcement experience, and the findings of ten studies published in the professional literature, indicate that many (but certainly not all) physicians respond to financial incentives by increasing their ordering of medical items and services. If unaddressed, this situation could result in unnecessarily higher costs to patients, insurers, and the Medicare and Medicaid programs, and can prevent patients from receiving the best quality of care. It could also expose patients to unnecessary medical procedures.

In response to this issue, in 1989 the Congress enacted Section 1877 of the Social Security Act, and in 1993 enacted significant amendments thereto. This statute, also known as the "Stark Law," established certain core concepts regarding self referral which have proved effective in preventing many abusive arrangements. For example, one cannot "joint venture" a clinical laboratory with a group of physicians whose only relationship to the laboratory is to refer laboratory work and share investment profits. Because this law is a condition of payment under the Medicare program, it is largely self enforcing, and it is accomplishing much of its basic purpose.

Section 1877 has been subject to considerable criticism, resulting from ambiguity in how the law applies to certain particular types of business arrangements among physicians and other health providers. In addition, we are well aware that the structure of medical practice is becoming increasingly complex, as physicians and other medical care entities try to deliver patient care through managed care and other integrated systems. We can well appreciate how complicated is the task of those physicians, medical service providers, and members of Congress who wish to reduce the potentially harmful incentives of physician ownership, while encouraging the development of modern medical care systems. Yet the statute and the proposed regulations of the Health Care Financing Administration do contain many exceptions in-

tended to accommodate these concerns. While it may be time to revisit the statute to see if its objectives can be achieved in simpler, more understandable ways, we would caution against changes which would allow arrangements to flourish which give financial rewards to physicians who may inappropriately increase their ordering of items and services separately paid by Medicare and Medicaid.

CONCERNS ABOUT SELF-REFERRAL

The overall concern about self-referral is that when a physician sits down with a Medicare or Medicaid beneficiary, that the medical decisions made should be on the basis of what is in the best medical interest of that beneficiary. That is what the beneficiaries have a right to expect, and do expect. They want to be assured that financial interests are not affecting physician decisions about their medical care.

There are other related concerns, including: over-utilization, patient choice, and competition. The over-utilization issue relates to the items and services ordered for patients which would not be ordered if the physician had not been rewarded financially. Such over-utilization becomes a direct cost to the health care system, including Medicare and Medicaid. The patient choice issue concern relates to the steering of patients to a less convenient, lower quality, or more expensive provider, just because that provider is rewarding the doctor. And lastly, where referrals are controlled by those sharing profits, the medical marketplace suffers since new competitors can no longer win the business with superior quality, service or price.

INSPECTOR GENERAL'S REPORT

In the late 1980's, a trend developed where various kinds of ancillary providers, such as laboratories, MRI facilities, physical therapy clinics and others, would syndicate or joint venture themselves with physicians in a position to refer business, often in exchange for only a nominal investment. In June 1988, the Congress mandated that the OIG conduct a study on physician ownership and compensation from health care entities to which they make referrals. We published the report in May 1989. (*Financial Arrangements Between Physicians and Health Care Businesses*, OAI-12-88-01410.)

Our methodology included surveys of health care providers and analysis of claims information. First, we conducted two surveys of health care providers to determine the prevalence of physician financial involvement with other health care entities and the nature of such arrangements. One survey was sent to physicians; the other to independent clinical laboratories, independent physiological laboratories, and durable medical equipment manufacturers. We used claims information from HCFA's Part B Medicare Annual Data files for 1987 to assess utilization patterns for patients of physician-owners identified through our survey of health care businesses. (Physicians with designated specialty codes indicating radiology or pathology were dropped from the analysis of clinical and physiological labs since these physicians are not in a position to refer patients.) Finally, we interviewed State officials, industry representatives, health care experts, and a sub-sample of provider respondents to our survey.

We found that 12 percent of physicians were owners of entities to which they referred patients and eight percent had compensation arrangements with such entities. Twenty-five percent of independent clinical laboratories, 27 percent of independent physiological laboratories, and eight percent of durable medical equipment companies were owned at least in part by physicians who made referrals of items or services to them.

We found that patients of referring physicians who own or invest in clinical laboratories received 45 percent more such services than all Medicare patients in general, regardless of place of service. We estimated that this increased utilization of services provided by independent clinical laboratories by patients of physician-owners cost the Medicare program \$28 million in 1987. The projected costs of the increased utilization of these services by patients of physician-owners would be \$103 million in 1995, if there were no change in utilization patterns.

The study also found that patients of physicians known to be owners or investors of independent physiological laboratories use 13 percent more physiological testing services than all Medicare patients in general. We found no difference in number of durable medical equipment services. However, our study did not examine cost differences for either physiological tests or durable medical equipment, nor did we examine differences in the kinds of medical equipment provided to patients of physician-owners and non-owners. In other words, we did not study the question of whether owners ordered more expensive tests or equipment compared to non-owners.

ADDITIONAL STUDIES OF THE EFFECT OF SELF-REFERRAL

Since our initial study in 1989, nine more major studies have appeared in the professional literature, including four in the *New England Journal of Medicine* and three in the *Journal of the American Medical Association*. They support and expand upon our original 1989 findings. For example, a quite comprehensive study published in September 1991 by the Florida Health Care Cost Containment Board found that 93 percent of diagnostic imaging facilities in Florida were joint ventures with physicians. It also found that compared to non-doctor affiliated facilities of the same type, doctor-affiliated *clinical labs, diagnostic imaging facilities, and physical therapy facilities*: performed more procedures on a per-patient basis; charged higher prices; and were not located in rural or urban under served areas.

Additional studies have found increased utilization for a variety of services when the physicians have ownership interests in the entities to which they refer their patients, including *clinical laboratory services, radiology services* (particularly for high costs services such as *MRI and CT scans*), *physical therapy and rehabilitation, radiation therapy* and *psychiatric evaluation*. I have attached a synopsis of the various studies on this subject.

The studies have been subject to criticism in that most of them do not eliminate or measure other factors besides financial rewards which could influence a physician to use more of an ancillary item or service. Some physicians have sicker patient populations than others. Some physicians are more familiar with and thus may be higher utilizers of certain ancillaries than other physicians. Most of the studies do not attempt to assess medical necessity of the ancillary items or services delivered. However, some of the studies address such issues. For example, a 1992 study in the *New England Journal of Medicine* by Swedlow, et al., assessed the medical appropriateness of MRI scans. The study found that self-referring physicians ordered medically inappropriate MRI scans about 36 percent more often than physicians making referrals where they had no financial arrangement.

A 1990 nationwide study by Hillman, et al. in the *New England Journal of Medicine* compared the frequency and costs of the use of diagnostic imaging for four clinical presentations (acute upper respiratory symptoms, pregnancy, low back pain, or (in men) difficulty in urinating) as performed by physicians who used imaging equipment in their offices (self-referring) and as ordered by physicians who always referred patients to radiologists (radiologist-referring). The authors concluded that self-referring physicians used imaging examinations at least four times more often than radiologist-referring physicians and the charges were usually higher when the imaging was done by the self-referring physicians. Significantly, the authors reported that these differences could not be attributed to differences in the mix of patients, the specialties of the physicians or the complexity of the imaging examinations performed.

Despite their shortcomings, these studies taken as a whole strongly support the proposition that many physicians respond to financial rewards. We are not aware of any body of professional literature to the contrary, nor is it likely the *New England Journal of Medicine* and *Journal of the American Medical Association* would publish a total of seven studies on this topic if the studies lacked probity. Moreover, our law enforcement experience tells us that some physicians respond inappropriately to financial rewards. Not infrequently, when we find cases of abnormally high and questionable utilization, there is a financial reward at work.

FEDERAL LEGISLATION PROHIBITING MEDICARE PAYMENT FOR SELF-REFERRED SERVICES

Before the enactment of section 1877 of the Social Security Act, the only statute available to handle the self-referral issue was the Medicare and Medicaid anti-kickback statute (42 U.S.C. § 1320a7b(b)). This is a broadly-worded, criminal statute which requires proof of "knowingly and willfully" paying anything of value in exchange for the referral of Federal program business. The statute is also a basis for exclusion from Medicare and Medicaid.

As of 1989, the anti-kickback statute had never been applied to the area of physician investment in ancillary facilities where the physician was sending patients. In April 1989, we issued a Fraud Alert on Joint Venture Arrangements, which specified those types of investment interests between physicians and the providers of ancillary medical facilities which we considered to be clearly violative of the anti-kickback law. This Fraud Alert was intended as a warning to those engaging in abusive self-referral schemes, and we sent a copy to each and every provider of health care services to the Medicare program.

Nevertheless, it was and is very unrealistic to rely on the anti-kickback statute as a means to control self referral. First, as noted above, in a kickback case the bur-

den of proof on the government is to establish a mental element—“knowingly and willfully” intending to induce referrals. The difficulty in proving such a subjective notion cannot be underestimated, as it requires proof of the mental thoughts and motivations of particular human beings. This difficulty is compounded by the fact that the Federal Courts of Appeal have adopted at least three distinctly different interpretations of the term “willfully” as used in the anti-kickback statute. [Contrast *Hanlester Network v. Shalala*, 51 F.3d 1390 (9th Cir. 1995), *U.S. v. Jain*, 93 F.3d 436 (8th Cir. 1996), *cert denied*, 520 U.S. 1273, 117 S.Ct. 2452, 138 L.Ed.2d 210 (1997), and *U.S. v. Starks*, 157 F.3d 833 (11th Cir. 1998).]

The serious limitations of the anti-kickback statute can be illustrated by our case against the Hanlester Network, which set up three clinical laboratory companies in Southern California which were largely shell labs—most of the actual testing was performed at a large SmithKline lab. Only physicians in a position to refer were solicited for investment, shares were offered in nominal total amounts, and the numbers of shares offered to each physician were related to the expected amount of referrals from them. Physicians were barred from investing in any other labs, and were required to sell back their shares if they ceased being in a position to refer. Very high rates of return (up to 300–400 percent) were discussed if the physicians would follow through with referrals. The laboratories monitored referrals from all the investors, harassed them if referrals were lower than expected, and even expelled some investors who did not refer enough. We believed that we had sufficient proof of a kickback violation, but the Ninth Circuit disagreed. See *Hanlester Network, supra*. The court held that we had to show that the defendants specifically knew about the anti-kickback statute and specifically intended to violate that statute.

The Hanlester joint ventures were formed before Section 1877 went into effect in 1992. Under Section 1877, none of the above evidence regarding intent would be needed to handle the situation; billings for such clinical laboratory services ordered by physician investors were then not payable, period.

With the realization that the anti kickback statute would not handle the self-referral issue, and based in part on the results of our 1989 study, in November, 1989, Congress passed Section 1877 of the Social Security Act (“Stark I”). Section 1877 prohibited Medicare payment for clinical laboratory services where the physician (or immediate family member) who orders the service has a “financial relationship” with the laboratory. The statute defined the term “financial relationship” to include both ownership or investment interests in an entity (which may be through equity, debt or other means) and compensation arrangements with an entity (which are defined as arrangements involving any remuneration between a physician and an entity). The statute contained a number of detailed exceptions to the definition of financial relationship to provide for legitimate arrangements between physicians and laboratories.

In the Omnibus Budget Reconciliation Act of 1993 (OBRA '93), Congress expanded the scope of section 1877 to include 10 additional services—so-called “designated health services.” (These amendments are often referred to as “Stark II.”) In addition to clinical laboratory services, the statute now covers:

- physical therapy services;
- occupational therapy services;
- radiology services, including MRIs, CAT scans and ultrasound services;
- radiation therapy services and supplies;
- durable medical equipment and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services.

In addition, the statute was expanded from applying to just Medicare to apply to Medicaid as well. OBRA '93 also added new exceptions and revised the existing exceptions so that legitimate arrangements between entities and physicians can be accommodated.

Significantly, Section 1877 is a condition of Medicare and Medicaid payment; in other words, by law a provider must be in compliance in order to be entitled to be paid by the programs. Those not in compliance with Section 1877 may not bill the programs, and if they have, they are liable to return program payments. For this basic remedy, the government need not prove that the defendant “knowingly and willfully” intended to induce referrals, as it must under the anti-kickback statute.

While Section 1877 contains areas of ambiguity, the statute has established certain core principles for Medicare and Medicaid providers which have been of great benefit to these programs and their beneficiaries. Most of these principles are relatively clear and unambiguous. For example, under Section 1877, one cannot bill the

programs for clinical laboratory services from a joint venture owned by a disparate group of physician investors. The same simple rule applies to the other designated health services, and there are some reasonable exceptions, such as for physician ownership in whole hospitals. Similarly, one cannot enter a personal services contract with a referring physician for more than fair market value, nor can the compensation vary according to the volume or value of referrals.

The importance of these core principles should not be underestimated. They have made it much more difficult to structure business relationships in the health care industry to financially reward physicians for referrals. For example, while questionable joint ventures were proliferating in the late 1980's and early 1990's, they are much less common today. Much of the credit for this development must be given to Section 1877.

Another positive feature of Section 1877 is that it is to a large degree self-enforcing. As noted above, the primary remedy for Section 1877 is denial of payment, with no mental element of the offense. This simple approach has led to self enforcement through the actions of accountants and attorneys performing due diligence examinations in connection with health care corporate restructuring and financing. Health care companies being purchased, merged or refinanced, which has certainly been a predominant trend in the 1990's, are legally required to undergo a "due diligence" examination, including an examination of current contracts with physicians and ancillary providers. We are informed that compliance with Section 1877, being a payment requirement, is commonly one of the subjects carefully studied by those performing due diligence.

On the other hand, it is comparatively rare that OIG finds evidence of violations sufficient to meet the strict legal standard in the civil monetary penalty authorities in Section 1877, which require the government to establish that an offense was committed with the following states of mind: that the improper claim was filed with actual knowledge, recklessness, or conscious disregard of the law. All these tests require proof of a mental element. Where evidence sufficient to meet this standard is uncovered, the case usually involves offenses other than Section 1877, and the cases are handled by the Department of Justice under the False Claims Act (which has the identical mental element to prove an offense).

CONCLUSION

The research on physician behavior indicates that financial incentives do increase the rate at which physicians order items and services. Obviously, this conclusion does not apply to every physician. But as a general matter, section 1877 does address an issue which has a real potential cost to the Medicare and Medicaid programs and their beneficiaries and could adversely affect quality of care. It may be appropriate to revisit the statute to assess whether its objectives could be achieved with any simpler provisions, but it would also be appropriate to determine if there are any significant loopholes. Our recommendation is that whatever changes are considered, the statute should continue to function as a bulwark against inappropriate financial incentives for physicians to order ancillary items and services. We are ready to assist the subcommittee in evaluating proposed changes to the statute.

Attachment

SELF-REFERRAL STUDIES

A. Financial Arrangements Between Physicians and Health Care Businesses: Office of Inspector General—OAI-12-88-01410 (May 1989)

In 1989, the Office of Inspector General (OIG) issued a study on physician ownership and compensation from entities to which they make referrals. The study found that patients of referring physicians who own or invest in independent *clinical laboratories* received 45% more clinical laboratory services than all Medicare patients in general, regardless of place of service. OIG also concluded that patients of physicians known to be owners or investors in *independent physiological laboratories* use 13% more physiological testing services than all Medicare patients in general. Finally, while OIG found significant variation on a State by State basis, OIG concluded that patients of physicians known to be owners or investors in durable medical equipment (DME) suppliers use no more DME services than all Medicare patients in general.

B. Physicians' Responses to Financial Incentives—Evidence from a For-Profit Ambulatory Care Center, Hemenway D, Killen A, Cashman SB, Parks CL, Bicknell WJ. New England Journal of Medicine, 1990;322:1059–1063

Health Stop, a chain of for-profit ambulatory care centers, changed its compensation system from a flat hourly wage to a system where doctors could earn bonuses that varied depending upon the gross income they generated individually. A comparison of the practice patterns of fifteen doctors before and after the change revealed that the physicians increased the number of *laboratory tests* performed per patient visit by 23% and the number of *x-ray films* per visit by 16%. The total charges per month, adjusted for inflation, grew 20%, largely due to an increase in the number of patient visits per month. The authors concluded that substantial monetary incentives based on individual performance may induce a group of physicians to increase the intensity of their practice, even though not all of them benefit from the incentives.

C. Frequency and Costs of Diagnostic Imaging in Office Practice—A Comparison of Self-Referring and Radiologist-Referring Physicians; Hillman BJ, Joseph CA, Mabry MR, Sunshine JH, Kennedy SD, Noehner M. New England Journal of Medicine, 1990;322:1604–1608

This study compared the frequency and costs of the use diagnostic imaging for four clinical presentations (acute upper respiratory symptoms, pregnancy, low back pain, or (in men) difficulty in urinating) as performed by physicians who used *imaging equipment* in their offices (self-referring) and as ordered by physicians who always referred patients to radiologists (radiologist-referring). The authors concluded that self-referring physicians use imaging examinations at least four times more often than radiologist-referring physicians and that the charges are usually higher when the imaging is done by the self-referring physicians. These differences could not be attributed to differences in the mix of patients, the specialties of the physicians or the complexity of the imaging examinations performed.

D. Joint Ventures Among Health Care Providers in Florida: State of Florida Cost Containment Board (September 1991)

This study analyzed the effect of joint venture arrangements (defined as any ownership, investment interest or compensation arrangement between persons providing health care) on access, costs, charges, utilization, and quality. The results indicated that problems in one or more of these areas existed in the following types of services: (1) *clinical laboratory services*; (2) *diagnostic imaging services*; and (3) *physical therapy services-rehabilitation centers*. The study concluded that there could be problems or that the results did not allow clear conclusions with respect to the following health care services: (1) ambulatory surgical centers; (2) durable medical equipment suppliers; (3) home health agencies; and (4) radiation therapy centers. The study revealed no effect on access, costs, charges, utilization, or quality of health care services for: (1) acute care hospitals; and (2) nursing homes.

E. New Evidence of the Prevalence and Scope of Physician Joint Ventures; Mitchell JK Scott E. Journal of the American Medical Association, 1992;268:80–84

This report examines the prevalence and scope of physician joint ventures in Florida based on data collected under a legislative mandate. The results indicate that physician ownership of health care businesses providing diagnostic testing or other ancillary services is common in Florida. While the study is based on a survey of health care businesses in Florida, it is at least indicative that such arrangements are likely to occur elsewhere.

The study found that at least 40% of Florida physicians involved in direct patient care have an investment interest in a health care business to which they may refer their patients for services; over 91% of the physician owners are concentrated in specialties that may refer patients for services. About 40% of the physician investors have a financial interest in *diagnostic imaging centers*. These estimates indicate that the proportion of referring physicians involved in direct patient care who participate in joint ventures is much higher than previous estimates suggest.

F. Physicians' Utilization and Charges for Outpatient Diagnostic Imaging in a Medicare Population; Hillman BJ, Olson GT, Griffith PE, Sunshine JH, Joseph CA, Kennedy SD, Nelson WR, Bernhardt LB. Journal of the American Medical Association, 1992, 268:2050–2054

This study extends and confirms the previous research discussed in section C, above, by focusing on a broader range of clinical presentations (ten common clinical presentations were included in this study); a mostly elderly, retired population (a

patient population that is of particular interest with respect to Medicare reimbursement); and the inclusion of *higher-technology imaging* examinations. The study concluded that physicians who own imaging technology employ diagnostic imaging in the evaluation of their patients significantly more often and as a result, generate 1.6 to 6.2 times higher average imaging charges per episode of medical care than do physicians who refer imaging examinations to radiologists.

G. Physician Ownership of Physical Therapy Services: Effects on Charges, Utilization, Profits, and Service Characteristics; Mitchell JM, Scott E: Journal of the American Medical Association, 1992; 268:2055–2059

Using information obtained under a legislative mandate in Florida, the authors evaluated the effects of physician ownership of freestanding *physical therapy and rehabilitation facilities* (joint venture facilities) on utilization, charges, profits, and service characteristics. The study found that visits per patient were 39% to 45% higher in facilities owned by referring physicians and that both gross and net revenue per patient were 30% to 40% higher in such facilities. Percent operating income and percent markup were significantly higher in joint venture physical therapy and rehabilitation facilities. The study concluded that licensed physical therapists and licensed therapist assistants employed in non-joint venture facilities spend about 66% more time per visit treating patients than those licensed workers in joint venture facilities. Finally, the study found that joint ventures also generate more of their revenues from patients with well-paying insurance.

H. Consequences of Physicians, Ownership of Health Care Facilities—Joint Ventures in Radiation Therapy; Mitchell JM, Sunshine JH: New England Journal of Medicine, 1992;327:1497–1501

This study examined the effects of the ownership of freestanding *radiation therapy* centers by referring physicians who do not directly provide services (“joint ventures”) by comparing data from Florida (where 44% of such centers were joint ventures during the period of the study) to data from elsewhere (where only 7% of such centers were joint ventures). The frequency and costs of radiation therapy treatments at free-standing centers were 40% to 60% higher in Florida than in the rest of the United States; there was no below-average use of radiation therapy at hospitals or higher cancer rates to explain the higher use or higher costs. In addition the analysis shows that the joint ventures in Florida provide less access to poorly served populations (rural counties and inner-cities) than non-joint venture facilities. Some indicators (amount of time spent by radiation physicists with patients and mortality among patients with cancer) show that joint ventures cause either no improvement in quality or a decline.

I. Increased Costs and Rates of Use in the California Workers’ Compensation System as a Result of Self Referral by Physicians; Swedlow A, Johnson G, Smithline N, Milstein A: New England Journal of Medicine, 1992;327:1502–1506

The authors analyzed the effects of physician self-referral on three high-cost medical services covered under California’s workers’ compensation: *physical therapy, psychiatric evaluation* and *magnetic resonance imaging (MRI)*. They compared the patterns of physicians who referred patients to facilities of which they were owners (self-referral group) to patterns of physicians who referred patients to independent facilities (independent-referral group). The study found that physical therapy was initiated 2.3 times more often by the self-referral group than those in the independent-referral group (which more than offset the slight decrease in cost per case). The mean cost of psychiatric evaluation services was significantly higher in the self-referral group (psychometric testing, 34% higher; psychiatric evaluation reports 22% higher) and the total cost per case of psychiatric evaluation services was 26% higher in the self-referral group than in the independent-referral group. Finally, the study concluded that of all the MRI scans requested by the self-referring physicians, 38% were found to be medically inappropriate, as compared to 28% of those requested by physicians in the independent-referral group. There were no significant differences in the cost per case between the two groups.

J. Medicare: Referrals to Physician-Owned Imaging Facilities Warrant HCFA’s Scrutiny (GAO Report No. B-253835; October 1994)

The U.S. General Accounting Office (GAO) issued a report regarding: (1) referrals by physicians with a financial interest in joint-venture imaging centers; and (2) referrals for imaging provided within the referring physicians’ practice settings. The analyzes are based on information collected by researchers in Florida for the Florida Health Care Cost Containment Board and include information on 1990 Medicare claims for imaging services ordered by Florida physicians. GAO analyzed approxi-

mately 1.3 million imaging services performed at facilities outside the ordering physicians' practice settings and approximately 1.2 million imaging services provided within the ordering physicians' practice settings. These results are significant because they are based on a large-scale analysis of physician referral practices.

GAO found that physician owners of Florida diagnostic imaging facilities had higher referral rates than nonowners for almost all types of imaging services. The differences in referral rates were greatest for costly, high technology imaging services: physician owners ordered 54% more MRI scans, 27% more computed tomography (CT) scans, 37% more nuclear medicine scans, 27% more echocardiograms, 22% more ultrasound services, and 22% more complex X rays. Referral rates for simple X rays were comparable for owners and nonowners. In addition, while referral practices among specialties differed, physician owners in most specialties had higher referral rates than nonowners in the same specialty.

GAO also compared the imaging rates of physicians who have in-practice imaging patterns (i.e., more than 50% of the imaging services they ordered were provided within their practice affiliations) with physicians with referral imaging patterns (i.e., more than 50% of the imaging services they ordered were provided at facilities outside their practice affiliations). GAO found that physician with in-practice imaging patterns had significantly higher imaging rates than those with referral imaging patterns—the imaging rates were about 3 times higher for MRI scans; about 2 times higher for CT scans; 4.5 to 5.1 times higher for ultrasound, echocardiography, and diagnostic nuclear medicine imaging; and about 2 times higher for complex and simple X rays.

Chairman THOMAS. Thank you very much. I guess you went up the hill and then came down again.

One of the difficulties I have in dealing with what it is that we are going to do with this is, in large part, the testimony you just gave, that this is a very important provision. However, if we are going to change it, we ought to make sure that we change it in a way that it doesn't diminish and so forth, and so forth. And what we need to do ultimately is figure out what you folks are going to do with it.

When are we going to get something that could be used? And I want to put it in this context because I believe everybody in this effort is attempting honestly to make the law work. In fact, as I said in my opening comments, we, in 1996 and 1997, gave you enormous new tools. And I know on a couple of them you fought—kind of resisted accepting them. I think you are now comfortable with them.

Let me ask the question this way: If we had the HIPAA provisions and the BBA provisions in place today, and the proposal was the legislation called self-referral legislation, 1993, what hole would the self-referral legislation fill, if we had the 1996 and 1997 laws on the books, as we have now? What would you want it to look like to give you a more complete arsenal, but not difficult to administer, overlapping, or confusing, or impossible to implement provisions?

Either one of you. I don't mind.

Mr. THORNTON. Mr. Chairman, I think as a practical matter, the vast majority of the questionable physician-incentives schemes that we used to see would be legalized and probably would come back into being if there was no self-referral law. The HIPAA statute and BBA statute, although they contained many very laudable provisions, do not address this issue.

And neither does the anti-kickback statute. As a practical matter, the anti-kickback statute would be available to attack a self-referral scheme only if it was egregious.

Chairman THOMAS. If we are really trying for what the lawyers call a “bright-line structure,” it makes some sense, I think, on the ownership question. I mean, I think there you can draw lines and it is fairly easy to determine.

Are you basically saying then that you are going back to 1993 and defending in its entirety—because I thought at the end of your testimony I didn’t hear that—defending in its entirety the self-referral law? Or is it possible for us to discuss that the ownership aspect is an important part, but it is the compensation attempt to figure out what the bright lines are in an ever-changing, modifying relationship that is causing you most of the problems? Is that an accurate statement?

Would it be OK if the law was just the ownership part, or would you still have holes if it was just that?

Mr. THORNTON. The basic problem is that this issue is a little bit like squeezing on a balloon: If we squeezed only on the ownership part of the balloon, the other part would get bigger in volume. By that, I mean that it would be relatively simple to reward physicians through compensation arrangements if there were controls only on, say, joint-venture investments.

Just an example, the group practice exception, if it didn’t exist at all, could be used to reward doctors for referrals that wouldn’t be in the form of ownership; it would be another form but economically the same thing.

Ms. BUTO. If I could just add to what Mac was saying. I think one of the things that we tried to do in our proposed rule on designated health services was to simplify as much as possible the compensation test to fair-market value, not related to volume and value of referrals. We have gotten some comments on that and other suggestions we are taking a look at—by and large, the fair market value exception was very well received as a way to simplify the compensation side of these provisions and as a way to apply, if you will, a common-sense approach to it.

So we feel like that has assisted a great deal in terms of the complexity of what we see on the compensation side.

Chairman THOMAS. Well, Ms. Buto, in your testimony, both on page 1 and on page 3, you talk about exceptions. And when you take a look at trying to write these regulations, you start with a general prohibition of any referral by a doctor to a facility with which a doctor has a financial relationship. Then you have four exceptions on the ownership and compensation provision, four exceptions to the law’s investment provision, and eight exceptions to the law’s financial arrangement. You have, right there, 16 different exceptions.

And it sounds to me that the way you are going to be finally getting this thing structured is to simply continue to make exceptions. At what point do all of the exceptions that you have structured, swallow the idea of trying to write a general rule that works?

Ms. BUTO. Well, that has obviously been the tough part of writing the regulation. And I think the way I have approached it, and I know the staff have done this in working with medical groups

and others, is that we actually believe there is some evidence on the joint venture side in terms of some of the abuses that were pre-1989, that the law actually has a real due-diligence effect. What we are trying to do, and actually we are doing this very much at the urging of medical associations, medical groups, and others, is to craft the law in a way that recognizes legitimate, bona fide relationships. And that is why there are exceptions. If we were not to have them, I think the law would really be too blunt an instrument. We do need to recognize legitimate arrangements.

Chairman THOMAS. Just let me leave you with this thought, because I think my colleague from Louisiana is going to pursue a line of questioning which will also reinforce my argument: that if there was a belief that Republicans, as a new majority, were not interested in going after crooks, if we weren't interested in making sure that fraud and abuse were eradicated, we would not have done a number of things that we did.

In fact, I would still continue to pursue Dr. Gonzalez, who was convicted of Medicare fraud in New York and was supposed to go to prison and fled this country and went to the Dominican Republic, and your Administration has refused to extradite him. I have written letter after letter to try to get, as the gentleman from California said, a public hanging, figuratively, I assume, which would be very helpful in this area.

I have a nominee. Only trouble is, he is down in Santo Domingo. He was convicted and should be in prison and was required to reinstate \$3.2 million worth of money.

I think that would be a far better example to chill fraud and abuse if you could get the Administration to extradite him so that we can illustrate that we are all interested in eradicating fraud and abuse.

But your example of trying to create legitimate exceptions to try to make a law work still doesn't make sense to me. When I first encountered geometry, I spent a summer trying to draw a triangle that had more or less than 180 degrees. At what point, do we decide that maybe we ought to take a look at what we now have on the books, as I indicated at the beginning of this discussion, and where would it be best to structure it in a way that maximizes our ability to do this and get some regs out and then enforce the law?

I don't know that the way you are going about it will ever produce a really useful tool in conjunction with the newer tools that we have given you. The purpose of this hearing is to ask what I consider to be a fairly fundamental question.

Even if this was a good idea in 1993, if we have what we now have on the books that we passed in 1996 and 1997, what would you be asking for to provide you with the tools that we would get into place relatively quickly and that we could write regs for?

And that may be an adjustment to the 1993 law so that we can move forward. I think the idea that you are trying to justify a position that 5 years after you still can't write a reg for, except with exceptions, proves the point.

And that is all I hope we can get out of these hearings. Our goal is the same. Your defense of an indefensible position I think is relatively difficult, unless, of course, you want to provide us with the regs. And if you don't, I think it is self-evident.

The gentlewoman from Connecticut wishes to inquire?

Mrs. JOHNSON of Connecticut. Why did it take 6 years? I want to try to keep the answers short so we get through the whole thing.

You know, just briefly, here we are 6 years after the law was written and no regs. In a nutshell, why?

Ms. BUTO. Well, in a nutshell, we actually focused on getting the first self-referral regs out on lab services. And we did that. Our notion was that there were some basic definitions, like definitions of group practice, that needed to get on the books. Those were published in 1995.

We then began to work with the designated health services, and I have to say that going from labs to 10 different health services, including home health and outpatient hospital services, and inpatient services, and DME, and so on was not 10 times more difficult, but involved a lot of other considerations—

Mrs. JOHNSON of Connecticut. In other words, in a word, it was terribly complex?

Ms. BUTO. Well, it is just the number of organizations involved and the interests that they had were important to listen to. I actually think it is good we took that time because I think the rule and the fair-market value exception grew out of those series of discussions—

Mrs. JOHNSON of Connecticut. So, in fact, one-size-did-not-fit-all?

Ms. BUTO. Well, actually, on the fair-market value rule, we moved to simplify a lot of the compensation exceptions based on the fact that a number of folks from different suppliers pointed out that we needed that simplification.

Mrs. JOHNSON of Connecticut. Rule of thumb, it is my belief that if any law takes 6 years to write into regulations, it is much too complicated and your regulations are going to be almost impossible for the real-world person to comply with. You are asking a small VNA who wants to merge with another small D and VNA to understand what you are doing here. And it has taken you 6 years to figure it out, and you haven't finished.

So I would really say when I hear testimony, Mr. Thornton, from you saying areas of ambiguity? After 6 years. So go back to that anti-kickback standard. Of course it has a high standard: It is criminal. So it has to be willful and knowing. If you want a lower standard in a civil area, let's get a simpler, lower standard. But we have a model.

And of fraudulent payment, that is our interest here. Just because you are ownership doesn't mean it is fraudulent. If you are in a small town—we went through this years ago when we passed this. And the only people who can afford to invest in the MRI or the cat scan originally were the physicians. They had to do it to keep medical practice up, to give people options.

And we came forward and said that is criminal. See so this was hard to write because it doesn't work across the board in every single area. So I think, you know, in all fairness to the real world, when you are still sitting here testifying that there are areas of ambiguity, that you had, what was it, 1,200 comments still. I appreciate your diligence.

Ms. BUTO. Twelve thousand.

Mrs. JOHNSON of Connecticut. Twelve thousand. But that tells you, 6 years later you still have 12,000 comments. So progress? What did you have the first time, 120,000 comments?

Ms. BUTO. No. I have forgotten what the number was, but it wasn't even—I don't think it was even as high as 12,000 the first time.

Mrs. JOHNSON of Connecticut. My concern is, when you saw us passing the BBA of 1997, you will remember that one of our big interests was to encourage the whole medical sector to develop a provider-sponsored network because we want to be able to have somebody to compete with the insurance company, and, frankly, cut the insurers out. So there wouldn't be insurers second-guessing medical decisions.

How can you develop a provider-sponsored network with your interpretation of this law, and particularly without it being clarified? I mean how could you do that?

And then second, how can you guard against—I mean, we do have good fraud statutes that do seem to be guarding against fraud at the same time, at least in certain sectors, collaborative relationships are developed. I want to see more collaborative relationships develop among providers so we don't have the question of insurance issues, of an insurer making medical decisions.

How can we do that, and especially when you don't have any clear path laid out that a small little group could follow?

Ms. BUTO. If I could address the PSO issue. The Medicare-plus choice plans, as I am sure you know, and PSO's that are Medicare capitated plans are exempt from the self-referral provision.

Mrs. JOHNSON of Connecticut. See. What does that tell you? What does that tell you? Those are the systems in the private sector that are the majority, I mean, if you are just looking at the real world out there. And they are the ones we hope to grow. But if you want the providers out there that are serving the current fee-for-service clients, to do this, to be part of groups, to create groups, to get into them, how can they do it with this? How can hospitals talk to local physicians with this law?

Ms. BUTO. Well, we think that the law actually allows a lot of collaboration, and that is one reason why, although it has taken a long time, we have spent the time to work with those organizations to try to make it possible for those kinds of legitimate arrangements that apply.

Mrs. JOHNSON of Connecticut. Yes. And I appreciate that. You worked with us in writing the law to help recognize some of those relationships. But it does raise very significant questions in my mind that you are having to adjust to what is happening in the real world. And you are. And I appreciate that. I appreciate your thinking about these things and hearing that input.

But what it has meant is that we can't get clear law on the books because the law no longer fits what is happening in the world. So I would go back to my Chairman's original question, given what is on the books, like anti-kickback standards and such, and given what is happening, where is that simple hole that you need. Because not all self-referral is a bad thing, and that is why we have a lot of exceptions.

Certainly collaboration is a good thing. It is one of the ways we are cutting administrative costs. And that is a good thing. So I would urge you to really help us look at how do we wipe the complexity off the books and start with some simple way of attacking the remainder, instead of trying to attack something that is endemic and systemic to the kind of change that in the end is going to be the future.

You are, in a sense, legislating what would be a diminishing group. They have already diminished way down in the under-65 group. And they will diminish way down once we get ourselves established better in the modern programs for seniors because that is the only way to manage chronic illness. And so that is what is going to happen.

So you are legislating to a diminishing problem. We have strong, now, fraud and abuse—we didn't have those. We didn't have fraud and abuse capability when this law was written that we have now.

So I will relinquish my time. I know we have to go vote. But I would ask you—OK. We will recess the hearing so we can go vote. But I would ask you to take seriously the Chairman's admonition that after 6 years of regulation-writing and 12,000 more comments, that ought to tell us that this is a path that by the time we ever get to the end of it, it will be so anachronistic that we ought to be thinking about the right path to go down, not the wrong path to go down.

It just paralyzes the kind of, the development of the collaborative relationships that are so vital to us. Medicine has changed. So regulation and law has to change. And it is a little discouraging to hear you so tied up with doing something that just is already a mindset away from where we have to go.

And I notice, Mr. Thornton, none of you answered clearly Mr. Thomas' question, what is that hole? what is that piece that the new tools don't let you get at, that this law you might need to get at. You need to do that for us.

Mr. THORNTON. May I respond?

Mrs. JOHNSON of Connecticut. Yes.

Mr. THORNTON. I think the percentage of Medicare beneficiaries in managed-care plans is 17 percent now, and I think CBO's estimate is that it goes to 34 percent. But whether that is right or wrong, there is going to be a considerable Medicare population still in fee-for-service for quite a long time. And we are of the opinion that the Stark Law does address basically a fee-for-service problem. So yes, it is a diminishing problem but still a very substantial one.

Mrs. JOHNSON of Connecticut. Well, it is diminishing and it is substantial. I would certainly agree with that. It is also true that the law hasn't been in force all these 6 years because there have been no regulations. So we are getting both some bad over-effects and some under-effects. And I don't see—I mean, tell me when you are going to do this. Are you going to be done in 6 months? Are you going to be done in a year? Are you going to be done in 2 years? Twelve thousand comments is a lot of comments.

Ms. BUTO. Yes. Let me try to address that. It is always hard to predict when a regulation is going to come out.

Mrs. JOHNSON of Connecticut. Right.

Ms. BUTO. But we are committed to getting it done in HCFA within the next 6 months, and we hope to get it published within the next year. We are going to try very hard to do that. We are certainly well aware that it has been too long, and we will proceed to try to do that on that schedule.

Mrs. JOHNSON of Connecticut. Well, I hope that in doing it, you really will make space for the development of the collaborative relationships that are essential. There will be parts of the country where managed care will not serve. Still, they will need collaborative relationships of a different type than we have had in the past. We simply can't, we can't reward, in a sense, the isolation of services that the old system tended to develop.

And in your regulations, I think you have to be very, very careful to allow rural to collaborate. And when providers collaborate, there is integration of reward systems—of compensation systems. And so, representing an area that is quite rural, and watching the inability—I mean, they don't have the legal resources and I tell them well they can get an advisory opinion now, this does not make them feel good. They don't have time for that.

This is big change in the next year, the next 2 years in our rural systems and our small hospital systems. And you are compromising the quality of that change. It must go on. And it is going to go on faster. If you are going to take year before these are final, so much will happen in this next year. So I do worry about your not being willing to say this is the little piece we need given these new pieces.

So, I know it is a big question and with little time, but I am appalled that we, in government, could pass a law and not tell people what we mean by it for 6 years, and particularly 6 years at a time of really extraordinary change.

We will recess just for a minute, I must go vote, and then resume our questioning.

[Recess.]

Mr. MCCRERY [presiding]. The Committee will come to order. Thank you for being patient. We hope we won't be interrupted again this afternoon.

I would like to follow up on some of the line of questioning regarding advisory opinions because I know as we have considered the advisability of advisory opinions in the past, I think first in 1995 and then more recently in 1997, those of you who have worked in HCFA and around Medicare for awhile, resisted that. And I understand some of the reasons for that.

But, now that we have that available to the marketplace and considering the complexity that you all have discovered in trying to write regulations that cover every conceivable development in the marketplace, do you now think that maybe advisory opinions are a little more advisable than they were a few years ago?

Mr. Thornton.

Mr. THORNTON. Sir, we did express our concerns about advisory opinions very strongly, but we have done our best since 1996 to implement that authority. At the Inspector General's Office, it is our responsibility to issue advisory opinions under the anti-kickback statute and the other major sanction statutes. And HCFA was

recently given the authority to issue advisory opinions under the Stark Law.

I think our advisory opinion process was set up in a way, working with the staff of this Committee and with some advice from the industry, in which some of our concerns have been alleviated. And I believe that any commentator would have to agree that we have implemented in good faith. We have issued 31 advisory opinions to date; 24 of them have been favorable to the requestors. And we established an office to handle these advisory opinions.

We still have some concern that they may prove to be a problem in some kickback cases. But I would say to you that it has not been a significant problem so far.

So, yes, the process has not been as fraught with problems as we had feared.

Mr. MCCRERY. Ms. Buto, it is going to be HCFA's responsibility to issue the advisory opinions under the self-referral rules, what do you expect to be the volume this year of advisory opinions coming out of HCFA?

Ms. BUTO. We have received over the past year or so about 20 requests for advisory opinions. A number of those, it turned out, didn't actually have to do with self-referral or designated health services, and they were essentially withdrawn. We have about eight right now that we are working on. And we have issued two opinions that were favorable to the requestors.

I think they serve a useful purpose, and they certainly alleviate concerns that requestors have. As long as they understand, you know, the context in which the advice is given, I think they are very helpful.

Mr. MCCRERY. As Mr. Thomas pointed out earlier, there are four exceptions to the ownership and compensation provisions, four exceptions to the investment provisions, eight exceptions to the financial arrangement provisions, and, I understand, you are working on more exceptions. Physicians are worried that they can't even accept meals at a place where they might refer patients for fear that that would be financial arrangement.

And I understand that you are in the process of maybe crafting a small-item exception, which is all swell, but it just seems to me that you would welcome advisory—the opportunity to respond to requests from physicians for advisory opinions, knowing that you cannot possibly anticipate every situation and craft an exception for.

You would be—I mean, you would be doing nothing but writing exceptions to regulations which aren't even finalized yet.

It just seems to me that if you all aren't already, you should advertise the availability of advisory opinions among those in the marketplace. And that may relieve you of the burden of trying to craft all these exceptions. And you could use the advisory opinion instead.

Ms. BUTO. I agree. We are very aware of the fact that we need to get the regulations out because a number of the advisory-opinion requests go to, now what is fair-market value? This was a proposal we made to simplify the compensation part of these exceptions. We would like to be able to give some advice on that, but until we

finalize the regulations, which I hope we will do, as I said, within the schedule I laid out, it is hard to give any definitive advice.

So I think you are right that once the regulations are out, it will be a vehicle that we want to use to clarify.

Mr. MCCRERY. Mr. Thornton, you talked a little bit about the kinds of arrangements that physicians might have with, say, a clinical lab that would not be an ownership interest but would be some sort of compensation that would fall under the self-referral prohibition. Could you give me an example of that?

Mr. THORNTON. Well, one area is compensation arrangements which are functionally the same as joint ventures, which causes concern. Am I in the right ballpark?

Mr. MCCRERY. Yes. Explain.

Mr. THORNTON. Sir?

Mr. MCCRERY. Explain.

Mr. THORNTON. Yes, sir. I call it clinics without walls, or group practices without walls. We recognize that legitimate group practices should have an exception. But if that exception is too large, too loose, then physicians who are unrelated and who don't even know each other can be brought into a legal entity, not as investors, but brought in under contracts, compensation contracts. Ancillaries can be established in the middle of this wheel of referrals, if I could be metaphorical for a second, and that the doctors could proceed to profit, split the profits of what they order from the set of ancillary facilities in the middle of the wheel.

That is sort of a basic description of a joint venture, but it can be legally created using compensation arrangements. That is one concern.

Mr. MCCRERY. You also referred to an arrangement, or maybe it was Ms. Buto that referred to this, an arrangement in which a physician would be compensated based on the volume of referrals. That would fall under the self-referral prohibition? Is that right?

Ms. BUTO. Yes. You are talking about physicians who benefit from the volume of referrals?

Mr. MCCRERY. Yes.

Ms. BUTO. Yes. That is essentially one of the underpinnings of the self-referral statute. That is one of the things that the law is intended to try to discourage. Now, there are some exceptions, as people have pointed out, like the in-office ancillary exception, which allows a solo practitioner to order tests and perform them in his or her own office. And that is obviously a benefit from referral, but that exception is clearly spelled out in the statute.

Group practices also have the ability to benefit as a group from referrals within the group. So, again, that is a group practice exception.

Mr. MCCRERY. Do you think that these types of arrangements are distinguishable from those that are meant to be covered by the anti-kickback statute?

Mr. THORNTON. Yes, sir.

Mr. MCCRERY. That seems pretty close to me that, I mean, if you paid based on the number of referrals, that is tantamount to a kickback.

Mr. THORNTON. Well, I can only tell you, having tried to construct many kickback cases over my career, that proving knowing

and willful conduct in a criminal trial beyond a reasonable doubt is really quite a burden and is really only practical where the proof is very obvious and very egregious. It is simply not a violation of the kickback statute per se to have one of these clinics without walls that I referred to or a typical joint venture.

And as I described in my testimony, we found a joint venture in California, the Hanlester group, where we thought we had a lot of other evidence of intent to induce referrals by payment of money. We had tapes of sales pitches. We had lots of good evidence about what was going on, and yet, the courts hold us to a very high standard with respect to anti-kickback statutes, as they probably should.

I believe the Ninth Circuit was inappropriately selective, shall we say, or inappropriately burdensome in their analysis of what we had to prove, but they have the last word.

Mr. MCCREY. Well, let me just close by saying that I agree with you that courts should hold us, hold the Government to a high standard in proving its case. Maybe we should think about the same standard when we are talking about self-referral, not assuming that all physicians are in it to make the maximum amount of money. Not all physicians are crooks. So maybe we should keep that in mind as we go through fashioning these regulations.

Mr. Stark.

Mr. STARK. Thank you, Mr. Chairman.

I know earlier, Chairman Thomas referred to someone who is hiding out in the Dominican Republic, and I share his concern over a guy named Recarey from Florida, who allegedly gave \$74,000 to Jeb Bush as a kind of a bribe, is hiding out in Spain after stealing millions of dollars from the Government. We know where he is, but we are unable to extradite him as well.

I am sure that there are a lot of examples where we could be more strenuous in law enforcement, and I certainly would join with Chairman Thomas—maybe we can get Jeb Bush to call him [Recarey] up and ask him to come back for a visit.

But, be that as it may, I suppose there are bad apples in every barrel.

Ms. Buto, in view of the President's commitment against fraud, waste, and abuse in Medicare, will you commit to us that you are going to assign the staff to this project and get it done in the year 2000?

Ms. BUTO. Yes, I am willing to make that commitment, and I will do everything we can to make sure we can get that done.

Mr. STARK. Thank you. I am sure you will make a lot of people happy, and maybe one or two people unhappy in getting it done.

Ms. BUTO. I think they are sitting right behind me.

Mr. STARK. Mr. Thornton, you indicated that you had about 30 or 40 cases of people who asked for advisory opinions, and that about three-quarters of the people who asked for those got approval and about a quarter did not. Why would somebody then go and hire a law firm to do due diligence when they could just get a letter from you?

Mr. THORNTON. Yes, sir. Well, actually those are two, I think, quite different functions. Any time a healthcare entity is sold or merged or refinanced, the purchasing company, the merging com-

pany, or the bank, or whoever, for their own legal protection, does what we call a due diligence examination.

Mr. STARK. But could they, if they were worried about something that was involved in referrals or kickbacks in that combination, wouldn't you give them a ruling on that?

Mr. THORNTON. We certainly would if they asked.

Mr. STARK. How much do you charge?

Mr. THORNTON. A very reasonable rate, sir. We—[Laughter.]

We issue our advisory opinions for a couple of thousand.

Mr. STARK. So what you are telling me is that HCA and Columbia's attorneys should have come to you instead of going to whomever they paid before they got into trouble because it would have been a lot cheaper. Right?

Mr. THORNTON. I had better not comment on that question, sir. But one of the next witnesses does a lot of due diligence work, and compliance with section 1877 is one of the primary things that they look at. And they don't—and my point is that the court—

Mr. STARK. They charge more than you do?

Mr. THORNTON. Well, they certainly see more than I do, but the core concepts of section 1877, which we believe are relatively clear and unambiguous, are looked at in those due diligence examinations, and many corrections are made.

Mr. STARK. Let me try this: In the American Medical Association's code of medical ethics, this is a statement, "In general, physicians should not refer patients to a healthcare facility which is outside their office practice and at which they do not directly provide care or services when they have an investment in that facility."

Now, if you don't agree to that, you are ineligible for the AMA. If that were changed to say, "any financial interest or remuneration"—in other words, if you broadened that or said that an investment interest can very quickly be turned into a compensation agreement, would you say that simple AMA medical ethics would cover most of the cases that you see?

Mr. THORNTON. Well, it clearly would. That would basically keep physicians completely isolated from relationships with other medical providers—

Mr. STARK. Financially isolated.

Mr. THORNTON. Yes, sir. I think that that would be going too far, that section 1877 sets up certain core principles which are useful but allow many types of compensation and investment interests, and that the AMA should be applauded, as we have stated to them, for coming out with their ethical standards along those lines.

Mr. STARK. Can you outline for us some of the loopholes that you have seen evolve since 1993, and might you care to make any recommendations about what we should do about closing those loopholes?

Mr. THORNTON. Yes, sir. As we say, we have learned a lot since 1993, and the statute could be made both more flexible and there are a couple of loopholes that we would recommend attention to, such as the exception to the investment or ownership provisions, which relate to a hospital. I believe the statute says that what is excepted is an investment in a hospital itself, but not a subdivision of a hospital.

What we are seeing, Mr. Stark, more and more is what is called a "hospital within a hospital," that a wing of the hospital will be separately incorporated and syndicated with the physicians who practice in that particular part of the hospital. That is a problem. That is a way to circumvent the intent of this exception.

But there are other ways where the statute could probably be made more flexible as well, sir.

Mr. STARK. Thank you. Thank you both for your work in this, and, in the face of a lot of criticism, for continuing to serve the taxpayers, at least patients, well.

Mr. THORNTON. Thank you, sir.

Mr. MCCRERY. Mrs. Johnson.

Mrs. JOHNSON of Connecticut. We could argue about whether this does, in fact, serve the patients well in a number of instances. But, I wanted to ask you about your logic in the issue of ambulance restocking and interpreting restocking as an inducement. Why do you think it is an inducement?

Mr. THORNTON. Well, the advisory opinion said that we could not exclude that practice from being an inducement. Now, we were asked whether it could—

Mrs. JOHNSON of Connecticut. That doesn't make you include it as an inducement.

Mr. THORNTON. Well, we could only give a favorable advisory opinion if we could conclude that the restocking of ambulances was incapable of influencing where the ambulance goes. And we could not reach that conclusion. We didn't say it was violative of the anti-kickback statute, but we could not conclude that it was never, ever a problem.

Mrs. JOHNSON of Connecticut. This is a perfect case in point. You referred to, in your testimony, to ambiguity. Because of the ambiguity, and you could not rule this out, hospitals in self-defense have had to stop restocking. That means that if an ambulance delivers a patient to the hospital, in the old days, whatever equipment was used in that trip was restocked by the hospital. And the ambulance was ready to answer the next call.

Now, they have to go—remember, a lot of these are volunteer organizations. They have to go through the system, restock, and only then are they ready for the next call. Furthermore, they don't get the low cost that the hospitals get in the purchase. So this is increasing costs for the taxpayer and reducing responsiveness of the system.

Now, maybe my area of Connecticut is unique, but in the rural areas, there is no choice of hospitals. And in the urban area, there is very little. I mean, clearly, if you had a person with a certain kind of extreme complexity, you would go to one of the big Hartford hospitals, or you might go to Yale if you are closer. But to think that restocking is an inducement—furthermore, if you get restocking in any hospital you go to, then it is not inducement.

So what you have done by refusing to recognize it, as long as this is everywhere, it is not preferential.

Mr. THORNTON. We actually have issued several advisory opinions that hold just that, actually, that where there is a system for restocking ambulances, everybody does it, and there is not the potential problem of one hospital offering restocking and influencing

people to come to just that one hospital. Where you have an EMS system in place that the ambulances go to and all the hospitals restock, we have approved, I think, two or three arrangements just like that.

Mrs. JOHNSON of Connecticut. But see, you have to approve them one by one. This is a very big nation. You know, why are you putting that burden on the system when there is no evidence at all that this has ever worked to do that? On paper, of course, it might possibly. No evidence at all. The problem with this law is that it comes to influence situations like this in which there is no evidence of inducement, there is no evidence of fraud.

And yet, furthermore, there is evidence of efficiency, of better service, of more responsiveness. But when you take that limited approach, which you feel you have to under this law, it frankly hurts the healthcare system. It hurts access and it hurts cost.

Now, recognizing this and having made some favorable rulings, do you or do you not have the authority to say, this is off the table, under this law?

Mr. THORNTON. Well, we would have that authority under the advisory opinion procedure.

Mrs. JOHNSON of Connecticut. Can you do an advisory opinion for the Nation on this subject?

Mr. THORNTON. No. We do advisory opinions for particular people, although all of our advisory opinions are posted on the Internet and are good advice for everyone.

Mrs. JOHNSON of Connecticut. I understand. Yes. But that is not sufficient. It really isn't. In this case, would you have the authority under the law to say that we do not see this as a situation of inducement?

Mr. THORNTON. And we have several opinions.

Mrs. JOHNSON of Connecticut. I don't mean that. I am saying blanketly across the country. If you can't, I want to see the examples of situations in which you proved that it is an inducement.

Mr. THORNTON. Well, we just said that giving away the products was an inducement. If the hospital were to charge the ambulance company and they were to pay, that would be perfectly legal.

Mrs. JOHNSON of Connecticut. Well, as I say, I would like to see some examples of where this is proved to be an inducement, where you see it as an inducement. Give me an example; not right now, but please give me an example of a system where you decided this was an inducement.

Mr. THORNTON. I would be happy to provide what information we have about this—

Mrs. JOHNSON of Connecticut. Well, I want information on a specific example. If you are making a ruling like this that is making it harder for every little ambulance company throughout the district and, particularly, the volunteers, to operate, I want an example of where it has worked against the taxpayer and against the patient because I see it, your decisions working against the taxpayer and against the patient.

So just give me, afterward—I know you can't do it off the top of your head—an example of how the law in this instance is protecting us, the taxpayer and the patient. I would appreciate that. Thank you.

Mr. THORNTON. All right. We will get back to you.
[The letter and advisories follow:]

DEPARTMENT OF HEALTH & HUMAN SERVICES
Washington, D.C., May 2, 1999

The Honorable Nancy L. Johnson
*U.S. House of Representatives
Washington, D.C.*

Dear Ms. Johnson:

During my testimony at the hearing on May 13, 1999, regarding the physician self-referral statute (the "Stark Law"), you asked me to provide you with further information relating to the issue of ambulance restocking. In particular, you requested examples of abusive ambulance restocking arrangements.

By way of background, the ambulance restocking issue arises under the Federal anti-kickback statute. The anti-kickback statute, section 1128B(b) of the Social Security Act, is a criminal statute that prohibits the intentional payment of remuneration to induce or reward referrals of Federal health care program business. By contrast, as you know, the Stark Law is a civil authority limited to self-referral by physicians.

Pursuant to a congressional directive, the Office of Inspector General ("OIG") issues advisory opinions addressing whether particular existing or proposed arrangements potentially violate the anti-kickback statute, and, if so, whether the OIG would subject them to sanctions, including civil money penalties and program exclusion. In essence, we are asked to opine as to the anti-kickback implications of a particular set of facts presented by the requesting party. Advisory opinions must be issued within a relatively short time frame that precludes independent OIG investigation of the facts.

One of the difficulties of the advisory opinion process is that we are required to respond to all proper requests based on the facts presented, irrespective of whether we believe the subject matter represents a significant fraud and abuse problem. Thus, issuance of an advisory opinion in and of itself is not necessarily indicative of an OIG enforcement priority. This was the case with ambulance restocking. I am unable to provide you with any specific examples of fraudulent or abusive restocking programs, largely because ambulance restocking programs have not been the subject of OIG enforcement activity.

In crafting an advisory opinion, the OIG does not determine the intent of the parties based on their documentary submissions. We issue a favorable opinion only where we conclude that an arrangement includes safeguards sufficient to ensure there is little or no risk of program fraud or abuse, regardless of the parties' intent. Accordingly, an unfavorable opinion is not a determination that an arrangement violates the statute; it means only that (i) the arrangement may violate the statute if the requisite intent to induce referrals is present and (ii) we are not satisfied that the arrangement as described by the party requesting the opinion poses only a minimal risk of fraud or abuse.

In many respects, ambulance restocking raises issues that fit squarely within established anti-kickback jurisprudence. The restocking of supplies and medications without charge constitutes the provision of free goods by the hospital to the ambulance provider. The OIG's concern with the provision of free goods to potential referral sources is longstanding and clear: such arrangements are highly suspect. To take a clear hypothetical example, the provision of free goods to a referral source pursuant to a written contract that expressly conditions the free goods on referrals of Federal program beneficiaries would violate the anti-kickback statute. In other words, if a hospital were to enter into a written contract with an ambulance provider that stated that the hospital would give the ambulance company free supplies and medications if the ambulance company agreed to steer Medicare patients to the hospital, the provision of free supplies and medications pursuant to such contract would clearly constitute prohibited remuneration under the statute.

The medical center that requested the first advisory opinion dealing with ambulance restocking (OIG Advisory Opinion 97-6) described a particular set of facts that clearly implicated the anti-kickback statute. Based on the facts presented, we could not reasonably conclude that the anti-kickback statute was not implicated. Indeed, it appears that the hospital sought a negative opinion to justify terminating a restocking arrangement, so as to lower hospital costs.

Following publication of Advisory Opinion 97-6, we heard from many representatives of ambulance companies, municipal emergency medical services ("EMS") providers, and hospitals concerned about the legality of ambulance restocking arrange-

ments. In our many conversations with these providers, three general facts emerged. First, a wide range of ambulance restocking arrangements exists. Second, some hospitals were threatening to eliminate restocking programs, creating a potential financial issue for volunteer and municipal EMS providers. Third, the perception of many ambulance providers was that some hospitals were looking for reasons to eliminate costly restocking programs.

To allay some of these concerns, we issued a clarifying letter to the American Ambulance Association on November 25, 1997, clearly stating that ambulance restocking arrangements are not all potentially illegal, and we made several suggestions for compliance with the anti-kickback statute. For example, if the ambulance company reimburses the hospital at fair market value for the restocked goods, the anti-kickback concern is alleviated. A copy of that letter is enclosed.

In the ensuing months we received three additional requests from hospitals engaged in ambulance restocking programs. The facts described in these requests were markedly different from the first request. All three of the new requests involved ambulance restocking programs conducted pursuant to comprehensive, coordinated EMS delivery systems involving all of an area's ambulance providers and hospitals. With the limited exception of one part of one of the three programs, we approved all of these arrangements because we were persuaded that they posed little or no risk of Federal health care program fraud or abuse.¹ We have received no further advisory opinion requests on the topic of ambulance restocking and very few further informal inquiries. Copies of these favorable opinions are enclosed.

I hope this information is helpful. If you or your staff have further questions, please contact me or Kevin McAnaney, Chief, Industry Guidance Branch.

Sincerely,

D. McCARTY THORNTON
Chief Counsel to the Inspector General

Enclosures

Advisory Opinion No. 98-7

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion, in which you ask whether an ambulance restocking and continuing education arrangement (the "Arrangement"¹) constitutes prohibited remuneration under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act") and, if so, whether the Arrangement constitutes grounds for the imposition of sanctions under the anti-kickback statute, section 1128B(b) of the Act, the exclusion authority related to kickbacks, section 1128(b)(7) of the Act, or the civil monetary penalty provision for kickbacks, section 1128A(a)(7) of the Act.

You have certified that all of the information you provided in your request, including all supplementary letters, is true and correct, and constitutes a complete description of the material facts regarding the Arrangement. In issuing this opinion, we have relied solely on the facts and information you presented to us. We have not undertaken any independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion, we conclude that the Arrangement could constitute prohibited remuneration under the anti-kickback statute if the requisite intent to induce referrals were present, but that the OIG will not subject the Arrangement, as described in the request and supplemental submissions, to sanctions arising under the anti-kickback statute pursuant to sections 1128B(b), 1128(b)(7), or 1128A(a)(7) of the Act.

This opinion may not be relied on by any persons other than the addressees and is further qualified as set out in Part III below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

The requesters of this advisory opinion are twenty non-profit hospitals located in ten counties in the City A area of State B (the "Hospitals") and the City A Hospital Association (the "Association"), a non-profit corporation exempt from federal income

¹ See OIG Advisory Opinions Nos. 98-7, 98-13, and 98-14.

¹ Specifically, the Arrangement includes (1) a "drug box" exchange program; (2) a linens and medical supply exchange program; (3) a "pedi bag" exchange program for pediatric supplies; and (4) a continuing emergency medical services education program.

tax pursuant to section 501(c)(6) of the Internal Revenue Code.² The Hospitals represent all of the hospitals in the City A area.

The Hospitals and the Association are dues paying members of the Region C Emergency Medical Services Council, Inc. (the “Council”), a State B nonprofit and tax exempt corporation founded in 1972, whose membership also includes all private and public ambulance providers in the area, local educational institutions, physicians, and at-large community members. The Council’s mission is to coordinate the efforts of public and private ambulance service pre-hospital care providers, hospital emergency department staff, and consumers to ensure the best possible pre-hospital medical care for the victims of sudden illness or injury. The Council develops protocols for, and conducts ongoing evaluation and improvement of, the local emergency medical services (“EMS”) delivery system, performs EMS quality assurance audits, distributes drug boxes to the local ambulances, provides continuing education to EMS personnel, sponsors education programs related to EMS for the general public, acts as an information clearinghouse for EMS activities, and otherwise seeks to promote high quality EMS care for the region.

Under the Council’s auspices and pursuant to Council-developed protocols, the Hospitals and EMS organizations in the City A area have engaged in various drug and medical supply exchange programs in connection with emergency medical transports since approximately 1973. Typically under these exchange programs, a receiving hospital restocks an ambulance with medications and supplies used in connection with emergency medical pre-hospital services provided to the transported patient. The ambulance providers are not charged, and do not pay, for the restocked items. Drugs are exchanged through a “drug box” program, pursuant to which EMS squads exchange depleted drug boxes used during a patient run for fully-stocked boxes provided by the receiving hospital. Hospital pharmacists review the used drug boxes, replenishing used, outdated, or improperly sealed items, and return them to inventory for future exchange.³

Under the linens and medical supplies exchange program, receiving hospitals restock ambulances with linens and medical supplies used on patients during emergency pre-hospital services. The program enables ambulances to be fully stocked at all times and ensures standardization of supplies, so that, for example, tubing used by EMS units can be connected to hospital systems without interruption.

The continuing education programs in which the Hospitals participate serve to update EMS personnel on the latest techniques in patient care. These programs also enable EMS personnel to remain current with emergency room protocols in the Hospitals. Hospital personnel also visit EMS squads to test the skills of EMS personnel, as required by regional standing orders pertaining to EMS certification.

Also under the Arrangement, Hospital Z in City A, the area’s children’s specialty hospital and a requestor of this opinion, distributes “pedi bags” to EMS providers to ensure that EMS units carry a variety of pediatric-sized airway tubes and related equipment for use with children. These bags have been distributed to all EMS squads in the City A area. Private EMS squads pay a nominal start-up fee of \$100 per bag. Hospital Z provides the bags to community and volunteer EMS squads at no charge. As with the other exchange programs, the supplies within the bags are restocked on an exchange basis, and all adult hospitals in the area keep on hand a small supply of these children’s items.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by any Federal health care program.

²The Hospitals are all members of the Association. The Association has presented itself as an additional requestor on the ground that it facilitates the uniform participation of the Hospitals in the Arrangement. Although trade associations are not typically appropriate requestors on behalf of their members, see 42 C.F.R. §1008.11, a trade association may be a proper requestor if it is itself a party to an arrangement that is the subject of a request for an advisory opinion.

³The drug box exchange program has been approved by the State B Board of Pharmacy and complies with [code section redacted], which provides a mechanism for EMS units to obtain drug stocks legally “on a replacement basis” from hospitals to which patients are delivered. We have previously stated our belief that ambulance restocking performed pursuant to a state law mandate would not violate the anti-kickback statute. However, because [code section redacted] permits, but does not require, drug restocking by hospitals, the statute is insufficient by itself to foreclose the possibility of improper intent to induce referrals.

See 42 U.S.C. § 1320a-7b(b). Where remuneration is paid purposefully to induce referrals of items or services for which payment may be made by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). “Remuneration” for purposes of the anti-kickback statute includes the transfer of anything of value, in cash or in kind, directly or indirectly, covertly or overtly. Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. This Office may also initiate administrative proceedings to exclude persons from Federal and state health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.⁴

This Office’s concern with the provision of goods and services for free or at below-market rates to potential referral sources is longstanding and clear: such arrangements are suspect under the anti-kickback statute. The provision of free or below-market rate goods or services to a referral source may violate the anti-kickback statute if one purpose of the gift is to induce referrals of Federal health care program business.

The provision by a hospital of free supplies, medications, and services to an ambulance service fits squarely within the meaning of remuneration for purposes of the anti-kickback statute. An inference may be drawn that one purpose of such remuneration is to induce the ambulance company to bring patients to the hospital. However, the strength of that inference may vary with the circumstances of the specific arrangement.

In assessing the potential risk of fraud or abuse under the anti-kickback statute, our concerns are principally fourfold: increased risk of over utilization, increased program costs, patient freedom of choice, and unfair competition. Because it is limited to emergency medical services, the Arrangement does not increase the risk of over utilization and is unlikely to lead to increased costs to Federal health care programs. Neither the number of Federal program beneficiaries requiring emergency transport in the City A area, nor the treatment these patients will require or receive at the Hospitals, is related to the existence or operation of the Arrangement.⁵

With respect to freedom of choice and unfair competition, under the Arrangement it appears that emergency ambulance crews have relatively limited opportunities to steer patients to particular hospitals. In life threatening cases, the selection of a receiving hospital will be dictated by the patient’s condition. In other circumstances, the choice of receiving hospital will frequently be dictated by the patient, the patient’s physician, or the patient’s insurer. Notwithstanding, there will inevitably be situations in which ambulance company personnel would be able to steer patients who do not have a preference to a particular facility. In the circumstances presented here, however, there would appear to be no financial reason arising from the Arrangement for ambulance personnel to steer patients to a particular hospital, since all area hospitals participate in the Arrangement.

However, the mere fact that all hospitals may be restocking ambulances without charge does not immunize conduct that might otherwise violate the anti-kickback statute. Some institutions may well participate in the restocking because of fear of adverse competitive consequences if they do not. In short, remuneration that is given to retain or maintain existing referrals may violate the anti-kickback statute.

We previously addressed the application of the anti-kickback statute to an ambulance restocking arrangement in OIG Advisory Opinion 97-6 (October 8, 1997). Based on the specific facts presented by the hospital requestor, we found that, notwithstanding a state administrative regulation that required ambulances to transport patients to the facility of the patient’s choice except in exigent circumstances, the hospital’s proposed arrangement for free restocking of supplies and medications

⁴ Because both the criminal and administrative sanctions related to the anti-kickback implications of the Arrangement are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under both.

⁵ This advisory opinion only relates to drugs, supplies, and educational programs provided by the Hospitals that directly relate to the provision of emergency pre-hospital services in the City A area. Restocking of drugs or supplies used in the course of non-emergency services and educational programs not directly related to emergency medical services are outside the scope of this opinion.

posed a risk of improper steering and unfair competition. Accordingly, we concluded that the arrangement could potentially violate the anti-kickback statute if the requisite intent to induce referrals were present.

The facts presented here differ in material respects from those presented in OIG Advisory Opinion 97-6. First, the Arrangement is not a unilateral arrangement; rather, it was developed and implemented pursuant to an ongoing effort by the Council and its members to maintain and improve a regional emergency medical system through a comprehensive program that coordinates all EMS components. The Council, a non-profit corporation founded in 1972, is open to all hospitals and emergency ambulance providers in the area, as well as local educational institutions, physicians, and other community members. Regional EMS councils, like the one at issue here, were formed in the early 1970s in response to a growing recognition of the inadequacy of then existing emergency medical care and the high cost in human lives and physical disabilities due to accidents and sudden illness and injury.⁶ EMS councils were established to coordinate emergency care among all levels of a region's EMS system, including public safety organizations, private and hospital-based ambulance services, hospitals and other critical care facilities, and local physicians and community groups.

Second, the restocking aspects of the Arrangement are not free-standing; the Arrangement is part and parcel of a comprehensive and coordinated regional effort to integrate and improve all aspects of the emergency medical care system. In addition to the drug and supply exchange programs, the Council establishes protocols addressing various aspects of the emergency medical system and otherwise administers the exchange and educational programs.⁷ It also conducts ongoing evaluation and improvement of the local EMS delivery system, performs EMS quality assurance audits, sponsors educational programs related to EMS for the general public, acts as an information clearinghouse for EMS activities, and otherwise seeks to promote high quality EMS care for the region.

Third, regional and local programs to improve and coordinate the delivery of quality emergency medical services have been actively encouraged and promoted by the Federal government over the past twenty-five years. In 1973—the year the first exchange program began in the City A area—the Federal government enacted the Emergency Medical Services Systems Act of 1973 (“EMSSA”), Pub. L. 93–154, 87 Stat. 594 (1973), which provided federal funding for the development of regional EMS systems at the state, regional, and local levels.⁸ These regional systems were to develop comprehensive programs to improve such areas as communications (including “911” systems); transportation; provision and training of emergency personnel; facilities; critical care units; use of public safety agencies; accessibility to care; consumer participation, education, and information; transfer of patients; standard medical record keeping; independent review and evaluation of EMS; disaster linkage; and mutual aid agreements among communities. EMSSA was one of several Federal legislative efforts to promote EMS delivery systems, including the Highway Safety Act of 1966, Pub. L. 89–594, 80 Stat. 731 (1966), which established an EMS program in the Department of Transportation; the Emergency Medical Services for Children Program, under the Public Health Act, Pub. L. 98–555, 99 Stat. 2854 (1984), which provided funds for enhancing pediatric EMS; and the Trauma Care Systems Planning and Development Act of 1990, Pub. L. 101–590, 104 Stat. 2915 (1990).

Finally—and importantly—the Arrangement is likely to have a positive impact on the quality of patient care. By providing a mechanism to ensure that ambulances are fully stocked with current medications and appropriate supplies compatible with all local hospital emergency rooms and that EMS personnel are adequately trained, the Arrangement is likely to foster fast, efficient, and effective pre-hospital emergency care for the City A area community. This significant community benefit, coupled with the conditions, requirements, and limitations outlined above, persuade us that the Arrangement poses minimal risk of fraud and abuse under the anti-kickback statute, and therefore the OIG would not subject it to sanction.

⁶ See, e.g. *Accidental Death and Disability: The Neglected Disease of Modern Society*, National Academy of Sciences and National Research Council (September 1966).

⁷ The “pedi bag” program is administered by the local children’s medical center, but is part of the comprehensive regional EMS system and is included in the Arrangement for purposes of this advisory opinion.

⁸ EMSSA defined “emergency medical services system” as “a system which provides for the arrangement of personnel, facilities, and equipment for the effective and coordinated delivery in an appropriate geographical area of health care services under emergency conditions . . . and which is administered by a public or nonprofit private entity which has the authority and the resources to provide effective administration of the system.” 87 Stat. at 595.

III. CONCLUSION

The advisory opinion process is a “means of relating the anti-kickback statute to the particular facts of a specific arrangement.” 62 Fed. Reg. 7350, 7351 (February 19, 1997). The advisory opinion process permits this Office to protect specific arrangements that contain limitations, requirements, or controls that give adequate assurance that Federal health care programs cannot be abused.” *Id.* In evaluating an arrangement’s potential to lead to fraud or abuse of Federal health care programs, no one fact or element is necessarily dispositive. Here, we are persuaded that the Arrangement is likely to result in substantial community benefit consistent with longstanding national policy objectives. We are further persuaded that, taken as a whole, the aspects of the Arrangement described above—including, but not limited to, the Arrangement’s relationship to a coordinated regional EMS system, the role of the regional Council, the Arrangement’s limitation to emergency medical services, and the uniformity of the Arrangement across providers—create sufficient limitations, requirements, or controls so as to give adequate assurance that the Arrangement will not lead to program abuse under the anti-kickback statute.⁹

Accordingly, we conclude that while the Arrangement might technically violate the anti-kickback statute if the requisite intent to induce referrals were present, the OIG will not impose sanctions on the requesters under sections 1128(b)(7) (as it relates to kickbacks) or 1128A(a)(7) of the Act, based on the facts certified in the requesters’ request for an advisory opinion.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to the requesters listed on the Attached Distribution List, which are the requesters of this opinion. This advisory opinion has no application, and cannot be relied upon, by any other individual or entity.
- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a Requestor to this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted in the first paragraph of this advisory opinion. No opinion is herein expressed or implied with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement.
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the requesters with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, modify or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against any requestor with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion.

Sincerely,

D. McCARTY THORNTON
Chief Counsel to the Inspector General

⁹We express no opinion regarding liability of the requesters under the False Claims Act or other legal authorities in connection with any improper billing or claims submission directly or indirectly related to, or arising from, the Arrangement.

Advisory Opinion No. 98-13

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion, in which you ask whether an ambulance restocking program, coordinated through a local emergency medical services council (the "Program"), constitutes prohibited remuneration under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), and, if so, whether the Program constitutes grounds for the imposition of sanctions under the anti-kickback statute, section 1128B(b) of the Act, the exclusion authority related to kickbacks, section 1128(b)(7) of the Act, or the civil monetary penalty provision for kickbacks, section 1128A(a)(7) of the Act.

You have certified that all of the information you provided in your request, including all supplementary information, is true and correct, and constitutes a complete description of the material facts regarding the Program. In issuing this opinion, we have relied solely on the facts and information you presented to us. We have not undertaken any independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion, we conclude that the Program could constitute prohibited remuneration under the anti-kickback statute if the requisite intent to induce referrals were present, but that the OIG will not subject the Program, as described in the request and supplemental submissions, to sanctions arising under the anti-kickback statute pursuant to sections 1128B(b), 1128(b)(7), or 1128A(a)(7) of the Act.

This opinion may not be relied on by any persons other than the addressees and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

The requesters of this advisory opinion are eight fire departments (listed on the attached distribution list) and The County X Ambulance District located in County X, State Y. All of the fire departments and the ambulance district are owned and operated by municipal governments and provide emergency medical services ("EMS").

The requesters are members of the County X Emergency Medical Services Council (the "Council"), a non-profit association founded in 1980. The Council is an advisory and coordinating organization whose mission is to promote and advance EMS throughout County X. Membership on the Council includes those who are providing EMS and those who are interested in furthering the goals of the Council. The Council's current membership includes public and private ambulance providers, hospitals, medical directors, and local educational facilities. The Council's goals include: standardization of EMS practices and equipment; provision of education and training for EMS providers; and improvement of EMS capabilities in the Council's service area. Through its Executive Committee, the Council may appoint working committees to accomplish its goals. One such committee is a practice committee.

The practice committee has oversight of the restocking Program and is responsible for standardizing the Program within the local EMS community, educating Council members regarding the Program, and disseminating information about the Program. The Program has been in operation in County X for eighteen years. The Program provides for the free exchange of drugs and medical supplies used by EMS providers when they bring an individual to a hospital for emergency treatment. Currently, all hospitals and EMS providers in the County X service area participate in the Program. Under the Program protocol, the hospital that receives the patient restocks the ambulance with the medications and supplies used in connection with the patient's emergency medical treatment. Both an EMS provider and a representative of the receiving hospital fill out and sign an emergency medical response for each patient (the "Report"). One copy of the Report is placed in the patient's record and one copy of the Report is used for inventory documentation of the expended drugs and medical supplies. The ambulance providers are not charged, and do not pay, for restocked items. The cost of the drugs and medical supplies is charged to the patient by the receiving hospital in the manner of other billing for the services to the patient.

II. LEGAL ANALYSIS

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by any Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce referrals of items or services for which payment may be made by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid.

This Office may also initiate administrative proceedings to exclude persons from Federal and state health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.

This Office’s concern with the provision of goods and services for free or at below-market rates to potential referral sources is longstanding and clear: such arrangements are suspect under the anti-kickback statute. The provision of free or below-market rate goods or services to a referral source may violate the anti-kickback statute if one purpose of the gift is to induce referrals of Federal health care program business.

The provision by a hospital of free supplies and medications to an ambulance provider fits squarely within the meaning of remuneration for purposes of the anti-kickback statute. An inference may be drawn that one purpose of such remuneration is to induce the ambulance provider to bring patients to the hospital. However, the strength of that inference may vary with the circumstances of the specific arrangement.

In assessing the potential risk of fraud or abuse under the anti-kickback statute, our concerns are principally fourfold: increased risk of over utilization, increased program costs, patient freedom of choice, and unfair competition. Because it is limited to emergency medical services, the Program does not increase the risk of over utilization and is unlikely to lead to increased costs to Federal health care programs. Neither the number of Federal program beneficiaries requiring emergency transport in County X, nor the treatment these patients will require or receive at a hospital, is related to the existence or operation of the Program.

With respect to freedom of choice and unfair competition, emergency ambulance crews have relatively limited opportunities to steer patients to particular hospitals. In life threatening cases, the selection of a receiving hospital will be dictated by the patient’s condition. In other circumstances, the choice of receiving hospital will frequently be dictated by the patient, the patient’s physician, or the patient’s insurer. Notwithstanding, there will inevitably be situations in which ambulance provider personnel would be able to steer patients who do not have a preference to a particular facility. In the circumstances presented here, however, there would appear to be no financial reason arising from the Program for ambulance personnel to steer patients to a particular hospital, since all area hospitals participate in the Program.

However, the mere fact that all hospitals may be restocking ambulances without charge does not immunize conduct that might otherwise violate the anti-kickback statute. Some institutions may well participate in the restocking because of fear of adverse competitive consequences if they do not. In short, remuneration that is given to retain or maintain existing referrals may violate the anti-kickback statute.

We previously addressed an ambulance restocking arrangement that raised concerns under the anti-kickback statute in OIG Advisory Opinion 97-6 (October 8, 1997). Based on the specific facts presented by the hospital requester, we found that, notwithstanding a state administrative regulation that required ambulances to transport patients to the facility of the patient’s choice except in exigent circumstances, the hospital’s proposed arrangement for free restocking of supplies and medications posed a risk of improper steering and unfair competition. Accordingly, we concluded that the arrangement could potentially violate the anti-kickback statute if the requisite intent to induce referrals were present.

The facts presented here differ in material respects from those presented in OIG Advisory Opinion 97-6 for the following reasons:

First, the Program is not a unilateral arrangement; rather, it is part of an ongoing effort by the Council and its members to maintain and improve EMS throughout the County X service area. The Council, a non-profit association founded in 1980, is open to all hospitals and emergency ambulance providers in the area, as well as local educational institutions, physicians, and other community members. Regional EMS councils, like the one at issue here, were formed in the early 1970s in response to a growing recognition of the inadequacy of then existing emergency medical care and the high cost in human lives and physical disabilities due to accidents and sudden illness and injury. EMS councils were established to coordinate emergency care among all levels of a region's EMS system, including public safety organizations, private and hospital-based ambulance providers, hospitals and other critical care facilities, and local physicians and community groups.

Second, the restocking aspects of the Program are not free-standing; the Program is part and parcel of a coordinated regional effort to integrate and improve the emergency medical care system. In addition to the drug and supply exchange programs, the Council promotes the standardization of practices and equipment within the emergency medical system and provides education and training for EMS providers. It also evaluates and supports requests for improvements to the local EMS delivery system, sponsors educational programs related to EMS, and otherwise seeks to promote high quality EMS care for the region.

Third, regional and local programs to improve and coordinate the delivery of quality EMS have been actively encouraged and promoted by the Federal government over the past twenty-five years. In 1973 the Federal government enacted the Emergency Medical Services Systems Act of 1973 ("EMSSA"), Pub L. 93-154, 87 Stat. 594 (1973), which provided federal funding for the development of regional EMS systems at the state, regional, and local levels. These regional systems were to develop comprehensive programs to improve such areas as communications (including "911" systems); transportation; provision and training of emergency personnel; facilities; critical care units; use of public safety agencies; accessibility to care; consumer participation, education, and information; transfer of patients; standard medical record keeping; independent review and evaluation of EMS; disaster linkage; and mutual aid agreements among communities. EMSSA was one of several Federal legislative efforts to promote EMS delivery systems, including the Highway Safety Act of 1966, Pub. L. 89-594, 80 Stat. 731 (1966), which established an EMS program in the Department of Transportation; the Emergency Medical Services for Children Program, under the Public Health Act, Pub. L. 98-555, 99 Stat. 2854 (1984), which provided funds for enhancing pediatric EMS; and the Trauma Care Systems Planning and Development Act of 1990, Pub. L. 101-590, 104 Stat. 2915 (1990).

Finally—and importantly—the Program is likely to have a positive impact on the quality of patient care. By providing a mechanism to ensure that ambulances are fully stocked with current medications and appropriate supplies, the Program is likely to foster fast, efficient, and effective pre-hospital emergency care for the County X service area. These significant community benefits, coupled with the conditions, requirements, and limitations outlined above, persuade us that the Program poses minimal risk of fraud and abuse under the anti-kickback statute, and therefore the OIG would not subject it to sanction.

III. CONCLUSION

The advisory opinion process is a "means of relating the anti-kickback statute to the particular facts of a specific arrangement." 62 Fed. Reg. 7350,7351 (February 19, 1997). The advisory opinion process permits this Office to protect specific arrangements that "contain limitations, requirements, or controls that give adequate assurance that Federal health care programs cannot be abused." *Id.* In evaluating an arrangement's potential to lead to fraud or abuse of Federal health care programs, no one fact or element is necessarily dispositive. Here, we are persuaded that the Program is likely to result in substantial community benefit consistent with longstanding national policy objectives. We are further persuaded that, taken as a whole, the aspects of the Program described above—including, but not limited to, the Program's relationship to a coordinated regional EMS system, the role of the regional Council, the Program's limitation to emergency medical services, and the uniformity of the Program across providers—create sufficient limitations, requirements, or controls so as to give adequate assurance that the Program will not lead to program abuse under the anti-kickback statute.

Accordingly, we conclude that while the Program might technically violate the anti-kickback statute if the requisite intent to induce referrals were present, the OIG will not impose sanctions on the requesters under sections 1128(b)(7) (as it re-

lates to kickbacks) or 1128A(a)(7) of the Act, based on the facts certified in the requesters' request for an advisory opinion.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

This advisory opinion is issued only to the requesters listed on the Attached Distribution List, which are the requesters of this opinion. This advisory opinion has no application, and cannot be relied upon, by any other individual or entity.

This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requester to this opinion.

This advisory opinion is applicable only to the statutory provisions specifically noted in the first paragraph of this advisory opinion. No opinion is herein expressed or implied with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Program.

This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the requesters with respect to any action that is part of the Program taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, and the Program in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against any requester with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

D. McCARTY THORNTON
Chief Counsel to the Inspector General

Advisory Opinion No. 98-14

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion, in which you ask whether an existing pharmaceutical restocking program (the "Drug Program") and a proposed medical supplies restocking program (the "Supply Program") (collectively, the "Arrangements") constitute prohibited remuneration under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), and, if so, whether the Arrangements constitute grounds for the imposition of sanctions under the anti-kickback statute, section 1128B(b) of the Act, the exclusion authority related to kickbacks, section 1128(b)(7) of the Act, or the civil monetary penalty provision for kickbacks, section 1128A(a)(7) of the Act.

You have certified that all of the information you provided in your request, including all supplementary information, is true and correct, and constitutes a complete description of the material facts regarding the Arrangements. In issuing this opinion, we have relied solely on the facts and information you presented to us. We have not undertaken any independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion, we conclude that the Arrangements described in your advisory opinion request and supplemental submissions could constitute prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals of Federal health care program business were present, but that the OIG will not subject the Drug Program, as described in the request and supplemental submissions, to sanctions arising under the anti-kickback statute pursuant to sections 1128B(b), 1128(b)(7), or 1128A(a)(7) of the Act.

This opinion may not be relied on by any persons other than the addressees and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

The requesters of this advisory opinion are four hospital providers located in four counties in the northeast of State X (the "Hospitals"). The first requester is Hospital One ("Hospital One"), which operates one hospital in County A, State X, and three hospitals in County B, State X. The second requester is Hospital Two ("Hospital Two"), which operates one hospital in County A, State X, one hospital in County B, State X, and one free-standing emergency facility in County C, State X. The third requester is Hospital Three ("Hospital Three") located in County D, State X. The final requester is Hospital Four ("Hospital Four") located in County B, State X. These Hospitals represent all of the hospital providers in the greater [four county] metropolitan emergency medical services area (the "Four County EMS Area").¹

Each Hospital is a member of at least one of the three emergency medical services ("EMS") councils operating in the four-county area (the "EMS Councils"). The first EMS council is Council F ("Council F"), which operates in County A. Council F's mission is, among other things, to coordinate the various levels of EMS, educational programs, and interaction between pre-hospital care providers and other health care providers in the county and to encourage the implementation of EMS standards and criteria pursuant to local, state, and national guidelines. Hospital One and Hospital Two are members of Council F. The second EMS council is Council G ("Council G"), which operates in Counties B and D. Council G's mission includes upgrading emergency medical care in the region; serving as a central coordinating body; and implementing and monitoring systems of quality assurance for EMS in the region. Hospitals One, Two, Three, and Four are all members of Council G. The third EMS council is Council H ("Council H"). Council H was formed to oversee pre-hospital emergency medical care in the county, including promulgating standard, community-wide pre-hospital EMS operating protocols. Hospital Two is a member of Council H. Each EMS Council has diverse membership, including, among others, local physicians, hospital representatives, paramedics, EMS technicians, consumer representatives, EMS education providers, and local officials.

The Hospitals participate in a pharmaceutical restocking program (the "Drug Program") with area ambulance providers in connection with emergency medical transports. Typically under the Drug Program, a receiving hospital restocks an ambulance with the medications used in connection with emergency pre-hospital services provided by the ambulance provider to the transported patient. The EMS units are not charged, and do not pay, for restocked items. As part of the exchange, the EMS unit must provide documentation of the drugs used during the ambulance run. All hospitals in the Four County EMS Area participate in the Drug Program; any other hospital located within the four-county area may participate. The restocked pharmaceuticals are provided to any ambulance provider that transports an emergency patient to the hospital.

Council F, Council G, and Council H have facilitated the Drug Program within the four-county area in various ways. The EMS Councils' activities have included, for example: initiating drug exchange programs; approving policies and protocols that govern drug exchange programs; creating and implementing protocols for the administration of drugs used during patient transport; and coordinating efforts between public and private pre-hospital providers, hospital emergency staff, and consumers to promote the highest quality medical care for victims of sudden illness or injury.

The Hospitals also propose a limited medical supplies restocking program (the "Supply Program"), pursuant to which the Hospitals would restock certain supplies used by ambulance providers during emergency pre-hospital transportation. To initiate, coordinate, and monitor the Supply Program, the Hospitals have established a joint committee, comprised of the EMS coordinator or a higher level employee from each Hospital. Any hospital located within the four-county area may participate. The restocked medical supplies will be provided to any ambulance provider that transports an emergency patient to a participating hospital.

The Hospitals want to establish a limited supply exchange program targeting specific supplies that they believe will enhance efficient coordination and integration between their emergency rooms and emergency pre-hospital care providers. To this end, the joint committee developed the following list of medical supplies to be restocked under the auspices of the Supply Program: intravenous solutions; intra-

¹There are other hospitals in the four-county area that are geographically distant from the Hospitals and therefore not part of the Four County EMS Area.

venous tubing; intravenous catheters and needles; oxygen cannulas and oxygen masks; endotracheal tubes; tuberculin, intramuscular and 10 cc syringes; blood collection tubes; and linens.²

The Supply Program will allow ambulances to be fully stocked with a standard complement of these supplies, making it easier, for example, for patients arriving by emergency ambulance to be connected to Hospital emergency room systems without interruption.

II. LEGAL ANALYSIS

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by any Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce referrals of items or services for which payment may be made by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, in cash or in kind, directly or indirectly, covertly or overtly.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. This Office may also initiate administrative proceedings to exclude persons from Federal and state health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.³

This Office's concern with the provision of goods and services for free or at below-market rates to potential referral sources is longstanding and clear: such arrangements are suspect and may violate the anti-kickback statute if one purpose is to induce referrals of Federal health care program business.

The provision by a hospital of free supplies and medications to an ambulance provider fits squarely within the meaning of remuneration for purposes of the anti-kickback statute. An inference may be drawn that one purpose of such remuneration is to induce the ambulance provider to bring patients to the hospital. However, the strength of that inference may vary with the circumstances of the specific arrangement.

With respect to the Drug Program, the factual circumstances presented here are substantially similar to those present in the factual circumstances addressed by OIG Advisory Opinions 98-7 and 98-13. Thus, for the reasons stated in those opinions, we conclude that the OIG would not subject the Drug Program, as described in the request letter and supplemental submissions, to sanctions under section 1128B(b), 1128(b)(7), or 1128A(a)(7) of the Act.⁴ As in those opinions, the involvement of the entire EMS community in the Drug Program, including hospitals, EMS physicians, ambulance providers, paramedics, EMS education providers, consumer representatives, and local officials, provides adequate assurance that the plan is designed to improve and enhance the delivery of EMS in the Four County EMS Area for the benefit of the entire community.

While we recognize that the Supply Program may also provide a community benefit, we are unable to reach a similar conclusion with respect to the application of the anti-kickback statute to that program. The Supply Program would be implemented under the auspices of a committee formed exclusively of Hospital representatives, rather than an EMS council or similar group more broadly representative of the EMS community at large. The involvement of a broad range of representatives of the EMS community provides substantial assurance that an ambulance restocking program will operate for the benefit of the local community and will not be undertaken solely for the benefit of a single provider or group of providers.

²Linens are included to ensure appropriate compliance with sanitization requirements for laundering linens used by hospital and ambulance patients.

³Because both the criminal and administrative sanctions related to the anti-kickback implications of the Arrangements are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under both.

⁴This advisory opinion only relates to the restocking of drugs and supplies directly related to the provision of emergency pre-hospital services. Restocking of drugs or supplies used in connection with non-emergency services are outside the scope of this opinion.

We wish to make clear that this opinion does not mean that the Supply Program (or similar ambulance restocking programs) would violate the anti-kickback statute. Rather, because it involves the provision of free goods to potential referral sources, the Supply Program might violate the statute if one purpose of the Program is to induce Federal health care program business. Thus, whether the proposed Supply Program would, in fact, be unlawful requires a case-by-case determination of the actual intent of the parties based on all relevant facts and circumstances. We cannot determine intent based solely on documentary submissions; accordingly, a determination of intent is beyond the scope of the advisory opinion process. See 62 Fed. Reg. 7351 (Feb. 19, 1997).

III. CONCLUSION

The advisory opinion process is a “means of relating the anti-kickback statute to the particular facts of a specific arrangement.” 62 Fed. Reg. 7350, 7351 (Feb. 19, 1997). The advisory opinion process permits this Office to protect specific arrangements that “contain[] limitations, requirements, or controls that give adequate assurance that Federal health care programs cannot be abused.” *Id.* In evaluating an arrangement’s potential to lead to fraud or abuse of Federal health care programs, no one fact or element is necessarily dispositive. We are further persuaded that, taken as a whole, the aspects of the Drug Program described above—including, but not limited to, the Hospitals’ relationships with coordinated regional EMS systems, the role of the regional EMS councils, and the Program’s limitation to emergency medical services—create sufficient limitations, requirements, or controls so as to give adequate assurance that the Drug Program will not lead to program abuse under the anti-kickback statute.⁵ The Supply program does not contain similar safeguards.

Accordingly, we conclude that while the Arrangements might technically violate the anti-kickback statute, if the requisite intent to induce referrals were present, the OIG will not impose sanctions on the requesters in connection with the Drug Program under sections 1128(b)(7) (as it relates to kickbacks) or 1128A(a)(7) of the Act, based on the facts certified in the requesters’ request for an advisory opinion. The OIG cannot give a similar assurance that the Supply Program would not be subject to sanction if the parties were to have the requisite intent to induce referrals of Federal health care program business.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

This advisory opinion is issued only to the Hospitals listed on the Attached Distribution List, which are the requesters of this opinion. This advisory opinion has no application, and cannot be relied upon, by any other individual or entity.

This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requester to this opinion.

This advisory opinion is applicable only to the statutory provisions specifically noted in the first paragraph of this advisory opinion. No opinion is herein expressed or implied with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangements.

This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

This advisory opinion is limited in scope to the specific arrangements described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The Office of Inspector General (“OIG”) will not proceed against the requesters with respect to any action that is part of the Arrangements taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangements in practice comport with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against any requester

⁵ We express no opinion regarding liability of the requesters under the False Claims Act or other legal authorities in connection with any improper billing or claims submission directly or indirectly related to, or arising from, the Arrangements.

with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

D. McCARTY THORNTON
Chief Counsel to the Inspector General

Chairman THOMAS [presiding.] Inquiries briefly?

Mr. STARK. Yes. I was just going to say, was there not a case, a case you were talking about in Ohio for restocking?

Mr. THORNTON. Yes. The subject of some of the restocking opinions have come from Ohio. That is correct.

Mr. STARK. And where hospitals were offering to restock free?

Mr. THORNTON. For free, right. If the hospitals were charging fair-market value for what they restocked, that would be perfectly legal. That would be perfectly fine.

Mr. STARK. Is that any different than, you know, offering a physician a free tank of gas every time he comes to call on a patient in the hospital? It seems to me that you could get into the question of whether you are just restocking the driver's coffee or whether you are restocking thousands of dollars worth of pharmaceutical products. And it would depend on—it would seem to me you either force all hospitals to do that or you are offering an inducement.

Now I don't care whether—if it's not an inducement—what if you offered the driver of the ambulance frequent flier miles for every patient they bring in? So you come to the Little Sisters of Mercy Hospital, we'll give you 5,000 free United Airline miles. Is that an inducement? Is that legal?

Mr. THORNTON. It would certainly not be—we could not write an advisory opinion that it is legal for sure.

Mr. STARK. Yes. It could be that there are some things that are *de minimis*, but my suspicion is that it was other hospitals who complained that it [the restocking] was unfair and/or that it was, in fact, an inducement, a commission. I don't care what you want to call it. Now, the amount of that might, it might be *de minimis*. I guess that is always a problem.

But there is no question that the hospital benefits by getting business, patients if you will. And therefore, it seems to me—and I don't know how many examples the gentlelady would like, but this has happened and the question is, is that proper. That is the issue.

Mr. THORNTON. And we didn't say it was a violation of the anti-kickback statute. The advisory opinion process crafted by this Committee, was carefully done. It excluded questions of intent. We are not to rule on questions of intent. So when an advisory opinion comes in, we don't deal with intent. We are asked on these facts, could this ever be a kickback or not.

OK? And we work with requestors, and oftentimes they will make adjustments in their requests so that we can give them a favorable result. We have done that three-quarters of the time, including some ambulance services and ambulance response systems,

including a city down in Texas that was putting into effect a new EMS system. We worked with them.

But having intent off the table, the question is, could a hospital ever intend to induce ambulance companies to favor them by giving away things, well they could. They could.

Mr. STARK. Of course.

Mr. THORNTON. But under some circumstances, well, many circumstances, it could be done legally. And we volunteered that advice to the people too. All that has to be done is the items have to be paid for, or if every hospital in the locality is doing it according to a standard EMS system. That is OK too.

Mr. STARK. Makes good sense to me. Thank you.

Mrs. JOHNSON of Connecticut. I think you did not understand—

Chairman THOMAS. The gentlewoman from Connecticut.

Mrs. JOHNSON of Connecticut. Thank you. Thank you very much, Mr. Chairman.

I think you did not understand the intent of my line of questioning. First of all, when you are 6 years behind on the regulations, you frankly don't have time to do a waiver by waiver on this particular kind of issue. Where you clearly see a pattern—it would be all right if you pay or be all right if everybody does it. So it is not an inducement.

What I was asking you was, do you have the power then, either through an exception in this or some kind of power of the central government to say, if these two patterns are met, don't come to us for a waiver because this is legal.

Mr. THORNTON. Yes. We do.

Mrs. JOHNSON of Connecticut. So you create certainty. See, you didn't create certainty through your first ruling saying this isn't necessarily so. See. And you don't have to prove intent on a self-referral. So intent is irrelevant.

Mr. THORNTON. That's right. Everything that we in the Inspector General's Office does is on the anti-kickback statute. HCFA has total charge of the self-referral statute. All of my advisory opinions are under anti-kickback. And we do have the authority to make safe harbors, which is exactly what you are referring to.

Mrs. JOHNSON of Connecticut. But you haven't done that yet, have you?

Mr. THORNTON. Not for ambulance restocking.

Mrs. JOHNSON of Connecticut. Why not?

Mr. THORNTON. Actually, we are considering a safe harbor for that practice resulting from what—

Mrs. JOHNSON of Connecticut. This has been going on—this has been a big problem for a year and a half. It is not hard to see that it is an easy safe harbor if you are all doing it or if you are paying. Why didn't you have that done like 6 months ago, 9 months ago, a year ago? Why are you letting them hang out there?

Mr. THORNTON. We have eight safe harbors just about to come out. That is not one of them, but we have identified several ways to make arrangements legal and publish them, put it up on our Web site.

Mrs. JOHNSON of Connecticut. I think my point is made, and I hope sometime you will act on it.

Chairman THOMAS. Thank the gentlewoman. I apologize for not being here. I was over at a meeting with the Speaker, but I have been informed by staff and others that maybe some statements were made that, if not gratifying, would at least be comforting. I understand, Mr. Thornton, in partial response to the gentleman from Louisiana's question in reference to the comment I made before we started the program, that when we were trying to deal with advisory opinions, you were somewhat vociferous about how it would, if not be the end of the world, be damn close.

And my question to you just recently before we started this was, if you knew then what you know now, would you have been as opposed to the idea of advisory opinions? And you said, well, I won't put words in your mouth. What did you say?

Mr. THORNTON. I said, honestly, yes.

Chairman THOMAS. OK. Would it be useful, since you have mentioned now several times that you only have the advisory opinion power in the area of anti-kickback, if you had advisory opinion in the area of self-referral?

Mr. THORNTON. That is actually on the books. And since HCFA has responsibility for that section, they have that authority.

Chairman THOMAS. I notice you divided that very neatly. But in part, all of the trends of these questions are going in exactly the direction that I think I, unfortunately, was talking about when I left. And I don't know if we have made much progress.

If you haven't put the regs out and people give horrendous examples of the kinds of things they could be punished for, for example, parking, meals, et cetera, and you have indicated that you are going to be carving out various exceptions for these, again trying to figure out where the bright line is, then where do you stop? For example, everyone would agree free parking doesn't make a whole lot of sense in terms of somehow providing a self-referral, an inducement.

What about picking you up in a limousine and dropping him off in a limousine? Does that cross the line?

Ms. BUTO. I am sorry. I didn't quite hear that.

Chairman THOMAS. Well, we are talking about inducements. And the problem is, if you catch my drift, I can begin asking you examples which are only gradations above the one that you feel comfortable with now, saying that is *de minimis* and we are going to go ahead and say, free parking is not an inducement, meals are not an inducement.

Are we talking about meals in the hospital cafeteria? What about meals at the nicest restaurant in town? What about, as I said, picking up and being dropped off by a limousine?

The point I am trying to make is, if you start down that road with a law which forces you to begin to do that, you simply will never keep up with the people who are as at least as clever as you are, but who are paid a whole lot more. So they will probably burn the midnight oil to stay ahead of you.

And I do not understand why you just absolutely want to stay where you are in a situation where, even if you are able to play the fringe arrangements, are you going to require hospitals to report any of these kinds of activities?

Ms. BUTO. No.

Chairman THOMAS. You are not going—how do you know they are going on then if you don't require them to report them?

Ms. BUTO. What we want to do is, I think what I hear you saying you want to do, is to simplify the rules in a way that—

Chairman THOMAS. No. I want to change or drop the law, if you didn't understand that from my opening statement. I think the compensation part you can chase but you can never catch. Now, here is the second part: Are you still going to require hospitals to submit to you information about the financial relationships with physicians?

Ms. BUTO. No. We are not. We are not going to ask hospitals or other providers and suppliers to submit information to us. We are essentially, saying that we expect them to keep the same records on their relationships that they would keep for the IRS or the SEC or for Medicare and Medicaid generally that we look for in an audit.

And we are not going to ask them to be submitting this information to us. Now many of them want advisory opinions on whether something is permissible.

Chairman THOMAS. Yes.

Ms. BUTO. That is fine. They come into us and we will take a look at it. But we are not asking for reporting.

Chairman THOMAS. And would that advisory opinion be restricted only to that particular relationship, or would it go up on the net so that everybody now has a kind of a safe harbor?

Ms. BUTO. We want to publicize and make available the advisory opinions, just as the Inspector General does, to anyone who is interested in these opinions.

Chairman THOMAS. And would that then be a rebuttable presumption in terms of them being covered if they argue that that is what they are doing? Or do they do it at their own risk?

Ms. BUTO. Again, unless we either have a complaint or we do an audit and we challenge what they are doing, we are assuming that they are complying. We are assuming the providers are complying with the statute. Our experience is they are complying with the statute. They are all essentially, from the standpoint of due diligence, looking at what they are responsible for in Medicare and Medicaid and they are following those rules.

Chairman THOMAS. One of the difficulties I have is, is even in the opening statement of my friend and, obviously, we all have our particular views of this. I honestly think the genesis of this legislation was exactly the opposite of the statement that you just made. That, in fact, these health care professionals, by and large, are crooks. And that what you have got to do is set up a procedure which allows you to show they are crooks.

And that what you are forced to do, is to examine a series of relationships and say, "yes" or "no."

The ownership side, I can understand how you can follow that. The compensation side I think you will never, ever be able to get on top of unless you write so many exceptions that it is a nonsense. Or, you tell them, keep accurate records just like the IRS because we may pounce at any time.

That kind of a veiled threat hanging over someone who is trying to be creative and save dollars but deliver health care the best way

they can, is nonsense in today's world, as well as the changing relationship of the mix of healthcare delivery structures and the pattern of healthcare delivery.

And I just don't know why we can't get together and talk about where we can create a very solid enforcement structure to get at fraud and abuse without the kind of harassing and worrying structure that this kind of a self-referral law produces.

That, I think, is the bottom line.

Now, I thank you very much for your testimony. If there are no other questions, thanks. And, Mr. Thornton, I look forward to you coming before this Committee with me as Chairman in a couple of years saying, "If I knew then what I know now, the change that we made in the self-referral laws was a good one," because we are going to make one.

Thanks a lot.

Mr. THORNTON. We are ready to help you, sir.

Chairman THOMAS. If we could ask the second panel to come forward. Thank you for your patience.

The next panel consists of Mr. Sanford Teplitzky who has immersed himself in this area as a past president of the National Health Lawyers Association; Mr. Mitchell Wiet. I will only say that he is representing Northwestern University Memorial Hospital in Chicago because the gentleman from Illinois, Mr. Crane, wishes to provide a more complete personal introduction. And he will be here in just a moment.

And then we have Dr. David Morehead, who is chief executive officer of Scott and White, who is a pediatrician, and Dr. Bruce Hauser with the American College of Radiology.

Any written testimony that you will have will be made a part of the record. And you can address us in the time you have in any way you see fit. And we will start with Mr. Teplitzky and move across the line.

STATEMENT OF SANFORD V. TEPLITZKY, PARTNER, OBER, KALER, GRIMES & SHRIVER, AND PAST PRESIDENT, NATIONAL HEALTH LAWYERS ASSOCIATION

Mr. TEPLITZKY. Mr. Chairman, Mr. Stark, and other Members of the Subcommittee, my name is Sanford Teplitzky, and I appear before you today as a lawyer in private practice who is asked to answer questions regarding the self-referral legislation on a daily basis.

Approximately 20 years ago, I was in the general counsel's office of what was then known as the Department of Health, Education, and Welfare. I actually predate HCFA, which is a scary thought to me. But that experience has provided me with a perspective on the development, implementation, and enforcement of fraud and abuse laws.

It is why I have been very active in advocating for laws that are straight forward and unambiguous, and penalties that are severe enough to punish wrongdoers and to deter others who might steal from the Federal taxpayer.

I have been the Chairman of the National Health Lawyers Association annual health care fraud and abuse program for approxi-

mately 10 years and I am a past president of the National Health Lawyers Association.

In our efforts to secure laws that are clear, and responsible government action with respect to those laws, we advocated strenuously for the advisory-opinion legislation which has been the subject of earlier discussion today. And I am pleased to see that legislation is bringing us the results, the exact results, that we intended at the time. It didn't bring about the end of the world. Rather, for the first time real and substantive guidance is being provided to the health care industry.

I have clients that both support and oppose the self-referral legislation. But their problems are identical, they don't understand the law. Even those who support the law call me with questions about it on a daily basis.

There are four particular concerns I would like to raise with you today in my very brief time. First, the original intent of the law has been unmet. It is very clear that the framers of the legislation wanted a bright-line rule. The law has brought no bright-line rule to this area.

This is a copy of the proposed regulations issued by HCFA under this statute. This is what I have to look at everyday when someone calls with a question. The law was effective in 1995. We are in 1999. There are still no final implementing regulations.

Second, the law and proposed regulations are ambiguous and confusing. A document was published by the National Health Lawyers Association in cooperation with six law firms with extensive experience in this area. This publication consists of 54 single-spaced pages and addresses questions that either the proposed regulations didn't answer or questions that were created by the proposed regulations.

Third, the law is inconsistent with recent government initiatives. The development of integrated systems and the change in reimbursement systems by the Federal Government itself are inconsistent with the concept that physicians and other healthcare providers can have no financial relationships with each other. In fact, the incentives that the Government has created are intended to push providers closer together to identify new ways to deliver health care in this country.

And finally, the current law both duplicates and is inconsistent with other Federal and State provisions. The anti-kickback statute, which was the subject of earlier testimony, addresses the issue of financial compensation relationships between healthcare entities. Further, many of the States in this country have enacted their own self-referral laws, and I would suggest to you that each of those laws is different in some respects from the Federal self-referral legislation.

There are provisions that are different. There are prohibitions that are different. There are exceptions that are different. For example, the Federal self-referral legislation has an exception for equipment rentals. The Maryland statute does not. So how does the provider determine whether or not the relationship is appropriate?

Going back to the original intent of the statute, we know that there were *perceived* abuses at the time based upon a number of studies that indicated that physician involvement increased utiliza-

tion. Those studies did not indicate, however, that the increased utilization was wrong; only that there was increased utilization.

There was a concern that the anti-kickback statute was too broad and, therefore, could not be understood. To some extent, that has changed. This committee and Congress created a civil penalty under the anti-kickback statute, and has allowed the Inspector General to move in that direction. As I said earlier, advisory opinions have also provided much needed guidance.

With respect to the attempt to identify a bright line, I have before me a chart which identifies the path we take as private attorneys in answering questions for our clients. It is not a bright line. It can't be a bright line.

When one works with the anti-kickback statute, after awhile you tend to "get it." Advisory opinions help you understand it. However, I don't "get" the self-referral law and I work with it almost every day. And my clients don't get it, even the clients that support the law.

I can't even scratch the number of questions that exist. For example, is lithotripsy a designated health service? Is cardiac catheterization a designated health service?

How can a teaching hospital provide critical support to a faculty practice plan to ensure the future of academic medicine? The answer is that it can't under the way the proposed regulations are written. The proposed regulations will kill academic medicine in this country.

And the Chairman has already mentioned the issues of free parking and free coffee and the like.

If the Congress and the Administration want to truly develop a bright line, which can be understood by all, the current legislation cannot remain unchanged.

I do not seek to destroy the ability of the Federal healthcare programs to protect themselves against fraud and abuse. Rather, I advocate for a system of laws which can be understood by all so that those who seek to comply can do so, and those who choose not to comply, will be consistently and severely punished.

Thank you for allowing me to appear before you today.

[The prepared statement follows:]

Statement of Sanford V. Teplitzky, Partner, Ober, Kaler, Grimes & Shriver, and past President, National Health Lawyers Association

Mr. Chairman and Members of the Committee, my name is Sanford Teplitzky and I appear before you today as a private attorney who is asked to answer questions about how to interpret and comply with the self-referral legislation on a daily basis. More than twenty five years ago, I worked in the General Counsel's office in what was then the Department of Health, Education & Welfare. That experience has given me a perspective on the development, implementation and enforcement of laws and administrative policies aimed at protecting the federal health care programs and their beneficiaries. During my tenure in the government, I was assigned primary responsibility for the implementation of the Medicare and Medicaid fraud and abuse amendments of 1977. That law significantly expanded both the scope and nature of the Medicare and Medicaid anti-kickback statute.

My work with federal and state fraud and abuse legislation has continued in private practice. I am the Chair of the Annual Health Care Fraud and Abuse Program sponsored by the American Health Lawyers Association, formerly the National Health Lawyers Association. Additionally, I served as President of the National Health Lawyers Association in 1993 and 1994.

I believe that a majority of health care providers in this country strive to comply fully with all applicable laws. In this regard, I have continually advocated for laws

that are straightforward and unambiguous, and for penalties that are severe enough to punish the wrongdoers and to deter those who would abuse the federal taxpayer. Clarity of the law is crucial in my view, and that is why I advocated strenuously for the advisory opinion legislation which this Committee and the Congress approved as part of HIPAA and the Balanced Budget Act of 1997. This legislation has already served to provide critical guidance to the industry with respect to the federal anti-kickback statute and the self-referral legislation, which is the subject of today's hearing. Let me briefly summarize the concerns I have with the current self-referral legislation:

- I. The original intent of the law is unmet:
 - To address the possibility of over utilization or increased costs resulting from physician ownership of ancillary health care providers;
 - The law was designed to, but has not developed, a "bright line";
 - The law became effective for services furnished on or after January 1, 1995—HCFA did not publish proposed regulations until January, 1998—final regulations may be two additional years;
- II. The law and proposed regulations are ambiguous and confusing:
 - The proposed regulations were 400 double-spaced pages;
 - The proposed regulations raise a number of questions that were not answered;
 - Providers implementing corporate compliance programs must have answers—it is not sufficient to await enforcement actions by the government or *qui tam* actions by private litigants;
- III. The law is inconsistent with other government initiatives:
 - HCFA and other payors are encouraging the development of integrated delivery systems with physician participation;
 - The current self-referral law serves as a hurdle to physician participation;
 - The law generally requires the establishment of a fixed fair market value payment—integrated delivery systems requires incentives to provide more efficient health care services.
- IV. The current law duplicates other federal provisions:
 - The anti-kickback statute addresses compensation relationships and has been amended to authorize the imposition of civil money penalties;
 - Numerous states have enacted provisions that are different than, and often inconsistent with, the federal anti-self-referral law.

I believe that it is critical for this Subcommittee to review the original intent behind the self-referral legislation and the perceived abuses that were the subject of the legislation. As stated by its sponsors, this legislation was intended to prevent physicians from abusing the trust of their patients by receiving an economic benefit based upon the services they prescribe for their patients.

In the late 1980s and early 1990s, there was concern in Congress and the Administration that the laws in effect at that time were insufficient to punish providers who place their personal financial gain over the interests of their patients. The Medicare and Medicaid anti-kickback statute was viewed as overly broad and difficult to enforce, and its penalties were limited to criminal fines and jail or exclusion from the Medicare and Medicaid programs. Additionally, little guidance had been issued by the OIG regarding the types of arrangements that would be viewed as violating the anti-kickback statute.

You may recall the statement of Congressman Stark regarding the purpose of the self-referral legislation:

What is needed is what lawyers call a bright line rule to give providers and physicians unequivocal guidance as to the types of arrangements that are permissible and the types that are prohibited. If the law is clear and the penalties are severe, we can rely on self-enforcement in the great majority of cases.

Unfortunately, the existing self-referral legislation does not establish a bright line rule. In fact, it is now clear to me that it may simply not be possible to establish a bright line rule in the face of a dynamic regulatory environment. The Medicare and Medicaid rules continue to change every year. Both the Congress and Federal Government have moved away from traditional fee-for-service payment methodologies in favor of reimbursement mechanisms that are designed to challenge providers to fundamentally change the manner in which health care services are provided. Such initiatives include the development of prospective payment systems, fee schedules, and other initiatives intended to encourage and promote the delivery of cost effective high quality health care services for Medicare beneficiaries.

Behind me is a chart that indicates the chronology of the development of the self-referral legislation. You will note that the original law was enacted in 1989 with an effective date of January 1, 1992. Even before that effective date, certain amendments were passed in 1990.

A major amendment to the statute was enacted in 1993 with an effective date of January 1, 1995, and again almost immediately, in 1994, additional changes to the law were enacted. Thus, it is clear that Congress itself has struggled with the concept of defining a bright line.

Furthermore, we now sit here almost six years after the passage of the law, and four years after the effective date of the law, without definitive guidance from HCFA. I have before me a copy of the proposed regulations that were published in January of 1998. Additionally, I have a copy of an analysis of the proposed regulations that were issued by the American Health Lawyers Association. The document was drafted through a cooperative effort of at least six different law firms with extensive experience in fraud and abuse and self-referral issues. The document is 54 pages single-spaced and raises numerous questions that were either unanswered by the proposed regulations or, in some cases, generated by the proposed regulations.

If we can return for a moment to the original intent of the statute, I want to raise a number of particularly troublesome issues. As I noted earlier, the original intent of the statute was to address situations in which a physician's conflict of interest is resolved in favor of the physician's economic interests and against the health care interests of the patient. However, the original legislation included an exception for services provided in the physician's own office. In other words, while the law would prohibit the referral of a patient by the physician to an outside entity, that physician could provide the exact same services within his or her own office and be paid for those services. The area in which the potential conflict of interest is probably most apparent was immediately exempted from the prohibitions of the statute.

Moreover, it is clear that the legislation has become a tool of competition and turf battles. Throughout the years, various groups have advocated or opposed, the inclusion, or exclusion, of certain designated health services. Are these health care groups generally thinking of the health care interests of Medicare and Medicaid beneficiaries? I think not. Rather, they are assessing their role in the health care delivery system and the desire to preclude physicians and others from becoming competitors.

I noted earlier that the legislation, at least in my view, resulted from a belief that existing laws could not address the abuses sought to be prohibited by this legislation. However, even that world has changed. For example, the OIG published regulations in 1991 describing business relationships that would not be subject to sanctions under the statute. These regulations are known as the safe harbor regulations. I understand that they are currently working on another set of safe harbor regulations.

Let me return for a moment to the issue of the concept of a bright line. I must tell you that having worked with the federal anti-kickback statute for many years, you tend to "get it." There is a rationale to the statute, and in part due to the advisory opinions issued by the OIG over the last two years, a recognizable analysis that is applied to all health care business transactions in order to determine whether they conflict with the anti-kickback statute.

Unfortunately, the same cannot be said for the self-referral legislation. I could be asked a question at 9:00 o'clock in the morning and I will have to fight my way through the maze of the proposed regulations. If that same question is asked at 1:00 o'clock in the afternoon, I simply can't remember the path I took to respond to the question earlier in the day and I must go through the exercise again. I am getting older, but I do not believe that my age has anything to do with this condition. Behind me is a chart of the machinations that are required to analyze any fact pattern under the self-referral legislation.

I have appeared on numerous panels with representatives of HCFA and the OIG during which this legislation has been discussed. Those individuals have been quite honest and candid in responding to questions. However, their responses have not constituted for the most part, answers. Rather, they respond with their own questions, assumptions, and predictions of what the final regulations might look like. This is simply unacceptable to the great majority of providers who want, need, and deserve answers. I cannot provide definitive guidance to my clients.

I cannot even scratch the surface of the types of questions I receive on a daily basis regarding this legislation. For example, is lithotripsy a designated health service; is cardiac catheterization a designated health service?

How can a teaching hospital provide critical support to physicians in a faculty practice plan to ensure the future of academic medicine? And, issues that appear as trivial as can a hospital provide free parking to physicians.

If Congress and the Administration truly want to develop a bright line which can be understood by all, the current legislation cannot remain unchanged. I advocate for a system of laws that can readily be understood by all.

I look forward to your questions. Thank you.

Chairman THOMAS. Thank you very much.
Mr. White.

**STATEMENT OF MITCHELL J. WIET, J.D., VICE PRESIDENT AND
GENERAL COUNSEL, NORTHWESTERN MEMORIAL HOS-
PITAL, CHICAGO, ILLINOIS**

Mr. WIET. Thank you very much, Chairman Thomas, Ranking Minority Member Stark, and other distinguished Members of the Subcommittee. I am Mitchell Wiet, vice president and general counsel at Northwestern Memorial Hospital. Thank you for the opportunity to testify here today.

Northwestern Memorial Hospital is a 750-bed academic medical center located in downtown Chicago and is the primary teaching hospital affiliated with Northwestern University Medical School. As with many academic medical centers, our full-time faculty is organized in a 450-physician, multi-specialty group practice called the Northwestern Medical Faculty Foundation. NMFF, as we call it, is completely independent of the hospital.

My goal today is to do my best to give you a snapshot of what it is like on a day-to-day basis for one hospital, albeit, a major academic medical center, to try to comply with the self-referral laws.

At Northwestern, we take our patients-first philosophy very seriously. We try to provide very high-quality and cost-effective care to our patients in the most appropriate settings. At times, the self-referral laws become insuperable obstacles to our efforts to meet the needs of our patients and the physicians who care for them.

Most troublesome in our view is that the self-referral prohibitions are absolute. If the law is implicated, an exception must apply or the arrangement is illegal. Intent is irrelevant. The element of knowledge or scienter plays no role. There is no consideration of motive. No room for judgment. No margin of error. The law is a strict liability statute, and the penalties are severe.

In my view, that absoluteness is the fatal flaw of the current self-referral law and regulations and is also what drives what is to me the mind-boggling complexity and volume of the rules published to date and those under consideration as further proposed rules.

The self-referral law's motives are good: prevent waste in our system by eliminating financial arrangements that put physicians' and/or hospitals' self-interests above the patients and patient care and lead to health resource utilization with questionable medical need.

In attempting to achieve this goal, however, the law has added tremendous costs to the system. The law has resulted in organizations incurring significant costs to determine to the best of their ability through exhaustive review and scrutiny whether common, well-meaning arrangements comply with this law.

We spend hundreds of thousands of dollars in staff time, in outside counsel expenses to comply with this law. Almost everyday cli-

nicians and administrators contact me and my staff seeking assurance that their plans to improve patient care are not in violation of a law they do not understand.

Please allow me to provide the following example that arose last year. This example has been simplified for the purpose of illustration of what was at the time an extremely complex issue.

We have a comprehensive breast center with a skyrocketing demand for mammography. Current reimbursement for mammography from Medicare as well as managed-care payers, has not caught up with the extraordinary advances in mammography technology that find smaller and smaller tumors.

Reimbursement also fails to recognize how much more labor-and resource-intensive this new technology is. Therefore, inadequate reimbursement is a reality for hospitals and physicians in this area.

Our patient-care goal in the breast center was to assure that we had an adequate number of radiologists so that we could meet the growing needs of our patients for mammograms. We were looking for a way to support our radiologists in order to provide high-quality, ever-increasing demand levels of care to our patients.

We entered into negotiations with the faculty practice plan. This entailed inside counsel review, then outside counsel consultation, looking at the statutory language, the proposed regulations, and legislative history and intent. We had memorandums back and forth between their self-referral expert and ours for weeks on end.

I provide this example for two reasons. First, after all this work by all these lawyers, we still couldn't agree on how to structure a deal to comply with the self-referral law.

As a result, we have not expanded our mammography services to meet the community's needs. In fact, we lost two mammographers, and only after 6 months have been able to replace them.

The wait time has increased dramatically in the breast center for an initial screening. And we continue to have a patient care demand we struggle to meet.

Second, both the hospital and the group practice spent thousands of dollars on outside counsel. This escalated to the point where we had dueling lawyers with opposite interpretations of what we could or could not do. Both sides opinions were supported by contradictory language in the proposed regulations, comments, and legislative history.

Those thousands of dollars collectively would have been much better spent on getting the mammography services to our patients. And the answer was, nothing was done.

Am I allowed further time?

Chairman THOMAS. Very briefly.

Mr. WIET. Pardon me.

Chairman THOMAS. You can sum it up.

Mr. WIET. Very well. Our suggestions. The current self-referral laws are hopelessly and irremediably unhelpful and counter-productive and wasteful. My strong recommendation is that what is commonly referred to as Stark II be replaced with clearer, simpler, and user-friendly measures. I suggest removing the absolute character of these laws and reintroducing the elements of intent and scienter.

The fraud and abuse laws are a good model. Then trust the courts and the legal process.

The ethical principles on which the self-referral laws are founded and which they seek to safeguard are not only correct, they are critically important, and should be retained, but in a far more balanced, much simpler and more practically helpful form that will facilitate ready compliance based on bright-line guidance.

Thank you, Mr. Chairman, Members of the Committee for the opportunity—

[The prepared statement follows:]

**Statement of Mitchell J. Wiet, Vice President and General Counsel,
Northwestern Memorial Hospital, Chicago, Illinois**

Chairman Thomas, Ranking Minority Member Stark, Congressman Crane and other distinguished Members of the Subcommittee, I am Mitchell Wiet, Vice President and General Counsel at Northwestern Memorial Hospital. Thank you for the opportunity to testify today.

Northwestern Memorial Hospital (NMH) is a 750 bed academic medical center located in downtown Chicago, and is the primary teaching hospital affiliated with Northwestern University Medical School. As with many academic medical centers, our full-time faculty is organized in a 450 physician multi-specialty group practice, called the Northwestern Medical Faculty Foundation (NMFF). NMFF is completely independent of NMH. In addition, while a part of (under common control with) the Northwestern Memorial corporate system, separately incorporated is the Northwestern Memorial Physicians Group, a 50-physician primary care practice. It is in the context of the hospital relationship with these two physician groups, that many of the self-referral issues arise.

My goal today is to give you a snapshot of what it is like for one hospital, albeit a major academic medical center, on a day-to-day basis to try to comply with these self-referral laws. At Northwestern we take our Patients First philosophy very seriously. We try to provide the best possible care to our patients in the most appropriate settings. At times, the self-referral laws become insuperable obstacles to our efforts to meet the needs of our patients and physicians who care for them.

Every arrangement entered into between a hospital and a physician, no matter how large or small, must be, and is, analyzed for compliance under the self-referral law. Hospitals are burdened in this manner largely because of four factors:

1. The law applies to all compensation arrangements between health care facilities and their physicians;
2. Designated health services include all inpatient and outpatient hospital services;
3. Notwithstanding the law's breadth and ambiguity, the law is absolute in its prohibitions; and
4. Unhelpful (dizzily complex and non-beneficial) exceptions which are narrow and apply to few common arrangements.

ALL COMPENSATION ARRANGEMENTS

The self-referral law applies to all financial arrangements, which include not only ownership or investment interests, but also all compensation arrangements. In the language of Stark, a compensation arrangement means "any arrangement involving any remuneration, direct or indirect, between a physician or a member of a physician's immediate family." Remuneration means "any payment, discount, forgiveness of debt, or other benefit made directly or indirectly, overtly or covertly, in cash or in kind." Therefore, the transfer of anything of value implicates the law. We joke that the provision of free coffee and doughnuts in the physicians' lounge may violate the law. But how much further can you go before the law applies. Discounted meals? Free meals? Discounted parking?

INPATIENT AND OUTPATIENT HOSPITAL SERVICES

Designated health services include all inpatient and outpatient hospital services. Therefore, every physician who is on staff at a hospital, unless the physician is inactive, refers patients to the hospital for inpatient and outpatient services. Every one. Therefore, no physician on the medical staff of a hospital is exempt from the law's scope—any transaction the hospital does with any physician on staff must be vigorously scrutinized.

ABSOLUTE PROHIBITIONS

Most troublesome to us is that the Stark Law's prohibitions are absolute. If the law is implicated, an exception must apply or the arrangement is illegal. Intent is irrelevant. The element of knowledge or scienter plays no role. There is no consideration of motive. No room for judgment. No margin of error. The law is a strict liability statute and the penalties are severe. In my view, that absoluteness is the fatal flaw of the current self-referral law and regulations and is what drives the mind numbing complexity and volume of the rules published to date.

THE RESULT

The self-referral law's motives are good—prevent waste in our system by eliminating financial arrangements that put physicians' and/or hospitals' financial self-interests above patient care and lead to health resource utilization with questionable medical need. In attempting to achieve this goal, however, the law has added tremendous costs to the system. The law has resulted in organizations' incurring significant costs to determine to the best of their ability through exhaustive review and scrutiny whether common, well-meaning arrangements comply with the law. We spend hundreds of thousands of dollars in staff time and outside counsel expenses to comply with the law.

For hospitals and other providers, the law applies to anything we do for or with any physician on our staff. Because of its absolute prohibition, there is zero tolerance for non-compliance. Therefore, every day clinicians and administrators contact me and my staff seeking assurance that their plans to work together with physicians to improve patient care are not in violation of a law they do not understand.

To give you an understanding of the types of arrangements that we must analyze on a day-to-day basis, I submit the following real life issues that general counsels all over the country face and must analyze for compliance and then make core decisions about whether the application of the self-referral law is triggered by any of the following:

- May we provide physicians the free use of certain equipment in providing osteoporosis-screening services to the community?
- May we pay for a physician's transportation costs to a community event that will promote wellness services that include hospital and physician services?
- May we recruit a trauma surgeon to a community in order to maintain a Level III trauma designation and then pay the physician a per surgery amount?
- May we advertise in our hospital's community newsletter that a new physician has joined our medical staff, including his office location, telephone number and hours?
- May we pay physicians on an hourly basis for taking time away from their practices and attending meetings related to the improvement of care in their clinical specialty?
- May we enter into exclusive arrangements with medical directors to manage and provide clinical oversight for hospital departments?
- May we pay physicians for helping us achieve appropriate cost savings in the hospital (commonly called "gainsharing")?

Each and every one of these questions has been asked. All of them implicate the self-referral law. Do they comply with the self-referral law? In some cases, we can develop arguments that they do. However, we struggle to achieve great comfort in the strict liability context of the self-referral laws. In other cases, even HCFA personnel have indicated that they do not know or that there is a difference of opinion. What is certain is that we spend a significant amount of time and money trying to comply, but often we have no answer as to whether we have complied or we have failed. At other times, our review has led to the scuttling of initiatives from which the community would benefit.

Please allow me to provide the following example that arose last year. This example has been simplified for the purpose of illustration of what was at the time an extremely complex issue. We have a comprehensive Breast Center with a skyrocketing demand for mammography. Current reimbursement for mammography, from Medicare as well as managed care payers, has not caught up with the extraordinary advances in mammography technology that find smaller and smaller tumors. Reimbursement also fails to recognize how much more labor and resource intensive this new technology is. Therefore, inadequate reimbursement is a reality for hospitals and physicians in this area.

Our patient care goal in the Breast Center was to assure that we had an adequate number of radiologists so that we could meet the growing needs of our patients for mammograms. We were looking for a way to support our radiologists in order to provide high quality ever increasing demand levels of care to our patients. We en-

tered into negotiations with the faculty practice plan. This entailed inside counsel review, then outside counsel consultation looking at the statutory language, proposed regulations, and legislative intent. We had memorandums back and forth between outside counsel for both parties for weeks on end.

I provide this example for two reasons. First, after all this work by all these lawyers, we still couldn't agree on how to structure a deal to comply with the self-referral law. As a result, we have not expanded our mammography services to meet the community's needs. In fact, we lost two mammographers and only after 6 months have been able to replace them. The wait time has increased dramatically in the Breast Center for an initial screening. And we continue to have a patient care demand we struggle to meet.

Second, both the hospital and the group practice spent thousands of dollars on outside counsel. This escalated to the point where we had dueling lawyers with opposite interpretations of what we could or could not do. Both sides opinions were supported by contradictory language in the proposed regulations, comments and legislative history. Those thousands of dollars collectively would have been much better spent on getting the mammography services to our patients and the answer was nothing was done. All the costs were spent and no resolution of the issues was achieved.

What is clear is that we need a simple and effective way of analyzing arrangements. However, without the ability to articulate clearly those arrangements that the law should prevent, we as lawyers and our organizations' compliance officers, are left without the practically beneficial means to advise our clients effectively. The self-referral law is an over-broad, unbelievably complex law that results in difficult, uncertain and, often, ineffective policing of arrangements. Clear, simple guidance will enable us to enforce more effectively the law because we will be better equipped to apply it.

Our suggestions for how to simplify? The current self-referral law and rules are hopelessly and irremediably unhelpful, counter-productive and wasteful. My strong recommendation is that what is commonly referred to as Stark II be replaced with clear, simpler and user-friendly measures. I suggest removing the absolute character of this law and reintroducing the elements of intent and scienter. The Fraud and Abuse laws are a good model. Then, trust the courts and the legal process to help produce clearer and simpler bright line guidance rather than create an endless morass of rules in an attempt to individually address a potentially infinite number of exceptions and exceptions to exceptions.

The ethical principles on which the self-referral laws are founded and which they seek to safeguard are not only correct, they are critically important and should be retained, but in a far more balanced, much simpler and practically helpful form that will facilitate ready compliance based on bright line guidance.

Thank you Chairman Thomas and Members of the Subcommittee for the opportunity to testify. I am pleased to answer any questions that you may have.

Chairman THOMAS. Thank you, Mr. Wiet. Your written testimony will be made a part of the record. And now for an ATT introduction, that is after-the-testimony introduction.

The gentleman from Illinois, our colleague, Mr. Crane.

Mr. CRANE. I thank you very much, Mr. Chairman. And it is indeed a pleasure to welcome Mitchell Wiet, vice president and general counsel of Northwestern Memorial Hospital in Chicago. In addition to his duties at Northwestern, Mr. Wiet is a member of the graduate legal education practitioner faculty of the Health Law Institute of Loyola University, Chicago School of Law. He is also a faculty member of the Cook County Graduate School of Medicine.

Northwestern is an urban academic medical center located in the heart of downtown Chicago. It is the principal adult care teaching affiliate of the Northwestern Medical School.

As Mr. Wiet can attest to, Northwestern is one of the finest medical facilities in the country and is providing the best cutting-edge health care for tens of thousands of Illinoisans of every income

level each year. To that end last month, Northwestern opened a state-of-the-art facility that surpasses anything we have seen in the Chicago area.

We are all expecting even greater things from Northwestern in the future.

With Mr. Wiet's professional credentials and Northwestern's recognized commitment to providing all-around health care, Mr. Wiet is uniquely qualified to comment on today's topic, and I am grateful that I got back here in time to hear his testimony. And I apologize to all of you for being suddenly moved over into the Speaker's office for a quickie meeting.

But I want to also add one footnote. My dad got his medical degree at Northwestern Medical School, and we lived on Superior Street. Now, where we lived was an apartment building that has long since been razed, but those were good days in Chicago. And I remember vividly riding my tricycle through the alley and back and forth, up and down the streets.

But Mr. Wiet, it is certainly good to have you here today. Thank you.

Chairman THOMAS. Thank you very much.

And Dr. Morehead, you may proceed.

**STATEMENT OF C. DAVID MOREHEAD, M.D., PRESIDENT,
SCOTT & WHITE HEALTH PLAN, TEMPLE, TEXAS, ON BEHALF
OF THE AMERICAN MEDICAL GROUP ASSOCIATION**

Dr. MOREHEAD. Thank you. I am Dr. Dave Morehead. I have been a physician for over 35 years, and most of my career has been spent at Scott & White. Mr. Chairman, I ask permission to submit written testimony to the Committee and permission to abbreviate that testimony for my oral presentation.

Chairman THOMAS. Without objection.

Dr. MOREHEAD. I represent the American Medical Group Association, which is the leading advocacy group on behalf of the Nation's larger multi-specialty group practices. I work for Scott & White, which is a regional medical center located in central Texas, composed of a hospital of over 400 beds, over 500 physicians who practice with the clinic, and a health plan of over 165,000 members, twenty thousand of which are Medicare enrollees.

I appreciate very much the opportunity to testify because group practices, including my own are uniquely affected by this physician self-referral law.

First of all, although my comments will sound rather harsh, I don't want them to be misinterpreted because, as someone who has watched the practice of medicine for a long time, I have seen, as a result of this statute, the disappearance of some imprudent business arrangements which emerged during the 1980's. The AMGA and I recognize the good that the law has accomplished.

On the other hand, 10 years is a long time. Medicine has changed greatly during the past decade and some of the vagaries of the law have surfaced. Section 1877 needed to be revised.

AMGA's two major concerns are the ambiguity of section 1877 as well as the shifting regulatory interpretations of what the law actually means. Specifically, testimony will focus on two provisions of

the physician self-referral law—the provision covering the definition of a group practice, and the compensation arrangements.

First, the definition of group practice. This is very important because, the only definition of group practice found in the Medicare law is located in section 1877.

Most of the groups that I know of can meet the statutory requirements for group practices as they now stand. But we are concerned about the shift in the definition about what group practice is. Will we qualify in the future? Let me cite two examples.

In the HCFA rules proposed in January 1998, the definition of group practice changed. For example, contracted physicians were included as members of the group in the original law, but were excluded in the most recent provisions.

Second, if the 1998 provisions become final, Scott & White will be forced as an organization to change the accounting methods we employ for our regional clinics. These are examples of shifts in the interpretation of what the law means that cause group practices great concern.

The AMGA requests that Congress restrict the ability of regulatory agencies to reinterpret the meaning of the law as it relates to defining group practice.

Second, provisions covering compensation arrangements in section 1877 cause group practices considerable distress. Our group qualifies for the exception to the compensation arrangement under the in-house ancillary services provision. However, the provision also states that no member of the group can be remunerated based on the volume or value of his or her referrals.

Prohibiting remuneration based on volume of referrals places all compensation formulas that I know of in great jeopardy because it is the physicians that see the most patients who order the most tests, i.e., initiate the most referrals. They are the heavy hitters who work the hardest and who expect and deserve a greater percentage of the net revenue at the end of the year.

In order to attract the best and the brightest to our rural community, we must pay competitive salaries. And to do that, we must connect compensation to the production of the individual physicians. Those who refer the most make the most money—are we in violation?

Let me close with a hypothetical but accurate example. I will describe a place that I might be.

In this scenario, I am practicing in a small rural community of 4,000 citizens in west Texas. I grew up in this community, and I have a strong sense of obligation to its citizens. These are my people.

As in other parts of rural America, most of my patients are elderly and poor. Many live in the local skilled nursing home, and a large number suffer with heart disease. The closest major hospital and group practice is 75 miles away; I usually send my patients there because they provide good care.

I work 7 days a week and I close my office on Wednesday afternoons. Suddenly I have a great idea. What if I could convince that group practice 75 miles away to send a cardiologist twice a month to use my facilities while I am off on Wednesday afternoons and

provide care to the frail patients who cannot easily travel 75 miles for care.

I also need to borrow a Holter monitor, a tool which would allow me to monitor my patients' heart rates to help the cardiologist when he comes.

There are a number of problems with this arrangement. The clinic may or may not be interested in providing a cardiologist because they will lose money doing so. They may comply but just to help the community. They probably won't be willing to pay for my office space, and I cannot afford to purchase the Holter monitor.

The right thing to do is for the large clinic to provide both the cardiologist and the monitor and for me to provide my office space free of charge. But for the clinic to enter the arrangements they will have to hire a group of lawyers who will assess the situation and perhaps structure a deal that does not violate the self-referral law. The legal work is expensive and unnecessary.

Some have suggested that there is a lot of money in medicine but I assure you that there is no more money than is necessary. Every single dollar we waste on legal fees, are dollars we cannot use to develop patient-care programs.

American group practices recognize our obligation to comply with the law. We obey to the very best of our understanding. What we ask, is that the law be clarified so that that we understand the rules before we are judged by them.

Thank you very much for your attention. I will be happy to answer questions.

[The prepared statement follows:]

Statement of C. David Morehead, M.D., President, Scott & White Health Plan, Temple, Texas, on behalf of the American Medical Group Association

Chairman Thomas, Mr. Stark and Members of the Subcommittee, my name is David Morehead. I am President of the Scott & White Health Plan in Temple, Texas. I have spent 35 years in medicine, including 28 years with Scott & White. Scott & White is a fully integrated multi-specialty group practice of 500 salaried physicians. Scott & White Hospital is a nonprofit hospital of 400 beds located immediately adjacent to the Clinic on our main campus in Temple. The Scott & White Health Plan is a nonprofit HMO with over 165,000 enrollees, including 20,000 Medicare beneficiaries enrolled in our Medicare Health Plan.

I am here today on behalf of the American Medical Group Association. AMGA is the leading advocacy group on behalf of the nation's larger multi-specialty group practices. Our membership is uniquely affected by the physician self-referral law (Section 1877 of the Social Security Act) and we appreciate the opportunity to submit our views on this law.

We would note at the outset that this is not the first time we have testified before this subcommittee on this issue. Just a little over four (4) years ago, this subcommittee held a hearing on the self-referral law. In reviewing what we said that day, we are struck by the fact that none of the concerns we raised on that occasion have been addressed yet. While our concerns were more than adequately addressed by provisions drafted by this subcommittee, and approved by both the House and Senate in the Balanced Budget Act of 1995, as you may recall, this legislation was vetoed by the President for other, unrelated reasons. Now to make matters worse, new concerns have arisen as a result of the proposed rule issued by the Health Care Financing Administration on January 9, 1998.

Our testimony today will focus on those matters that are of particular concern to group practices. As we noted at the outset, we believe group practices are uniquely impacted by the law.

DEFINITION OF GROUP PRACTICE

There is a common misperception that there is a "group practice" exception under the statute. That is not correct. The important distinction to make is that there are

several exceptions that are specifically designed to accommodate a group practice. They do not always protect services provided by group practices. In fact in many circumstances they interfere with group practice integration and provision of services. Because of those exceptions, the statute has contained a definition of "group practice" from the very outset. It has been a continuing source of confusion.

Several examples from the preamble to the January 9, 1998 proposed rule will illustrate the problem:

- A single shareholder professional corporation may not be a "group practice" even though it may employ many physicians. (63 FR 1687).
- A group practice must be "one legal entity" but can have members who are professional corporations or individuals who are incorporated (63 FR 1687).
- In the final rule implementing, the first iteration of the self-referral law, HCFA stated that independent contractors would count as "members" of the group. In the new proposed rule, they do not. (63 FR 1689).
- "Substantially all" of the services of group members must be furnished through the group and billed under the group's billing number. HCFA has defined "substantially all" to mean 75% based on time spent on "patient care services." (63 FR 1688).
- Overhead expenses of and the income from the practice must be distributed "according to methods that indicate that the practice is a unified business." In other words, a group's internal accounting methods "must reflect centralized decision making, a pooling of expenses and revenues, and a distribution system that is not based on each satellite office operating as if it were a separate enterprise." This requirement is not found anywhere in the statute, but HCFA claims it can put it in place anyway because HCFA has the authority to add new standards to the group practice definition under the statute. (63 FR 1690).

Mr. Chairman, these are just a few examples involving just this one issue. We could supply you with many others if you wish.

As the foregoing examples illustrate, the definition of a group practice is something of a moving target. This causes us great discomfort. We would like some certainty brought to this process. For example, Scott & White has been around for over a hundred years as a group practice of physicians servicing the population of central Texas. We believe that no reasonable person could ever dispute that we are a "group practice" under the statute. But we are uncertain about our status as a group practice under the regulations and in the eyes of HCFA.

We cannot overemphasize enough the importance of this matter. If a group fails to meet the "group practice" definition, then it is at tremendous risk for being found in violation of the self-referral prohibition. For many groups, that would be a death knell.

We urge Congress to address this matter legislatively. Specifically, we would request that Congress delete HCFA's authority to create additional criteria beyond those that are found in the statute for defining what a group practice is.

COMPENSATION ARRANGEMENTS

In a more general vein, we wish to reiterate a recommendation we made four years ago. We strongly urge Congress to amend the self-referral law to limit its applicability to ownership interests. If this were done, the vast majority of group practices in this country could provide needed patient care unencumbered by the fear that its legal counsel had misinterpreted the statute and the application of the many exceptions.

Both the anti-kickback law and the compensation provisions of the self-referral law seek to prohibit payments in exchange for referrals and the associated potential for over utilization of services. It is unclear how the compensation aspect of the self-referral law provides any real benefit over the anti-kickback law. In fact, its existence is having the negative effect of impairing legitimate marketplace transactions. Deleting the compensation provision, while preserving the ownership prohibition, would maintain the law's integrity and remove its detrimental effect on the market.

AMGA recommends that the physician referral statute be clarified by eliminating the compensation arrangement provision.

Analysis of compensation arrangements under the law is a daunting task. Currently providers must analyze fourteen different anti-kickback safe harbors, and sixteen different self-referral exceptions for every ownership, compensation or other financial relationship involving a physician or a member of the physicians family. Each of the safe harbors in the case of the anti-kickback law and the exceptions in the case of the self referral law are technically complex. Some overlap in the area of risk-sharing arrangements, with vastly different technical requirements.

The reality of the self referral law is that the rules implementing the law have been structured so that the exceptions apply to only very narrow classes of arrange-

ments. Since the law is a prohibitory statute, and a provider has to disclose any unlawful referral within 60 days that the provider “knew or should have known” was unlawful, the narrowness of HCFA’s reading of each exception creates enormous potential liability for health care providers, and enormous difficulty in providing needed and medically necessary care particularly to under-served populations.

In the following text I will describe six areas of the law where HCFA has faithfully applied the terms and meaning of the statute, but in so doing has undermined the intent of the law.

COMPENSATION RELATED TO THE VOLUME OR VALUE OF SERVICES

In order for a compensation relationship between parties to a practice to qualify for an exception in the law, most of the exceptions require that the compensation not be based upon the volume or value of referrals. This was believed by most analysts of the law to mean that (1) payments cannot vary with referrals; and (2) payments must be fair market value for the items or services purchased, with no additional mark-up to reflect the value of referrals. The proposed regulations added another interpretation of the statute that further interferes with our ability to integrate patient services. The new interpretation of the statute states that there can be no requirement even within a group practice, to refer to the group practice. This interpretation will lead to the prohibition of exclusive contracts and non-compete restrictions that enable desirable efficiencies and allow for improved patient care. The value of multi-specialty organizational arrangements for patients is the convenience of one stop healthcare. The exclusivity of the arrangements allows groups to maintain a unified patient record, and coordinate utilization of services. The result is more conservative, evidence-based medicine, better outcomes of patient care, and measurably more satisfied patients.

REFERRALS TO AFFILIATED INDEPENDENT CONTRACTOR PHYSICIANS

Under the proposed rule a physician in a group practice may not refer to an affiliated independent contractor physician unless the nonmember physician services are provided “under the personal supervision” of another member of the group. This means that another group practice physician is legally responsible for monitoring the test or the designated service, and must be available to assist and supervise the physician who is furnishing the service, doubling the cost of the professional component of the service. Why two physicians are necessary to deal with the service is unfathomable, but required.

COMPENSATION NOT RELATED TO DESIGNATED HEALTH SERVICES

The physician ownership and self referral law provides an exception for payments by a hospital to a physician for services that are not related to designated health services. The regulations, on the other hand, indicate that payment by a hospital to purchase a heart valve is sufficiently related to hospital services, which are designated health services, so that it does not qualify for an exception. The proposed regulations indicate that the items or services purchased by the hospital must be “completely” unrelated to a designated health service. Since all hospital services are designated services, it is difficult to imagine a legitimate purchase by a hospital that is not somehow indirectly related to hospital services.

THE DISCOUNT MARK-UP PROHIBITION

In the proposed rule HCFA assumes that any purchase of an item or service by a physician at a discount from an entity which provides designated health services means that the acquisition was not consistent with fair market value. This assumption totally ignores the ordinary and customary distinction between doing business at wholesale and doing business at retail. If a physician or a group practice is able to purchase items at a discount because of the volume of such purchases, and the price paid is consistent with what others pay, including non-physicians who purchase a comparable quantity of the item, then there would appear to be no basis for the conclusion that such purchase price terms are not consistent with fair market value. In fact, purchasing items at the same price paid by someone else who is purchasing fewer items or services would be inconsistent with fair market value. Thus, if a group practice were to purchase chemotherapy drugs from a pharmacy on price terms consistent with what other purchasers pay for comparable quantities of drugs, such as hospitals, the price terms are clearly consistent with fair market value.

PERSONAL PRODUCTIVITY BONUSES

In the January 9 rule HCFA has proposed limiting the scope of permitted personal productivity bonuses for employees to bonuses which are not "directly related to the volume or value of a physician's own referrals." HCFA also noted elsewhere that "directly" should be interpreted as "directly or indirectly." With that in mind virtually any bonus would be precluded for employed physicians in certain specialties outside of a group practice, such as radiologists and pathologists whose entire practice or a substantial majority of it is dedicated to the provision of designated health services. Surely HCFA can not intend a prohibition that prevents fair compensation for the services provided by employed physicians.

STARK LAW PROHIBITIONS AGAINST PROVIDERS OFFERING FEE-FOR-SERVICE AND MANAGED CARE SERVICES IN THE SAME NETWORK

The prepaid health plan exception under the statute protects all services any provider may make available to enrollees of a prepaid health plan. But providers are only protected if they have a contract directly with the prepaid health plan. Downstream arrangements with subcontracting providers are not protected unless they fall within the personal services exception. Moreover, a prepaid health plan arrangement might taint any fee-for-service relationship involving the same providers. HCFA has taken the position that if a provider has a contract with a health plan to provide prepaid healthcare services to enrollees of the health plan that provider or physician could not refer fee-for-service patients to the other providers or physicians within the health care delivery system providing services to enrollees because of the managed care relationship. If such arrangements are within the scope of the physician ownership and self-referral statute, and are not protected by any exceptions then it is impossible for providers to make available both fee-for-service and managed care services within the same network of care. This does not make sense from any public policy, regulatory, or business point of view. In fact, it restricts a patient's choice of care arrangements.

The physician ownership and self-referral statute is a strict liability law that physicians, group practice leaders, attorneys and regulators can't figure out. This is an unfair situation because the penalties are so severe. But even more unfair, and unrealistic, is that it drives up the costs of providing services and, especially in under-served and difficult to serve areas, may determine if services are provided at all.

I would like to conclude this testimony but describing the actual circumstances of a group practice in a rural part of the country. The group practice is a community-governed, tax exempt health care organization that employs approximately 160 physicians, located in 10 sites, in two predominantly rural states. Its main campus includes a large clinic and hospital, and, from that base, the clinic's specialists and sub-specialists work with the few providers located in rural and frontier communities often hundreds of miles away to provide care to many older patients with chronic conditions who have difficulty traveling. The group practice offers approximately 60 outreach clinics, involving 9 different specialties, in sites all over this vast, under-served area. The group practice provides these services because of its public mission to serve under-served areas. The group practice loses money by offering these outreach services; its direct costs exceed direct outreach revenue expenses.

The physician ownership and self-referral law has made providing health care in this difficult situation more difficult by increasing the economic costs and legal risks of providing services in those areas. It should be simple enough:

- the local clinic or hospital should be able to make space available for free to the group practice for outreach clinics, recognizing that, because of fluctuating need, clinics by particular specialists may be in operation sporadically;
- the group practice should be able to make equipment available for free to monitor patients with heart disease or manage diabetes, even if those patients are referred to the central campus for services that are designated health services;
- the group practice should be able to recruit providers and manage part-time practices in these areas without having to fear whether they are meeting all of the criteria of the exceptions for equipment and space leases and providing personal services.

Applying the physician ownership and self-referral law to these situations is difficult. Lawyers frequently answer with "arguably yes and arguably no" when asked if the law applies. The problem of vagueness of application is compounded by the fact that the exceptions to the physician ownership and self-referral law often do not make sense financially. For instance, it is apparently illegal under the physician ownership and self-referral law to vary the amount of reimbursement by actual productivity or the number of patients served at each site, if productivity is related to designated health services. In difficult to serve areas, setting compensation terms

for a year at a time, without regard to productivity, can be a formula for an economic failure. But that is what the law requires.

This is what should happen. The clinic administrator or sole family practice provider in a town or county with 3,000 residents, located 200 miles from a hospital with more than 50 beds, in a town with no significant lab or radiology, and no other providers, should be able to call the main campus and say, "We seem to have an outbreak of rashes. Could you please run some tests in your lab and send a dermatologist up for a day." Or, "We've got at least 10 people out here with heart disease and many are frail and in the local skilled nursing home. If you could lend us a Holter monitor and send a cardiologist out every 3 months, that would be a great service." The clinic should be able to respond to such simple requests without having to do what it currently does—the general counsel hires an outside attorney to do an analysis under the physician ownership and self-referral laws which taeks needed resources from patient care, and then the parties sign written agreements with terms that make little economic sense. The clinic is obliged to do this because anything less not only potentially violates the physician ownership and self-referral law, but is potentially a violation of the False Claims Act.

In complex situations, involving recruitment of providers and the management of rural practices where the group practice would like to offer outreach clinics and provide some simple monitoring, lab, and diagnostic equipment, the difficulty of applying the physician ownership and self-referral laws and the additional expense of complying with those laws, may make it impossible to do—even though the group practice wants to do so, and it would clearly be beneficial to the community.

CONCLUSION

Mr. Chairman, the group practices of America recognize their obligation to comply with the physician ownership and self-referral law. We do our best every day to comply with the law as we understand it. To its credit the Health Care Financing Administration has done the best in drafting regulations that comport with the statute that it could have under the circumstances. The statute was written with good intentions applicable to the perceived situation at the time. Since that time the business environment for health care has changed, and we have found that the anti-kickback statute effectively enables federal prosecution of compensation arrangements that are inappropriately intended to induce referrals.

It is only fair, however, that we KNOW WHAT THE LAW MEANS AND WHAT THE RULES ARE before we are held accountable for them. The original version of this law is now almost ten years old, and we still don't know how to apply them to deliver needed care in our communities.

It is too easy to just assign blame for this regulatory failure. AMGA would rather live in the solution than live in the problem. We believe the solution lies in a further legislative effort to (1) delete HCFA's authority to create additional criteria beyond those found in the statute for defining what a group practice is; and (2) eliminate the compensation arrangement provision in current law.

Thank you for your attention. I'll be happy to try to answer any questions you might have.

Mr. MCCRERY [presiding]. Dr. Hauser.

STATEMENT OF J. BRUCE HAUSER, M.D., FACR, MEMBER, BOARD OF CHANCELLORS, AMERICAN COLLEGE OF RADIOLOGY

Dr. HAUSER. Good afternoon. Thank you, Mr. Chairman. My name is Bruce Hauser, and I am a practicing radiologist from Roanoke, Virginia. I am testifying today on behalf of the American College of Radiology, a 30,000-member organization of which I am a member of its board of chancellors.

It is an honor to be with you today, and as we did in 1995, we appreciate being invited again to share our views on this important matter.

The American College of Radiology has been a strong proponent of prohibiting the practice of self-referral. This position is shared by numerous physicians and healthcare organizations, including the American Medical Association.

This strong stance has helped lead to the enactment of the self-referral prohibition legislation we are discussing today. However, prior to the enactment of this legislation, numerous studies, including studies conducted by the General Accounting Office, showed the physicians that referred patients to outside entities, where they had a financial interest, were much more likely to order tests than physicians who did not have such investment interests.

These investigations clearly showed that this type of market control leads to increased utilization, higher prices, and lower quality while generating large profits. This practice also resulted in higher costs for government programs such as Medicare and Medicaid, as well as private insurers.

At the time of its passage in 1993, self-referral prohibition was slated to save the Federal Government \$350 million over the next 5 years. In 1995, when Congress was considering changes to the self-referral law, the Congressional Budget Office estimated that those changes would cost taxpayers \$400 million over 7 years.

Obviously, the college continues to believe that self-referral prohibitions are still necessary, although the delay in the implementation of the final rule is troublesome. The ACR agrees that HCFA must double its effort to implement the regulations. HCFA urgently needs to provide physicians some guidance on structuring their financial and referral relationships to comply with the statute. In addition, the proposed rule has many technical and substantive problems that should be addressed.

However, an imperfect regulatory process does not merit weakening the underlying law. As for those in the medical community who argue that the current trend toward managed care has lessened the need for self-referral prohibitions, we respectfully disagree. Although managed-care organizations have established varying levels of market influence throughout the Nation, over 80 percent of Medicare beneficiaries still do not belong to managed-care health plans.

Most Medicare beneficiaries still receive their medical care on a fee-for-service basis. We acknowledge that the healthcare system has become more integrated since self-referral legislation was first enacted in 1989, yet the landscape has not shifted so dramatically as to eliminate the medical and economic costs of self-referral.

In conclusion, the ACR believes that the market forces that led to Congress enacting self-referral prohibitions have not disappeared in the past several years. Furthermore, the college finds it troublesome that during a time when the Federal Government is devoting millions of dollars to fighting fraud and abuse in the Medicare system, it would consider diminishing the effect of self-referral prohibition, one of the most effective Federal efforts developed to stem fraud and abuse.

Therefore, the ACR finds no justification for substantially modifying restrictions against abuse of self-referral arrangements.

Thank you, Mr. Chairman for the opportunity to present our view. I will be happy to answer any questions the Subcommittee may have.

[The prepared statement follows:]

**Statement of J. Bruce Hauser, M.D., FACR, Member, Board of Chancellors,
American College of Radiology**

The American College of Radiology, which represents 30,000 physician and physicist members, is pleased to present the following statement regarding the status of the physician self-referral prohibitions in the Social Security Act as passed under the Omnibus Budget Reconciliation Act of 1993 (OBRA 1993).

Historically, the ACR has held that self-referral arrangements lead to inappropriate utilization of medical services and that the justification for development of these arrangements is largely contrived. Since 1985, we have advocated the ethical principle that physicians should not have a direct or indirect financial interest in facilities to which they refer patients. We continue to support legislative and regulatory efforts that would eliminate this conflict of interest by prohibiting such ownership arrangements in health care. This position is shared by numerous physician and health care organizations including the American Medical Association (AMA).

Compelling evidence of fraudulent and abusive referrals has been recognized and documented by the Inspector General and the General Accounting Offices. Moreover, studies from prestigious peer-reviewed scientific publications such as the New England Journal of Medicine (NEJM) and the Journal of the American Medical Association (JAMA) have repeatedly found that where referring physician joint ventures exist, the normal economic forces of competition do not apply. These investigations clearly showed that this type of market control leads to increased utilization, higher prices and lower quality, while generating large profits.

The College still believes that the self-referral prohibitions that resulted from these studies and investigations are still necessary, although the delay in the implementation of a final rule is troublesome. The ACR agrees that HCFA must double its effort to implement Stark II regulations. HCFA urgently needs to provide physicians some guidance on structuring their financial and referral relationships to comply with the statute. In addition, the proposed rule has many technical and substantive problems that should be addressed. However, an imperfect regulatory process does not merit weakening the underlying law. Furthermore, HCFA has pledged to review controversial provisions in the rule and modify them where regulatory changes will not compromise the congressional intent in protecting against patient or program abuse.

As for those in the medical community who argue that the current trend towards managed care has lessened the need for self-referral prohibitions, we respectfully disagree. Although managed care organizations have established varying levels of market influence throughout the nation, over 80 percent of Medicare beneficiaries still do not belong to managed care health plans—only 16.6 percent enrolled as of 1998. Most Medicare beneficiaries still receive their medical care on a fee-for-service basis. We acknowledge that the health care system has become more integrated since Stark I was enacted in 1989, yet the landscape has not shifted so dramatically as to eliminate the medical and economic costs of self-referral. The market forces that led to Congress enacting self-referral prohibitions have not disappeared in the past several years. Therefore, the ACR finds no justification for substantially amending, let alone repealing, restrictions against abusive self-referral arrangements.

ACR POLICY

The current position of the American College of Radiology is based on our members' experience with such financial arrangements. As these joint ventures proliferated in the early 1980's, the ACR debated the merits and disadvantages of these arrangements. In 1984, our policy-making council initially adopted the position that radiologists could ethically participate in financial arrangements, such as joint ventures, in order to provide diagnostic and therapeutic care to patients. But our position also warned our members of the potential for abuse in financial arrangements that involved referring physicians. With that caution, we believed that financial arrangements to fund imaging centers and radiation oncology centers could be constructed to avoid conflict of interest, fraud, and abuse of patient confidence.

We found we were wrong. In 1988, our council recognized that it needed to reconsider this position. In the four years between 1984 and 1988, we found that the potential for, and exploitation of patients by unethical practices and the flagrant dis-

regard of physicians' ethical responsibilities to the patient to be so great and so pervasive, we subsequently strengthened our policy.

Our policy adopted in 1988 and again strengthened in 1992 states:

The practice of physicians referring patients to health care facilities in which they have a financial interest is not in the best interest of patients. This practice of self-referral may also serve as an improper economic incentive for the provision of unnecessary treatment of services. Even the appearance of such conflicts or incentives can compromise professional integrity. Disclosing referring physicians' investment interests to patients or implementing other affirmative procedures to reduce, but not completely eliminate, the potential for abuse created by self-referral is not sufficient . . . The American College of Radiology believes that radiologists and radiation oncologists should make efforts to restructure the ownership interests in existing imaging or radiation therapy facilities because self-referral may improperly influence the professional judgments of those physicians referring patients to such facilities.

AMA ETHICAL POLICY

The scope of these problems has also been recognized in the AMA's Council on Ethical and Judicial Affairs report on physician conflicts of interest, as adopted in 1991 and reaffirmed in late 1992. The report, which remains part of the AMA's code of ethics, holds that the practice of self-referral is "presumptively inconsistent with physicians' fiduciary duty" to their patients. These ethical guidelines state that "only when a physician can demonstrate both the absence of adequate facilities—a plain medical need—and absence of alternative financing should referral take place." But even when such a need may exist, the AMA also recommends that physician-owned facilities meet nine additional requirements to ensure that over utilization and patient exploitation will not occur.

COSTS

While we support efforts to provide high quality patient care through the more cost-effective delivery mechanisms, we must urge caution in proposing any modification in the laws which could create loop holes for referring physicians' financial involvement in health facilities. If facilities currently in operation are allowed to simply declare themselves as extensions of group practices or private physician offices, the intent of the legislation will have been circumvented because referring physicians will continue to self-refer. The problem with increased utilization in referring physician owned facilities will be simply changed to a problem of increased utilization of services within physician's offices.

Unfortunately, there will always be those who will want to create new elaborate kickback schemes and abusive referral arrangements to augment their income as the Congress seeks to restrict the growth of the federal health programs and the market restricts income from private sources. But the passage of the referral prohibitions in the Social Security Act has already had a substantial impact in reducing over-utilization of radiologic and other designated health services, thus saving tax payer as well as private sector dollars.

It must also be recognized that the costs of modifying, weakening or repealing these self-referral prohibitions will be borne by the American tax payer. In 1995, when Congress was considering changes to the self-referral law, the Congressional Budget Office (CBO) estimated that those changes would cost tax payers \$400 million over seven years. When this was combined with another provision that would have weakened the government's ability to prosecute fraud and kickback scams, CBO estimated that the overall cost would be \$1.1 billion.

The self-referral ban in Medicare and Medicaid has also had an indirect effect of eliminating similar corresponding costs in the private sector. In short, we believe that alternate methods for controlling the fraudulent and abusive referrals will cost the U.S. health care systems and the federal government more.

We believe that any consideration in modifying these laws should not create an incentive or circumstance where services are provided by untrained or unskilled physicians, who are either unconcerned with or unaware of proper practice standards. In the best interest of patients, we should assure access to medical care from physicians qualified to provide the service.

CONCLUSION

The American College of Radiology recognizes that many of these abusive referral practices arise from the pressures of the highly competitive health care marketplace and we empathize with the desire to form legislative managed care arrangements.

However, we believe strongly that exploitive and unethical practices should not be condoned under the guise of competition. These arrangements hamper rather than encourage competition and should not be allowed.

Mr. MCCRERY. Thank you, Dr. Hauser. And thank all of you for your testimony. Being a graduate of the LSU Law School, I am not sure what weight should be given to Mr. Teplitzky's testimony. He is a Tulane grad. [Laughter.]

However, I do have a question for you, Mr. Teplitzky. And we talked about this a little bit with the HCFA and the Inspector General's Office, and that is the burden of proof that is required under the self-referral law and the burden of proof that is required under criminal statutes.

Do you have any thoughts on how the self-referral law might be modified in terms of the burden of proof required of the Government?

Mr. TEPLITZKY. Yes, I do, sir. The current self-referral law does not consider the issue of intent, which is an interesting approach because the law makes it clear to me that not all self-referral is bad. There are approximately 14 exceptions. I understand that additional exceptions are being proposed to recognize that, in fact, there are situations when the physicians are the people who know best what can be done, and what should be done, for their patients.

The law does not prohibit physician ownership in health care entities. It prohibits the referral of Medicare and Medicaid patients to those entities. Thus, if a physician in good faith develops a high-quality service at a reasonable price, every patient in that community can receive that service *except* that physician's own patients.

I believe that there probably should be some level of intent to determine whether there is a potential for abuse.

Mr. Thornton indicated that of the advisory opinions they issued, 24 of them were favorable. It is interesting to note that in many of those, the OIG found that the transaction described was a technical violation of the law, but notwithstanding that violation, because of the safeguards built into the transaction, the OIG chose not to impose sanctions.

They don't—neither HCFA nor the OIG has that same ability under the current self-referral law. If it is a technical violation of the law, it can't happen, even if it is being done for all the right reasons.

So I believe an intent standard different from a criminal statute, i.e., a lesser standard, would be appropriate.

Mr. MCCRERY. Perhaps something akin to a negligence standard, he should have known that this would be in violation, or something like that.

Mr. TEPLITZKY. Exactly the same standard that this Committee and the Congress enacted as part of HIPAA with respect to civil money penalties, "know or should know."

Yes, sir.

Mr. MCCRERY. Thank you. Not bad for a Tulane grad. [Laughter.]

Mr. TEPLITZKY. We never could beat you in football. [Laughter.]

Mr. MCCRERY. Dr. Morehead, I want to explore with you a little bit more of the impact that the self-referral rules have had on group practice. Most economists that we talk to, agree that physician practices, group practices, are good for the consumer, good for the patient, as well as good for expenditures in the healthcare system in terms of holding costs down.

Have self-referral laws, in your opinion, undermined the formation of group practices?

Dr. MOREHEAD. Yes, I think so. It has become much more complex to make our decisions as a group practice. For example, as physicians bond into groups, or as groups grow, the complexities increase in order of magnitude. For example, the number of arrangements, the number of payers that one must deal with, the number of locations where facilities are required, and so forth, all of these increase the complexity and cause us to have to test each of these decisions against the self-referral law, the provisions thereof.

So, I think it has been a deterrent because it is so expensive and so consuming of energy and time to make the decisions about how we can accomplish something.

Mr. MCCRERY. You say in your testimony, the definition of a group practice is something of a moving target. What do you mean by that? Can you elaborate?

Dr. MOREHEAD. In the original law, there were certain provisions to define a group practice, but the last provision was any other criteria that the Secretary should adopt in terms of defining a group practice. So with each iteration, additional criteria of what constitute a group practice has emerged.

That causes great concern. We can comply today. It causes us concern because it, again, is one exception or one rule that may be good for a certain situation but it is—makes it difficult for the other situations.

So we would propose that the Secretary's ability to do this, that is, to change the definition, be struck from the law. We find that burdensome. Just keeping up with it is expensive and consuming.

Mr. MCCRERY. Thank you. Mr. Stark.

Mr. STARK. Thank you, Mr. Chairman. Mr. Wiet, I am sorry to hear that your hospital has trouble with its legal complexities. It seemed to me, I was advised by HCFA that for a thousand bucks they could have gotten an advisory opinion that would have saved all that high-priced lawyers fees, but they can do whatever they choose, I guess.

It is important to note that Florida Hospital Association has endorsed what are referred to as the Stark I and Stark II laws. I quote here from their statement for the record on behalf of the 230-member hospitals and healthcare systems who serve their communities throughout the State: "The Florida Hospital Association urges Congress to maintain the critical consumer protections"—I haven't heard anything about consumer protections today; just taking care of rich doctors—"provided in the Omnibus Budget Reconciliation Act, and in Stark I and II."

And they go on to suggest that this has been vital in Florida. So maybe things operate differently in Illinois, but at least that hospital group thinks we should continue the way we are going.

I think it is also important to note that it was suggested earlier by my colleague from Connecticut that there was a problem with the Visiting Nurses Association. And I would like to point out that the Visiting Nurses Association of Philadelphia is very supportive, and I am quoting from them, over the Stark II position: "We believe the law is sound public policy and we are pleased the proposed rules implementing the law were finally published. We are dismayed that it is May—as an I—and no final rule has appeared."

But it seems that, even though the gentlelady from Connecticut may not like it, the Visiting Nurses do.

Chairman THOMAS [presiding]. Of Philadelphia.

Mr. STARK. Of Philadelphia. And I believe that that is true of all of the lobbying groups for the Visiting Nurses Association, but I don't have a letter from all of them.

Further, and I would like to direct this to Dr. Hauser. This is something that I heard years ago and I thought that people would now understand. There was a reference to the fact that without the investment of primary-care physicians into diagnostic, electronic diagnostic equipment like MRI's there wouldn't ever have been any. That we needed this private investment from referring physicians to allow the poor underpaid, undercapitalized radiologists to go out and buy MRI equipment.

Now I would ask Dr. Hauser if he knows of any radiologist in this country when MRI's came out that wouldn't have had all the assistance they need from General Electric Finance Corp. to get them an MRI overnight to, either on a lease or low terms or any other way.

Was there any shortage of capital available, Dr. Hauser, to your knowledge for diagnostic equipment?

Dr. HAUSER. No, sir. I do not believe so. MRI was developed by a radiologist, and radiology was instrumental in developing the locations for it and distributing it. And it would appear that only after the value of it was finally discerned by the public and by the medical community that such joint ventures started to become more in fact.

Mr. STARK. One other question, Doctor. Has it ever come to your attention, or would you find it reasonable to assume that there is any problem along the North Shore of Chicago for a woman to get a high-quality mammogram at a reasonable price. Any shortage of that service that you know of?

Dr. HAUSER. I can't speak to the exact nuances of the North Shore of Chicago, but—

Mr. STARK. Evanston, Chicago, you know, around in that area.

Dr. HAUSER. I would not think so. I would think that they would be readily available, Mr. Stark that is certainly my understanding of the problem.

Mr. STARK. Well, as I say, I don't know where this hearing goes. I guess I come back to the question that nobody has suggested that beneficiaries are having trouble finding services. Eight-four percent of them as you indicated, Dr. Hauser, are still getting their service through fee-for-service.

The American Medical Association has suggested that it is unethical to have an ownership interest. I guess I will just close by

saying, if somebody wanted to make the distinction that a compensation arrangement doesn't have the same benefits as an investment, my guess is that they ought to go back and either take accounting or economics all over again.

I can't see the difference between how you receive the money. You can call it a salary or a fee or a limited-partnership distribution or anything else you want, but it seems to me that when those fees relate to, as the American Medical Association says, a service outside the physician's office or outside his practice, that there is always a suspect issue there. And we know that it costs the taxpayers more.

And we have heard no evidence that we get any better quality. All we know is that we end up spending more money on outrageous legal bills, on stockholder dividends, on high chief executive officer profits, and no better medical care. And the taxpayers end up paying more.

And it seems to me that we should urge HCFA, as the Chairman has suggested, to get the regulations out in a timely fashion, be tough. I think—I still think we ought put a few people in jail now and again just to set a good example.

I don't think we have any trouble understanding compensation arrangements. We operate under them here. The Chairman makes me pay for parking. I don't know why I have to, but I got to have my income taxed for the parking I get, which used to be free. I understand it. It is simple. I mean I know the numbers. You can do that with your shoes and socks on.

So we know where we are limited to outside compensation, and under what circumstances we can receive it or not. We have had a couple of Speakers, on both sides of the aisle, who have tried to circumvent those regulations, I think to their dismay.

So, it works in every profession. And usually the greedy people get caught, and I just hope we keep going after those physicians who ought to tend to their patients and not worry about dipping into the public till for unjust enrichment.

I appreciate your having this hearing, Mr. Chairman. Thank you.

Chairman THOMAS. Thank you very much. Although this may not interest many people in this room, the reason you pay for your parking is because when your party was in control, the gentleman from California, Mr. Matsui, was out looking for ways to pay for one of his ideas and the offsetting revenue was to charge members for parking.

So I believe the gentleman might have some concern with his colleague from Sacramento. Go travel 80 and visit with him. He may let you park for free; then again, he may not.

Perhaps, also, I did not say consumers, but in my opening statement I said Members of the Subcommittee can agree, I hope, that the overarching goal is to provide to our seniors the proper medical care in the proper setting.

One of my concerns from the very beginning was that the underpinning of this law was based upon some studies whose methodology I, to this day, do not understand how they support the arguments that were made when the gentleman's party was in the majority. And I will just give you an illustration as far as I am concerned of how that methodology worked.

Dr. Hauser, if this law were not in place, would your professional job be better off or worse off? That is, would there be other people doing what you do now more so, or less so?

Dr. HAUSER. I believe that there would be more people doing parts of what I do. There are parts that I do that others cannot provide.

Chairman THOMAS. So, am I to interpret that to say that if the law were not in place, you would not be doing as much as you would be doing otherwise, but since the law is in place, you are doing more than you would do otherwise?

Dr. HAUSER. That may only be one factor—

Chairman THOMAS. No, no, no. I am just trying to figure it out. I mean if you did a straight study of the volume of work that you do under the law versus the volume of work that you would do if the law wasn't there, you'd do more volume under the law as opposed to if the law wasn't there.

Dr. HAUSER. I believe that I do more volume under the law.

Chairman THOMAS. Fine. That was exactly the methodology that was used to determine whether or not we should go after people. The conclusion is the problem that I have. And the conclusion was these people, therefore, did that because they wanted to make money.

You are here, Dr. Hauser, using the same assumptions because you are simply motivated by economic self-interest. And you are in support of this law because you make bucks with it in place. And if it weren't in place, you wouldn't make bucks with it. So I can clearly understand why you are in front of this Committee, you are fighting to keep your game structured to advantage you.

Now I don't think that is fair, do you?

I don't think that is a fair analysis of why you are here, but that was the analysis of people who spent to find out about equipment, and then decided that since they found out about the equipment and thought it was a good idea, used it more. There was never an attempt to find out whether or not the total cost of care increased or decreased utilizing the equipment.

They never determined whether the diagnosis was more accurate more often and, therefore, didn't have to put the patient a far more traumatic procedure to determine what the appropriate problem was.

None of that was done in methodology to put this law in place. They simply compared volume and drew a conclusion that they were crooks. I will not draw the conclusion that you came here to testify because if this law stays in place you make more money than you would otherwise.

I don't think that is fair. But that is exactly the methodology that was used as outlined to justify this law. And I don't think that serves beneficiaries. I don't think that serves providers. I don't think we ought to create a war or pit providers against beneficiaries. I think, as I said in my opening statement, that I hope the Subcommittee members can agree that the overarching goal is to provide to our seniors the proper medical care in the proper setting.

And since we became the majority, we have passed very tough laws to go after fraud and abuse. And it just seems to me at some

point we have to re-examine something that is not in place that causes real concerns because of the intense structure, as brought out by my colleague from Louisiana, and that still after all this time does not have final regs in place. And I would be willing to offer anyone a bet on when they are in place, and how long they would last, how useful they are going to be, when you are chasing a bright line that can never stay in one place.

Unfortunately, this law will produce a laser show, and with bright lights going off in all directions, or exceptions carved out to make it work, at some point I hope people will say, "Why don't we quit carving out exceptions, examine the law, get the intent right, create advisories off of this so people can know what it is that they are supposed to do, and move forward with delivering care in the proper context and catching people who are crooks."

We will catch the crooks. What we ought not to do is put up a net that prohibits responsible, reasonable, and appropriate delivery of care.

And Dr. Morehead's example of the west Texas town is right on top of something that ought to be allowed that can't be because you wanted to, if I wanted to continue the analogy, have the advantage slanted your way. I don't think that is fair.

Now, any other members have any questions? I want to thank all of you for coming. I will be looking for assistance as we begin to look at what is an appropriate response to trying to make sure that, at some point, filling whatever gap there is, if this law were not on the books, since it can't be enforced. No one has been prosecuted. Putting in place something that does work, that does get after ownership, and that does make sure that people who do want to break the rules willfully will be caught.

Thank you very much.

The Subcommittee stands adjourned.

[Whereupon, at 3:40 p.m., the hearing was adjourned.]

[Submissions for the record follow:]

Statement of the Alliance for Referral Integrity, Alexandria, VA

We, the member organizations of the Alliance for Referral Integrity (ARI), an ad hoc grouping of concerned organizations representing the "designated health services" defined by the self-referral statute, write to express our opposition to dismantling the current law restricting physician self-referral under the Medicare and Medicaid programs.

ARI asks the Committee to stand firm against efforts to dismantle or devalue this important statute which seeks to eliminate incentives for physicians to over utilize health care services for the purpose of personal financial gain.

"Self-referral" occurs when a health care provider refers a patient to a facility in which they have a direct or indirect financial interest. Physician self-referral is inappropriate because physicians who have a financial relationship with such facilities earn greater returns as referrals to the ventures increase. Providers who invest in health care facilities have an incentive to refer more patients to the facility. As a result, increased health care costs are incurred by the health care system.

In 1993, when the scope of the Federal physician self-referral law was expanded, the Congressional Budget Office (CBO) projected that the Medicare program would save \$350 million over five years. The CBO estimated that amendments to the self-referral law included as part of the proposed Balanced Budget Act of 1995 would have cost the Medicare program some \$400 million over seven years. The cost of dismantling this important deterrent to fraud and abuse would be even higher today.

Perhaps even more significant than the budgetary implications is the breach of the public trust that would result from weakening the self-referral law. Consumers of health care services should not need to question whether the services they are

receiving are being provided due to medical necessity or for the personal financial gain of the physician referring the service.

While the statute must be preserved and enhanced, it is necessary to highlight the failure of the Health Care Financing Administration to issue timely regulations that would provide guidance to the health care community on how to comply with the intent of the statute. ARI urges the immediate promulgation of final regulations relating to the existing ban.

As an alliance of concerned health care organizations, ARI asks the Committee to maintain the prohibition on self-referral and preserve the public trust with respect to the delivery of quality health care services under the Medicare program.

Thank you for your consideration of our views on this important matter.

MEMBER ORGANIZATIONS OF THE ALLIANCE FOR REFERRAL INTEGRITY

Alliance for Referral Integrity
 American Clinical Laboratory Association (ACLA)
 American Federation of HomeCare Providers (AFHCP)
 American Orthotic and Prosthetic Association (AOPA)
 American Pharmaceutical Association (APhA)
 American Physical Therapy Association (APTA)
 American Occupational Therapy Association (AOTA)
 American Society for Clinical Laboratory Science (ASCLS)
 National Association of Chain Drug Stores (NACDS)
 National Association for Home Care (NAHC)
 National Community Pharmacists Association (NCPA), formerly known as the National Association of Retail Druggists (NARD)
 Opticians Association of America (OAA)

ALLIANCE IMAGING, INC.
 ANAHEIM, CA,
 May 25, 1999

A.L. Singleton
 Chief of Staff, Committee on Ways and Means
 U.S. House of Representatives
 Washington, D.C.

Dear Mr. Singleton:

I write on behalf of Alliance Imaging, Inc. with comments for the printed record of May 13, 1999 hearing on the Health Care Financing Administration (HCFA) implementation of the Medicare self-referral laws and its impact on the health care marketplace. I trust you will find these very focused and brief comments helpful. Alliance Imaging and its subsidiaries collectively operate over 285 mobile and fixed site MRI systems, 34 CT systems, and 12 (mobile) lithotripsy systems. My comments fall into two categories: (1) The proposed "Stark II" regulations and the comments in the preamble concerning mobile imaging and other mobile services in relation to the "in-office ancillary services" exception are unsound as a matter of policy and inconsistent with Congressional intent. (2) Lithotripsy should be expressly included as a "designated health service" under Stark II.

(1) MOBILE SERVICES

The proposed Stark II regulations risk rendering mobile imaging services unavailable to physician groups, which could reduce competition and have disruptive, anti-competitive and inflationary effects for all payors, not just Medicare. There is a Stark II exception for "in-office" referral of ancillary services within a group practice. However, the proposed regulations would preclude ancillary services that are provided in a mobile unit parked just outside a group practice's office from being considered "in-office." This aspect of the proposed regulations represents unsound policy, and is inconsistent with Congressional intent that mobile imaging and ambulatory facilities be deemed part of a group practice's building even if operated on an adjacent parking lot. My comments emphasize mobile MRI systems because that is Alliance Imaging's largest business segment, although the principles apply with equal force to other modalities such as CT scans, lithotripsy, and ultrasound.

Unsound Policy

Mobile diagnostic imaging businesses have brought a number of benefits. They make sophisticated diagnostic services available where they would not otherwise be available at all; because mobile systems can operate in a number of locations, more sophisticated equipment can be economically viable than would be the case at a fixed site used by a small population; and they provide competitive alternatives to in-house systems such as those operated by hospitals and large physician groups, and independent imaging centers.

The proposed regulations may have the anti-competitive effect of leaving hospitals and independent imaging centers as the only viable location for MRI exams. In some circumstances it would not be feasible to have a mobile unit make two stops in the same community, one at the hospital and another at the local physician group, because a certain number of scans must be performed in order to make each stop economically viable, and there are a number of site preparation tasks and costs required, including a pad to support the weight of the trailer and equipment, utility hook-ups, securing trained and licensed personnel, and the like.

Another potential anti-competitive effect is that the reduced availability of mobile services may enhance the market position of an in-house MRI unit in a smaller community (irrespective of whether the unit is in a hospital or non-hospital imaging center). Such in-house systems may not be of the same technological quality of a shared mobile unit, because they cannot spread their costs over as large population base of potential patients. The market may not be large enough to justify a competitor's capital investment in a new in-house installation. Accordingly, if physician groups cannot contract for shared mobile service there may not be meaningful competition in communities with an existing in-house MRI unit, especially if the in-house unit is at the local hospital.

Although Medicare may not be terribly concerned about these potential effects on competition because it pays for imaging services and other diagnostic tests in accordance with the physician fee schedule (and in the case of outpatient hospital services, under a prospective payment system beginning next year), Medicare is a relatively small proportion of total volume. Other payors may end up paying more than would have been the case, if choice in a community is limited to in-house hospital systems and to mobile providers that service hospitals. And, if the new Medicare prospective payment system for hospital outpatient services sets reimbursement for imaging services higher than for the same service under the physician fee schedule, the proposed regulations will have the effect of driving utilization in favor of higher cost hospital providers, and away from lower cost physician providers.¹

Another unfortunate effect of the proposed regulations could be to induce more physician groups to acquire in-house MRI systems of their own. While this would tend to counteract the competitive concerns, it would spawn two other negative consequences.

First, in a locale in which the size of the population indicates that mobile service is more cost effective, if a physician group installs an in-house unit it may cut corners on the quality of the unit and installation. In contrast, because utilization of mobile systems is spread over a larger number of users, a higher and more effective level of technology can be available at a lower cost per procedure.

The second and even worse effect from Medicare's standpoint is that once a physician group makes an investment in an in-house unit, it will have a much greater incentive to overutilize the unit would than be the case with respect to a mobile unit. In this regard, I note that the studies relied upon and referred to in the Federal Register preamble to the proposed regulations apparently involved situations in which the physicians owned the facilities and were put in the position of having to recover their investment in an expensive fixed site unit.² In contrast, in the mobile imaging business mobile providers such as Alliance Imaging typically charge the physician group a per procedure price, or per diem rent, so that the physician group is not in a position of having to generate utilization in order to recover a substantial investment that may have been made out of the pockets of the individual physicians. Notably, the proposed regulations do not preclude physician groups from installing and operating in-house systems, as long as they meet the definition of a group practice and satisfy the requirements with respect to location.

I believe the risk of overutilization decreases when MRI exams are performed on a mobile system, due to the fact that a patient has to adjust his or her schedule to coincide with the scheduled day of mobile MRI service. Additionally, MRI patients

¹ Given the fact that a service performed in a hospital will usually cost more than the same service rendered in a physician's office, it is reasonable to believe that prospective payments to hospitals for outpatient diagnostic imaging services will be higher than the physician fee schedule pays for the same service.

² Federal Register, Friday, January 9, 1998 at page 1661.

are typically in pain, possibly “anxious” or truly claustrophobic, and an MRI exam can be time consuming and uncomfortable. The risk of overutilization by an ordering physician is virtually nonexistent due to the nature of the patient’s physical symptoms, anxiety or inconvenience.

Legislative History

The present version of the anti-referral statute describes the in-office ancillary service exception as applicable where (subject to compliance with other rules such as the definition of a group practice) the services are rendered “in a building in which the referring physician (or another physician who is a member of the same group practice) furnishes physicians’ services unrelated to the furnishing of designated health services, or . . . in another building which is used by the group practice . . . for the centralized provision of the group’s designated health services . . .”³ The proposed regulations take the “same building” and “building” concepts even further by stating that the “same building” means the same physical structure, with one address, and not multiple structures connected by tunnels or walkways.⁴ The preamble to the proposed regulations is directly hostile to mobile imaging and diagnostic testing businesses: “In addition, we believe ‘the building’ consists of parts of the physical structure that are used as office or other commercial space. For example, mobile x-ray van that is pulled into the garage of the building would not be part of that building.”⁵

This hostility to the mobile diagnostic imaging business finds no support in the legislative history of the 1993 amendments to the anti-referral statute. Furthermore, if one goes back to the original adoption of the anti-referral legislation, there is no compelling legislative history on that point. The original anti-referral legislation was adopted in 1989.⁶ The law as then enacted applied only to clinical laboratory services; consequently, there was no need for the legislative history to address the question of mobile imaging or similar services.⁷ The law originated in the House of Representatives, and in the form that passed the House would have applied to a broad spectrum of health services, not just clinical laboratory services. The House report on the broader version of the bill stated: “The committee intends that services in a building physically connected to the building housing the practice, or in the case of services provided by a mobile unit, immediately adjacent to the building housing the practice, would also be accepted under [the in-office ancillary services exception.]”⁸ In the face of this quite clear expression of Congressional intent when the anti-referral law was originally adopted in 1989, combined with the absence of any contrary intent in the 1993 amendments and legislative history relating thereto, I believe the proposed regulations and related passage in the Federal Register preamble violate Congressional intent to the extent that mobile imaging services are rendered ineligible for the in-office ancillary services exception.

Mobile MRI systems are based in large tractor trailers that are in effect buildings on wheels, with independent telephone, computer, heating and air conditioning systems. Congress never intended that they be disqualified from the in-office ancillary services exception, and such disqualification would increase rather than decrease health care costs.

Consequently, I urge that a technical correction be made to Stark II, to accord with Congress’ original intent. This could be accomplished simply by amending the definition of “in-office ancillary services” so that section 1877(b)(2)(A)(ii)(I) of the Social Security Act reads “in a building (or in a mobile unit housing diagnostic or therapeutic facilities while it is stationed reasonably proximate to such building) in which the referring physician . . .” And clause (II) reads “. . . in another building (or in a mobile unit housing diagnostic or therapeutic facilities while it is stationed reasonably proximate to such building) . . .” The addition of the clauses in parentheses would be the only change necessary to the effect this correction.

(2) LITHOTRIPSY SHOULD BE COVERED BY STARK II

Lithotripsy is not currently included among the list of “designated health services” subject to Stark II. If performed in the hospital setting, however, it is included as a “hospital service” and therefore it is in the somewhat anomalous position of being covered or not depending on the setting. I believe that it should be specifically in-

³ Social Security Act, Section 1877(b)(2), codified at 42 U.S.C. Section 1395nn.

⁴ Federal Register, Friday, January 9, 1998 at page 1723.

⁵ *Id.* At page 1695.

⁶ Omnibus Budget Reconciliation Act of 1989. Public Law 101–239.

⁷ See House Conference Report No. 101–386 at page 853.

⁸ House Report No. 101–247 at page 1039.

cluded as a designated health service, so that it would be covered in all settings. Although I recognize that lithotripsy does not seem prone to overutilization, there are two considerations that favor subjecting lithotripsy to Stark II.

First, in general I believe that Medicare laws and regulations should not reflect bias in favor or against services being performed in a particular setting—i.e., hospital or non-hospital—unless there is a particular reason for doing so. In the case of lithotripsy, permitting referring physicians to have financial relationships with lithotripsy providers that are not-hospital based, while prohibiting the same relationship if the provider is a hospital, creates an unsound incentive. The choice as to whether a particular procedure is performed in a hospital or non-hospital setting should be driven by factors such as clinical considerations and cost efficiencies, and not by a physician's economic interest.

Second, by permitting referring physicians to have financial relationships with a non-hospital lithotripsy provider the current version of Stark II is anticompetitive. The physicians who control referral patterns can be locked up by those who would engage in financial relationships with the physicians. This effectively forecloses other entrants into a market.

You will have noticed that there is a consistent theme to my comments on mobile services, and my comments on lithotripsy—both encourage development of the law in a way that encourages competition. That is the best way to assure the highest quality care at the lowest cost.

I would be happy to answer any questions that you might have.

Very truly yours,

RUSSELL PHILLIPS
General Counsel

Statement of the American Academy of Family Physicians

This statement on the Medicare self-referral law and its rulemaking is submitted on behalf of the 88,000 members of the American Academy of Family Physicians.

The Academy is concerned that Medicare self-referral laws, as written, no longer serve the purpose they were originally intended to address, which was to eliminate “inappropriate” referrals by physicians to health care facilities where they had financial interests. In addition, the proposed rulemaking to implement the law, as it was published in January, 1998, is far too complicated to ever provide the “bright line” of clarity sought by its sponsor. The Academy believes that Medicare self-referral laws are not serving their intended purpose and have been superseded by more recently enacted federal statutes addressing fraudulent and inappropriate referral practices. It is important to note that these newly enacted statutes achieve the same ends sought by the Medicare self-referral laws without federal mandates on private business practices.

Academy members are family physicians practicing primary care. As a group, they practice in perhaps the widest variety of settings of any single medical specialty society. These can range from school clinics and solo practice to large multi-specialty groups. Therefore, the range of concerns that family physicians have with self-referral laws are numerous and complex. This statement contains explanations of the Academy's more specific concerns with provisions of the proposed rule.

BACKGROUND

Medicare self-referral laws were enacted by Congress to address reports that some physicians with financial interests in health care services facilities were “inappropriately” referring to those facilities. However, the Medicare self-referral laws passed in 1989 and amended in 1993, and again in 1994, are extremely confusing, inconsistent and fail to recognize the realities of the current health care delivery environment. The Health Care Financing Administration's (HCFA) proposed rulemaking would create a great deal of confusion for family physicians practicing in an extremely competitive environment. It is both so burdensome and so difficult to understand that physicians would expend a tremendous effort simply trying to determine if they were in compliance. Likewise, the proposed rule could cause excessive costs for the federal government as it pursued compliance and enforcement efforts. The Academy has asked HCFA to withdraw this rule until it can be implemented in a clear and consistent manner.

The Academy requests that Congress reassess whether the myriad of health fraud and abuse laws passed and implemented in the last decade are already stopping the abusive practices that self-referral laws were intended to address.

RECENT FEDERAL LAWS AND REGULATIONS ADDRESSING FRAUD & ABUSE

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) contained an assortment of provisions to give HCFA increased authority and enhanced ability to provide oversight of Medicare health care providers. Specifically, HIPAA increased funding for Medicare program safeguards. This new funding is divided between the Office of the Inspector General (OIG) and the Department of Justice (DOJ) to coordinate federal, state and local health care law enforcement programs; conduct investigations, audits, evaluations and inspections relating to the delivery and payment of health care; help facilitate enforcement of civil, criminal and administrative statutes on health care fraud and abuse; and provide guidance to the health care industry on fraudulent health care practices.

HIPAA also established the Medicare Integrity Program (MIP), which is intended to "promote the integrity of the Medicare program by entering into contracts" with private entities, among its other responsibilities, to review the activities of providers furnishing items and services reimbursable under Medicare, including medical and utilization review and fraud review.

More recently, under the Balanced Budget Act of 1997 (BBA '97), HCFA now has authority to apply the federal anti-kickback statute prohibiting remuneration for referral of Medicare or Medicaid patients. In addition, HCFA carriers have established computer claims payment edits to alert them to areas of overutilization by screening practice patterns.

These new enforcement tools are already reaping significant increases in identification of fraudulent claims and adverse actions against those who make them. Just within the first six months of HCFA's and DOJ's new authority, nearly 3,000 individuals and entities were excluded from Medicare and Medicaid. That is a 93% increase in program exclusions in the first six months of 1997, compared to all of 1996. During this same reporting period, the OIG reported \$1.2 billion in recouped moneys through investigations and an additional \$125 million through disallowing questioned costs. In addition, in 1998, the OIG reported 215 convictions for criminal activities and 1,255 civil settlements.

All of the enforcement tools outlined above represent more than enough authority and resources to address Congress' original concern about physician self-referral. It is time to revisit the basis upon which self-referral legislation was founded, and compare those concerns with the current regulatory environment.

While unnecessary overutilization should be targeted and penalties imposed where it exists, unintended underutilization is also a very real consequence of the proposed regulation as it is written. In fact, underutilization is a far greater threat to Congress' intent of assuring access and quality health care to all Medicare and Medicaid beneficiaries.

CONCERNS WITH PROPOSED RULEMAKING ON SELF-REFERRAL

With regard to the proposed rule, the Academy has concerns with the rule's intrusion on compensation arrangements and the definition of a group practice. Below are outlined the Academy's specific concerns with the proposed regulation. *Until these concerns are favorably resolved, the Academy must reiterate its support for the withdrawal of this regulation in its entirety.*

1. Definition of "Direct Supervision"

Medicare self-referral law contains an exception for "in office ancillary services." To qualify, the services must be furnished personally by a referring physician or another physician in the same group practice, or be furnished by individuals "directly supervised" by one of these physicians. "Direct supervision" is defined as supervision by a physician who is present in the office suite and immediately available to assist and direct the "designated service." The exception does not apply to services performed in a location separate and distinct from where the physician conducts his or her own everyday activities. The rule will allow for physician time away for brief unexpected emergencies and short breaks (lunch).

AAFP Recommendation: (a) The Academy strongly objects to the definition of "direct supervision" and suggests it be replaced with "general supervision" or a revised definition of "direct supervision" such as that recommended by the American College of Physicians-American Society of Internal Medicine, which reads as follows:

The physician or group is legally responsible for the services performed by non-physician personnel and for ensuring that such personnel meet licensure and certification requirements, if any, applicable under other provisions of the law. Direct supervision does not require that physicians be physically present when an item or service is provided.

In a small family physician office of one to three physicians, it is likely that activities such as deliveries or surgical assisting, combined with scheduled days off or vacations, could lead to periods of time when there is no physician in the office. It is extremely reasonable to expect that other office personnel, such as nurse practitioners and physician assistants would be available to provide appropriate services to patients. However, this rule would preclude such care being rendered to Medicare and Medicaid patients. Physicians often do not provide direct supervision of noninvasive procedures on a regular basis, and imposing such a requirement will increase costs while limiting patient access during the period when physicians are not present. The proposed rule would be particularly problematic in rural areas where access to care is already a major concern. In many states, medical and nurse practitioner acts enable mid-level providers to practice without onsite physician supervision, enabling care to be provided in rural communities where it would not otherwise be available.

(b) The Academy strongly recommends, based on the definition described above, a shared facility exemption from the self-referral prohibitions. It is common practice for several solo practitioners to have corporations and share office space, labs, call, etc. This exemption would permit two or more physicians in independent practices to share ancillary services, enabling them to provide more comprehensive patient services, reduce practice overhead (shared space, equipment and personnel) and provide high quality care without creating increased potential for fraud, abuse or waste. This is a position the Academy has long supported in relation to “shared labs.” The proposed rule would again have the potential to reduce access to patient care and increase the cost of care by criminalizing many common and legitimate business arrangements.

2. *Discounts*

The proposed regulations would create a new exception for discounts made to a physician that are passed on either to the patient or to the patient’s insurer, including Medicare, and that do not “inure” to the benefit of the referring physician. However, discounts that do “inure to the benefit of the referring physician,” such as discounts on drugs given to patients during their visit, would not qualify for the exception, or meet the “fair market value” requirement and would be considered a self-referral violation. The elimination of many common discounting practices could be disruptive for many physician practices, compromise effective patient care and reduce compliance with medications. The most effective way to ensure that a patient begins a drug regimen is to do so during the visit to the physician, and ensure that the drug is priced at a cost he or she can afford.

AAFP Recommendation: Physicians should be able to charge patients at least the Average Wholesale Price (AWP) on drugs purchased and administered as part of routine care to their patients, regardless of the discount they were able to negotiate with their suppliers. If the physician has no incentive to purchase wisely, savings will accrue to the pharmaceutical manufacturer or distributor, not the patient. AWP is standard and published. If physicians have to track actual acquisition costs and provide documentation, there is an administrative cost that will ultimately discourage physicians from providing medications in their offices and again, decrease access to care.

3. *Physician Recruitment Exception*

In the regulations, there is an exception for hospitals to pay costs associated with a physician’s relocation, but it only applies when the physician resides outside the geographic area and must actually relocate in order to join the hospital staff. The physician cannot be required to refer patients to the hospital, and the remuneration must not be tied to the volume or value of any referrals.

AAFP Recommendation: It is not clear why similar inducements should not be provided to other physicians in the area, or residents in order to retain them in the area. We recommend a written legal agreement clearly address the referral and remuneration issues.

4. *Definition of “Referral”*

The Stark law carefully defines the key term “referral” to include any “request by a physician for an item or service for which payment may be made under Part B . . .” and the Preamble to the proposed regulation clarifies the definition by adding “even if the physician furnishes (the referred service) personally.” Therefore, for a physician to order a designated health service covered by Part B for the physician’s own patient from an entity with which the physician has a financial relationship, he or she must meet an applicable exception.

AAFP Recommendation: This provision is often referred to as the “group practice exception,” however, the definition means that a solo practitioner who provides “designated services” in his or her office must meet an exception (e.g., “in-office ancillary services exception) and all of its requirements (e.g., direct supervision definition) to avoid a self-referral violation. The rule creates layers of complexity for these physicians that seem unreasonable and unnecessary. The Academy recommends that HCFA redefine “referral” to simplify the requirements for physicians who “refer” to themselves for “incident to” and “in office ancillary services” (also, see the following comments on “in-office ancillary services).”

5. In-Office Ancillary Services Exception, Site of Service

The in-office ancillary services exception, as modified by the proposed regulations, requires that services be “furnished . . . in a building in which the referring physician furnishes services unrelated to furnishing of designated health services. . . .” The Preamble to the proposed regulations indicates that a service is “furnished” wherever the procedure is actually performed on a patient, or in the location in which a patient receives and begins using an item. Any item that is given to a patient, but is meant for use at home, or outside the physician’s office would not be deemed to be “furnished” in the physician’s office, according to the proposed rule. This proposed interpretation, if adopted in final form, could eliminate completely physician dispensing of covered self-administered drugs to Medicare and Medicaid patients, a result never intended by Congress. Additionally, durable medical equipment (DME) is excluded from in-office ancillary services by statute, further impeding patient access to needed products and services.

Finally, the Preamble proposes that the “same building” requirement means one physical structure with one address. Consequently, physician offices with multiple structures that are connected by walk ways or tunnels are specifically excluded from HCFA’s interpretation in the proposed regulations.

AAFP Recommendation: Interpretation of the in-office ancillary services exception would, if adopted as proposed, cause serious disruptions in many ordinary arrangements in family physician offices. The Academy requests that HCFA support a legislative remedy to exclude outpatient prescription drugs as a designated health service, as well as durable medical equipment. Other safeguards to prevent fraud and abuse relating to these services have been previously articulated in our introductory comments. Their inclusion as designated services will result in additional delays in treatment and barriers to access for the nation’s poor and elderly populations.

The Academy strongly encourages HCFA to create a more flexible rule in lieu of the “same building” definition. This definition will result in ongoing confusion for physicians, subjective, and thus differing, carrier interpretations, and unnecessary dislocation, disruptions and excessive cost for physicians attempting to comply.

6. Definition of Group Practice

The statute defines group practice as two or more physicians organized as a professional corporation or association. HCFA indicates that both the shareholders in a group practice and the physician employees of the group practice will be considered as members of the group. The proposed regulation also indicates that a group of physicians practicing together will not qualify under the definition of group practice unless at least two of the physicians are shareholders, thus disqualifying the many group practices consisting of a single physician shareholder and one or more employed physicians.

AAFP Recommendation: The Academy believes that this is an artificial differentiation in the definition of group practice, and that HCFA should modify the final regulation to define group practice to include single shareholder groups with multiple employed physicians otherwise meeting the definition. There are numerous single shareholder groups, including those established in states with corporate practice of medicine acts. A physician corporation with two shareholders, and which employs additional physicians, should be treated no differently than a single shareholder physician corporation which employs additional physicians.

CONCLUSION

The Academy appreciates this opportunity to provide a statement to the Ways and Means Committee Subcommittee on Health on the Medicare self-referral laws and proposed rulemaking. In summary, we believe that self-referral laws have added unnecessarily to the complexity of rules governing physician behavior in their business arrangements and trust that the Subcommittee will carefully consider all the comments received and take appropriate action. The committee’s attention to our sug-

gestions will be greatly appreciated by the nation's family physicians and their patients.

Statement of William Rich, III, M.D., American Academy of Ophthalmology (AAO)

Dear Chairman Thomas and other distinguished Members of the Subcommittee, on behalf of the American Academy of Ophthalmology, I am pleased to provide comment regarding the proposed rule on physician referrals to health entities in which they have ownership, also known as Stark II. The American Academy of Ophthalmology represents over 16,000 eye physicians and surgeons nationwide. Over fifty-one percent of most ophthalmologists' practices consist of Medicare services. Because of the significant impact that these regulations would impose on our members, we urge the Subcommittee to take the following recommendations into consideration.

This proposal has been of grave importance to the ophthalmic community, as well as the entire physician community, for many years. We had hoped that clarity would be provided in the publishing of last year's Notice of Proposed Rulemaking (NPRM); however, we have found that the number of questions relating to ownership and referrals have increased. The current law includes untenable obstacles for ophthalmologists and their patients. In addition, the proposed rule raises uncertainty about some of the basic definitions relating to ownership. The NPRM, if implemented to expand upon current law would make understanding and enforcing the self-referral laws virtually impossible. In essence, the law and the NPRM undermine their intended purpose merely on the basis of confusion. For example, according to the NPRM, a referral includes a physician-employee relationship where for example, a physician employs an optometrist or optician. Was this definition accurate? An employer-employee relationship should not be considered a referral.

Even HCFA isn't sure how to interpret the law. This can be seen from the fact that throughout the comment period, HCFA staff were unable to interpret the proposed rule, adding to its unworkable and often contradictory nature. HCFA was expected in the NPRM to offer advisory opinions from physicians, and no opinions would serve as applicable to any other situation. HCFA does not have the staff time, nor is it efficient for the government to impose a law that would require each physician and health care entity in the US which might be affected by Stark II to seek an opinion. HCFA ultimately realized the problems with the NPRM when the proposed rule was rescinded and HCFA announced that it was re-evaluating the proposal. Congress' perceived intention was to limit blatant self-referral problems under the Medicare system. Instead, the varied interpretations of the Stark II law have led to an unworkable law that cannot be enforced by the agency directed to oversee it.

Our concerns, specific to ophthalmology, are two-fold and we urge Congress to guide HCFA in reconsidering its actions. First, we seek the exclusion of post-cataract eyeglasses and contact lenses from the list of designated health services. Second, we urge that the definition of direct supervision be amended so that patient quality of care and access are not needlessly impeded.

EXEMPTION OF OPHTHALMIC GOODS

Since the consideration of self-referral legislation began, Rep. Stark has repeatedly stated that post-cataract eyeglasses and contact lenses should be excluded from the list of designated health services. Post-cataract eyewear is a one-time benefit provided by Medicare and has a limited reimbursement rate. Ophthalmologists who own optical shops are required by law to advise patients of their freedom to buy their eyeglasses anywhere they please (FTC). Given the fact that only one pair of lenses is available to each beneficiary, the opportunity for fraudulent activity is highly unlikely. The chance of beneficiary coercion or lack of choice in who provides this optical service is addressed by the Federal Trade Commission (57 FR 18822). In addition, in a recent informal survey of ophthalmologists who own optical shops, we found that post-cataract lenses only account for an average 4% of total medical and optical practice income.

DEFINITION OF DIRECT SUPERVISION

The NPRM indicates that a physician must directly supervise an employee, providing a service in a medical practice. We understand HCFA's desire to maintain consistency across definitions throughout the agency's policies; however, the defini-

tion of direct supervision makes it almost impossible for certain practices to remain in compliance with Stark II and will gravely impact patient care. For example, if a post-cataract patient wanted to buy his or her eyeglasses from the physician's optical shop, he or she could only do so when a physician is readily available to provide assistance if necessary. This means that on days when the physician is in surgery, the Medicare patient would be denied service because the physician was not readily available. This practice would single-out Medicare patients in a potentially embarrassing manner, essentially telling them that because they have Medicare they cannot get the same level of care as all other patients. The Balanced Budget Act of 1997 included numerous provisions that would expand access, choice and quality for Medicare patients. The definition of direct supervision, as it reads in the NPRM, would prohibit a patient from benefiting from those provisions in the BBA.

We understand that Medicare defines a physician as a "doctor of medicine or osteopathy . . . doctor of dental surgery or dental medicine . . . a doctor of optometry, and a chiropractor" (Section 1877, 1861(r)). Because of this, we are very concerned that the definition of direct supervision is inconsistent with state scope-of-practice laws relating to opticians. Opticians generally are permitted by state law to fit, grind and dispense eyeglasses without physician supervision—direct or indirect. Requiring a physician to be present to meet the direct supervision requirement would nullify laws permitting opticians to dispense without physician oversight. We agree that in certain medical situations, some level of supervision should be required, but in the case of opticians, this requirement is over-reaching and inappropriate.

CONCLUSION

Mr. Chairman, the current self-referral law is cumbersome and the proposed Stark II provisions will make it nearly impossible for a physician to know whether or not they are in compliance with federal law. Many lawyers have indicated that they are experiencing great difficulty in interpreting the regulations and will not know how to advise their clients. We believe that the compounding requirements for compliance will add to the current over-burdening of work that HCFA is experiencing as a result of the Balanced Budget Act of 1997. The overlapping requirements surely will increase the number of requests for advisory opinions, and the volume of calls to HCFA staff. Physicians are intimidated and nervous about these proposed changes and they will by-pass their own legal counsel and contact HCFA directly for guidance. Already, we have a number of calls seeking information about applying for the opinions. In closing, the American Academy of Ophthalmology strongly recommends that HCFA: (1) exempt eyeglasses and contact lenses from the list of designated health services as a prosthetic device on the basis that post-cataract eyeglasses are a very limited Medicare benefit and already subject to oversight regarding fair business practices; and (2) Revise and clarify the definitions of certain terms such as "Referral" and "Direct Supervision." Thank you for the opportunity to present comment on this important issue. We look forward to working with Congress and HCFA staff in any way possible. Should you have any questions, please contact Kim Colman, our Reimbursement Policy Manager.

Statement of the American Association of Ambulatory Surgery Centers, Chicago, Illinois

The American Association of Ambulatory Surgery Centers (AAASC) is a professional medical association of physicians, nurses, and administrators who specialize in providing surgical procedures in cost-effective outpatient environments, primarily in Medicare-certified ambulatory surgery centers (ASCs). In fact, a substantial number of our members either own or perform surgery in a Medicare-certified ASC. As such, our membership is very interested in potential changes to Medicare physician self-referral laws, particularly as they would affect ASCs.

The physician "self-referral" provisions were enacted, in large part, because several studies suggested that physicians who have financial arrangements with entities to which they refer patients may increase utilization. However, these studies lacked evidence that physician ownership increases utilization of ASC services. In fact, a number of studies, including the noted Florida Cost Commission Review of physician self-referral patterns, examined services provided in the ASC setting and concluded that there was no ascertainable abuse with respect to the referral of patients by operating surgeons to ASCs in which they have an ownership interest.

As such, when Congress first devised the physician "self-referral" provisions, and subsequently the 1993 amendments, it did not include ASC services among the list of designated health services. Nonetheless, because of the broad way in which the

law was written and subsequently interpreted, it potentially applies to physician investments in ASCs.

While Congress clearly did not intend for the physician self-referral ban to apply to services performed in the ASC setting, the law could be read to apply to certain services provided in ASCs. For example, prosthetics, orthotics, and prosthetic devices are designated health services. Many common implants—*e.g.*, intraocular lenses, prosthetic implants after mastectomy procedures, testicular prostheses, and tympanotomy tubes in children—are considered prosthetics. Thus, the physician-self-referral ban could be interpreted to reach situations where surgeons implant prosthetics in ASCs which they own and to which they refer their patients and for which Medicare is not making separate reimbursement because it's a component of the facility fee. Likewise, radiology services, which also are designated health services, could be interpreted to include any procedure which involves imaging, which would include a number of endoscopy and arthroscopy procedures.

AAASC is pleased that HCFA recognized that there is no risk of program or patient abuse when a physician refers a patient to his or her ASC, and that the Agency is proposing to expressly exempt from the physician self-referral proscriptions services performed in ASCs. See 63 Fed. Reg At 1666 (Jan. 9, 1998) and 42 C.F.R. §411.355(d)(1) (proposed). Nonetheless, for the following reasons we urge Congress to codify an express exception for ASC services in the statute. First, HCFA's proposed regulation remains in proposed form and apparently will not be finalized for at least another year. Until then, physician investment in ASCs is an uncertain endeavor. Physicians who choose to invest in ASCs take a calculated risk based on HCFA's stated approval of these arrangements, but expose themselves to possible prosecution should HCFA change its view of these arrangements or choose not to include the express exception in the final regulations. Congress should express its approval of physician ownership of ASCs and ensure that these arrangements are exempt from the self-referral prohibition by including an express exception in the statute.

Second, if physician self-referral restrictions were to prohibit doctor ownership of ASCs, there would be virtually no ASCs left. More than two-thirds of the ASCs in the country have been developed and owned by physicians to achieve control of the surgical environment (lacking in the hospital), convenience for their patients, and reduced costs.

Third, unlike services provided by clinical laboratories and diagnostic imaging centers, surgical services performed in an ASC are subject to a utilization review by peer review organizations; as such, there is a check on inappropriate utilization.

Fourth, the physician operates in the ASC as an extension of his or her office, much like an internist might offer in-office ancillary laboratory or radiology services. The surgeon is not a passive investor; a "referral" is not really taking place.

Finally, ASCs save the Medicare program hundreds of millions of dollars each year. Medicare payments to ASCs for outpatient surgical procedures are usually substantially lower than payments to hospitals (both on an inpatient and outpatient basis). In fact, according to the Medicare Payment Advisory Commission (MedPAC), the median payment to a hospital for a cataract removal procedure (*i.e.*, CPT code 66984) in 1996 was approximately \$1,150, while the median payment to an ASC for that same procedure was only \$903, a savings of \$247. Or more than 20% (See MedPAC Report to Congress, June 1998). Moreover, ASCs have brought the benefits of competition to the entire outpatient surgery market: the opening of an ASC in a particular area has frequently been followed by a significant reduction in the charges of local hospitals for outpatient surgery, as well as increased attention on the part of the hospitals to quality of care and patient satisfaction.

AAASC supports clear, unambiguous physician self-referral prohibitions that prevent unethical financial relationships and reinforce the critical element of trust in the physician-patient relationship. However, these prohibitions need not and should not apply to services provided in the ASC setting. Congress should clarify the physician self-referral statute to expressly exclude ASCs from it. Specifically, we recommend that Congress adopt the language it approved in § 8204(f) of the "Balanced Budget Act of 1995," H.R. 2491 (vetoed), which expressly excluded ASC services from the self-referral law.

AAASC appreciates the opportunity to present this testimony to the Subcommittee. Please do not hesitate to contact Washington counsel, Michael Romansky, if you have any questions about this matter.

[Note: Attachment is being retained in the Committee files.]

Statement of William W. Tipton, Jr., American Association of Orthopaedic Surgeons, Rosemont, Illinois

Mr. Chairman and members of the Committee, I am William W. Tipton, Jr, MD, an orthopaedic surgeon and Executive Vice-President of the American Association of Orthopaedic Surgeons.

On behalf of the 15,000 board-certified fellows of the Association, thank you for the opportunity to present testimony before your Committee on the physician ban on self-referral statute, otherwise known as the "Stark" provisions.

Let me begin by saying that the Association shares the Committee's concern about fraud and abuse in the Medicare program. In addition, we support fully what we understand to be the original intent of the "Stark" provisions—prevention of fraud and the over-utilization of services. Nonetheless, the Association believes that the "Stark" provisions produced several unintended consequences. Specifically, many common in-office procedures that orthopaedic surgeons provide to their patients are now technical violations of Federal law as a direct result of these "Stark" provisions.

Unfortunately, the proposed rule published by the Health Care Financing Administration (HCFA) in the Federal Register on January 9, 1998 did little to correct or clarify the unintended consequences of the law. Instead, the proposed rule created even more ambiguities to the "Stark" provisions.

We believe that Congressional action is now needed to correct this matter, since the self-referral ban is so broad that its implementation impedes the normal practice of medicine, including that of orthopaedics. Equally, we believe the law's prohibition on self-referral is unnecessarily burdensome to honest physicians and the patients under their care.

Let me highlight the main problems and areas of confusion that we believe the "Stark" provisions are causing for practicing orthopaedic surgeons. Our concerns cover the following issues:

- Definition of a referral
- Durable medical equipment used as part of in-office ancillary care
- Shared facilities
- Shared employees
- Compensation arrangements

DEFINITION OF REFERRAL

The most important issue in determining whether or not an arrangement is prohibited under the "Stark" provisions is identifying whether a referral for a designated health service has taken place.

Under the law, a "referral" is defined as: "the request by a physician for an item or service for which payment may be made under Part B, including the request for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision of) that other physician—including the request or establishment of a plan of care by a physician that includes the provision of a designated health service."

There has been a great deal of confusion surrounding this issue, especially in regard to referrals made among members of the same group practice. HCFA's interpretation, as illustrated by its proposed rule, is that a referral is subject to the "Stark" provisions whenever a physician requests any designated health service covered by Medicare, even if that physician furnishes the services personally, unless a specific exemption is met.

Instead of a definition that cannot be implemented fairly, we believe a reasonable and impartial standard for determining when a referral takes place should be adopted, such as the policy covering solo practitioners. Under this standard, those activities that a solo practitioner performs as an ordinary and essential part of patient care are not considered a referral. The Association believes this definition could be expanded to cover physicians in any practice or business arrangement.

DURABLE MEDICAL EQUIPMENT

Another area of great concern is the continued exclusion of durable medical equipment (DME) from the in-office ancillary services exception.

The typical orthopaedic practice uses a wide range of DME, as well as orthotics, prosthetics, and other supplies in the office. These items are an integral part of orthopaedic practice, yet the use of many of these items would constitute a violation of the "Stark" provisions.

In its proposed rule, HCFA tried to address this issue by specifically carving out an exception for crutches, indicating it regards them as different from other DME because a patient often needs them immediately after treatment from an injury or an unexpected traumatic event. While we are pleased that HCFA recognized that crutches are an integral part of patient care, this did not go far enough. For example, a walker may be more appropriate than crutches, yet walkers are prohibited under the "Stark" provisions.

Mr. Chairman, I would like to share with you the following examples that illustrate why the "Stark" provisions are problematic in regard to DME:

In the first example, a 70-year-old female twists her foot and is brought to the office in a wheel chair, unable to walk because of pain in the lateral aspect of her foot. X-rays reveal a fracture at the base of the 5th metatarsal. Proper treatment includes a compression wrap to minimize pain and control swelling, a wooden-soled sandal to distribute weight across the uninjured part of the foot to allow limited weight bearing, and either crutches or a walker to aide in independent ambulation. The physician must provide instruction to the patient in proper application of the compression wrap, proper wearing of the sandal, and training in use of the crutch or walker. If crutches are used, the physician may dispense these in his or her office. However, if the physician determines that a walker is more appropriate for this elderly patient, under the "Stark" provisions, she must travel to a DME supplier several miles away.

In the second illustration, a 65-year-old female patient with a wrist fracture that has been placed in a short arm cast comes in for follow up X-rays. The physician finds that the fracture has healed sufficiently that another cast is not required, but a wrist brace or splint is required for a week or two to allow the patient's wrist to become stronger. Under the "Stark" provisions, this device may not be dispensed in the physician's office, so the patient is either given a prescription to purchase a splint at a surgical supply store several miles away, or the patient is referred to Occupational Therapy to have an orthosis custom-made, at a much greater cost.

In the third instance, a 66-year-old male develops severe neck pain with radiation of the pain down one arm with tingling numbness to the fingertips. Examination and review of X-rays assists in the diagnosis of acute cervical radiculitis (pinched nerve). Appropriate treatment is rest, medication, and a cervical collar. Under the "Stark" provisions, the physician is unable to dispense this item in his or her office or provide instruction in its use, so the patient must travel several miles to a DME supplier. If the cervical collar is not properly sized or the patient does not receive appropriate instruction, the result will be additional pain to the patient.

Finally, a 70-year-old male tennis player injures his knee, and examination and treatment reveal a hemarthrosis requiring knee aspiration. However, pain precludes walking and knee motion. Appropriate treatment is the use of crutches and a knee immobilizer splint. The crutches are dispensed in the office; however, under the "Stark" provisions, the patient must travel several miles to a DME supplier.

In the interest of patient safety, convenience and quality care, orthopaedists and other physicians should be allowed to give out these commonly used items immediately in their offices. Yet, if they did so, they would probably be in violation of the "Stark" provisions.

SHARED FACILITIES

The next problem I would like to speak about involves shared facilities. A shared facility is a practice arrangement in which orthopaedic surgeons and other physicians deliver services in a defined and separate facility that may contain X-ray equipment, physical therapy, a cast application room, and all essential nursing and administrative support.

Under this arrangement, these physicians are not part of a group practice, but retain their independence through separate billing numbers with insurance carriers. Though separation is maintained through different billing numbers, the physicians share the costs of the common facility, including rent nursing and office expenses, as well as costs and revenue for X-ray and physical therapy services on a pre-determined basis.

A shared facility is the most common type of integrated health care delivery arrangement and it behaves exactly like a group practice. Yet, it is not covered by the "group practice" exemption under the "Stark" provisions.

Let me cite an example of why this jeopardizes quality patient care.

A Medicare patient comes to a shared facility for an X-ray. Since these types of practice arrangements are not exempt under the “Stark” provisions, the patient cannot be X-rayed in a separate room in the common facility, but has to go to a separate facility for the X-ray, and then back to the orthopaedist for diagnosis and treatment. Likewise, if the patient has a broken bone, and the orthopaedic surgeon decides to treat the fracture without surgery, the patient must return to the outside facility for another X-ray and then back to the orthopaedist to determine if the treatment was successful.

Mr. Chairman, I am sure you will agree that shuttling patients between the X-ray facility and the orthopaedist is not in the best interest of the patient, nor is it cost-effective or quality service. Yet, if the patient gets his or her X-ray at the orthopaedist’s office, it may be a violation of the “Stark” provisions.

SHARED EMPLOYEES

Mr. Chairman, another problem for orthopaedic surgeons and other physicians involves the issue of shared employees.

Orthopaedic surgeons have developed arrangements with DME suppliers, wherein the suppliers rent DME closets in the orthopaedists’ offices at fair market value (meeting the leasing exemption). The technicians who measure for braces or other DME supplies are shared employees of the orthopaedists and the suppliers, and the suppliers pay for the time the technicians spend measuring braces and supplying the DME to patients.

In this situation, the orthopaedists bill for a Level 1 visit only if they see the patient and provide professional services (beyond those provided by the technician). Otherwise, the orthopaedist does not bill Medicare, and is not in any way involved in a financial arrangement, since the billing is done by the vendor and the technician is a part-time employee of the vendor.

This type of common practice arrangement contributes to effective and convenient patient care, yet it may be a violation of the “Stark” provisions.

COMPENSATION ARRANGEMENTS

Mr. Chairman, another problem for orthopaedic surgeons and other physicians involves compensation arrangements.

The “Stark” provisions contain a presumption that if a physician is receiving a payment of any kind from any other provider of designated health services, the physician should not refer the patient to that service provider, with some very limited exceptions.

We believe that these exceptions are not broad enough to include the myriad of compensation arrangements that do not pose a risk of program or patient abuse. Examples of these arrangements are as follows:

Installment payments over a period of time—An orthopaedic surgeon or group practice sells a “designated health service” facility (such as an MRI or physical therapy center), and continues to send patients to the facility. Installment payments are made over a period of time, at a fixed price (fair market value), and not based upon volume of referrals to that sold facility.

Independent contractors—One day per week, a physical therapist (non-employee, independent contractor) rents space in the office of a physician or group practice. The physician(s) charge rent (at fair market value) to the independent contractor, and refer patients. There is no additional compensation for making such referrals.

Therefore, we believe a process needs to be established whereby compensation arrangement can be evaluated on a case-by-case basis using clear criteria to determine whether or not they are appropriate.

In conclusion, Mr. Chairman and members of the Committee, the American Association of Orthopaedic Surgeons believes that the “Stark” provisions are unclear and confusing. As a result, HCFA has been unable to provide any comprehensive and understandable guidelines for complying with it.

While the Association has not taken a position on the repeal of the “Stark” provisions, we believe that your Committee should at least consider approving the amendments to the “Stark” provisions which were included in the Balanced Budget Act of 1995, which were approved by both the full House of Representatives and the Senate, but were never enacted into Public Law. Moreover, before any final rule is published by HCFA, Congress must make changes in the law so that an undue burden is not placed on honest physicians and their patients.

Mr. Chairman, the Association stands ready to work with your Committee to correct these unintended consequences of the "Stark" provisions. Thank you again for the opportunity to present testimony to your Committee on this important issue.

Statement of the American Clinical Laboratory Association

The American Clinical Laboratory Association ("ACLA") is pleased to have this opportunity to submit testimony with regard to the Subcommittee's consideration of issues related to physician self-referral. ACLA is an association of federally-regulated independent clinical laboratories located throughout the United States. All ACLA members are directly affected by the prohibition on physician self-referral contained in Section 1877 of the Social Security Act. In our statement, we will review the basis for the current self-referral prohibition on laboratory services, discuss the current status of the self-referral law as it applies to laboratory services and provide ACLA's views on some possible modifications of the law.

I. SELF-REFERRAL OF CLINICAL LABORATORY SERVICES SHOULD CONTINUE TO BE PROHIBITED

Congress enacted the prohibition on self-referral for laboratory services in 1989, as part of OBRA '89. This was the first time Congress had prohibited self-referral on a large scale. While Congress did not apply the prohibition to other services at that time, it found the record amply demonstrated the need for a limitation on self-referral of clinical laboratory services.

When Congress passed the self-referral prohibition on laboratory services, it did so based on a number of significant studies. In 1989, the Office of Inspector General ("OIG") conducted a study entitled "Financial Arrangements Between Physicians and Health Care Businesses." That study concluded that physicians who owned or invested in independent clinical laboratories ordered 34% more clinical laboratory services than did physicians who had no ownership or investment interest in a laboratory. Moreover, in testimony before this Subcommittee, then-Inspector General Kusserow estimated that this increased testing was "quite troubling" and a "cause for concern to the Medicare Program." Subsequent studies in Florida also found increases in clinical laboratory utilization among physician-owned facilities. In that study, laboratories that were owned by referring physicians performed almost twice as many diagnostic tests per patient as similar non-joint venture laboratories. Not surprisingly the study also found that the higher utilization per patient led to significantly higher gross revenues per patient.

ACLA recognizes that such studies do not specifically show that the clinical laboratory services performed at physician owned laboratories were unnecessary. Still, on balance, there appears little justification for higher utilization of laboratory services at physician-owned laboratories than at non-physician owned facilities. There is no *clinical* rationale that explains why a patient would need more services when the referring physician was an owner of the laboratory performing the test than when the physician did not have such an interest. Nor is there any clinical reason that physicians with an ownership interest in a laboratory should order more services than physicians without such an interest. The simplest, and most plausible explanation, is that physicians respond to the incentives for additional profit by ordering more services.

It was in response to its concern about such incentives that Congress enacted the initial self-referral prohibition on laboratory services. Under the original Stark I provision, which became effective in January 1992, physicians were prohibited from referring their Medicare patients' testing to clinical laboratories with which they had an ownership or investment interest or a compensation arrangement. Final regulations covering the prohibition of self-referral of laboratory services have been in effect since August, 1995. Thus, unlike other services that were added by OBRA '93, the health care system has, for the most part, had time to adapt to the self-referral prohibition on laboratory services.

ACLA continues to believe that a prohibition on self-referral for clinical laboratory services is crucial to controlling unnecessary utilization of clinical laboratory services. ACLA believes it would be inadvisable, at this time, to eliminate the law's prohibition on self-referral of laboratory services, even if changes are made in the list of other services covered by the prohibition. Although we recognize that managed care is a greater presence in the health care market place today than it was when the self-referral law was originally passed, the vast majority of services furnished to *Medicare* patients are still paid for on a fee-for-service basis and it is to these

services that the law primarily applies. Thus, ACLA believes the law continues to serve a very important role in curbing increased utilization.

In sum, although ACLA recognizes that some have called for removing certain services from the list of "designated health services" that was added to Section 1877 by OBRA '93, ACLA does not believe it would be appropriate to remove clinical laboratory services from that list.

II. SOME LIMITED MODIFICATIONS MAY BE NECESSARY

ACLA does recognize that the statute as implemented is a complex one to interpret and enforce. Therefore, ACLA members do recognize that some modification may be necessary to ameliorate the technical problems that have been identified and to simplify the application and interpretation of Section 1877. Some of ACLA's concerns are set out below.

ACLA recognizes that the compensation provisions have been the most difficult to apply for many providers. In the Notice of Proposed Rulemaking ("NPRM") for Stark II, issued in January 1998, HCFA proposed a number of provisions to simplify the application of the compensation arrangement provisions. Among the proposals considered were a de minimis exception and a provision to make the self-referral law more consistent with the safe harbors provisions interpreting the antikickback law. ACLA believes that some modifications in the application of the compensation arrangement provisions, including those proposed by HCFA in the Stark II NPRM, may be appropriate.

ACLA also is concerned about the reporting requirements that may be adopted to enforce the self-referral provision. HCFA stated in the January 1998 NPRM it would develop a new reporting form, although it has not yet done so. ACLA believes it is very important that any reporting requirements be carefully tailored to avoid adding new reporting responsibilities to those that already apply to most health care providers participating in Medicare.

ACLA appreciates the opportunity to comment on these issues. We would be happy to work with the Subcommittee on helping to resolve any of these issues.

Statement of the American College of Cardiology, Bethesda, MD

The American College of Cardiology (ACC), which represents nearly 25,000 cardiovascular specialists, appreciates the opportunity to present the following statement regarding the Medicare physician "self-referral" law, commonly referred to as Stark II (enacted as part of the Omnibus Budget Reconciliation Act of 1993 [P.L. 103-66]).

As a professional medical society and educational institution, the ACC's mission is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, and leadership in the development of standards and guidelines and the formulation of health policy.

Over five years ago, Congress was motivated to enact legislation with the good intention of preventing abuses in physician referral patterns resulting from economic self-interest. Although the ACC understands the rationale that prompted enactment of the law in 1993, we strongly believe the vast changes in the health care marketplace that have since occurred, including the broad use of specific utilization controls and documentation requirements, have rendered the need for additional regulatory controls unnecessary and burdensome. In addition, before publication of the proposed regulations in 1998, HCFA and the Office of the Inspector General published rules addressing a range of issues, including anti-kickbacks, that overlap with the proposed Stark II regulations. Furthermore, the ACC believes that the proposed regulations implementing the Stark II law contradict congressional intent by interpreting the law in such a convoluted, incomprehensible, and irrational manner as to render even ethical and necessary medical practice arrangements potentially unacceptable.

For example, the proposed regulations include an overly broad definition of what constitutes a "compensation arrangement" that would thereby trigger a referral prohibition. The definition would include any kind of "indirect" remuneration, without qualification or limitation. This unrestricted definition would encompass virtually any benefit received, on any level, and is much broader than needed to combat fraud and abuse. In addition, the definition of "radiology services" under the list of designated health services has been vaguely interpreted so that it is not clear whether this definition includes certain invasive procedures that are not subject to abuse. In fact, the use of these types of procedures in daily practice provides unique and essential information for the treatment of patients with cardiovascular disease and en-

sure a continuum of care for patients. The definition of radiology services also continues to include ultrasound, which is not a radiology service, and has not been found subject to abuse.

The ACC thanks the subcommittee for taking steps to examine the complexity of the statute and the proposed regulations. We believe that congressional interest is only in eliminating true fraud and abuse to protect patients and the Medicare program, not in exposing physicians and other providers to criminal penalties resulting from an ambiguous and unnecessary new set of rules. We look forward to working with you to enact any meaningful changes to the law.

Statement of the American College of Physicians—American Society of Internal Medicine

The American College of Physicians—American Society of Internal Medicine (ACP-ASIM), the nation's largest medical specialty society, representing over 116,000 physicians who specialize in internal medicine and medical students, appreciates the opportunity to submit a statement for the record to the Committee on Ways and Means Subcommittee on Health on how the Stark I and Stark II physician Self-referral laws and their corresponding regulations are having a negative impact on the practice of medicine.

ACP-ASIM is concerned that many of the issues we raised in our comments on the Stark I final rule of August 14, 1995, and that we hoped would be clarified in the Health Care Financing Administration's (HCFA) proposed rule of January 9, 1998, were not satisfactorily addressed. Furthermore, several new problems have arisen in this proposed rule as well. Our overall impression of the rule is that it is confusing, inconsistent, and does not reflect the current health care delivery environment. For these reasons, we have asked that HCFA rectify the concerns discussed in these comments before a final rule is published, implemented, and enforced. HCFA's current proposal will create serious enforcement and compliance problems and generate significant unnecessary financial costs for physicians and other entities that attempt to comply, as well as for HCFA, the Department of Health and Human Services (HHS) Office of Inspector General (OIG), and the Medicare carriers. Ultimately, the proposed rule will create unintended access and quality of care problems for Medicare and Medicaid beneficiaries attempting to receive the following Stark II "designated health services:"

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

The Stark I and II self-referral legislation was enacted by Congress in response to reports that certain health care services were being "abused" by physicians with financial interests or investments in entities that provided the service(s). Congress passed legislation that prohibited physicians from referring to those entities in which they (or an immediate family member) had such an interest or investment. Congress subsequently added safeguards and revisions to Medicare and Medicaid reimbursement policies involving referral activities.

ALTERNATIVE APPROACHES TO REDUCING PROGRAM ABUSE

ACP-ASIM is pleased that Congress called the above hearing to re-examine the Stark I and II laws, given the fact that HCFA, the Office of Inspector General (OIG), and the Department of Justice (DoJ), have numerous other tools to target abusive practices. Without changes to the Stark laws themselves, any rule proposed by HCFA is likely to introduce a degree of regulatory complexity and rigidity that will interfere with legitimate arrangements between physicians and health care facilities. Other legislative and regulatory approaches can instead be used by HCFA to target abusive arrangements.

The False Claims Act (FCA), enacted over a hundred years ago, imposes civil liability on any person or entity who submits a false or fraudulent claim for payment to the United States government. The False Claims Act also allows an individual who knows about a person or entity who is submitting false claims to bring a suit, on behalf of the government, and to share in the damages recovered as a result of the suit. A person who violates the FCA must repay three times the amount of damages suffered by the government plus a mandatory civil monetary penalty (CMP) of at least \$5,000 and no more than \$10,000 per claim.

The Anti-kickback Statute (enacted in 1972) provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce the furnishing of items or services covered by Medicare or State health care programs (including Medicaid, and any State program receiving funds under titles V or XX of the Act). A CMP of up to \$50,000 plus up to three times the amount of remuneration offered, paid, solicited or received could be levied for each violation of the anti-kickback provisions of title XI of the Social Security Act (as amended by the Balanced Budget Act of 1997—"BBA '97").

Furthermore, in the interim between the enactment of the Stark II legislation and the publication of the Stark II proposed rule, Congress and HCFA have taken numerous steps to reduce abusive self-referral practices. The BBA '97, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are two major legislative efforts designed to increase and enhance the scrutiny of providers of health care services to Medicare recipients. The BBA '97 increases penalties associated with fraud and abuse, revises payment to skilled nursing facilities, and improves communication with beneficiaries.

HIPAA has increased funding for Medicare program safeguards. HIPAA funding is divided between the OIG and the DoJ to coordinate federal, state and local health care law enforcement programs; conduct investigations, audits, evaluations and inspections relating to the delivery and payment of health care; help facilitate enforcement of civil, criminal and administrative statutes on health care fraud and abuse; provide guidance to the health care industry on fraudulent health care practices; and establish a national data bank to receive and report final adverse actions against health care providers.

HCFA's contractors were also allocated additional resources to educate the provider billing community, including hospitals, physicians, home health agencies and laboratories about Medicare payment rules and fraudulent activity. This education covers current payment policy, documentation requirements and coding changes through quarterly bulletins, fraud alerts, seminars and through local medical review policy.

HIPAA also established the Medicare Integrity Program (MIP), which is intended to "promote the integrity of the Medicare program by entering into contracts" with private entities to: (1) review the activities of providers furnishing items and services reimbursable under Medicare, including medical and utilization review and fraud review; (2) audit cost reports; (3) educate providers, beneficiaries, and other persons with respect to program integrity and benefit quality assurance issues; and (4) develop and periodically update a list of items of durable medical equipment which are subject to prior authorization.

In addition, HCFA carriers have established computer claims payment edits to alert them to areas of overutilization by screening practice patterns. The National Practitioner Data Bank and the National Suppliers Clearinghouse were founded to provide information on physicians and other health care providers, including information on exclusions from plan participation due to fraudulent and abusive activities. Finally, inappropriate referrals of Medicare and Medicaid patients to outside laboratories and other designated diagnostic facilities are already prohibited under the Federal anti-kickback law.

The enhancements to the Medicare and Medicaid programs described above should help allay Congress' original concern about physician self-referral. ACP-ASIM thus strongly supports Congress' revisiting of the premises upon which the self-referral legislation was founded and comparing those premises to the current regulatory environment to determine if there still is a need for the broad regulatory provisions of this proposed rule.

A consequence of the lack of specificity in some sections of the Stark II proposed rule is that both the health care industry and federal government will have to expend tremendous resources on compliance and enforcement activities. Seeking legal counsel or OIG advisory opinions will cost physicians an enormous amount of time and money to determine if they are in compliance with this proposed rule that was intended to give physicians a "bright line" to guide their business arrangements. Ultimately much of this effort will be wasted because the proposed rule is confusing and open to multiple conflicting interpretations. ACP-ASIM has obtained seven dif-

ferent legal briefs analyzing the proposed rule and many of the legal interpretations differ substantially. Furthermore, there is no guarantee that any of these interpretations will be the same as the OIG's interpretation.

Should physicians and providers assume a more conservative approach in the delivery of any of the Stark II designated health services as a result of the proposed rule, the impact on patient access and the quality of health care would certainly suffer. While unnecessary overutilization should be targeted and penalties imposed, unintended underutilization is a potential consequence of the proposed rule that creates a far greater threat to Congress' interest in assuring access and quality health care to the Medicare/Medicaid enrollees.

ISSUES UNRESOLVED BY THE STARK II PROPOSED RULE

ACP-ASIM has previously asked HCFA to modify the proposed regulation to: (1) accommodate a shared facilities exception; (2) substitute the definition of "general supervision" for "direct supervision" in the in-office ancillary exception; (3) support Congressional legislation to eliminate the group practice compensation requirements; and (4) revise the definition of a group practice. We had hoped that the Stark II proposed rule would address these issues. The proposed rule did little to address ACP-ASIM's concerns, providing no mention of shared facilities, making virtually no change in the supervision definition, expanding rather than eliminating the regulations for group compensation requirements, and adding more confusion to the group practice definition. To rectify these problems that originated with the Stark I final rule, ACP-ASIM urges legislative or regulatory relief to allow the four changes to the Stark II proposed self-referral rule described below.

1. Create a shared facility exemption

ACP-ASIM is extremely disappointed that HCFA did not create a separate shared facility exemption in the Stark I final rule, published on August 14, 1995, or in the January 9, 1998 proposed rule. We believe that creating such an exemption is within the authority of the Secretary. Furthermore, ACP-ASIM disagrees with HCFA's assertion that the risk of program or patient abuse associated with a shared facilities exemption would be significant—no sufficient data to support this conclusion have yet been offered by HCFA. ACP-ASIM urges HCFA to reconsider its position on creating a shared facility exemption for shared laboratories and other designated health services; barring such a change, we feel a legislative remedy is clearly indicated.

ACP-ASIM has repeatedly called for a narrowed shared facility exception to the Stark self-referral regulations to alleviate the Stark I burden placed on thousands of physicians' practices. Many solo practitioners want to continue to share equipment, rental space, and personnel in order to control their overhead costs while providing a necessary service to their patients. The absence of a shared facility arrangement in the Stark I regulation has disrupted physician practices. Without an exception for in-office facilities shared between two or more physicians who are not members of a group, physicians are seemingly left with one of two options: form or become part of a group practice (which are exempted under the Stark laws); or, close their shared facilities. While the lack of a shared facility exemption in the Stark I rule adversely affected access to clinical laboratory services only, the lack of such an exception in the Stark II proposed rule places numerous other shared facilities—those that are included on the list of designated health services—at risk.

ACP-ASIM believes that a narrowed shared facilities exception will not violate the intent of the self-referral statute. HCFA stated in the Stark I final rule that the "in-office ancillary" exception would provide the necessary protections for sharing of certain facilities between two or more physicians who do not meet the definition of a group practice. However, ACP-ASIM continues to believe that a shared facility exception is necessary because the current in-office ancillary exception is not broad enough for the variety of shared facility arrangements that physicians wish to create to reduce overhead cost, while providing service to their own patients, and that do not pose any threat of patient or program abuse.

ACP-ASIM's position has been supported by legislation that passed the Congress in 1995 (but was subsequently vetoed for unrelated reasons) and by the HHS Practicing Physicians Advisory Council (PPAC). ACP-ASIM urges that this be rectified in either a Stark II final rule from HCFA, or through legislative remedy. ACP-ASIM supports the following language as it appeared in the BBA '95:

A general exception from the self-referral prohibition would be established for shared in-office ancillary services that are furnished:

- (i) personally by the referring physician who is a shared facility physician or personally by an individual directly employed or under the general supervision of such a physician;
- (ii) by a shared facility in a building in which the referring physician furnishes substantially all of the services of the physician that are unrelated to the furnishing of shared facility services; and
- (iii) to a patient of a shared facility physician; and
- (iv) that is billed by the referring physician or a group practice of which the physician is a member.

2. *Change the in-office ancillary services exception governing supervision*

The Stark I final rule provided a modest exception for in-office ancillary services. A requirement of this exception was that the physician had to personally perform or “directly supervise” laboratory tests ordered under Medicare Part B. The direct supervision requirement was interpreted in the Stark I final rule to mean that the physician must be “. . . present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.”

ACP-ASIM believes that HCFA’s direct supervision requirement is unreasonable and unnecessary. Direct supervision imposes significant hardship and unrealistic demands on all physicians with in-house shared facilities. If physicians are required to spend their days supervising the work of their technicians—trained employees whose performance is constantly evaluated—they will be hard pressed to find time to see patients and make hospital rounds. Additionally, this requirement is unnecessary because physicians already assume legal responsibility for all work performed in their shared facilities.

ACP-ASIM has previously asked HCFA to change the direct supervision requirement to a general supervision requirement or that HCFA adopt the more flexible definition of direct supervision contained in the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This definition states that “. . . the physician or group is legally responsible for the services performed by the testing personnel and for ensuring that such personnel meet licensure and certification requirements, if any, under other provisions of the law.” The physician, or person responsible for overseeing the testing in question (e.g., the lab director or general supervisor in the case of the CLIA regulations) should be available, but not necessarily on-site, when testing occurs, in case testing personnel need assistance.

The current direct supervision requirement clearly conflicts with the intent of the conferee language accompanying the Stark II Self-Referral provisions in the Omnibus Budget Reconciliation Act of 1993, which specified that: “The conferees intend that the requirement for direct supervision by a physician would be met if the lab is in a physician’s office which is personally supervised by a lab director, or a physician, even if the physician is not always on site.” (emphasis added).

The Stark II proposed rule does not provide any changes in the direct supervision definition in the manner requested by ACP-ASIM. It does, however, provide for short, emergency and routine absences by the physician. The appropriate length of these absences is left to the carriers to determine on an individual basis. This modest change in the definition of general supervision is inadequate. ACP-ASIM has urged HCFA to replace “direct supervision” with “general supervision” in the in-office ancillary services exception language in the Stark II final rule. If HCFA decides instead to maintain a “direct supervision” requirement, then we would seek legislative relief for a change in the definition as follows:

The physician or group is legally responsible for the services performed by non-physician personnel and for ensuring that such personnel meet licensure and certification requirements, if any, applicable under other provisions of the law. Direct supervision does not require that physicians be physically present when an item or service is provided.

This definition would allow physicians to perform all of their professional duties while continuing to be personally responsible for the services provided by the laboratory personnel.

We are greatly troubled that after directly quoting language from the conferees’ report, HCFA went to great length to explain why Congress did not really intend to allow the physician to be at an alternative site when the tests are being performed. The conferees’ report is unambiguous; Congress clearly intended for the direct supervision requirement to be met “even if the physician is not always on site.”

3. *Eliminate the prohibition on referrals based on compensation arrangements*

The Stark II proposed rule retains a prohibition on certain compensation arrangements and contains a number of new provisions that address how a group practice

must distribute group costs and revenues. Group practices are required to have a method of distributing costs and revenue that has been “previously determined.” Group practice payments to individual group members may not be made on the basis of the value or volume of that individual member’s referrals. The Stark II proposed rule does not allow for the distribution of profits that belong to a particular specialty or subspecialty because of concern that such specialty profit pools could result in payments for referrals. A physician in a group practice may be paid a share of the overall profits of the group, or a productivity bonus based on services personally performed or services “incident-to” the personally performed services.

Physicians in a group practice should be allowed to devise their compensation arrangements without unnecessary government intrusion into their business practices. The ability to structure compensation arrangements within a group by taking into account varying services at different sites, along with associated differences in expense structure, is vital to any business. The group practice compensation requirement, as retained and expanded in the Stark II proposed rule, represents an onerous and unnecessary intrusion into the internal affairs of physician practices, and is impossible to implement in a fair and equitable manner.

As a practical matter, it is impossible for group practices to redistribute income from ancillary services without at least indirectly taking into account the volume or value of the referrals made by the physicians within that group. The ambiguous language of the Stark II proposed rule, however, will cause group practices to question whether the distinctions, no matter how well drawn, are appropriate. ACP-ASIM urges HCFA to provide clear, bright-line standards if the group compensation requirements are retained in the final rule.

Finally, these prohibitions force physicians to arrange their financial affairs differently for the Stark II designated health services than for all other health services they provide (which may include the designated health services for non-Medicare/Medicaid patients). This will increase the administrative burden and costs to comply for physicians, and could lead to problems of patient access should physicians become overly conservative in their practice patterns as a result of the proposed rule’s interpretations of group compensation arrangements. ACP-ASIM seeks elimination of as much of the group practice compensation arrangement prohibitions from the proposed regulation as is allowed under the current law and would support a legislative repeal of this entire portion of the Stark law.

4. Revise the definition of a group practice

The definition of “group practice” is critical to compliance with the Stark in-office ancillary exceptions. Unfortunately, the Stark I final regulation poorly defined membership in a group practice. Although most group practices consider only those who are owners and/or employees of the practice as a group member, the Stark I final regulation included all independent contractors, regardless of the amount of time that they spent at the practice, as members of a group practice. Consequently, many group practices would have difficulty meeting HCFA’s regulation that “substantially all” of the services provided by the group be done so by members of that group practice.

The Stark II proposed rule now appropriately excludes independent contractors from the definition of group membership. However, the revised definition now creates a new problem—it also proposes to no longer allow independent contractors to supervise the provision of designated health services under the in-office ancillary services exception. ACP-ASIM has asked HCFA to revise this definition in the Stark II final rule to allow independent contractors to supervise the provision of designated health services under the in-office ancillary services exception—but continue to not count the independent contractors as true members of the group under the patient-care “substantially all” requirement. If HCFA is unwilling to make this change, then we would ask that it be effected with a legislative change by Congress.

NEW PROBLEMS CREATED BY THE STARK II PROPOSED RULE

The Stark II proposed rule creates several new problems that will be a detriment to patient access to timely medical care. ACP-ASIM has previously asked HCFA to make the following four changes to the Stark II proposed self-referral rule described in detail below to rectify these new problems with the proposed regulation: (1) reduce the number of Stark II prohibited designated services (under the authority given the Secretary to exempt services that do not pose a risk of program or patient abuse); (2) do not include prescription drugs administered in the physician’s office as “outpatient prescription drugs;” (3) create an exception for durable medical equipment provided in the physician office; and (4) eliminate the group practice attesta-

tion requirements. If HCFA is unwilling to make these changes, then we would ask that Congress implement them through legislative changes.

1. Reduce the number of Stark II prohibited designated services

A number of services covered by the Stark II prohibition have not been associated with Medicare program abuse, and offer little or no opportunity for overutilization. ACP-ASIM believes that their inclusion on the list of designated services is disruptive and interferes with patient access to care, producing the unintended consequence of underutilization. We thus urge that the list of designated health services be reduced, thereby increasing access to care. We would specifically recommend that all services from the designated health services list be exempted, with the exception of clinical laboratory services, radiology, physical therapy, and occupational therapy.

2. Do not include prescription drugs administered in the physician's office as "outpatient prescription drugs"

The above recommendation asked HCFA to reduce all Stark II designated services to lab, radiology, physical and occupational therapy. If this were not administratively or legislatively possible, ACP-ASIM would request the exclusion of drugs administered in the physician's office from HCFA's current definition of outpatient prescription drugs and to create an exception for durable medical equipment (DME) provided in the physician's office (described in recommendation 3 below) as well.

The Stark II proposed rule defines outpatient prescription drugs as "those drugs (including biologicals) that a patient can obtain from a pharmacy with a prescription (even if patients can only receive the drug under medical supervision), and that are furnished to an individual under Medicare Part B." Erythropoietin (EPO) and other drugs furnished as part of a dialysis treatment for an individual who dialyzes at home or in a facility are excluded.

Without further instruction from Congress on what constitutes "outpatient prescription drugs," HCFA has assumed that Congress intended to include only drugs furnished to individuals under the Medicare Part B benefit and to exclude drugs furnished by providers under Medicare Part A. HCFA's definition includes a variety of prescription drugs given in the physician's office which are administered during the patient's visit. Such drugs would include treatments for cancer, antibiotics, renal therapy, and vaccines. Prohibiting the prescription of such drugs in the physician's office would clearly create serious patient access problems.

3. Create an exception for durable medical equipment provided in the physician office

Similar to our concerns regarding outpatient prescription drugs delivered to the patient in the physician office, the January 9, 1998 proposed rule prohibits the delivery of DME, which are integral to the practice of office-based medicine. Without the ability of physicians to provide these essential therapeutic services, patient care will suffer as access to care is delayed. These in-office services have not been associated with program abuse and offer little or no opportunity for overutilization. The inclusion of these services on the designated services list is disruptive and interferes with patient access to care, producing the unintended consequence of underutilization. ACP-ASIM's position has been supported in the 1995 Balanced Budget Conference Agreement, the 1995 "Blue Dog" Democratic budget alternative (H.R. 2530) and in President Clinton's FY '97 proposed budget. Furthermore, HCFA's inclusion of crutches as an exception under the DME in-office ancillary services proposal suggests that HCFA is aware of the problems that will be created if patients are denied access to DME in their physicians' office.

4. Eliminate the group practice attestation requirements

ACP-ASIM has urged HCFA to eliminate the group practice attestation requirements contained within the proposed rule. These requirements are overly burdensome and time consuming. The administration in its 1995 "Reinventing Health Care Regulations" initiative, determined that similar physician attestation requirements to certify the accuracy of hospital diagnosis-related group (DRG) coding were cumbersome and resulted in billing delays. Consequently, HCFA eliminated the physician attestation requirement in hospitals and instead hold hospitals responsible for the accuracy of their diagnoses and procedures. The same logic should be adopted for the proposed attestation requirements for group practices.

CONCLUSION

The health care industry continues to be in flux, characterized by the variety of ways health care is being delivered and financed. Managed care consolidation and

integration of physician practices are increasingly having an impact on accessibility and affordability of health care services, as well as methods of payment and operation. By accepting substantial financial risks, physicians in these types of arrangements have no incentive for overutilization or inappropriate referrals.

Efforts by Congress to maintain and ensure federal health care program integrity must take into account the dynamics within the health care industry that have an impact upon the delivery and quality of patient care. In developing the final rule, ASIM urges HCFA to carefully consider these and other fundamental changes in the health care marketplace.

ACP-ASIM believes that the Stark II proposed rule is confusing, does not provide appropriate relief within its regulatory jurisdiction, does not consider changes in the current health care delivery environment, and needs to be substantially revised prior to implementation. Without a comprehensive re-evaluation of the Statute and the proposed rule, serious compliance and oversight problems will be created that will likely have a negative impact on patient access to health care. We believe this type of intrusive overregulation is unnecessary given the changes that have occurred in the health care marketplace and programs recently designed and instituted within the federal health care programs to ensure the integrity of such programs.

Statement of the American Hospital Association

The American Hospital Association (AHA) represents nearly 5,000 hospitals and health systems, networks and other providers of care. We appreciate this opportunity to submit our views on Medicare "Self-Referral" laws.

Physician self-referral is an important issue to hospitals and health systems. AHA members believe that getting patients the right care in the right setting should guide referrals, not financial self-interest.

AHA members have demonstrated their desire to fully comply with Federal health program fraud and abuse statutes by adopting comprehensive compliance plans. However, achieving full compliance with the myriad of federal and state laws, regulations and program instructions is already difficult. The voluminous, complex and confusing proposed rule implementing the Medicare self-referral law would add to that burden.

Currently, hospitals, health systems and networks must spend significant resources obtaining legal opinions to make sure they comply with the requirements of physician self-referral legislation. The physician self-referral law is a strict liability statute, so no provider would dare risk moving forward with a transaction or arrangement without legal advice. While an advisory opinion process, strongly lobbied for by AHA, exists, it cannot always provide the timely response necessary in our rapidly changing health care delivery system.

Hospitals, health systems and networks have a tremendous variety of financial relationships and arrangements with physicians as they seek to provide high quality, efficient health care services. The goal of self-referral legislation should be to guard against inappropriate referrals without impeding arrangements that will improve the quality of health care, increase access and be cost effective.

Any proposed changes to the physician self-referral law should:

- Support current and emerging systems of care.
- Support physicians' ability to collaborate with hospitals and health systems.
- Support the delivery of efficient, high quality health care and allow physicians to make decisions that are best for their patients
- Promote a level playing field that fosters competition among providers.
- Simplify compliance.

Given the great diversity within our health care delivery system, finding a simple approach that encompasses these principles is difficult.

AHA recommends reducing the complexity of the law by removing provisions that relate to compensation arrangements. The existing anti-kickback statute, which allows for both civil as well as criminal penalties, can be used to police any abusive arrangements. The remaining provisions of the Medicare self-referral law would continue to prohibit physician referral to entities in which they have an ownership or investment interest for certain designated health services.

This approach would allow the statute to focus on its original purpose: a ban on physicians inappropriately referring to entities they own. It would also eliminate many pages of the voluminous proposed rule. Providers would not have to hire attorneys to navigate the maze created by the current law and the proposed regulations. The Health Care Financing Administration would not have to micromanage health care contracts by regulation. The government would retain a powerful en-

forcement tool, the anti-kickback statute. And limited provider resources could be used for patient care rather than legal opinions.

This change would also strike a more appropriate balance. It would guard against inappropriate referrals while still supporting the desire of hospitals, health systems and physicians to work together to reduce health care costs, while also improving the quality of health care we deliver to our patients.

The AHA commented on HCFA's proposed rule implementing the Medicare self-referral law, published on January 9, 1998, and would like to reiterate some of our specific comments that Congress could also address as part of any legislative changes to the statute.

PHYSICIAN OWNERSHIP OF HOSPITALS THAT PROVIDE NON-HOSPITAL SERVICES

The Medicare self-referral law contains an exception for physician ownership interests in a hospital if the referring physician is authorized to perform services at the hospital and the ownership or investment interest is in the hospital itself and not merely in a subdivision of the hospital. This exception applies only to designated health services that are furnished by the hospital and does not apply to designated health services furnished by another health care provider the hospital may own (e.g., a hospital-owned home health agency or a skilled nursing facility).

There does not appear to be a rationale for making this distinction when the exception allows referral for the designated services listed in the Medicare self-referral law provided by the hospital. Such disparate treatment imposes an unreasonable barrier for hospitals seeking to provide a full continuum of care. The interpretation by HCFA appears to contradict the intention of the hospital ownership exception.

Treatment of physicians with financial relationships with hospitals, whether contractual or ownership, should not vary unless there is a significant public policy reason for doing so. Hospitals and their physician owners should not face an artificial impediment to providing the full array of health services to patients whether directly through the hospital itself, or other hospital-owned providers.

MANAGED CARE AND INTEGRATED HEALTH CARE DELIVERY SYSTEMS

The Balanced Budget Act of 1997, created the "Medicare+Choice" program and authorized provider sponsored organizations (PSOs) to directly contract with the Medicare program. Similar to health maintenance organizations contracting with Medicare under Sec. 1876, those PSOs participating in Medicare+Choice will receive a capitated payment from the Medicare program. Therefore, as similar risk-based entities, clearly they should be included in the same exception as HMO's contracting with Medicare.

Any arrangement that involves significant risk-sharing such as PPOs, PHOs and IPAs should come within the exception. A centerpiece of AHA's and its members' vision for reform of the health care delivery system is the PSO. These are community-based integrated networks of providers that offer a spectrum of care, including at least hospital and physician care. As provider-driven organizations, PSOs can uniquely respond to the twin demands for control of health care costs and delivery of quality services. They can achieve the cost efficiencies necessary to hold down health care costs by directly managing both the use of services and the cost of providing those services. They put clinical decisions in the hands of those most capable of balancing efficiency and patient care-local community-based health care providers.

PSOs can take many forms and may be accomplished through various organizational structures that represent different degrees of integration. Those that are more integrated and have begun entering into contracts to accept responsibility for managing utilization will share a significant economic interest through common ownership or control, or substantial shared financial risk. Such integration should lead to better coordination of care among providers and to greater efficiency. Depending on the circumstances, a PSO may be paid on a full risk or a partial risk basis (e.g. flat capitation, budget target with risk corridor, or withholds). A variety of payment methods may be used within a PSO. Intrinsic to the design of PSOs is the need to align the economic incentives of the providers who constitute the PSO and the need for control over where and from whom a patient receives care. In the absence of protection through an exception to the self-referral prohibition, PSOs will bear the unreasonable risk that arrangements and relationships essential to coordination of care and cost control will be inhibited. This is particularly significant with the Medicare self-referral law which imposes a "bright line" test.

Congress should grant an exception to provider organizations sharing risk through a variety of means as mentioned above, full capitation, partial capitation, withholds and/or bonuses, to cite a few examples. Whether these entities contract

directly with the Medicare program or with the Medicaid program, or health plans that are risk contractors under those programs, beneficiaries should be able to select community-based delivery systems to coordinate their care. The Medicare self-referral law should not create an unnecessary barrier to such choices.

PHYSICIAN INCENTIVE PLANS

The Medicare self-referral law provides an exception for personal service arrangements between an entity and physicians that meets certain requirements. The personal services exception states that the compensation paid under a personal services arrangement cannot be determined in a manner that takes into account the “volume or value of referrals” for designated health services or other business between the parties. However, this prohibition is qualified for a physician incentive plan so long as the requirements for physician incentive plans which are applicable to Medicare and Medicaid risk contracting arrangements are met. A “physician incentive plan”(PIP) is defined as “any compensation arrangement between an entity and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.”

The Proposed Regulation states that the physician incentive plan qualification applies only when the entity paying the physician or physician group is the kind of entity that enrolls its patients, such as HMOs. We believe that this is an overly narrow provision. There exist many provider-based organizations contracting with entities that enroll beneficiaries, such as Physician Hospital Organizations (PHOs), using a variety of managed care payment techniques such as capitation, withholds, bonus corridors or per diems, that should also qualify for this exception through their use of physician incentive plans.

PHYSICIAN RECRUITMENT EXCEPTION

The Medicare self-referral law includes an exception for remuneration provided by a hospital to an individual physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the medical staff of the hospital, provided that the physician is not required to refer patients to the hospital, the amounts paid under the arrangements are not determined in a manner that takes into account the volume or value of referrals, and other applicable regulatory requirements are met.

The current exception for remuneration provided by a hospital to a physician to induce the physician to relocate to the hospital's geographic area to join the hospital's medical staff should be expanded to include physicians who are new to the practice of medicine. They do not have a referral base of patients, just as a physician new to a geographical area does not bring along patient business. Including new physicians in the recruitment exception meets the public policy requirement embodied in the existing recruitment exception for physicians already practicing medicine, which is limited to those new to the hospital's geographic area. That is, they are not recruited for their existing referral base. This expansion of the exception would provide institutions training physicians or other hospitals in the same geographic area where the physician is trained, the same opportunity to recruit medical residents in training as hospitals in a different geographic area.

INDIRECT COMPENSATION

The Proposed Rule published by HCFA greatly expands the financial relationships affected by the Medicare self-referral law and would have consequences beyond the intent of the statute. The example cited by HCFA is that of a hospital that has contracted with a group practice for the group to furnish physician services and to otherwise staff the hospital. The hospital pays the group practice for these services under a personal services arrangement. The group practice pays the physicians a salary. HCFA takes the position that each physician has been indirectly compensated by the hospital and therefore the physicians have a compensation arrangement with the hospital. Accordingly, each physician in the group practice must also meet an exception.

This is an overly broad interpretation of the statute. The indirect compensation from the hospital to the individual physicians in the group practice is not based on their referrals if the hospital contract with the group practice meets the personal services exception. Once the compensation arrangement between the hospital and the group employing the physicians is determined not to be based on the volume or value of referrals, the individual physicians employed by the group practice should not be required to meet additional exceptions.

REPORTING REQUIREMENTS

The Medicare self-referral law requires entities providing Medicare-covered designated health services to report to HCFA the covered items and services provided by the entity and the identity of physicians or the immediate relatives of physicians with ownership or investment interests, or compensation arrangements. The Medicare self-referral law states that the reporting requirements apply only to ownership or investment interests as defined by Section 1877(a)(2)(A) and compensation arrangements as defined by Section 1877(a)(2)(B). These two sections include only those interests and compensation arrangements that fail to meet the Stark exceptions under Section 1877(c), (d) or (e).

However, the Proposed Regulations would require entities to report all financial relationships, whether or not they meet an exception. The Preamble states that the reporting requirement applies to all financial relationships the entity "knows or should know about in the course of prudently conducting business." We believe this goes well beyond the statute and Congressional intent and should not be implemented by HCFA.

This expansive and somewhat vague reporting requirement would place an extraordinary burden on providers without providing any significant benefit. Such a reporting requirement would apply to every hospital and divert significant resources away from patient care to unnecessary administrative overhead. HCFA itself acknowledges that it could be "overwhelming and perhaps impossible" for entities providing designated health services to comply with the reporting requirement require reporting only for those financial relationships that do not meet an exception to the Medicare self-referral law.

ADDITIONAL EXCEPTIONS FOR ANTI-KICKBACK SAFE HARBORS

The Medicare self-referral law should provide an exception for any practice that falls into a safe harbor under the anti-kickback statute. Financial arrangements meeting the criteria necessary to come within a safe harbor are determined to pose no risk to the Medicare and Medicaid programs and are therefore immune from prosecution. Consequently, the safe harbors are narrow in scope, and arrangements falling outside a safe harbor do not necessarily violate the anti-kickback statute. This is in sharp contrast to the Medicare self-referral law which establishes a "bright line" test. Arrangements failing to meet the requirements of the Medicare self-referral law automatically result in prohibited referrals for designated health services. There is no reason protections extended under the anti-kickback statute should not be allowed under the physician self-referral statute.

CONCLUSION

Only one of the changes or clarifications AHA recommends relates to the ownership provisions of the Medicare self-referral law. The other changes or clarifications we seek concern compensation arrangements. Thus if Congress would modify the self-referral statute by eliminating compensation, hospitals would have the flexibility to collaborate with physicians, while the anti-kickback statute will serve to protect the Medicare program and its beneficiaries from any abusive or fraudulent arrangements.

We look forward to working with members of the Subcommittee to improve the Medicare self-referral law in a way that provides our members the flexibility necessary to provide quality health care to patients in a rapidly changing health care delivery system. We also seek a law that will provide clear guidance for hospitals and other health care providers.

AMERICAN MEDICAL ASSOCIATION
May 12, 1999

The Honorable William Thomas,
 Chairman, Committee on Ways and Means
 Subcommittee on Health
U.S. House of Representatives
Washington, D.C.

Dear Chairman Thomas:

On behalf of our 300,000 physicians and medical student members, the American Medical Association (AMA) would like to thank you for holding tomorrow's hearing

to discuss possible changes to the self-referral statute. As you know, this statute has significant patient access implications, and it adversely affects the vast majority of physicians.

We are pleased that you and the Committee are addressing possible self-referral changes. While the AMA developed the ethical standards relating self-referrals, we believe that the law and the proposed regulations go too far. If implemented, they would result in many physicians having to completely restructure their practices to ensure that Medicare beneficiaries obtain designated health care services from other entities. This will inconvenience millions of patients in order to meet burdensome regulatory requirements that do not address the concerns Congress was originally trying to address in passing these laws.

The self-referral statute and the proposed regulations are so complex, as they now stand, that congressional action is needed to streamline the statute. Even attorneys specializing in self-referral issues and other experts cannot give physicians definitive answers concerning the law's implications. In this era of heightened scrutiny of physicians by law enforcement agencies, it is especially vital to provide physicians with clarity regarding self-referral prohibitions. The Health Care Financing Administration (HCFA) has acknowledged the complex nature of the statute, but has exacerbated physicians' concerns by issuing a 400 page Notice of Proposed Rulemaking (NPRM) on January 9, 1998 (six years after the statute was enacted) which actually made many issues even more confusing. The AMA urges Congress to enact changes to the statute before final regulations are promulgated so that patients and physicians are not forced into untenable situations.

The AMA believes that Congress should also reevaluate the self-referral law in light of the significant changes in the marketplace that have occurred since the 1993 expansion of the original self-referral law (previously applicable just to clinical laboratory services). In an era when medical practice configurations and health care coverage arrangements are changing at an increasingly rapid rate, the overly complex and questionable requirements imposed by the self-referral law and its lack of clarity create added and substantial difficulties for physicians, with only questionable benefits for patients.

The Committee should also consider that physicians are subject to severe civil and criminal penalties if they receive any type of remuneration for the referral of Medicare-covered services under the anti-kickback statute. This is a body of law still being developed in the courts, where numerous "safe harbors" have been established, and where the Office of the Inspector General (OIG) of the Department of Health and Human Services has begun to issue advisory opinions. Unlike the self-referral law, the anti-kickback statute applies to purposeful behavior, and physicians and others must satisfy an intent standard to be in violation of the statute. The self-referral law exposes business activities that would be considered routine outside of the health care environment to high civil monetary penalties and possible additional false claims prosecutions.

The AMA believes that the changes that this Committee approved in 1995 as part of the Omnibus Budget Reconciliation Act of 1995 are a good starting point to ameliorating the unintended consequences of this statute. We have attached to this letter our key concerns with the statute and the proposed regulations promulgated by HCFA. The AMA submitted 29 pages of written comments to HCFA last year, which more thoroughly explain our concerns with the proposed regulation. We would be happy to share with you and members of the Committee.

The AMA appreciates your dedication to this and other health care related issues. We look forward to working with the Committee to examine the market realities and to revising the self-referral statute to ensure that inappropriate referrals do not occur, while stopping short of imposing significant inconveniences on our patients as a result of physicians being required to restructure their practices.

Respectfully,

E. RATCLIFFE ANDERSON, JR., MD

Key Concerns with Proposed Regulations on Self-Referral

This document outlines several of the AMA's concerns with the self-referral statute and how its implementation as proposed would encroach upon the day-to-day activities of patients and physicians. For a more complete picture of the AMA's concerns, please contact the AMA's Washington Office (789-7409) for a copy of our written comments on the Notice of Proposed Rulemaking (NPRM) submitted to the Health Care Financing Administration (HCFA) on May 11, 1998.

DESIGNATED HEALTH SERVICES

The self-referral law applies only to designated health services. These are defined in statute as:

- clinical laboratory services;
- physical therapy services;
- occupational therapy services;
- durable medical equipment and supplies;
- parenteral and enteral nutrients, equipment, and supplies;
- prosthetics, orthotics, and prosthetic devices and supplies;
- home health services;
- outpatient prescription drugs; and
- inpatient and outpatient hospital services.

HCFA has interpreted these categories too broadly and has drawn illogical distinctions between certain designated health services. For instance, under the durable medical equipment category, crutches would be exempt, but the designation would apply to all other types of durable medical equipment and supplies. Intraocular lenses and corrective glasses would be considered prosthetic devices even though they could still be provided in certain circumstances under an ambulatory surgical center exception to the self-referral law. In addition, HCFA has construed the physical therapy definition much more broadly than intended by Congress. In the NPRM, HCFA stated that physical therapy would be any "assessment or treatment" designed to alleviate pain or disability. This could inappropriately subject large areas of physicians' practices to self-referral constraints. Some of the situations that would result from these arbitrary distinctions that HCFA has made between designated health services are the following:

- A Medicare patient who breaks her foot could receive crutches in her physician's office at the time of diagnosis, but if the physician decides that a walker would be more appropriate for the patient, she would have to travel to another location to obtain the walker.

- A Medicare patient who has undergone cataract surgery and is entitled to Medicare coverage of one pair of corrective glasses or contact lenses would not be able to purchase those glasses from the physician completing the surgery. This is the case, even though the Federal Trade Commission (FTC) has stated that an ophthalmologist or optometrist must give the patient a copy of the patient's prescription immediately following the eye exam so that the patient can shop anywhere he chooses but specifically allows physicians to dispense if that is the patient's choice. These FTC rules have been in place for decades and current arrangements have not limited patients' ability to obtain corrective glasses or contacts from other locations.

The AMA strongly supports the 1995 amendments to the self-referral law which would have clarified that only the following areas would be classified as designated health services: clinical laboratory tests; parenteral and enteral nutrient, equipment, and supplies; magnetic resonance imaging and computerized tomography services; and outpatient physical or occupational therapy services.

COMPENSATION EXCEPTIONS

Under the self-referral law, a compensation relationship between the referring physician and the entity providing a designated health service can trigger a violation of the statute. Although HCFA has set forth several helpful exceptions in the NPRM, the AMA remains troubled by several areas of the statute and regulation which are overly broad and extremely confusing to physicians.

- The AMA is concerned with HCFA's interpretation of the compensation test for group practices. It appears that the NPRM would require that profits from designated health services be distributed without regard to practice needs or even how revenues were generated. This would preclude a group from allocating different expenses to different sites or different physicians and considering different revenue streams. This section of the NPRM would regulate the internal workings of group practices, and would have little or no impact on referrals of designated health services.

- The fair market value exception to compensation arrangements would be of very limited application as it would apply only when compensation or compensation methods of fair market value are set in advance, and are not related to the volume or value of referrals (either Medicare/Medicaid or outside of the programs) or other business between the parties. This exception is so narrow that it would not allow anyone to take any type of business relationship into consideration when setting up compensation arrangements. Since the transaction must be at fair market value in all instances, it is unclear why the volume and value of referral language is necessary.

• We believe that the language in the NPRM would incorrectly require a physician practice owned or controlled by a hospital to meet the “personal services” exception for compensation arrangements. If the group is owned by, or is a non-profit entity controlled by a hospital, and the only financial relationship between the physician and group is an employment relationship, then there should be no need for the financial arrangement between the group and the hospital to meet any other exception, because the relationship is between two hospital-affiliated entities. The personal services exception should only be required for financial relationships between a hospital and a physician-owned group.

In reviewing the legislative history for this section of the statute, it is clear that Congress was not as concerned with the internal compensation relationships within integrated medical groups, but rather with the use of compensation between a physician and an entity which was a sham compensation relationship solely for the purpose of inducing referrals. The AMA believes that the compensation requirements and their exceptions are the most complex portion of this statute and are largely redundant of the anti-kickback laws. We strongly support the 1995 amendments’ elimination of the compensation arrangement provisions, which would limit the definition of a financial relationship to an ownership interest in debt or equity.

SUPERVISION OF INDEPENDENT CONTRACTORS—COMPONENT #1 OF THE IN-OFFICE ANCILLARY SERVICES EXCEPTION

The statute states that to qualify for the in-office ancillary services exemption, designated health services (other than most durable medical equipment and parental and enteral nutrients, equipment and supplies) that are referred either by a solo practitioner or by a member of a group practice must be furnished either by:

- (i) the referring physician;
- (ii) another physician in the same group practice as the referring physician; or
- (iii) an individual directly supervised by the referring physician or another member of the same group practice. (emphasis added)

In the NPRM, HCFA states that “directly supervised” means that the supervising physician must be in the same office suite and immediately available (except for very brief absences) to provide assistance and direction at the time the services are furnished. While this may seem a small inconvenience, it would have the effect of forcing physicians to restructure their practices and decreasing the facilities’ hours of operation for patients, while having no impact on the self-referrals for designated health services.

For instance, physicians who hire independent contractors to work as technicians or physical therapists would have to be present in the office suite at all times that the independent contractor was seeing patients. There are many instances when physicians are operating or otherwise seeing patients away from the office, that patients come to a practice for follow-up x-rays or lab tests, that the physician does not need to see the patient. HCFA’s interpretation could lead many physicians to inconvenience patients by closing their offices whenever they are providing care in other settings to ensure that they are not in violation of the self-referral law.

The AMA supports the 1995 amendment provision stating that general supervision requirements would be met if the physician or group is legally responsible for the services performed by the individual regardless of whether or not the physician is physically present when the individual furnishes an item or service.

SITE OF SERVICE REQUIREMENT—COMPONENT #2 OF THE IN-OFFICE ANCILLARY SERVICES EXCEPTION

The second component needed to qualify for the in-office ancillary services exception is that the designated health services must be furnished in either:

- (i) the same building where the referring physician or another member of his group practice furnishes physician services unrelated to designated health services; or
- (ii) a building used by the group practice for all or some of the group’s clinical lab services; or
- (iii) a building used by the group practice for the centralized provision of the group’s designated health services, other than clinical lab services. (emphasis added)

In the NPRM, HCFA has interpreted this site of service requirement to mean that the service would not qualify for the in-office ancillary services exception if the referring physician’s building and the second building are connected via tunnels or walkways. This interpretation would curtail the operations of larger medical complexes where the group practice refers a patient for tests in the next building which is connected to the physician’s office building above or below ground or by a walkway, but which is not part of the same building.

In addition, HCFA has stated that it considers “furnished” at the site of service to mean that the service must be performed on the patient at that location or that the patient must receive and begin using an item in that location. With this interpretation, it is possible that covered outpatient prescription drugs, such as those used by patients undergoing chemotherapy, would not be eligible for the in-office ancillary exception, as many patients begin to take these drugs while they are at home. The AMA believes that HCFA’s view is contrary to congressional intent, since it would make Medicare drugs that in some circumstances may be self-administered, much more difficult to obtain. Self-referral policy should not have the effect of countermanding Medicare coverage policy.

The AMA believes that Congress should address the issues surrounding shared facilities, which are the most common way for physicians to save resources by sharing overhead for common equipment rather than setting up duplicate facilities in the same building. For example, physicians often share x-ray machines, and other in-office diagnostic equipment with other physicians in their office building so they can provide their patients with on-site health services, such as EKGs and ultrasounds. Under HCFA’s current interpretation, shared facilities would not be entitled to the in-office ancillary services exception.

The AMA supports the 1995 amendment provisions in this area as a starting point and suggests broadening the shared facility exception to ensure that physicians referring to an entity within the same medical complex would not be in violation of the self-referral law.

GROUP PRACTICE DEFINITION—COMPONENT #3 OF THE IN-OFFICE ANCILLARY SERVICES EXCEPTION

Unless a physician is a solo practitioner, the only way to qualify for the in-office ancillary services exception is to meet the definition of a group practice. The self-referral statute states that to qualify as a group practice, the practice must consist of two or more physicians legally organized as a single partnership, professional corporation, foundation, not-for-profit corporation, faculty practice plan, or similar association. The AMA believes that Congress should clarify that a practice can qualify as a group practice as long as the physician owner hires at least one other physician to work in her practice as either a partner or an employee.

If this proposed regulatory definition remains, many practice structures will be disrupted. In the medical community, more established physicians often bring in younger physicians as employees until they are invited to become a partner in the practice. HCFA’s overly expansive proposed interpretation of the statute would micromanage the inner workings of physician practices in a manner that is wholly unrelated to the provision of designated health services.

The AMA supports clarifying the statute to ensure that a physician practice can qualify as a group practice as long as it has at least one physician owner and other physician employees.

REPORTING REQUIREMENTS AND CIVIL MONETARY PENALTIES (CMP)

The reporting requirements set forth in the NPRM both exceed HCFA’s statutory authority and would exponentially increase physicians’ regulatory burdens. The statute requires entities providing Medicare-covered designated health services to provide HCFA with two types of information:

- (i) covered items and services provided by the entity; and
- (ii) the identity of physicians or the immediate relatives of physicians, with ownership or investment interests, or compensation arrangements

According to the statute, physicians should not have to report ownership or investment interests that qualify under the group practice or compensation exception. However, the NPRM would require entities to report all financial relationships regardless of whether the relationship meets an exception. First, the AMA believes that the administrative and recordkeeping tasks such broad reporting would entail are significant and far outweigh any benefit that may be derived from such expansion. Second, the exposure to a \$10,000 civil monetary penalty per day under the statute for failing to submit this information is exorbitant and disproportionate to the offense. We urge Congress to eliminate this CMP.

The AMA supports the 1995 amendments’ language which would abolish the civil monetary penalties for not reporting this information. The existing civil monetary penalty of \$15,000 per improper designated health service is an extremely effective deterrent to physicians violating the self-referral statute, and the additional reporting civil monetary penalty is unneeded.

Statement of the American Physical Therapy Association, Alexandria, VA

Mr. Chairman and Subcommittee members, the American Physical Therapy Association (APTA) wishes to express its continuing support for the elimination of financial incentives within the Medicare program that encourage the over utilization and inappropriate use of physical therapy services. APTA believes that the existing ban, while imperfect, is an appropriate mechanism to achieve this goal. APTA wishes to work with the Subcommittee to improve the existing statute, but urges the Subcommittee not to reverse the progress that has been made thus far through the existing ban.

APTA is the national association representing more than 73,000 physical therapists, physical therapist assistants, and students of physical therapy. APTA shares the desire of the American public, political leaders and other health care providers to make quality health services more accessible and affordable for all Americans.

Seven years ago, APTA appeared before this Subcommittee to testify in support of expanding a ban on physician self-referral under Medicare to include physical therapy services. APTA encourages the Subcommittee not to retreat from this important public policy, and to ask that the Subcommittee urge the Administration to speed its implementation and strong enforcement.

While APTA is supportive of the intent of the existing ban, the Association wishes to express its disappointment with the Administration's inability to promulgate final regulations relating to the self-referral ban. Regulations are needed to enforce the prohibition and aid health care providers in their efforts to comply with the existing law.

In 1993, Congress expanded the ban on physician self-referral to include physical therapy services. This action was based upon strong empirical data illustrating excessive utilization associated with self-referral arrangements. Nowhere is this better documented than in the 1992 study of the California Workers' Compensation program conducted by William M. Mercer, Inc.

This study found that if an injured worker received initial treatment from a physician with an ownership interest in physical therapy services, that patient received a referral to physical therapy 66% of the time. If, on the other hand, the injured worker received initial treatment from a physician with no ownership interest in physical therapy services, the patient was referred to physical therapy 32% of the time or less than half of that of the owner frequency.

In the face of such findings, patients and the public are left with much cause for concern. The crucial question is whether Medicare beneficiaries should have to wonder whether the care they are receiving is based upon medical necessity or economic motivation.

The Mercer study concluded that financial incentives played a major role in these decisions. According to the study, the added incentive for investing physicians to refer to physical therapy generated approximately \$233 million per year in services delivered for economic rather than clinical reasons. These are costs neither our nation's health care system nor our nation's Medicare beneficiaries should be asked to bear.

CONSUMER CHOICE

The issue of consumer choice is of critical importance. The Subcommittee must ask itself the following questions: "What types of choices are available to Medicare beneficiaries today?" "What types of choices would be available to these beneficiaries without the existing ban on physician-self referral?" "Prior to the ban, were patients given the freedom to choose their physical therapist, or were they simply referred to a facility in which their physician maintained a financial interest?"

The existing ban, while imperfect, has provided Medicare beneficiaries with enhanced choices regarding the care they receive. With the elimination of the financial incentive to refer services to external facilities, the physician is free to refer patients based upon proximity to the patient and the quality of care provided. Competition in the Medicare program, based upon the quality of care provided is a positive outcome of the prohibition.

ADDITIONAL VALUABLE STUDIES

Several other studies demonstrate that physician self-referral drives up utilization and health care costs. In 1989, the Florida legislature mandated that its Health Care Cost Containment Board examine the impact of joint ventures in health care

on the cost, quality, and access to services in Florida. Physical therapy services were surveyed in two settings: free-standing physical therapy facilities and comprehensive rehabilitation centers that provide physical therapy services. The findings were dramatic.

Joint-ventures that are physician-owned physical therapy facilities provided 43% more visits per patient than did nonjoint-venture (or non-physician owned) physical therapy facilities. Consequently, the physician-owned joint-ventures generated approximately 31% more revenue per patient than in nonjoint-venture facilities. At comprehensive rehabilitation facilities, 35% more physical therapy visits were provided per patient in joint-venture facilities than in non-joint-venture facilities.

More importantly, the Florida study found that quality of care in physician owned joint-venture facilities was lower than in nonjoint-venture facilities, and that joint-venture facilities did not increase access to services. In fact, the nonjoint-venture facilities offered increased access to a wider range of clients. Higher quality of care and increased access to services are often cited as rationales to defend joint-ventures. Clearly these arguments do not hold water in the face of objective data.

Subsequent to the study conducted in the State of Florida, the Center for Health Policy Studies located in Columbia, Maryland, estimated the impact of physician joint-ventures on medical care costs in Florida. Estimates for 1991 were developed based on findings from an analysis of Medicare claims data, results from the report by the Florida Health Care Cost Containment Board, and from other sources. The estimated 1991 cost impact of joint-ventures for physical therapy services was \$10.9 million. This figure is likely underestimated given that only additional costs for users of physical therapy were estimated.

DIRECT PHYSICIAN SUPERVISION

APTA opposes any attempt to amend the physician supervision requirement of non-physician personnel. Current law calls for "direct supervision," but recommendations have been made to replace this requirement with a "general supervision" requirement. The direct supervision requirement reduces the incentive for a physician to abuse his or her referral power with respect to services provided by non-physician practitioners under the physician's employment.

The incentive for a physician to refer to outside facilities in which he or she might have an investment interest is not the only problem regarding self-referral. In fact, physicians stand to profit even more directly by expanding their individual or group practices to offer physical therapy or one or more of the various other health services to which they control access through their power of referral.

A study of physician self-referral was presented to Virginia's Joint Commission on Health Care in January 1993 by Virginia's Deputy Secretary of Health and Human Services. One of the findings was that Blue Cross/Blue Shield claims-paid-data indicated 60% of physical therapy claims were paid to physician provider numbers. That amounted to \$8.3 million out of \$14 million.

Additionally, the Office of Inspector General found that in almost four out of five cases reimbursed as physical therapy in physician's offices do not represent true physical therapy services. The study found that \$47 million was inappropriately paid in 1991.

REMOVAL OF PHYSICAL THERAPY FROM THE LIST OF DESIGNATED HEALTH SERVICES

APTA is opposed to any proposal that would eliminate physical therapy from the list of designated health services under the current statute. As we have shown today, numerous studies indicate the relationship between physicians and referrals to physical therapy services in which they have a financial interest leads to increased utilization and significantly higher cost to the payer. To remove physical therapy from the list of regulated services would allow this over utilization to go unchecked, costing the American people and the Medicare program many millions of dollars. To eliminate physical therapy from the designated health service list would increase Medicare costs unnecessarily and create further problems for a system that is already struggling.

INVESTMENT IN REHABILITATION FACILITIES

APTA understands rehabilitative care is a growing segment of the health care industry and that physicians would want to invest in or possibly own a physical therapy center. The self-referral statute does not preclude such investments or ownership. However, we cannot support an expansion of the exceptions for physician ownership in hospitals to include ownership in other facilities such as surgery centers, hospices, nursing homes, dialysis facilities, and Comprehensive Outpatient Rehabili-

tation Facilities (CORFs). The law merely provides some reasonable assurances to the consumer that investment or ownership interest will not impede a health provider's judgement when referring to physical therapy and other health services. Physical therapists do not wish to limit physician's investment opportunities; only to ensure that physicians do not misuse their referral powers to such facilities in order to increase their own profit.

REPORTING REQUIREMENTS

APTA strongly opposes proposals to eliminate or in any way weaken reporting requirements under the current statute. These requirements provide information necessary to effectively enforce the law and must be maintained. These requirements are reasonable, particularly in light of the objective data which demonstrates the existing abuse of referral power for financial gain. To eliminate this notion of the statute is to repeal the current ban on physician self-referral.

PREEMPTION OF STATE LAWS

APTA firmly opposes the preemption of state laws governing physician ownership and referral. The legislatures of at least 30 states found this problem troubling enough that they passed their own prohibitions on self referral. State legislatures addressed the problem in numerous and creative ways. Some states, such as California, Nevada, Illinois, Maryland, and Georgia, have banned referrals by various health care providers to outside entities in which the provider (or sometimes a member of his immediate family) has a financial interest, or is an investor. Other states, such as Connecticut, Louisiana, and Maryland have laws requiring the provider to disclose his financial interest in the facilities where his patients are referred. Additionally, California and Montana enacted separate bans under its Worker's Compensation Program. Texas and Rhode Island enacted anti-kickback laws stating that a person can neither pay nor accept remuneration for securing or soliciting patients. Federal preemption of these state laws interferes with the states' ability to enact cost-saving legislation critical to their budget processes.

NECESSARY IMPROVEMENTS TO THE EXISTING BAN

While the ban has been successful in eliminating incentives for physicians to refer services to external facilities in which they maintain a financial interest, exceptions to the prohibition raise doubts about its overall effectiveness. Presently, a physician is allowed to refer physical therapy and other health-related services to employees of their solo or group practice. This "backroom" or captive referral is not considered an illegal self-referral due to the "in-office ancillary care" exception of the existing ban. APTA fails to understand how this type of referral is in any way different than external referrals for identical services, and feels strongly that an appropriate change in the statute is needed to remedy this loophole.

APTA finds it disturbing that in its impact analysis on p. 1717 of the Federal Register for the January 9, 1998 proposed regulation relating to the ban, the Health Care Financing Administration (HCFA) states that the economic impact of the regulations will be minimal because this statute contains exceptions that will allow physicians to continue to refer to any entity furnishing designated health services if certain criteria are met. HCFA states that physicians will reconfigure their practices to fit within exceptions. In fact, HCFA provides an example of how a practice could be reorganized to meet the in-office ancillary group practices exception.

Physicians that once may have held ownership in an external physical therapy clinic to which they referred services for financial gain, now merely employ physical therapists and non-physical therapists who provide services within their solo or group practice which are then billed to Medicare under the physician's provider number.

In 1997, with the help of this Subcommittee, APTA pushed for necessary changes in the manner in which physical therapy services are provided in physician practices. Passage of the "Outpatient Physical Therapy Standards Act" now requires physician practices to meet almost all of the same coverage guidelines which physical therapy private practices have operated under for some time. Unfortunately, HCFA failed to require that a physical therapist provide or supervise services when not provided directly by the physician. This means that a physician can refer "physical therapy services" to any employee, including clerical help, and bill those services under his/her physician provider number. HCFA has also recently concluded that physician assistants and nurse practitioners can refer and provide physical therapy services. APTA asks for the Subcommittee's assistance in remedying these concerns.

While it is hoped that the Outpatient Physical Therapy Standards Act will improve the quality of care provided in physician practices, APTA feels that it is also necessary to eliminate financial incentives that encourage over utilization of physical therapy services in physician practices.

Therefore, APTA proposes that the ban on physician self-referral be amended to narrow the "in-office ancillary care exception." Specifically, APTA feels that the self-referral restrictions should apply with respect to a physician's referral to an employee or independent contractor for physical therapy services. To achieve this end, APTA urges the Subcommittee to require physical therapy services to be billed under Medicare utilizing the provider number of the licensed physical therapist that provided the service. In addition, physical therapy should be made an exception to the "in-office ancillary care" exception.

The impact of this policy would be significant. In addition to eliminating the financial incentive for physicians to refer for physical therapy services, these proposed changes would place responsibility for billing, and ultimately for the quality of care provided, in the hands of the practitioner that actually provided the service. These changes are necessary, practical, and overdue.

CONCLUSION

APTA continues to support the current prohibition on physician self-referral and encourages the Subcommittee to urge the Administration to actively implement and enforce the existing law. APTA stands ready to assist the Subcommittee in any manner to ensure appropriate delivery of necessary physical therapy services. APTA appreciates the opportunity to share its views on this subject.

Statement of the American Society of Clinical Pathologists

The American Society of Clinical Pathologists (ASCP) is a nonprofit medical specialty society organized for educational and scientific purposes. Its 75,000 members include board certified pathologists, other physicians, clinical scientists and certified medical technologists and technicians. These professionals recognize the Society as the principal source of continuing education in pathology and laboratory medicine, and as the leading organization for the certification of laboratory personnel.

ASCP believes the practice of physician self-referral for profit is a conflict of interest that threatens the quality and cost of patient care. ASCP supports limitations on physician referrals to clinical laboratories or other health care facilities in which the referring physician or immediate family has a financial interest.

ASCP recognizes the importance of and the complexities associated with interpreting Sections 1877 of the Social Security Act added by the Omnibus Budget Reconciliation Act of 1989 (OBRA 89, P.L. 101-508) and revised by the Omnibus Budget Reconciliation Act of 1993 (OBRA 93, P.L. 103-66).

The proposed regulatory interpretation of OBRA 93 (Federal Register January 9, 1998) revises the "members of a group" definition, from its original interpretation (60 FR 41914) of the OBRA 89 law. The new interpretation includes only owner and employee physicians as "members of a group," thus eliminating contractors.

The January 9, 1998, proposed regulatory interpretation gives exception to the referral ban for members of a group practice when an in-office ancillary service is performed or supervised by a member of the group practice.

In-office ancillary services "must be furnished personally by the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual who is directly supervised by the physician or by another physician in the group" (Federal Register January 9, 1998 pg. 1655).

If a contractor, potentially a pathologist, is not considered a member of the group practice, he or she will potentially be in violation of the law as defined by the in-office ancillary services definition. Meaning, a group practice will be in violation of the self-referral ban because a pathologist on contract to advise a physician's clinical laboratory will be rendering or supervising the service.

This contractor exclusion presents a problem to the practice of pathology and laboratory medicine. ASCP recommends maintaining the "members of a group" definition to include contractors, as noted in the original interpretation (60 FR 41914) of the OBRA 89 law.

Thank you for this opportunity to share the views of the American Society of Clinical Pathologists.

Statement of the American Society of Echocardiography, Raleigh, NC

The American Society of Echocardiography ("ASE"), is delighted to have this opportunity to submit written testimony with regard to the federal prohibition on physician self-referrals (the "Stark Law").

Our comments with regard to the Stark Law may be summarized as follows:

- The Stark Law includes as a designated health service "radiology, including MRI, CAT, and ultrasound." (Emphasis added). Because echocardiography is cardiac ultrasound, the Health Care Financing Administration's (HCFA's) proposed rules include echocardiography as a designated health service. ASE does not believe that the inclusion of echocardiography as a designated health service subject to the Stark Law is appropriate. ASE requests the Stark Law be amended to delete any reference to ultrasound as a designated health service and to narrowly define those radiology services that are considered designated health services. We understand that this Committee did in fact approve the elimination of ultrasound in H.R. 2425, which was incorporated into H.R. 2491 on October 26, 1995 in the Omnibus Budget Reconciliation Act of 1995.

- If ultrasound services remain subject to the Stark Law, those ultrasound services that are performed by a non-radiologist as the result of a request for a consultation by another physician should be exempted from the scope of the statute, just as radiology procedures performed by a radiologist as the result of a request for a consultation from another physician is considered exempt from the statute.

- Even if echocardiography technical component services are included within the scope of the Stark Law, professional component services are physicians' personal services that should not be included within the scope of the statutory prohibition.

ASE also urges the Committee to adopt the other provisions approved in 1995 in H.R. 2425. These provisions would, among other things, repeal those sections of the Stark Law that preclude physician compensation arrangements with entities to which they refer Medicare and Medicaid patients.

I. ECHOCARDIOGRAPHY IS NOT A RADIOLOGY SERVICE AND THEREFORE SHOULD NOT BE SUBJECT TO THE STARK LAW

The Stark Law includes as a designated health service "*radiology* services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services . . ." Social Security Act, §1877(h)(6)(D) (emphasis added). While echocardiography is an ultrasound service, it unequivocally is *not* a radiology service. Echocardiography is a service developed primarily by cardiologists, performed primarily by cardiologists, provided primarily in the cardiology departments of hospitals, billed under cardiology CPT codes, and performed for cardiologists' patients.

Echocardiography involves the use of diagnostic ultrasound to evaluate the structure and function of the heart and great vessels; however, since the technique requires a detailed understanding of the cardiac anatomy and physiology, the service is generally provided by cardiac sonographers and cardiologists. With regard to cardiac sonographers, it should be noted that specialized training is required, and that the registration process for cardiac sonographers is a rigorous one that includes a formal examination and ongoing CME requirements; there is no reciprocity between registration as a diagnostic cardiac sonographer and registration in other ultrasound modalities.

In addition, the interpretation of echocardiograms requires specialized physician training. The current training guidelines of the American College of Cardiology stipulate that to be able to interpret transthoracic studies independently, a trainee must devote a minimum of five months to echocardiography; supervision of an echocardiography laboratory requires an additional six months of training; and a large number of cardiology training programs provide third and fourth years of cardiology training devoted exclusively to echocardiography. Review of HCFA data for echocardiographic services indicates that the great majority of all echocardiographic studies are performed by cardiologists, and review of the *Index Medicus* indicates that over 75% of all medical literature on echocardiography were published by cardiologists. In addition, the technologic advances in the field have been developed almost exclusively by cardiologists.

ASE also notes that a number of other specialists are routinely involved in the performance of ultrasound services, and it is clear that a number of such ultrasound services are not radiology services. For example, ophthalmic ultrasound services are performed exclusively by ophthalmologists and are never performed by radiologists;

it would therefore stretch credulity to categorize these services as “radiology” services simply because ultrasound is used. We urge Congress to clarify this matter by deleting any reference to ultrasound as a “radiology” service and by specifically defining those radiology services subject to the physician self-referral limitations or as a service that is subject to the Stark Law in any manner.

II. ECHOCARDIOGRAPHY SERVICES SUPERVISED BY CARDIOLOGISTS AND PERFORMED PURSUANT TO A REQUEST FOR A CONSULTATION BY ANOTHER PHYSICIAN SHOULD BE EXEMPT FROM THE SCOPE OF THE STARK LAW

If the Stark Law remains applicable to echocardiography services and other ultrasound services that are routinely supervised and interpreted by cardiologists and other non-radiologists, the exemption provided by § 1877(h)(5)(C) should be extended to cardiologists and other non-radiologists on the same terms available to radiologists. The Stark Law provides that the term “referral” does not apply to the request by a radiologist for a radiology service where the radiology service is performed under the radiologist’s supervision and is performed pursuant to a request for a consultation by another physician. Social Security Act, § 1877(h)(5)(C). If the governing statute continues to categorize all ultrasound as a “radiology” service, regardless of whether it is performed by a radiologist, the law should be amended to enable a non-radiologist who supervises an ultrasound service performed pursuant to a consultation requested by another physician to qualify for this exception, rather than limiting the exception to “radiologists.”

In this regard, it should be noted that general internists often request cardiologists who specialize in the interpretation of echocardiograms to supervise and interpret echocardiographic studies in much the same manner as an internist or other non-radiologist might request a radiologist to supervise and interpret an MRI, CT, or other radiological study. Where a cardiologist supervises the performance of an echocardiogram pursuant to a consultation requested by another physician, the performance of the study does not raise a potential for abuse and should not be considered a “self-referral” within the meaning of the Stark Law.

III. PROFESSIONAL SERVICES SHOULD NOT BE SUBJECT TO THE STARK LAW

We also note that HCFA has interpreted the term radiology services to include both the professional and the technical components of ultrasound services. We do not believe that the Stark Law was intended to apply where a cardiologist interprets an echocardiogram performed on his own patients where the echocardiogram is performed at a hospital with which the cardiologist has no prohibited financial relationship; yet, this would appear to be the result if echocardiography *professional* services were considered “designated health services.” We urge Congress to clarify this matter in any legislation enacted to amend the Stark Law.

IV. OTHER ISSUES

The Stark Law is extraordinarily complex and unnecessarily confusing insofar as it attempts to regulate physicians’ compensation relationships with entities to which the refer Medicare and Medicaid patients. For example, this legislation includes three different formulas that may be applicable to a physician’s compensation—one that is applicable where the physician is also an owner of a group practice, one that is applicable to physician employees and one that is applicable to physician independent contractors. Each of these formulas is ambiguous and they are in some respects internally inconsistent—each in its own way. Health care lawyers differ among themselves in interpreting these and other important terms of this complicated law.

In our view, the anti-kickback provisions of the Medicare/Medicaid Fraud and Abuse Law already provide sufficient authority for the Government to proceed against physicians who have entered into inappropriate compensation relationships with entities to which they refer patients. This is especially true in light of the efforts that have been made by Congress to improve the remedies available to prosecutors and agencies for violations of the anti-kickback provisions and by the law enforcement officials to improve enforcement efforts. In light of these developments, we believe that it would be most appropriate for Congress to repeal the compensation-related provisions of the Stark Law altogether—an action approved by this Committee in 1995.

If you have any questions regarding ASE’s position on this matter, please contact ASE’s Washington counsel, Diane S. Millman, at (202) 756-8021.

AMERICAN UROLOGICAL ASSOCIATION, INC.
BALTIMORE, MD
May 13, 1999

The Honorable William M. Thomas
Chairman, Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives
Washington, D.C.

Dear Chairman Thomas:

The American Urological Association (AUA), representing 9,200 American urologists, is pleased to have the opportunity to offer its views on physician self-referral laws, commonly known as Stark I and Stark II. We request that this letter be made part of the Subcommittee's record for its May 13 hearing on this subject.

Physician self-referral legislation was enacted in response to concerns that physicians may overutilize certain medical services in which they have a financial interest. Studies conducted in the late 1980s and early in this decade suggested that physician ownership of diagnostic services, such as laboratory and x-ray, was associated with patterns of higher utilization. The self-referral laws were designed to address this situation and clarify which activities would be permissible. For a number of reasons discussed below, the AUA feels that these laws are now less relevant and need to be substantially revised, if not repealed.

The exponential growth of managed care has dramatically changed the medical practice landscape. In an effort to reduce health care spending, managed care has selectively contracted for a variety of services, such as lab and imaging, thus substantially reducing the opportunity for physicians to make financially advantageous referrals. In Medicare, the development of the sustainable growth rate and other curbs on service volume effectively limit growth that may be fueled by ownership and investment.

The pressures on the medical marketplace have also forced physicians, hospitals and other providers of care to seek new, more cost effective business arrangements. However, the move to greater efficiency has been hampered by the complexity of the Stark statutes and the proposed regulations. Instead of providing guidance, the law and regulation have confused attorneys, accountants and providers alike. It has made it virtually impossible for AUA to help its members comply with the law. If market-based solutions to health-care costs are to be achieved, then Congress needs to let the market evolve. The breadth of the self-referral laws and the resulting confusion over their applicability to different situations inhibit the development of new, efficient arrangements. This has delayed the cost efficiency sought by all parties.

Extracorporeal Shock Wave Lithotripsy (ESWL)

The law has had unintended consequences on one of the most effective and widely used urology services, extracorporeal shock wave lithotripsy (ESWL). ESWL is nowhere mentioned in the statute, but is caught up in the regulatory web. ESWL is a non-invasive procedure that uses shock waves to fragment ureteral and kidney stones. At the time of its introduction to the United States in 1984, it offered a welcome alternative to invasive surgery, which was the traditional method for removing kidney stones. ESWL usually requires no anesthesia, offering the advantages over surgery of reduced pain and suffering for patients, a rehabilitation time of only 1-2 days, and reduced risk and expense. In fact, former HCFA Administrator Gail Wilensky noted in 1991 that lithotripsy was one of the few instances in which a new medical technology decreased rather than increased health care costs.

Because many hospitals did not originally have the financial resources required to purchase lithotriptors, urologists often pooled their own resources to finance the substantial capital costs required to obtain and operate a lithotripter. Physician ownership of independent lithotriptors is still common today, and the procedure is usually performed on an outpatient basis in either fixed-site or mobile-unit facilities serving hospitals and ambulatory surgical centers (ASCs). Because lithotripsy services for Medicare beneficiaries are usually billed through a hospital outpatient department, ESWL is considered by HCFA to be an "outpatient hospital service," causing it to fall into the realm of prohibited services under Stark II. Therefore, ESWL is covered by the Stark II law simply because of the Medicare billing arrangement that HCFA originally recommended.

If HCFA's proposed rule is finalized as written, urologists with ownership interests in lithotriptors will not be able to treat Medicare and Medicaid patients at that facility, but will be forced to refer these patients to a different facility. This will almost certainly lead to disruptions in patient access by forcing patients to travel to

another lithotripter not owned by the treating physician. In some states there are no lithotriptors not owned by urologists, so patients would potentially have to leave the state to receive treatment.

This is particularly unfair to the elderly population, and it interferes with the continuity of care that usually accompanies lithotripsy treatment, since the practicing physician is responsible for all aspects of treatment, including pre-treatment diagnosis, the treatment itself, and post-treatment care.

Additionally, some non-urologist owned facilities could become flooded with Medicare and Medicaid patients, leading to delays in service for patients waiting in pain. This could create a two-tiered health care system, with non-Medicare patients having the same access and convenience as before while Medicare patients suffer because of the ban. Also, because capitated arrangements are excepted under Stark II, Medicare fee-for-service patients will be affected more than those in managed care.

Even Rep. Pete Stark, primary author of the laws, has indicated during debate on the House floor and in written communications to HCFA that Congress did not intend for lithotripsy to be covered by the self-referral law.

Heat therapy treatments for BPH

An additional concern about the proposed rule on physician self-referral is the possible chilling effect it may have on new technologies that treat benign prostatic hyperplasia (BPH). BPH, or enlarged prostate, is a very common disease, which afflicts about 13 million men over the age of 50 in the United States. There are now promising new technologies to treat BPH, such as transurethral microwave thermotherapy (TUMT), transurethral needle ablation (TUNA) and interstitial laser coagulation (ILC). These therapies use heat to destroy enlarged prostate tissue. Similar to ESWL, the equipment needed to perform these procedures represents a considerably large capital investment, with some heat therapy units costing over \$200,000. Many physicians are considering whether to purchase the equipment to enhance patient care, but it is uncertain if the Stark II proposed rule would allow physicians to own this expensive equipment under common arrangements.

Although several urologists in a community could share this equipment, it is not clear if this cost-effective arrangement would be possible unless the physicians qualified as a group practice. Thus, the ability of smaller practices to join together to acquire this equipment is constrained by the statute, and the law will have the effect of increasing expenditures for this equipment because sharing will be virtually impossible.

TUNA, TUMT and ILC are well suited for the office setting. If physicians have ownership interests in the equipment used to perform these services in the office, it is our understanding that the in-office ancillary services exception would exempt these procedures from Stark II. However, we are concerned that these procedures—like ESWL—may end up in the outpatient hospital services category by default if insufficient practice expense reimbursements force physicians to perform them in an outpatient setting. If such a situation does occur, TUNA, TUMT and ILC should be exempt from the definition of outpatient hospital services, since they are therapeutic procedures that do not pose a risk for overutilization.

In closing, AUA believes that the federal physician self-referral laws have been rendered obsolete by the passage of time and the dramatic changes in the medical system. We urge the Subcommittee to consider substantial revisions, or repeal of, the self-referral laws this year.

Sincerely,

LLOYD H. HARRISON, MD
President, American Urological Association

Statement of the Association of American Medical Colleges

On behalf of over 400 major teaching hospitals and 80,000 faculty physicians, the Association of American Medical Colleges welcomes this opportunity to comment on possible changes to the Physician Self-Referral Statute, (section 1877 of the Social Security Act, 42 USC section 1395nn). The May 13 hearing held by the Health Subcommittee of the House Ways & Means Committee made clear that while the original intent of the Physician Self-Referral remains laudable, the law may no longer be appropriate to the way in which health care is provided. As will be explained below, this is particularly true for academic faculty practice plans where transfers of funds among various entities of the academic health delivery system (comprising the medical school, the faculty practice plan and the teaching hospital(s), and other

entities such as research centers) are essential to support the core missions of teaching, research and patient care. The term “faculty practice plan” describes an academic physician group practice arrangement, whereby the group’s physicians serve as the full-or part-time clinical faculty of a medical school.

Whether it be through a major overhaul of the law, focused amendments to the existing legislation, or a regulation, it is essential that the academic institutions and faculty physicians are not inadvertently harmed by the implementation of the Physician Self-Referral Law. The AAMC urges the Subcommittee to ensure either that the law is changed to allow faculty practice plans to function as they must, or to direct HCFA to create a broad exception for practice plans and their organizational partners.

The remainder of these comments: (1) address the structure of faculty practice plans; (2) discuss the ways in which funds are transferred; and (3) briefly examine further problems created by the Self-Referral Law.

AN EXCEPTION FOR FACULTY PRACTICE PLANS

The AAMC wishes to ensure that physicians who are members of faculty practice plans will not violate the law. The AAMC believes that many faculty practice plans may not qualify for an existing or proposed exception, even though opportunities for program and patient abuse by faculty physicians are extremely limited. Due to the complexities of legal structures and monetary transfers among clinical departments in the practice plan as well as other medical center entities, the “group practice exception” may not be available to many faculty practice plans. For instance, in the proposed regulation HCFA retains the requirement that to be considered a group for purposes of a number of exceptions, there must be only one legal entity. In academic settings, it is not uncommon to find multiple entities, each of which may be compensating the physician and to which the physician may make referrals for designated health services. Additionally, many contractual relationships exist between the faculty practice plan and other parts of what compose the academic health delivery system. Regardless of the legal structure, in most instances a full-time faculty physician’s entire practice occurs within the scope of the department (e.g., internal medicine or obstetrics/gynecology) in which the physician practices.

Legal Structure of Faculty Practice Plans

The AAMC has collected data on the various legal structures of faculty practice plans for many years. We find that a majority of faculty practice plans (47%) are not separate legal entities, but rather “part of the medical school/university,” not-for-profit legal organization. Other practice plans (38%) are legally structured as “separate,” not-for-profit entities. The remaining medical schools, practice plans (15%) are organized legally in a variety of ways, including departmental professional corporations (PC’s), for-profit limited liability partnerships, etc. Financially speaking, it is not unusual for there to be multiple fund transfers among the different entities that comprise today’s integrated academic health delivery systems.

Transfers in an Academic Practice

A further complicating factor in academic health delivery systems is that many funds transfers have the potential for creating unintended violations of the physician self-referral regulations due to the fact that such transfers may be direct or indirect compensation. Also, it is likely that referrals will be made for designated health services among specialty departments, the teaching hospital and perhaps other delivery sites within the system. The majority of medical schools use revenues and taxes to “redistribute” individual faculty revenues. It is typical for all income generated by the faculty to be pooled at the departmental (i.e., specialty) level and distributed as follows:

- A dean’s tax is paid to support teaching, research and the infrastructure expenses. For example, there also may be cross-subsidization by higher earning departments of lower-earning departments. Also, some medical schools will transfer funds to other organizations in the delivery system to support their teaching mission. This may include funds for a medical library, classroom space or special laboratories, for example.
- Faculty compensation. Typically the compensation of an academic faculty physician has three components: (1) the base salary is for teaching and research and generally is paid according to a contractually agreed amount; (2) the clinical supplement is for patient care and is usually divided among members of a department on a predetermined formula typically not related to productivity; and (3) an incentive bonus which generally is based on a predetermined productivity formula and is the

smallest portion of the physician's total compensation. A majority of practice plan income funds components 2 and 3 of a faculty physician's total compensation.

In addition to funds transfers, there may be donations of equipment from one entity in the academic setting to another with the intent of supporting teaching, patient care and research. Such a transfer could be considered indirect compensation and thus may violate the Physician Self-Referral Law.

INCENTIVE PLANS

A further problem with the law is that it does not allow for the use of incentive plans that are designed to reward desirable behavior such as minimizing the use of tests and other costly interventions without compromising the quality of care, customer satisfaction, peer evaluation of clinical performance, and support of colleagues and patients by promptly seeing patients when requested. Each of these behaviors is laudable and should be encouraged, even when it is related to designated health services. Such compensation plans should be allowed by amending the legislation or making provisions in the final regulations.

CONCLUSION

HCFA has acknowledged that faculty practice plans are unique organizations that require supportive and special rules under the Medicare program. An upcoming Medicare carrier instruction (MCM 3060.3D) on the reassignment of physician payments under the Medicare program to be published soon by HCFA reinforces the proposition that faculty practice plans are unique and deserve special treatment. It was created because many faculty practice plans were unable to fit into the four exceptions already available and is available to any practice plan that meets the 9 criteria listed.

The AAMC believes that among the unintended consequences of the Physician Self-Referral Law is the possibility that faculty practice plans will violate the law if they continue to transfer funds or find other ways in which to support the missions of teaching, research and patient care as they always have. Also of concern is that at a time when resources are diminishing, and all payers seeking to provide better quality, more efficient care, there will be no opportunity to reward physicians for providing just this type of care. As long as what occurs in an academic health delivery system—or elsewhere—does not increase the volume or value of referrals, or give Medicare or Medicaid beneficiaries care that is unnecessary or inappropriate, it should be permitted. The government has sufficient and varied enforcement tools to protect beneficiaries and to discipline providers who abuse the system. Even if major changes are not made to the Physician Self-Referral Law, it should not be used to restrict the activities of academic practices since they are the places providing care that is unavailable elsewhere, training the next generation of physicians and other health care practitioners, and conducting research that improves the care that is available to all.

Statement of the Association of Freestanding Radiation Oncology Centers, Laguna Beach, CA

I. THE ASSOCIATION OF FREESTANDING RADIATION ONCOLOGY CENTERS

The Association of Freestanding Radiation Oncology Centers ("AFROC") is an association of over 150 freestanding radiation oncology centers located throughout the country. Freestanding radiation oncology centers are health care facilities organized and operated to provide high quality, cost-efficient radiation oncology services to patients in their communities outside the hospital setting.

There are approximately 2,400 radiation oncologists practicing in the United States; about half work in freestanding facilities. Most freestanding radiation oncology facilities are owned by the radiation oncologists who provide professional services there. It is estimated that there are approximately 300 to 350 freestanding radiation oncology centers located throughout the country.

II. PHYSICIAN SELF-REFERRAL AND RADIATION ONCOLOGY

While certain provisions of the existing physician self-referral law undoubtedly require clarification and revision, AFROC believes that self-referral restrictions remain critical for radiation therapy services.

Radiation oncologists work strictly on a referral basis. The cancer diagnosis is most commonly made by a surgeon, internist, or medical oncologist, who sends the patient to a radiation oncologist for examination and determination of whether radiation is an appropriate treatment. Where a referring physician has a financial interest in a radiation therapy facility, a serious conflict of interest exists which may interfere with the referring physician's judgment concerning the most appropriate center for the provision of radiation oncology services. A 1992 study in the *New England Journal of Medicine* illustrated the negative effects of this conflict of interest. The *Journal* study found that, where referring physicians had an ownership interest in radiation therapy facilities, the frequency and costs of treatment were 40–60% higher than at facilities without referring physician ownership. Moreover, personnel of joint-ventured radiation therapy facilities were found to spend 18% less time in quality control activities than their counterparts at facilities without referring physician ownership.

Current physician self-referral proscriptions are generally sufficient to limit the risk of over-utilization of radiation oncology services. Radiation oncologists themselves cannot engage in self-referral because radiation oncology is entirely dependent on referrals from the diagnosing physician, and the number of treatments that can be given to a particular area of the body is narrowly limited by effectiveness of dose on the one hand and tolerance of normal surrounding tissues on the other.

For these reasons, AFROC continues to strongly support physician "self-referral" restrictions for providers of radiation therapy services.

III. RECOMMENDATIONS

Existing Medicare-Medicaid anti-kickback statutes and safe harbor guidelines alone are inadequate to deter self-referral of radiation oncology services. Voluntary ethical guidelines are also insufficient to contain self-referral. Federal legislation and regulations explicitly banning self-referral for radiation therapy services are needed. Again, while some criticisms of Stark II are merited, the prohibition on self-referral for radiation therapy remains valid and important.

If Congress does modify the self-referral restrictions, we urge Congress to take great care to ensure that such modifications do not inadvertently preclude radiation oncologists from owning their own facilities. Because a radiation oncologist's ownership of his or her own facility does not raise the types of conflicts of interest issues raised by medical oncologist or surgeon ownership of these facilities, radiation oncologists' ownership arrangements are currently exempt from the physician self-referral restrictions. This exemption should remain intact, with minor technical revisions. For example, the current exemption applies only where a radiation oncologist supervises the radiation oncology services that he or she prescribes and does not, by its terms, apply where these services are supervised by a member of the same group practice as the referring radiation oncologist. This provision should be clarified to enable the supervision to be provided by a group practice member.

We would be delighted to help draft appropriate amendments, but believe that the basic self-referral prohibitions should remain applicable to radiation oncology services. If you have any questions concerning physician self-referral or AFROC, please do not hesitate to call AFROC's President, Jeffrey Lopez, M.D., at (800) 225-8161.

Statement of the Federation of American Health Systems

The Self-Referral Statute is an extremely complicated law that consumes a great deal of resources to analyze and implement both for the government and for providers. It is an anachronism in today's health care environment. It was drafted to regulate physician relationships in the fee-for-service world and makes little sense in the current health care environment. Because of its rigidity it cannot be adapted to meet the changing shape of current and future health care.

The Self-Referral Statute has had a marked impact on the health care marketplace. It has created an uneven playing field between types of providers whose services fall within the designated health care services covered by the law and providers whose services do not. Furthermore, providers covered by the Self-Referral Statute have had to struggle to structure their arrangements to qualify for an exception.

As a result, the Statute has discouraged more innovative arrangements that could lead to reduced costs or improved quality simply because they cannot fit the exact specifications of the exceptions, and therefore are prohibited.

The Statute has created a great deal of confusion, stemming not only from the complexity of the law itself, but also from its overlap with other health care stat-

utes, such as the Anti-Kickback Statute, state laws, etc. Health care providers have ended up with two (and sometimes more) different approaches and two (and sometimes more) different sets of requirements regulating the same conduct or arrangement.

For example, both the Anti-Kickback Statute and the Self-Referral Statute regulate financial relationships between doctors and hospitals in situations where the doctors are making patient referrals to the hospital. However, they take two different approaches. The Anti-Kickback Statute starts with a presumption that a referral is not problematic unless it is determined that the arrangement provides an improper inducement. It has safe harbors that grant approval of certain arrangements under specified circumstances, but failing to meet a safe harbor does not necessarily mean the referral is prohibited or subject to penalty.

On the other hand, the Self-Referral Statute starts with a presumption that absolutely prohibits referrals by physicians with financial relationships with the hospital, unless the parties can fit their arrangements precisely within the enumerated exceptions. Therefore, what you find is that for any given arrangement, there may be both a safe harbor under the Anti-Kickback Statute and an exception under the Self-Referral Statute, but there are slightly different criteria set forth in each. This is true, for example, with respect to personal service arrangements and employment relationships.

We are concerned that because of the Self-Referral Law's presumption prohibiting referrals in all situations which do not fit into an exception, numerous standard, non-abusive arrangements are prohibited and subject providers—sometimes for very technical reasons—to harsh penalties. Unlike the Anti-Kickback Statute, the Self-Referral Statute is not intent-based and providers can violate it unwittingly. There is no allowance made for minor, insignificant variations or inadvertent noncompliance with the statute's rigid requirements, thus potentially subjecting innocent parties to devastating civil monetary penalties.

For example, there are exceptions for leases and personal services contracts. These require, among other things, signed, written agreements with a term of at least one year. If a hospital leases a medical office to a physician for a five year term and it expires while the parties are negotiating the renewal terms, then the lease no longer complies with the law, even if the physician continues to pay fair market rent during the period between when the original lease expires and the renewal is signed. In such a circumstance, every referral made by the physician during that interim period would technically be a violation of the Self-Referral Statute and would subject the physician and hospital to liability for return of all payment received from Medicare for those referrals. In addition, civil money penalties of \$15,000 for each service billed in violation of the Self-Referral Statute would also apply, not to mention the potential for a civil and/or criminal False Claims Act action, initiated by either a government representative or a qui tam relator. This seems to be a very harsh result for a minor oversight.

Similarly, a completely legitimate hospital medical director agreement might inadvertently (and unknown to the physician) not be signed by the hospital CEO until one month after the physician begins to provide services and receive payment under the agreement. Technically, the medical director agreement would not meet an exception during the first month. Any referrals made by the physician that month would violate the law, and if the hospital billed for them, substantial penalties could be imposed. Certainly these types of inadvertent violations do not raise the issues that the Self-Referral Statute was meant to address and should not be subject to the Self-Referral Statute's harsh penalties.

There are also numerous instances in which parties are unable to enter into reasonable, legitimate arrangements, simply because no exception is available. If a physician moves into a new area six months before the remodeling of the physician's permanent office space is scheduled for completion, the physician would not be able to enter into a six month office lease with a nearby hospital to meet the physician's interim needs, even if the lease were legitimate and commercially reasonable in every respect, because of the one year requirement in the lease exception. Also, physicians (and their immediate family members) may not sell supplies or other items to a hospital, even on commercially reasonable terms, at fair market prices, because there is no exception in the law for such arrangements (although there is an exception that permits physicians to purchase items).

The confusion caused by the Self-Referral Statute has been compounded by the delay in publication of implementing regulations.

SPECIFIC PROPOSALS FOR REFORM

In light of these concerns regarding the difficulties of analyzing and implementing the Self-Referral Statute, FAHS would like to work with the Chairman, Congressman Stark and others on the Committee and throughout Congress to consider potential reforms. We will discuss some of the issues we are exploring below, going from the broadest based reforms to the more technical. Several of these proposals were contained in the Balanced Budget Act of 1995.

REPEAL APPLICATION OF STATUTE TO COMPENSATION ARRANGEMENTS

The Anti-Kickback Statute provides the government with ample firepower to combat improper compensation arrangements. Any payment intended to induce the referral of patients for the provision of any goods or services reimbursable by a federal health care program is a crime under the Anti-Kickback Statute. 42 U.S.C. 1320a-7b(b).

In addition, the Balanced Budget Act of 1997 added a civil basis for liability, providing for the imposition of substantial civil monetary penalties for violations of the Anti-Kickback Statute. With the addition of these civil penalties, the government can now prove its case under the Anti-Kickback Statute by a preponderance of the evidence, thus giving enforcement agencies added leverage in enforcing this statute against parties to abusive compensation arrangements.

We know this was a provision included by the Chairman in the Balanced Budget Act of 1995 (BBA 95). Given the addition of the new civil monetary penalty for violations of the Anti-Kickback Statute and in light of the common purpose of the Self-Referral Statute and the Anti-Kickback Statute—to prohibit and penalize improper inducements to make referrals—we believe there is even greater justification for repealing the Self-Referral Statute's application to compensation arrangements today than there was during BBA 95.

In addition, the compensation provisions of the Self-Referral Statute are clearly the area that has caused the greatest amount of confusion in implementation. For example, if you look at the proposed rule, you will note that the great majority of that voluminous rule relates to tortured interpretations of the compensation provisions. Thus, it seems that the Self-Referral Statute is much more effective at accomplishing its purpose, without creating unnecessary complications and confusion for the industry and those who regulate it, when it is limited to ownership/investment interests.

To the extent that Congress would repeal the compensation provisions, a number of the more specific proposals below would no longer be needed.

CLARIFY REPORTING REQUIREMENTS

There is an urgent need to clarify the reporting requirements under the Self-Referral Statute. HCFA initially interpreted the Self-Referral Statute as requiring Medicare providers, such as hospitals, to report their financial relationships with physicians only if they did not meet an exception under the law. However, in the proposed rule, HCFA contemplates a requirement that providers be prepared to report all their financial relationships with physicians (and their relatives)—whether or not they comply with an exception—if the provider “knows or should know” about the relationship “in the course of prudently conducting business.”

This requirement would be overwhelming and would require providers to devote enormous time, effort and resources into tracking hundreds, thousands or even tens of thousands of completely lawful, benign relationships with shareholders, bondholders, vendors, services providers, employees, landlords, tenants, etc., each of whom might be a relative of a physician who refers to the provider. Even then, a provider could be found in violation of the law for failing to report a single, innocuous financial relationship that it was unaware if the provider “should have” known of the relationship.

There has been some suggestion by HCFA that it will not require reporting of information, and providers need only retain on file information to respond to a spot audit, at least until a final rule is issued. Unfortunately, providers will have problems whether HCFA ultimately requires providers to report all of this information, or simply track it, or even limits the reporting requirement to non-compliant financial relationships.

A requirement to report all financial relationships with physicians (or their relatives) is overwhelming and infeasible at worst, and extremely time consuming, burdensome and costly at best. On the other hand, a requirement to report to HCFA those financial arrangements with physicians (or their relatives) that do not meet a Self-Referral Statute exception, requires a clarity of understanding about what

complies with and what violates the Self-Referral Statute that has been unachievable, even for the government. In addition, there is an inherent unfairness in mandating that people report their own violations. Certainly, it is inconsistent with the concept of voluntary disclosure, which the health care community believes holds great potential to revolutionize and facilitate self-policing, if a stronger process can be developed. Furthermore, providers would rightfully be concerned that reports of non-compliant arrangements, even those which are only technical violations or even beneficial arrangements which just can't fit neatly into an existing exception, would then serve as a basis for assessing fines and penalties, if not as a beacon attracting other investigation and prosecution.

A much clearer and more rational policy could be established if the compensation portion of the Self-Referral Statute is repealed, since then entities would be faced with the more manageable task of reporting only ownership and investment interests (although presumably there should be some minimum threshold, such as 5% ownership, to avoid the complications involved in reporting every stockholder in a publicly traded company).

EFFECTIVE DATE

Change the effective date for "Stark II" to one year after the regulations become final. It is unfair to enforce the Self-Referral Statute before final regulations are issued, given the enormous confusion caused by the statute (which HCFA itself notes is ambiguous and contains many undefined terms); the length of time it has taken to develop and publish proposed regulations; the enormous volume of comments submitted in response to the draft regulations (because they raise almost as many questions as they answer); and the severe penalties imposed even for innocent violations of the statute by well-meaning persons who misinterpreted ambiguities in the law.

Also, once the regulations are final, providers will need time to restructure or unwind arrangements that they believed complied with the statute, but which do not meet any exception in the regulations as finally published or in the statute as it is ultimately interpreted in the final regulations.

FAIR MARKET VALUE EXCEPTION

If the Self-Referral Statute continues to apply to compensation arrangements, then a new "fair market value compensation" exception should be added to the statute. The new exception should be designed to protect all compensation arrangements for items or services that meet certain minimum requirements. The exception should protect any legitimate, commercially reasonable compensation arrangement that is set forth in a written agreement, signed by the parties, which describes the items and services provided, establishes a timeframe for the agreement, and provides for compensation that is consistent with fair market value contract, without taking referrals into account.

HCFA included such an exception in its proposed rule, although one of the requirements included in HCFA's version introduces an element of uncertainty that would undermine providers' ability to rely on the exception. Specifically, the proposed rule requires that the arrangement comply with the Anti-Kickback Statute. The Anti-Kickback Statute, as described above, is an intent-based statute. Requiring compliance with the Anti-Kickback Statute introduces the concept of intent into the Self-Referral Statute, thus casting doubt on the exception. For example, a hospital could innocently enter into an apparently legitimate compensation arrangement with a physician that meets all of the other requirements of HCFA's proposed exception. However, if the physician (unknown to the hospital) has a bad "intent" under the Anti-Kickback Statute, then the hospital, even if it has no bad intent, and no way of knowing that the physician had a bad intent, would be unable to use the exception under the Self-Referral Statute.

Furthermore, until the proposed rule becomes final (which will be at least a year from now), physicians and providers have no general compensation exception to protect their fair, legitimate, and reasonable arrangements that do not meet any of the other, specific exceptions. We believe this is such a crucial exception that it should be a statutory, rather than a regulatory provision, especially in light of the potential delay involved in waiting for finalization of the regulation.

Notwithstanding the potential value of this type of exception, it is important to recognize that it is not a reasonable alternative to actually repealing the Self-Referral Statute's application to compensation arrangements. This exception, for example, would not protect legitimate unwritten compensation arrangements. Also, providers would continue to struggle with one of the most vexing issues under the Self-Referral Statute - what services and items, which often are not covered by written agree-

ment, must be counted as “compensation” to physicians (e.g., free parking, coffee, computer or library access, training, etc).

PHYSICIAN RECRUITMENT

The Physician Recruitment Exception currently requires the physician to “relocate to the geographic area served by the hospital.” However, in certain circumstances, practitioners establishing new practices might already be within a hospital’s geographic area. Hospitals should be permitted to recruit such physicians so long as they do not have an existing patient base and compensation does not vary based on the volume or value of referrals. At a minimum, a hospital should be permitted to recruit a resident or fellow who is already in the hospital service area, but does not have any private practice and wishes to start one in that geographic area. In such cases, there is little likelihood of abuse, because the physician, although practicing medicine in the area, is in the same position as a physician from outside the area in that he or she has no existing patients to refer to the hospital.

The current wording of this exception penalizes entities who accept responsibility for training residents and fellows, since these residents and fellows cannot subsequently be recruited by the hospital that trained them, and can only be recruited by more distant hospitals. This creates great inefficiency, with hospitals recruiting residents from other, distant hospitals, because they cannot recruit local residents, even though the local residents might prefer to stay where they did their residency. This requirement also has a negative impact on smaller towns and more rural areas, because they are more likely to find a good match with residents, fellows and physicians who have spent time in that town or area and know they will like it there.

HOSPITAL OWNERSHIP EXCEPTION

Clarify that the exception for physician ownership of a hospital applies to all designated health services provided by the hospital, not just hospital services (i.e., if the hospital also owns a clinic, a home health agency, or has a distinct part skilled nursing facility, etc., than a physician with an ownership interest in the hospital that meets the Self-Referral Statute exception may also refer to the hospital for these other services). Although the exception in the Self-Referral Statute seems to apply to all services provided by a physician-owned hospital, HCFA has construed it more narrowly in the proposed rule, as permitting referrals for hospital services, but not other services. There is no policy reason for this distinction, and puts physician-owned hospitals at an unfair disadvantage.

FEDERAL PREEMPTION

Mandate federal preemption of state law in this area. Not only must providers comply with numerous complex federal statutes regulating their financial relationships with physicians and others, many states have also adopted physician self-referral statutes. These state statutes create a set of duplicative, overlapping, and confusing requirements that substantially increase the time, effort and expense required to comply with the law, without providing commensurate benefit to the public in protecting against abusive financial arrangements.

ANTI-KICKBACK STATUTE SAFE HARBORS

Another important reform to the compensation provisions would be to establish a statutory exception in the Self-Referral Statute for arrangements that fall within a safe harbor to the Anti-Kickback Statute. Under the Anti-Kickback Statute the safe harbors are drawn quite narrowly with the understanding that just because you are not in the safe harbor does not mean your conduct violates the Anti-Kickback Statute, it just means you will not receive safe harbor protection. Arrangements that are able to qualify for the safe harbors have met a very high standard and therefore deserve protection under the Self-Referral Statute as well. This becomes particularly important in light of the fact that there are often safe harbors under the Anti-Kickback Statute and exceptions under the Self-Referral Statute that deal with the same issues and/or arrangements, but due to their separate development, and interpretation by different agencies (OIG versus HCFA), they contain differences which make them hard to reconcile. It would also be very beneficial for providers and physicians who are trying to respond to the shift to managed care to be able to rely on the new shared risk exception under the Anti-Kickback Statute for purposes of the Self-Referral Statute also.

HOSPITAL INPATIENT AND OUTPATIENT SERVICES

Hospital inpatient and outpatient services should be removed from the list of designated health services. By and large, the other designated health services were all identified in studies that demonstrated increased utilization when physicians had a financial relationship with the provider of the service. To our knowledge, no such studies demonstrate a correlation for hospital services in general. Moreover, in most cases, there is little risk of over-utilization of hospital services, which tend to be emergency services, major surgery, or similar services of the type that are not generally over-used.

Thank you for the opportunity to provide our comments for the record. We appreciate the Subcommittee's interest in this subject and believe reform is vitally needed in order to clarify and better target the rules at true fraud.

**Statement of Dwight S. Cenac, Home Care Association of America,
Jacksonville, FL**

Mr. Chairman and Members of the Committee: Thank you for the opportunity to offer written testimony on the critical subject of Medicare Self-Referral Laws. My name is Dwight Cenac and I am the Chairman of the Board of Home Care Association of America (HCAA). HCAA represents several hundred freestanding home health agencies across the United States.

Mr. Chairman, as I did in my recent written testimony regarding the Medicare Coverage Decisions and Beneficiary Appeals, let me again urge you to schedule hearings (perhaps in June) regarding the issue of the Interim Payment System for home health care. At last count, over 2000 home health agencies have been forced out of business, causing the patients of those agencies to be forced into more costly nursing homes, more costly emergency rooms, or worse, left at home without receiving necessary patient care.

While the GAO and others are conducting studies pertaining to access to home health services, this committee must address the fact that the BBA of 1997 has placed an unfunded mandate on the states. By the federal government placing a per-beneficiary cap on home health care, agencies across the U.S. are filing for bankruptcy and discharging their patients. Clearly this was not the intent of Congress.

In addition, due to recent press reports regarding privacy issues pertaining to the OASIS data collection effort, it seems possible that HCFA will not be able to comply with implementing PPS for home health care as mandated on October 1, 2000. It is imperative that you ask HCFA Administrator Nancy Ann Min-DeParle if indeed HCFA will be able to implement PPS for home health care on October 1, 2000. It would also be beneficial to ask Administrator Min-DeParle how the implementation of PPS for skilled nursing is progressing.

Mr. Chairman, I understand that your primary concern is adequate access for doctor-certified Medicare beneficiaries, however, it is important to understand that the most recent CBO numbers show that home health care has been cut \$48 billion dollars over 5 years. This is far greater of a cut than Congress intended. On behalf of the members of HCAA I urge you hold hearings in the very near future on home health issues including the viability of a co-pay on home health, the impact of the IPS on home health agencies, and the recent data from the CBO that \$48 billion has been cut from the home health benefit.

It is also frustrating for me to hear from members of Congress to say that Congress is powerless over HCFA. It is time for Congress to conduct serious oversight hearings on HCFA and hold to HCFA accountable for their failures. The MTS computer debacle; the IPS for home health care that has forced thousands of honorable home health agencies out of business; the ill-conceived PPS for skilled nursing; and the privacy issue regarding data collection pertaining to OASIS (which is so severe, that Vice-President Gore is now involved), are just a few examples of a HCFA run amok.

I would appreciate the opportunity to personally testify before this committee on home health issues in the future.

I. THE STARK LAWS ARE NOT OBSOLETE

Mr. Chairman, with all due respect, I find this paragraph from your advisory to be humorous:

The guiding principle for the self-referral laws was to prevent physicians from inappropriately referring patients based on the potential for financial gain. Yet, the health care delivery system has changed profoundly since passage of the first self-referral laws. Since 1989, the health care system has rapidly moved away from the traditional fee-for-service way of delivering medical care. Today, the health care system has moved towards a more coordinated, integrated approach.

“Since 1989, the health care system has rapidly moved away from the traditional fee-for-service way of delivering medical care.” Mr. Chairman, thousands of Medicare patients have been displaced because patients are rapidly moving AWAY from HMO’s, and other “brainchild’s” (PHO’s PSO’s and Medicare-Choice plans) of the Administration and the Republican leadership.

“A more coordinated, integrated approach?” Mr. Chairman, that sounds strangely familiar to the Clinton big-government plan that failed in 1992/1993! If you recall, the Clinton plan was to put our nation’s health care (1/7th of our economy) into the hands of 7 “regional alliances.” These alliances would be in charge of distributing Medicare dollars to providers for services rendered. Mr. Chairman, as a registered Republican, I urge you and your Republican colleagues to reject this warmed over version of the Clinton one-size-fits-all big-government take-over of our health care system!

Mr. Chairman and Members of this Committee, the question is, have HMO’s, PHO’s and the Medicare-Choice programs been a success? The answer is “no.” Thousands of Medicare beneficiaries have been displaced because quite frankly, the profit margin for HMO’s was not as great as originally predicted. Because of this fact, some HMO’s opted not to renew their Medicare contracts because HCFA would not allow them to make financial adjustments to make the HMO even more profitable. This clearly shows me that the primary motive for some HMO’s may be PROFIT, not patient care! This is the danger of having stockholders holding company executives accountable for return on investment!

Regarding PHO’s and PSO’s, I have read news accounts here in my state of Florida that these “brainchild’s” are also not profitable, that doctor’s, hospital’s and other entities are having difficulty keeping doctors in the programs, and patients are having difficulty getting access to specialists. It saddens me to hear, “If we only give them more money” or, “HCFA hasn’t educated beneficiaries well enough.” The truth is that in most cases, Medicare beneficiaries prefer the traditional fee-for-service Medicare program. Sure, when beneficiaries are well, HMO’s are very attractive, and yes, they provide much needed services (prescription drugs) that are not covered by fee-for-service Medicare, but when a Medicare beneficiary is sick, seriously sick, the traditional fee-for-service Medicare plan seems to be the plan of choice!

Mr. Chairman, allow me to refer you and your colleagues to an OIG “Special Fraud Alert” entitled, “Hospital Incentives to Physicians.”

In this OIG Special Fraud Alert, it states,

The Office of Inspector General has become aware of a variety of hospital incentive programs used to compensate physicians (directly or indirectly) for referring patients to the hospital. These arrangements are implicated by the anti-kickback statute because they can constitute remuneration offered to induce, or in return for, the referral of business paid for by Medicare or Medicaid. In addition, they are not protected under the existing “safe harbor” regulations.

These incentive programs can interfere with the physician’s judgment of what is the most appropriate care for a patient. They can inflate costs to the Medicare program by causing physicians to overuse inappropriately the services of a particular hospital. The incentives may result in the delivery of inappropriate care to Medicare beneficiaries and Medicaid recipients by inducing the physician to refer patients to the hospital providing financial incentives rather than to another hospital (or non-acute facility) offering the best or more appropriate care for that patient.

Mr. Chairman and members of the subcommittee, in this Special Fraud Alert, there are several examples of potentially unlawful activity which are outlined:

- Payment of any sort of incentive by the hospital each time a physician refers a patient to the hospital
- The use of free or significantly discounted office space or equipment (in facilities usually close to the hospital)
- Provision of free or significantly discounted billing, nursing, or other staff services
- Guarantees which provide that, if the physician’s income fails to reach a predetermined level, the hospital will supplement the remainder up to a certain amount

- Payment of the cost of a physician's travel and expenses for conferences
- Payment for services (which may include consultations at the hospital) which require few, if any, substantive duties by the physician, or payment for services in excess of the fair market value of services rendered

Mr. Chairman, it is clear that this OIG Special Fraud Alert gives significant reasons why the Stark laws (and other laws to prevent undue costs to the Medicare program) must remain intact. In fact, it is imperative that laws pertaining to hospital self-referrals regarding home health care must be enforced. Hospitals have a "captive-patient" when it comes to home health referrals. In some cases the hospital discharge planner may "steer" a relatively healthy Medicare patient into the hospital-based home health agency, while allowing the sicker, more medically complex home health patient into a freestanding agency in the community. This helps the hospital financially under the severely flawed Interim Payment System (IPS) for home health care that was included in the BBA of 1997.

Mr. Chairman, an OIG report entitled "Hospital Stays for Medicare Beneficiaries Who are Discharged to Home Health Agencies," dated August 1998 (OEI-02-94-00321) also discusses the self-referral issue. Under the paragraph entitled, "Discharge Planning Referral" it states:

Medicare requires hospitals to have a discharge planning process that identified patient's post-hospital needs soon after admission and puts in place a plan that will ensure a safe discharge from the hospital. Section 1802 of the Social Security Act seeks to ensure that free choice is guaranteed to all Medicare patients in choosing a post-hospital provider, such as a home health agency. When there is hospital ownership of post-hospital services, it raises concerns about the discharge planning process. First, will patients be given the freedom to choose a post-hospital provider in an environment where the hospital discharge planner works for an organization which also owns post-hospital services? And secondly, in an effort to maximize Medicare reimbursement, will hospitals use the discharge planning process inappropriately to shorten patient hospital stays and transfer patients to post-hospital services they own?

One topic that the OIG overlooks in this report is the influence that the physician has in this important process. Doctors certify the patient for home health services. If a doctor has a financial interest in the hospital, if bonuses are tied to hospital profit, it may be a strong incentive for the doctor to refer patients to the hospital-based home health or skilled nursing facility.

Mr. Chairman and members of this subcommittee, I sincerely hope that your intention is to maintain and enforce laws to prohibit self-referrals by doctors and hospitals, not to loosen such laws. It is my concern that under the guise of Medicare-Choice, an attempt will be made to loosen self-referral laws. I hope that members of this subcommittee make such self-referrals laws more clear and strongly enforce 42 CFR 424.22 pertaining to hospital self-referrals.

In conclusion, I deeply appreciate the opportunity to share my thoughts with the subcommittee on the critical issue of self-referrals. If members of Congress are successful in weakening the Stark self-referral laws, you will see the results in higher Medicare outlays. I urge you to inform the proper authorities to enforce current Stark laws and I urge this committee to avoid weakening these appropriate laws.

Once again, I would welcome the opportunity to personally testify before this committee on home health care issues in the future.

Statement of the Joint Council of Allergy Asthma and Immunology, Palatine, IL

Mr. Chairman: The Joint Council of Allergy, Asthma and Immunology ("JCAAI") appreciates this opportunity to submit testimony on the effect of the proposed rule implementing the Stark II law. JCAAI is an organization sponsored by the American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology. Its members are over 4,000 physicians board-certified in allergy, asthma and immunology. JCAAI members practice in a wide variety of arrangements including solo practices, single-specialty groups, multi-specialty groups and large university faculty practice plans.

1. APPLICABILITY OF LAW TO PULMONARY FUNCTION TESTS

JCAAI is concerned that the proposed rule inadvertently includes pulmonary function tests or spirometry as a "designated health service." While pulmonary function

tests or general diagnostic tests are not defined as designated health services by the Physician Referral statute (Stark law), physical therapy services are included in such term. HCFA is proposing to define "physical therapy services" with reference to another Medicare regulation which describes the types of services which are covered by Medicare in comprehensive outpatient rehabilitation facilities ("CORFs"). That regulation (42 C.F.R. § 410.100(b)) defines "physical therapy services" to include:

Testing and measurement of the function or dysfunction of the neuromuscular, musculoskeletal, cardiovascular, and respiratory systems, (emphasis added).

Pulmonary function tests are tests for the measurement of the function of the respiratory system. However, they have nothing to do with physical therapy. Allergists specializing in the care of asthma patients frequently perform these tests in their office to determine if a patient has asthma and the severity of the asthma. The test itself is not therapeutic in nature. Nor does it result in a referral of the patient for physical therapy.

We do not believe that Congress intended that pulmonary function tests be included in the definition of "physical therapy services." In fact, we note that Congress specifically deleted the language in the 1993 law which defined designated health services to include radiology "and other diagnostic tests." That provision now covers only certain types of radiology tests including MRIs, CAT scans and ultrasound. There is nothing in the law which suggests Congress intended to treat pulmonary function tests as a "designated health service" for purposes of the Stark law.

We have recommended that HCFA modify the definition of "physical therapy services" to delete the reference to respiratory tests in our comments on the Stark II rule and if HCFA did not follow this recommendation we would urge Congress to so provide through amendments to the statute.

2. APPLICABILITY OF STARK II LAW TO ANTIGENS

Antigens are prepared by physicians in solution to be used by injection to provide immunotherapy to patients with a diagnosis of significant allergic reactions. Antigens are extracts of pollens or venoms, for example, and are defined in the Food Drug and Cosmetic Act as biologicals not drugs. Historically, antigens have not been prescribed for preparation and provision by pharmacies. We do not believe Congress intended to include antigens as outpatient prescription drugs and therefore as covered designated health services. There is also no evidence of abuse by physicians of utilizing antigens and immunotherapy which could justify an extension of this definition of outpatient prescription drugs to antigens.

In the Stark II proposed regulations of January 1998, however, HCFA states, in its discussion of the definition of "outpatient prescription drugs, that this category of designated health services could include antigens covered under section 1861(s)(2)(G). HCFA's test for whether a drug or biological covered by Medicare on an outpatient basis is included in the definition of "outpatient prescription drugs" is whether the product could be obtained from a pharmacy with a prescription.

Although current practice is for the physician to prepare antigens for allergy immunotherapy in the office, we believe is likely that in the future they may also be provided through a pharmacy under a physician's prescription especially as managed care organizations and large integrated health delivery systems seek to consolidate the delivery of services.

In this regard, we note that, in accordance with section 1861(s)(2)(G), Medicare only covers antigens which are *prepared by a physician*. That provision of the law provides coverage for antigens as follows:

(G) antigens (subject to quantity limitations prescribed in regulations by the Secretary) prepared by a physician, as defined in section 1861(r)(1), for a particular patient, including antigens so prepared which are forwarded to another qualified person (including a rural health clinic) for administration to such patient, from time to time, by or under the supervision of another such physician;

Thus, even if antigens were available by prescription from an institutional pharmacy, they would not be covered by Medicare. For this reason, we do not believe the Stark prohibitions would apply since the Stark law only prohibits referrals "for which payment otherwise may be made under this title. . . ." Section 1877(a)(1)(A).

However, it is possible that state Medicaid agencies would elect to cover antigens furnished by a pharmacy even though they would not be covered by Medicare. HCFA states in the commentary to the regulations that a physician has made a referral if he or she requests a Medicaid covered designated health service that is

“comparable to a service covered under Part B of Medicare. . . .” (January 9 Federal Register at p. 1692.) However, HCFA also states that the State Plan’s definition of a service will take precedence even if the definition will encompass services that are not covered under Medicare. (January 9 Federal Register at p. 1673.) These statements seem inconsistent. It is unclear how HCFA would treat antigens furnished by a pharmacy which are covered under a state plan.

In order to promote consistency in the application of the Stark law to Medicare and Medicaid and to avoid confusion, we believe the policy with respect to Medicaid should conform to Medicare. Thus, since antigens would not be covered by Medicare if provided by a pharmacy, we believe they should not be treated as a designated health service for Medicaid purposes even if provided by a pharmacy.

We have therefore requested that HCFA either establish an exception in the regulatory definition of “outpatient prescription drugs” for antigens covered under Section 1861(a)(2)(G) or clarify in the commentary to the final Stark II regulation that even if antigens were to become available from pharmacies under a physician prescription, they would not be considered designated health services for purposes of the Stark law because they would not be covered by Medicare Part B.

Further, with respect to Medicaid, we have asked that HCFA clarify that if a Medicaid agency were to cover antigens furnished through a pharmacy, this would not be considered a “designated health service” because it is not comparable to a service covered by Medicare.

Without this change in the regulation or clarification, there is likely to be confusion as to whether antigens are a designated health service for purposes of both Medicare and Medicaid.

If these changes are not adopted by HCFA, we would urge that Congress specifically include such clarifications in Medicare legislation this year.

3. DEFINITION OF GROUP PRACTICE

We are also concerned about the definition of group practice and its implications for the ways that physicians in groups deal with compensation. HCFA’s proposed definition of group practice fundamentally alters the basic way that physicians in group practice organize themselves economically. The new “unified business test” which is not found in the statute, puts at risk many longstanding and legitimate practices. Its purpose seems to be to prevent practices from qualifying as groups under Stark if they treat different specialties, departments or office sites as separate cost centers. There is nothing in the law or legislative history which suggests that Congress believed a group was not a “true group” simply because expenses are allocated by department or by physician.

Moreover, it is unclear from the commentary to the proposed rule which types of compensation methodologies are permitted and which are prohibited. Although the statute clearly permits productivity bonuses, HCFA appears to have interpreted it in a way which renders it almost meaningless. The agency’s position is that designated health services which are personally performed by the physician must be treated as profits of the entire group. We do not believe Congress intended that physicians could not be compensated for services they perform personally.

Further, we do not believe the law requires that, in order to meet the definition of group practice, group practice revenue cannot be distributed based on cost centers or departments. We urge that HCFA carefully consider the disruptive effects these aspects of the proposed rule will have on legitimate and longstanding group practice arrangements.

If HCFA finalizes the proposed rule without change, we would urge Congress to pass legislation eliminating the unified business test recommended by HCFA and clarifying permitted payment methodologies as we have recommended.

Statement of the Medical Group Management Association

INTRODUCTION

Mr. Chairman and Members of the Subcommittee, the Medical Group Management Association (MGMA) is pleased to submit this statement regarding the Medicare self-referral law and its regulations. MGMA members confront the complexities and ambiguities surrounding the Medicare self-referral law and its accompanying regulations on a daily basis.

MGMA is the oldest and largest organization representing physician group practices with more than 8,300 health care organizations nationwide in which over

209,000 physicians practice medicine. MGMA's membership reflects the full diversity of physician organizational structures today, including world-renowned tax-exempt integrated delivery systems, taxable multi-specialty clinics, small single specialty practices, hospital-based clinics, academic practice plans, integrated delivery systems, management service organizations, and physician practice management companies.

While physicians understand that they must comply with the self-referral statute, it is the medical practice managers who most often are responsible for the unenviable task of trying to understand the complexities of the law to ensure proper compliance. In fact, many small and medium practices, which comprise a vast majority of overall group practices, do not have a formally designated compliance officer. Therefore, in addition to the responsibility of managing the day-to-day business of the group practice, practice managers are responsible for monitoring activities that may involve the self-referral law.

MGMA supports fully the intent behind the self-referral law—to prevent physicians from ordering unnecessary ancillary services in order to profit from the Medicare and Medicaid programs. However, the self-referral law has gone far beyond its original intent and it now interferes with the delivery of efficient, quality health care. At this time, the law and its proposed regulations are so confusing and complex, it is virtually impossible to conclusively determine whether certain ancillary service arrangements are or are not in violation of the self-referral law.

During the Medicare reform debate of 1995, your Subcommittee addressed several concerns which would be of value to MGMA members (e.g., limiting the number of designated services, removing the compensation arrangement prohibition in the definition of financial relationship, etc.). At this time, MGMA believes that by focusing on the following proposals, Congress would provide tremendous relief to a broad set of providers in a variety of health care settings. This would enable physician group practices, clinics, hospitals, and other providers to provide care in the most efficient manner possible.

- MGMA requests that Congress remove the “compensation arrangement” prohibition of the law. This will enable group practices, clinics, hospitals, and other providers that exist in the constantly evolving health care marketplace to provide care in the most efficient manner possible.
- MGMA requests that Congress clarify the definition of “group practice” to allow for the diversity and flexibility of physician group practices as they grow and change to meet the needs of the evolving health care marketplace.

“Compensation Arrangement”

MGMA believes that Congress should remove the “compensation arrangement” provision in the “financial relationship” definition of the physician self-referral law.

Section 1877 of the Social Security Act prohibits certain referrals where a physician has a financial relationship with the entity to which a patient is referred. “Financial relationship” is defined as either “an ownership or investment in the entity” or a “compensation arrangement.” When applied to the practice of medicine for medical groups, the inclusion of this prohibition as it relates to compensation arrangements is extremely confusing and unworkable. The broad sweep of this definition precludes many business activities which are essential to the successful operation of multifaceted, integrated health care organizations.

Under the self-referral statute, it is often unclear whether a compensation relationship, either by employment or contract, is directly or indirectly related to a physician's referral. As medicine evolves and entities move to integrate and create diverse health care delivery systems, various complex financial interrelationships occur, raising many questions regarding the self-referral law's applicability. The statute becomes an impediment to innovation causing routine transactions to be questioned in terms of their potential indirect relationships throughout the integrated system.

The compensation exceptions have two major requirements:

- A. The compensation arrangement must not directly or indirectly relate to the volume or value of referrals or other business generated between the parties; and
- B. The compensation arrangement must meet a fair market value test.

The difficulty posed by the physician self-referral statute is that it is virtually impossible to meet the first requirement because it forces one to prove a negative. This makes it extremely difficult to determine with certainty whether or not a compensation arrangement complies with the law.

Example 1: A hospital-based practice has multiple financial relationships (e.g., leases, medical director fees, physician practice income guarantees, shared use of equipment). Does the compensation generated through these complex interrelationships have an indirect relationship to referrals? Often, the answer is “yes.” Theoretically,

cally, ancillary revenue would be indirectly used in various compensation situations resulting in numerous technical violations of the physician self-referral law. In addition, in many cases it is impossible to determine fair market value. For example, the shared use of diagnostic equipment. How can a fair market value be assigned to segments of shared ancillary services? Again, in the absence of a method to measure "fair market" value, it is impossible to know for certain if the arrangement complies with the statute.

Example 2: In the case of a hospital employed physician, a hospital wants to pay a physician more than the physician's professional service collections during the first year of employment. The hospital will do so in order to compensate the physician at a level which is competitive with the local marketplace. Under this example, the hospital must use funds from other sources. How can one prove that this money was not directly or indirectly derived from hospital inpatient or outpatient services ordered by that same physician? Even if the physician's salary meets a fair market value measure of other physicians in the area, it is impossible to know for certain if the arrangement complies with the law.

Example 3: Group A is a primary care physician group practice which provides certain specialized nuclear medicine testing. Group B is an unrelated cardiology group practice. Group A contracts with Group B to provide the professional interpretation of the nuclear tests which the Group A physicians order and Group B's physicians come to Group A's facility on a regular basis to provide these services. In addition, there are referrals back and forth between the two groups which are unrelated to this particular contract.

Group A pays Group B based on the number of tests interpreted on a flat fee per test basis. Under this scenario, if a test is ordered by a Group A physician, the compensation arrangement likely will qualify for the personal services exception to the compensation arrangement prohibition in the physician self-referral law. However, if the Group B specialist orders an additional test that he thinks is necessary for a Group A patient and interprets that test result under this contract, the exception likely would not apply because now the payment for the interpretation does relate directly to the Group B specialist's own referral.

In order to address this potential violation of the statute, Group A may enter into a fixed fee per month compensation arrangement not based on the number of interpretations provided by Group B. However, given that there are other referral relationships between the two practices which may include other designated services, how can Group A be certain that even this fixed fee payment contract does not reflect indirectly the volume of value of additional referrals for other designated services?

One may take this example a step further to highlight the complexities and inequities in the statute. If Group B is a radiology practice and Group A first refers a patient to Group B for a consultation, and the radiologist then orders an additional test, that order is not a considered a "referral" according to the physician self-referral law. In fact, the payment arrangement would not be acceptable in the case of the cardiologist, but it would be permissible in the case of the radiologist.

DEFINITION OF GROUP PRACTICE

MGMA requests that Congress clarify the definition of "group practice" to allow for the diversity and flexibility of physician group practices as they grow and change to meet the needs of the evolving health care marketplace.

The physician self-referral law is the only place in the entire Medicare statute in which the term "group practice" is defined. Thus, it is very important that the definition be clear. The law must assure a uniform application to the broad spectrum of physician group practices that exist today; it should not impede the ongoing evolution of group practices in an ever-changing marketplace. The definition of "group practice" should contain only those elements necessary to give effect to the other provisions of the self-referral law in which the term is used.

The compensation test in the statute and the newly defined unified business test in HCFA's proposed self-referral rule illustrate the problems with the current definition of group practice. These restrictive provisions go well beyond the intent of addressing abusive referrals in the Medicare and Medicaid programs. Simply put, they dictate how group practices must operate as businesses. MGMA knows of no other federal law which dictates how businesses, small or large, must distribute revenue and account for overall income and expenses in order to meet a government—rather than a market—definition of what constitutes that particular type of business entity.

Compensation Test: The compensation test within the definition of group practice highlights the inequity with which the statute and proposed regulations treat physi-

cians practicing in different settings. For example, using the law's "in-office ancillary exception," a single specialty group of internists would be able to retain 100% of the compensation derived from designated health services. The same physicians practicing in a multi-specialty setting, however, would be required to bring those same revenues up to the level of the entire group and share them as "profits" with all members of the multi-specialty practice. In this example, no referral patterns have changed, only the type of group where the services are delivered.

Other Standards: The law authorizes the Secretary to add by regulation and without limitation, any other standards to the definition of "group practice," above and beyond those detailed in the legislation. This open-ended delegation defeats any kind of regulatory certainty for group practices and invites regulatory intrusion into the basic structure and operation of thousands of private practices throughout the country.

Under the proposed regulations issued in January of 1998, for example, HCFA would require groups to operate as "unified businesses." The exact meaning of this standard is far from clear. It is a standard that Congress did not believe was necessary when considering the legislation. It exists nowhere else in Medicare law or regulation. There is nothing in the statute to suggest that Congress considered a practice to be any less of a group practice simply because certain expenses are allocated to different sites or departments, or indeed to individual physicians, or where physicians in certain departments or sites enjoy autonomy over certain aspects of their practices. As groups become larger, more sophisticated, and more diverse in their mix of locations, specialties, and capabilities, there is a greater need to allocate and apportion both direct and indirect costs to the separate areas of the practice in which the costs are incurred, and similarly to allocate revenue streams to various components of the practice in which those revenues are generated. Otherwise, certain specialties would be placed at a tremendous disadvantage when joining multi-specialty practices as compared to their peers in solo or single specialty practices.

These narrow, inflexible provisions in the group practice definition penalize physicians practicing in certain types of group practices. As a result, physicians in large integrated practices are at a disadvantage to physicians practicing in single site and/or single specialty practices. In addition, physicians in group practices generally are at a disadvantage to solo practitioners who provide the same routine ancillary services in the office setting.

Example: A multi-specialty, multiple location practice with family practitioners, general internists, and several sub-specialties of internal medicine provides various ancillary services covered by the statute. At one office location are the family practitioners who practice primarily in the office setting and rely heavily on routine in office lab and x-ray. Across town are the sub-specialists who are heavily geared toward hospital inpatient services and use only very specialized diagnostic equipment that relates specifically to the sub-specialty.

Under the compensation test and unified business test, the family practitioners at one practice location must pool their ancillary revenues and divide them with the members at all practice locations, regardless of specialty and utilization of services. In addition, under the unified business test, they must allocate income and expenses at the group level, not at a specific practice location. This would hold true for each specialty operating at the three practice sites.

Again, as described above, the bias in the law is illustrated by the fact that, if these separate locations were three separate single specialty practices, the physicians would be permitted to retain the very same ancillary revenues within each site and/or specialty. In other words, members of a single specialty group with one office would retain 100% of their ancillary revenues while the same members in a multi-specialty group with multiple offices would have to distribute the very same revenues to the various physicians at different practice sites. In addition, the individual locations could not allocate overall operating income and expensed at the site which they practice. These must be allocated at the overall group level. This prevents the group from controlling expenses by operating each site as its own profit and loss center. Again to further illustrate the inequity of the law, if these physicians were solo practitioners, each could retain 100% of the ancillary revenues for the services they provided in their own office and allocate overall income and expenses to fit their business and investment needs.

CONCLUSION

The physician self-referral law is a maze that group practices must navigate on a daily basis. MGMA recognizes the importance of eradicating the health care system of fraud and abuse. However, while the intentions behind the self-referral law are commendable, it has created unintended consequences. The self-referral law

shackles group practices and often prevents them from meeting patients' needs. As a result of the law, group practices cannot evolve and integrate in a manner which would enable them to provide patients with the most convenient, high quality care. Furthermore, group practices spend an inordinate amount of time and money trying to decipher the complexities and ambiguities of the self-referral law, while they should be focusing their efforts on providing care.

Today, the health care marketplace is more complex than ever. This is due not only to the integration of the health care system but also to the numerous rules and regulations that govern the delivery of health care. Physician group practices are a vital component of this complex health care system. However, it has become increasingly more difficult for group practices to provide efficient, high quality health care.

MGMA urges Congress to make these legislative changes to the self-referral law. Specifically, MGMA requests Congress clarify the definition of "group practice" and remove the "compensation arrangement" provision of the law. These changes would provide significant relief for all providers who must comply with the self-referral law and the patients they serve.

MGMA looks forward to working with Congress to address this important health care issue. If you should have any questions, please contact Aaron Krupp, Government Affairs Representative.

Statement of the National Coalition for Quality Diagnostic Imaging Services, Houston, TX

The National Coalition for Quality Diagnostic Imaging Services ("NCQDIS") is delighted to have this opportunity to submit this written testimony with regard to the prohibition on physician self-referrals set forth in § 1877 of the Social Security Act (the "Stark Law"). NCQDIS is an association of both public and private companies dedicated to the conduct of high quality diagnostic imaging services in outpatient settings.

NCQDIS applauds the objectives of the Stark Law and firmly believes that physicians' decisions regarding the facilities to which they refer should be driven by considerations of quality, patient convenience, and cost efficiency, and should not be influenced by financial incentives. However, we do have a number of concerns regarding the potential impact of this complex law on diagnostic imaging centers' legitimate financial relationships with radiologists and other physicians.

More specifically, NCQDIS believes that Congress should consider a new exception for certain public companies with less than \$75 million in shareholders equity and clarification of a number of other provisions of the exception for public companies. In addition, NCQDIS believes that Congress should clarify the definition of "referral" as that term applies to a radiologist's request for radiology services; clarify the impact of the Stark Law on diagnostic imaging services supervised or interpreted by non-radiologists; modify the medical supervision requirements that must be met under the in-office ancillary services exception; modify the in-office ancillary service exception to make this exception more readily available to clinics that utilize mobile units for the provision of diagnostic imaging services to their patients; and modify the compensation provisions in the personal services exception. Each of these issues is discussed at further length below.

I. PUBLICLY TRADED SECURITIES EXCEPTION

The Stark Law provides no exception for public companies with less than \$75 million in shareholder equity. Yet, such companies do not have access to sufficient information concerning the identity of their shareholders to assure compliance with the Stark Law. For example, it is impossible for a public company of any size to assure that no family member of a referring physician purchases its stock. A public company's inability to provide absolute assurances of its compliance with the Stark Law may affect its ability to obtain capital and may interfere with audit and other financial and other disclosure obligations. Moreover, it is unclear how such a company can comply with the reporting requirements set forth in the proposed regulations issued by the Health Care Financing Administration in January, 1998 (the Proposed Regulations), especially reporting requirements applicable to financial relationships that are eligible for an exception.

II. DESIGNATED HEALTH SERVICES

A. Exclusion of Radiology Services Requested By a Radiologist Pursuant To a Request For a Consultation By Another Physician

The Stark Law excludes from the definition of a “referral” a request by a radiologist for the provision of radiology services “if such services are furnished by (or under the supervision of) such . . . radiologist . . . pursuant to a consultation requested by another physician.” Social Security Act § 1877(h)(5)(C). NCQDIS believes that this exclusion is intended to exempt from the scope of the Stark Law radiology services provided by a diagnostic imaging center where such services are performed pursuant to a referral by a physician who has no financial relationship with the diagnostic imaging center, even where the referral is made to the center itself and not to a particular radiologist. We also believe that this exception applies where the services are performed by a diagnostic imaging center and then interpreted by the radiologist who is an independent contractor for the center. Finally, we believe that this exception is applicable where the interpretive report is communicated to the referring physician, even where the radiologist himself does not explicitly “request” the performance of the study or bill for a “consultation.” We request that Congress modify the language of § 1877(h)(5)(C) to reflect this understanding of the intent underlying this important exception.

Also, if the Stark Law is to be extended to imaging services that are routinely supervised and interpreted by cardiologists, neurologists, and other non-radiologists on the grounds that such services are nonetheless “radiology” services, the exemption provided by § 1877(h)(5)(C) should be extended to non-radiologists on the same terms as are available for radiologists. As HCFA notes in the preamble to the Proposed Regulations, the Stark Law provides that the term “referral” does not apply to the request by a radiologist for a radiology service where the radiology service is performed under the radiologist’s supervision and is performed pursuant to a request for a consultation by another physician. Social Security Act, § 1877(h)(5)(C). While the Proposed Regulations provide that a number of imaging services that are routinely performed or interpreted by non-radiologists (*e.g.*, echocardiography services) as “radiology” services, they do not enable non-radiologists who supervise such services to qualify for the exception that would be applicable if the imaging service were supervised by a radiologist.

In this regard, it should be noted that referring physicians often request non-radiologists who specialize in the interpretation of various diagnostic studies to supervise and interpret those studies in much the same manner as an internist or other non-radiologist might request a radiologist to supervise and interpret an MRI, CT, or other radiological study. Where a non-radiologist specialist supervises the performance of a diagnostic study pursuant to a consultation requested by another physician, the performance of the study does not raise a potential for abuse and should not be considered a “self-referral” within the meaning of the Stark Law.

B. Definition of Radiology Services Included As Designated Health Services

The Proposed Regulations have resulted in considerable confusion regarding the meaning of the term “radiology services” as used in the Stark Law. For example, confusion has arisen regarding whether invasive radiology procedures are included within the scope of the Stark Law, whether the Stark Law applies where an imaging procedure is performed primarily by non-radiologists, and where the use of an imaging modality is incidental to a surgical procedure. Accordingly, we request that Congress more precisely define those “radiology” services that are subject to the Stark Law.

In this regard, it should be noted that, under the Proposed Regulations, HCFA is proposing to include the professional component of radiology services as a “designated health service.” We urge Congress HCFA to clarify that professional services were not intended to be included within the scope of the Stark Law.

III. MEDICAL SUPERVISION REQUIREMENTS

Order to be exempt from the Stark Law under the in-office ancillary services exception, a radiology service must be performed under the “direct supervision” of a “group practice member.” The Proposed Regulations would define “direct supervision” to require that a group practice member be on site and available during the performance of the service but would preclude a physician engaged by the group as an independent contractor for the interpretation of the study from providing such supervision, since independent contractors are not considered “group practice members” for Stark Law purposes.

We believe that this language should be modified to delete the term “direct supervision” and to substitute “clinically appropriate level of supervision” and that the language should be further amended to clarify that the supervision can be provided by an independent contractor. In final rules published on October 31, 1997 HCFA categorized diagnostic tests into three categories, based on the level of medical supervision that is considered clinically necessary. It would be inappropriate and extremely confusing for HCFA to impose supervision requirements under the Stark Law that are potentially in conflict with the supervision requirements imposed for Medicare coverage purposes.

Also, while we understand that HCFA excluded independent contractors from the definition of “group practice member” in order to make it easier for some groups to meet the “75% test” (*i.e.*, the requirement that at least 75% of the services of group practice members be provided through the group), this modification would also preclude independent contractors from supervising designated health services provided to the group’s patients. Thus, for example, a radiologist who is engaged by a group practice as an independent contractor to interpret radiological studies would not be permitted to supervise the performance of those studies. In our view, this result simply makes no sense and, for this reason, we would suggest that the Stark Law be modified to allow independent contractors to be considered group practice members for the purposes of the “direct supervision” requirement of the in-office ancillary services exception, regardless of how they are treated for the purposes of the 75% test.

IV. LOCATION REQUIREMENTS UNDER GROUP PRACTICE EXCEPTION

The Preamble to the Proposed Regulations exception suggests that services provided by a mobile unit will not be considered to be provided at the same location as a physician’s office, for the purposes of meeting the location requirements of the in-office ancillary services exception. This interpretation will make it significantly more difficult for group practices to qualify for this exception. Mobile units provide needed access to costly services in rural and medically underserved areas, and mobile units often provide these services in close proximity to the medical group whose patients are being treated. We do not believe that there is any reason to preclude services that are performed for a group’s patients in a mobile unit in the group’s parking facilities from being considered part of the group’s office for the purposes of the “location” requirements of the in-office ancillary services exception, and we respectfully request that Congress modify the language of the Stark Law to ensure that mobile units brought into an area to provide needed services to physicians patients be treated as part of the physician’s office for the purposes of the “in office ancillary services” exception.

V. THE “PERSONAL SERVICES” EXCEPTION

The Proposed Regulations require that, in order to meet the requirements of the personal services independent contractor exception, payment to independent contractors must be determined in advance. This requirement may have to be met in order for radiologist to be retained on an independent contractor basis to interpret studies performed for a diagnostic imaging centers.

Unlike the language used in the new proposed “fair market value” exception—which requires only that the *formula* for determining compensation be determined in advance—the language used in the independent contractor exception appears to require that actual (presumably aggregate) compensation be determined in advance. Interpreted in this manner, the Proposed Regulations would appear to preclude physicians engaged as independent contractors from providing interpretations of radiological studies on a fee schedule, percentage of revenues, or other productivity basis, since aggregate compensation cannot be determined in advance under such productivity-based formulas.

The legislative history of the Stark Law specifically suggests that Congress intended to allow independent contractors to be paid on a fee schedule basis, and we would suggest that the Stark Law be modified to allow independent contractors to be paid on the basis of fee schedules, percentage of revenue formulas and other productivity-based methods. Unless this modification is made, it may prove difficult, if not impossible, for diagnostic imaging centers and hospitals to obtain high quality interpretations of diagnostic studies on a cost efficient basis.

If you have any questions regarding this testimony, please do not hesitate to contact NCQDIS counsel, Diane Millman at (202) 756–8021.

Statement of James W. McLane, NovaCare, Inc., King of Prussia, PA

On behalf of NovaCare, Inc., a leading national provider of rehabilitation and human resource management services, we commend the Subcommittee on Health for providing an opportunity to comment on the Medicare “self-referral” laws. We are particularly focused on the implementation of Section 13562 of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66) and Section 152 of the Social Security Amendments of 1994 (Public Law 103–432). These laws held the promise that the Health Care Financing Administration would implement a regulatory environment that would assure fair competition in the delivery of designated health services including physical and occupational therapy services. Unfortunately, delays in implementation, haphazard attention to enforcement and changing market conditions have undermined confidence that fair competitive systems in the provision of physical therapy and occupational therapy will be assured by public policy.

We call to the committee’s attention three specific issues:

- There is a continued need for government to establish fair guidance to prevent unwarranted self-referrals and to assure competitive delivery of physical and occupational therapy services:
- The changing health market environment does not alter the need for government to establish fair guidance preventing unwarranted self-referral of patients. Furthermore, we believe Congress must consider tightening the statute which currently exempts certain physician owned ancillary services. We believe the limited exemptions permitted under the law have become a loophole for physicians to self-refer in securing physical and occupational therapy services. Given the vagueness of the statute and the lack of meaningful enforcement, the exemption is being abused.

As Dennis Weissman wrote in the preface to the Washington G–2 report’s manuscript, *Federal Limits on Physician Referrals*:

. . . a bright line between what is legal and what is not—that’s what health care providers were promised when the federal government was concerned over fraudulent or abusive over-utilization of medical services reimbursable under its health care programs began curbing referrals by physicians to entities with which they have a financial relationship But the bright line promised by the Stark law never materialized. Instead the statutory prohibitions and the exceptions have lead to much uncertainty, confusion and frustration among affected providers over how to structure their business arrangements in order to comply with federal requirements.”¹

Fairness and the balance of cost and quality of care continue to be necessary goals of health public policy. We are experiencing critical periods of changes where there have been major dislocations, especially in the health care services ancillary sector because of the radical changes enacted as part of the Balanced Budget Act of 1997. Within the therapy sector, the BBA altered acute hospital discharge practices, imposed new payment systems on skilled nursing facilities, home health agencies and rehabilitation hospitals, and capped outpatient Part B therapy services. The labor market for professional therapists is in free-fall, with salaries dropping over 25% for those professionals successful in finding jobs. The lack of realistic rules for competition has added to the market chaos. We are experiencing the worst of all worlds—lack of clarity, incentives for manipulation, avoidance of the self-referral requirements, and indifference about enforcement.

The failure to promulgate rules decisively and to enforce those rules has created an environment of “opportunistic venturing,” eroding the intent of Congress. Absent final regulations, providers such as NovaCare whose reputations for compliance and integrity are paramount in the values by which the company operates are cautious in execution. Unfortunately, those who are prepared to cross the line are taking full advantage of the delayed implementation.

We strongly urge the committee to press the Health Care Financing Administration to promulgate the appropriate self-referral rules and to provide meaningful enforcement of the law.

- Government must curb abuses of the in-office ancillary exception.

There is a need to assure a level playing field in interpreting the in-office ancillary exception. In a number of markets where we provide outpatient rehabilitation, we are witnessing widespread disregard of the exemption restrictions and flagrant

¹Dennis W. Weissman, Publisher & President, Washington G–2 Reports; Preface, *Federal Limits on Physician Referrals—How the Stark Law Affects Your Business Arrangements*.

violations of the intent of the self-referral law. The litanies of abuses are astonishing. For instance, we have heard of doctors restricting referrals to their own exclusive relationships, of invitations to our existing staffs to leave our employment and create split fee relationships with physician practices, and of “dummy” relationships that abuse “incident to” relationships to bill non-qualified services as professional therapy.

The statute is very clear in stating that the referring physician, a member of his/her medical group, or an individual directly supervised by the referring physician or another qualified group member, must perform services, such as physical therapy and occupational therapy, personally. The direct supervision is scoffed at by many physicians. While HCFA has recently promulgated strict interpretations for supervision of PTs and OTs, it has proposed through program memorandums stringent interpretations of CPT4 code instructions. Unfortunately, the enforcement focus has been focused myopically at the provision of outpatient therapy services in the outpatient clinic and nursing home settings and has ignored the requirements for physician based services.

The law is specific that the services must be furnished in a building in which the physician and/or his/her medical group provide physician services unrelated to designated health services. This additional exception for in-office ancillary services was viewed as a way to facilitate group practices. Unfortunately, we periodically learn of relationships that are at best creative and at worst violate the location requirement. In some markets, we are observing physicians purchasing existing CORFs and outpatient therapy clinics and running them as if they meet the medical group exemption.

Both the statute and regulations are explicit in defining bonafide employment relationships. We support the HCFA interpretation for leased employees such as occur under a contractual relationship with a professional employee organization (PEO) or a temporary staffing agency. Unfortunately, we encounter relationships that are far less structured and appear to be nothing more than physicians providing billing camouflage for therapy services. In the most questionable form, the physician is employing individuals who are not qualified under state practice acts to perform therapy services. Attached is a summary of 2 recent court decisions in Pennsylvania where the courts concluded that in-office ancillary service exceptions provided the physician the opportunity to use unlicensed personnel.

- Relaxed enforcement creates potential for abuse of therapy services in physician offices.

Implementation of Section 4541 of the BBA of 1997 has created an illusion that HCFA no longer has a concern about over-utilization of Part B therapy services in physician offices because the arbitrary therapy cap creates a limit on program liability.

As data which we have shared with the committee shows, the impact of the cap is most severe on individuals with the most acute rehabilitation needs. These are not the individuals who are seen in physician offices. In fact, the relaxation of utilization criteria for physician services will have significant cost as the per capita billings for the types of rehabilitation required by beneficiaries being served in physician settings fall well below the mean of total per capita expenditures for Part B rehabilitation services. While there has been modest statutory direction to establish a level playing field for the provision of physical and occupational therapy, enforcement is non-existent.

CONCLUSION

The failure to have rules promulgated in a timely manner and uneven enforcement of existing rules leaves an unfair advantage and an unsettled market environment. HCFA's delay in issuing the rules and enforcing the law exacerbates competitive forces. Rehabilitation agencies are besieged with new requirements and stringent enforcement. HCFA is so focused on select issues affecting the delivery of rehabilitation services that it is ignoring some of the most important issues.

Putting appropriate self-referral rules in place and assuring that they are properly implemented and monitored must become a priority for the Congress and the Health Care Financing Administration.

[Attachments are being retained in the Committee files.]

Statement of the Outpatient Ophthalmic Surgery Society, Bellevue, WA

The Outpatient Ophthalmic Surgery Society (OOSS), an organization composed of approximately 600 ophthalmologists dedicated to providing high-quality ophthalmic surgical care in various outpatient settings, is delighted to present testimony to the House Ways & Means Subcommittee on Health regarding physician ownership and referral laws. Over three hundred of OOSS members own and operate ambulatory surgery centers that serve Medicare patients undergoing cataract surgery, and are therefore both familiar with, and qualified to comment on, physician self-referral restrictions in these settings.

AMBULATORY SURGERY CENTERS

For purposes of Medicare reimbursement, an ambulatory surgery center (ASC) is defined as a distinct facility that provides exclusively outpatient surgical services, and meets certain Medicare conditions of participation.

ASCs have proliferated since the 1980s. At the end of 1983, there were 239 Medicare certified-ASCs. Today, there are nearly 2,500 ASCs. The number of procedures performed in the ASC setting has grown, too. In 1996, more than 1.5 million Medicare allowed services were performed in the ASC setting. Nearly 50% of those procedures were ophthalmic services. Congress and the Health Care Financing Administration (HCFA) have helped promote ASC industry growth, recognizing that ASCs provide a patient-friendly, high-quality, low-cost alternative to hospital-based surgery.

ASCs save the Medicare program hundreds of millions of dollars each year. Medicare payments to ASCs for outpatient surgical procedures are usually substantially lower than payments to hospitals (both on an inpatient and outpatient basis). In fact, according to the Medicare Payment Advisory Commission (MedPAC), the median payment to a hospital for a cataract removal procedure (i.e., CPT code 66984) in 1996 was approximately \$1,150, while the median payment to an ASC for that same procedure was only \$903, a savings of \$247, or more than 20% (See MedPAC Report to Congress, June 1998). Moreover, ASCs have brought the benefits of competition to the entire outpatient surgery market: the opening of an ASC in a particular area has frequently been followed by a significant reduction in the charges of local hospitals for outpatient surgery, as well as increased attention on the part of the hospitals to quality of care and patient satisfaction.

OOSS supports clear, unambiguous physician self-referral prohibitions that prevent unethical financial relationships and reinforce the critical element of trust in the physician-patient relationship. However, these prohibitions need not and should not apply to services provided in the ASC setting. As discussed above, ASCs save the Medicare program hundreds of millions of dollars. Moreover, a number of studies, including a noted Florida Cost Commission Review of physician self-referral patterns, examined services provided in the ASC setting and concluded that there was no ascertainable abuse with respect to the referral of patients by operating surgeons to ASCs in which they have an ownership interest. Indeed, the Office of the Inspector General has issued a proposed safe harbor which explicitly protects the physician investment in the ASC, and HCFA has proposed that physician investments in ASCs be specifically exempt from the self-referral proscription. Specifically, HCFA said the following in the preamble to its proposed regulation regarding the physician self-referral law: "The Secretary has determined . . . that referrals for . . . [designated health] services furnished in an ambulatory surgical center . . . do not pose a risk of Medicare program or patient abuse." (63 Fed. Reg. at 1666, Jan. 9, 1998).

Why is the ASC different from other ventures with regard to which fraud and abuse is more likely to occur? There are several reasons. First, more than two-thirds of the ASCs in the country have been developed and owned by physicians to maximize patient safety and optimize clinical results through control of the surgical environment, which oftentimes is lacking in the hospital. Indeed, if physician self-referral restrictions were to prohibit doctor ownership of ASCs, there would be virtually no ASCs left. Second, unlike services provided by clinical laboratories and diagnostic imaging centers, surgical services performed in an ASC are subject to a utilization review by peer review organizations; as such, there is a check on inappropriate utilization. Finally, the physician operates in the ASC as an extension of his or her office, much like an internist might offer in-office ancillary laboratory or radiology services. The surgeon is *not* a passive investor; a "referral" is not really taking place. Moreover, unlike in situations involving in-office laboratory or radiology serv-

ices, where the physician performs little of the ancillary work, in cases of surgery, the physician him or herself is actually performing the work for which the patient was sent to the surgery center.

While Congress clearly did not intend for the physician self-referral ban to apply to services performed in the ASC setting, the law could be read to apply to certain services provided in ASCs. For example, prosthetics, orthotics, and prosthetic devices are designated health services. Many common implants—e.g., intraocular lenses—are considered prosthetics. Thus, the physician-self referral ban could be interpreted to reach situations where surgeons implant prosthetics in ASCs which they own and to which they “refer” their patients and for which Medicare is not making separate reimbursement because it’s a component of the facility fee.

OOSS is pleased that HCFA recognized that there is no risk of program or patient abuse when a physician refers a patient to his or her ASC, and that the Agency is proposing to expressly exempt from the physician self-referral proscriptions services performed in ASCs. See 63 Fed. Reg. At 1666 (Jan. 9, 1998) and 42 C.F.R. § 411.355(d)(1) (proposed). Nonetheless, we urge Congress to codify this exception in the statute. HCFA’s proposed regulation remains in proposed form and apparently will not be finalized for at least another year. Until then, physician investment in ASCs is an uncertain endeavor. Physicians who choose to invest in ASCs take a calculated risk based on HCFA’s stated approval of these arrangements, but expose themselves to possible prosecution should HCFA change its view of these arrangements or choose not to include the express exception in the final regulations. Congress should express its approval of physician ownership of ASCs and ensure that these arrangements are exempt from the self-referral prohibition by including an express exception in the statute. Specifically, we recommend that Congress adopt the language it approved in § 8204(f) of the “Balanced Budget Act of 1995,” H.R.2491 (vetoed), which expressly excluded ASC services from the self-referral law.

INTRAOCULAR LENS, EYEGLASSES AND CONTACT LENSES

In devising the original self-referral statute, and its subsequent 1993 amendments, Congress set forth a list services to which the self-referral prohibition applies. This list of “designated health services” includes, among other things, “prosthetics, orthotics, and prosthetic devices and supplies.” HCFA has interpreted the term “prosthetic devices” to include eyeglasses and contact lenses furnished subsequent to cataract surgery. (63 Fed. Reg. at 1722, Jan. 9, 1998). HCFA has defined “prosthetic devices” in this way because § 1861(s)(8) of the Social Security Act defines the term “prosthetic devices,” for coverage purposes, as “including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens.”

Congress should amend the statute to expressly exclude eyeglasses and contact lenses furnished subsequent to cataract surgery from the definition of “prosthetic devices.” There is no incentive to overutilize or abuse this post-cataract surgery benefit since (1) one pair of conventional eyeglasses or contact lenses has been acknowledged by HCFA to be medically necessary under such circumstances, (2) Medicare payment for post-cataract eyeglasses or contact lenses is on a reasonable charge basis, and (3) Medicare covers only one pair of eyeglasses or contact lenses, and only when following cataract surgery. Moreover, there is no evidence of which we are aware that a physician is more likely to order eyeglasses or contact lenses because he or she operates an optical shop. These optical dispensaries exist for the convenience of the patient and as a modest source of revenue to the owner-physicians. They are generally operated as an integral part of the physician’s private practice. Furthermore, patients are certainly aware of the myriad of alternative sources of eyeglasses and contact lenses from national chains to local opticians.

OOSS also urges Congress to exempt intraocular lenses (IOLs) from the definition of prosthetic devices. While HCFA did not propose to include IOLs in this definition of prosthetic devices in its proposed regulation, there remains ambiguity as to whether the statute likewise includes IOLs. Intraocular lenses replace the natural lens of the eye that is removed during cataract surgery. As cataract surgeons, OOSS members know—perhaps better than anyone—the extraordinary benefits that have resulted from the development and refinement of this cutting-edge technology. Instead of the thick “Coke bottle” glasses with which cataract patients once had to contend, patients who receive an IOL during cataract surgery often have vision that is better than what they had as teenagers. Moreover, IOL technology has dramatically reduced the trauma and complications associated with the cataract procedure itself; recent developments have made it possible to perform cataract surgery through an incision so small that it can be closed without even a single stitch. And research now underway will likely make it possible to implant lenses with multiple

focal lengths, further reducing the need for eyeglasses in the post-cataract patient. Over one million Medicare beneficiaries receive this remarkable vision-restoring procedure each year.

IOLs should not be considered a prosthetic device. Rather IOLs should be considered a component of ASC facility services, especially for physician self-referral purposes. The implementing regulations for ASC services (42 C.F.R. § 416.61) include IOLs in the definition of ASC facility services. Thus, IOLs implanted in ASCs are covered as a component of ASC "facility services" and are distinguishable from other "prosthetic devices," under the governing statute and implementing regulations.

Moreover, reimbursement for IOLs is made through the ASC facility payment, and pre-set by Congress at \$150. As noted above, "[t]he Secretary found no risk of abuse when payment for . . . services was included in the ambulatory surgical center payment rate . . ." (63 Fed. Reg. at 1666, Jan. 9, 1998).

Finally, any application of the physician "self-referral" provision to IOLs implanted in ASCs could have a substantial, devastating impact on ASCs, the Medicare beneficiaries they serve, and the Medicare program. Virtually all cataract procedures are performed for Medicare patients and require the implantation of an IOL. Cataract facility services performed in ASCs are provided at substantially lower cost than in hospital outpatient departments. Therefore, applying the physician "self-referral" provisions to IOLs implanted in ASCs would likely jeopardize the financial viability of ASCs throughout the country and result in a significant increase in Medicare outlays for cataract facility services. This result is neither intended by Congress nor required by the express terms of the physician "self-referral" provisions.

OOSS strongly recommends that Congress clarify the statute to expressly provide that the implantation of an intraocular lens during cataract surgery does not represent the provision of a designated health service (i.e., "prosthetic devices"), triggering Stark referral restrictions, and to provide that "eyeglasses or contact lenses" also are not subject to the physician self-referral ban. Specifically, OOSS suggests that Congress accomplish this objective in one of two ways:

- Delete "prosthetics, orthotics, and prosthetic devices and supplies" as a designated health service, as Congress did in § 8202 of the "Balanced Budget Act of 1995," H.R.2491 (vetoed), or
- Amend § 1877(h)(6)(H) of the Social Security Act to read "prosthetics, orthotics and prosthetic devices and supplies, other than an intraocular lens inserted during or subsequent to cataract surgery, eyeglasses, or contact lenses."

The latter approach was suggested by Congressman Stark in a proposed bill that he introduced in 1995.

DIRECT SUPERVISION

Finally, OOSS urges Congress to amend the section of the in-office ancillary services exception to clarify the meaning of "direct supervision. Section 1877(b)(2) provides a general exception to both ownership and compensation arrangements for certain services (i.e., in-office ancillary services, subject to certain exceptions) that are, among other things, furnished personally by the referring physician, personally by a physician who is a member of the same group practice as the referring physician, or *personally by individuals who are directly supervised by the physician or by another physician in the group practice.* HCFA proposed to define the "direct supervision" criterion to require that the supervising physician be on site and immediately available when a designated health service is provided (although brief absences are permitted). See 63 Fed. Reg. at 1684 (Jan. 9, 1998) and § 411.351 (proposed).

HCFA's proposed definition of the "direct supervision" criterion would impose unnecessary burdens on Medicare beneficiaries in certain instances. For example, in the situation where an ophthalmologist and optometrist are in practice together, and jointly own and operate an optical shop within their office, the ophthalmologist would not be able to refer Medicare beneficiaries to that optical shop for Medicare-covered post-cataract surgery eyeglasses unless the physician personally fitted the glasses or was on site and immediately available when the optometrist fitted the glasses. On days when the ophthalmologist performed surgery, he or she could not be considered to be "immediately available" to the optometrist, and thus could not offer his or her patients the convenience of purchasing post-cataract surgery eyeglasses from the optical shop within his or her office.

This limitation discriminates against Medicare beneficiaries and Medicaid enrollees. Private pay patients would be permitted to purchase eyeglasses right in the physician's office while Medicare beneficiaries and Medicaid enrollees would be forced to purchase eyeglasses from another location.

Moreover, it is unnecessarily restrictive. Optometrists, or optometrists in conjunction with opticians are generally permitted by state law to fit, grind, and dispense eyeglasses without physician supervision. Requiring direct supervision from an ophthalmologist in this instance serves no medical purpose.

Furthermore, HCFA's interpretation of the statute appears to be inconsistent with Congressional intent. The Conferees to the amendments to the Stark legislation enacted in 1993 stated as follows:

The Conferees intend that the requirement that direct supervision . . . by a physician would be met if the lab is in a physician's office which is personally supervised by a lab director, or a physician, even if the physician is not always on site. Cong. Rec. at H6003 (Aug. 4, 1993) (emphasis added).

OOSS urges Congress to amend this section of the statute to clarify that the supervising physician need not be on site at all times. Specifically, Congress should replace § 1877(b)(2)(A) with the following:

“(A) that are furnished personally by the referring physician, personally by a physician who is a member of the same group practice as the referring physician, or personally by individuals who are under the general supervision of the physician or of another physician in the group practice, and.”

Additionally, Congress should add at the end of § 1877(h) the following new paragraph:

“(7) General Supervision.—An individual is considered to be under the ‘general supervision’ of a physician if the physician (or group practice of which the physician is a member) is legally responsible for the services performed by the individual and for ensuring that the individual meets licensure and certification requirements, if any, applicable under other provisions of law, regardless of whether or not the physician is physically present when the individual furnishes an item or service.”

The amendments suggested above were included in the “Balanced Budget Act of 1995,” H.R. 2491 (vetoed), as § 8204(a)(1).

The Outpatient Ophthalmic Surgery Society appreciates the opportunity to present this testimony to the Subcommittee. Please do not hesitate to contact Washington counsel, Michael Romansky at (202) 756-8069, if you have any questions about this matter.

PREMIER, INC.
May 27, 1999

The Honorable William M. Thomas
Chairman, Subcommittee on Health
Committee on Ways and Means
U.S. House of Representatives
Washington, D.C.

Dear Chairman Thomas:

On behalf of the Premier, Inc., I am submitting the following statement for the record of the hearing held May 13 on the “Medicare Self-Referral Law” before the Health Subcommittee of the Committee on Ways and Means.

Premier, Inc., represents over 220 owner hospitals and hospital systems that own or operate 700 healthcare institutions and have purchasing affiliations with another 1,200. Premier owners operate hospitals, HMOs and PPOs, skilled nursing facilities, rehabilitation facilities, home health agencies, and physician practices. We appreciate the opportunity to urge your support to make the federal physician self-referral prohibition laws more reflective of today's healthcare market place.

Hospitals and physicians are changing the way in which they organize themselves and their approach to healthcare delivery. The impetus of this change comes from private and government initiatives that challenge us to deliver high quality care at the lowest possible cost. Integration of service delivery, a central component of health system change, promotes the coordination of care in a manner that is both cost effective and a higher quality.

Hospitals are concerned about the adverse consequences of physicians choosing to refer solely based on financial self-interest. However, the laws against self-referral have created substantial obstacles to hospital and physician integration. The current physician self-referral law (Stark II) and the related proposed implementation rules are far too complex and confusing. The proposed rule published January 9, 1998 by HCFA took five years to write and drew 13,000 comment letters. HCFA

does not expect the final rule to be published until 2000. Even though HCFA is working to address the concerns raised in the comment letters, we believe a more reasonable approach is to simplify the law.

A fundamental problem is that the law is built on precise exceptions to a general prohibition of any referral by a doctor to an entity with which he or she has a "financial relationship." Regardless of intent, an arrangement can be deemed illegal if it does not fit into an exception. One way to minimize the complexity of the self-referral law would be the elimination of the compensation restrictions. This provision is unnecessary in that it essentially duplicates the relevant provisions of the Federal Medicare and Medicaid anti-kickback law. The anti-kickback statute addresses compensation relationships and has been amended to authorize the imposition of civil money penalties. Hospital fraud and abuse compliance programs provide a more appropriate method of checking any potential abuses.

Thank you for the opportunity to share our perspectives on the physician self-referral prohibition law. The result of the compensation provision is confusion and the loss of hospital and physician opportunities to advance the integration of delivery that benefits our patients.

Sincerely,

JAMES L. SCOTT
President

SOCIETY OF CARDIOVASCULAR & INTERVENTIONAL RADIOLOGY
FAIRFAX, VA
May 27, 1999

The Honorable Bill Thomas
Chairman, Subcommittee on Health
House Ways and Means Committee
Washington, D.C.

Dear Mr. Chairman:

The Society of Cardiovascular & Interventional Radiology (SCVIR), which represents more than 3,200 physicians who specialize in the field of minimally invasive or interventional procedures, requests that the following statement be entered into the record for the May 13, 1999, hearing regarding the physician self-referral prohibitions included in the Social Security Act.

SCVIR supports the elimination of financial incentives within the Medicare program that encourage the over-utilization of medical services. The provision of medically unnecessary and inappropriate care that results from over-utilization compromises the public's perception of the medical profession as well as the physician decision-making process in rendering medical care to patients. Providing appropriate medical care should be of foremost concern to all physicians. Financial incentives that compromise the treatment decisions of physicians should be discouraged and eliminated. The physician self-referral ban was intended to accomplish that objective and for that reason SCVIR continues to support some restrictions on physician self-referrals.

The physician self-referral ban was also intended to provide clarity to the health care profession by establishing "bright lines" to guide physician and provider conduct and financial relationships. This laudable goal has yet to be achieved due to the failure of the Health Care Financing Administration (HCFA) to implement timely and readily understood regulations that would provide insight into areas that may be confusing or unclear under the statute. The failure to promulgate a final rule has generated considerable uncertainty for physicians and others who seek guidance on how to structure ownership or compensation arrangements that do not violate the statute.

SCVIR would urge the Subcommittee to direct HCFA to issue final rules to implement the physician self-referral ban for designated health services as soon as possible. By so doing, HCFA will greatly assist physicians and providers in understanding how to structure relationships that comply with the law. Allowing over five years to elapse between passage of the prohibitions and implementation of the statute is clearly unacceptable where the penalties for non-compliance can be severe.

SCVIR also suggests that the Subcommittee revisit the statute to review the efficacy of its provisions. While supporting restrictions on physician self-referrals to entities in which the physician has a financial relationship, SCVIR believes that the statute should take into account intent or distinguish between truly minor violations and the abuse that contributed to the adoption of the statute in this first place.

While many physicians are frustrated by the labyrinth of the exceptions that must be navigated to determine compliance, the original purpose of the statute was to ensure that physicians provide high quality medical care unmotivated by ownership or compensation arrangements. The statute also protects the taxpayer dollar. SCVIR believes that the original purpose and need for the statute should not be forgotten in the frustration over HCFA's inability to develop clear and understandable regulations.

Thank you for taking the time to consider our views and for providing the opportunity to submit this statement.

Sincerely,

MATTHEW A. MAURO, M.D.
President, SCVIR

Statement of the Stark Law Coalition

This testimony is submitted by the Stark Law Coalition (the "Coalition") and sets forth the Coalition's recommendations with regard to possible amendments of § 1877 of the Social Security Act, as amended ("the Stark Law"). The Stark Law Coalition is a Coalition of medical groups and physician practice management companies ("PPMCs") that have coalesced around issues of common concern that are raised by the Stark Law. Members of the Coalition include a number of clinics, physician practice management companies and physician practices in a number of medical specialty areas.

1. PUBLICLY-TRADED SECURITIES EXCEPTION

The Stark Law should be modified to exempt publicly-traded companies with less than \$75 million in stockholder equity or to authorize PPMCs to sell shares to referring physicians in de minimus amounts.

Approximately 10% of all physicians actively practicing in the United States have their practices managed by a physician practice management company ("PPMC"). Many PPMCs acquire the non-medical assets of physician practices and then provide those assets back to the practices under long term management contracts. Many such PPMCs do not have \$75 million in shareholder equity and therefore are not eligible for an exception to the Stark Law.

These PPMCs typically pay for the non-medical assets of such practices with a combination of cash, notes and stock of the PPMC. If stock issued to a physician in connection with such a PPMC transaction does not meet the Stark Law's publicly-traded securities exception, then the physician-stockholder is prohibited under the Stark Law from referring Medicare/Medicaid patients to the PPMC for designated health services.

In addition, if PPMC stock issued to a physician does not meet the publicly-traded securities exception, then that physician may be prohibited from referring Medicare/Medicaid patients for designated health services to physicians in other groups affiliated with the PPMC, particularly if the group that receives the referral pays a percentage of revenues to the PPMC as a management fee. Under such arrangements, each referral to the affiliated group generates revenue for the PPMC under the management agreement, which, in turn may increase the value of the PPMC stock owned by the referring physician. The publicly-traded securities exception, when applicable, would appear to protect such cross-referrals among physicians or groups affiliated with a PPMC. Where stock is actively and publicly traded on a recognized stock exchange, it generally does not provide significant inducement for referrals. We believe that the current exception should be extended to companies with less than \$75 million in shareholder equity, where the company's stock is actively and publicly traded on a recognized stock exchange, regardless of the amount of shareholder equity.

In addition, to qualify for the publicly-traded securities exception under § 1877(c)(1), the physician's (or immediate family member's) investment must be an ownership interest (whether through debt, equity or other means) "which may be purchased on terms generally available to the public." The Proposed Regulations also indicate that ownership in investment securities are only protected if "at the time they were obtained [they] could be purchased on the open market." Section 411.356(a). Taken together these provisions would deny the public company exception to a physician who acquired shares through the exercise of options or who acquired stock before the company became public. Neither of these results are necessary to preserve the integrity of the self-referral law.

We believe that a physician (or immediate family member) holding up to 5% of any publicly-traded security (and any investment instrument, such as a stock option, from which that publicly-traded security is derived) should qualify for the publicly-traded securities exception regardless of whether the securities were acquired before the company became public (assuming the other requirements of the publicly-traded security exception are met), as long as neither the amount of securities so obtained, nor any distribution made with respect to such securities, is based on the volume or value of designated health services referred by the physician (or immediate family member) to the company or its affiliates. We select a 5% threshold because that is the standard used by the SEC for public reporting of “control” interests. Less than a 5% interest is considered to be a “drop in the bucket”—a non-control interest—and any referrals by a less than 5% physician-owner should similarly be viewed as having an inconsequential impact on the profitability of a publicly-traded company (and hence on the physician-owner’s incentive to refer to that company).

2. IN-OFFICE ANCILLARY SERVICES EXCEPTION

(a) The Stark Law’s definition of “group practice” should be liberalized to preclude HCFA from unnecessarily interfering in the compensation formulas adopted by physician groups.

Under the in-office ancillary services exception (§ 1877(b)(2)) a physician may refer Medicare/Medicaid patients for certain designated health services to a group practice in which the physician has a financial relationship. However, in the Proposed Regulations, HCFA has interpreted the Stark Law in a number of ways that interfere unnecessarily with physician compensation formulas within groups, even where the compensation is unrelated to referrals for designated health services.

First, the Proposed Regulations would add the following new “unified business” requirement to the definition of a “group practice:”

The overhead expenses of and the income from the practice are distributed according to methods that indicate that the practice is a unified business. That is, the methods must reflect centralized decision making, a pooling of expenses and revenues, and a distribution system that is not based on each satellite office operating as if it were separate enterprise.

This is a new requirement promulgated by the Secretary under the purported authority of § 1877(b)(4)(A)(vi). It is unclear under this new definitional provision when a practice will be considered to be a “unified business.” In particular, what does it mean to have a “distribution system” based on “each satellite office operating as separate enterprise?” This language could be interpreted broadly to disqualify any medical group that employs profit center accounting on an office specific basis, from receiving Medicare/Medicaid referrals for designated health services from its physician-owners. Many medical groups employ profit center accounting on an office specific basis. These groups are nonetheless bona fide group practices.

Second, HCFA has proposed the following new condition to qualify as a “group practice:”

The overhead expenses of and income from the practice are distributed according to methods that are determined prior to the time period during which the group has earned the income or incurred the cost.” Proposed Regulation § 411.351, Group Practice Definition, Section (3).

This new provision appears to permit changes in compensation methodologies, but only if the change is effective for income and expenses incurred after the date the change is implemented. This new “prior to incurrence” requirement will therefore limit the ability of groups to make retroactive adjustments in compensation methodologies, even if such adjustments do not result in distribution of funds based on the volume or value of referrals for Medicare/Medicaid designated health services.

Third, a physician may spend a significant amount of time supervising the provision of designated health services that are provided “incident to” that physician’s services, for his or her own patients. The statutory language of the in-office ancillary services exception, on its face, would appear to authorize the payment of productivity bonuses based in part on such “incident-to” services. Yet, the Proposed Regulations would appear to preclude a group practice from taking these services into account in determining the physician’s productivity bonus, if the “incident to” services are provided for a physician’s own patients.

Finally, we are concerned about implications in the preamble to the Proposed Regulations that suggest that payment to a physician-employee may be “related to the volume or value of referrals” even if compensation is fixed, if the continuation of

the payment arrangement depends on the physician's explicit or implicit commitment to refer payments to the entity. This reading of the statute would enable law enforcement officials to look behind even the most reasonable payment arrangements to examine the underlying intent of the parties. While such an approach may be warranted under the anti-kickback provisions, it is not warranted under the Stark Law, which is not an intent-based statute.

We believe that medical groups should have flexibility to utilize cost center or profit center accounting and to adjust compensation methodologies prospectively or retroactively, as necessary, to assure equitable distributions among group members. We further believe that group practices should be free to pay group practice members productivity bonuses based on designated health services personally performed by those physicians or performed "incident to" those physicians' services. Where no physician member of a physician group receives compensation based on the volume or value of designated health services that he refers to the group but does not perform or supervise, the Stark Law should not apply. We request that Congress clarify the statutory language to make this clear.

(b) Congress should repeal the requirement for "direct supervision" of designated health services under the in-office ancillary services exception.

The Stark Law requires that designated health services be furnished by "individuals who are directly supervised by the physician or by another physician in the group practice." 42 U.S.C. § 1395nn(B)(2)(A)(i). The Proposed Regulations interpret this language to require that the supervising physician be on site and immediately available when a designated health service is provided (although brief absences are permitted).

The Stark Law makes reference to the need for a physician to "directly supervise" a person who performs a designated health service. Congress may have intended "direct supervision" in this context to be interpreted in the same manner that that term is interpreted for coverage purposes. However, enshrining in legislation a coverage standard that may have existed at the time the Stark Law was enacted means that if coverage standards change, inevitably inconsistencies will develop between the standards for Stark and for coverage. Indeed, this has already occurred as a result of regulations finalized in the *Federal Register* on October 31, 1997,¹ in which HCFA established three levels of supervision for diagnostic tests, most of which are designated health services. Under these regulations, codified at 42 C.F.R. § 410.32, a diagnostic test may require general supervision (which does not require a physician's presence on-site); direct supervision (which does require a physician's presence on-site and which, unlike the definition of "direct supervision" in the Proposed Regulations, does not provide any allowance for "brief absences"); or personal supervision (which requires that the physician not only be on-site but in the room where the diagnostic test is being performed). In light of the foregoing, we recommend that Congress delete the direct supervision requirement in the in-office ancillary services exception to the Stark Law and instead require that the services meet the coverage requirements of the Medicare program or, in the case of a Medicaid patient, the Medicaid program.

(c) The Stark Law should be modified to enable independent contractors to supervise designated health services.

Historically, many group practices have contracted with specialists, such as radiologists, to supervise and interpret more complex diagnostic tests which are commonly rendered (for efficiency and patient convenience) within a group practice. For example, an ob/gyn group may retain a radiologist on an independent contractor basis to supervise and interpret fetal ultrasounds performed on women with high-risk pregnancies. Such arrangements are fully consistent with Medicare's coverage rules for physician office-based diagnostic and therapeutic services. Yet, under the Proposed Regulations, a radiologist retained as an independent contractor by a group practice would not be able to supervise a group's in-office imaging services, since designated health services must be supervised by group practice members and independent contractors do not qualify as group practice members. To address this anomalous result, we recommend that the statutory language be amended to clarify that independent contractors may supervise the provision of designated health services, under the in-office ancillary services exception.

¹ 62 Fed. Reg. 59047 at 59057-59070.

3. COMPENSATION PROVISIONS

(a) The compensation provisions of the Stark Law should be repealed.

Our comments thus far have related to amendments that we believe are necessary to address problems with the provisions of the Stark Law that apply to ownership interests. However with respect to those provisions of the law which apply to compensation relationships we urge outright repeal, as Congress has previously voted to do. We strongly urge Congress to vote again to repeal the compensation provisions as it did once before in the Balanced Budget Act of 1995.

The provisions of Stark that apply to compensation have created a regulatory nightmare both for the provider community and HCFA in applying them in everyday business dealings. While the law contains a number of exceptions, they are by and large narrow and fall far short of permitting parties to enter into an array of perfectly legitimate transactions that are unobjectionable under the fraud and abuse statutes. Unlike that statute which is intent based, the Stark Law is completely arbitrary in the sense that if there is no specific exception that protects the compensation relationship, no referrals are permitted. The bona fides of the parties or the benefit to the community are irrelevant. These provisions have resulted in substantial barriers to the clinical and financial integration of the health care delivery system. For example, if a hospital recruits a physician to a medically underserved community, the recruitment payments to the physician may be protected by an exception. However, if the physician is already in a community, such as a resident graduating from a training program in that community, the recruitment payments would not be protected and the physician might be unable to serve the Medicare and Medicaid patients of that community.

The original impetus for the Stark Law were studies which purported to show a relationship between physician ownership interests in clinical laboratories and imaging centers and increased levels in numbers of tests ordered. There have never been any studies linking compensation with increased numbers of tests. Indeed, this may be one reason why states that have adopted their own self-referral laws have generally limited them to ownership relationships. Repeal of the compensation provisions would greatly aid the provider community in freeing it from the arbitrariness of the Stark Law but would not lead to abuse. In light of the legal tools available to prosecutors and governmental agencies, and in light of the increased resources dedicated to enforcement of the anti-kickback provisions of the Medicare/Medicaid Fraud and Abuse Law, the compensation provisions of the Stark Law are not necessary to guard against obscure financial arrangements between providers and referring physicians.

(b) Compensation Exception Reforms

In the event that the compensation provisions of the Stark Law are not repealed, the members of the coalition urge that the compensation exceptions be reformed to expand the rural exception to include compensation and to create a statutory fair market value exception.

(1) The rural exception should be expanded to include compensation relationships. The same considerations that led Congress to provide an exception to the ownership prohibition for investment interests in entities located in and serving primarily a rural population, support an extension of the exception to compensation relationships. In many instances health care providers and physicians, particularly group practices, may wish to share services that may include designated health services to achieve efficiencies and economies of scale but, for tax and other considerations, do not want to do so through a separate legal entity. The Stark Law currently would likely be interpreted by HCFA as precluding such arrangements if they involved the provision of designated health services. As long as such arrangements are consistent with the fraud and abuse laws, they should be permitted in order to facilitate the delivery of cost-effective care in rural communities.

(2) Congress should create an exception to the compensation prohibition for all "fair market value" transactions. As discussed above, the major difficulty with the compensation prohibition is that it covers all arrangements whether they pose a risk of overutilization or not. Only those transactions for which Congress saw fit to provide an exception are protected. While the Law includes eight exceptions specific to compensation, they are limited and narrowly drawn. The inevitable consequence of legislating in this manner is that many appropriate and beneficial transactions may be prohibited because they do not fit into one of these exceptions. HCFA has recognized this problem with the Stark Law by proposing a generic "fair market value" exception. The members of the coalition support the creation of such an exception and urge Congress to specifically provide for such an exception in the law itself to

eliminate any ambiguities concerning the Secretary's authority to create such a wide ranging exception.

4. DESIGNATED HEALTH SERVICES

(a) The definition of "designated health services" should be amended to exclude eyeglasses and contact lenses from the term "prosthetic devices" as that term is used in the Stark Law

Under the Proposed Regulations, "prosthetic device" is defined to include "one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens." 42 C.F.R. § 411.351 (definition of prosthetic device). There is no incentive to overutilize or abuse this post-cataract surgery benefit since one pair of conventional eyeglasses or contact lenses has been acknowledged by HCFA to be medically necessary. We therefore urge Congress to revise the definition of "prosthetic device," as that term is used under the Stark Law to exclude eyeglasses and contact lenses.

(b) Congress should clarify the radiology services subject to the Stark Law.

A number of significant issues have arisen with respect to the definition of "radiology services" as designated health services. The Proposed Regulations would define the term "radiology" expansively to include the professional component and the technical component of virtually all imaging services. Accordingly, we request that Congress amend the statute to narrowly limit the radiology services subject the physician self-referral prohibition, to exclude the professional component of radiology services as a designated health service, and to exclude imaging services that are interpreted by nonradiologists (e.g., A and B scans interpreted by ophthalmologists or echocardiograms interpreted by cardiologists).

In this regard, we note that, in general, the Stark Law was not intended to, and does not, prohibit physicians from benefiting from the fruits of their own labor (except that productivity bonuses to group practice members may not be based on the volume or value of Medicare/Medicaid designated health services referred by the physician).

(c) Drugs furnished "incident-to" physician services should be excluded from the definition of "outpatient prescription drugs" under the Stark Law

The Proposed Regulations include chemotherapeutic agents and other drugs administered "incident to" physicians' services within the definition of "outpatient prescription drugs" subject to the Stark Law. However, such drugs are covered by the Medicare program only as a component of a physician's service, and physicians' services were never intended to be included within the Stark Law prohibition. Moreover, the administration of chemotherapeutic drugs is not a service that is subject to abuse, since it is highly unlikely that a physician would administer such drugs unnecessarily. In fact, the administration of chemotherapy in physicians' office settings is significantly less costly to the Medicare program than the administration of such drugs in hospital settings, and for this reason it would be contrary to sound public policy to subject physicians who provide this service in their offices to significant regulatory constraints. For these reasons, we request that Congress exclude drugs furnished "incident to" physicians' services from the scope of the Stark Law.

5. DEFINITION OF "REFERRAL"

The Proposed Regulations should not preclude cross-referrals for designated health services among physician-owners of a PPMC.

In the Proposed Regulations, HCFA suggests defining a prohibited "ownership interest" to include direct or indirect ownership "no matter how many levels removed from a direct interest." HCFA also proposes to define a prohibited "indirect compensation relationship" to include "any payment to a physician that passes from an entity that provides for the furnishing of designated health services, no matter how many intervening 'levels' the payment passes through or how often it changes form." In addition, the Stark Law's definitional language specifically provides that the term "referral" includes a "request by a physician for a consultation with another physician (and any test or procedure ordered by, or to be performed by (or under the supervision) of that other physician), . . ."

The combination of these definitional provisions may be interpreted to prohibit certain physician cross-referral arrangements within PPMCs. Generally, physician-owned PPMCs acquire a number of physician practices within a targeted geographic area; generally, too, the purchase price for each physician practice's assets is comprised of some combination of PPMC stock, notes, and cash. The practices, each of

which may remain legally separate, then enter into long-term management contracts with the PPMC, under which the PPMC is often compensated for its management services on the basis of a percentage of each practice's revenues or net operating income.

In order to succeed in their business objectives, a PPMC must increase the productivity and efficiency of the practices it manages. Often, this can be accomplished by consolidating the provision of services and unifying operations among the practices to the extent possible. The Stark Law may impede the consolidation of services by precluding certain cross-referrals among the affiliated practices. For example, the Stark Law may be interpreted to prohibit an internist whose practice is managed by a PPMC from referring a Medicare/Medicaid patient to a cardiologist whose practice is likewise managed by the same PPMC, if both of the physicians have an ownership interest in the PPMC and if the PPMC's management fee is determined based in part on a percentage of the cardiologist's revenues. In this event, the internist's referral of a patient to the cardiologist may generate income from designated health services which is shared with the PPMC by way of a percentage-based management fee paid by the cardiologist to the PPMC. It could be argued that, because the PPMC's value is likely to grow as the result of such revenues, the internist in this example is indirectly receiving compensation from his or her referrals to the cardiologist for Medicare/Medicaid designated health services and that the entire arrangement is prohibited under the Stark Law.

In order to simplify the administration of the Stark Law and in order to ensure that legitimate business arrangements among physicians whose practices are managed by a PPMC are not impeded, we would recommend that the Stark Law be amended to make it clear that an ownership interest in an entity that does not directly provide designated health services will not be treated as an indirect compensation relationship under the Stark Law.

6. CLARIFICATION OF PREPAID PLAN EXCEPTION

The prepaid plan exception is an exception to both ownership and compensation. However, the scope of the exception, particularly as it applies to "downstream" contractual arrangements between physicians who have accepted financial risk and entities with which the physician may contract for services, is unclear. In the proposed regulations, HCFA has attempted to clarify that the exception does protect downstream arrangements. Nonetheless, we urge Congress to consider amending the exception to specifically provide that any and all arrangements entered into by entities that have assumed financial risk to obtain services for their managed care patients will be protected. For example, it should be clear that a physician group which has accepted full risk for all services required by an HMO's enrollees, including hospital services, may negotiate for discounts from a hospital with respect to such enrollees in return for referring all such enrollees to the hospital. Group practices and other entities assuming risk under HMO arrangements need to have certainty that their contractual arrangements do not run afoul of the Stark Law.

7. DISCLOSURE IN LIEU OF PROHIBITION ON PHYSICIAN OWNERSHIP

We also believe that the time has come for Congress to consider substituting a comprehensive disclosure requirement for the Stark Law's prohibition on physician ownership. Where a physician discloses his ownership interest in an entity to which he refers and also provides a list of alternative providers, the patient's health care choices are maximized, and market forces will ensure the quality of the services provided. Such an approach is likely to prove far more effective than the Stark Law's complex regulatory scheme in ensuring that physician financial interests do not increase the cost or adversely affect the quality of health care services rendered to Medicare and Medicaid patients.

8. RETROACTIVE APPLICATION OF THE STARK LAW

Finally, we urge Congress to amend the Stark Law to preclude its enforcement prior to the issuance of final implementing regulations by HCFA. In light of the harshness of the sanctions that may be imposed under the Stark Law and the ambiguity of the statutory language, it would be manifestly unjust for HCFA to enforce this statute before adopting legally binding regulations.

9. REPORTING REQUIREMENTS

Congress should limit the reporting requirements imposed under the Stark Law to unprotected financial relationships.

Section 1877(f) of the Stark Law requires that each entity that provides Medicare-covered services report to the Secretary the entity's ownership, investment and compensation arrangements with physicians and their immediate family members. Under the Proposed Regulations, HCFA would require that an entity report this information annually. HCFA indicates it is leaning towards requiring the entity to report all ownership and compensation arrangements with physicians regardless of whether those arrangements are protected by an exception. While it is highly questionable whether HCFA has the authority under the current statutory language to impose this requirement, we urge Congress to clarify this matter by amending the Stark Law's reporting requirements to clarify that the obligation to report financial relationships pertains only to those arrangements that are not protected by a statutory exception.

10. GROUP PRACTICE ATTESTATION REQUIREMENTS

Since the group practice attestation requirement provides no useful information to HCFA, increases the burdens of reporting and does not materially increase the array of sanctions which can be brought to bear against those who submit claims in violation of the Stark Law, the requirement should be eliminated.

Section 411.360 of the Stark I final regulations (42 C.F.R. § 411.360) contains a requirement that an entity which believes it qualifies as a group practice, or, in the case of a new entity believes it will qualify as a group practice, must annually submit to its carrier a written attestation that the entity meets or will meet the requirements to qualify as a group practice as set forth in § 411.351. The regulation also requires that the attestation be signed by an authorized representative of the group who is knowledgeable about the group. The Proposed Regulations retain the physician attestation requirement with only a few modifications. As revised, the Proposed Regulations would require that the attestation contain a statement that the information furnished in the attestation is true and accurate to the best of the representative's "knowledge and belief." In addition, the Proposed Regulations also recite that any person filing a false statement may be subject to criminal and/civil penalties. In light of the all too evident ambiguities in the statutory and regulatory language involved, we request Congress to direct HCFA to refrain from implementing the group practice attestation requirement.

The foregoing are the principal issues of concern for members of the Coalition. If you require any further information regarding the matters addressed in this testimony, or if we can be of further assistance, please contact the Coalition's Washington counsel, Diane S. Millman.

Statement of Waldheger • Coyne, A Legal Professional Association, Cleveland, OH

Waldheger • Coyne submits this statement as a physician-focused law firm which represents several thousand physicians and their professional practices. Our physician clientele ranges from solo practitioners to large multi-specialty clinics to regionally dispersed physician networks. Our attorneys are frequently asked to answer questions about how to interpret and comply with the self-referral law.

We believe that the self-referral law is unfair in its application, is not an effective means to eliminate or reduce fraud and waste in the health care system, and chills development and innovation in health care delivery.

The self-referral law is unfair in its application because it is a strict liability statute. The law does not attempt to determine whether a particular relationship is abusive, but instead creates classes of "acceptable" and "unacceptable." The illogical result is that an "acceptable" relationship under the statute could be abusive, and an unacceptable relationship under the statute could be non-abusive. For example, a three physician group practice can purchase and operate an x-ray machine and overutilize without ever running afoul of the self-referral law. Three independent physicians, however, who create a new joint venture entity to purchase and operate an x-ray machine for their patients, would violate the law even if they did not overutilize. Contrast this arbitrary standard with the intent-based standards imposed by the Anti-Kickback Statute and False Claims Act under which specific activities are evaluated by analyzing the intent of the parties. Additionally, by failing to include an element of intent in the statute, a planning opportunity is created for ill-intentioned actors to work around the law and create an abusive relationship which is acceptable under the law.

The self-referral law is not an effective means to eliminate or reduce fraud and waste in the health care system because it does not directly target abusive or wasteful behavior, but instead generalizes certain classes of relationships. The False Claims Act targets false and fraudulent billing. The Anti-Kickback Statute targets kickbacks and other abusive payment arrangements. While not perfect, these laws are rational, and a plausible rationale explains their application. The self-referral law, on the other hand, generally prohibits a class of relationships on the theory that abusive behavior will be eliminated. By not focusing on specific abusive or wasteful behavior, the self-referral law fails to effectively curb that type of behavior.

The self-referral law chills development and innovation in health care delivery by restricting and discouraging the people in the best position to improve the health care system—physicians—from pursuing many opportunities. Physicians are faced with extensive civil monetary penalties and exclusion from federal payment programs for violating the self-referral law. Accordingly, rather than pursuing new ventures which could ultimately improve the health care system, such as a joint venture with a hospital to bring a new service to patients, physicians often-times elect to maintain the status quo and the system suffers.

In short, we believe that the self-referral law is unnecessary. Other federal and state laws are better suited to correcting abuses and waste within the system without unfairly treating physicians and unnecessarily chilling the industry.

